THE STATE OF KNOWLEDGE ABOUT PREVENTION/EARLY INTERVENTION

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PART I - PREVENTION/ EARLY INTERVENTION RESEARCH CONFERENCE

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EXECUTIVE SUMMARY

Invest in Kids undertook an examination of scientific rigor of prevention/early intervention research. They commissioned Drs. Patricia Mrazek and Hendricks Brown to conduct a systematic literature review of evidence-based studies which contained at least a psychosocial component and focused on young children, pre-natally through age six. Drs. Mrazek and Brown used a methodology they have developed to classify research studies by level of scientific rigor.

Mrazek and Brown identified over 4,000 studies, worldwide in English language peer-reviewed journals, or through expert referrals when final reports were not yet published. Only 165 of these studies were found to have at least a comparison group. Of these only 21 came from Canada. Of these only 2 were included in the top 25% of studies ranked from high to low on measures of trial integrity. Also of concern were findings presented in a subsequent analysis of the studies by Crooks and Peters, showing that of the top 25% of the studies, only 5 were longitudinal, and they contained only 18 outcomes which were significantly beneficial for children and only 13 which were significantly beneficial for parents. However, although these findings are fewer than many people expect, they are not unimportant findings. The types of outcomes include reduced child abuse, improved cognitive performance and decreased use of social assistance. All of which have very important social policy implications. It is thus essential to avoid over-rating or under-rating the results of high quality prevention/early intervention initiatives.

Human Resources Development Canada and Health Canada joined with Invest in Kids to obtain external peer reviews of the reports and to hold a national conference of researchers and policymakers to discuss the implications of these reports. The conference took place on October 24, 2000.

The conference participants agreed that the Mrazek and Brown reports are an important contribution to the field of early childhood prevention and early intervention research, because policymakers, researchers and service providers need to know which studies meet rigorous scientific design criteria. However, the conference participants identified four principal concerns with the Mrazek and Brown approach. It limits its definition of high quality research only to trials, thus neglecting other strong non-trials research designs. It surfaced few Canadian studies, which places limits on transferability of the identified studies to Canadian settings. The scoring of studies was not transparent, making it difficult to understand why studies were scored high or low. Finally, the broad scope of the review meant the group studies which were identified as high quality were quite diverse. This makes it challenging to capture generalities across the studies.

Invest in Kids and its Research Advisors, while acknowledging the important caveats and issues raised about placing too much emphasis on trials-type research, fundamentally agree that trials-type research has held, and continues to hold, an important place in establishing evidence of intervention effectiveness in Canada. Therefore, Invest in Kids has prepared a complete package of these materials for dissemination.

In addition, upon reviewing the directions from the conference participants, Invest in Kids and its Research Advisors make the following recommendations:

1. **The federal and provincial governments jointly support the development of a flexible, accessible Canadian Registry of prevention and early intervention research focusing on the early years,** backed by an inter-disciplinary, intersectoral Steering Committee of researchers and policymakers, who will establish the criteria for entry of studies into the Registry.
   - The Steering Committee to establish standards of rigorous research design, not limited to trials-type research, for entry into the Registry.
   - Entry into the Registry to be based on transparent decision-making regarding the inclusion/exclusion of each study.
   - The Registry to include research currently underway, as well as completed research.
   - The Registry to include categories of consequence for researchers (design type, sample size, measures), policymakers (costs, settings, outcomes), and practitioners (staff ratios, training, operations).
   - The Steering Committee to maintain close links to other international experts evaluating research quality of interventions.
   - The Registry to become a central repository for all Canadian research underway with a focus on the early years.

   The conference participants clearly wanted the Registry to serve as a nexus for research, policy and practice --a thriving centre of information on past, current and future research in Canada, disseminating information about the registered studies throughout Canada, while noting gaps and overlaps, and identifying where additional research is needed.

2. In addition to a strong focus on Canadian research **the Invest in Kids and its Research Advisors recommend the federal government support involvement of Canadian researchers and policymakers in parallel international review groups, especially if they can be influenced to undertake reviews on topics of importance to Canada's Early Child Development initiative.** This approach would permit identification of research evidence that is robust worldwide. It will also place Canadian researchers and policymakers in an important global effort to establish international parameters high quality research.

   Finally, although a Registry of Canadian research and participation in international reviews should stimulate improved quality of research in Canada, the conference participants were particularly concerned about whether the level of research funds available as part of the National Children's Agenda will ensure children will receive the most effective programs tailored to their needs. Therefore, Invest in Kids and it Research Advisors recommend:

3. **The federal government should work with the provinces to set aside funds to undertake rigorous efficacy research of worthy innovative interventions, where the amount for research should be funded at an additional 30 percent over and above what is allocated for program.** Efficacy is the extent to which a specific intervention or service produces a beneficial result under ideal conditions. This type of research requires substantial funding because many environmental, programmatic and individual factors must be thoroughly examined to reliably and validly determine the effects of the intervention.

4. When the efficacy of an intervention has been rigorously demonstrated the **federal government should work with the provinces to establish effectiveness trials in "real life" diverse settings, where the amount of funding should be a minimum of an additional 15 percent over and above the allocation for program.** Effectiveness trials examine how to maintain fidelity to the original model while testing the intervention with broader environments and populations.

5. **When it is not possible to undertake efficacy and effectiveness trials before a new program is announced, the federal and provincial governments should follow the same formula, but implement it simultaneously.**

SUMMARY OF RECOMMENDATIONS

To assure that Canadian prevention and early intervention programs are effective for our children, Canada needs a comprehensive agenda of prevention and early intervention research. Canada needs to:

- Create a centralized, coordinated hub of prevention and early intervention knowledge exchange focusing on the early years -- a Registry;

- Participate in and have access to international reviews of important early child development research; and

- Undertake a substantial efficacy and effectiveness research agenda as new interventions are planned and implemented.

A comprehensive approach to prevention and early intervention research can lead to policies and programs tailored to the Canadian context and substantiated by research conducted in Canada. We would be able to answer the simple questions: What is the evidence for what works? For whom? Under what circumstances?

The fundamental challenge that faces early intervention services is to merge the knowledge and insights of scholars and practitioners with the creative talents of those who design and implement social policy initiatives and to invest the products of this alliance in the future of our children and thereby in the well-being of our society as a whole.

Sam Meisels and Jack Shonkoff (2000)
Handbook of Early Childhood Intervention

BACKGROUND

In 1998, Invest in Kids commissioned Drs. Patricia Mrazek and Hendricks Brown of Prevention Technologies LLD to conduct a systematic literature review of evidence-based prevention and early intervention studies which contained at least a psychosocial component and focused on young children, prenatally through age six.

Invest in Kids undertook this examination of the field on the advice of its Research Advisory Group, which recommended the review because Canadian policymakers and foundations, including Invest in Kids, are under pressure by the public and a variety of experts to fund prevention and early intervention programs. But at that time there existed no central source of information on what evidence might exist to support these initiatives. All such proposals are accompanied with claims of being "best practices" or "proven interventions," but the criteria upon which such assertions are based are rarely made explicit. The purpose of the review was to identify those studies that clearly met high empirical standards, so the most effective interventions could be nurtured through additional funding and research.

Drs. Mrazek and Brown have developed a methodology to classify research studies by level of scientific rigor. Their methodology has been refined over time, and is based on criteria in current use by notable scientific organizations, such as the Institute of Medicine Committee on Prevention of Mental Disorders. The methodology consists of two classification systems to assess the quality of research design. The first system catalogs research by Grade of Evidence, and the second evaluates Threats to Trial Integrity. The Research Advisory Group and Invest in Kids approved the Mrazek and Brown review methodology as an appropriate way to begin to assess the empirical evidence-based knowledge of prevention/early intervention research, which focuses on the early years.

Subsequently, Invest in Kids engaged Claire Crooks and Dr. Ray DeV. Peters of Queen's University to further group the results of Mrazek and Brown's top 25 percent

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of studies by policy relevant categories, thus making it easier for policymakers to directly locate the information relevant to their needs. Crooks and Peters concentrated on both the characteristics of the studies, as well as the outcomes.

The following are short summaries of these reports.

SUMMARY:

"An Evidence-Based Literature Review: Outcomes in Psychosocial Prevention and Early Intervention in Young Children, Volume I: Final Report; Volume II, Figures and Tables; Volume III: Summary of Key Research Studies," *by Patricia Mrazek, M.S.W., Ph.D. and C. Hendricks Brown, Ph.D.*

The Mrazek and Brown review methodology was applied according to the following parameters:

Focus: Interventions would be considered eligible for inclusion in the review it they had one or more of the following foci: parents during the prenatal period; parent-child relationships; cognitive, language and social development of the child; broader community as it interacts with young children and their families; and medical conditions that overlap with psychosocial conditions. Interventions were excluded if they had no psychosocial components.

Intervention type: The types of intervention designs included broad populations or universal interventions; particular risk groups or selective and indicated interventions; and some clinical programs or case identification and treatment programs.

Methodology: The Mrazek and Brown methodology includes seven Grades of Evidence:

Grade I: Evidence obtained from multiple randomized controlled trials (confirmatory and replication trials and large-scale field trials).

Grade II: Evidence obtained from multiple randomized controlled trials (confirmatory and replications trials, but no large-scale field trial).

Grade III: Evidence obtained from at least one properly randomized controlled trial.

Grade IV: Evidence obtained from well-designed controlled trials without randomization.

Grade V: Evidence obtained from well-designed cohort or case-control studies, preferably more than one.

Grade VI: Evidence obtained from multiple time series studies with or without the intervention.

Grade VII: Evidence suggested by respected authorities, based on clinical experience, descriptive studies, prior service delivery programs, or reports by expert committees.

For purposes of their review, Mrazek and Brown included any study with a Grade IV or lower level of evidence. (In short, Mrazek and Brown included studies with at least a comparison group.)

However, scientific rigor can be threatened in other ways. Mrazek and Brown identified ten "Threats to Trial Integrity. " The threats are fundamental research design elements, taught in most Introduction to

Research courses. (For the definitions of these threats, please refer to "Volume I, The Final Report.") Mrazek and Brown graded each threat as null, low, moderate or high (0, 1, 2, 3). Some of the more important threats were weighted more heavily.

Threats	Weight
Selection bias threat	3
Statistical power threat	3
Assignment threat	3
Participation threat	1
Condition bias threat	1
Implementation threat	1
Measurement threat	3
Assessment threat	3
Attrition threat	3
Analysis threat	3

Results: Using these parameters, Mrazek and Brown identified:

- Over 4,000 studies, worldwide in English language peer-reviewed journals, or through expert referrals where final reports were available but not yet published.

- Only 165 of these studies had at least a comparison group (i.e., achieved a Grade IV Level of Evidence or better as described above).

- These studies came from 21 different countries, with most from the United States (114) and Canada (21).

- Only 158 of these were completed trials (the rest were designated as "concurrent trials" and excluded from further analysis).

These 158 studies were further analyzed for other possible major threats, and were scored and ranked from low to high. Based on Trial Quality, there are 11 studies in the top 5 percent of the ranks, which Mrazek and Brown designated as Five-Star studies, and an additional 23 studies are included in the top 25 percent of the ranks and are designated as Four-Star studies. Only two of these top 34 studies are Canadian (Tremblay, et al., and Cunningham, et al.).

Significance and effect size: In these top 34 studies, Mrazek and Brown identified 969 outcome effects reported with sufficient detail to be included in their report.

657 (or 68%) are NOT significant
280 (or 28%) showed significant improvement for the intervention groups.
32 (or 3%) showed significant harm (note, one would expect 2.5% of outcomes to show significant harm on the basis of chance alone).

Mrazek and Brown also presented the effect sizes or log odds ratios. By statistical conventions, effect sizes are categorized as negligible, small, medium or large as follows:

Category	Effect Size	Log Odds Ratio
Negligible	under 0.20	under 0.30
Small	0.20 - 0 49	0.30 - 0.74
Medium	0.50 - 0.79	0.75 - 1.49
Large	0.80 - or greater	1.50 or greater

Of the 280 outcomes in the top 25 percent of studies that were found to be significant, only 32 have large magnitudes of effect. These 32 outcomes account for only 3 percent of the total outcome effects, or 11 percent of the outcome effects that were significant.

What this review shows as research gaps in this field: Mrazek and Brown conclude by citing notable gaps in the top 34 studies as a whole:

- There is a lack of understanding about non-responders in these studies, and virtually no effort to develop special interventions targeting them.

- There is a lack of interventions focusing on fathers.

- More sophisticated analyses are needed.

- There has been minimal research on whether timing interventions to specific times of life (e.g., prenatal; post-natal; preschool; etc.) influences the effectiveness of the intervention.

- There has been virtually no attempt to test a combination of effective programs simultaneously or sequentially.

- More investigation is needed into the critical elements of effective home visiting programs, particularly concerning content (e.g., structured protocols vs. relationship-building), type of intervenor (professional vs. paraprofessional), and timing (age of child at first contact and length of intervention).

- There is minimal investigation of how to facilitate and measure a high level of fidelity to the intervention design, that is, to be sure the intervenors do what they are supposed to do.

- Much more investigation is needed on the community's intervening relationship with families and children, especially on how large-scale policies affect young children.

- There is minimal, if any, research on how to take effective research programs to large-scale community-wide effectiveness trials.

Comparison with RAND study: Mrazek and Brown's approach differs from the RAND study, entitled "Investing in Our Children: What We Know and Don't Know about the Costs and Benefits of Early Childhood Interventions," by Karoly and colleagues in the following ways:

- Karoly et al., focused only on programs targeted to lower socioeconomic groups of children; Mrazek and Brown included targeted programs, but also universal and clinical programs.

- Karoly et al., focused on 10 prototypical government agency or similar programs with good research designs; Mrazek and Brown focused on 34 programs that met stringent research design criteria, that are much more comprehensive and are critical for the assessment of the validity of the outcomes.

- Karoly et al., focused only on U.S. programs; Mrazek and Brown conducted a worldwide review.

- Karoly et al., assessed a group of selected outcomes; Mrazek and Brown reported on all outcomes for which information was available.

Conclusions: There have been many prevention/early intervention trials focusing on the zero to six age range. The quality of the design of the majority of the trials is poor enough that the results are often of questionable validity. Most of the outcomes of the trials with Five-Star and Four-Star designs are not overly impressive. Only 10 percent of the significant findings have strong magnitudes of effect. There are also serious gaps in the content areas that have been addressed to date. On the other hand, there are many interesting intervention programs that warrant a second look in better designed trials.

SUMMARY:

"Several Methods of Summarizing Outcome Findings from Mrazek & Brown's Evidence-Based Literature Review of Psychosocial Prevention and Early Intervention Programs for Young Children"
-a report by Claire Crooks and Ray DeV. Peters

Crooks and Peters note that Mrazek and Brown have presented a valuable and comprehensive review of the evidence-based literature regarding outcomes in prevention and early intervention projects for young children from birth to six years of age. The purpose of the Crooks and Peters report is to group the Mrazek and Brown results by policy relevant categories, thus making it easier for policymakers to directly locate the information relevant to their needs.

The Crooks and Peters report summarizes and categorizes all outcome effects from each of the 34 projects that received a Four- or Five-Star rating in the Mrazek and Brown literature review. However, in preparing their report, Crooks and Peters noted three cautions for reviewers:

- **Significance:** Because both the Mrazek and Brown study itself, and some of the individual studies included in the Mrazek and Brown report, examine large numbers of outcomes, one might expect some of those findings, which are reported as "significant," to appear that way simply by chance. Although there are statistical corrections available to account for multiple comparisons, this was not addressed in the Mrazek and Brown report.

- **Outcome trajectories:** Some of the studies reporting a large number of outcomes, are simply the same outcome reported at different points in time, and would be more accurately reported as a trajectory or growth curve, rather than as independent outcomes. Therefore, the total number of outcomes may be somewhat inflated.

- **Quality of outcome measure:** It is important that readers carefully examine the study-specific definitions of variables, and avoid taking the variable name, or even the variable classification, at face value. A few of the variable names and classifications are questionable, and could lead to inappropriate conclusions.

Focal Age Group of Children: In the Four- and Five-Star studies, Crooks and Peters show **most of the studies cluster in the prenatal and infancy age groups:**

Age of Onset:	# of 4 and 5 star projects:
Prenatal	13
Parturition	2
Infancy	11
Toddler	1
Preschool	5
Early school-aged	1
Not specified	1
TOTAL	34

Sample Size: In the Four- and Five-Star studies, Crooks and Peters show **most of the sample sizes to be relatively small.**

Sample Size:	# of 4 and 5 star projects:
Under 200	12
200 - 499	10
500 - 799	1
800 - 1099	2
1100+	7
Not specified	2
TOTAL	34

Crooks and Peters note this is a somewhat bimodal distribution, with studies clustering as either quite small or very large. But they further note that of the seven projects with 1100+ sample sizes, six of them are prenatal interventions and the seventh is an infancy intervention within the first ten days of life. They speculate that the costs of conducting large scale interventions are greatly reduced when carried out in hospitals, where most babies are born, or by conducting one home visit shortly after birth, when most parents are likely to be located at home.

Type and Subtype of Outcome: Crooks and Peters cluster the Mrazek and Brown outcomes reported in the Four- and Five-Star studies into the following types and subtypes:

Child outcome	%
Temperament/behaviour/symptoms	36
Social relations	3
Cognitive	26
Speech and language	3
Motor development	2
Physical health/growth/health	9
Safety or injuries	7
School performance	11
Legal offences	3

Parent/family outcome	%
Parenting/parent-child relationship	16
Child maltreatment	8
Pregnancy/pregnancy-outcomes	47
Mother's stress	<.5
Mother's social support	4
Mother's mental health	4
Mother's physical health	6
Mother's education/employment	7
Mother's public assistance	7

Clearly the largest category of measures entail pregnancy outcomes for the mother. This reflects the fact that prenatal and parturition programs account for 15 of the 34 Four- and Five-Star projects. Crooks and Peters note **a relative dearth of family or parent outcomes that measure characteristics of the family or the parenting relationship, and there is no attention to fathers' influence on child development.**

Another weakness in these 34 studies as a group is that **only one study included any measure of community outcome,** and that outcome (Government Cost) can be considered a distal indicator, and would not be expected to disentangle the relationship between community (or neighbourhood) and child development. Nonetheless, the Government Cost outcome, measured by the PEIP (Olds, et al.) project, was calculated as a composite factor (associated with reduced health services utilization, welfare and criminal justice costs and taxes from increased income). This measure was shown to be associated with 3 intermediate term beneficial outcomes.

Comprehensiveness of measures: Crooks and Peters show that 35 percent of the Four- and Five-Star studies measured only parent/family outcomes but no child outcomes, or measured only child outcomes but no parent/family outcomes. Throughout the report Crooks and Peters note that such **a narrow research focus is not congruent with the theoretical shift to more comprehensive, ecologically based models of child development,** wherein the infant or young child is viewed in the context of the family and the family in the context of the community, and the community in the context of the society.

Significance and Effect Size: When examining only those child outcomes that produced statistically beneficial effects and had medium or large effect sizes,

the highest percentage of beneficial results occur with cognitive, safety, school and behaviour outcomes. If just those child outcomes with medium or high effect sizes are considered, then cognitive measures account for 50 percent of the outcomes, with school performance measures being the next highest at 20 percent. Crooks and Peters combine these findings with the earlier findings on frequency of measuring an outcome, and they conclude:

- **Child cognitive measures seem to reflect the greatest impact of early intervention, since they have been collected most frequently and have most consistently yielded positive and substantially strong outcomes.**

- **Child behaviour measures, although collected frequently, have yielded half the percentage (30 percent) of beneficial outcomes compared with cognitive measures, and a substantially lower percentage of medium and large effect sizes compared to cognitive measures (14 percent vs. 50 percent).**

For the parent outcomes, Crooks and Peters show:

- **Mothers' physical health, social support and parenting measures show the highest percentages of beneficial effects.**

- **However, it is mothers' physical health, public assistance, legal offences and social support categories that show the highest percentages of medium or large size effects, even though these outcomes account for only 6 percent, 7 percent and 4 percent of all parent measures respectively.**

- **Pregnancy outcomes, though these outcomes were by far the largest category (47 percent) of all parent measures reported in the reviewed studies, pregnancy outcomes showed comparatively low rates of beneficial effects (18 percent) and also low rates of medium or large size of effects (10 percent).**

Duration of Effects: Crooks and Peters categorized the Mrazek and Brown outcomes by the amount of time elapsed after the intervention until the outcome was actually measured. They clustered the outcomes as follows:

Duration of all effects:	Definition of duration:	Child Outcomes %	Parent Outcomes %
Short-term	During or immediately after intervention	55	77
Medium-term	Up to 2.5 years after intervention	25	16
Long-term	2.5 years or more after intervention	20	7

It can be seen that for both child and parent/family outcomes, **by far the greatest number of outcomes are short-term.** When Crooks and Peters limited the child outcomes to only those which had a beneficial outcome, they found 70 percent of those outcomes were short-term (126 of a total of 180), and similarly 70 percent of outcomes with medium or large effect sizes (79 of 113) were short-term. For the parent and family measures, short-term effects account for 80 percent of the beneficial outcomes (77 of 96) and 70 percent of the medium or large effect sizes (37 of 53).

Only 5 of the 34 studies reported long-term child outcomes, in the tables presented by Mrazek and Brown:

- The Carolina Abecedarian Project (Ramey and Ramey)
- The Busselton Study
- The Infant Health and Development Project (IHDP)
- The High/Scope Preschool Curriculum Study (Weikart and Schweinhart)
- The Montreal Longitudinal Experiment. (Tremblay, et al.)

Of the 107 long-term child outcome measures reported in these five studies, only 18 were significantly beneficial and 13 of them were cognitive or school performance outcomes, 2 were behavioural and 1 was physical health.

Only 2 studies of the top 34 analyzed by Mrazek and Brown reported long-term outcomes on parent measures: The Elmira PEIP home visiting program (Olds, et al.) and the Montreal Study (Tremblay, et al.). **Of the 33 long-term outcomes measures for parents, only 13 were beneficial,** and they were all in the Elmira PEIP intervention. These included 2 beneficial outcomes on child maltreatment, 3 on mother's physical health and 8 on use of social assistance. Nearly all of these long-term parent outcomes in the Elmira Project occurred only in a small subsample of the most high-risk mothers.

CONFERENCE PURPOSE AND DESIGN

Allen Zeesman, Acting Director General, Applied Research Branch of Human Resources Development Canada and Brian Ward, Director of the Child and Youth Division of Health Canada found the methodology and the findings in the Mrazek and Brown and the Crooks and Peters reports to be of great interest, given the Canadian federal government's commitment to a National Children's Agenda, with its important focus on early child development. They also agreed the reports deserved broader attention from the field. They arranged for their respective Ministries to co-sponsor, with Invest in Kids, the following activities:

- **external written reviews** of the reports from the following perspectives:
  - a methodologist, familiar with evidence-based reviews
  - an academic early intervention policy advisor
  - an early intervention senior program administrator

- **a meeting of researchers and policymakers** from across Canada to
  - jointly appraise the Mrazek and Brown methodology
  - react to the findings from the reports
  - form recommendations about how researchers and policymakers might improve evidence-based knowledge development of prevention and early intervention initiatives in Canada

The conference took place on October 24, 2000. (A list of conference participants is provided at the end of this section.)

The meeting was arranged to provide the participants with first hand summary presentations of the Mrazek and Brown report by Dr. Patricia Mrazek, and the Crooks and Peters report by Dr. Ray Peters.

This was followed by presentations of the external peer reviews of the reports. The following experts conducted the peer reviews:

- **Dr. Michael Boyle,** a Professor in the Department of Psychiatry and Behavioural Neuroscience, Associate Member Department of Clinical Epidemiology and Biostatistics, and Member of the Center for Studies of Children at Risk, McMaster University, Hamilton, Ontario, was engaged to provide reactions to the methodology of the review.

- **Dr. Clyde Hertzman** is a professor in the Department of Health Care and Epidemiology and Associate Director of the Centre for Health Services and Policy Research at the University of British Columbia. He is also a Fellow in the Human Development Program, as well as Director of the Population Health Program of the Canadian Institute for Advanced Research. Dr. Hertzman was asked to evaluate the methods and findings of the Mrazek and Brown report and the Crooks and Peters analysis against the early childhood intervention field as a whole.

- **Dr. Susan Bradley,** a Professor in the Department of Psychiatry, University of Toronto, formerly Head of the Division of Child Psychiatry and Psychiatrist-in-Chief at the Hospital for Sick Children, was selected to provide a perspective of a front-line administrator who relies on research to guide service planning.

As planned, Dr. Boyle discussed the methodological strengths and weaknesses of the Mrazek and Brown approach, Dr. Hertzman placed the Mrazek and Brown approach in the larger policy and intervention context of current academic debates as well as Canadian national and provincial developments and Dr. Bradley

addressed the use of these reports by senior program administrators. Their views were discussed and debated in both the plenary and the small group discussions during the conference. (The complete external reviews, provided by Drs. Boyle, Hertzman and Bradley, appear in Appendix B to this report.)

Following the summaries of the reports and the external reviews a panel of provincial policymakers presented their views of how research influences their policy and program decision-making. The policymakers included:

- **Jane Fitzgerald,** Executive Director, Family and Children's Services, Department of Community Services, Province of Nova Scotia.

- **Lynne Livingstone,** Director of the Early Years and Healthy Child Development, Ministry of Community and Social Services, Province of Ontario

- **Leanne Boyd,** Manager, Policy Development, Research and Evaluation, Healthy Child Manitoba

While all three policymakers shared similar views on the interface of research and policy, Ms. Boyd's description of how Manitoba is framing of the interface of research and policy captured the spirit of all three policymakers views by highlighting two important challenges:

The First Challenge: bridging research and policy. How do we reconcile the different priorities of policymakers and researchers?

- **Policy imperatives,** examples:

  - Working to demonstrate positive results to the public within short time frames (4 - 5 year electoral cycles)

  - Decisions to implement new programs based primarily on stakeholder pressure and political expediency

  - Need for immediate and unequivocal findings

- **Research imperatives,** examples:

  - Publish or perish: working to demonstrate scholarly excellence

  - Value of research findings based primarily on methodological qualities (e.g., reliability, validity, replication)

  - Findings are probabilistic and provisional

Manitoba has also developed a list of opportunities to address the differences between the two types of imperatives:

- **Policy-relevant longitudinal studies:** longitudinal research that identifies key short-term outcomes at specific transitions over the life course (e.g., measuring readiness to learn in Canada's National Longitudinal Survey of Children and Youth)

- **New training models:** internships that provide experiences integrating research with government policy work (e.g., predoctoral internships with government)

- **Occasions for dialogue** between researchers and policymakers (e.g., today's conference)

The Second Challenge: bridging efficacy and effectiveness:

- **How can research tell us what works under real-world conditions?** For example, in early childhood development, what works for whom, under what conditions? (Current existing examples include Ontario's Better Beginnings, Better Futures longitudinal research demonstration project; and the United States' National Institute of Child Health and Human Development Early Child Care Research Network.)

- **What mechanisms lead to positive change?**

Manitoba sees opportunities to address the efficacy/effectiveness challenge by:

- Synthesizing previous research studies: Supporting meta-analyses of early childhood intervention under real-world conditions, similar to recent meta-analyses of psychotherapy under clinical representative conditions (Shadish et al., 2000)

- Increasing the evaluability of early childhood interventions: Planning and delivering programs in a manner that permits more rigorous evaluation designs (e.g., regression-discontinuity design in provincial evaluation of Manitoba's BabyFirst program) to provide stronger evidence for guiding policy decisionmaking.

- Funding effectiveness trials with longitudinal follow-up: Providing sustainable funding for research on early childhood intervention in the real world context, similar to recent commitments in the United States (e.g., National Institute of Mental Health [NIMH] funding for effectiveness trials of interventions for major mental disorders)

At the conclusion of the policymakers' panel, the conference participants were primed to discuss the nexus of prevention and early intervention programs, policy and research.

SUMMARY OF VIEWS

The purpose of the conference was to surface the most salient views about gathering empirical evidence that would be of value in assisting policy and program decision making. The intention was to hold open deliberations, without the necessity of driving to consensus.

Discussions of classification systems that assess empirical research nearly always provoke debate of the broader issue of "what is knowledge?" and its companion, "what is evidence?" Circulating Mrazek and Brown's approach proved to be no exception. Beginning prior to the conference with the peer reviews, and continuing throughout, these larger questions generally predominated. However, there was vacillation back and forth between assessing whether Mrazek and Brown's "trials approach" is valid and valuable within its own framework, and examining how to classify and include several additional diverse empirical approaches that could ensure the most compelling and constructive evidence for Canadian policymakers.

At the end of the day, it was clear that Mrazek and Brown's approach is important on its own merits. But even more significant for policymakers and other funders in Canada, is the need to develop a broad-based source of information on high quality Canadian research, which includes, but is not limited to trials.

The following sections are summaries of views expressed from all sources associated with this conference. These include the views of the Research Advisory Committee to Invest in Kids, the authors of the reports, the peer reviews, the conference policymakers panel, audience feedback, small group discussions and staff from HRDC, Health Canada and Invest in Kids.

EVALUATING THE MRAZEK AND BROWN APPROACH ON ITS OWN MERITS

STRENGTHS: The strengths of the Mrazek and Brown report fall into two categories: the methodology and the results.

STRENGTHS OF THE METHODOLOGY: what are the strengths of Mrazek and Brown's approach for researchers and policymakers concerned with developing policy and programs based on evidence?

1. **The methodology offers a careful application of a promising "trials approach" to classifying and evaluating empirical research on prevention/early intervention in the early years, without the traditional restrictions of a randomized controlled trials (RCT) approach.** In evaluating the Mrazek and Brown classification system, it is essential to follow their definition of what constitutes a trial. For this review they did not require randomization, to qualify as either a four or five star study. Their approach should not be confused with randomized controlled trials (RCTs). Mrazek and Brown simply required that studies have "evidence obtained from well-designed controlled trials without randomization," as their minimum standard of evidence (Grade IV) for inclusion in this review. It is important to note this, because throughout the conference, there was a tendency to equate Mrazek and Brown's approach with a more strict RCT approach. Although the Mrazek and Brown approach can be called a "trials approach," it is not correct to equate their methods with those of an RCT approach.

2. **The methodology reports harmful and null effects, as well as helpful effects.** Very few reviews report harmful outcomes. Researchers and policymakers can learn as much from the harmful effects as from the beneficial effects. Although only 32 out of a total of 969 effects were reported by Mrazek and Brown as harmful, by noting their existence, and in particular by noting the type of outcomes wherein the harmful effects appear was viewed as very helpful to researchers and policymakers alike. As Hertzman notes in his review, this analysis of harmful effects can be extended even further by calculating the ratio of helpful to harmful interventions by domain; identifying the domains where it is very high (e.g., the cognitive domain); identifying the common features of the interventions in this domain; and stating them in transferable form. Including harmful effects is seen as a valuable aspect of Mrazek and Brown's reports.

3. **The methodology provides enough information for careful focused additional analyses and summaries.** The breadth of types of information provided by Mrazek and Brown provides an organized database from which researchers and policymakers can immediately assemble further meaningful analyses. This is best demonstrated in the subsequent Crooks and Peters report, which categorizes the studies by duration of effects, age of onset, sample size, categories of effect size, etc.

4. **The methodology includes unpublished studies.** Relying strictly on published studies would keep otherwise meritorious research from coming to the attention of policymakers. Lack of available published research can occur because of lengthy time lags between a study's completion and its subsequent publication; a limited number of journals are devoted to publishing prevention and early intervention research, so there are limited avenues for publishing; provincial and federally funded project evaluations often go unpublished; and some journals are biased in choosing whom to publish. Thus, without this procedure of including unpublished studies, some highly relevant studies would have been excluded from the review.

5. **The methodology includes research from around the world.** The Mrazek and Brown approach permitted the inclusion of studies from 22 countries. This procedure should allow the review to identify those findings that are robust regardless of social or political structure. However, because the proportion of studies from countries other than the U.S. was so small, this is still more of a goal than a reality.

STRENGTHS OF THE RESULTS: for Canadian researchers and policymakers concerned with policy and programs based on evidence, the following are advantages of this review:

1. **The results provide an important first filter of a massive number of studies and a huge number of research outcomes.** For those interested in early child development prevention and early intervention studies, Mrazek and Brown conducted an extensive review. For some conference participants, this was viewed as a specific strength, because it permits further analyses of the database of studies, according to their own needs. Some participants prefer this approach, which first identifies the cream of the studies by research methodology, and then categorizes the studies by various types, as opposed to one which restricts eligible studies by type early in the filtering process.

2. **The results begin to focus on the creation of a much-needed empirical benchmark from which to base summary statements about the quality and quantity of research.** Too frequently people in positions of some authority will state, "We know prevention and early intervention works, and research proves it." It is difficult to know how such people define "research," but with some there is the strong implication that valid trials have been done, and the results have been beneficial. The Mrazek and Brown report provides an empirical path leading to a benchmark set of findings about the quality and quantity of prevention/early intervention research.

3. **The results demonstrate the limits of what is known and not known about prevention and early intervention studies, within a carefully defined trials approach to research methods.** To some conference participants, the absolute numbers of studies, significant findings and effect sizes were disappointingly small. But for others, there was relief that because of Mrazek and Brown's carefully documented approach, that at least we know how the numbers were derived. These reports show that out of thousands of eligible studies, only 34 meet Mrazek and Brown's definition of high quality. Although those 34 studies contain over 900 outcomes, only about 1/3 are significant and of those only about 18 percent have moderate to high magnitudes of effect. Furthermore, as Crooks and Peters showed, only 6 of the studies followed the children for more than two and a half years after the intervention was complete and the sample sizes of some of the most well known studies are very small (less than 100 children receiving the intervention).

4. **The results helpfully point out "gaps in research."** The gaps are areas, which require immediate research to provide policymakers with the evidence they require for planning. It is easy to miss the ten gaps in research identified by Mrazek and Brown in their report, because in comparison to the amount of space devoted to their descriptions of the methodology and findings, the proportion of space in the report devoted to describing the research gaps is small. Yet, the gaps Mrazek and Brown identify, such as "minimal research on the timing of preventive interventions" in the early years, and "virtually no attempt to test a combination of efficacious programs..." are very important issues to policymakers in particular.

5. **The results raise important questions about the quality and quantity of prevention and early intervention trials-type research in Canada.** Because only two of the Four- and Five-Star studies are Canadian, the Mrazek and Brown approach leads to questions about why more Canadian studies did not make it through this type of empirical filter. Do we have enough high quality trials-type of prevention/early intervention early child development studies in Canada? If we have enough high quality trials-type research, what prevents Canadian research from being published? Do we have enough funds going into high quality research? Or is it diluted in some way because funders would rather spread the money over more low quality (low cost) research, than concentrate it among a few high quality (high cost) studies? Or, do Canadian funders focus on non-trials, but nonetheless high quality, research, which is not captured in a review of trials-type research? Overall, what is the quality and quantity of prevention/early intervention research that focuses on the 0 - 5 age range in Canada?

6. **The results provide a systematic framework for classifying the outcome variables and measures used in the research studies.** In addition to classifying the research methods of each study, Mrazek and Brown also organize the outcome

variables by type (such as pregnancy, parenting, safety, maltreatment, growth, temperament, social relations, legal offences, school performance, etc.). This is particularly helpful for policymakers, who are often asked to propose programs that address specific outcomes. Additionally, Mrazek and Brown also provide the name of each measure used to assess each outcome, which is particularly valuable to researchers and program planners. If policymakers are able to determine what measures others have used in similar studies, they can make more informed decisions about which measures to employ in their own studies.

7. **The results provide the p-value and effect size/log odds ratio for nearly 900 outcomes.** Situating this much information in one report is almost unprecedented. It is extremely valuable, and provides readers with access to the details of information they need to determine whether a particular study comes close to their interests.

LIMITATIONS OF THE METHODOLOGY: What are the limitations in the Mrazek and Brown approach to assisting policymakers and researchers in Canada?

1. **The methodology is a rigid schema, which excludes otherwise potentially relevant research.** The discussions throughout the day identified a lack of consensus about trials type research in Canada.

   - Some strongly approved the Mrazek and Brown classification system, but just wanted the flexibility to specify why certain well-known studies were excluded. (Without requiring Mrazek and Brown to report the scoring for all excluded studies.)

   - Others wanted the same Mrazek and Brown classification system, but just expanded to include Grades V and VI Trial Elements.

   - Others wanted a more generic classification system where, on a case-by-case basis, additional studies would be included, even if not trials type, but were judged to be research designs of equally high quality.

   - There were some who wanted to include studies that many would acknowledge as lacking methodological rigor, but which compensated for this by unique program features, or more policy-relevant outcomes. For example, a less rigorous study might have been first rate in tracking program costs. This is a very important feature to policymakers, and excluding such important studies can leave policymakers very vulnerable, if they do not have access to information on key program features.

   - Finally, there was a debate about whether a comparison group is even necessary for some research studies. In general there is agreement that there are very high risk groups for whom there are probably no comparable groups with which to compare. A few participants thought this issue is over-blown, and there are often appropriate comparison groups available, but because of the extra time and money involved in identifying and working with comparison groups, that some researchers and policymakers are hiding behind the supposed "lack" of appropriate groups, and not making efforts to identify them. Still others think that there are other equally valuable quasi-experimental designs that can be substituted for control/comparison group designs. There appeared to be general agreement that there can be good research designs without comparison groups, but that for each such case, the researchers should be strongly encouraged to thoroughly explore suitable comparison groups first, before deciding it is inappropriate.

In response to these suggestions, Dr. Mrazek indicated that they would be open to expanding their review to include studies that qualified as a Grade V (which would include well-designed cohort or case-control studies), as well as well those which qualified as a Grade VI (which would include well-designed quasi-experiments or observational studies, with appropriately matched controls).

2. **The methodology of classifying of trials is not transparent -** Dr. Michael Boyle (one of the peer reviewers), among others, noted that overall, there is too little detail provided on the search and assessment methods used in the review. His position is that in systematic reviews, a reasonable standard is to expect enough information on these methods to permit replication. Assessments in review studies are "reproducible" when different raters exposed to the same data and naive to each other's findings provide the same or similar results. In the report, the authors note that they had "... 10 percent disagreement ..." among coders when they initially classified their intervention types. No other information is provided in the review about the reproducibility of the ratings obtained in the review, especially concerning the Threats to Trial Integrity. Differences in opinion about what constitutes a program with a psychosocial component and what constitutes a relevant outcome for this review could, on replication, lead to differences among raters in the selection of studies for review.

   Mrazek and Brown provide two key reasons for this lack of transparency. First is cost. The cost of having each of 4,000 decisions (the original number of studies identified as potentially eligible) reviewed by two or more judges would have been very expensive. Secondly, transparency would open Mrazek and Brown to intense lobbying by researchers over any of 11 decisions (1 for the Trial Elements Score, and 10 for each of the Threats to Trial Integrity scores). This would require a cadre of research associates focused almost totally on establishing evaluator agreement, and then defending them to individual researchers who were dissatisfied with the assessment of their work. In a perfect world this level of transparency would be viewed as an integral part of the part of science based on trials. But, the debates would be fierce, as well as costly, especially for such a broad review. In the end, readers of the Mrazek and Brown report will have to determine for themselves if they can accept the reported reliability of Mrazek and Brown's classification process, and the integrity with which they conducted their review.

3. **The methodology treats serial measures as independent outcomes.** Crook and Peters found several instances of outcomes that were reported as independent, but were not in fact independent. Instead, these outcomes were the same outcome reported from the same study at different points in time. Crooks and Peters suggest that these serial measures should be viewed as growth curves. A growth curve analysis would indicate whether rates of change were different between groups over time, or conversely, whether a difference arising between Time 1 and Time 2 was merely being maintained over subsequent data points. Thus, the total of 969 outcomes reported in Mrazek and Brown, is somewhat less than that, if the serial measures were only to be counted once, rather than counted individually at several different points in time.

4. **The methodology requires a caution about reporting the number of significant outcomes.** Crooks and Peters also note that both the Mrazek and Brown study itself, as well as some of the individual studies included in the Mrazek and Brown

report, examine large numbers of outcomes. Under such circumstances one might expect some of those findings, which are reported as "significant," to appear that way simply by chance. Crooks and Peters note that although there are statistical corrections available to account for multiple comparisons, this was not addressed in the Mrazek and Brown report.

5. **The methodology misses key studies, excluding otherwise relevant trials.** There was some concern that the 27-year follow-up to Perry Preschool study was not included in the analysis. However, Mrazek and Brown determined that it was included, but only received three stars. This is one of those cases where the credibility of the methodology could be viewed as suspect, because the evaluation is lower than most researchers and policymakers in Canada would expect it to be. Certainly, this one study has been quoted more than almost any other in supporting positive effects of this model over the short and long term.

   However, Dr. Mrazek did acknowledge that no matter how hard one tries, it is almost certain that important studies could have been inadvertently excluded, and Drs. Mrazek and Brown are willing to evaluate such studies for possible inclusion, should they be brought forward.

   This dialogue about whether a study should be included, and how high it should be ranked, highlights the reason why Invest in Kids' Research Advisory Group recommended this methodology and this review. It permits a benchmark against which studies, especially high profile studies, can be measured.

6. **The methodology for classifying effect size is still very contentious.** Mrazek and Brown adopted a method of grouping effect sizes, which they and Crooks and Peters report to be "generally accepted in the field." Yet Dr. Clyde Hertzman (a peer reviewer) raised important questions about such a classification scheme. He asked, "How much of a boost in one domain is required to "tip" the balance toward overall health?" If we pay too much attention to the outcomes with medium and large effect sizes, we might ignore a valuable model with a smaller effect size, but which would be all that is required to "tip" the balance of health of a population. And he also noted the size of the original problem might be more important than the size of the effect. Even within the Research Advisory Group there was much debate about asking Mrazek and Brown to calculate the effect sizes of the outcomes. There was grave concern that non-statisticians and statisticians alike might misinterpret the effect sizes. This dispute was not resolved during the conference. Although most participants came away with a deeper understanding of how effect size could be misused to derail an otherwise important intervention, many still conclude it is important to report effect sizes.

LIMITATIONS OF THE RESULTS: Even if the Mrazek and Brown methods were implemented flawlessly, what are the limitations of the results of the Mrazek and Brown approach?

1. **The top ranked studies are dominated by single-focus, limited outcome research designs.** One of the biggest disappointments with the results of the Mrazek and Brown approach, was that so many of the top studies turned out to be very limited interventions focusing on very few outcomes. They are of limited relevance today. Most of the current theory and practice about healthy child

development today focuses on more ecological models, which include measures of the "whole child" - physical, social, behavioural, cognitive and emotional development; measures of parent and family functioning and characteristics and measures of neighbourhood characteristics and change. Consequently, most social policy interventions under consideration today are multi-modal, multi-sectoral, multi-outcome oriented. Very few are as limited as the single-focus studies that are predominant among the top 25 percent of studies identified with the Mrazek and Brown approach.

Additionally, there is an emphasis today on "process" outcomes. It is generally understood that how a model is implemented plays a crucial role in determining outcomes. Yet, virtually no process outcomes are included in the Four- and Five-Star studies.

The conference participants speculated about why the bulk of the studies were so narrowly focused. One suggestion for this bias is because the Mrazek and Brown approach favours identification of studies that have been completed and published, which leads to a domination of what is often now viewed as old-style, out-dated interventions, methods and outcomes. These published studies were generally gestated in the 1970s, '80s and early '90s, when applied broad-scale research in early child development was in its infancy. Consequently, as noted by Crooks and Peters the top studies are skewed toward single-focus programs, delivered in institutional settings with captive audiences, and no information on the specifics of program delivery. The newer ecological research models of prevention and early intervention are not included, even though some impressive ecological models are now underway. Furthermore, although more studies are now including "process" outcomes in their studies, 10 or 15 years ago it was rarely considered important to capture this type of information.

It should be noted that nothing in Mrazek and Brown's methodology led to this result. Rather it is the progress of the early intervention field proceeding ahead of the published studies. There is nothing in Mrazek and Brown's approach that excludes multi-method, multi-site, multi-outcome, multi-target research models that also include process outcomes, provided the studies use a trials approach. Mrazek and Brown have been very open to expanding their work to capture information about concurrent research that is underway in an effort to include more relevant models of today. But that would require more effort on behalf of current researchers to bring those models to Mrazek and Brown's attention.

However, other participants voiced concern that a trials-type approach inherently favours single-focus research, and that single focus research will remain disproportionately large, as long as reviews continue to limit the definition of what constitutes high quality research to trials approaches.

Additionally, there was a strong feeling among the policymakers and researchers at the conference that the large outlay of funds to adequately undertake multi-modal, multi-method, multi-outcome research will also keep the actual number of this type of studies small.

2. **The results did not include studies of social assistance and housing.** Social assistance and housing can be regarded as prevention and early intervention initiatives. Research shows that welfare and subsidized housing are key variables in affecting child development, especially children's school performance and mental health. Perhaps the

search procedures were not inclusive enough to reach these topics or perhaps the outcomes from housing and welfare studies do not focus on the development of infants and young children. But including these types of interventions in their searches would enrich this review.

3. **The results are primarily non-Canadian:** American models dominate the published literature. Even international journals contain few examples of Canadian research. There are serious concerns among Canadian researchers and policymakers about whether they can expect American interventions, replicated in Canada, to produce similar significance levels and effect sizes across social and political boundaries.

4. **The results show only a few long-term studies exist -** most of the outcome effects reported in the 34 studies reviewed by Mrazek and Brown are short term - collected during or immediately after the intervention period.

5. **The results of the longitudinal studies are based on very small sample sizes with very high-risk populations.** Dr. Ray Peters showed that two of the most well-known studies had fewer than 75 families receiving the intervention. This includes the Perry Pre-school Study (58 in the treatment group and 65 in the control group)[1] and the Abecedarian Study (n = 122). [2] Additionally, either the studies themselves, or the benefits, were relegated to the children and families at highest risk. For example, in the Perry Preschool Study the children had to test in the "'educably mentally retarded' range (IQ score of 50 – 85)."[3] In the Carolina Abecedarian Project the high risk indicators included, " … a history of mild retardation or school failure in family members, and psychopathology or social maladaptation."[4] The David Olds Elmira Nurse Home Visiting Study showed the benefits mainly to those women at highest risk.[5] Thus, in general, the studies that are most well-known to Canadian service providers and policymakers employed definitions of risk that exceed the types of risk for most populations in Canada that are receiving similar interventions.

6. **The scope of the review is broad, which makes it difficult to summarize results beyond a study-by-study basis.** Two points of view surfaced during the conference. As Dr. Boyle explained in his peer review, the process of defining the scope of the review very broadly and setting the selection criteria very narrowly will lead almost invariably to large study-to-study variation or heterogeneity. This makes it very difficult to summarize the findings of the review in anything other than a study-by-study basis, which he points out is not very useful for policymakers.

As noted by Dr. Boyle, there are a number of issues associated with the construction of summary estimates and one of the most contentious focuses on the constraints imposed by study heterogeneity. Although "standards" have not been developed, trialists refrain from combining effect sizes when large variation exists in the magnitude of these effects or the study elements associated with them. When large study-to-study variation exists in estimated effects, then it is extremely important to analyse this variation in an effort to understand its methodological or substantive origins. If the

[1] Weber, C.U., Foster, P.W. and Weikart, D. P., 1978. An Economic Analysis of the Ypsilanti Perry Preschool Project, Monographs of the High/Scope Educational Research Foundation Number Five, p. 2.
[2] Ramey, C. T. and Campbell, F.A., 1984. "Preventive education for high-risk children: Cognitive consequences of the Carolina Abecedarian Project," American Journal on Mental Deficiency, 88(5), 515 - 523.
[3] See Footnote 1.
[4] See Footnote 2.
[5] Olds, D.L., Henderson, C.R., Chamberlin, R. and Tatelbaum, R., 1986. "Preventing child abuse and neglect: A randomized trial of nurse home visitation," Pediatrics, 78(1), 65 - 78.

variation can be explained, then the summary estimates of effects can be put into proper context. As a consequence, the Mrazek and Brown studies reviewed are not drawn from a sample of studies that can be used to make generalizations about programs and strategies likely to have a positive impact on healthy child development. Rather, inferences from the Mrazek and Brown review must be drawn on a study-by-study basis.

On the other hand, a number of conference participants had an equally strong view that the methodologically high quality studies are not similar, and for the most part estimates of effect should not be combined. They were comfortable with clustering the studies by characteristics, such as age of child, type of outcome, etc. They accept that heterogeneity is an accurate description of what exists among the high quality research studies, given this classification system, and they do not feel pushed to establish cross-study effect sizes.

ADDITIONAL ADVICE

re Establishing An Empirical Knowledge Base for Canadian Policy and Programs for Early Child Development

The conference moved to another level in its latter stages. There was a consensus that we are a country that pays attention to evidence. Many participants were eager to move to the broader question of what would be required to establish a thorough knowledge base for policymakers and researchers about the empirical evidence appropriate for early childhood policy and programs in Canada. It was clear to them that we would need to move beyond a straight trials approach, to include a broader definition of relevant high quality research.

1. **What is evidence? Who gets to decide? For which studies?** The Mrazek and Brown review surfaced some real gaps in prevention and early intervention field as a whole. Dr. Hertzman provoked some careful re-consideration of the basis of classifying research based on methodology. He noted that to some extent all such classifications have suffered from lack of clear definitions of what is meant by level of evidence and strength of recommendation, and from difficulties in simplifying a complex assessment into a simple model. We clearly need a debate on the parameters of an ideal database. Dr. Hertzman noted in his peer review, that if level of evidence is defined as the extent to which one can be confident that an estimate of effect or association is correct, the following considerations are relevant, which are similar to considerations for assessing causal inferences (which he presents from Clarke, 1999):

   - How good is the quality of the included studies?
   - How large and significant are the observed effects?
   - How consistent are the effects across studies?
   - Is there a clear dose-response relationship?
   - Is there indirect evidence that supports the inference?
   - Have other plausible competing explanations of the observed effects been ruled out?

2. **Include a mix of trials and non-trials designs.** There was strong support at the conference for including a broader range of study designs, examining each study for threats to validity, rather than pre-empting all non-trials and only beginning the evaluation among them.

3. **Provide incentives for more studies with other characteristics that will make the research more policy relevant.** Include more studies

   - **In natural settings,** which will make it easier to generalize to the real world.

   - **Of social change activity,** which is difficult to capture well in a trials approach, yet social change may be what is most needed to improve developmental trajectories for many young children.

   - **That speaks to costs, feasibility and other important considerations of importance to policymakers.**

3. **Develop a conceptual framework and structure used for assembling evidence that is capable of being cut in a variety of ways.** Some researchers and some policymakers focus primarily on interventions, others focus on outcomes, others focus on both. Some are more concerned with process of the intervention or characteristics of the sample. All of the foci are in addition to methodology.

   - **Interventions:** approaches which focus on methodology or outcomes often lose much of the variety and detail about interventions in which practitioners and policy-makers are most interested, and which they view as critical. There are times when a particular type of intervention becomes politically favoured, which leads to questions about its service delivery mechanisms and costs, as well as outcomes, across various versions of it. For example, policymakers may want to know what the research says about lay home visiting versus nurse home visiting programs. An emphasis on type of intervention provides information of more policy-relevance, especially where decisions have to be made between the costs and benefits of different versions of the same intervention, or even across different types of intervention or service delivery mechanisms.

   - **Outcomes** - many social interventions are explicitly targeted at a range of outcomes. For example, an intervention may focus simultaneously on such outcomes as cognitive development, injury prevention and parenting knowledge. Politicians often ask bureaucrats to, "Show me all the programs that will reduce (fill in the blank — e.g., aggression; child maltreatment, etc.)." And it can be even more complicated than that. Policymakers, practitioners and clients alike may want to know, for example, about teen parenting interventions which offer the 'best value' for money in doing something about a range of outcomes taken together, rather than about a single outcome. That is, the relevant policy question could be: what type of teen parenting intervention is most likely to promote healthy development of the baby, prevent child abuse, facilitate secondary school completion by the mother, and possess financial, organizational and political feasibility within a (fill in the blank —e.g., social assistance, secondary school, public health) context. At the policy level, interventions with similar outcomes may have very different costs and program implementation features.

   - **Other relevant categories:** In addition to structuring the database so it provides information on both interventions and outcomes, it also needs to be capable of being analyzed by other important characteristics. For example, sample characteristics are crucial (e.g., marital status; age; gender; income). Type of intervention (targeted or universal). Type of program (e.g., education;

social support; income support). And so on. Creators of a Canadian database need to develop a framework of categories, that will give the researchers and policymakers access to the information needed to answer the important questions of the day.

4. **Involve both policymakers and practitioners, in addition to researchers, in developing a relevant classification approach.** Throughout the day of the conference, researchers and policymakers were increasingly pleased to find genuine mutual interest in understanding the reality of each other's working world. Both groups wanted to assist the other. Researchers wanted to know about the realities of policymaking, so their research could be more useful to policymakers. Policymakers wanted to understand the flexibilities and inflexibilities of high quality research, so they could better support future research funding and appropriately translate research into policy.

At the end of the day, the conference participants were in general agreement that if the consumers of the research reviews are ultimately the policymakers and practitioners, they need to be involved in setting up a review from the beginning. This will ensure the review:

- Is targeted at problems that are important to policymakers
- Take account of outcomes that are important to policymakers
- Are evaluated in terms of real life service delivery realities by practitioners
- Are accessible to practitioners, policymakers and politicians making decisions, and
- Adequately reflect variability in the values and conditions of service delivery and governments

SUMMARY

At the end of the conference, participants were pleased to have had the opportunity to so thoroughly explore the pros and cons of both the Mrazek and Brown approach to classifying research, and the larger context of evidence-based knowledge development. In summary, both researchers and policymakers left with the understanding that people use research information differently. The participants were very pleased to have the Mrazek and Brown information at hand. It opens the door to further policy and research relevant analyses of data that were previously out of reach, due to the size and unorganized state of the evidence. At the same time, since the pros and cons of Mrazek and Brown's approach were so completely explored, both researchers and policymakers felt they could put both Mrazek and Brown's and Crooks and Peters' reports into perspective, as they begin to use the findings to guide their work.

On the other hand, Mrazek and Brown's approach surfaces very little Canadian research that meets their definition of high quality. Further, much of the most relevant Canadian research is currently underway (not yet completed). Both the researchers and policymakers wanted an empirical base of research that is useful, current and vibrant. There was strong support for something like a Registry that would be designed to include program information, in addition to research and methodological information. There was some concern that if too much funding went to retro-fitting Mrazek and Brown, there might not be enough funding to establish this kind of Registry.

SUMMARY OF SIMILAR INTER-NATIONAL REVIEW ENDEAVORS

At the time Invest in Kids commissioned the Mrazek and Brown review, an international research group centred in Britain (called the Cochrane Collaboration) had been undertaking reviews of randomized controlled trials (RCTs) of medical interventions. Although the Cochrane Collaboration had recently expanded its scope to include reviews of health promotion interventions, for the most part it was wed to RCTs and a medical model framework. Invest in Kids and its Research Advisory Group did not consider that this approach would work well in evaluating the largely applied research base, that is generally found in the prevention/early interventions for young children. Thus, it was a relief to find Mrazek and Brown, who are dedicated to social science and education interventions.

However, In February, 2000 a parallel international group (an offshoot of the Cochrane Collaboration), but centred in the United States was begun to help people make well-informed policy decisions by preparing, maintaining and promoting access to systematic reviews of studies on the effects of social and educational policies and practices. This group is the Campbell Collaboration, named after an American psychologist and thinker, Donald Campbell, who is famous for defining rigorous quasi-experimental research design. He spent a lifetime drawing attention to the need for societies to rigorously assess the effects of their social and educational experiments, that is, the policies and practices that they introduce and promote.[2]

What are the objectives of the Campbell Collaboration?[3] To prepare and maintain systematic reviews of studies of the effects of policies and practices.

- In education, and the social and behavioural sectors
- Are useful to people in policy, professions, research and public participants
- Are developed by international review groups
- Use standards for quality of evidence that are transparent and criticizable
- Rely on a world wide web-based system and on conventional media for dissemination and periodic updating
- Focus on randomized field trials first and on high quality nonrandomized field trials second

Both the Cochrane and the Campbell Collaborations have Canadian members and leaders. The Cochrane Centre for Health Promotion is located at McMaster University, and Professor Helen Thomas, also from McMaster University, is on the Steering Committee of the Campbell Collaboration.

At its formative meeting, the Campbell Collaboration asked experts from the Cochrane Collaboration to provide advice on Lessons Learned that would be applicable to this newer incarnation, the Campbell Collaboration.

Professor Ann Oakley is an eminent authority in developing research classification criteria. Part of the Mrazek and Brown approach reflects Oakley's work. Professor Oakley made the following observations for the emerging Campbell Collaboration.[4] She noted that some people might argue that you could never have enough RCTs. However, she observed that the Campbell Collaboration, dedicated to assessing the effects of social and educational interventions, would confront a proportionately larger literature on non-randomized (and non-controlled) 'evidence.' Thus, methodological questions about how best to synthesize non-RCT evi-

[2] http://campbell.gse.upenn.edu/intro.html
[3] http://campbell.gse.upenn.edu/faq.html
[4] **An infrastructure for assessing social and educational interventions: the same or different?** Ann Oakley, **Social Science Research Unit, University of London Institute of Education.**
Background paper for meeting at the School of Public Policy, University College London, 15/16 July 1999.
http://campbell.gse.upenn.edu/papers/oakley.doc

dence would be correspondingly more important. One methodological challenge will be to develop efficient search strategies for different levels of evidence. Another main priority will be to undertake parallel systematic reviews of randomized and non-randomized evidence in order to demonstrate the biases that are likely to occur from each.

Finally, she concluded that the healthiest route to shaping this flexibility in balancing these priorities is what Campbell called 'a disputatious community of scholars' who are prepared to argue about something for long enough to substantially increase their collective chances of making the best decision.

The Campbell and the Cochrane Collaborations show there is an inter-national drive to bring the tangled web of policy relevant research, with its myriad of disciplinary and methodological threads, together into a coherent form. These collaborations also alert us to the possibility of being able to learn from such efforts.

MOVING FORWARD

Out of the conference discussions there arose a clear desire on the part of both policymakers and researchers to have access to current, relevant Canadian research. At the end of the day, the big question of what to do next was not resolved. At the time of the conference, two main options were discussed. The first proposed option was to negotiate with Mrazek and Brown to see if some of the limitations to their approach could be removed. This approach would permit Canadian researchers and policymakers to maintain a finger on what is happening around the world in prevention and early intervention. The second option was create a smaller, Canadian-only, Registry of high quality current and recent past research. It was expected that this database would use a broader definition of quality than is available with Mrazek and Brown. It could even be decided on a case by case basis.

However, since the Campbell Collaboration is now underway, and Canadians are involved in this approach, it is important to consider whether a third option might be available that would address some of the issues surfaced during the conference.

These three options are elaborated further below.

I. Continue with the Mrazek and Brown trials approach, but expand it:

Consultation could be initiated with Mrazek and Brown to determine whether they would be interested in expanding their approach, and if so, what the cost and level of effort would be to include the following extensions of their approach.

Expanding the breadth of acceptable types of methodology: Provide funding to expand the current review to include 3 star studies (don't just limit to 4 and 5 Star studies).

Including more concurrent studies: Provide funding to expand the number of ongoing studies through non-traditional search techniques.

Increasing transparency: Provide funding to support reliability testing of the methodology that assesses the scientific rigor, with the objective of making the decision-making regarding the categorization of each factor transparent.

Advantages:

- Although few studies in the Mrazek and Brown review are Canadian, National Children's Agenda Early Child Development policy decisions are now underway and policymakers would benefit from having access to this type of review.

- Improvements in the Mrazek and Brown methodology would give Canadians policymakers more comfort that the top studies have been reliably selected.

- If the Levels of Evidence were expanded to include Grades V and VI, more Canadian studies would be included.

- The international scope allows comparison of findings from Canadian studies to similar studies from all over the world.

Disadvantages:

- Investment required to make the decisions transparent will be substantial.

- Requires investment in a process where the proportion of Canadian studies overall will probably remain small.

- Although expanded, the emphasis remains on methodology, and not on intervention detail.

II. Take the leadership in one or more Campbell Collaboration Review Groups focusing on early child development

Consultation could be initiated with the Campbell Collaboration to determine what would be required for panels of appropriate Canadian researchers, policymakers and practitioners to undertake the lead in one or more Campbell Collaboration Review Groups. These reviews would focus on worldwide reviews of research on topics of importance to Canadian policymakers regarding prevention and early intervention. For example, early language development interventions, infant mental health programs, etc.

Advantages:

- Links with the Cochrane/Campbell Collaborations will allow the establishment of the reviews without re-inventing some of the processes:

  - Access to Methods Groups, which provide training and support, on such topics as statistical methods, non-randomized studies, qualitative research and reporting bias, etc.

  - Closer links to the Cochrane Health Promotion and Public Health Field located at McMaster University, which shares some interests in child development and parenting.

  - Links to Review Groups, which help reviewers develop protocols, and includes use of the Review Manager software.

- Avoids chances of duplication of effort, which could happen if either of the other options was selected.

- Favours smaller more focused reviews, which allows more appropriate analysis of cross-study effect sizes.

- Provides access to international scholars, with similar interests.

Disadvantages:

- Focus is on international reviews. Again, Canadian research will take back seat to methodology, which assumes pre-eminence over the social structure in which the policies and programs are implemented.

- The Campbell Collaboration is still under development. It is not an established initiative.

III. Undertake development of a Canadian-only searchable Registry of high quality research

The purpose of this option is to build a Canadian database of all high quality recent past, current and future studies and make the information available to researchers, policymakers and practitioners now and over foreseeable future. It would be lead by a Steering Committee of Canadian researchers, policymakers and practitioners to guide the development of standards and protocols. ("A disputatious community of scholars...")

The Registry would include:

- Broader range of acceptable methodologies than was included in Mrazek and Brown, developed and reviewed regularly

- All studies, which began by a certain date (1990, for example), including those that are still underway.

The Registry would build and expand over time with the goal of having a complete Registry of all research that meets certain criteria available within a specified period of time.

It would have the potential to be more:

- interactive, because this is more feasible with a smaller database

- searchable, because it could be designed with this feature from the beginning

- applicable to the Canadian policy and program context, because it would have been designed for this purpose.

It would benefit from links with Mrazek and Brown and the Campbell Collaboration, similar to the links the National Longitudinal Survey of Children and Youth has had with international scholars.

Advantages:

- Begins Canadian knowledge exchange very soon.
- Tailors information to Canadian policymakers.
- Focuses attention on strengths and gaps of Canadian research
- Focuses attention on the proportion of Canadian research that is longitudinal
- Focuses attention on the proportion of Canadian research that is ecological
- Focuses attention on the size of samples in Canadian research

Disadvantages:

- Will take 5 years or more for this database to fulfill its promise. That is a long time for policymakers to wait.

CONCLUSIONS

Having examined all the perspectives brought to bear through the external reviews in advance of the conference and through the discussions during the conference, **Invest in Kids and its Research Advisors agree with the conference participants that the Mrazek and Brown reports are an important contribution to the field.** Policymakers can use the reports to examine the characteristics of rigorously researched interventions, the outcomes and the populations on which the research was based to assist in their policy and program planning.

Although Invest in Kids and its Research Advisors acknowledge the important caveats and issues raised about placing too much emphasis on trials-type research, they fundamentally agree that trials-type research has held, and continues to hold, an important place in establishing evidence of intervention effectiveness in Canada.

The Mrazek and Brown review shows there are just too few high quality Canadian trials-type studies. When examining the Mrazek and Brown information on Canadian studies, we see that of the 165 studies designed to have at least a comparison group, we see a total of 21 studies which are Canadian. Yet of these 21 studies, only two had low enough levels of other threats to trial integrity to be included in the top 25% of the studies.

The Mrazek and Brown Threats to Trial Integrity are basic standards of research quality, usually taught in Introduction to Research courses. They are not obscure trick criteria with which researchers are unfamiliar. Then why, if knowledge about trial threats is so elementary, did Canadian research studies contain such high levels of these threats? Invest in Kids and its Research Advisors suspect it is at least partially due to a lack of funds to cover the costs of addressing these threats. It takes more funds than are generally available in most "Requests for Proposals (RFPs)" to ensure: comparison groups are truly comparable, the sample size is large enough, the intervention is delivered as described, the measures are appropriate, the assessors are blind to the intervention and that drop-out rates remain low. The level of funding for research is a very serious issue, because when research rigor is insufficient, the funding is essentially useless because the results are compromised, and thus not generalizable. **Therefore, Invest in Kids and its Research Advisors conclude that to avoid wasting research and evaluation funds, the level of funding for every prevention/early intervention study needs to be high enough to ensure the threats to the integrity of the research can be addressed.**

Invest in Kids and its Research Advisors also agree with the conference participants that trials-type research, although essential, is but one part of the total evidence available to assess intervention or program effectiveness. **It is important to expand beyond trials type research to identify additional research designs, which can provide high quality evidence of effectiveness.**

Additionally, Invest in Kids and its Research Advisors conclude that Canada needs to have a stronger focus on Canadian prevention and early intervention research while simultaneously becoming closely involved with international research review efforts. If we focus just on Canadian research, we could miss important international trends in both research and interventions. On the other hand, if we do not have some source of strictly Canadian research, we will not be able to understand the gaps and overlaps in our own research and intervention initiatives.

Finally, Invest in Kids and its Research Advisors conclude there are only a limited number of high quality prevention and early intervention research studies, trials type and otherwise, which are directly relevant to Canadian policymakers and practitioners in undertaking the National Children's Agenda, Early Child Development initiative. Even more worrisome, researchers and policymakers could be in exactly the same position ten years from now, if we continue with the same unorganized approach to research over the next decade that we have used in the past. **As its final conclusion, Invest in Kids and its Research Advisors conclude there is a need to develop a national comprehensive research agenda to ensure the programs of the present are as good as they can be, and the programs of the future are based on evidence of effectiveness.**

RECOMMENDATIONS

To assist in this undertaking, Invest in Kids and its Research Advisors think there is value in disseminating the Mrazek and Brown reports, the Crooks and Peters expansion of the findings, the external reviews and this conference report to people beyond the conference participants. **Therefore, Invest in Kids will prepare and release a complete package of these materials for dissemination.** The package will be especially useful to federal and provincial policymakers in departments with strong investment in prevention and early intervention programs, as well as the many related researchers and practitioners who focus on the early years.

Taking into consideration the essence of the discussions from the research conference, as well as the international efforts underway to evaluate research rigor and to conduct world-wide reviews, Invest in Kids and its Research Advisors make the following recommendations:

1. **The federal and provincial governments jointly support the development of a flexible, accessible Canadian Registry of Prevention and Early Intervention Research focusing on the early years.** Policymakers and researchers at the conference expressed a strong desire to have access to this type of database. The conference participants proposed the formation of a Steering Committee of researchers and policymakers, from across the major early childhood disciplines and sectors, to establish the criteria for entry of studies into the Registry.

   - The Steering Committee to establish standards of rigorous research design, not limited to trials-type research, for entry into the Registry.

   - Entry into the Registry to be based on transparent decision-making regarding the inclusion/exclusion of each study.

   - The Registry to include research currently underway, as well as completed research.

   - The Registry to include categories of consequence for researchers (design type, sample size, measures), policymakers (costs, settings, outcomes), and practitioners (staff ratios, training, operations).

   - The Steering Committee to maintain close links to the Campbell Collaboration and other national and international expert groups evaluating research quality, to benefit from the international debates on what constitutes high quality research.

   - The Registry to become a central repository for all research underway with a focus on the early years, including research from across various divisions of Human Resources Development Canada and Health Canada, the applicable research underway through the National Crime Prevention Council, the Medical Research Council, SSHRCC, provincial research and research in Canada funded by sources from outside Canada. (E.g., UNICEF, Aga Khan Foundation, U.S. National Institute of Mental Health, etc.).

The conference participants clearly wanted the Registry to become more than an ivory tower database. It should serve as a nexus for research, policy and practice —a thriving centre of information on past, current and future research in Canada. In addition to setting standards for the Registry, and assessing whether studies should be included in the Registry, the Registry Steering Committee should assure the implementation of two additional vital functions:

- Disseminating information about the registered studies so Canadian researchers, policymakers and practitioners become very familiar with prevention and early intervention research in Canada.

- Evaluating the field of prevention and early intervention research, and noting the gaps and overlaps as they develop, and actively recommending the areas where additional research is needed.

2. Invest in Kids and its Research Advisors noted the strong counsel by researchers and policymakers alike that reviews with more restricted scopes of subject matter and broader definitions of rigor would produce higher quality information for practitioners and policymakers. **Therefore, Invest in Kids and its Research Advisors recommend the federal government support involvement of Canadian researchers and policymakers in the establish ment of parallel international review groups, such as the Campbell Collaboration, especially if they can be influenced to undertake reviews on topics of importance to the Early Child Development initiative.** This approach would per mit Canadian researchers and policymakers to identify research evidence worldwide that is robust and therefore more applicable to Canada. It will also put Canadian researchers and policymakers in the company of an important global effort to jointly establish an international set of parameters regarding what is considered to be high quality applied research.

   Finally, although a Registry and strong participation in international reviews such as the Campbell Collaboration should stimulate improved quality of Canadian research, the conference participants were also concerned about whether there are funds available for high quality efficacy research and effectiveness studies. They were particularly concerned about whether there are enough research funds available as part of the National Children's Agenda to ensure children will receive the most effective programs tailored to their needs. Therefore, Invest in Kids and it Research Advisors recommend:

3. **The federal government should work with the provinces to set aside funds to undertake rigorous efficacy research of worthy innovative interventions, where the amount for research should be funded at an additional 30 percent over and above what is allocated for program.** (e.g., If the total funding from all sources for an innovative intervention is $300,000, the efficacy research component at that site would amount to an additional $90,000.) Efficacy is the extent to which a specific intervention or service produces a beneficial result under ideal conditions. Efficacy research is crucial because it allows an initial assessment of whether there are actual benefits or harm associated with an innovative intervention, and also permits an appraisal of whether the effects are due to the intervention, or to chance and/or confounding factors. This type of research requires substantial funding because many environmental, programmatic and individual factors must be thoroughly examined to determine reliably and validly the potential effects of the intervention.

4. When the efficacy of an intervention has been rigorously demonstrated the **federal government should work with the provinces to establish effectiveness trials in "real life" diverse settings, where the amount of funding should be a minimum of an additional 15 percent over and above the allocation for program.** (e.g., If the

allocation for a trial program is $10 million, the effectiveness research for that program would be an additional $1.5 million.) Effectiveness is the extent to which a specific intervention, procedure, regimen, or service, when deployed in the field, does what it is intended to do, without the daily direction of the original program or research directors. Effectiveness trials are a mid-step between efficacy research and full-scale population-wide implementation. Effectiveness trials examine how best to maintain fidelity to the original model while testing the intervention with broader environments and populations than was done with the efficacy trial.

5. **When it is not possible to undertake efficacy and effectiveness trials sequentially before a new program is announced, the federal and provincial governments should follow the same formula, but implement it simultaneously, when the new program is announced. Specifically:**

   - **Designate a portion of the program's new sites as efficacy demonstration sites, funding research at the rate of an additional 30 percent over and above the amount for those sites' program funds.**

   - **Designate the remaining sites as effectiveness demonstration sites, funding research at the rate of an additional 15 percent over and above the amount allocated for those sites' program funds.**

SUMMARY OF RECOMMENDATIONS

To assure ourselves that our prevention and early intervention programs are effective for our children, Canada needs a comprehensive agenda of prevention and early intervention research. Canada needs to:

- Create a more centralized, coordinated hub of prevention and early intervention knowledge exchange focusing on the early years — a Registry;

- Participate in and have access to international reviews of important early child development research, such as the Campbell Collaboration; and

- Undertake a substantial efficacy and effectiveness research agenda as new interventions are planned and implemented.

Right now, even with the National Children's Agenda Early Child Development initiative, each program or project focuses primarily on itself. The knowledge exchange is haphazard. A comprehensive approach to prevention and early intervention research can change this. It can lead to policies and programs tailored to the Canadian context and substantiated by research conducted in Canada. We would be able to answer the simple questions: What is the evidence for what works? For whom? Under what circumstances? We would be on our way to meeting the fundamental challenge, described by Meisels and Shonkoff at the beginning of this report: the merging of knowledge and insights of

scholars and practitioners with the creative talents of those who design and implement social policy initiatives, and investing the products of this alliance in the future of our children and thereby in the well-being of Canada as a whole.

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PART II - THE REPORTS AND PEER REVIEWS

A. FINAL REPORT

AN EVIDENCE-BASED LITERATURE REVIEW REGARDING OUTCOMES IN PSYCHOSOCIAL PREVENTION AND EARLY INTERVENTION IN YOUNG CHILDREN

Prepared for Invest in Kids
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PREAMBLE

The following report was funded by Invest in Kids of Toronto, Ontario, Canada. Invest in Kids' mission is "to enhance the capacity of all Canadians to positively influence the social, emotional, and cognitive development of our youngest children." Invest in Kids has three goals: to enhance the understanding of healthy development of children between the ages of 0-5; to create a climate of support for healthy child development for all Canadian children; and to motivate adoption of best practices and policies to ensure the most effective development of our youngest children.

In 1997, on the advice of Invest in Kids' Research Advisory Group, Invest in Kids contracted with Prevention Technologies (Dr. Patricia Mrazek and Dr. Hendricks Brown) to conduct an evidence-based, systematic literature review regarding outcomes in psychosocial prevention and early intervention in children

from zero to six years of age. The Research Advisory Group recommended this review because Canadian policymakers and foundations, including Invest in Kids, are under intense pressure by the public and a variety of experts to fund prevention and early intervention programs. All such proposals are accompanied with claims of being "best practices" or "proven interventions," but the criteria for such assertions are rarely made explicit. The Research Advisory Group determined that the prevention/early intervention field would greatly benefit from a systematic review of research studies, grounded on a methodology designed to rank the studies on the basis of scientific rigor. It was believed that this review would provide a basic foundation for the prevention/early intervention field.

As a public service, Invest in Kids is now providing the results of this review to researchers, policymakers, practitioners and the general public. The results are contained in two parts: a Summary of Key Research Studies (including results as reported by the investigators of each trial) and a Final Report (appraising and summarizing the literature). The materials will be available through Invest in Kids website: www.investinkids.ca.

Invest in Kids, its Research Advisory Group and the studies' authors, Drs. Patricia Mrazek and Hendricks Brown, hope these materials will be useful to researchers and policy-makers as they conceptualize the design and funding of new research endeavors. There are many gaps in the early intervention research field that need to be addressed, and this review highlights some of them. We would also like to point out that while these reports concentrate on those studies with 4 and 5-Star designs, we all recognize there are approaches, strategies and components in the less rigourous studies that may be very important in producing positive outcomes for children and families. Therefore, while we maintain that the models with the most rigourous designs should be examined first and foremost, we also see the value of researchers and policymakers carefully inspecting other less rigourous studies, to determine what could or should be included, when designing the new generation of prevention/early intervention research models. Above all, we hope the level of funding which is required to enable the more rigourous research designs, will be provided, and this, we believe, will lead to more 4 and 5-Star designs in the future.

We are aware that many communities and levels of government are eager to learn about prevention programs that could be helpful to young children and their families. We encourage policy-makers and program administrators to use these materials for guidance, with the understanding that the materials constitute a literature review with a systematic evaluation of the quality of study design and methods. They are not clinical preventive practice guidelines. (The latter are commonly defined as statements to assist decisions about provision of interventions or services.) Rather, they are the kinds of materials that could help others formulate such guidelines.

Translating science into practice recommendations has become a major endeavor within all of medicine and the social sciences. The criteria for what constitutes sufficient scientific evidence that a particular practice, program, or policy should be disseminated are being hotly debated. In attempting to define priorities and strategies for translating child-oriented prevention research into effective practice, we have faced the same issues.

It was clear to Invest in Kids and the Research Advisory Group when we began the review that we had to start with good science, and we believed that the first place to start in science was to look at the evidence for efficacy. (Efficacy is the extent to which a specific intervention, procedure, regimen, or service

produces a beneficial result under ideal conditions.) We had to be able to conclude that any benefits that were observed were due to the effects of a specific preventive intervention and not due to chance or confounding factors. We also had to be able to assess whether an intervention was causing any harm. To make these conclusions Drs. Mrazek and Brown of Prevention Technologies were asked to focus on the type of study design and its quality as well as on the direction, strength, and duration of the outcomes. Thus, their goal was to systematically categorize and, when possible, to quantify the details of every child-oriented preventive intervention research program for the zero to six age group. The search was extensive but not exhaustive. It should be noted, however, that explicit selection criteria were used to determine which studies were reviewed and included. This was done to avoid the bias and error that commonly accompanies the retrospective exercise of reviewing studies. The results in the Final Report provide the backbone for what could potentially become a more complete registry of preventive trials.

On the basis of their review, Drs. Mrazek and Brown conclude there is evidence from high-quality efficacy trials that particular child-oriented preventive interventions produce significant positive effects. This is encouraging news. At the same time, it is discouraging that so few of these trials have been replicated, by either the original or independent investigators, and few of them have been tested in effectiveness trials in "real-life settings" without the daily direction of the investigator. (Effectiveness is the extent to which a specific intervention, procedure, regimen, or service, when deployed in the field, does what it is intended to do for a defined population.) The approach of effectiveness trials following high quality efficacy trials that have been replicated by independent investigators is the gold standard for which we should strive. It is also clear that evaluation of the efficacy and effectiveness of interventions should precede dissemination of programs, otherwise communities will continue to lack information about whether established programs do more harm than good for children and families. For this to happen, policy-makers who control research budgets will need to make such research a priority.

Meanwhile, communities are designing and providing preventive services-with or without the benefit of the results that we already have. Prevention scientists should be cautious in holding out for a standard that currently is impossible to meet and one that is not yet required in other fields. Also, we must all be mindful that a majority of preventive services lack any science basis at all. Disseminating high quality studies with randomized controlled designs that have significant positive effects is an in-between step until the effectiveness data have been gathered.

It is also important to remember that health and behavioral health outcomes are not the only criteria used when communities consider adopting preventive practices. Policy concerns such as costs and cost-savings, the acceptability of a program into a particular community (i.e., the "fit" between the program's goals and local values), and the availability of training and consultation are also critical. These are the kind of issues that can be addressed in effectiveness research.

This dilemma of where to put the emphasis when considering what programs are ready for dissemination is not unique to prevention. In the well-known work of Chambless and Hollon, a plan is proposed for defining empirically supported psychological treatments for specific problems or disorders. They, too, put the primary emphasis on evidence of efficacy but acknowledged that not everyone will agree with their premise that "efficacy takes priority over effectiveness" (p.16). Chambless and Hollon suggest that "..... in evaluating the benefits of a given treatment, the greatest weight should be given to efficacy trials but that these trials

should be followed by research on effectiveness in clinical settings and with various populations and by cost-effectiveness research" (p. 7).

When policy-makers and administrative program directors are choosing what prevention programs to provide for children and families in their communities, we encourage them to use the scientific evidence that is available in their decision-making. Hopefully, the evidence (or lack of evidence) in each of the trials in this report will provide some guidance. Policy-makers frequently must decide what to do about prevention programs that have no clear scientific basis but are popular in a particular community. Indeed, these programs may have significant positive outcomes, but without the systematic study of the approach, there is no decisive way of knowing. Collaborations between these practitioners and researchers may yield some creative ways of systematically assessing their outcomes.

THE SCOPE OF THE REVIEW

Prevention Technologies, LLC has prepared for the Invest in Kids an evidence-based literature review regarding outcomes in psychosocial prevention and early intervention in young children. The focus of this review is on empirically tested psychosocial interventions targeting the following areas:

1. the parents during the prenatal period;

2. the parent-child relationship from zero through six (including interventions aimed at attachment issues and parenting)

3. the cognitive, language and social development of the child (such as Head Start);

4. the broader community in its intervening relationship to young children and their families; and

5. medical conditions that overlap substantially with psychosocial conditions (such as failure to thrive and other forms of child maltreatment).

Included in the review are programs designed for broad populations (also known as universal preventive interventions), programs aimed at particular risk groups (also known as selective and indicated preventive interventions), and clinical programs (also known as case identification and treatment).

The issue of boundaries was relevant as a cut-point issue. For example, there have been many home visitation trials to prevent prematurity and low birthweight. These were included as long as the intervention had a central psychosocial component. If medications or medical technology alone were the main focus (e.g. home visitors using portable ultrasound machines), the trial was not included.

STANDARDS OF EVIDENCE

The standards of evidence used in this literature review are based on prior work by the Canadian Task Force on the Periodic Health Examination, the U.S. Preventive Services Task Force, the Institute of Medicine (IOM) Committee on Prevention of Mental Disorders, and the Cochrane Collaboration, as well as key papers on the quality of trials by Thomas Chalmers, and Ann Oakley and colleagues (1995). This last reference contains an 8-point rating scale for an intervention trial, the Trial Elements Score that we have adapted for our use in this review. Also, we make use of a newly developed, comprehensive evidence rating system, the Threats to Trial Integrity Score (TTIS), in this report. Each trial is

rated on both the Trial Elements Score and the TTIS, and a comparison is made of these two systems. The TTIS score is also transferred into a Trial Quality Grade.

Our starting point for searching through the literature was to include all trials which, on reading the abstract, appeared to have a potentially viable design to address a program's prevention effect. We also tested whether this search strategy was too exclusive on a small sample of studies, and concluded that the search strategy was successful. We searched for preventive trials with sufficiently high grade of evidence based on the Institute of Medicine Committee on Prevention of Mental Disorders (Mrazek and Haggerty's 1994) hierarchy of evidence. This grading system was derived from the U.S. Preventive Services Task Force grading system, which itself was adapted from the Canadian Task Force. It uses seven levels of "quality of evidence," with the highest level being evidence obtained from at multiple randomized controlled trials. These basic levels of evidence are as follows.

Grade I: Evidence obtained from multiple randomized controlled trials (confirmatory and replication trials and large-scale field trials).

Grade II: Evidence obtained from multiple randomized controlled trials (confirmatory and replication trials but no large-scale field trial).

Grade III: Evidence obtained from at least one properly randomized controlled trial.

Grade IV: Evidence obtained from well-designed controlled trials without randomization.

Grade V: Evidence obtained from well-designed cohort or case-control studies, preferably more than one.

Grade VI: Evidence obtained from multiple time series studies, with or without the intervention. Specifically, this would include well designed quasi-experiments or observational studies with appropriately matched controls.

Grade VII: Evidence suggested by respected authorities, based on clinical experience, descriptive studies, prior service delivery programs, or reports by expert committees.

The choice of minimum grade level we required for this review was dictated by the existing grade levels among trials aimed at zero through six-year-olds. The state of current knowledge is that only a handful of intervention programs would meet either of the top two grade levels. There are, however, a substantial number of related controlled trials. The level of evidence that we use in this report to review the zero through six preventive intervention literature is limited to that of Grade IV or above.

METHODOLOGY FOR SCREENING TRIALS

We searched for randomized controlled trials, quasi-experimental designs, and subsampled a few studies that appeared to be case control studies or unevaluated programs. Specifically excluded from our search were pre-test post-test designs with no control or comparison groups because these studies cannot differentiate intervention effects from developmental effects, particularly in the years 0-6.

Prevention Technologies developed a 3-stage screening process for selecting trials for inclusion. This three-phase screening process was designed to identify all the trials which would reach acceptable design and outcome criteria.

Stage 1. In this stage we completed literature searches that were based on the abstract itself. Stage 1 was designed to cast a large net so all high quality studies would be included and all studies of low design quality would be excluded. A study was included if the abstract explicitly stated or suggested in any way that the intervention was a prevention program intended to prevent first onset of a condition for those aged 0 to 6, and a) it had a control or comparison group, or b) it had assignment to varying levels of intervention dosage, or c) it specifically stated that there was random assignment to intervention. In addition, we included all pertinent reviews in this stage since they helped us identify trials. Our searching through Medline, PsychInfo, ERIC, Current Contents, CINAHL, and other databases produced between 10-50% hit rates using that database's standard subject headings in advanced searches. While we set no specific lower limit to the year searched or the language of the article, we found relevant articles that had been published in 1970 or later, and all were in English.

Stage 2. In this second stage we screened the full published papers or reports of all Stage 1 studies to identify those which clearly did not meet the criteria for an adequate design, ones that most likely would meet the criteria, and a middle group where we were uncertain. For each of these groups we completed an abbreviated form of the classification system to score the adequacy of the design.

Stage 3. Using all of Stage 2's trials which were likely to meet criteria or where there was uncertainty as to whether they would meet initial criteria, and using an additional 5% of the trials which were classified initially as having an inadequate design, we completed a full assessment of the quality of the design and analytical procedures, as well as an assessment of outcomes. We found that the studies we initially ranked as having an inadequate design actually did have an inadequate design. There were a number of papers originally classified as uncertain that were found on closer examination to be appropriate for inclusion.

Most of the classified studies were located in professional journals through databases or by hand searching. We also identified some trials through our contacts with agencies, institutes, and key scientific leaders in the field. Obtaining some of the publications proved to be a more difficult task than expected because some of the journals are not widely available. Unpublished trials, evaluation reports to agencies regarding specific prevention projects, and trials reported in book chapters were included if they could be located, but this also proved to be difficult, especially for older materials. Research projects that were in progress were of special interest; if the design methodologies were available to us, they are included in this review as Concurrent Trials. We were concerned that studies with null or negative outcomes would be less likely to be published and therefore would be unavailable to us. This selection bias issue is of concern in any review that is based primarily on published papers. We did, however, find papers that reported either null effects or iatrogenic effects but we cannot at this stage quantify how much publication bias may be present.

NUMBER OF TRIALS FOUND

Through this search procedure we located 215 relevant scientific papers which we used in this review. There were occasions where multiple papers referred to the same trial, i.e., one paper examining short-term effects and a second examining longer effects. Occasionally, one paper reported the design and results of more than one trial. Thus the number of trials described in this review, 165, is different from the number of papers. Much of this report is based on individual trials. To help link which papers refer to which trial, we have provided various cross-referencing. We have included at the end of this Final Report a set of tables and figures, and we describe them in the text.

METHODOLOGY FOR CLASSIFYING TRIALS

The three-step inclusion process described above is somewhat like a funnel, very broad at the top and narrowing with cut-off points to a much smaller end point. The best of the designs made it to this end point, and they are the backbone of this Final Report. However, they are supplemented by supporting evidence from less rigorously designed studies.

The Summary of Key Research Studies, which is based on papers rather than trials, accompanies this Final Report. Each relevant trial is annotated by paper(s), alphabetically by first author, with a complete reference, description of the target population, sample size at the time the population was identified and randomized, the type of design, the type of intervention, description of the intervention, and the outcomes as reported by the author(s). Key characteristics and the quality of each trial are provided here in this report.

DESCRIPTORS OF THE TRIALS

We report on the country where the trial took place. The country code reflects where the trial occurred. It may not be the same as the home country of the researcher or the country where the trial was eventually published. Studies are identified by authors, year of publication, name of the intervention or trial (often missing), where the intervention took place, i.e., home visitation or clinic-based, age and stage of life during intervention period, and targeted outcome category.

AGE AND STAGE OF LIFE

In coding for stage of life, we used the following convenient categories:

Prenatal — before child's birth
Parturition — at time of delivery
Infancy — 1 day to 23 months
Toddler — 24 months to 35 months old
Preschool/Kindergarten — 36 months to 71 months
Early School-Aged — 6 years of age

Stage of life was based on the age of the child during the intervention period. We report both the stage of life for the child when the intervention began (based on average age of the child at that time), and for those trials where relevant, the multiple stages of life where an intervention is given.

OUTCOME CATEGORIES

We developed 20 categories of targeted outcomes. Each trial could, and often did have multiple outcome categories. In the interests of expediency, we have limited our coding of these outcome categories to the outcome measures reported for the best designed trials. (The validity of outcomes in poorer designed trials would be questionable.) There are 969 different outcomes found in the 62 papers describing the 34 best-designed trials.

1. Pregnancy/Pregnancy Outcomes. This includes attitudes and behavior while pregnant, including smoking behavior. It also includes perinatal outcomes, i.e., the extent of neonatal care.

2. Parenting or Parent-Child Relationship. This includes home environment.

3. Safety or Injuries. This includes hospitalizations.

4. Maltreatment. This includes abuse or neglect but not hospitalizations per se.

5. Physical or Growth. This includes health care visits, immunization, and breast feeding as well as general health of the child.

6. Motor Development.

7. Cognitive. This includes developmental and early childhood problem solving.

8. Speech and Language.

9. Temperament/Behavior/Symptoms. This includes assessments by parents or teachers as well as clinicians regarding child behavior.

10. Social. This includes social development.

11. Legal Offenses. This includes substance use as well as delinquent or criminal acts.

12. School Performance. This includes school success or failure, school readiness, and skills related specifically to reading or achievement.

13. Government Cost.

14. Mother's Social Support. This includes formal and informal, as well as informational support and social service referrals.

15. Mother's Stress.

16. Mother's Mental Health. This includes coping, problem solving, symptoms and diagnoses.

17. Mother's Education.

18. Mother's Employment

19. Mother's Public Assistance.

20. Mother's Physical Health. This includes all physical health measures unrelated to the index child's pregnancy but includes birth spacing.

INTERVENTION TYPE (GORDON/IOM)

The interventions in the trials reviewed in this report are classified according to a system first developed by Gordon (1987, 1983) for physical disease prevention and later adapted by the Institute of Medicine (1994) for use in the classification of mental health interventions for mental disorders. The system is used here to classify interventions to prevent social, emotional, cognitive, and language problems and disorders in children from zero through age 6. Some of the interventions in the trials were classified as treatment rather than prevention because the social or emotional or cognitive or language problems were already of such a magnitude that a diagnosable condition was present.

In making these classifications, we kept in mind the following:

1. The preventive intervention targets risk factors associated with a main outcome (that could be proximal, distal, or both) that is social or

emotional or cognitive or language oriented. However, intermediate outcomes that are biologic in nature and are known to be associated with the onset of social or emotional or cognitive or language problems could also be addressed. Examples included in this review are trials to prevent low birthweight. Physical condition or disease is not a main outcome in this review.

2. The ultimate target population in this review is always the child even though much if not all of the preventive intervention is directed toward the mother.

3. If the target population is chosen because of early symptoms or problems in the areas of social or emotional or cognitive or language development and functioning, the intervention is classified as indicated even though many other risk factors that are also inclusion criteria are selective in nature (parental unemployment or having low birthweight).

The following definitions were used:

Universal Preventive interventions

1. Occur before the initial onset of disorder(s) or problem/condition(s)

2. Aim to reduce the number of new cases of disorder(s) or problem/condition(s) (incidence)

3. Might also aim to delay the onset of disorder(s) or problem/condition(s) (short-term reduction of new cases)

4. Are targeted to the general public or a whole population group that has not been identified on the basis of individual risk

5. Are desirable for everyone in the target group

6. Some individual members of the target group may already have a significantly high risk for developing the disorder, or have biological markers or early subthreshold symptoms of the disorder, or have the disorder, but such information is irrelevant to the choice of the target group and such individuals are still offered the universal intervention

7. Have advantages when the cost per individual is low (but may have large overall group cost); when the intervention is effective and acceptable to the population; and when there is a low risk from the intervention

8. Do not label individuals and therefore may be more "socially" acceptable to politicians and communities

9. Might have greatest effect on individuals who needed intervention the least and who might have made similar changes without the intervention

10. Utilize strategies to decrease risk factors and increase protective factors

Selective Preventive interventions

1. Occur before the initial onset of disorder(s) or problem/condition(s)

2. Aim to reduce the number of new cases of disorder(s) or problem/condition(s) (incidence)

3. Might also aim to delay the onset of disorder(s) or problem/condition(s) (short-term reduction of new cases)

4. Are targeted to individuals or a subgroup of the population whose risk of developing the disorder(s) or problem/condition(s) is significantly higher than average
   a. the risk may be imminent or it may be a lifetime risk
   b. the risks may be biological, psychological, or social and must be known to be associated with the onset of the disorder(s) or problem/condition(s)

5. Are desirable for everyone in the identified high risk target group

6. Some individuals of the target group may already have biological markers or early subthreshold symptoms of the disorder, or have the disorder, but such information is irrelevant to the choice of the target group and such individuals are still offered the selective intervention.

7. Are most appropriate if the interventions do not exceed a moderate level of cost and if negative effects are minimal or nonexistent

8. Label individuals or subgroups as being at "high risk"

9. Utilize strategies to decrease risk factors and increase protective factors

10. There is a wide range of risk conditions targeted by selective preventive interventions. Some risks reside within the community; many reside with the parents; occasionally they reside with the individual child. Risks range in severity from living in low socioeconomic neighborhood to imminent risk of out-of-home placement due to parental substance abuse, violence, or psychiatric disorder.
    a. Whenever a target population in a trial was chosen because the population was impoverished or low SES, the intervention is classified as selective. Therefore, all Head Start programs are selective.

    b. The target population may be chosen because it has multiple and specific risks or because it has one of several possible risks. For example, the Prenatal/Early Infancy Project had three possible inclusion risks which all related to parenting problems: low SES, being young, and being unmarried.

    c. When siblings of the subject child have a disorder or have been subjected to a high risk circumstance and it is this status that had identified the population of subjects, the intervention targeting the subjects is selective.

    d. Examples of targeted populations in selective preventive interventions: pregnant women smoking antenatally (the target is the fetus); low birthweight babies; children of depressed mothers; children living in impoverished neighborhoods.

INDICATED PREVENTIVE INTERVENTIONS

1. Occur before the initial onset of disorder(s) or problem/condition(s)

2. Aim to reduce the number of new cases of disorder or problem/condition(s) (incidence)

3. Might also aim to delay the onset of disorder(s) or problem/condition(s) (short-term reduction of new cases)

4. Might also aim to reduce the length of time the early symptoms continue and halt a progression of severity so that the individuals do not meet, nor do they come close to meeting, standard diagnostic levels

5. Might also aim to reduce the duration and/or severity of the disorder in individuals who develop the disorder despite the indicated preventive intervention

6. Are targeted to high risk individuals who are identified as having minimal but detectable signs or symptoms foreshadowing disorder or biological makers indicating predisposition for disorder but who do not meet standard diagnostic levels at the current time
   a. the high risk individuals may be symptomatic but have biological markers or they may be symptomatic but have symptoms that are still early and are not sufficiently severe to merit a diagnosis of disorder

7. Are desirable for all individuals who are identified with signs or biological markers or early symptoms

8. Some individuals may be identified in the initial individual screening process for markers and symptoms as already having the disorder; they are excluded from the indicated preventive intervention (and referred for treatment)

9. May be reasonable even if intervention costs are high and even if the intervention entails some risk

10. Label individuals as being at "very high risk"

11. Utilize strategies to decrease risk factors and increase protective factors

TREATMENT INTERVENTIONS

1. Occur at the time of or after the onset of disorder(s) or problem/condition(s)
2. Aim to reduce the rate of established cases of the disorder(s) or problem/condition(s) in the population (prevalence)

3. Are directed to individuals who meet standard diagnostic levels

4. Are therapeutic in nature

5. Include both case identification and standard treatment for the known disorder, which includes interventions to reduce the likelihood of future co-occurring disorders

6. Aims to reduce the length of time the disorder exists, halt a progression of severity, and halt the recurrence of the original disorder, or if not possible, to increase the length of time between episodes

7. Individuals are identified as patients

8. If the intervention addresses serious long-standing problems (such as more than 3 to 6 months) of a social, emotional, cognitive, or language nature, the intervention is classified as treatment. For example, interventions targeting children with DSM diagnoses of conduct disorder or children with Down syndrome are seen as treatment.

Summary

The boundaries between the four different type categories in this classification system are arbitrary in nature, but when these definitions and clarifications are consistently applied, it is possible to get reasonable

inter-rater reliability. The two authors of this report initially classified the intervention types using only the above definitions and had 10% disagreement. All disagreements were resolved through consensus.

QUALITY OF THE DESIGN

Two classification systems are used to assess the quality of the study design, with primary interest on outcome evaluation. The **Trial Elements Score** is an 8-point scale that consists of whether certain elements of a good design are reported. Oakley et al. (1995), in describing this system, indicated that the elements were proposed by the Cochrane Collaboration. They include

1. Aims stated clearly
2. Randomized controlled trial, or a comparable comparison group
3. Replicable (described) intervention
4. Numbers recruited provided
5. Pre-intervention data provided
6. Attrition discussed
7. All outcomes discussed
8. Post intervention data provided for all groups

Exact criteria for these dimensions were not available at the time of this review. We therefore developed our own guidelines for coding these criteria. For example, we coded "attrition was discussed" if the authors presented the rate of attrition, even if this rate was unacceptably high. Similarly, if the authors used the term "randomized trial," we scored it as randomized regardless of the care they took to ensure proper assignment. This scale as we have coded it thus represents a minimal standard to indicate whether elements of a good design are included, not necessarily that the design was implemented carefully.

Oakley and colleagues (1995) used their own scoring system based on these eight criteria to assess 68 outcome evaluation studies pertaining to HIV/AIDS prevention. It is not clear whether the coding decisions followed in that report were analogous to the ones reported here. Only 31% of these HIV prevention studies scored 7 or 8 on this measure. In contrast, fully 90% of the trials described in this report scored a 7 or 8. This suggests that our screening procedure was relatively efficient in screening for designs, which met a basic standard for design elements.

Within each of the design classes listed in the above hierarchy, and in the broad categories covered by the Trial Elements Score, there is great heterogeneity. Many randomized trials are not conducted properly, so they may provide little information on intervention effectiveness. There are, for example, randomized trials where many of those randomly assigned do not receive the intended intervention. We have developed an instrument called the **Threats to Trial Integrity Score (TTIS)** that allowed us to measure the quality of the design of a controlled trial, whether it be randomized or not. The ten dimensions of design quality are the following:

I. Selection Bias Threat — Low external validity arising from differences between target population and successfully recruited, eligible, and consented sample. Evidence that this threat is present comes from a statistical comparison of the target and sample comparison. Many studies do not record this information, so we rely on other measures as well. A higher threat occurs when the proportion of subjects who do not consent to be in the study is high, when there is no description of the inclusion/exclusion criteria, when exclusions are severe, or when there is no procedure to locate hard to reach subjects. The threat is smaller when a population-based sampling approach is used or when multiple methods are used to identify potential study participants.

II. Statistical Power Threat — If the study has a limited sample size or lacks appropriate covariates, there is little chance that the study design would be able to reveal important results. This dimension's score is based on the highest level of statistical power for an appropriate analysis on a key variable.

III. Assignment Threat — Assignment of individuals to intervention group is done in such a way that comparability is compromised. This is the most complex threat to assess because it must pertain equally well to designs, which are randomized trials to interrupted time series models. Studies that are randomized typically receive a better rating; however even randomized studies can receive a High Threat Risk.

IV. Participation Threat — Participation refers to the subject's exposure to the intervention condition, as distinct from the specific parts of the intervention that are delivered by the intervenors. (See implementation threat, below.) Participation can include attendance at intervention sessions but does not include any functional measures that pertain to the individual's success with the intervention. With low participation of subjects assigned to intervention condition, the attribution of intervention and control group differences to the intervention itself is suspect.

V. Condition Bias Threat — Some of those assigned to one intervention condition receive parts or all of another intervention condition. There may be leakage of an intervention condition to a control setting or control subjects may be exposed to parts of intervention after intervention period has ended

VI. Implementation Threat — If the intervention is not delivered as intended, either from lack of training, not covering required sections of material, or substantial deviation from protocol, then the implementation threat is high. While some of these characteristics of program implementation are difficult to measure, in well-designed studies there are clear procedures, which are followed to limit this risk.

VII. Measurement Threat — The measures used or their timing are inappropriate, invalid, or unreliable. Threat is higher if standardized measures are used that have never been validated for this particular population. Measurement threat is high if the last measure is taken at the end of the intervention period rather than after the completion of the intervention.

VIII. Assessment Threat — Systematic differences exist in ways that individuals in the different conditions are evaluated. Threat is highest when blinding or masking of assessors to intervention condition does not occur, when assessor is also the intervenor (i.e., a parent rating used to evaluate a parent intervention), or surveillance bias, such as observed child abuse where observation times in intervention and control are very different.

IX. Attrition Threat — Incompleteness in follow-up affects the quality of inferences based on trial data. Attrition threat is higher if the rate of attrition in an intervention or control group is high, if the attrition rates in intervention and control groups differ, if they vary systematically with baseline variables, and if there is evidence of non-ignorable or differential attrition.

X. Analysis Threat — Improper or incomplete management or analysis compromises any conclusions from the data. Some papers contain completely discrepant sample sizes in tables so that conclusions are suspect. Common analytical problems are improper analysis of categorical as interval scale data, improper unit of analysis, intent to treat analysis not done, suspicious outliers not handled, or use of follow-up analyses based on a follow-up measure taken after wait-listed controls have been received the intervention.

Each of these dimensions were scored from zero to three based on a 4-point scale from Null or Minimal Risk (N or 0), Low Risk (L or 1), Moderate Risk (M or 2), and High Risk (H or 3). When no determination could be made from the written information about a trial, the risk was scored as High Risk. It is quite possible that this missing information if available would have improved the scores on some of the trial designs. However, for the purposes of this report we adopt the convention that missing information indicates high risk. Also, to avoid penalizing trials, which are ongoing and therefore may not yet have reported on all the components of the design, we chose not to present ratings for any ongoing trial. In reporting each trial's result in this Final Report, we simplify the presentation by including an overall combined score, the **Threats to Trial Integrity Score,** or **TTIS.** Each of the ten scores is combined in a weighted fashion to form a scale which ranges from 0 to 72, with high scores indicating a higher threat. Specifically, we used weights of 1 for Threats IV, V, and VI, and weights of 3 for all other threats. These numeric values are shown in the Figures 1-4. We have also categorized this ordinal scale into a five level **Trial Quality Grade.** The highest scoring trials (about 5%) are designated as 5-Star designs, "*****." The 4-Star Designs "****" are among the top quarter of trials based on TTIS score, and similarly the 3-Star Designs "***" are in the second quartile, the 2-Star Designs "**" are in the third quartile, and the 1-Star Designs are in the lower quartile. While the actual categorizations for trial quality are somewhat arbitrary— they were selected as natural break points in TTIS scores— trials with 5-Star and 4-Star designs are clearly well designed studies with sufficient design integrity that the illustrative list of preventive intervention research programs compiled by the Institute of Medicine (Mrazek and Haggerty, 1994) includes some of these same trials. There are also important trials, which have lower TTIS evaluations. However, this report concentrates on the 5-Star and 4-Star designs in making summaries about our best knowledge about preventive impact.

SUMMARIES OF ANALYSES

A typical paper reported on 5 to 10 separate measures, so coding every analysis was beyond the scope of this report. We handled this in two ways. First, we reported summaries of each paper's results in the Summary of Key Research Studies. Surprisingly, we found that our conclusions did not always agree with the authors'. Secondly, this Final Report includes a summary table of all reported analyses from all trials with 5-Star or 4-Star designs. There were a total of 34 trials so designated; 11 of the 158 completed trials had 5-Star designs, and an additional 23 had 4-Star designs. Overall there were 62 papers which described these 34 trials.

We then looked at all outcome analyses reported in these 62 papers. There were 969 outcomes that were reported in sufficient detail to be included in this report. Our criteria for inclusion were the following:

1. The outcome measure was treated as either as a continuous variable (analysis of variance or covariance), or the outcome could be analyzed as a binary variable (cross-tabulations, logistic regression or related methods).

2. Sufficient summary data existed in either table or text form that allowed for both significance level and effect size (for continuous variables) or log-odds ratio (for binary outcomes).

Since only a few studies reported effect size or log-odds ratio, we computed the vast majority of these from other summary statistics such as sample sizes, mean differences, pooled standard deviations, and confidence intervals.

Many of the papers contained multiple analyses on the same dependent variable. For example, sometimes the authors would report unadjusted mean differences and adjusted mean differences where baseline variables were taken into account. Whenever possible, we report adjusted effect sizes or log-odds ratios and adjusted significance levels of intervention effect. These adjusted values are likely to suffer less from potential baseline differences among the intervention groups. In some situations there were more than two intervention groups in a trial. We chose to report the results as closely as possible to that of the authors. For example, if some groups were combined by the author, such as two control or low-dosage groups, we would report intervention effects against the combined set of controls. In a very few circumstances there were multiple active intervention conditions. In this case we chose to report outcome results that compared each of these conditions separately against the control. Finally, authors sometimes reported separate analyses on subgroups of the entire sample. For completeness we report effect sizes or log odds ratios on these sub-analyses as well as the main effect analyses whenever possible. One important caution should be noted. In accordance with general statistical practice, when significant interactions exist, it is impossible to interpret main effects' analyses. Thus one should check for significant analyses involving subgroups before reaching conclusions on intervention impact using main effect analyses.

INTERPRETATION OF EFFECT SIZES, LOG-ODDS RATIOS, AND SIGNIFICANCE LEVELS

Both effect sizes and log-odds ratios carry information regarding the magnitude of the intervention effect compared to control and to the direction of effect, i.e., whether it is beneficial or harmful compared to control on that particular outcome. As far as magnitude is concerned, effect sizes above 0.5 in magnitude are typically considered moderate size effects. This value corresponds to a shift of half a standard deviation shift in the mean of the intervention group compared to the control group mean. For most distributions, the proportion of control subjects above its mean will be around 50%. With a 0.5 effect size, there will be about 30% of the intervention group falling below the control group's mean. This level of change from 50% to 30% would be a sizable change in the proportion of adverse outcomes. An effect size as large as 1.0 is substantial. It corresponds to a level of change from approximately 50% above the control group's mean to 16%.

Log-odds ratios measure the association between two binary variables. Here we use log-odds ratios to assess the strength of the relationship between the binary outcome measure and the intervention/control group assignment. Like effect sizes, log-odds ratios are zero when there is no difference in the rate for intervention and control groups. A useful rule of thumb is to consider any log-odds ratio value above 0.75 as a moderate effect while any above 1.5 is a large effect.

The significance level provides a single additional piece of information. It indicates whether the effect size or log-odds ratio is significantly different from zero, or no difference between intervention and control groups. When the significance level is smaller than 0.05, there is a statistically significant difference between intervention and control groups. (We have not reported confidence intervals solely because of space considerations).

To improve interpretation of these effect sizes and log-odds ratios, we have reported not only the magnitude but also the direction of the effect size/log-odds ratio. These summary measures can be either negative or positive, and their interpretation depends entirely on the way the measure is coded. For those measures *where a higher outcome value signifies a poorer outcome*, i.e., a symptom measure, *a negative effect size indicates a beneficial effect* of the intervention compared to the comparison group. Alternatively, for measures *where a*

higher outcome value signifies a better outcome, i.e., an achievement score, *a positive effect size indicates a beneficial effect*. Similarly, for binary outcomes, *if the defined outcome is a poor outcome*, such as pre-term delivery, then *a negative log-odds ratio signifies beneficial effects*. If, on the other hand, *the defined outcome is a good outcome*, such as secure attachment, then *a negative log-odds ratio signifies beneficial effects*. To avoid confusion, we have added a label in the table for each outcome finding to make clear whether the findings shows either beneficial, harmful, or equal results.

It should also be noted that the designation of beneficial or harmful effect is based on the ordinary range of values for that outcome. Thus, in most comparisons of intervention and control means on birth weight, for example, we would consider a higher birthweight for the intervention group as beneficial, based on better outcomes in general for higher birthweight infants. However, very high birthweight infants may experience serious health problems as well. The same situation is true for a number of other outcome measures. Ordinarily, a higher number of reports of abuse would be considered harmful. However, the larger number or abuse reports could lead to the child being placed in a safer environment. Likewise, we label longer birth spacings as a beneficial effect. This is not meant to imply that very long spacings or single children families are necessarily the most beneficial.

SPECIFIC DETAILS ON EFFECT SIZE CALCULATION

The effect size attempts to put disparate continuous outcomes on a similar scale. The general definition of effect size is the difference in means for intervention and control groups on an outcome variable divided by the standard deviation. There are, however, multiple ways of calculating effect sizes since there are several standard deviations that are possible, i.e., that in the control group, that in the intervention, and that pooled over intervention and control groups. In line with recent practice, we use effect sizes defined in terms of the pooled variance whenever possible. Secondly, whenever available, we report effect sizes based on adjustments for covariates presented by the author, typically in covariate analyses. It sometimes happens that these definitions differ slightly from the few reported effect sizes reported by the authors in these 62 papers.

SPECIFIC DETAILS ON LOG-ODDS RATIOS

Log-odds ratios are computed either from two-by-two tables or from logistic regression analyses. In two-by-two tables which do not have any cell with zero counts, the observed odds ratio is computed from the cell counts and then its logarithm (log-odds ratio) is reported. If any of the tables have zero cells, we have followed a standard practice of adding one-half to each of the cells before computing the odds ratio. Such a procedure is known to remove substantial bias in estimating odds ratios.

THE RESULTS

We first provide a brief overview of the trials. The 165 trials that were identified and located took place in 21 different countries, with one unknown. Most of the work was done in the United States (114) and Canada (21), see Table 1a. A complete listing of the trials and associated papers is given in Table 1b, which is alphabetized by first author. The Canadian trials are listed in Table 1c. Just under half of the Canadian trials involve home visiting, another half are based in the clinic, agency, or community, and three are based in the schools. There were 7 incomplete trials that were sufficiently developed on which we could provide adequate information to include (several other ongoing trials could not be included because of lack of information about them). These have been classified as CONCURRENT in Table 1c.

CLASSIFYING THE TRIALS BY STAGE OF LIFE WHEN THE INTERVENTION BEGAN

Tables 2a and 2b show the number of all trials and the number of Canadian trials according to six stages of life (prenatal, parturition, infancy, toddler, preschool/kindergarten, and early school-aged) when the intervention began. This is not necessarily when the trial began because sometimes targeting and recruiting the population occurred much earlier.

Most of the trials overall (73) and in Canada (8) began during infancy. Prenatal and preschool/kindergarten each had about half that number, 36 and 34 respectively. Very few programs were initiated in early school-age, but this reflects the scope of the review being zero through six.

Prenatal. Table 2c shows for each trial the stage of life and the child's age at the start of intervention as well as all stages of life during the intervention. If the intervention was long enough, the child might enter the next stage of life before the intervention was completed. Table 2d shows this information for the Canadian trials. Among the 34 trials where the intervention began in the prenatal period, 20% continued beyond birth. The two studies with the longest intervention period were Gutelius (1977, #5083), and Seitz (1984, 1994, #5190). In many ways, Gutelius' study is similar to Olds' Elmira study, except it had home visits for 3 years and also used a mobile van for health care. Altogether, it was one of the most intensive interventions involving home visitation and clinical care that has ever been done. While the results are impressive, the quality of the design, given how long ago it took place, is not very good compared to newer trials. However, because of its unique features, including its community outreach, this intervention method warrants consideration in a new trial. In fact, Olds originally wanted to continue his Elmira-based intervention trial beyond two years of intervention; however, he was unable to obtain continued funding.

The Seitz study continued with home visits 30 months postpartum and coordinated medical and social services. It is noteworthy that the trials newer than those of Gutelius and Seitz are based on interventions, which are not as comprehensive and not as long in duration. Long-term results have been reported on the Seitz study. Again, the quality of the design (TTIS) was rather low. In summary, because the trials are of marginal design quality, we know very little about the importance of home intervention beginning prenatally and continuing past infancy.

There is still an unanswered question regarding the benefit, both in outcomes and in cost, for continued intervention for families who are not doing well. We were able to identify only one study that had any ability at all to address the question of when to stop an intervention for a family. All interventions in this dataset either stop at a specified time or have no systematic control over when an intervention ends. It would be possible, for example, to design a study, which assessed risk status at the first outcome period, followed by a random assignment to continue or to end the intervention.

Table 2c is sorted by gestational age. There are studies that begin very early in pregnancy (roughly 8 weeks), some near the median of 20 weeks, and some begin very late in pregnancy. It appears that the Better Beginning, Better Futures (#5155), a concurrent trial with two current age cohorts from birth to 4 and from 4 to 8 and a planned prenatal sample soon after pregnancy, would be in an ideal position to test an early prenatal intervention as well.

Parturition. A number of trials examine how labour outcomes can be affected by the presence of doula's in the delivery room. Some trials are extremely well designed For example, Kennell's #5434 is among the 11

trials with 5-Star designs. Even though the results are quite impressive on birth outcomes, it is not clear whether child outcomes are affected or for how long. A concurrent trial by Kennell is being used to test 1-year attachment outcomes between the mother and the child. The intervention period, however, extends minimally past birth.

Infancy. This period contains the majority of the trials (73). Two-thirds of these trials are selective by intervention type, with varying degrees of risk used to identify the target group. Many target general health or community related conditions, such as impoverished community or family, while others focus on specific medical conditions such as low-birthweight. We looked further at the trials with 5-Star and 4-Star designs and had an intervention begin during infancy. Among the 14 trials in infancy, nearly all include home visits either as the entire intervention or part of a comprehensive program. About half involve interventions with premature or low-birthweight infants (Black, #5018; Kang, #5098; IHDP, #5131; Beckwith, #5292; and Rauh, #5418), while the remaining ones are primarily day care programs for cognitive development (Ramey, 5030; Johnson, 5117; and Ramey, 5288). The results for educational day care programs are very strong, particularly when they are placed in a comprehensive setting. The results for impact on the developmental course of low-birthweight, pre-term, and failure to thrive infants are generally positive but not as supportive as those involving comprehensive cognitive interventions for low-income families.

Toddler. These 14 programs range from universal (Scarr, #5185; Whitehurst, #5221; Bass, #5014; and Arnold, #5401) to selective (Madden, # 5126; Levenstein, #5113; Powell, #5442; Cronan, #5037; Wolfe, #5224, and Esdaile, #5057) to indicated (Giromaletto,# 5071 and #5072; Valdez-Menchacha, #5207; and the Florida Department of Education, #5066). Unfortunately, as a group the trials in this area are of low quality— only one (Scarr, #5185) is a 4-Star, two are 3-Star (Girolametto, #5071 and Cronan, #5037), and the remaining ones are 2-Star or 1-Star.

As a group, these intervention trials have provided relatively small increments in our knowledge about what works. Except for Powell (#5442) and the two MCHP programs mentioned below, these interventions are limited in scope, focusing on either brief interventions (Girolametto, #5071 and #5072) or short but potentially useful reading programs (Whitehurst, #5221; Valdez-Menchaca, #5207). As for the MCHP studies, the two taken together provide some equivocality since the earlier Levenstein trial (#5113), which was selective, was not replicated. It makes sense to consider initiating well-designed trials in this period of life because of the existing gap.

Preschool/Kindergarten. There are 34 trials in this period of life, and one trial (Seifert, 5189) is 5-Star. There are a wide variety of parent training programs, which are tested in this stage of life, and valuable trials exist to test whether a cost-effective delivery system using videotapes is successful (Webster-Stratton, #5440). A number of preschool education programs have been tested, and while the trials are on the whole not outstanding in design, we have clear evidence of beginning effects on oppositional-defiant disorder and cognitive problem solving.

Early School-Aged. Primarily because of the restriction on age used in this search, there were only three studies in this category, Tremblay (#5255), and two concurrent trials (Walsh, #5125 and Boyle, #5446). Tremblay's study received a grade of 4-Star, and the other two studies appear to have good designs as well.

CLASSIFYING THE NUMBER OF TRIALS BY THE TYPE OF INTERVENTION

Tables 3a and 3b show that the most common type of psychosocial intervention is selective, with about equal numbers of universal and indicated (15% each). The percentage of universal intervention trials is the same in the prenatal and infancy periods.

There is a lack of intensive, universal intervention trials during the prenatal period. Of the 6 prenatal universal interventions, only one of them provides home visits by trained university graduates (Larson, #5410). Despite some serious flaws in the design, the intervention itself is worthy enough of further investigation. This design is also unique among all the trials in this dataset. It is the only trial that allows for a comparison of the timing of the intervention (beginning prenatally versus in infancy).

Two trials involved reduction of prenatal care visits. Starting with a general or intentionally low-risk population, McDuffie (#5130) and Munjanja in Zimbabwe (#5139) both found no deleterious effects from a reduced number of prenatal visits. These two trials are very narrow in their outcomes.

Dawson (#5041, 2-Star Design Grade) involves paraprofessional home visitors and only achieved minimal impact. This trial did find greater use of childcare among those families experiencing high stress. This finding of a moderation effect of the intervention was found in Olds' Elmira study as well. The scientific question yet to be answered is how much intensity, professional training, and when to start the intervention to achieve effective outcomes and cost effectiveness. It is our recommendation that universal intervention trials be used to address these questions. One design would be to include a stratified sample of low and high risk individuals, and assign a paraprofessional or control condition to those at low risk, and either a paraprofessional, a professional, or a control to the high risk group. Olds and colleagues in an concurrent trial in Denver are testing the latter half of this design. (The Denver trial has not been released yet, and we have not included it formally in our list of trials.)

CLASSIFYING TRIALS BY DESIGN QUALITY USING THE TRIAL ELEMENTS SCALE

A listing of all the completed trials' TTIS rating is provided in Table 4. There were 11 trials that received a 5-Star rating and 23 trials that received a 4-Star rating. Figure 1 compares the Trial Elements Score against the Threats to Trial Integrity Scores (TTIS). The box plots on the figure represent in pictorial form where the middle half of the data lie and where the values fall in the upper and lower quartiles. The dark bar represents the middle half, while the extended vertical lines are the quartiles. The white striped line indicates the median. All of the trials with a score of 6 or less on the Trial Elements Score measure received the lowest two grade levels of TTIS, either "*" or "**"; almost all of them were "*". However, about 25% of those scoring 7 or 8 on the Trial Elements score also received a "*" rating. Very few of the Trial Elements "7" trials received a "****" grade. Overall there is a clear relationship between the two scales with many of the Trial Elements "8" trials still receiving a very low grade on TTIS.

CLASSIFYING THE NUMBER OF TRIALS IN EACH COUNTRY BY DESIGN QUALITY USING THE TTIS SCALE

There is relatively little difference in either Trial Elements scores or TTIS (Figure 2) across the different countries.

CLASSIFYING INTERVENTION TYPE AND SITE BY TTIS.

Figure 3 shows a relatively modest relationship between TTIS and intervention type. Selective interventions are the only ones that received a 5-Star grade for design. No treatment intervention received a 5-Star or 4-Star. Figure 4 show the relationship between TTIS and intervention site.

OUTCOMES FROM EXEMPLARY DESIGNED TRIALS

As a whole the 11 trials with 5-Star designs and the 23 trials with 4-Star designs show substantial benefit in particular categories of outcome. Overall there were 969 different outcomes reported in these trials. In Table 5 we report the breakdown of the number of significant beneficial, non-significant, and significant harmful effects found among these 969 outcomes. While 657 or two-thirds of the outcomes were not found to be significant, 280 or approximately 30% of the results showed significant improvement for the intervention group compared to control. In contrast only 32 or about 3% showed significant harm. It is informative to note that one would expect by chance alone that 2.5% of the results would show significant harmful effects. The categories of outcome that show the highest proportion of significant effects are in Cognitive (59% with significant benefit), Safety or Injuries (47%), Mother's Physical Health (37%), School Performance and Mother's Social Support (both 35%), Parenting/Parent Child Relationships (32%), and Temperament/Behavior/Symptoms (30%).

Table 6a provides a detailed summary of all the outcomes for the 11 trials with 5-Star designs and similarly Table 6b provides the same summary for all outcomes for the 23 trials with 4-Star designs. In these tables, we use *BENEFICIAL* to refer to significant beneficial effect and *HARMFUL* to refer to significant harmful effect. When the effect is nonsignificant, we report the direction of the effect as either "beneficial", "harmful", or "equal".

In general, the effect sizes found in many of these studies range from minimal to very large. There are 19 effect sizes greater than 1 in the 5-Star trials. For binary outcomes there are 13 log-odds ratios greater than 1.5. Thus altogether 32 or 10% of the significant findings have strong magnitudes of effect.

The following information summarizes by paper the main outcomes as reported by the author(s) of the eleven exemplary trials rated as 5-Star on the TTIS; i.e., the upper 5%. We then summarize the results as reported by the author(s) for the studies ranked as 4-Star on the TTIS. A description of the population and the intervention is provided for each trial prior to the summary of outcomes. (This information can also be found, alphabetically by first author of each paper in The Summary of Key Research Studies.)

KEY TO THE CODES IN THE ANNOTATION:

All papers have been given a paper identification number and a trial number. The first number that is listed is the paper number. The second number that is listed is in parentheses and is the trial number. Some trials have been reported in multiple papers. In these cases, each paper will have its own number but the papers will share a trial number, e.g. 1 (5131) and 24 (5131).

auth: All authors are listed.

project title: Only some papers identify the trial by a project name.

country: This is the country where the trial took place.

N: This is the sample size at the point in time when the targeted population has been selected and randomization occurs. The number is sometimes larger than the number who actually received the intervention, and almost always larger than the sample size at follow-up evaluation.

method: This is a broad designation regarding design. (Specific quality of design measurements are included in the Final Report.)

population: This is the subject pool that was targeted. If the author specified inclusion and exclusion criteria, these are stated.

inter. type: This is the type of intervention that is targeted toward a specific population pool with various kinds of risk. The four intervention types are universal, selective, and indicated preventive intervention and treatment intervention. (A full explanation is included in the Final Report).

intervention: The experimental and comparison intervention(s) are described.

outcomes: Evidence from the trial is summarized from the author's perspective. Cost-benefit data are provided when available.

TRIALS WITH 5-STAR DESIGNS

1. Trial 5030

Project Title: Carolina Abecedarian Project

population 1: Subjects were high risk mothers and their newborn infants. High risk indicators included a lack of parental education and income, a history of mild retardation or school failure in family members, and psychopathology or social maladaptation. All mothers were given a standardized intelligence to help determine eligibility. The index children were determined to be at high-risk for nonbiologically based mild mental retardation. **population 2:** Subjects were the same children who had been identified at birth as being at high risk for school failure based on social and economic variables. These children who had been assigned to experimental and control groups were again randomly assigned at kindergarten to a school-age intervention or control group. Also, an average-risk group was recruited as a comparison group from the same schools as the high-risk children.

inter. type: Selective preventive intervention

intervention 1: The experimental children were treated in a child-centered prevention-oriented intervention program delivered in a daycare setting from infancy to age 5. Language, cognitive, perceptual-motor, and social development were stressed. The preschool intervention operated 8 hours per days 50 weeks per year and included an infant curriculum to enhance development and parent activities. The control preschool children were given free formula and diapers.

intervention 2: There were 4 groups: preschool treatment (infancy through 5 years) plus 3 years primary school treatment (up to age 8); preschool treatment only (infancy to age 5); primary school treatment only (age 5-8 years); and untreated control group. The school age intervention included individualized educational activities taught in biweekly home visits plus referrals for community resources. The experimental kindergarten children received 15 home visits per year for 3 years from a teacher who prepared a home program to supplement the school's basic curriculum. The teacher also consulted with the regular classroom teacher, averaging 18 school visits per family per year.

169

auth: Ramey, CT

title: The plasticity of intellectual development: Insights from preventive intervention

year: 1984

outcomes: IQ differences are not significant at 6 and 12 months of age but are significant and favor the experimental group children at 18, 24, 36, and 48 months. These findings lend some support to the notion that IQ is not fixed and can be influenced by early intervention.

170
auth: Ramey, CT
title: Preventive education for high-risk children: Cognitive consequences of the Carolina Abecedarian Project
year: 1984
outcomes: The children were examined with age-appropriate tests of development at 6, 12, 18, 24, 30, 42,48, and 54 months of age. Beginning at 18 months, and on every test thereafter, the experimental children outscored control children on mental tests. Experimental children consistently scored at the national average whereas control children's scores declined from the average level at 12 months to below average at 18 months and thereafter.

91
auth: Horacek, HJ
title: Predicting school failure and assessing early intervention with high-risk children
year: 1987
ref: Journal of the American Academy of Child and Adolescent Psychiatry
outcomes: High-risk children experienced 3.8 times the rate of grade failure (50 percent) of their average-risk peers (13 percent). The double educational intervention — preschool and elementary school — reduced the incidence of grade failure to 16 percent.

129
auth: Martin, SL
title: The prevention of intellectual impairment in children of impoverished families: Findings of a randomized trial of educational day care
year: 1990
outcomes: The experimental group had higher IQs from 6 months through this most recent assessment at 54 months than those of the control children when maternal mental retardation and home environment effects were controlled. At every age, a greater proportion of the experimental program children had normal range IQs.

198
auth: Spitz, HH
title: Does the Carolina Abecedarian early intervention project prevent sociocultural mental retardation?
year: 1992
outcomes: This paper is a critical analysis and commentary on whether the claim that the Carolina Abecedarian Project produced and maintained higher IQs in experimental children at risk for mild mental retardation than control children is indeed true. Four cohorts were recruited over a 5-year period. The experimental groups in cohorts 3 and 4 produced unusually high scores on the Bayley, but these scores were never reported separately, only as part of all 4 cohorts combined. Therefore, the overall IQ for the intervention groups was raised. The author questions whether the difference in cohorts 3 and 4 might be explained by chance allocation of brighter children to the experimental group. Also, unexpectedly the total group of control children did quite well cognitively. Although they were behind the experimental children at 6 months, they recovered by 54 and 60 months of age.

30

auth: Campbell, FA

auth: Ramey, CT

title: Effects of early intervention on intellectual and academic achievement: A follow-up study of children from low-income families

year: 1994

outcomes: At 4 year follow-up (children were 12 years of age), there were positive results of the preschool treatment on intellectual development and academic achievement; school-age treatment alone was less effective. The positive effects of preschool treatment on intellectual development and academic achievement were maintained through age 12 (4 years after the full experimental intervention ended).

2. Trial 5054

No Project Title

population 1: Subjects were the socioeconomically and ethnically diverse English-speaking members of a large health maintenance organization who reported that they were smoking at the time of their first prenatal visit. They were less than 18 weeks pregnant at intake. **population 2:** Subjects were an ethnically diverse group of pregnant women enrolled in a large health maintenance organization. They were less than 18 weeks pregnant and identified themselves as prepregnancy smokers. They indicated on a form that they had quit smoking since becoming pregnant (spontaneous quitters).

inter. type: Selective preventive intervention

intervention 1: At the first prenatal visit, a health educator conducted a 45 minute interview with all the patients and they then were given a pamphlet on the hazards of cigarette smoking during pregnancy and the importance of quitting. The health educator reinforced this in a 2 minute discussion. The experimental group then received a serialized cessation program including 8 booklets on a weekly basis. intervention 2: All women received a 45 minute smoking-related interview conducted by a health educator when they began their prenatal care. They also received a 2 page pamphlet on the hazards of smoking during pregnancy. The health educator reinforced the written information in a 2 minute discussion. The experimental group then received 4 of 8 self-help booklets, together with a 3 minute overview of the program. The remaining 4 booklets were mailed thereafter at weekly intervals. They contained a step-by-step program to increase motivation for quitting smoking and taught behavioral strategies for cessation and relapse prevention. Controls were given a 1 page tip sheet on behavioral techniques to help avoid relapse.

258

auth: Ershoff, DH

title: Pregnancy and medical cost outcomes of a self-help prenatal smoking cessation program in a HMO

year: 1990

outcomes: The experimental women were more likely to achieve smoking cessation for the majority of their pregnancy (22.2 percent vs. 8.6 percent), gave birth to infants weighing on average 57 grams more, and were 45 percent less likely to deliver a low birth weight infant. The intervention had a benefit-cost ratio of 2.8:1.

3. Trial 5130

No Project Title

population: Subjects were women in the first trimester of their pregnancies who presented for the intake visit at a group-model health maintenance organization. They were between 18 and 39 years of age, had completed less than 13 weeks of gestation, had no history of obstetrical risk or current medical condition, were English-speaking, and were not planning to change insurance carriers during the pregnancy.
inter. type: Universal preventive intervention
intervention: Following risk assessment, experimental subjects received 9 prenatal visits and controls received 14. Additional visits were available as indicated or as desired by the patients in both groups. The study was a test of the 1989 Expert Panel on the Content of Prenatal Care guidelines on the timing and content of prenatal care, including a schedule consisting of fewer prenatal visits than traditionally provided for women at low risk of adverse peri-natal outcomes.

130
auth: McDuffie, RS
title: Effect of frequency of prenatal care visits on perinatal outcome among low-risk women: A randomized controlled trial
year: 1996
outcomes: On average, there were 2.7 fewer visits observed in the experimental group than in the control group. There were no significant increases in the main outcomes of the experimental group: pre-term delivery, pre-eclampsia, cesarean delivery, low birth weight or patients' satisfaction with quality of prenatal care. There were more provider visits in the experimental group than predicted (10.3 vs. 9.0). The mean difference of 2.7 in the number of visits between the 2 groups could result in substantial savings in direct medical costs for the 2 million low-risk pregnant women who receive care each year in the US.

4. Trial 5131

Project Title: Infant Health and Development Program

population: Subjects were infants weighing 2500 grams or less and whose gestational age at birth was 37 weeks or less. Siblings of eligible twins and infants with severe conditions were precluded. Non-English speaking mothers and mothers who reported drug, alcohol, or psychiatric hospitalization were also excluded. The 8 clinical sites were socioeconomically heterogeneous.
inter. type: Selective preventive intervention
intervention: The intervention was provided from neonatal discharge through age 3 years. The experimental group received home visits to age 3, 5 day per week center-based schooling from 12 months to 3 years, and pediatric surveillance; the control group received pediatric surveillance.

1
auth: The Infant Health and Development Program
title: Enhancing the outcomes of low-birth-weight, premature infants: A multi-site, randomized trial.
year: 1990
outcomes: At 36 month follow-up (age corrected for prematurity), the experimental group had significantly higher mean IQ scores than the follow-up group (mean difference in the heavier group was 13.2 and in the lighter group 6.6), significantly fewer maternally reported behavior problems, and a small, but statistically significant, increase in maternally reported minor illnesses for the lighter-birth-weight group only, with no difference in serious health conditions.

235
auth: Kraemer, HC
title: Random assignment in clinical trials: Issues in planning (Infant Health and Development Program)
year: 1990
method: RCT; this paper discusses options available for the randomization of subjects into groups in a clinical trial and uses the IHDP as an example; of special note are the mid-course changes in randomization procedures that were necessary in IHDP to procure an adequate sample size
outcomes: NA

166
auth: Ramey, CT
title: Infant Health and Development Program for low birth weight, premature infants: Program elements, family participation, and child intelligence
year: 1992
outcomes: A Family Participation Index showed that program implementation was not different across the 8 sites. High levels of participation were linked to positive cognitive outcomes at age 3 in the children in the experimental group.

102
auth: Kirby, RS
title: Identifying at-risk children for early intervention services: Lessons from the Infant Health and Development Program
year: 1993
outcomes: Risk factors have been identified by participating states who are trying to meet Public Law 99-457 and develop early intervention services for infants and young children who have, or are at risk for, developmental problems. The states' risk factors are compared to the risk factors and 36 month development outcomes obtained in the IHDP. Few of the individual risk factors identified by the states were associated with poor developmental outcomes, and the composites lacked specificity (yielding positive predictive values of 25 to 35 percent, with poor specificities ranging from 12 to 40 percent).

32
auth: Casey, PH
title: A multifaceted intervention for infants with failure to thrive: A prospective study
year: 1994
outcomes: At the end of the 3 year intervention, there were no differences in incidence of failure to thrive (FTT: defined as the failure to maintain the expected rate of weight gain over time) between the experimental and control groups. The children in the experimental group who developed FTT received less of the intervention than those who did not develop FTT. The effects of the intervention, particularly on IQ and behavior, were greater for those children with FTT whose families were the most compliant with the intervention.

25
auth: Brooks-Gunn, J
title: The effects of early education intervention on maternal employment, public assistance, and health insurance: The Infant Health and Development Program
year: 1994
outcomes: Effects of the intervention were on 2 generations — infants and their mothers. The intervention mothers were employed more months and returned to the work force earlier than the follow-up only group. There were no differences on subsequent fertility. Mothers with some college education as well as those who were employed received more public assistance. Use of health care services was more frequent in the experimental group.

24
auth: Brooks-Gunn, J
title: Early intervention in low-birth-weight premature infants: Results through age 5 years from the Infant Health and Development Program
year: 1994
outcomes: The intervention effects that had been seen on IQ and vocabulary at age 3 years for the total sample and in both low birthweight groups were no longer present at 5 years, 2 years after the intervention ended. Overall IQ scores were similar in the 2 groups. However, the intervention did have positive effects on IQ and verbal performance at age 5 years for the heavier low birthweight infants. There were no differences on behavior and health measures between the experimental and control groups.

87
auth: Haas, JS
title: Hospital use and health status of women during the 5 years following the birth of a premature, low-birthweight infant
year: 1997
outcomes: Women who have had a premature, low-birthweight infant experience substantial morbidity that continues for at least 5 years following the birth of the child. Almost 60 percent of the women required hospitalization during this 5 year period. While pregnancy accounted for approximately half of these hospitalizations, the remainder were unrelated to pregnancy. Almost 20 percent of these women reported themselves to be in poor to fair health.

131
auth: McCarton, CM
title: Results at age 8 years of early intervention for low-birth-weight premature infants: The Infant Health and Development Program
year: 1997
outcomes: At 5 years follow-up when the subjects were 8 years of age, attenuation of the large favorable effects seen at 3 years was observed in both the heavier and lighter LBW groups. The experimental and control groups were similar on all primary outcome measures. There were modest intervention-related differences in cognitive and academic skills of heavier LBW premature children. A higher-than-average (i.e., compared to the standardized sample) rate of behavioral difficulties was found on the Child Behavior Checklist for both the heavier and lighter low birth weight groups in the total study population. The cost of delivering the 3 programmatic components of the full intervention was estimated at $15,146 per year per child.

5. Trial 5143

Project Title: Prenatal/Early Infancy Project

population: Subjects were pregnant women living in a small, semi-rural county. They had had no previous live births and had any one of the following characteristics that predispose to infant health and development problems: young age (less than 19 years), single-parent status, or low SES. The design, however, allowed any woman who asked to participate and who was bearing a first child to be enrolled. Women more than 25 weeks pregnant were to be excluded but 30 women were between the 26th and 29th week of pregnancy due to difficulty in estimating length of gestation.

inter. type: Selective preventive intervention

intervention: There were 4 conditions: developmental screening at ages 1 and 2; screening and free transportation to health care; screening, transportation, and nurse home-visitation once every 2 weeks during pregnancy; and all the above plus continued nurse home-visitation on a diminishing schedule until the infants were 24 months of age. The nurses followed protocols and record-keeping and reviews were used to monitor implementation. The intervention focused on parent education, enhancement of the women's informal support systems, and linkage of the parents with community services.

236

auth: Olds, DL

title: Improving the delivery of prenatal care and outcomes of pregnancy: A randomized trial of nurse home visitation

year: 1986

outcomes: Women who were nurse-visited had many positive behavioral and health outcomes compared to the control group combined with the group who received only transportation. Although there were no overall main intervention effects for birth weight or length of gestation, there were positive effects of the program on birth weight and length of gestation for the offspring of young adolescents and smokers. In contrast to their comparison-group counterparts, young adolescents who were visited by nurses gave birth to newborns that were an average of 395 grams heavier, and women who smoked and were visited by nurses exhibited a 75 percent reduction in the incidence of pre-term delivery.

143

auth: Olds, DL

title: Preventing child abuse and neglect: A randomized trial of nurse home visitation

year: 1986

outcomes: Among the women at highest risk for caregiving dysfunction, those who were visited by a nurse had fewer instances of verified child abuse and neglect during the first 2 years of their children's lives. They were observed in their homes to restrict and punish their children less frequently, and they provided more appropriate play materials. Their babies were seen in the emergency room less frequently during the first year of life. During the second year of life, the babies of all nurse-visited women, regardless of the families' risk status, were seen in the emergency room fewer times, and they were seen by physicians less frequently for accidents and poisonings than comparison group babies.

145
auth: Olds, DL
title: Improving the life-course development of socially disadvantaged mothers: A randomized trial of nurse home visitation
year: 1988
outcomes: During the first 4 years after delivery of their first child, in contrast to the comparison group, nurse-visited white women who had not graduated from high school when they registered in the study returned to school more rapidly. Nurse-visited, poor, unmarried white women showed an 82 percent increase in the number of months they were employed, had 43 percent fewer subsequent pregnancies, and postponed the birth of second children an average of 12 months longer.

239
auth: Olds, D
year: 1988
ref: In R Price, E Cowen, R Lorion, and J Ramos-McKay (Eds.), Fourteen Ounces of Prevention: A Casebook for Practitioners

252
auth: Olds, DL
title: Effect of prenatal and infancy nurse home visitation on government spending
year: 1993
outcomes: A cost-benefit analysis estimated program costs (direct costs of nurse-visitation, costs of services to which nurses linked families, and costs of the taxi-cab service); benefits (cost outcomes presumed to be affected by the program through improved maternal and child functioning such as AFCD, Medicaid, Food Stamps, Child Protective Services, and tax revenues generated by women's working); and discounts of savings across time (used a 3 percent discounting rate). Within 2 years after the program ended, the net cost of the program for the sample as a whole was $1,582 per family. For low-income families, the cost of the program was recovered with a dividend of $180 per family.

237
auth: Olds, DL
title: Prevention of intellectual impairment in children of women who smoke cigarettes during pregnancy
year: 1994
outcomes: Children born to women who smoked 10 or more cigarettes per day at registration during pregnancy and who were nurse-visited had IQs at 3 and 4 years of age that were 4.86 points higher after adjustment for covariates than did children born to women who smoked 10 or more cigarettes per day and who were not home-visited. The improvement seems to be associated with a reduction in maternal smoking and improvements in diet during pregnancy.

238
auth: Olds, DL
title: Does prenatal and infancy nurse home visitation have enduring effects on qualities of parental caregiving and child health at 25-50 months of life?
year: 1994
outcomes: There were no differences between the experimental and comparison groups in the rates of new cases of child abuse and neglect or in the children's intellectual function in the period when the children were 25 to 48 months of age. However, nurse-visited children had fewer injuries and ingestions, fewer behavioral and parental coping problems (as noted in the physician record), and made fewer visits to the emergency department. Nurse-visited mothers were observed to be more involved with and to punish their children to a greater extent than were mothers in the comparison groups.

144
auth: Olds, D
title: Effects of prenatal and infancy nurse home visitation on surveillance of child maltreatment
year: 1995
outcomes: Outcomes pertain to a subsample of maltreated children from 56 families. All of these children had a state-verified report of child abuse or neglect during the first 4 years of the child's life. Of the maltreated children, those who had been nurse home visited for the first 2 years of the child's life had less serious expressions of caregiving dysfunction. They also had 87 percent fewer visits to the physician for injuries or ingestions and 38 percent fewer visits to the emergency department.

183
auth: Samples, FL
title: The differential impact of a comprehensive early intervention program on the level of support received by African-American and white adolescent mothers
year: 1996
outcomes: (Secondary analysis) A sample of 141 primiparous women was selected from the original data set for inclusion. Nurse-visited mothers were more likely than control group mothers to expect high levels of social support from significant others with child care and household chores. Black mothers in the control group reported more support for chores during pregnancy and in the postpartum period than did black or white mothers in the nurse-visited group.

147
auth: Olds, DL
year: 1997
title: Long-term effects of home visitation on maternal life course and child abuse and neglect: Fifteen-year follow-up of a randomized trial
ref: JAMA.
outcomes: At 15 years after the birth of the child (13 years since termination of the intervention), women who were visited by nurses during pregnancy and infancy had significantly fewer subsequent pregnancies, less use of welfare, fewer verified reports of abuse and neglect, fewer behavioral impairments due to use of alcohol and other drugs, and fewer arrests.

6. Trial 5189
No Project Title
population: Subjects were children between 3 and 6 years of age in 4 Head Start classrooms. All children in Head Start classroom whose second language was English or who had a known cognitive deficit were excluded from the data analysis; however, if they were in the experimental classroom, they received the intervention with the rest of their classmates.
inter. type: Selective preventive intervention
intervention: The experimental classroom received direct instruction from a speech-language pathologist on basic concept knowledge 30 minutes a day, twice a week for 7 consecutive weeks. An explicit sequence of concepts was taught to the children, and this was followed by interactive instruction.

189
auth: Seifert, H
title: Treatment effectiveness of large group basic concept instruction with Head Start students
year: 1991
outcomes: The basic concepts scores of the experimental group were significantly improved.

7. Trial 5210

Project Title: The Latin America Multi-center Trial

population: Subjects were women at 4 centers in Latin America who were at higher-than-average risk for delivering a low-birth-weight infant and were recruited before the 20th week of pregnancy.
inter. type: Selective preventive intervention
intervention: The experimental group received 4-6 home visits by nurses or social workers in addition to routine prenatal care. The control group received only routine prenatal care.

210
auth: Villar, J
title: A randomized trial of psychosocial support during high-risk pregnancies. The Latin American Network for Perinatal and Reproductive Research
year: 1992
outcomes: There were few differences in outcomes between the experimental and control groups, even among the mothers at highest risk.

8. Trial 5220

No Project Title

population: Subjects were 4-year-olds who attended classrooms in 4 Head Start centers that were geographically close to the university conducting the research.
inter. type: Selective preventive intervention
intervention: The children in the experimental classrooms received an add-on emergent literacy curriculum to their Head Start curriculum. The add-on curriculum had 2 components: dialogic reading, which is an interactive style of adult-child shared picture book reading, and a program to teach children about the phonemic structure of language. The dialogic reading program took place at school with the teachers and at home with the parents. Teachers and parents were trained by means of a 20 minute video, brief role-playing, and discussion. The program continued over the course of the school year, one book per week. The phonics program was conducted in the classroom on 3 days per week for 5 months. There was some on-going monitoring of teachers and parent trainers. A child who participated maximally over the course of the school year would have invested about 42 hours of time in the classroom program. The control children received the typical Head Start curriculum.

220
auth: Whitehurst, GJ
title: Outcomes of an emergent literacy intervention in Head Start
year: 1994
outcomes: Effects on language were large but only for those children whose primary caregivers had been actively involved in the at-home component of the program (perhaps because of frequency of exposure). The classroom-based interactive reading did not, by itself, generate increases in children's language skills. Despite the gains in emergent literacy skills, the curriculum did not bring these children up to the typical level of performance of children of their age.

9. Trial 5259

No Project Title

population: Women were identified as current smokers through screening interviews at their first prenatal visit at 1 of 4 maternity clinics in a public health department. They were included in the study if they were eligible for care, sought care before 32 weeks gestation, returned for a second visit, were not prisoners, and could read the baseline questionnaire.
inter. type: Selective preventive intervention
intervention: The experimental group received a 15 minute behavioral intervention from a trained health counselor during the first visit; this included standardized cessation skills and risk counseling plus self-help materials (component 1). In component 2, a chart reminder was put in the medical record and a letter sent to the patient. In component 3, social support methods were provided in the form of a "buddy" letter, contract, and tip sheet. Both the experimental and control groups received 2 pamphlets urging them to quit smoking and 2 minutes discussion from a nurse during a prenatal education class at the first visit.

259
auth: Windsor, RA
title: Health education for pregnant smokers: Its behavioral impact and cost benefit
year: 1993
outcomes: Significantly more experimental mothers quit smoking than control mothers. The intervention increased quit rates by 7.4 percent among black patients and 4.9 percent among white patients. Of the women who quit or significantly reduced, a 200 gram and a 92 gram difference, respectively, was observed when birthweights were compared with those of smokers. Detailed cost-benefit data are provided. The cost-benefit ratio low estimate is $1:$17.93 and high estimate is $1:$45.83. The number of pregnant smokers in the US annually is estimated to be more than 1 million.

10. Trial 5415

No Project Title

population: Subjects, recruited from the antenatal clinics of 4 hospitals, were eligible provided they had had at least 1 previous normally formed baby weighing under 2500 grams following spontaneous onset of labour, were less than 24 weeks gestation with a singleton pregnancy, and were fluent in English. All of the mothers were socially disadvantaged, and 41 percent were smoking at the time of booking.
inter. type: Selective preventive intervention
intervention: The control group received standard antenatal care. The experimental group received that same care plus a midwife social support intervention which included at a minimum 3 home visits at 14, 29, and 28 weeks gestation, plus 2 telephone contacts or brief home visits in between these times. The midwives were also available by phone 24 hours a day. They followed a semi-structured interview schedule and gave advice only if requested to do so. They did not give any clinical care. Forms and audiotapes provided some monitoring of the intervention.

415
auth: Oakley, A
title: Social support and pregnancy outcome
year: 1990
outcomes: Babies of the experimental mothers had a mean birthweight 38 grams higher than those of control mothers. Experimental group mothers were significantly healthier in the early weeks than those in the control group as judged by reported physical and psychosocial health and use of health services. Women's attitudes to the social support intervention were very positive.

11. Trial 5434

No Project Title

population: Subjects were nulliparous women ranging in age from 13 to 34 years, with single-gestation, term, uncomplicated pregnancies. They were admitted to the study after they were admitted to the hospital and were in active labor, with initial cervical dilatation of 3 or 4 cm. and without high risk medical conditions including history of drug or alcohol abuse. Women were assigned to experimental or observation groups; a control group was assigned after delivery.
inter. type: Universal preventive intervention
intervention: The experimental group received continuous support during labor from a doula, a nonprofessional woman who had received 3 weeks of training and ongoing supervision in ways to physically and emotionally comfort the patients. The doula and the pregnant woman met for the first time during labor. The observation group received routine care, and an observer kept records of all that happened.

434
auth: Kennell, J
title: Continuous emotional support during labor in a US hospital: A randomized controlled trial
year: 1991
outcomes: Continuous labor support from the doula significantly reduced the rate of cesarean section deliveries and reduced the use of epidural anesthesia for spontaneous vaginal deliveries. Oxytocin use, duration of labor, prolonged infant hospitalization, and maternal fever followed a similar pattern. Medical costs were reduced, especially from the decrease in cesarean deliveries, but no dollar figures are given.

TRIALS WITH 4-STAR DESIGNS

1. Trial 5007

No Project Title

population: The subjects were women who delivered their babies in a large inner-city hospital. They came from a low-income clinic that was predominantly Hispanic and black. Subjects had to be between 18 and 37 years of age, with a parity from 1 through 4. They had to have received prenatal care, have healthy infants, be enrolled in a pediatric practice for medical follow-up of the infants, planning not to return to work or school for at least 3 months after delivery, have access to a telephone, and speak conversational English. Mothers who had already decided to use a soft carrier for their infant and those who would not consider using one were eliminated.
inter. type: Selective preventive intervention.
intervention: Mothers in the experimental group were given soft baby carriers to use with their newborns (to increase physical contact); controls received infant seats.

7
auth: Anisfeld, E
title: Does infant carrying promote attachment? An experimental study of the effects of increased physical contact on the development of attachment
year: 1990
outcomes: At 13 months, the experimental infants more securely attached to their mothers than the control infants, and experimental mothers' responsivity to their infants was increased.

2. Trial 5016

No Project Title

population: Study mothers were recruited from 2 large metropolitan teaching hospitals if they spoke English, had a telephone, lived within an hour's drive from the laboratory, and had no plans to move within 2 years. Inclusion criteria for the infants included full term delivery, "clinically normal" health status, and no more than 24 hours in neonatal special care. Two groups of infants were recruited: half were intrauterine growth retarded (small for gestational age) and half were average for gestational age.
inter. type: Selective preventive intervention
intervention: There were 2 types of short-term perinatal intervention: an infant-centered intervention which used the Brazelton Neonatal Assessment Scale to highlight newborn behavior to new mothers, and a mother-centered intervention which used in-depth interviews to focus on the mother's concerns about parenting. Both interventions used reliable protocols and were delivered by highly trained clinicians at day 3 in the hospital and at 14 and 30 days at home. Clinicians were trained in both protocols and were rechecked on reliability.

16
auth: Beeghly, M
title: Specificity of preventative pediatric intervention effects in early infancy
year: 1995
outcomes: At 4 months there were no significant differences between the 2 groups. Mothers at higher psychological risk had the poorest outcomes at 4 months and were unaffected by participation in either intervention, regardless of demographic status.

3. Trial 5018

No Project Title

population: The subjects were recruited from urban pediatric clinics serving low income families. The children were younger than 25 mos. (mean age 12.7 mos.), had weights for age below the 5th percentile even though their birth weights had been appropriate for gestational age (of at least 36 weeks), and had no other significant medical history. Six of the 130 children had histories of hospitalization for poor growth. Most subjects were African Americans whose mothers were single, receiving assistance, and had limited education.
inter. type: Selective preventive intervention
intervention: The experimental group received weekly home visits for 1 year from trained lay home visitors who were supervised by a community health nurse. The children also received nutrition intervention at a clinic. The home visitors focused on the parent-child relationship, including feeding, as well as on issues raised by the mothers. The cost per child for the 1 year home intervention was $2828. The control group received clinic services.

18
auth: Black, MM
title: A randomized clinical trial of home intervention for children with failure to thrive
year: 1995
ref: Pediatrics
outcomes: The children's' weight improved during the 1 year study period regardless of intervention group. The experimental group had better receptive language over time and more child-oriented home environments. Only the younger children showed improvement on cognitive development.

4. Trial 5020

No Project Title

population: Subjects were women with moderate threatened pre-term delivery between 26 and 36 weeks of gestation from 4 maternity units of public or private hospitals.
inter. type: Selective preventive intervention
intervention: The experimental group received 1 or 2 home visits per week by domiciliary mid-wives and had telephone contact. The focus was on medical examination and encouragement to rest and involve others in housework. Women also received prenatal care at clinics and hospitalization when necessary. The control group received clinic visits only.

20
auth: Blondel, B
title: Evaluation of the home-visiting system for women with threatened pre-term labor: Results of a randomized controlled trial
year: 1990
outcomes: The number of days in hospital was not decreased for the experimental group but the number of prenatal visits was. The mothers' satisfaction with medical care was much greater in the experimental group.

5. Trial 5023

No Project Title

population: Subjects were high social risk women who sought prenatal services from public health department clinics. They were 22 weeks pregnant or less and had 1 or more of the following risks: alcohol or drug addiction, psychiatric diagnosis, previous child maltreatment, both low educational level and low social support, young and low social support, low educational level and young and low income.
inter. type: Selective preventive intervention
intervention: The 2 types of intervention, both provided by nurses in home visits, lasted 18 months, from mid-pregnancy to the child's first birthday. A 1 step Information/Resource model was contrasted with a 2 step Mental Health model, focusing first on social skills and then on parenting. Both interventions had written protocols.

23
auth: Booth, CL
year: 1989
title: Development of maternal social skills in multi-problem families: Effects on the mother-child relationship.
outcomes: Evaluations were made at the end of the intervention and 1 month later. The 2 groups did not differ in their post intervention social skills or in mother-child interaction. However, for women who began the program with low social skills, social skills and mother-child interaction were improved in the 2 step model.

6. Trial 5026

No Project Title

population: Subjects were pregnant women with poor obstetric histories (prior pre-term or low birthweight births, perinatal deaths, miscarriages) from 3 public antenatal clinics and the private offices of 87 obstetricians and general practitioners.
inter. type: Selective preventive intervention
intervention: Routine antenatal care was provided for the experimental and control groups. The experimental group also received expressive (emotional) social support through home visitors and telephone calls by midwives who had received extensive training in this method. The midwives did not provide antenatal advice.

26
auth: Bryce, RL
title: Randomized controlled trial of antenatal social support to prevent pre-term birth
year: 1991
outcomes: The observed relative reduction in pre-term births in the experimental groups were 13.8 percent. The expected clinically significant reduction in pre-term births was not obtained. There was no effect in the lowest social class, but there was in the highest professional social class.

7. Trial 5027

No Project Title

population: Subjects were infants determined to be at risk for school failure due to socioeconomic factors. Most mothers were black, single, young, and had less than a high school education. The children in the experimental group were 6 weeks to 3 months of age when they began the intervention.
inter. type: Selective preventive intervention
intervention: The experimental group attended a cognitively oriented university day care center from infancy until they entered kindergarten. Many of the control children had varying amounts of time in "quality" community day care centers. Other control children had no center-based day care.

27
auth: Burchinal, M
year: 1989
title: Type of day-care and preschool intellectual development in disadvantaged children
outcomes: Assessments were made semiannually from 6 to 54 months of age. The experimental group showed higher IQs overall and less linear decline in cognitive ability between late infancy and early preschool (seemingly a vulnerable period) than the control children as a whole or than the subgroup of control children in the community day care group. However, the latter group who had at least 1 year of day care experience also showed benefits in intellectual development both in the overall level and in trends across time.

8. Trial 5036

No Project Title

population: Subjects were women at high risk for preterm labor at 3 centers.
inter. type: Selective preventive intervention
intervention: Experimental women received standard high risk prenatal care plus twice-daily home uterine activity monitoring without increased nursing support. The controls received standard high risk prenatal care.

36
auth: Corwin, MJ
title: Multi-center randomized clinical trial of home uterine activity monitoring: Pregnancy outcomes for all women randomized
year: 1996
outcomes: The experimental group had improved pregnancy outcomes, prolonged gestation, larger birth weight infants, and a decreased need for neonatal intensive care. These infants experienced 469 fewer days in the neonatal intensive care unit, which compares favorably with the cost of the average of 49 days of monitoring per woman in this experimental group.

9. Trial 5039

Project Title: Busselton Study

population: From 1964 to 1967, children were recruited by allotment of alternate
births in the local hospital into experimental and control groups with prior stratification according to the child's sex and position in the family.
inter. type: Universal preventive intervention
intervention: In the child's first year of life, 4 counseling sessions, 20 to 30 minutes in length, were conducted by the family's general practitioner. This was followed by 2 interviews per year for the next 4 years. One general practitioner provided all the intervention counseling, which aimed to enhance the self worth of the mother, foster gentle physical interaction with the child, and to encourage the mother to adopt a positive attitude about modifying the child's behavior. Control parents were interviewed annually by the secretary of the study, and pictures of the children were taken at 6 month intervals.

405
auth: Cullen, KJ
year: 1976
title: A six-year controlled trial of prevention of children's behavioral disorders
outcomes: The experimental children had significantly fewer fears, sleep disorders, eating problems, loud modes of speech, and aggression toward others than did the controls. Generally the results were more positive for experimental girls than boys. The experimental girls revealed significantly more positive feelings toward their mothers than did the controls, but the boys revealed significantly more negative feelings. Overall, the results were modest.

39

auth: Cullen, KJ

title: Long-term follow-up of the Busselton six-year controlled trial of prevention of children's behavior disorders

year: 1996

outcomes: Initial benefits at 6 years of age appear to have lasted to ages 27-29. On self report, there were significantly fewer neurotic symptoms, and the women had significantly fewer depressive symptoms. More intervention subjects had received university degrees. Intervention women were less obese, and there was somewhat less smoking in the whole intervention group.

10. Trial 5040

No Project Title

population: Subjects were junior kindergartners who had been identified through universal screening of all public and separate schools in one community. Screening questionnaires for behavior problems had been sent home by teachers to parents. If the children rated at least 1.5 standard deviations above the mean on the screening tool, they were considered high risk for later disruptive behavior disorders, and their parents were offered the intervention.

inter. type: Indicated preventive intervention

intervention: Parents were randomly assigned to 1 of 3 groups: a 11-12 session clinic-based parenting course for individual families; a 11-12 session large group community-based parenting course; or a waiting list control condition. Both interventions employed a coping modeling problem solving model. The large community-based groups devoted time to informal supportive interaction and personal network building. Monthly booster sessions were offered in both types of intervention. The professional group leaders received extensive training and monitoring. Parents in both interventions were able to enroll their children in an activity-based social skills program, which was conducted conjointly with parenting sessions.

40

auth: Cunningham, CE

title: Large group community-based parenting programs for families of preschoolers at risk for disruptive behavior disorders: Utilization, cost effectiveness, and outcome

year: 1995

outcomes: Parents in the large community groups reported greater improvements in behavior problems at home and better maintenance of these gains at 6 month follow-up. Immigrant families, those using English as a second language, and parents of children with severe behavior problems were significantly more likely to enroll in the community groups than in the clinic based individual parent training. With groups of 18 families, the community group intervention was more than 6 times as cost effective as the clinic/individual program.

11. Trial 5088

No Project Title

population: Subjects were women at high risk for low birth weight outcome according to a risk factor scale or delivery of a low birth weight baby in their last pregnancy. The women were free of known medical or pregnancy complications.

inter. type: Selective preventive intervention

intervention: The experimental group received nurse-midwifery care in a separate low birth weight prevention clinic. In addition to medical care, they received stress reduction counseling, social support, and substance abuse counseling. They were seen in the clinic at 1-2 week intervals. The control group attended the regular high-risk obstetric clinic.

88

auth: Heins, HC

title: A randomized trial of nurse-midwifery prenatal care to reduce low birth weight

year: 1990

outcomes: There were few differences between the groups. There was some indication that black women at high statistical risk of giving birth to a low birth weight infant may have derived some benefit from the program.

12. Trial 5103

Project Title: Prenatal/Early Infancy - Memphis

population: Subjects were women less than 29 weeks pregnant who were being seen at an obstetrical clinic at a regional medical center in a large city. Subjects were required to have had no previous live births, no specific chronic illnesses thought to contribute to fetal growth retardation or pre-term delivery, and at least 2 of the following risk conditions: unmarried, less than 12 years of education, and unemployed. Most subjects were African American.

inter. type: Selective preventive intervention

intervention: There were 4 intervention conditions: 1) free round-trip taxicab transportation for scheduled prenatal care appointments; 2) free transportation plus developmental screening and referral services for the child at 6,12, and 24 months of age; 3) free transportation and screening plus intensive nurse home-visitation services during pregnancy, 1 postpartum visit in the hospital, and 1 postpartum visit at home; 4) same as #3 plus continued nurse home visits throughout he child's second birthday.

103

auth: Kitzman, H

title: Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing: A randomized controlled trial

year: 1997

outcomes: During the first 2 years of the child's life, there were no intervention effects on birth weight, length of gestation, low birth weight, pre-term delivery, Apgar scores, duration of breast-feeding, immunization rates, mental development, behavioral problems, or mothers' education and employment. There were intervention effects on pregnancy-induced hypertension, frequency of health care encounters for children in which injuries or ingestions were detected, and second pregnancies.

13. Trial 5117

Project Title: Houston Parent-Child Development Center

population: Subjects were 1 year old children whose Mexican-American families were impoverished. Families were excluded if the child had a neurological impairment or was chronically ill or the mother was employed in ways that would interfere with participation.

inter. type: Selective preventive intervention

intervention: The intervention was specifically designed for this minority group and therefore had its first year in the home, included fathers, and conducted much of its verbal interactions in Spanish. The program began when the children were 1 and ended when they were 3, totaling approximately 550 hours of family involvement. The 25 home visits were conducted by paraprofessional women from the barrios who had been trained as resource persons, bringing information to the mother about child development and child training. There were also several family workshops held on weekends for whole families. Mothers also participated in English-language classes. The second year consisted by 4 mornings a week at the project Center where the children were in nursery school, the mothers attended classes, and videotaping of mother-child interaction was used as a teaching tool. Both professionals and paraprofessionals were involved.

117

auth: Johnson, DL

title: The Houston Parent-Child Development Center and the primary prevention of behavior problems in young children

year: 1982

ref: American Journal of Community Psychology

outcomes: A follow-up of part of the sample 1-4 years after the program was completed (when the children averaged 5 1/2 years) showed, according to mothers' reports, that experimental boys and girls presented very few problems and control girls were not too different from them. Control boys were more destructive, overactive, negative attention-seeking, and less emotionally sensitive than program boys and girls and control girls.

233

auth: Johnson, DL

title: Primary prevention of behavior problems in Mexican-American children

year: 1987

ref: American Journal of Community Psychology

outcomes: A second follow-up 5 to 8 years after the program's completion was based on teachers' ratings. The frequency of behavior problems, including acting-out, aggressive behaviors, in the experimental children was significantly less than in the control children. Differences between groups on moody, withdrawn behaviors approached but did not achieve significance. Experimental boys were less dependent than control boys. Although there were no teacher-reported group differences on learning problems, the experimental children obtained significantly higher Iowa Test of Basic Skills Composite scores. The authors note that this appears to be the first primary prevention program to have demonstrated effectiveness in reducing behavior problems over such a long time.

94

auth: Johnson, DL

title: Primary prevention of behavior problems in young children: The Houston Parent-Child Development Center

year: 1991

outcomes: At the end of the program, experimental mothers demonstrated better interactive skills with their child and provided a more educationally stimulating environment. The children demonstrated small but significantly better IQ scores. When the children were 4 to 7 years, boys in the control group demonstrated the most behavior problems. When the children were 5 to 8 years, control children had more behavior problems and significantly lower cognitive scores.

14. Trial 5139

No Project Title

population: Subjects were middle to low income pregnant women from the townships of a large region.

inter. type: Universal preventive intervention

intervention: All women were exposed to a mass media campaign that lasted for 6 months prior to the start of the trial. The campaign's aim was to encourage early booking of antenatal care. Before the trial began, training of staff was started in the clinics with the experimental program, and staff workshops were held throughout the 2 years of the study. Research staff also visited control clinics to be sure they were adhering to the standard program of antenatal care. The experimental clinics provided fewer but more objectively oriented prenatal visits and fewer procedures per visit than the control clinics.

139

auth: Munjanja, SP

title: Randomized controlled trial of a reduced-visits programme of antenatal care in Harare, Zimbabwe

year: 1996

outcomes: Experimental women made fewer prenatal visits and had significantly fewer referrals for pregnancy-induced hypertension or eclampsia than controls. The risk for pre-term delivery was significantly lower for experimental women. There were no other significant differences between the groups in other major indices of pregnancy outcomes, including obstetric interventions, low birthweight, and perinatal and maternal mortality and morbidity. There were no adverse effects on the main intermediate outcome pregnancy variables.

15. Trial 5150

No Project Title

population: Subjects were first time mothers who were 17 years of age or under who delivered a well baby at a large urban teaching hospital and intended to keep the baby. All of the mothers were unwed, on Medicaid, and black.

inter. type: Selective preventive intervention

intervention: The experimental mothers received routine well-baby care plus special services in a teen baby clinic in the same hospital. A pediatrician, a nurse practitioner, a social worker, and trained volunteers provided rigorous follow-up, discussions with the mother about her plans for return to school and use of family planning methods, and extra health teaching including videotapes. The control mothers received routine well-baby care. Both groups received services for 18 months.

150

auth: O'Sullivan, AL

title: A randomized trial of a health care program for first-time adolescent mothers and their infants

year: 1992

outcomes: At 18 months when the intervention ended, the experimental mothers showed significant differences in repeat pregnancy rates, but no differences in return to school rates. Their infants were more likely to have full immunization status, but there was no difference on the rate of use of the emergency room for infant care.

16. Trial 5185

Project Title: Bermuda Mother-Child Home Program

population: Subjects were 24 to 30 month old children and their mothers. Only 33 to 58 percent of the families could be considered disadvantaged. Nearly half the children were attending group care programs on a full-time basis from ages 2 to 4, the period in which the intervention took place.

inter. type: Universal preventive intervention

intervention: The experimental group received the Mother-Child Home Program, consisting of 46 semi-weekly visits by paraprofessional "toy demonstrators" over each of 2 years. The aim was to affect cognition, social behavior, and emotion. The home visitors were extensively trained and supervised. The control group did not receive a home-visiting program.

185

auth: Scarr, S

title: Far from home: An experimental evaluation of the Mother-Child Home Program in Bermuda.

year: 1988

outcomes: The experimental intervention had few demonstrable effects on any segment of the sample, even the socioeconomically disadvantaged. On average, children in Bermuda score above US norms on cognitive tests and are functioning well in the preschool period.

17. Trial 5188

Project Titles: High/Scope Preschool Curriculum Study

population: Subjects were 3 and 4 year old children who lived in families of low socioeconomic status and who, according to test scores, were at risk of failing in school.

inter. type: Selective preventive intervention

intervention: Three preschool curriculum, all part of the same research project, were compared. The High/Scope model used an open-framework approach in which teacher and child both planned and initiated activities and actively worked together. The Distar model used a programmed-learning approach in which the teacher initiated activities and the child responded to them. The model in the nursery school tradition used a child-centered approach in which the child initiated and the teacher responded. All 3 approaches had two components in common: classroom sessions lasting 2 1/2 hours 5 days a week and home visits by a teacher lasting 90 minutes once every 2 weeks with both the parent and child present.

188

auth: Schweinhart, LJ

title: Consequences of three preschool curriculum models through age 15

year: 1986

outcomes: Data was collected at age 15 for youngsters who had attended 1 of 3 preschool programs at ages 3 and 4: the High/Scope model, the Distar model, and a model in the nursery school tradition. The mean IQ of the children who had attended these 3 high-quality preschool programs rose 27 points during the first year of the program, from 78 to 105 and at age 10 was 92. The 3 preschool curriculum groups differed little in their patterns of IQ and school achievement over time. According to self-reports at age 15, the group that had attended the Distar preschool program engaged in twice as many delinquent acts as did the other 2 curriculum groups, including 5 times as many acts of property violence. The Distar group also reported relatively poor relations with their families, less participation in sports, fewer school job appointments, and less reaching out to others for help with personal problems. However, there is no evidence that the Distar group engaged in more delinquency than they would have if they had not attended the preschool program. It is clear that the other 2 models had a more favorable effect on social behavior.

18. Trial 5234

No Project Title

population: Subjects were low income parents who complained of at least 1 behavioral or emotional problem in their 2 to 5 year old children. Families whose primary language was not English or whose children had low vocabulary test scores were excluded.
inter. type: Indicated preventive intervention
intervention: The experimental group received group training involving instruction and role-playing practice and individual sessions involving modeling and written materials. The intervention was delivered to parents by research assistant paraprofessionals. The average amount of training received was 12.5 hours. A psychiatrist supervised the parent training. The control group received a pamphlet on parenting and watched 2 videotapes on the use of time-out and positive reinforcement.

234
auth: Strayhorn, JM
title: Reduction of attention-deficit and internalizing symptoms in preschoolers through Parent-Child Interaction Training
year: 1989
outcomes: The results constitute a mix between posttest results and follow-up (33 to 139 days after the last contact). The experimental parents reported significantly more improvement in their children's symptoms of attention deficit and internalizing symptoms. Both groups improved with respect to parents' ratings of children's oppositional symptoms. A blind measure of videotaped interaction between parent and child demonstrated significantly more improvement in the experimental group.

203
auth: Strayhorn, JM
title: Follow-up one year after parent-child interaction training: Effects on behavior of preschool children
year: 1991
outcomes: At 1 year follow-up after completion of the intervention, parent ratings and child achievement test scores showed no difference between the experimental and control groups. However, teacher ratings of child behavior, including attention deficit and hyperactivity symptoms, significantly favored the experimental group. Children's improvements in classroom behavior were significantly correlated with improvements parents had shown during the intervention in their behavior toward the children.

19. Trial 5255

Project Title: Trial within the Montreal Longitudinal Experimental Study

population: Subjects were kindergarten boys who were considered to be disruptive by their teachers and their families. The boys were from 53 schools in low SES areas of a large metropolitan city. Inclusion criteria included: both biological parents were born in Canada and their mother-tongue was French; neither parent had more than 14 years of schooling; the "at risk" boys had disruptive scores above the 70th percentile on screening questionnaires which were completed by teachers when the boys finished kindergarten (mean age 6). Subjects knew they were involved in a study on children's development, but they did not know they had been identified as being at-risk for antisocial behavior.

inter. type: Indicated preventive intervention

intervention: The experimental group received 2 school years of intervention (when the boys averaged 7 to 9 years of age). The intervention included parent training, based on the Patterson model for family intervention; social skills training with the boys; and teaching the boys to use fantasy and be critical of television. Two university-trained child care workers, a psychologist, and a social worker carried out the program with parents and teachers. On average parents averaged 17.4 sessions, with a maximum of 46. The social skills program involved pro-social skills training the 1st year and a program aimed at self-control the 2nd year. Another set of professionals provided this intervention. Graduate students provided 12 home sessions to the child and his siblings on fantasies and alternative to the expression of aggression and 9 sessions in a television training program. However, only half of the experimental children received the home visits by the graduate students because of lack of funds. The observation group received almost as much attention as the experimental group, but no effort was made to change the children or their families. The control group received no special attention or intervention. All 3 groups were free to seek additional interventions in the community.

255

auth: Tremblay, RE

title: Can disruptive boys be helped to become competent?

year: 1991

outcomes: Assessments were made at the end of the intervention and at 1 and 2 years follow-up. At the end of the intervention, there were no differences between groups on the teacher ratings for disruptive behavior, anxiety, inattentiveness, or pro-social behavior, and the experimental mothers were more likely than the other mothers to perceive their sons as disruptive. Two years later experimental mothers gave reliably lower ratings to their sons for pro-social behavior. At 1 year follow-up, all the boys were similar in the amount of misbehavior they reported. However, at 2 year follow-up, the experimental boys reported that during the prior year they were less likely to be fighting outside the home and at home and were less likely to be stealing at home. All disruptive boys from all groups were increasingly placed in special classrooms or held back in school, but the experimental boys were less likely to also be rated as highly disruptive by a teacher or by peers.

266

auth: Tremblay, RE

title: A bimodal preventive intervention for disruptive kindergarten boys: Its impact through mid-adolescence

year: 1995

outcomes: At long-term follow-up when the boys were in mid-adolescence, the experimental group was significantly less delinquent on self-report. However, court records did not reveal any significant differences between the groups. A significantly greater percentage of experimental boys remained in age-appropriate regular classrooms up to the end of elementary school. However, this impact disappeared by age 15; by this age 59.3 percent were not in an age-appropriate regular classroom.

20. Trial 5275

No Project Title

population: Subjects were medically indigent residents who delivered at a charity hospital.

inter. type: Selective preventive intervention

intervention: Each woman in the study was contacted on the maternity ward and given an appointment for a postpartum examination at 1 of the family planning clinics. Experimental women in group 1 were home visited by paraprofessional family health counselors 1 time postpartum to provide information on child care and self-care as well as encouragement to keep the postpartum appointment. The 6 counselors received a 3 week training program developed by a multidisciplinary team. Experimental women in group 2 were home visited by a different 6 paraprofessional health counselors who had received a 3 day training program. Their only role was to encourage the women to attend the clinic for postpartum examination. Both home visited groups received the contact within 10 days after hospital discharge. The control group women were not visited at home.

275

auth: Moore, FI

title: The influence of postpartum home visits on postpartum clinic attendance

year: 1974

outcomes: The percentages of kept appointments was 79.4 for group 1, 83.5 for group 2, and 75.8 for controls. The difference between group 1 and the controls was not significant, whereas the difference between group 2 and the controls was. Within each of the 3 groups, the percentage of kept appointments decreased as the number of pregnancies increased.

21. Trial 5288

Project Title: The Carolina Early Intervention Program

population: Subjects were infants with mothers who tended to be young, Black, poor, single and with less than a high school education. The children were considered at high risk for delayed intellectual development and poor readiness for public school success.
inter. type: Selective preventive intervention
intervention: There were 4 components: developmental day care at a child development child beginning when the infant was between 6 and 12 weeks of age and continuing through 54 months of age; a toy lending library; a home visiting program by the teachers; and a parent group program. Specific curriculum are used in each component.

288
auth: Ramey, CT
title: Early intervention for high-risk children: The Carolina Early Intervention Program
year: 1988
outcomes: The intervention had a measurable impact on cognition in the first year of life and this impact was sustained over the preschool period. Compared to the average performance of the control group on the Stanford-Binet at 2, 3, and 4 years of age, the intervention group had a significant impact. (The mean percentage of the control group who scored 84 or below was 39.6 percent and of the intervention children it was 8.3 percent. If the performance of the control group indicates risk during this developmental period, then the early intervention program reduced the risk for borderline or lower intellectual functioning by a total of 79 percent.

22. Trial 5431

No Project Title

population: Subjects were full term healthy primigravidous women in early labour who had a cervical dilatation of 3 cm or less and were without medical problems. Mother-infant pairs were excluded from the study if they developed a complication during labour, delivery, or postpartum that required special care.
inter. type: Universal preventive intervention
intervention: The control group received the usual hospital routines. The experimental group received that same care plus constant support and companionship from 1 of 3 lay women with no obstetric training, known as a doula. The support was both emotional and physical, and included rubbing the patient's back, holding her hands, and providing explanation and encouragement. The patient was told that she would never be left alone.

431
auth: Klaus, MH
title: Effects of social support during parturition on maternal and infant morbidity
year: 1986
outcomes: Experimental mothers had significantly fewer perinatal complications, including cesarean sections, and fewer infants who were admitted to neonatal intensive care. Of the women who had an uncomplicated labour and delivery, those with a doula had a significantly shorter duration of labour.

COMPARISON BETWEEN THE INVEST IN KIDS PROJECT AND THE RAND REPORT

After the Invest in Kids project was underway, the RAND report entitled "Investing in Our Children: What We Know and Don't Know about the Costs and Benefits of Early Childhood Interventions" by Karoly and colleagues was released. The question was raised by Invest in Kids as to similarities and differences between the reports.

The two reports, while using quite different approaches, share a common aim. They both focus on what has been learned by providing early interventions for children at risk, what the gaps in knowledge are, and what directions future policymakers and researchers should undertake. The reports dovetail, with the RAND report laying out a historical perspective on our country's willingness to invest in children and using illustrative examples to make its case, and the Invest in Kids report broadening the database on preventive interventions, laying out a framework for assessing the strength of evidence of the programs, and examining outcomes in well-designs trials.

There are five primary differences between the two reports.

1. **Initial task.** RAND was approached in 1997 by the "I Am Your Child" Early Childhood Public Engagement Campaign to conduct an independent, objective review of the scientific literature available on early childhood interventions (Karoly et al., 1998, preface iii), and funding for the project was provided by the California Wellness Foundation. The goal was to quantify the benefits of early childhood programs to children, their parents, and society at large. The early childhood interventions were defined as attempts by government agencies or other organizations to improve child health and development, educational attainment, and economic well-being. Implied in the initiative was a focus on health promotion. Prevention Technologies was approached, also in 1997, by the Invest in Kids to conduct a review regarding the best available evidence regarding psychosocial interventions for children under the age of six. The initiative was very much focused on prevention of onset of develop mental, social, and behavioral problems.
2. **Selection of target groups.** RAND chose to focus only on programs that were targeted to disadvantaged children, that is, of lower socioeconomic groups. The Invest in Kids Project included but was not limited to this focus.

3. **Selection criteria regarding the quality of the design of the study.** RAND used four criteria:
   a. experimental design, preferably with randomized assignment to treatment and control groups;
   b. a sample size of 50 children or more in treatment plus controls;
   c. a follow-up period, preferably past the period of program intervention;
   d. less than 50 percent attrition at follow-up.

The Invest in Kids project developed a new quality of design index that is much more comprehensive and lends itself to classifying the programs according to design strength. This is critical for the assessment of the validity of the outcomes that are found.

4. **Number of intervention programs assessed.** RAND chose ten well-known intervention programs for its review. Nine of the programs met the four selection criteria. The Head Start Program was also reviewed but its outcomes are not included in the tables. It is not that RAND was unaware that there were many other programs available to review; rather, they chose an in-depth review approach to a

limited number of nationally recognized programs with reputations for positive outcomes to make their case. The Invest in Kids report includes information on 165 trials (reported in 215 scientific papers). The review was meant to be as comprehensive as possible, though it is not exhaustive. Rather, it is the beginning of a registry of trials for this age group that could, with further funding, become an ongoing source of information. The report includes beneficial, harmful, and neutral outcomes.

5. **Number of outcomes assessed.** The Invest in Kids reporting of outcomes, even though limited to the top two groups of trials as to quality of design, is much more complete than the RAND report.

In summary, the two reports could be used together to help direct further research and community program planning.

GAPS IN THE RESEARCH

1. There is a lack of understanding about non-responders and virtually no effort to develop special interventions targeting them.

2. There is a lack of intervention trials targeting fathers of at-risk children. The literature is heavily focused on mothers only.

3. More sophisticated analyses are needed to clarify main effects as well as interactive effects.

4. There has been minimal research on the timing of very early preventive interventions, especially the difference in effects if an intervention begins prenatally, at the time of delivery and immediately postpartum, or within the first few months of a child's life.

5. Despite the large number of trials that have been done for children between zero and six years of age, there has been virtually no attempt to test a combination of efficacious programs that are delivered simultaneously or sequentially.

6. Cost-benefit research on the preventive trials is rarely done. There are excellent models (see papers by Barnett and by Olds in the annotated bibliography) to use to guide more work in this area.

7. More investigation is needed regarding the critical elements of efficacious home visitation programs. Examples that warrant study include content (structured protocols versus relationship building); type of intervenor (professional versus paraprofessional); timing (age of child at first contact and length of intervention).

8. There has been minimal investigation of how to facilitate and measure a high level of fidelity to the intervention design, that is, to be sure that the intervenors are doing what they are supposed to be doing.

9. Much more investigation is needed on the community's intervening relationship with families and children, especially on how large-scale policies affect young children.

10. There is minimal, if any, research on how to take efficacious research programs to scale in community-wide effectiveness trials.

CONCLUSIONS

Many more prevention trials focusing on zero to six have been conducted than we had anticipated, and our search was not exhaustive. The quality of the design of the majority of the trials is poor enough that the results that are reported are of questionable validity. There also are serious gaps in the content areas that have been addressed to date. On the other hand, there are many interesting intervention programs that warrant a second look in better designed trials.

Most of the outcomes of the trials with 5-Star and 4-Star designs are not overly impressive. Only 10 percent of the significant findings have strong magnitude of effect. Rarely have these outcomes been replicated, and there have been few if any effectiveness trials. However, there are exceptions, and it is these that should be a major focus of Invest in Kids. For example, the results of the Early Infancy Project in Elmira has some degree of replication in the trial in Memphis and the work by Ramey in the Carolina Early Intervention Program strongly influenced the design of the intervention in the Infant Health and Development Project. The impressive results of these trials warrant investment in effectiveness trials. Finally, some well-designed trials with a more limited target outcome should be considered for incorporation into other more comprehensively designed intervention programs.

It is our recommendation that Invest in Kids take a leading role in shaping future prevention research and well as implementation of effectiveness studies of the research programs whose design and strength of outcomes warrant the considerable investment that will be necessary.

REFERENCES

Mrazek PJ and Haggerty RJ (1994). *Reducing Risks for Mental Disorders: Frontiers for Preventive Intervention Research*. Washington, D.C.: National Academy Press.

Oakley A, Fullerton D, and Holland J (1995). Behavioral interventions for HIV/AIDS prevention. *AIDS*, 9, 479-486.

FIGURE 1. THREATS TO TRIAL INTEGRITY SCORES BY TRIAL ELEMENTS SCORE

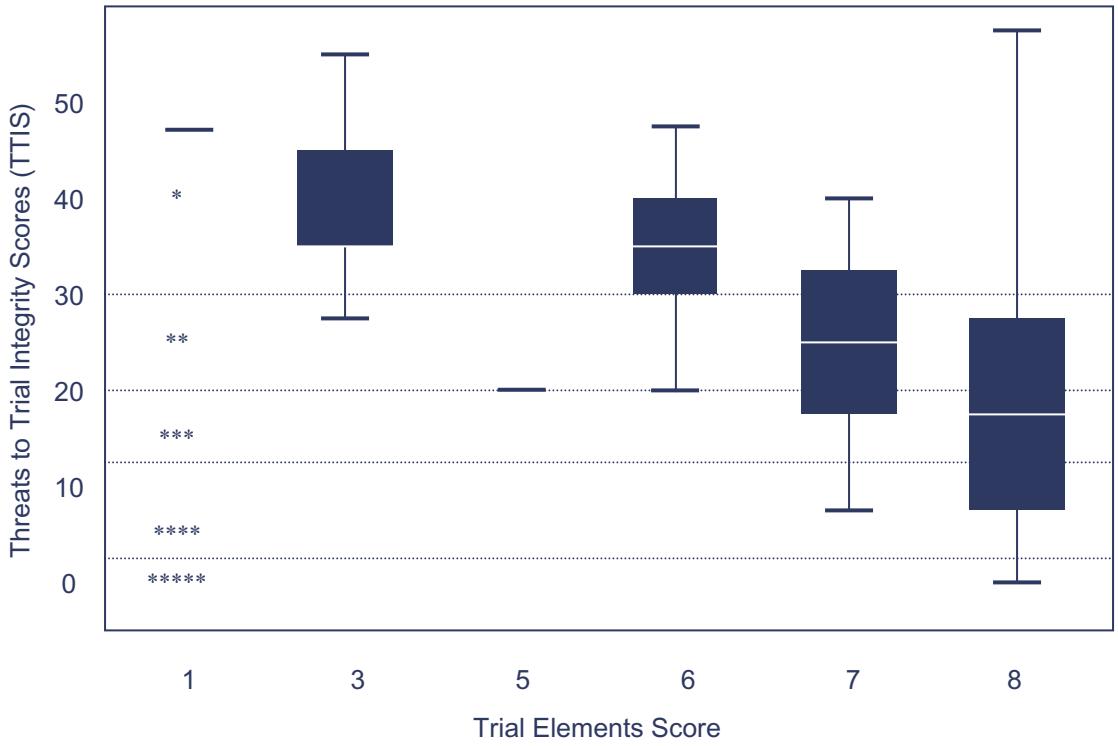

FIGURE 2. THREATS TO TRIAL INTEGRITY BY COUNTRY (EXCLUDES CONCURRENT TRIALS)

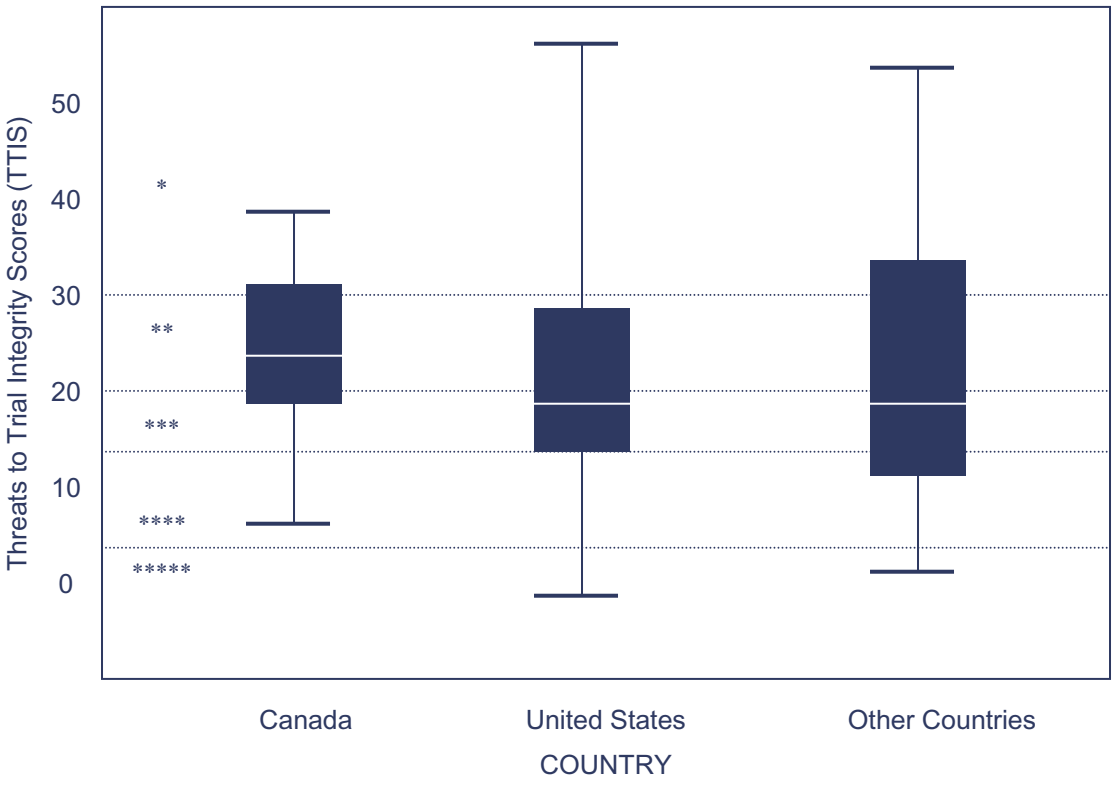

FIGURE 3. THREATS TO TRIAL INTEGRITY BY INTERVENTION TYPE

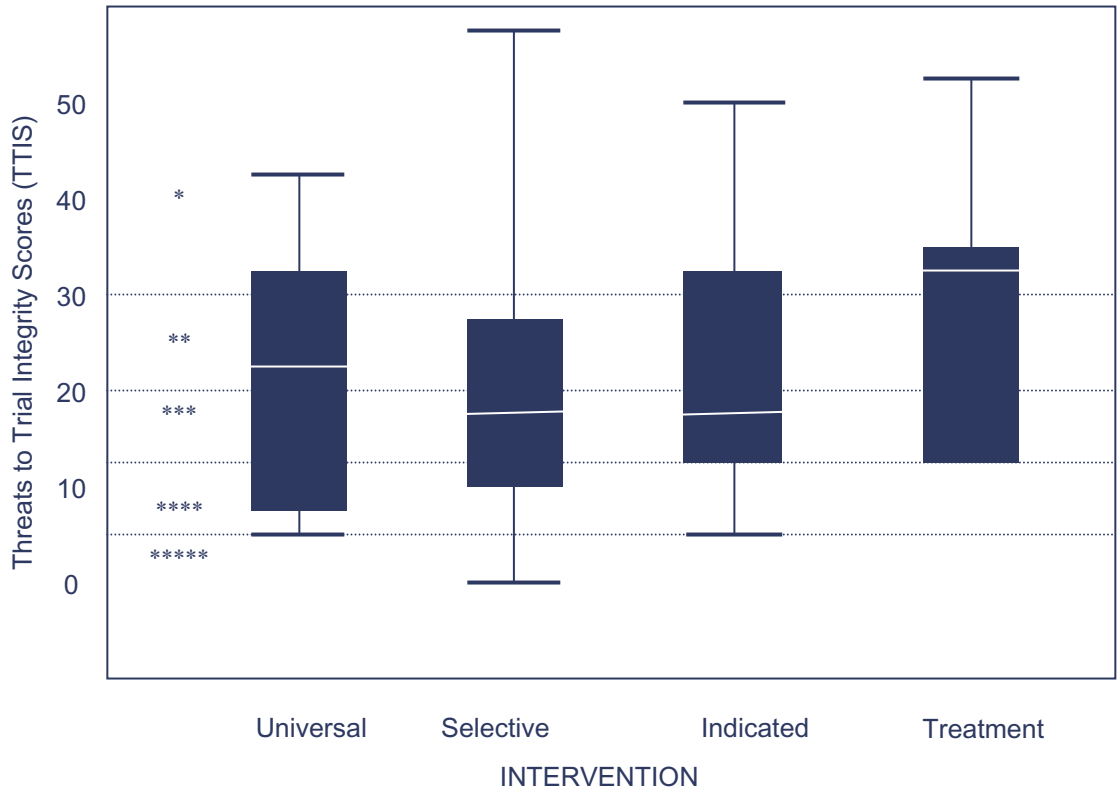

FIGURE 4. THREATS TO TRIAL INTEGRITY BY INTERVENTION SITE

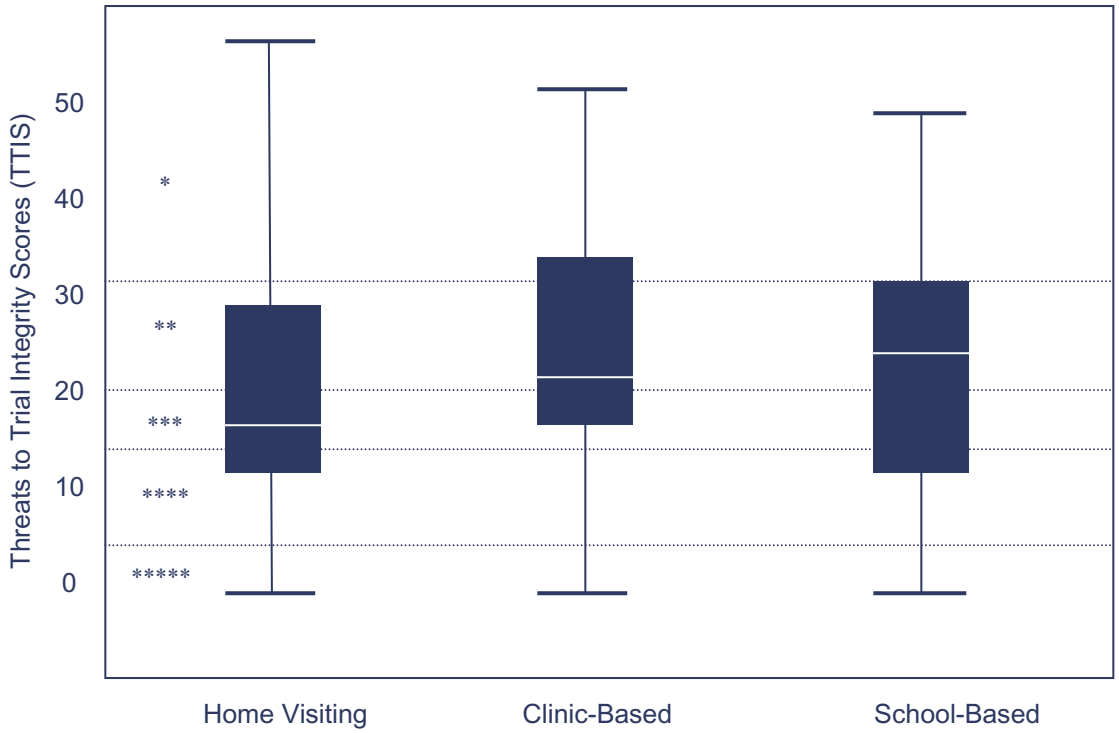

TABLE 1A. COUNTRY WHERE INTERVENTION BEGAN

Country	Number
Argentina/Brazil/Cuba/Mexico	1
Australia	3
Bermuda	1
Canada	21
England	5
Finland	1
France	1
Guatemala	1
Ireland	1
Israel	1
Jamaica	3
Mexico	1
Netherlands	1
New Zealand	1
Portugal	1
Scotland	3
South Africa	1
Switzerland	1
Turkey	1
USA	114
Zimbabwe	1
Unknown Country	1
Total	**165**

TABLE 1B. TRIALS AND REFERENCES TO PAPERS

Trial Number	Paper No.	Year Published	First Author	Type or Name of Intervention
5005	5	1990	Achenbach, T	hospital and home visits
5006	6	1994	Als, H	clinic-based developmental care
5007	7	1990	Anisfeld, E	infant carrying
5008	8	1983	Barkauskas, VH	home visits
5009	9	1993	Barnett, WS	preschool and home visits
	199	1993	Spitz, HH	preschool and home visits
	216	1988	Schweinhart, LJ	preschool and home visits
	290	1990	Barnett, WS	preschool and home visits
5011	11	1986	Barrera, ME	home visits
	12	1986	Barrera, ME	home visits
5014	14	1991	Bass, JL	clinic-based parent education
5016	16	1995	Beeghly, M	clinic-based parent education
5018	18	1995	Black, MM	home visits
5020	20	1990	Blondel, B	home visits
5021	21	1991	Bloom, B	home visits
5023	23	1989	Booth, CL	home visits
5026	26	1991	Bryce, RL	home visits
5027	27	1989	Burchinal, M	infancy day care
5028	28	1982	Burkett, CW	home visits
5029	29	1993	Butz, AM	clinic-based prenatal care
5030	30	1994	Campbell, FA	infant education
	91	1987	Horacek, HJ	infant education
	129	1990	Martin, SL	infant education
	169	1984	Ramey, CT	infant education
	170	1984	Ramey, CT	infant education
	198	1992	Spitz, HH	infant education
5035	35	1996	Connor-Kuntz, FJ	preschool-based language instruction
5036	36	1996	Connor-Kuntz, FJ	home-based uterine activity monitoring
5037	37	1996	Cronan, TA	community-based literacy program
	38	1994	Cronan, TA	community-based literacy program
5039	39	1996	Cullen, KJ	clinic-based interview
	405	1976	Cullen, KJ	clinic-based interview
5040	40	1995	Cunningham, CE	community-based parent training
5041	41	1989	Dawson, P	home visits
5043	43	1988	Dickens, WJ	classroom-based and home visits
5044	44	1994	Dihoff, RE	clinic-based education and therapy
5049	49	1997	Dunkley, J	clinic-based smoking cessations
5050	50	1987	Dworkin, PH	clinic-based parent education
5054	54	1995	Ershoff, DH	smoking-related interview
	258	1990	Ershoff, DH	smoking-related interview
5055	55	1989	Ershoff, EH	clinic-based and mailings
5056	56	1983	Ershoff, DH	clinic-based counseling and home correspondence
5057	57	1996	Esdaile, SA	clinic-based parent training
5058	58	1995	Eyberg, SM	clinic-based parent-child interaction therapy
5061	61	1982	Field, T	home visits and nursery intervention
5062	62	1980	Field, T	home visits for parent training
5063	63	1986	Field, TM	clinic-based stimulation
5065	65	1990	Finney, JW	clinic-based parent education
5066	66	1992	Florida Department of Education	home visits and health screenings
5067	67	1979	Forgatch, M	clinic-based, telephone contact
5069	69	1987	Fox, NL	clinic-based smoking cessations
5070	70	1996	Gelfand, DM	home visits
5071	71	1996	Girolametto, L	clinic-based education
5072	72	1994	Girolametto, L	clinic-based group sessions and home visits

TABLE 1B. TRIALS AND REFERENCES TO PAPERS, cont'd

Trial Number	Paper No.	Year Published	First Author	Type or Name of Intervention
5075	75	CONCURRENT	Bradley, SJ	clinic-based parenting groups
5076	76	1995	Gomes-Pedro, J	clinic-based parent education
5077	77	1987	Gotts, EE	home visits and mobile classroom van
5079	79	1994	Grantham-McGregor, S	home visits
	80	1983	Grantham-McGregor, S	home visits
5083	83	1977	Gutelius, MF	home visits and mobile coach
5084	84	1995	Hanks, C	home visits
5085	85	1996	Hansen, K	clinic-based parent education
5086	86	1989	Hardy, JB	home visits
5088	88	1990	Heins, HC	home visits
5089	89	1996	Herman, AA	community-based social support
5090	90	1982	Honig, AS	developmental day care and home visits
5096	96	1994	Jones, ME	community clinic vs. school-based prenatal care
5097	97	1985	Jordan, TJ	special class enrichment
5098	98	1995	Kang, R	home visits with NSTEP-P
5099	99	1987	Karnes, MB	preschool cognitive skills
5101	101	1996	Kerr, SM	home visits and booklet
5103	103	1997	Kitzmann, H	home visits
5111	111	1991	Lee, VE	preschool education
5112	112	1980	Leib, SA	clinic-based stimulations
5113	113	1970	Levenstein, P	home visits
	115	1989	Levenstein, P	home visits
	94	1991	Johnson, DL	home visits and development centre
5117	117	1982	Johnson, DL	home visits and development centre
	233	1987	Johnson, DL	home visits and development centre
5119	119	1993	Lieberman, AF	clinic-based therapy
5120	120	1990	Lyons, RK	home visits and group therapy
5122	122	1997	Lovell, ML	agency-based parent support
5125	125	CONCURRENT	Walsh, CA	home visits
5126	116	1992	Levenstein	home visits
	126	1976	Madden, J	home visits
5127	127	1984	Madden, J	home visits
	444	1992	Levenstein	home visits
5128	128	1994	Marcenko, MO	home visits
5130	130	1996	McDuffie, RS	clinic-based health care
5131	1	1990	The Infant Health and Development Program	home visits, child development centre, parent groups
	25	1994	Brooks-Gunn, J	home visits, child development centre, parent groups
	32	1994	Casey, PH	home visits, child development centre, parent groups
	87	1997	Haas, JS	home visits, child development centre, parent groups
	102	1993	Kirby, RS	home visits, child development centre, parent groups
	131	1997	McCarton, CM	home visits, child development centre, parent groups
	166	1992	Ramey, CT	home visits, child development centre, parent groups
	235	1990	Kraemer, HC	home visits, child development centre, parent groups
5133	133	1983	Moxley-Haegert, L	home visits
5134	134	1996	Neuman, SB	Head-Start-based parental reading
5135	135	1989	Messimer, SR	clinic-based smoking cessations
5136	136	1994	Minde, K	clinic-based counseling sessions
5139	139	1996	Munjanja, SP	clinic-based health program
5143	143	1986	Olds, DL	home visits
	144	1995	Olds, DL	home visits
	145	1988	Olds, DL	home visits
	147	1997	Olds, DL	home visits
	183	1996	Samples, FL	home visits
	236	1986	Olds, DL	home visits
	237	1994	Olds, DL	home visits
	238	1994	Olds, DL	home visits

TABLE 1B. TRIALS AND REFERENCES TO PAPERS, cont'd

Trial Number	Paper No.	Year Published	First Author	Type or Name of Intervention
	239	1988	Olds, DL	home visits
	252	1993	Olds, DL	home visits
5150	150	1992	O'Sullivan, AL	clinic-based parent education
5152	152	1997	Parush, S	clinic-based parent education
5153	153	1996	Pelaez Nogueras, M	clinic-based parent stimulation training
5154	154	1989	Seymour, FW	clinic-based versus written parent training
5155	155	CONCURRENT	Peters, R	home visits, class, parent, family, community
5159	159	1980	Piper, MC	clinic-based stimulation
5160	160	1992	Poland, ML	home visits
5161	161	1989	Powell, C	home visits
5164	164	1972	Radin, N	home visits and school-based groups
5171	171	1976	Ramey, CT	day-care education
5173	173	1979	Ramey, CT	centre-based education
5174	174	1988	Resnick, MB	clinic-based and home visits
5175	175	1995	Reynolds, AJ	preschool and comprehensive services
5176	176	1985	Richman, N	clinic-based therapy
5177	177	1981	Rickel, AU	individualized preschool programs
	230	1979	Rickel, AU	individualized preschool programs
5178	178	1988	Rickert, VI	behavioral approaches by phone
5181	181	1996	Rogers, MM	home visits
5184	184	1985	Sankey, CG	residential caretaking
5185	185	1988	Scarr, S	home visits
5186	186	1973	Scarr-Salapatek, S	stimulation in premature nursery
5188	188	1986	Schweinhart, LJ	preschool curricula
5189	189	1991	Seifert, H	classroom-based education
5190	190	1985	Seitz, V	home visits, pediatric care, day-care, developmental e
	191	1994	Seitz, V	home visits, pediatric care, day-care, developmental e
5192	192	1995	Shapiro, C	home visits
5193	193	1994	Sheeber, LB	group-based parent training
5195	194	1980	Shure, MD	interpersonal cognitive problem solving
	195	1982	Shure, MD	interpersonal cognitive problem solving
	196	1979	Shure, MD	interpersonal cognitive problem solving
	289	1988	Shure, MD	interpersonal cognitive problem solving
	291	1979	Shure, MD	interpersonal cognitive problem solving
5207	207	1992	Valdez-Menchaca, MC	preschool reading programs
5208	208	1994	van den Boom, DC	home visits
	229	1995	van den Boom, DC	home visits
5210	210	1992	Villar, J	home visits
5213	213	1990	Wasik, BH	day-care education and home visits
5220	220	1994	Whitehurst, GJ	home visits and Head Start
5221	221	1988	Whitehurst, GJ	parent instruction in university setting
5223	223	1981	Widmayer, S	Brazelton demonstration in clinics
5224	224	1988	Wolfe, DA	behavioral parent training in agency
5225	225	1981	Zeskind, PS	instructional day care centre
5226	226	1990	Zucker, RA	parent training
5228	228	1975	Arnold, JE	clinic-based parent training
5231	231	CONCURRENT	Ciccetti, D	Not available
5232	232	1995	Kagitcibasi, C	home visits and group-based child care centres
5234	203	1991	Strayhorn, JM	clinic based parent training
	234	1989	Strayhorn, JM	clinic based parent training
5240	240	1988	Barnard, KE	public health nursing contacts
5241	241	1987	Barnard, KE	home visits
5242	242	1988	Barnard, KE	home visits
5243	243	1988	Kronqvist, EL	clinic-based family counseling
5244	244	CONCURRENT	Ross, S	home visits, community integration
5245	245	1998	Landy, S	home visits, clinic visits
5246	246	1989	Holden, J	home visits

TABLE 1B. TRIALS AND REFERENCES TO PAPERS, cont'd

Trial Number	Paper No.	Year Published	First Author	Type or Name of Intervention
5247	247	1996	Malphurs, J	clinic-based parent training
5248	248	1990	Cramer, B	mother-infant psychotherapy
	443	1996	Robert-Tissot, C	mother-infant psychotherapy
5250	250	1997	Cooper, PJ	home visits
5251	251	1997	Field, T	social, educational, vocational program
5253	253	1996	Field, T	nursery-based massage
5254	254	1977	Field, T	clinic-based mother training
5255	255	1991	Tremblay, RE	school-based parent training and group skill training
	266	1995	Tremblay, RE	school-based parent training and group skill training
5256	256	CONCURRENT	Cohen, NJ	clinic-based psychotherapy
5259	259	1993	Windsor, RA	prenatal clinic counseling
5260	260	1984	Webster-Stratton, C	clinic-based parent training
5261	261	1990	Webster-Stratton, C	clinic-based parent training
5263	263	1994	Webster-Stratton, C	clinic-based parent training
5264	262	1990	Webster-Stratton, C	clinic-based parent training
	264	1988	Webster-Stratton, C	clinic-based parent training
	265	1989	Webster-Stratton, C	clinic-based parent training
5267	267	1991	Barth, RP	home visits
5268	268	1979	Gray, JD	home visits
5269	269	1993	Johnson, Z	home visits
5275	275	1974	Moore, F	home visits
5277	277	CONCURRENT	Ross, M	clinic-based group parent training
5288	288	1988	Ramey, CT	developmental day care, home visits, parent groups
5292	292	1988	Beckwith, L	home visits
5401	401	1994	Arnold, DS	preschool-based parental reading
5406	406	1976	Donachy, W	preschool-based parent education
5409	409	1980	Hall, LA	home visits
5410	410	1980	Larson, CP	home visits
5411	411	1970	Lowe, ML	home visits
5412	412	1985	Main, DM	clinic-based medical care, telephone hot line
5414	414	1980	Minde, K	premature nursery self-help groups
5415	415	1990	Oakley, A	home visits
5417	417	1992	Petersen, L	clinic-based counseling and mailings
5418	418	1988	Rauh, VA	hospital-based and home visits
5424	420	1984	Scherer, NJ	
	424	1996	Sikorski, J	
5431	431	1986	Klaus, MH	support during labour
	432	1980	Sosa, R	support during labour
5433	433	1991	Hofmeyr, GJ	support during labour
5434	434	1991	Kennell, J	clinic-based support
5435	435	1997	Webster-Stratton, C	group clinic-based child vs. parent training
5436	436	1982	Webster-Stratton, C	group clinic-based parent training
5438	437	1991	Becker, PT	NICU-based developmental care
	438	1993	Becker, PT	NICU-based developmental care
5439	439	1995	Fleisher, BE	NICU-based developmental care
5440	440	1996	Webster-Stratton, C	Head Start-based parent training by videotape
5442	442	1989	Powell, C	home visits
5446	446	CONCURRENT	Boyle, MH	school-based parent training, social skills and reading
Total	**215**			

TABLE 1C. CANADIAN TRIALS AND REFERENCES TO PAPER

Trial No.	Paper No.	Year Published	First Author	Type or Name Intervention
5011	11	1986	Barrera, ME	home visits
	12	1986	Barrera, ME	home visits
5021	21	1991	Bloom, B	home visits
5040	40	1995	Cunningham, CE	community-based parent training
5071	71	1996	Girolametto, L	clinic-based education
5072	72	1994	Girolametto, L	clinic-based group sessions and home visits
5075	75	CONCURRENT	Bradley, SJ	clinic-based parenting group
5122	122	1997	Lovell, ML	agency-based parent support
5125	125	CONCURRENT	Walsh, CA	home visits
5133	133	1983	Moxley-Haegert, L	home visits
5136	136	1994	Minde, K	clinic-based counseling sessions
5155	155	CONCURRENT	Peters, R	home visits, class, parent, family, community
5159	159	1980	Piper, MC	clinic-based stimulation
5192	192	1995	Shapiro, C	home visits
5224	224	1988	Wolfe, DA	behavioral parent training in agency
5244	244	CONCURRENT	Ross, S	home visits, community integration
5245	245	1998	Landy, S	home visits, clinic visits
5255	255	1991	Tremblay, RE	school-based parent training and group skill training
	266	1995	Tremblay, RE	school-based parent training and group skill training
5256	256	CONCURRENT	Cohen, NJ	clinic-based psychotherapy
5410	410	1980	Larson, CP	home visits
5414	414	1980	Minde, K	premature nursery self-help groups
5446	446	CONCURRENT	Boyle, MH	school-based parent training, social skills & reading
Total	**23**			

TABLE 2A. NUMBER OF TRIALS BY STAGE OF LIFE WHEN INTERVENTION BEGAN

Stage of Life	Number
Prenatal	34
Parturition	3
Infancy	75
Toddler	14
Preschool/Kindergarten	34
Early School-Aged	3
Not Available	2
Total	**165**

TABLE 2B. CANADIAN TRIALS - STAGE OF LIFE WHEN INTERVENTION BEGAN

Stage of Life at Start of Intervention	Trial Number	Lead Author	Year Published	Ave. Age at Start of Intervention	All Stages of Life during Intervention Period
Prenatal	5410	Larson, CP	1980	7 mos., Gesta'l Age	prenatal - infancy
Infancy	5155	Peters, R	CONCURRENT	1 Day	infancy - Presch
Infancy	5414	Minde, K	1980	3 Days	infancy
Infancy	5011	Barrera, ME	1986	1 wk	infancy
Infancy	5192	Shapiro, C	1995	1 wk	infancy
Infancy	5245	Landy, S	1998	1 mo.	infancy - Presch
Infancy	5159	Piper, MC	1980	8.9 mos.	infancy
Infancy	5256	Cohen, NJ	CONCURRENT	20 mos.	infancy - Presch
Infancy	5136	Minde, K	1994	20.6 mos.	toddler
Infancy	5133	Moxley-Haegert, L	1983	21.5 mos.	infancy - toddler
Toddler	5224	Wolfe, DA	1988	24 mos.	Presch
Toddler	5072	Girolametto, L	1994	28.5 mos.	Presch
Toddler	5071	Girolametto, L	1996	28.7 mos.	toddler
Presch/Kinderg	5122	Lovell, ML	1997	3 yrs.	Presch
Presch/Kinderg	5075	Bradley, SJ	CONCURRENT	3.7 yrs.	Presch
Presch/Kinderg	5040	Cunningham, CE	1995	53.5 mos.	Presch
Early Sch-Aged	5446	Boyle, MH	CONCURRENT	6 yrs.	early Sch-aged
Early Sch-Aged	5125	Walsh, CA	CONCURRENT	6 yrs.	Presch/EarlySch age
Early Sch-Aged	5255	Tremblay, RE	1991	7 yrs.	Kinderg
Not Avail	5244	Ross, S	CONCURRENT	Not Avail	Not Avail
Not Avail	5021	Bloom, B	1991	Not Avail	Not Avail

TABLE 2C. STAGE OF LIFE WHEN INTERVENTION BEGAN

Start of Intervention	Trial Number	Lead Author	Year Pub'd	Ave. Start of Intervention	All Stages during IntervPeriod
Prenatal	5130	McDuffie, RS	1996	8 wks Gest'l Age	prenatal
Prenatal	5054	Ershoff, DH	1995	10 wks Gest'l Age	prenatal
Prenatal	5412	Main, Dm	1985	12.8 wks Gest'l Age	prenatal
Prenatal	5181	Rogers, MM	1996	3 mos Gest'l Age	prenatal
Prenatal	5417	Petersen, L	1992	1st Trimester	prenatal
Prenatal	5415	Oakley, A	1990	14 wks Gest'l Age	prenatal
Prenatal	5069	Fox, NL	1987	15 wks Gest'l Age	prenatal
Prenatal	5411	Lowe, ML	1970	16 wks Gest'l Age	prenatal
Prenatal	5103	Kitzmann, H	1997	16.5 wks Gest'l Age	prenatal - infancy
Prenatal	5055	Ershoff, EH	1989	18 wks Gest'l Age	prenatal
Prenatal	5026	Bryce, RL	1991	18 wks Gest'l Age	prenatal
Prenatal	5049	Dunkley, J	1997	18 wks Gest'l Age	prenatal
Prenatal	5088	Heins, HC	1990	20 wks Gest'l Age	prenatal
Prenatal	5023	Booth, CL	1989	22 wks Gest'l Age	prenatal
Prenatal	5210	Villar, J	1992	22 wks Gest'l Age	prenatal
Prenatal	5242	Barnard, KE	1988	22 wks Gest'l Age	prenatal
Prenatal	5056	Ershoff, Dh	1983	24 wks Gest'l Age	prenatal
Prenatal	5267	Barth, RP	1991	5.7 mos Gest'l Age	prenatal
Prenatal	5143	Olds, DL	1986	25 wks Gest'l Age	prenatal - infancy
Prenatal	5160	Poland, ML	1992	2nd Trimester	prenatal
Prenatal	5096	Jones, ME	1994	2nd Trimester	prenatal
Prenatal	5277	Ross, M	CONCURRENT	26.5 wks Gest'l Age	prenatal
Prenatal	5036	Connor-Kuntz, FJ	1996	28 wks Gest'l Age	prenatal
Prenatal	5029	Butz, AM	1993	28 wks Gest'l Age	prenatal
Prenatal	5139	Munjanja, SP	1996	Gest'l Age	prenatal

TABLE 2C. STAGE OF LIFE WHEN INTERVENTION BEGAN, cont'd

Start of Intervention	Trial Number	Lead Author	Year Pub'd	Ave. Start of Intervention	All Stages during IntervPeriod
Prenatal	5083	Gutelius, MF	1977	28 wks Gest'l Age	prenatal - toddler
Prenatal	5135	Messimer, SR	1989	28 wks Gest'l Age	prenatal
Prenatal	5089	Herman, AA	1996	29 wks Gest'l Age	prenatal
Prenatal	5084	Hanks, C	1995	29 wks Gest'l Age	prenatal - infancy
Prenatal	5410	Larson, CP	1980	7 mos Gest'l Age	prenatal - infancy
Prenatal	5041	Dawson, P	1989	30 wks Gest'l Age	prenatal - infancy
Prenatal	5020	Blondel, B	1990	31 wks Gest'l Age	prenatal
Prenatal	5259	Windsor, RA	1993	32 wks Gest'l Age	prenatal
Prenatal	5190	Seitz, V	1985	3rd Trimester	prenatal - toddler
Parturition	5434	Kennell, J	1991	0 days	parturition
Parturition	5433	Hofmeyr, GJ	1991	0 days	parturition
Parturition	5431	Klaus, MH	1986	0 days	parturition
Infancy	5112	Leib, SA	1980	1 day	infancy
Infancy	5439	Fleisher, BE	1995	1 day	infancy
Infancy	5438	Becker, PT	1993	1 day	infancy
Infancy	5155	Peters, R	CONCURRENT	1 day	infancy - presch
Infancy	5223	Widmayer, S	1981	1 day	infancy
Infancy	5005	Achenbach, T	1990	1 day	infancy
Infancy	5006	Als, H	1994	1 day	infancy
Infancy	5174	Resnick, MB	1988	1 day	infancy
Infancy	5186	Scarr-Salapatek, S	1973	1 day	infancy
Infancy	5016	Beeghly, M	1995	2 days	infancy
Infancy	5007	Anisfeld, E	1990	2 days	infancy
Infancy	5414	Minde, K	1980	3 days	infancy
Infancy	5409	Hall, LA	1980	3 days	infancy
Infancy	5076	Gomes-Pedro, J	1995	3 days	infancy

TABLE 2C. STAGE OF LIFE WHEN INTERVENTION BEGAN, cont'd

Start of Intervention	Trial Number	Lead Author	Year Pub'd	Ave. Start of Intervention	All Stages during IntervPeriod
Infancy	5050	Dworkin, PH	1987	3 days	infancy
Infancy	5086	Hardy, JB	1989	7 days	infancy
Infancy	5418	Rauh, VA	1988	1 week	infancy
Infancy	5292	Beckwith, L	1988	1 week	infancy
Infancy	5128	Marcenko, MO	1994	1 week	infancy
Infancy	5098	Kang, R	1995	1 week	infancy
Infancy	5011	Barrera, ME	1986	1 week	infancy
Infancy	5192	Shapiro, C	1995	1 week	infancy
Infancy	5275	Moore, F	1974	10 days	infancy
Infancy	5254	Field, T	1977	2 wks	infancy
Infancy	5150	O'Sullivan, AL	1992	2 wks	infancy
Infancy	5240	Barnard, KE	1988	2 wks	infancy
Infancy	5008	Barkauskas, VH	1983	3 wks	infancy
Infancy	5063	Field, TM	1986	30 days	infancy
Infancy	5269	Johnson, Z	1993	1 month	infancy
Infancy	5268	Gray, JD	1979	1 month	infancy
Infancy	5245	Landy, S	1998	1 month	infancy - presch
Infancy	5062	Field, T	1980	1 month	infancy
Infancy	5243	Kronqvist, EL	1988	1 month	infancy - EarlySchAge
Infancy	5251	Field, T	1997	1 month	infancy
Infancy	5213	Wasik, BH	1990	1 month	infancy - presch
Infancy	5241	Barnard, KE	1987	5 wks	infancy
Infancy	5131	McCarton, CM	1997	7 wks	infancy - presch
Infancy	5250	Cooper, PJ	1997	8 wks	infancy
Infancy	5152	Parush, S	1997	8 wks	infancy
Infancy	5085	Hansen, K	1996	2 mos	infancy

TABLE 2C. STAGE OF LIFE WHEN INTERVENTION BEGAN, cont'd

Start of Intervention	Trial Number	Lead Author	Year Pub'd	Ave. Start of Intervention	All Stages during IntervPeriod
Infancy	5253	Field, T	1996	2 mos	infancy
Infancy	5030	Ramey, CT	1984	63 days	infancy
Infancy	5027	Burchinal, M	1989	9 wks	infancy
Infancy	5246	Holden, J	1989	12 wks	infancy
Infancy	5173	Ramey, CT	1979	3 mos	infancy
Infancy	5225	Zeskind, PS	1981	3 mos	infancy
Infancy	5288	Ramey, CT	1988	3 mos	infancy
Infancy	5061	Field, T	1982	3 mos	infancy
Infancy	5101	Kerr, SM	1996	3 mos	infancy
Infancy	5039	Cullen, KJ	1996	3 mos	infancy - presch
Infancy	5153	Pelaez Nogueras, M	1996	13.5 wks	infancy
Infancy	5184	Sankey, CG	1985	4 mos	infancy
Infancy	5247	Malphurs, J	1996	4.4 mos	infancy
Infancy	5120	Lyons, RK	1990	4.7 mos	infancy
Infancy	5208	van den Boom, DC	1994	6 mos	infancy
Infancy	5090	Honig, AS	1982	6 mos	infancy - presch
Infancy	5070	Gelfand, DM	1996	7.2 mos	infancy
Infancy	5171	Ramey, CT	1976	7.5 mos	infancy - presch
Infancy	5159	Piper, MC	1980	8.9 mos	infancy
Infancy	5065	Finney, JW	1990	10 mos	infancy - toddler
Infancy	5436	Webster-Stratton, C	1982	47 wks	presch
Infancy	5119	Lieberman, AF	1993	12 mos	infancy
Infancy	5117	Johnson, DL	1982	1 year	infancy - presch
Infancy	5018	Black, MM	1995	12.7 mos	infancy - toddler
Infancy	5079	Grantham-McGregor, S	1994	12.8 mos	infancy - toddler
Infancy	5248	Cramer, B	1990	15.6 mos	infancy - toddler

TABLE 2C. STAGE OF LIFE WHEN INTERVENTION BEGAN, cont'd

Start of Intervention	Trial Number	Lead Author	Year Pub'd	Ave. Start of Intervention	All Stages during IntervPeriod
Infancy	5161	Powell, C	1989	16 mos	infancy - presch
Infancy	5231	Ciccetti, D	CONCURRENT	18 mos	infancy
Infancy	5154	Seymour, FW	1989	18 mos	infancy - presch
Infancy	5044	Dihoff, RE	1994	1.5 yrs	infancy - toddler
Infancy	5178	Rickert, VI	1988	20 mos	infancy - toddler
Infancy	5256	Cohen, NJ	CONCURRENT	20 mos	infancy - presch
Infancy	5136	Minde, K	1994	20.6 mos	toddler
Infancy	5133	Moxley-Haegert, L	1983	21.5 mos	infancy - toddler
Infancy	5176	Richman, N	1985	22 mos	toddler - presch
Toddler	5224	Wolfe, DA	1988	24 mos	presch
Toddler	5066	Florida department of Education	1992	2 yrs	infancy - presch
Toddler	5207	Valdez-Menchaca, MC	1992	2 yrs	toddler
Toddler	5442	Powell, C	1989	24 mos	infancy - presch
Toddler	5113	Levenstein, P	1970	24 mos	toddler - presch
Toddler	5185	Scarr, S	1988	24 mos	toddler
Toddler	5057	Esdaile, SA	1996	27.7 mos	presch
Toddler	5037	Cronan, TA	1996	27.9 mos	presch
Toddler	5072	Girolametto, L	1994	28.5 mos	presch
Toddler	5401	Arnold, DS	1994	28.6 mos	presch
Toddler	5071	Girolametto, L	1996	28.7 mos	toddler
Toddler	5221	Whitehurst, GJ	1988	29.4 mos	presch
Toddler	5014	Bass, JL	1991	2.5 yrs	presch
Toddler	5126	Madden, J	1976	2.5 yrs	toddler - presch
Presch/Kinderg	5099	Karnes, MB	1987	3 yrs	presch
Presch/Kinderg	5122	Lovell, ML	1997	3 yrs	presch
Presch/Kinderg	5228	Arnold, JE	1975	3 yrs	presch

TABLE 2C. STAGE OF LIFE WHEN INTERVENTION BEGAN, cont'd

Start of Intervention	Trial Number	Lead Author	Year Pub'd	Ave. Start of Intervention	All Stages during IntervPeriod
Presch/Kinderg	5127	Madden, J	1984	3 yrs	toddler - presch
Presch/Kinderg	5067	Forgatch, M	1979	3.2 yrs	presch
Presch/Kinderg	5009	Barnett, WS	1993	42 mos	presch
Presch/Kinderg	5188	Schweinhart, LJ	1986	3.5 yrs	presch
Presch/Kinderg	5175	Reynolds, AJ	1995	3.5 yrs	presch
Presch/Kinderg	5406	Donachy, W	1976	3.7 yrs	presch
Presch/Kinderg	5075	Bradley, SJ	CONCURRENT	3.7 yrs	presch
Presch/Kinderg	5234	Strayhorn, JM	1989	3.75 yrs	presch
Presch/Kinderg	5220	Whitehurst, GJ	1994	4 yrs	presch
Presch/Kinderg	5077	Gotts, EE	1987	4 yrs	presch
Presch/Kinderg	5232	Kagitcibasi, C	1995	4 yrs	presch
Presch/Kinderg	5097	Jordan, TJ	1985	4 yrs	presch
Presch/Kinderg	5177	Rickel, AU	1981	4 yrs	presch
Presch/Kinderg	5193	Sheeber, LB	1994	4 yrs	presch
Presch/Kinderg	5134	Neuman, SB	1996	50.7 mos	presch
Presch/Kinderg	5195	Shure, MD	1982	51 mos	presch - kinderg
Presch/Kinderg	5164	Radin, N	1972	53 mos	presch
Presch/Kinderg	5040	Cunningham, CE	1995	53.5 mos	presch
Presch/Kinderg	5189	Seifert, H	1991	4.5 yrs	presch
Presch/Kinderg	5111	Lee, VE	1991	4.5 yrs	presch
Presch/Kinderg	5226	Zucker, RA	1990	4.5 yrs	presch
Presch/Kinderg	5264	Webster-Stratton, C	1988	4.5 yrs	presch
Presch/Kinderg	5058	Eyberg, SM	1995	4.5 yrs	presch
Presch/Kinderg	5440	Webster-Stratton, C	1996	56.5 mos	presch
Presch/Kinderg	5260	Webster-Stratton, C	1984	4.8 yrs	Presch/EarlySchAge
Presch/Kinderg	5263	Webster-Stratton, C	1994	58.7 mos	Presch/EarlySchAge

TABLE 2C. STAGE OF LIFE WHEN INTERVENTION BEGAN, cont'd

Start of Intervention	Trial Number	Lead Author	Year Pub'd	Ave. Start of Intervention	All Stages during IntervPeriod
Presch/Kinderg	5035	Connor-Kuntz, FJ	1996	5 yrs	presch
Presch/Kinderg	5043	Dickens, WJ	1988	5 yrs	presch - kinderg
Presch/Kinderg	5261	Webster-Stratton, C	1990	5.1 yrs	Presch/EarlySchAge
Presch/Kinderg	5028	Burkett, CW	1982	5.2 yrs	presch
Presch/Kinderg	5435	Webster-Stratton, C	1997	68.9 mos	EarlySchAge
EarlySchAge	5446	Boyle, MH	CONCURRENT	6 yrs	EarlySchAge
EarlySchAge	5125	Walsh, CA	CONCURRENT	6 yrs	Presch/EarlySchAge
EarlySchAge	5255	Tremblay, RE	1991	7 yrs	kinderg
Not avail	5244	Ross, S	CONCURRENT	Not avail	Not avail
Not avail	5021	Bloom, B	1991	Not avail	Not avail

TABLE 3A. INTERVENTION TYPE USING GORDON/10M CLASSIFICATION

Intervention Type	Number
Universal	27
Selective	104
Indicated	25
Treatment	8
Not Applicable	1
Total	**165**

TABLE 3B. CANADIAN TRIALS INTERVENTION TYPE USING GORDON/10M CLASSIFICATION

Intervention Type	Number
Universal	3
Selective	6
Indicated	7
Treatment	5
Total	**21**

TABLE 4. TRIAL THREAT TO INTEGRITY SCORE (TTIS) FOR ALL TRIALS

Trial Number	Lead Author	Year Published	TTIS
5005	Achenbach, T	1990	***
5006	Als, H	1994	***
5007	Anisfeld, E	1990	****
5008	Barkauskas, VH	1983	*
5009	Barnett, WS	1993	***
5011	Barrera, ME	1986	*
5014	Bass, JL	1991	*
5016	Beeghly, M	1995	****
5018	Black, MM	1995	****
5020	Blondel, B	1990	****
5023	Booth, CL	1989	****
5026	Bryce, RL	1991	****
5027	Burchinal, M	1989	****
5028	Burkett, CW	1982	*
5030	Ramey, CT	1984	*****
5035	Connor-Kuntz, FJ	1996	*
5036	Connor-Kuntz, FJ	1996	****
5037	Cronan, TA	1996	***
5039	Cullen, KJ	1996	****
5040	Cunningham, CE	1995	****
5041	Dawson, P	1989	**
5043	Dickens, WJ	1988	*
5044	Dihoff, RE	1994	*
5049	Dunkley, J	1997	*
5050	Dworkin, PH	1987	*
5054	Ershoff, DH	1995	*****
5056	Ershoff, DH	1983	*
5057	Esdaile, SA	1996	*
5058	Eyberg, SM	1995	*
5061	Field, T	1982	***
5062	Field, T	1980	***
5063	Field, TM	1986	***
5065	Finney, JW	1990	**
5067	Forgatch, M	1979	*
5069	Fox, NL	1987	*
5070	Gelfand, DM	1996	**
5071	Girolametto, L	1996	***
5072	Girolametto, L	1994	**
5076	Gomes-Pedro, J	1995	**
5077	Gotts, EE	1987	**
5079	Grantham-McGregor, S	1994	**
5083	Gutelius, MF	1977	*
5085	Hansen, K	1996	*
5086	Hardy, JB	1989	**
5088	Heins, HC	1990	****
5089	Herman, AA	1996	***
5090	Honig, AS	1982	*
5091	Horacek, HJ	1987	**
5096	Jones, ME	1994	*

TABLE 4. TRIAL THREAT TO INTEGRITY SCORE (TTIS) FOR ALL TRIALS, cont'd

Trial Number	Lead Author	Year Published	TTIS
5097	Jordan, TJ	1985	*
5098	Kang, R	1995	***
5099	Karnes, MB	1987	**
5101	Kerr, SM	1996	*
5103	Kitzmann, H	1997	****
5111	Lee, VE	1991	*
5112	Leib, SA	1980	***
5113	Levenstein, P	1970	*
5117	Johnson, DL	1982	****
5119	Lieberman, AF	1993	*
5120	Lyons, RK	1990	***
5122	Lovell, ML	1997	*
5126	Madden, J	1976	**
5127	Madden, J	1984	***
5128	Marcenko, MO	1994	***
5130	McDuffie, RS	1996	*****
5131	McCarton, CM	1997	*****
5133	Moxley-Haegert, L	1983	*
5135	Messimer, SR	1989	*
5136	Minde, K	1994	*
5139	Munjanja, SP	1996	****
5143	Olds, DL	1986	*****
5150	O'Sullivan, AL	1992	****
5152	Parush, S	1997	*
5153	Pelaez Nogueras, M	1996	**
5154	Seymour, FW	1989	*
5159	Piper, MC	1980	*
5160	Poland, MC	1992	**
5161	Powell, C	1989	***
5164	Radin, N	1972	*
5171	Ramey, CT	1976	*
5173	Ramey, CT	1979	*
5174	Resnick, MB	1988	***
5175	Reynolds, AJ	1995	**
5176	Richman, N	1985	*
5177	Rickel, AU	1981	***
5178	Rickert, VI	1988	*
5181	Rogers, MM	1996	*
5184	Sankey, CG	1985	*
5185	Scarr, S	1988	****
5186	Scarr-Salapatek, S	1973	**
5188	Schweinhart, LJ	1986	****
5189	Seifert, H	1991	*****
5190	Seitz, V	1985	**
5192	Shapiro, C	1995	*
5193	Sheeber, LB	1994	*
5195	Shure, MD	1982	***
5207	Valdez-Menchaca, MC	1992	*
5208	van den Boom, DC	1994	***
5210	Villar, J	1992	*****

TABLE 4. TRIAL THREAT TO INTEGRITY SCORE (TTIS) FOR ALL TRIALS, cont'd

Trial Number	Lead Author	Year Published	TTIS
5213	Wasik, BH	1990	***
5220	Whitehurst, GJ	1994	*****
5221	Whitehurst, GJ	1988	**
5223	Widmayer, S	1981	*
5224	Wolfe, DA	1988	**
5225	Zeskind, PS	1981	**
5226	Zucker, RA	1990	*
5228	Arnold, JE	1975	****
5232	Kagitcibasi, C	1995	*
5234	Strayhorn, JM	1989	****
5242	Barnard, KE	1988	***
5243	Kronqvist, EL	1988	*
5246	Holden, J	1989	***
5247	Malphurs, J	1996	*
5248	Cramer, B	1990	***
5250	Cooper, PJ	1997	***
5251	Field, T	1997	**
5253	Field, T	1996	**
5255	Tremblay, RE	1991	****
5256	Cohen, NJ	CONCURRENT	***
5259	Windsor, RA	1993	*****
5260	Webster-Stratton, C	1984	***
5261	Webster-Stratton, C	1990	***
5263	Webster-Stratton, C	1994	***
5264	Webster-Stratton, C	1988	***
5267	Barth, RP	1991	***
5268	Gray, JD	1979	*
5269	Johnson, Z	1993	***
5275	Moore, F	1974	****
5288	Ramey, CT	1988	****
5292	Beckwith, L	1988	**
5296			**
5297			*
5401	Arnold, DS	1994	**
5406	Donachy, W	1976	*
5409	Hall, LA	1980	*
5410	Larson, CP	1980	***
5411	Lowe, ML	1970	**
5412	Main, DM	1985	***
5414	Minde, K	1980	***
5415	Oakley, A	1990	*****
5417	Petersen, L	1992	*
5431	Klaus, MH	1986	****
5433	Hofmeyr, GJ	1991	***
5434	Kennell, J	1991	*****
5435	Webster-Stratton, C	1997	***
5436	Webster-Stratton, C	1982	**
5438	Becker, PT	1993	***
5439	Fleisher, BE	1995	**
5440	Webster-Stratton, C	1996	***
5442	Powell, C	1989	**

TABLE 5. NUMBER OF SIGNIFICANT BENEFICIAL, SIGNIFICANT HARMFUL, AND NON-SIGNIFICANT EFFECTS FOUND IN EACH TARGETED OUTCOME CATEGORY AMONG THE 32 BEST DESIGNED TRIALS

Outcomes	Pregnancy/ Pregnancy Outcomes	Parenting/ Parent Child Relationships	Safety or Injuries	Child Maltreatment	Phys'l Health/ Growth/ Health Care
Benefit	39	23	18	4	4
NS	175	46	18	31	38
Harm	3	2	2	1	3
Total	217	72	38	36	45

Outcomes	Motor Development	Cognitive	Speech or Language	Temperament/ Behavior/ Symptoms	Social Relations
Benefit	1	77	2	54	2
NS	10	54	14	115	11
Harm	0	0	0	13	0
Total	11	131	16	182	13

Outcomes	Legal Offences	School Performance	Government Costs	Mother's Social Support	Mother's Stress
Benefit	8	20	3	7	0
NS	18	33	3	13	2
Harm	1	4	0	0	0
Total	27	57	6	20	2

Outcomes	Mother's Mental Health	Mother's Education	Mother's Employment	Mother's Public Assistance	Mother's Physical Health
Benefit	2	0	4	2	10
NS	14	11	18	17	16
Harm	0	0	1	1	1
Total	16	11	23	20	27

Outcomes	Total
Benefit	280
NS	657
Harm	3
Total	969

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5030	Ramey, CT	Cognitive	*BENEFICIAL*	McCarthy GC Memory Scale Index		54 months	<0.01	0.51	
5030		Cognitive	*BENEFICIAL*	McCarthy GC Quantitative Scale Index		54 months	<0.01	0.57	
5030		Cognitive	*BENEFICIAL*	McCarthy GC Perceptual Performance Scale Index		54 months	<0.01	0.65	
5030		Cognitive	*BENEFICIAL*	McCarthy GC Verbal Scale Index		54 months	<0.01	0.68	
5030		Cognitive	*BENEFICIAL*	McCarthy General Cognitive Index		54 months	<0.001	0.73	
5030		Cognitive	*BENEFICIAL*	Standford-Binet IQ		48 months	<0.001	0.93	
5030		Cognitive	*BENEFICIAL*	McCarthy General Cognitive Quantitative		42 months	<0.01	0.71	
5030		Cognitive	*BENEFICIAL*	McCarthy General Cognitive Perceptual Performances		42 months	<0.01	0.64	
5030		Cognitive	*BENEFICIAL*	McCarthy General Cognitive Verbal Scale Index		42 months	<0.001	0.69	
5030		Cognitive	*BENEFICIAL*	McCarthy General Cognitive Index		42 months	<0.001	0.79	
5030		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		36 months	<0.001	1.22	
5030		Cognitive	*BENEFICIAL*	McCarthy Verbal Scale Index		30 months	<0.001	0.82	
5030		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		24 months	<0.001	1.22	
5030		Cognitive	*BENEFICIAL*	Bayley Mental Development Index		18 months	<0.001	1.45	
5030		Cognitive	*BENEFICIAL*	Bayley Mental Development Index		6 months	<0.004	0.65	
5030		Cognitive	*BENEFICIAL*	Bayley Mental Development Index		12 months	0.0004	0.64	
5030	Ramey, CT	Cognitive	*BENEFICIAL*	Bayley Mental Development Index		18 months	<0.0001	1.68	
5030		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		24 months	0.0002	0.83	
5030		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		36 months	<0.0001	1.49	
5030		Cognitive	*BENEFICIAL*	McCarthy Scales of Children's Ability		42 months	<0.0001	0.91	
5030		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		48 months	<0.0001	1.08	
5030		Cognitive	*BENEFICIAL*	McCarthy Scales of Children's Ability		54 months	0.0004	0.79	
5030		Cognitive	*BENEFICIAL*	Mentally Retarded (IQ < 70)		18 months	0.02		-2.2

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5030		Cognitive	*BENEFICIAL*	Mentally Retarded (IQ < 70)		36 months	0.02		-2.61
5030		Cognitive	*BENEFICIAL*	Borderline Intellectual Functioning (70 < IQ < 85)		24 months	<0.0001		-2.67
5030		Cognitive	*BENEFICIAL*	Borderline Intellectual Functioning (70 < IQ < 85)		36 months	0.0002		-2.47
5030		Cognitive	*BENEFICIAL*	Borderline Intellectual Functioning (70 < IQ < 85)		42 months	0.02		-1.72
5030		Cognitive	*BENEFICIAL*	Borderline Intellectual Functioning (70 < IQ < 85)		18 months	0.02		-2.56
5030		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		18 months	<0.001	1.39	
5030		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		24 months	<0.001	1.13	
5030		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		36 months	<0.001	1.26	
5030		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		48 months	<0.001	1.06	
5030		Cognitive	*BENEFICIAL*	Wechsler Intelligence Scale for Children-Revised Verbal		12 years	0.006	0.59	
5030	Ramey, CT	Cognitive	*BENEFICIAL*	Wechsler Intelligence Scale for Children-Revised Full Scale		12 years	0.02	0.5	
5030		Cognitive	beneficial	McCarthy General Cognitive Memory Scale Index		42 months	>0.05	0.3	
5030		Cognitive	beneficial	Bayley Mental Development Index		12 months	>0.05	0.39	
5030		Cognitive	beneficial	Bayley Mental Development Index		6 months	>0.05	0.39	
5030		Cognitive	beneficial	Mentally Retarded (IQ < 70)		6 months	0.34		-1.03
5030		Cognitive	beneficial	Mentally Retarded (IQ < 70)		12 months	0.34		-1.03
5030		Cognitive	beneficial	Mentally Retarded (IQ < 70)		42 months	0.17		-1.56
5030		Cognitive	beneficial	Mentally Retarded (IQ < 70)		48 months	0.06		-1.82
5030		Cognitive	beneficial	Mentally Retarded (IQ < 70)		54 months	0.2		-1.36
5030		Cognitive	beneficial	Borderline Intellectual Functioning (70 < IQ < 85)		54 months	0.56		-0.64
5030		Cognitive	beneficial	Borderline Intellectual Functioning (70 < IQ < 85)		48 months	0.06		-1.82
5030		Cognitive	beneficial	Borderline Intellectual Functioning (70 < IQ < 85)		12 months	0.09		-1.92
5030		Cognitive	beneficial	Borderline Intellectual Functioning (70 < IQ < 85)		6 months	0.17		-1.56
5030		Cognitive	beneficial	Stanford-Binet IQ		6 months	0.162	0.3	
5030	Ramey, CT	Cognitive	beneficial	Stanford-Binet IQ		12 months	0.059	0.41	
5030		Cognitive	beneficial	Wechsler Intelligence Scale for Children Revised Performance		12 years	0.215	0.26	
5030		Cognitive	equal	Mentally Retarded (IQ < 70)		24 months	>0.50		0.09

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5030	Ramey, CT	Motor Development	beneficial	McCarthy GC Motor Scale Index		54 months	>0.05	0.34	
5030		Motor Development	beneficial	McCarthy General Cognitive Motor Scale Index		42 months	>0.05	0.37	
5030		Motor Development	beneficial	Bayley Psychomotor Development Index		18 months	>0.05	0.03	
5030		Motor Development	beneficial	Bayley Psychomotor Development Index		12 months	>0.05	0.38	
5030		Motor Development	beneficial	Bayley Psychomotor Development Index		6 months	>0.05	0.28	
5030	Ramey, CT	Parenting/Parent Child Relationship	beneficial	Home Observation for Measurement of the Environment Inventory		6 months	0.46	0.16	
5030		Parenting/Parent Child Relationship	beneficial	Home Observation for Measurement of the Environment Inventory		18 months	0.24	0.255	
5030		Parenting/Parent Child Relationship	beneficial	Home Observation for Measurement of the Environment Inventory		42 months	0.85	0.04	
5030		Parenting/Parent Child Relationship	harmful	Home Observation for Measurement of the Environment Inventory		30 months	>0.05	-0.028	
5030	Ramey, CT	School Performance	*BENEFICIAL*	Woodcock-Johnson Psychoeducational Battery II Reading		12 years	0.04	0.43	
5030	Ramey, CT	School Performance	*BENEFICIAL*	Woodcock-Johnson Psychoeducational Battery II Knowledge		12 years	0.004	0.62	
5030		School Performance	beneficial	Woodcock-Johnson Psychoeducational Battery II Mathematics		12 years	0.07	0.39	
5030		School Performance	beneficial	Woodcock-Johnson Psychoeducational Battery II Written Language		12 years	0.065	0.39	
5054	Ershoff, DH	Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Non-Quitter of Cigarettes		0 days	0.04		-0.66
5054		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Early Quitter (<20 weeks gestational age)		20 weeks Gestational Age	<0.05		1.03
5054		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Intrauterine Growth Retardation		0 days	<0.05		-1.52
5054		Pregnancy/Pregnancy Outcome	beneficial	Birth Weight		0 days	>0.05	NA	
5054		Pregnancy/Pregnancy Outcome	beneficial	Preterm Delivery		0 days	>0.05		-0.08
5054		Pregnancy/Pregnancy Outcome	beneficial	Low Birth Weight		0 days	>0.05		-0.66

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5054		Pregnancy/Pregnancy Outcome	harmful	Biochemically Confirmed Maintenance of Smoking		36 weeks Gestational Age	0.49		0.28
5130	McDuffie, RS	Mother's Physical Health	beneficial	Multiple Gestation		0 days	0.67		-0.19
5130	McDuffie, RS	Mother's Social Support	harmful	Appropriate Amount of Written Educational Material		0 days	0.41		-0.12
5130	McDuffie, RS	Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Appropriate Number of Prenatal Visits		0 days	0.026		0.33
5130	McDuffie, RS	Pregnancy/Pregnancy Outcome	beneficial	Mild Preeclampsia		0 days	0.51		-0.12
5130		Pregnancy/Pregnancy Outcome	beneficial	Cesarean Delivery Fetal Distress		0 days	0.66		-0.13
5130		Pregnancy/Pregnancy Outcome	beneficial	Preterm Premature Rupture of Membranes (PROM)		0 days	0.99		-0.002
5130		Pregnancy/Pregnancy Outcome	beneficial	Gestational Diabetes		0 days	0.99		-0.002
5130		Pregnancy/Pregnancy Outcome	beneficial	Chorioamnionitis		0 days	0.68		-0.2
5130		Pregnancy/Pregnancy Outcome	beneficial	Placenta Previa		0 days	0.7		-0.26
5130		Pregnancy/Pregnancy Outcome	beneficial	Postpartum Hemorrhage (Vaginal Delivery)		0 days	0.89		-0.033
5130		Pregnancy/Pregnancy Outcome	beneficial	Cesarean Delivery		0 days	0.65		-0.41
5130		Pregnancy/Pregnancy Outcome	beneficial	Low Birth Weight		0 days	0.48		-0.12
5130		Pregnancy/Pregnancy Outcome	beneficial	Apgar Score <7 at 5 minutes		0 days	0.11		-0.49
5130		Pregnancy/Pregnancy Outcome	beneficial	Satisfied with Quality of Educational Materials		0 days	0.95		0.01
5130		Pregnancy/Pregnancy Outcome	equal	Stillbirth		0 days	0.99		0
5130		Pregnancy/Pregnancy Outcome	equal	Gestational Age		0 days	>0.50	0	
5130		Pregnancy/Pregnancy Outcome	harmful	Preterm Delivery		0 days	0.38		0.16
5130		Pregnancy/Pregnancy Outcome	harmful	Delivery < 32 Weeks		0 days	0.63		0.22
5130		Pregnancy/Pregnancy Outcome	harmful	Severe Preeclampsia		0 days	0.82		0.1
5130	McDuffie, RS	Pregnancy/Pregnancy Outcome	harmful	Cesarean Delivery		0 days	>0.05		0.08
5130		Pregnancy/Pregnancy Outcome	harmful	Preterm Labor		0 days	0.88		0.08
5130		Pregnancy/Pregnancy Outcome	harmful	Abruptio Placentae		0 days	0.13		0.44
5130		Pregnancy/Pregnancy Outcome	harmful	Very Low Birth Weight		0 days	0.78		0.16
5130		Pregnancy/Pregnancy Outcome	harmful	Small for Gestational Age		0 days	0.31		0.25
5130		Pregnancy/Pregnancy Outcome	harmful	Birth Weight		0 days	>0.05	-0.01	
5130		Pregnancy/Pregnancy Outcome	harmful	Quality of Prenatal Care Good or Excellent		0 days	0.67		-0.16
5130		Pregnancy/Pregnancy Outcome	harmful	Satisfied with Quality of Prenatal Educational Materials		0 days	0.29		-0.21
5131	Infant Health and Development	Cognitive	*BENEFICIAL*	Peabody Picture Vocabulary Test Revised	Birth weight 2-2.5 kgms	8 years	0.001	0.39	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5131		Cognitive	*BENEFICIAL*	Wechsler Intelligence Scale for Children III Full-Scale IQ	Birth weight 2-2.5 kgms	8 years	0.007	0.32	
5131		Cognitive	*BENEFICIAL*	Wechsler Intelligence Scale for Children III Performance IQ	Birth weight 2-2.5 kgms	8 years	0.02	0.27	
5131		Cognitive	*BENEFICIAL*	Wechsler Intelligence Scale for Children III Verbal IQ	Birth weight 2-2.5 kgms	8 years	0.01	0.3	
5131		Cognitive	*BENEFICIAL*	Stanford-Binet IQ form LM 3rd Ed	Failure to thrive	36 months	0.005	1.79	
5131		Cognitive	*BENEFICIAL*	Stanford-Binet IQ form LM 3rd Ed		36 months	<0.01	0.59	
5131	Infant Health and Development	Cognitive	*BENEFICIAL*	Stanford-Binet IQ form LM 3rd Ed	<2 kgms birth weight	36 months	<0.001	0.33	
5131		Cognitive	*BENEFICIAL*	Stanford-Binet IQ form LM 3rd Ed	2-2.5 kgms birth weight	36 months	<0.001	0.7	
5131		Cognitive	beneficial	Peabody Picture Vocabulary Test Revised		8 years	0.96	0.01	
5131		Cognitive	beneficial	Wechsler Intelligence Scale for Children III Full-Scale IQ		8 years	0.77	0.02	
5131		Cognitive	beneficial	Wechsler Intelligent Scale for Chilldren III Verbal IQ		8 years	0.36	0.06	
5131		Cognitive	equal	Wechsler Intelligence Scale for Children III Verbal IQ	Birth weight < 2 kgms	8 years	>0.50	0	
5131		Cognitive	harmful	Peabody Picture Vocabulary Test Revised	Birth weight < 2 kgms	8 years	0.1	-0.14	
5131		Cognitive	harmful	Wechsler Intelligence Scale for Children III Full-Scale IQ	Birth weight < 2 kgms	8 years	0.39	-0.07	
5131		Cognitive	harmful	Wechsler Intelligence Scale for Children III Performance IQ	Birth weight < 2 kgms	8 years	0.12	-0.14	
5131		Cognitive	harmful	Wechsler Intelligence Scale for Children III Performance IQ		8 years	0.75	-0.02	
5131	Infant Health and Development	Mother's Education	beneficial	Maternal Education	High School or less, Hispanic	36 months	>0.05	0.52	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5131		Mother's Education	beneficial	Maternal Education	High School or less, Black	36 months	>0.05	0.15	
5131		Mother's Education	beneficial	Maternal Education		36 months	>0.05	0.5	
5131	Infant Health	Mother's Education	beneficial	Maternal Education		36 months	>0.05	0.12	
5131		Mother's Education	harmful	Maternal Education	High school or less, White	36 months	>0.05	-0.1	
5131		Mother's Education	harmful	Maternal Education	College education, White	36 months	>.05	-0.22	
5131	Infant Health and Development	Mother's Employment	*BENEFICIAL*	Maternal Employment	High school edcation or less, white	36 months	<0.05	0.31	
5131		Mother's Employment	*BENEFICIAL*	Maternal Employment	High school education or less, Black	36 months	<0.05	0.16	
5131		Mother's Employment	*BENEFICIAL*	Maternal Employment		36 months	<0.05	0.08	
5131		Mother's Employment	beneficial	Maternal Employment	College education, White	36 months	>0.05	0.04	
5131		Mother's Employment	harmful	Maternal Employment	High school or less, Hispanic	36 months	>0.05	-0.17	
5131		Mother's Employment	harmful	Maternal Employment	College educated, Black	36 months	>0.05	-0.12	
5131	Infant Health and Development	Mother's Public Assistance	beneficial	Maternal Public Assistance	High school or less, White	36 months	>0.05	-0.08	
5131		Mother's Public Assistance	beneficial	Maternal Public Assistance	College education, Black	36 months	<0.10	0.59	
5131		Mother's Public Assistance	harmful	Maternal Public Assistance	High school education or less, Hispanic	36 months	>0.05	0.14	
5131		Mother's Public Assistance	harmful	Maternal Public Assistance	High school or less, Black	36 months	>0.05	0.02	
5131		Mother's Public Assistance	harmful	Maternal Public Assistance		36 months	>0.05	0.12	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5131		Mother's Public Assistance	*HARMFUL*	Maternal Public Assistance	College education, White	36 months	<0.05	1.88	
5131	Infant Health and Development	Parenting/Parent Child Relatio	*BENEFICIAL*	Home Observation for Measurement of the Environment Inventory	Failure to thrive	36 months	0.03	0.35	
5131	Infant Health and Development	Physical Health/ Growth/ Health	*BENEFICIAL*	Body Mass Index	Failure to thrive	36 months	0.01	0.4	
5131		Physical Health/ Growth/ Health	beneficial	Child General Health Survey Number of Maternal Responses	Birth weight 2-2.5 kgms	8 years	0.53	-0.07	
5131		Physical Health/ Growth/ Health	beneficial	General Health Mean Score		8 years	0.9	0.01	
5131		Physical Health/ Growth/ Health	beneficial	General Health Mean Score	Birth weight < 2 kgms	8 years	0.75	0.03	
5131		Physical Health/ Growth/ Health	beneficial	Bodily Pain Scale		8 years	0.75	-0.02	
5131		Physical Health/ Growth/ Health	beneficial	Bodily Pain Scale	Birth weight 2-2.5 kgms	10 years	0.58	-0.06	
5131		Physical Health/ Growth/ Health	beneficial	General Health Perceptions		8 years	0.5	0.05	
5131		Physical Health/ Growth/ Health	beneficial	General Health Perceptions	Birth weight < 2 kgms	8 years	0.78	0.02	
5131		Physical Health/ Growth/ Health	beneficial	General Health Perceptions	Birth weight 2-2.5 kgms	8 years	0.31	0.12	
5131		Physical Health/ Growth/ Health	beneficial	Body Length	Failure to thrive	36 months	>0.05	-0.12	
5131		Physical Health/ Growth/ Health	beneficial	Weight	Failure to thrive	36 months	0.27	0.18	
5131	Infant Health and Development	Physical Health/ Growth/ Health	beneficial	General Health Rating Index	Failure to thrive	36 months	0.46	0.12	
5131		Physical Health/ Growth/ Health	beneficial		Failure to thrive	36 months	0.54		-0.11
5131		Physical Health/ Growth/ Health	beneficial	General Health Rating Index		36 months	>0.05	0.08	
5131		Physical Health/ Growth/ Health	beneficial	Body Mass Index	<2 kgms birth weight	36 months	>0.05	0.08	
5131		Physical Health/ Growth/ Health	beneficial	Body Mass Index	2-2.5 kgms birth weight	36 months	>0.05	0.16	
5131		Physical Health/ Growth/ Health	beneficial	Body Length		36 months	>0.05	0.08	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5131		Physical Health/ Growth/ Health	beneficial	Functional Status II R Scale		36 months	>0.05	0.13	
5131		Physical Health/ Growth/ Health	beneficial	Mother's Report Serious Morbidity Index		36 months	>0.05	-0.03	
5131		Physical Health/ Growth/ Health	equal	Bodily Pain Scale	Birth weight < 2 kgms	8 years	>0.50	0	
5131		Physical Health/ Growth/ Health	harmful	Child General Health Survey Number of Maternal Responses		8 years	0.87	0.01	
5131		Physical Health/ Growth/ Health	harmful	Child General Health Survey Number of Maternal Responses	Birth weight < 2 kgms	8 years	0.52	0.06	
5131	Infant Health and Development	Physical Health/ Growth/ Health	harmful	General Health Mean Score	Birth weight 2-2.5 kgms	8 years	0.79	-0.03	
5131		Physical Health/ Growth/ Health	harmful	Physical Functioning Scale	Birth weight < 2 kgms	8 years	0.7	-0.03	
5131		Physical Health/ Growth/ Health	harmful	Physical Functioning Scale	Birth weight 2-2.5 kgms	8 years	0.2	-0.15	
5131		Physical Health/ Growth/ Health	harmful	Mother's Report Morbidity Index	2-2.5 kgms birth weight	36 months	>0.05	0.16	
5131		Physical Health/ Growth/ Health	*HARMFUL*	Physical Functioning Scale		8 years	0.03	-0.15	
5131		Physical Health/ Growth/ Health	*HARMFUL*	Mother's Report Morbidity Index		36 months	<0.001	0.27	
5131		Physical Health/ Growth/ Health	*HARMFUL*	Mother's Report Morbidity Index	<2 kgms birth weight	36 months	<0.01	0.27	
5131	Infant Health and Development	School Performance	beneficial	Needs Special Education	Birth weight 2-2.5 kgms	8 years	0.09		-0.54
5131		School Performance	beneficial	Needs Special Education	Birth weight < 2 kgms	8 years	0.93		-0.02
5131		School Performance	beneficial	Needs Special Education		8 years	0.33		-0.18
5131		School Performance	beneficial	Repeated Grade		8 years	0.72		-0.06
5131		School Performance	beneficial	Repeated Grade	Birth weight < 2 kgms	8 years	0.56		-0.13
5131		School Performance	beneficial	Woodcock-Johnson Tests of Achievement Revised Broad Reading		8 years	0.24	0.08	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5131	Infant Health and Development	School Performance	harmful	Repeated Grade	Birth weight 2-2.5 kgms	8 years	0.86		0.07
5131	Infant Health and Development	Social Relations	*BENEFICIAL*	Role/Social Limitations Scale Due to Behavior	Birth weight < 2 kgms	8 years	0.02	-0.2	
5131		Social Relations	beneficial	Role/Social Limitations Scale Due to Behavior		8 years	0.14	-0.1	
5131		Social Relations	beneficial	Role/Social Limitations Scale Due to Emotional Problems		8 years	0.62	-0.03	
5131		Social Relations	beneficial	Role/Social Limitations Scale Due to Emotional Problems	Birth weight < 2 kgms	8 years	0.32	-0.09	
5131		Social Relations	beneficial	Role/Social Limitations Scale Due to Physical Health		8 years	0.9	-0.01	
5131		Social Relations	beneficial	Role/Social Limitations Scale Due to Physical Health	Birth weight < 2 kgms	8 years	0.16	-0.12	
5131		Social Relations	beneficial	Role/Social Limitations Scale Due to Physical Health	Birth weight 2-2.5 kgms	8 years	0.4	-0.1	
5131		Social Relations	harmful	Role/Social Limitations Scale Due to Behavior	Birth weight 2-2.5 kgms	8 years	0.46	0.09	
5131		Social Relations	harmful	Role/Social Limitations Scale Due to Emotional Problems	Birth weight 2-2.5 kgms	8 years	0.7	0.004	
5131	Infant Health and Development	Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Child Behavior Checklist for Ages 2-3 years		36 months	0.003	-0.2	
5131		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Child Behavior Checklist for Ages 2-3 years		36 months	0.006	-0.18	
5131		Temperament/ Behavior/ Symptoms	beneficial	Behavior Problems Scale	Birth weight < 2 kgms	8 years	0.32	-0.09	
5131	Infant Health and Development	Temperament/ Behavior/ Symptoms	beneficial	Mental Health Scale	Birth weight 2-2.5 kgms	8 years	0.95	-0.01	
5131		Temperament/ Behavior/ Symptoms	beneficial	Self-Esteem Scale	Birth weight 2-2.5 kgms	8 years	0.64	0.05	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5131		Temperament/ Behavior/ Symptoms	beneficial	Child Behavior Checklist	Failure to thrive	36 months	>0.05	-0.09	
5131		Temperament/ Behavior/ Symptoms	equal	Self-Esteem Scale		8 years	>0.5	0	
5131		Temperament/ Behavior/ Symptoms	harmful	Behavior Problems Scale		8 years	0.9	0.01	
5131		Temperament/ Behavior/ Symptoms	harmful	Behavior Problems Scale	Birth weight 2-2.5 kgms	8 years	0.12	0.18	
5131		Temperament/ Behavior/ Symptoms	harmful	Mental Health Scale		8 years	0.87	0.01	
5131		Temperament/ Behavior/ Symptoms	harmful	Mental Health Scale	Birth weight < 2 kgms	8 years	0.91	0.01	
5131		Temperament/ Behavior/ Symptoms	harmful	Self-Esteem Scale	Birth weight < 2 kgms	8 years	0.66	-0.04	
5143	Olds, DL	Child Maltreatment	*BENEFICIAL*	Substantiated Reports of Child Abuse and Neglect		15 years	<0.01	-0.46	
5143		Child Maltreatment	*BENEFICIAL*	Substantiated Reports of Child Abuse and Neglect	Low SES unmarried	15 years	<0.01	-0.89	
5143		Child Maltreatment	*BENEFICIAL*	Avoidance of Restriction and Punishment	Poor unmarried teens	10 months	0.009	0.85	
5143		Child Maltreatment	beneficial	Multiple Neglect Notations in CPS Record	Nonminority, maltreated by 4 years old	4 years	0.83		-0.16
5143		Child Maltreatment	beneficial	Number of Neglect Notations in CPS Record	Nonminority, maltreated by 4 years old	4 years	0.33	-0.33	
5143		Child Maltreatment	beneficial	Multiple Maltreatment Reports in CPS Record	Nonminority, maltreated by 4 years old	4 years	0.46		-0.53
5143	Olds, DL	Child Maltreatment	beneficial	Number of Scheduled Health Supervision Visits with Problems/Sick Visits		50 months	0.16	-0.49	
5143		Child Maltreatment	beneficial	Number of Scheduled Health Supervision Visits 25-50 months	Nonminority, maltreated by 4 years old	50 months	0.29	-0.37	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143		Child Maltreatment	beneficial	Avoidance of Punishment	Nonminority, maltreated by 4 years old	34 months	0.25	0.43	
5143		Child Maltreatment	beneficial	Avoidance of Punishment	Nonminority, maltreated by 4 years old	46 months	0.76	-0.11	
5143		Child Maltreatment	beneficial	Total Length of Time Case Open	Nonminority, maltreated by 4 years old	4 years	0.05	-0.22	
5143		Child Maltreatment	beneficial	Avoidance of Restriction and Punishment	Poor unmarried teens	22 months	0.05	0.68	
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Non Risk	2 years	>0.05		-0.32
5143		Child Maltreatment	beneficial	Child Abuse or Neglect		2 years	>0.05		-0.14
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Married	2 years	>0.05		-0.18
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Poor	2 years	>0.05		-0.21
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Nonpoor	2 years	>0.05		-0.27
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Unmarried	2 years	>0.05		-0.19
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	teenagers	2 years	>0.05		-0.34
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Poor, unmarried teens	2 years	>0.05		-0.51
5143		Child Maltreatment	beneficial	Avoidance of Punishment		34 months	>0.05	0.05	
5143		Child Maltreatment	beneficial	Number of Scheduled Health Supervision Visits with Problems/Sick Visits		50 months	>0.05	-0.07	
5143		Child Maltreatment	beneficial	Number of Scheduled Health Supervision Visits	Low-income unmarried women	50 months	>0.05	-0.25	
5143	Olds, DL	Child Maltreatment	beneficial	Number of Scheduled Health Supervision Visits		50 months	>0.05	-1.49	
5143		Child Maltreatment	harmful	Number of Abuse Notations in CPS Record	Nonminority, maltreated by 4 years old	4 years	0.61	0.71	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143		Child Maltreatment	beneficial	Avoidance of Punishment	Nonminority, maltreated by 4 years old	34 months	0.25	0.43	
5143		Child Maltreatment	beneficial	Avoidance of Punishment	Nonminority, maltreated by 4 years old	46 months	0.76	-0.11	
5143		Child Maltreatment	beneficial	Total Length of Time Case Open	Nonminority, maltreated by 4 years old	4 years	0.05	-0.22	
5143		Child Maltreatment	beneficial	Avoidance of Restriction and Punishment	Poor unmarried teens	22 months	0.05	0.68	
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Non Risk	2 years	>0.05		-0.32
5143		Child Maltreatment	beneficial	Child Abuse or Neglect		2 years	>0.05		-0.14
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Married	2 years	>0.05		-0.18
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Poor	2 years	>0.05		-0.21
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Nonpoor	2 years	>0.05		-0.27
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Unmarried	2 years	>0.05		-0.19
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	teenagers	2 years	>0.05		-0.34
5143		Child Maltreatment	beneficial	Child Abuse or Neglect	Poor, unmarried teens	2 years	>0.05		-0.51
5143		Child Maltreatment	beneficial	Avoidance of Punishment		34 months	>0.05	0.05	
5143		Child Maltreatment	beneficial	Number of Scheduled Health Supervision Visits with Problems/Sick Visits		50 months	>0.05	-0.07	
5143		Child Maltreatment	beneficial	Number of Scheduled Health Supervision Visits	Low-income unmarried women	50 months	>0.05	-0.25	
5143	Olds, DL	Child Maltreatment	beneficial	Number of Scheduled Health Supervision Visits		50 months	>0.05	-1.49	
5143		Child Maltreatment	harmful	Number of Abuse Notations in CPS Record	Nonminority, maltreated by 4 years old	4 years	0.61	0.71	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143		Cognitive	beneficial	Cattell	Poor unmarried teens	24 months	0.09	0.56	
5143		Cognitive	beneficial	Bayley Mental Development Index	Poor unmarried teens	12 months	0.06	0.63	
5143		Cognitive	beneficial	Cattell		24 months	0.29	0.16	
5143		Cognitive	beneficial	Bayley Mental Development Index		12 months	0.65	0.07	
5143		Cognitive	beneficial	Stanford-Binet IQ	Low-income unmarried teens	48 months	>0.05	0.19	
5143		Cognitive	beneficial	Stanford-Binet IQ		48 months	>0.05	0.16	
5143		Cognitive	beneficial	Stanford-Binet IQ	Low-income unmarried teens	36 months	>0.05	0.2	
5143		Cognitive	beneficial	Stanford-Binet IQ		36 months	>0.05	0.096	
5143	Olds, DL	Government Cost	*BENEFICIAL*	Government Cost for 0-48 months	Low-income families	48 months	<0.05	-0.4	
5143		Government Cost	*BENEFICIAL*	Government Cost for 24-48 months	Low-income families	48 months	<0.01	-0.46	
5143		Government Cost	*BENEFICIAL*	Government Cost for 24-48 months		48 months	<0.05	-0.29	
5143		Government Cost	beneficial	Government Cost for 0-24 months	Low-income families	24 months	>0.05	-0.27	
5143		Government Cost	beneficial	Government Cost for 0-24 months		24 months	>0.05	-0.07	
5143		Government Cost	beneficial	Government Cost over First 4 years		48 months	>0.05	-0.19	
5143	Olds, DL	Legal Offenses	*BENEFICIAL*	Arrests	Low SES unmarried	15 years	<0.01	-0.7	
5143		Legal Offenses	*BENEFICIAL*	Convictions	Low SES unmarried	15 years	<0.01	-0.56	
5143		Legal Offenses	*BENEFICIAL*	Days in Jail	Low SES unmarried	15 years	<0.01	-1.18	
5143		Legal Offenses	*BENEFICIAL*	Arrests in New York State	Low SES unmarried	15 years	<0.01	-0.92	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143	Olds, DL	Legal Offenses	*BENEFICIAL*	Convictions in New York State	Low SES unmarried	15 years	<0.01	-0.8	
5143		Legal Offenses	*BENEFICIAL*	Substance Use Impairment	Low SES unmarried	15 years	<0.05	-0.45	
5143		Legal Offenses	beneficial	Convictions		15 years	>0.05	NA	
5143		Legal Offenses	beneficial	Arrests		15 years	>0.05	NA	
5143		Legal Offenses	beneficial	Days in Jail		15 years	>0.05	NA	
5143		Legal Offenses	beneficial	Arrests in New York State		15 years	>0.05	NA	
5143		Legal Offenses	beneficial	Convictions in New York State		15 years	>0.05	NA	
5143		Legal Offenses	beneficial	Substance Use Impairment		15 years	>0.05	-0.04	
5143		Legal Offenses	harmful	Illegal Drug Use			>0.05	0.15	
5143	Olds, DL	Mother's Education	beneficial	Number of Years Education Completed	Women < 12years education	46 months	0.48	0.15	
5143		Mother's Education	beneficial	Number of Years Education Completed	Unmarried women < 12 years education	4 years	0.8	0.06	
5143	Olds, DL	Mother's Employment	*BENEFICIAL*	Concern About Finding Work	Poor, unmarried >= 19 years old	22 months	0.04	-0.8	
5143		Mother's Employment	beneficial	Concern About Finding Work	Poor, unmarried >= 19 years old	10 months	0.36	-0.32	
5143		Mother's Employment	beneficial	Number of Months Employed	Poor, unmarried >= 19 years old	46 months	0.08	0.12	
5143		Mother's Employment	beneficial	Number of Months Employed	Poor, unmarried >= 19 years old	22 months	0.05	0.76	
5143		Mother's Employment	beneficial	Number of Months Employed	Poor, unmarried < 19 years old	46 months	0.39	0.33	
5143		Mother's Employment	beneficial	Number of Months Employed		22 Months	0.8	0.04	
5143		Mother's Employment	beneficial	Number of Months Employed		46 months	0.3	0.15	
5143	Olds, DL	Mother's Employment	beneficial	Months Employed		15 years	>0.05	0.12	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143		Mother's Employment	beneficial	Months Employed	Low SES unmarried	15 years	>0.05	0.32	
5143		Mother's Employment	harmful	Concern About Finding Work	Poor, unmarried < 19 years old	10 months	0.05	0.68	
5143		Mother's Employment	harmful	Number of Months Employed	Poor, unmarried < 19 years old	22 months	0.96	-0.02	
5143		Mother's Employment	harmful	Concern About Finding Work		10 months	0.27	0.16	
5143		Mother's Employment	harmful	Concern About Finding Work		22 months	0.8	0.04	
5143		Mother's Employment	*HARMFUL*	Concern About Finding Work	Poor, unmarried < 19 years old	22 months	0.04	0.8	
5143	Olds, DL	Mother's Physical Health	*BENEFICIAL*	Number of Pregnancies	Poor, unmarried women	46 months	0.04	-0.49	
5143		Mother's Physical Health	*BENEFICIAL*	Number of Pregnancies		22 months	0.02	-0.56	
5143		Mother's Physical Health	*BENEFICIAL*	Number of Months Between First and Second Child	Poor, unmarried women	46 months	0.002	0.69	
5143		Mother's Physical Health	*BENEFICIAL*	Subsequent Pregnancies	Low SES unmarried	15 years	<0.05	0.48	
5143		Mother's Physical Health	*BENEFICIAL*	Subsequent Births	Low SES unmarried	15 years	<0.05	-0.46	
5143		Mother's Physical Health	*BENEFICIAL*	Months Between Birth of First and Second Child	Low SES unmarried	15 years	<0.01	0.79	
5143		Mother's Physical Health	beneficial	Number of Birth	Poor, unmarried women	46 months	0.15	-0.32	
5143		Mother's Physical Health	beneficial	Number of Therapeutic Abortions	Poor, unmarried women	46 months	0.74	-0.08	
5143		Mother's Physical Health	beneficial	Number of Spontaneous Abortions	Poor, unmarried women	46 months	0.26	-0.26	
5143	Olds, DL	Mother's Physical Health	beneficial	Number of Births		46 months	0.28	-0.15	
5143		Mother's Physical Health	beneficial	Number of Spontaneous Abortions		46 months	0.61	-0.07	
5143		Mother's Physical Health	beneficial	Number of Pregnancies		46 months	0.09	-0.25	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143		Mother's Physical Health	beneficial	Number of Pregnancies		22 months	0.52	-0.1	
5143		Mother's Physical Health	beneficial	Number of Months Between First and Second Child		46 months	0.15	0.2	
5143		Mother's Physical Health	beneficial	Months Between Birth of First and Second Child		15 years	>0.05	0.17	
5143		Mother's Physical Health	beneficial	Subsequent Births		15 years	>0.05	-0.25	
5143		Mother's Physical Health	beneficial	Subsequent Pregnancies		15 years	>0.05	-0.37	
5143		Mother's Physical Health	harmful	Number of Therapeutic Abortions		46 months	0.77	0.42	
5143	Olds, DL	Mother's Public Assistance	*BENEFICIAL*	Months Receiving AFDC	Low SES unmarried	15 years	<0.01	-0.59	
5143		Mother's Public Assistance	*BENEFICIAL*	Months Receiving Food Stamps	Low SES unmarried	15 years	<0.01	-0.68	
5143		Mother's Public Assistance	beneficial	Number of Days on Public Assistance	Poor, unmarried >= 19 years old	48 months	0.39	-0.3	
5143		Mother's Public Assistance	beneficial	Number of Days on Public Assistance	Poor, unmarried >= 19 years old	22 months	0.09	-0.66	
5143		Mother's Public Assistance	beneficial	Number of Days on Public Assistance		22 months	0.85	-0.03	
5143		Mother's Public Assistance	beneficial	Number of Days on Public Assistance		48 months	0.28	-0.15	
5143		Mother's Public Assistance	beneficial	Months Receiving Food Stamps		15 years	>0.05	-0.15	
5143	Olds, DL	Mother's Public Assistance	beneficial	Months Receiving Medicaid		15 years	>0.05	-0.13	
5143		Mother's Public Assistance	beneficial	Months Receiving AFDC		15 years	>0.05	-0.24	
5143		Mother's Public Assistance	beneficial	Months Receiving Medicaid	Low SES unmarried	15 years	>0.05	-0.4	
5143		Mother's Public Assistance	harmful	Number of Days on Public Assistance	Poor, unmarried < 19 years old	48 months	0.61	0.12	
5143		Mother's Public Assistance	harmful	Number of Days on Public Assistance	Poor, unmarried < 19 years old	22 months	0.4	0.2	
5143	Olds, DL	Mother's Social Support	*BENEFICIAL*	Help with Childcare	Poor, unmarried >= 19 years old	10 months	0.02	0.87	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143		Mother's Social Support	*BENEFICIAL*	Social Support Accompany to Labor		0 days	0.015		1.09
5143		Mother's Social Support	*BENEFICIAL*	Social Support Father Interested in Pregnancy		32 weeks Gestational Age	<0.05	0.28	
5143		Mother's Social Support	*BENEFICIAL*	Social Support Talk About Problems		32 weeks Gestational Age	<0.05	0.27	
5143		Mother's Social Support	*BENEFICIAL*	Number of Services Known		32 weeks Gestational Age	<0.01	0.99	
5143		Mother's Social Support	beneficial	Help with Childcare	Poor, unmarried >= 19 years old	46 months	0.14	0.57	
5143		Mother's Social Support	beneficial	Help with Childcare	Poor, unmarried >= 19 years old	22 months	0.37	0.34	
5143		Mother's Social Support	beneficial	Help with Childcare	Poor, unmarried < 19 years old	22 months	0.72	0.12	
5143		Mother's Social Support	beneficial	Help with Childcare		10 months	0.43	0.11	
5143		Mother's Social Support	beneficial	Help with Childcare		22 months	0.68	0.06	
5143	Olds, DL	Mother's Social Support	beneficial	Help with Childcare		46 months	0.24	0.18	
5143		Mother's Social Support	beneficial	Social Support Accompany to Delivery		0 days	0.31		0.25
5143		Mother's Social Support	harmful	Help with Childcare	Poor, unmarried < 19 years old	46 months	0.82	-0.08	
5143		Mother's Social Support	harmful	Help with Childcare	Poor, unmarried < 19 years old	10 months	0.51	-0.2	
5143		Mother's Social Support	harmful	Social Support Help with Household		32 weeks Gestational Age	>0.05	-0.16	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143	Olds, DL	Parenting/Parent Child Relationship	*BENEFICIAL*	Provision of Toys, Games, Reading Materials	Nonminority, maltreated by 4 years old	46 months	0.01	1	
5143		Parenting/Parent Child Relationship	*BENEFICIAL*	Provision of Appropriate Play Materials	Poor, unmarried teens	22 months	0.003	1.01	
5143		Parenting/Parent Child Relationship	*BENEFICIAL*	Provision of Appropriate Play Materials	Poor, unmarried mothers	10 months	0.014	0.89	
5143		Parenting/Parent Child Relationship	*BENEFICIAL*	Provision of Toys, Games, Reading Materials	Low-income unmarried teens	34 months	0.03	0.67	
5143		Parenting/Parent Child Relationship	beneficial	Home Inventory Total Score	Nonminority, maltreated by 4 years old	34 months	0.36	0.31	
5143		Parenting/Parent Child Relationship	beneficial	Home Inventory Total Score	Nonminority, maltreated by 4 years old	46 months	0.07	0.62	
5143		Parenting/Parent Child Relationship	beneficial	Provision of Toys, Games, Reading Materials	Nonminority, maltreated by 4 years old	34 months	0.35	0.34	
5143		Parenting/Parent Child Relationship	beneficial	Provision of Appropriate Play Materials		12 months	0.84	0.05	
5143	Olds, DL	Parenting/Parent Child Relationship	beneficial	Provision of Appropriate Play Materials		10 months	0.73	0.05	
5143		Parenting/Parent Child Relationship	beneficial	Spank or Hit	Poor, unmarried teens	2 years	>0.05	-0.47	
5143		Parenting/Parent Child Relationship	beneficial	Spank or Hit		2 years	>0.05	-0.17	
5143		Parenting/Parent Child Relationship	beneficial	Provision of Toys, Games, Reading Materials	Low-income unmarried teens	46 months	>0.05	0.42	
5143		Parenting/Parent Child Relationship	beneficial	Home Inventory Total Score	Low-income unmarried teens	46 months	>0.05	0.38	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143		Parenting/Parent Child Relationship	beneficial	Home Inventory Total Score	Low-income unmarried teens	34 months	0.06	0.71	
5143		Parenting/Parent Child Relationship	beneficial	Home Inventory Total Score		34 months	>0.05	0.007	
5143		Parenting/Parent Child Relationship	equal	Provision of Toys, Games, Reading Materials		34 months	>0.05	0	
5143		Parenting/Parent Child Relationship	harmful	Provision of Toys, Games, Reading Materials		46 months	>0.05	-0.04	
5143		Parenting/Parent Child Relationship	harmful	Home Inventory Total Score		46 months	>0.05	-0.002	
5143	Olds, DL	Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Birth Weight	Young mother's enrolled early	0 days	<0.001	1.55	
5143		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Number of Cigarettes Per Day	Initial smokers	32 weeks Gestational Age	<0.001	-1.35	
5143		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Adequacy of Diet		32 weeks Gestational Age	<0.05	0.25	
5143	Olds, DL	Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Childbirth Education		32 weeks Gestational Age	0.01		0.67
5143		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Number of Nutritional Supplemantation Vouchers		32 weeks Gestational Age	<0.05	0.23	
5143		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Kidney Infection		32 weeks Gestational Age	<0.05		-2.38
5143		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Cigarettes Per Day		34 weeks Gestational Age	<0.05	-0.53	
5143		Pregnancy/Pregnancy Outcome	beneficial	Length of Gestation	Smokers (>= 5 cigarettes per day)	0 days	>0.05	0.28	
5143		Pregnancy/Pregnancy Outcome	beneficial	Birth Weight	Smokers (>= 5 cigarettes per day)	0 days	>0.05	0.26	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143		Pregnancy/Pregnancy Outcome	beneficial	Length of Gestation	Adolescents 14-16 years old	0 days	>0.05	0.28	
5143		Pregnancy/Pregnancy Outcome	beneficial	Birth Weight	Adolescents 14-16 years old	0 days	>0.05	0.69	
5143		Pregnancy/Pregnancy Outcome	beneficial	Birth Weight		0 days	>0.05	0.04	
5143		Pregnancy/Pregnancy Outcome	beneficial	Weight Gain during Pregancy		32 weeks Gestational Age	>0.05	0.22	
5143		Pregnancy/Pregnancy Outcome	beneficial	Hypertensive Disorder of Pregnancy		32 weeks Gestational Age	0.28		-0.54
5143		Pregnancy/Pregnancy Outcome	beneficial	Number of Calls to Physician or Clinic		32 weeks Gestational Age	>0.05	-0.17	
5143		Pregnancy/Pregnancy Outcome	beneficial	Days in Neonatal Intensive Care Unit		1 month	>0.05	-0.001	
5143	Olds, DL	Pregnancy/Pregnancy Outcome	beneficial	Length of Gestation		0 days	>0.05	0.27	
5143		Pregnancy/Pregnancy Outcome	beneficial	Head Circumference		0 days	>0.05	0.3	
5143		Pregnancy/Pregnancy Outcome	beneficial	Birth Weight		0 days	>0.05	0.27	
5143		Pregnancy/Pregnancy Outcome	beneficial	Maternal Weight at End of Gestation			>0.05	0.085	
5143		Pregnancy/Pregnancy Outcome	beneficial	Quality of Diet (Percent Recommended Dietary Allowance)		34 weeks	>0.05	0.23	
5143		Pregnancy/Pregnancy Outcome	equal	Bleeding During Pregnancy			>0.05		0
5143		Pregnancy/Pregnancy Outcome	harmful	Birth Weight	Young mother's enrolled late	0 days	>0.05	-0.72	
5143		Pregnancy/Pregnancy Outcome	harmful	Birth Weight	Older nonsmokers	0 days	>0.05	-0.3	
5143		Pregnancy/Pregnancy Outcome	harmful	Length of Gestation		0 days	>0.05	-0.07	
5143		Pregnancy/Pregnancy Outcome	harmful	Number of Alcoholic Drinks Per Week		32 weeks Gestational Age	>0.05		0.03
5143		Pregnancy/Pregnancy Outcome	harmful	Diastolic Blood Pressure			>0.05	0.04	
5143		Pregnancy/Pregnancy Outcome	harmful	Spotting During Preganancy			>0.05		0.89

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143		Pregnancy/Pregnancy Outcome	harmful	Edema		32 weeks Gestational Age	0.44		0.18
5143		Pregnancy/Pregnancy Outcome	harmful	Proteinuria		32 weeks Gestational Age	0.36		0.56
5143	Olds, DL	Pregnancy/Pregnancy Outcome	harmful	Hematocrit		32 weeks Gestational Age	0.98		0.006
5143		Pregnancy/Pregnancy Outcome	harmful	Bladder Infection		32 weeks Gestational Age	0.22		0.52
5143		Pregnancy/Pregnancy Outcome	harmful	Number of Antenatal Visits		0 days	>0.05	0.01	
5143		Pregnancy/Pregnancy Outcome	harmful	Apgar Score at 5 minutes		0 days	>0.05	-0.15	
5143		Pregnancy/Pregnancy Outcome	harmful	Number of Alcoholic Drinks Last Week		34 weeks Gestational Age	>0.05	0.04	
5143		Pregnancy/Pregnancy Outcome	*HARMFUL*	Length of Gestation	Older nonsmokers	0 days	<0.01	-0.51	
5143	Olds, DL	Safety or Injuries	*BENEFICIAL*	Number of Injuries/Injestions in Physician Record 25-50 months	Nonminority, maltreated by 4 years old	50 months	0.01	-0.89	
5143		Safety of Injuries	*BENEFICIAL*	Hazardous Exposures Observed in Home	Nonminority, maltreated by 4 years old	46 months	0.03	-0.81	
5143		Safety or Injuries	*BENEFICIAL*	Number of Emergency Room Visits 2nd year	Poor, unmarried teens	2 years	<0.05	-0.34	
5143		Safety or Injuries	*BENEFICIAL*	Number of Emergency Room Visits 1st year	Poor, unmarried teens	1 year	<0.05	-0.62	
5143		Safety or Injuries	*BENEFICIAL*	Number of Emergency Visits for Accidents and Poisonings 2nd year		2 years	<0.05	-0.32	
5143		Safety or Injuries	*BENEFICIAL*	Number of Emergency Room Visits 2nd year		2 years	<0.01	-0.36	
5143		Safety or Injuries	*BENEFICIAL*	Number of Emergency Room Visits 1st year		1 year	<0.01	-0.57	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143		Safety or Injuries	*BENEFICIAL*	Number of Emergency Department Visits		50 months	0.0008	-0.47	
5143	Olds, DL	Safety or Injuries	*BENEFICIAL*	Number of Injuries/Injestions in Physician Record		50 months	0.03	-0.27	
5143		Safety or Injuries	*BENEFICIAL*	Hazardous Exposures Observed in Home	Low-income unmarried women	46 months	<0.05	-0.51	
5143		Safety or Injuries	*BENEFICIAL*	Hazardous Exposures Observed in Home		46 months	0.003	-0.43	
5143		Safety or Injuries	*BENEFICIAL*	Hazardous Exposures Observed in Home		34 months	0.04	-0.28	
5143		Safety or Injuries	beneficial	Hazardous Exposures Observed in Home	Nonminority, maltreated by 4 years old	34 months	0.86	-0.06	
5143		Safety or Injuries	beneficial	Number of Hospital Admissions 25 - 50 months	Nonminority, maltreated by 4 years old	50 months	0.43	-0.27	
5143		Safety or Injuries	beneficial	Number of Days Hospitalized 25 - 50 months	Nonminority, maltreated by 4 years old	50 months	0.4	-0.29	
5143		Safety or Injuries	beneficial	Number of Emergency Visits for Accidents and Poisonings 2nd year	Poor unmarried teens	2 Years	>0.05	-0.1	
5143		Safety or Injuries	beneficial	Number of Emergency Visits for Accidents and Poisonings 1st year	Poor unmarried teens	1Year	>0.05	-0.914	
5143		Safety or Injuries	beneficial	Number of Hospital Admissions	Low-income unmarried women	50 months	>0.05	-0.04	
5143		Safety or Injuries	beneficial	Number of Emergency Department Visits Injuries/Injestions		50 months	>0.05	-0.23	
5143		Safety or Injuries	beneficial	Number of Emergency Department Visits	Low-income unmarried women	50 months	>0.05	-0.44	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143	Olds, DL	Safety or Injuries	beneficial	Number of Injuries/Injestions in Physician Record	Low-income unmarried women	50 months	>0.05	-0.21	
5143		Safety or Injuries	beneficial	Hazardous Exposures Observed in Home	Low-income unmarried women	34 months	>0.05	-0.42	
5143		Safety or Injuries	harmful	Number of Emergency Room visits for Accidents and Poisonings 1st Year		1 Year	0.41	0.12	
5143		Safety or Injuries	harmful	Number of Hospital Admissions		50 months	>0.05	0.16	
5143		Safety or Injuries	harmful	Number of Emergency Department Visits Injuries/Injestions	Low-income umarried woment	50 months	>0.05	0.09	
5143		Safety or Injuries	*HARMFUL*	Number of Days Hospitalized	Low-income unmarried women	50 months	<0.01	0.81	
5143		Safety or Injuries	*HARMFUL*	Number of Days Hospitalized		50 months	0.02	0.33	
5143	Olds, DL	School Performance	*BENEFICIAL*	Enrolled or Graduated from School	Women < 12years education	6 months	0.002		1.4
5143		School Performance	*BENEFICIAL*	Enrolled or Graduated from School	Unmarried women < 12 years education	6 months	0.008		1.34
5143		School Performance	*BENEFICIAL*	Enrolled or Graduated from School	Unmarried women < 12 years education	10 months	0.02		1.14
5143		School Performance	beneficial	Enrolled or Graduated from School	Women < 12years education	10 months	0.11		0.72
5143		School Performance	beneficial	Enrolled or Graduated from School	Women < 12years education	22 months	0.2		0.58
5143		School Performance	beneficial	Enrolled or Graduated from School	Unmarried women < 12 years education	22 months	0.6		0.27

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143	Olds, DL	Speech or Language	*BENEFICIAL*	Stimulation of Language Skills	Low-income unmarried teens	34 months	0.005	0.84	
5143		Speech or Language	beneficial	Stimulation of Language Skills	Nonminority, maltreated by 4 years old	34 months	0.71	0.13	
5143	Olds, DL	Speech or Language	beneficial	Stimulation of Language Skills	Nonminority, maltreated by 4 years old	46 months	0.75	0.67	
5143		Speech or Language	beneficial	Stimulation of Language Skills		46 months	>0.05	0.11	
5143		Speech or Language	beneficial	Stimulation of Language Skills	Low-income unmarried teens	46 months	>0.05	0.39	
5143		Speech or Language	beneficial	Stimulation of Language Skills		34 months	>0.05	0.11	
5143	Olds, DL	Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Poitive Mood		2 years	0.03	0.31	
5143		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Number of Behavioral/Coping Problems Physician Record		50 months	0.006	-0.27	
5143		Temperament/ Behavior/ Symptoms	beneficial	Yells or Scolds	Poor unmarried teens	2 Years	>0.05	-0.66	
5143		Temperament/ Behavior/ Symptoms	beneficial	Conflict	Poor unmarried teens	2 Years	>0.05	-0.72	
5143		Temperament/ Behavior/ Symptoms	beneficial	Crying Episodes		2 Years	>0.05	-0.61	
5143		Temperament/ Behavior/ Symptoms	beneficial	Positive Mood	Poor unmarried teens	2 Years	0.06	0.64	
5143		Temperament/ Behavior/ Symptoms	beneficial	Yells or Scolds		2 Years	>0.05	-0.25	
5143		Temperament/ Behavior/ Symptoms	beneficial	Awaken at Night		2 Years	>0.05	-0.07	
5143		Temperament/ Behavior/ Symptoms	beneficial	Crying, Number of Episodes last 2 weeks		2 Years	>0.05		-0.16
5143		Temperament/ Behavior/ Symptoms	harmful	Worry or Concern	Poor unmarried teens	2 Years	0.26	0.42	
5143		Temperament/ Behavior/ Symptoms	harmful	Awaken at Night	Poor unmarried teens	2 years	0.98	0.006	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5143		Temperament/ Behavior/ Symptoms	harmful	Resist Eating	Poor unmarried teens	2 Years	0.98	0.001	
5143	Olds, DL	Temperament/ Behavior/ Symptoms	harmful	Conflict		2 Years	0.7	0.06	
5143		Temperament/ Behavior/ Symptoms	harmful	Number of Behavioral/Coping Problems Physician Record	Low-income unmarried women	50 months	>0.05	0.11	
5143		Temperament/ Behavior/ Symptoms	*HARMFUL*	Worry or Concern		2 years	0.04	0.33	
5143		Temperament/ Behavior/ Symptoms	*HARMFUL*	Resist Eating		2 years	0.014	0.41	
5189	Seifert, H	School Performance	*BENEFICIAL*	Boehm Test of Basic Concepts all 50 items		5.2 Years	0.0012	0.91	
5189		School Performance	*BENEFICIAL*	Boehm Test of Basic Concepts 14 Target Concepts		5.2 Years	<0.005	1.03	
5189		School Performance	beneficial	Boehm Test of Basic Concepts 36 nontarget items		5.2 Years	>0.05	0.35	
5210	Villar, J	Pregnancy/Pregnancy Outcome	beneficial	Preterm Delivery < 37 weeks		0 Days	0.28		-0.14
5210		Pregnancy/Pregnancy Outcome	beneficial	Low Birth Weight < 2.5 kgms		0 Days	0.58		-0.08
5210		Pregnancy/Pregnancy Outcome	beneficial	Admission or Visits to Hospitals		40 Days	0.12		-0.39
5210		Pregnancy/Pregnancy Outcome	beneficial	Admission to Neonatal Intensive Care Unit		0 Days	0.79		-0.03
5210		Pregnancy/Pregnancy Outcome	beneficial	Cesarean Section		0 days	0.18		-0.14
5210		Pregnancy/Pregnancy Outcome	beneficial	Anesthesia During Labor		0 Days	0.09		-0.148
5210		Pregnancy/Pregnancy Outcome	beneficial	Stillbirth		0 Days	0.63		-0.13
5210	Villar, J	Pregnancy/Pregnancy Outcome	beneficial	Perinatal Death		1 month	0.59		-0.12
5210		Pregnancy/Pregnancy Outcome	beneficial	Intrauterine Growth Retardation < 10th percentile	High Stress and low support	0 days	0.47		-0.22
5210		Pregnancy/Pregnancy Outcome	beneficial	Preterm Delivery < 37 weeks	High Stress and low support	0 days	0.67		-0.13
5210		Pregnancy/Pregnancy Outcome	beneficial	Low Birth Weight < 2.5 kgms	High Stress and low support	0 days	0.81		-0.05
5210		Pregnancy/Pregnancy Outcome	beneficial	Intrauterine Growth Retardation < 10th percentile	High psychological distress	0 days	0.47		-0.15
5210		Pregnancy/Pregnancy Outcome	beneficial	Preterm Delivery < 37 weeks	High psychological distress	0 days	0.5		-0.13

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5210		Pregnancy/Pregnancy Outcome	beneficial	Low Birth Weight < 2.5 kgms	High psychological distress	0 days	0.31		-0.22
5210		Pregnancy/Pregnancy Outcome	beneficial	Intrauterine Growth Retardation < 10th percentile	Low level social support	0 days	0.14		-0.27
5210		Pregnancy/Pregnancy Outcome	beneficial	Preterm Delivery < 37 weeks	Low level social support	0 days	0.14		-0.27
5210		Pregnancy/Pregnancy Outcome	beneficial	Low Birth Weight < 2.5 kgms	Low level social support	0 days	0.11		-0.33
5210		Pregnancy/Pregnancy Outcome	harmful	Intrauterine Growth Retardation < 10th percentile		0 days	0.48		0.09
5210		Pregnancy/Pregnancy Outcome	harmful	Forceps Delivery		0 days	0.25		0.21
5210		Pregnancy/Pregnancy Outcome	harmful	Apgar Score < 7 at 5 minutes		0 days	0.74		0.1
5210		Pregnancy/Pregnancy Outcome	*HARMFUL*	Intrauterine Growth Retardation < 10th percentile		0 days	0.04		0.28
5220	Whitehurst, GJ	Cognitive	beneficial	Peabody Picture Vocabulary Test Revised		4.5 years	0.21	0.2	
5220	Whitehurst, GJ	School Performance	*BENEFICIAL*	Print First Name		4.5 years	0.04	0.33	
5220		School Performance	*BENEFICIAL*	Identify Function of Words Numbers		4.5 years	0.03	0.35	
5220		School Performance	*BENEFICIAL*	Distinguish Words Pictures Numbers		4.5 Years	0.03	0.34	
5220		School Performance	*BENEFICIAL*	Rhyming		4.5 years	0.002	0.49	
5220		School Performance	*BENEFICIAL*	Identify Sounds and Letters		4.5 years	0.005	0.44	
5220		School Performance	*BENEFICIAL*	Name Letters		4.5 years	0.0005	0.56	
5220		School Performance	beneficial	Write Message Mechanics		4.5 Years	0.1	0.26	
5220		School Performance	beneficial	Draw a Person		4.5 years	0.24	0.18	
5220		School Performance	beneficial	Print in Left Right Progression		4.5 years	0.08	0.28	
5220		School Performance	beneficial	Identify Components of Writing		4.5 years	0.11	0.25	
5220		School Performance	beneficial	Hold Book - Turn Pages		4.5 years	0.16	0.22	
5220		School Performance	beneficial	identify Same - Different		4.5 years	0.93	0.01	
5220		School Performance	harmful	Write Message Quality		4.5 years	>0.05	-0.54	
5220		School Performance	harmful	Identify People Reading		4.5 years	>0.05	-0.22	
5220	Whitehurst, GJ	Speech or Language	*BENEFICIAL*	Tell Story in Sequence		4.5 years	0.01	0.39	
5220	Whitehurst, GJ	Speech or Language	beneficial	Segment Words		4.5 years	0.61	0.08	
5220		Speech or Language	beneficial	Blend CVC Words		4.5 years	0.5	0.1	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5220		Speech or Language	beneficial	Expressive One Word Picture Vocabulary Test		4.5 years	0.06	0.3	
5220		Speech or Language	harmful	segment sentences		4.5 years	>0.05	-0.06	
5259	Windsor, RA	Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Quit Smoking	Black	32 weeks Gestational Age	0.025		0.61
5259		Pregnancy/Pregnancy Outcome	beneficial	Significant Reduction in Smoking	Whites	32 weeks Gestational Age	0.05		0.55
5259		Pregnancy/Pregnancy Outcome	beneficial	Significant Reduction in Smoking	Blacks	32 weeks Gestational Age	0.12		0.12
5259		Pregnancy/Pregnancy Outcome	beneficial	Quit Smoking	Whites	32 weeks Gestational Age	0.14		0.59
5415	Oakley, A	Mother's Mental Health	beneficial	Mother Feels Low/No Control over Life		6 Weeks	0.05		-0.39
5415		Mother's Mental Health	beneficial	Mother Depressed After Birth		6 Weeks	0.11		-0.3
5415		Mother's Mental Health	beneficial	Depressed During Pregnancy Obstetric Case Note		0 Days	0.14		-0.38
5415	Oakley, A	Mother's Physical Health	*BENEFICIAL*	Mother's Health Not Good		6 Weeks	0.03		-0.42
5415		Mother's Physical Health	beneficial	Mother had Visit to/from GP		6 Weeks	0.25		-0.24
5415		Mother's Physical Health	beneficial	Mother Had Hospital Visit (Excluding Routine Postnatal)		6 Weeks	0.08		-0.7
5415	Oakley, A	Mother's Social Support	beneficial	Partner Helpful Domestically		6 Weeks	0.05		0.6
5415	Oakley, A	Mother's Social Support	beneficial	Partner Helpful with Other Children	Partner and Other Children	6 Weeks	0.06		0.63
5415	Oakley, A	Parenting/Parent Child Relatio	*BENEFICIAL*	Mother Worried about Baby		6 Weeks	0.02		-0.73
5414	Oakley, A	Physical Health/ Growth/ Health	*BENEFICIAL*	Health Service After Discharge		6 Weeks	0.04		-0.4
5415	Oakley, A	Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Duration Tube Fed	Tube Fed Infants	6 Weeks	0.005	-1	
5415		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Antenatal Hospital Admission			0.014		-0.45
5415		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Antenatal Cardiotocography		0 Days	0.04		-0.37
5415		Pregnancy/Pregnancy Outcome	beneficial	Problems After Discharge		6 Weeks	0.06		-0.4
5415		Pregnancy/Pregnancy Outcome	beneficial	Breastfed at Discharge		1 Week	0.13		0.29
5415		Pregnancy/Pregnancy Outcome	beneficial	Duration on Supplemental Oxygen	Infants on Supplemental Oxygen	6 Weeks	0.16	-0.59	
5415		Pregnancy/Pregnancy Outcome	beneficial	Supplemental Oxygen		6 Weeks	0.16		-0.59
5415		Pregnancy/Pregnancy Outcome	beneficial	Duration of Ventilation	Ventilated Infants	6 Weeks	>.05	-0.33	

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5415		Pregnancy/Pregnancy Outcome	beneficial	Ventilated		0 Days	>.05		-0.51
5415		Pregnancy/Pregnancy Outcome	beneficial	Respiratory Distress		6 Weeks	0.26		-0.53
5415		Pregnancy/Pregnancy Outcome	beneficial	Endotracheal Intubation		0 Days	0.3		-0.5
5415		Pregnancy/Pregnancy Outcome	beneficial	Apgar Score < 7 at 5 minutes		0 Days	0.24		-0.71
5415		Pregnancy/Pregnancy Outcome	beneficial	Birth Weight		0 Days	>0.05	0.05	
5415	Oakley, A	Pregnancy/Pregnancy Outcome	beneficial	Cesarean Section		0 Days	0.26		-0.26
5415		Pregnancy/Pregnancy Outcome	beneficial	Instrumental Vaginal Delivery		0 Days	0.07		-0.95
5415		Pregnancy/Pregnancy Outcome	beneficial	Length of Labour		0 Days	>.05	-0.05	
5415		Pregnancy/Pregnancy Outcome	beneficial	Spontaneous Vaginal Delivery		0 Days	0.1		0.36
5415		Pregnancy/Pregnancy Outcome	beneficial	Epidural Anaesthesia		0 Days	0.11		-0.43
5415		Pregnancy/Pregnancy Outcome	beneficial	Prelabour Cesarean		0 Days	0.31		-0.43
5415		Pregnancy/Pregnancy Outcome	beneficial	Induced Onset of Labour		0 Days	0.2		-0.27
5415		Pregnancy/Pregnancy Outcome	beneficial	Spontaneous Onset of Labour		0 Days	0.14		0.3
5415		Pregnancy/Pregnancy Outcome	beneficial	Pregnancy Induced Hypertension (PIH)		0 Days	0.71		-0.11
5415		Pregnancy/Pregnancy Outcome	beneficial	Raised Blood Pressure with Proteinuria		0 Days	0.11		-0.35
5415		Pregnancy/Pregnancy Outcome	beneficial	Admission for Threatened Preterm Delivery		0 Days	0.23		-0.3
5415		Pregnancy/Pregnancy Outcome	beneficial	Days in Hospital	Antenatal hospital admission	2 weeks	>0.05	-0.09	
5415		Pregnancy/Pregnancy Outcome	beneficial	More than One Ultrasound Scan in Pregnancy		0 Days	0.32		0.22
5415		Pregnancy/Pregnancy Outcome	equal	Gestational Age		0 Days	>.5	0	
5415		Pregnancy/Pregnancy Outcome	equal	Number of Hospital Antenatal Clinic Visits		0 Days	>.5	0	
5415		Pregnancy/Pregnancy Outcome	harmful	Totally/Intravenously Tube-Fed		6 Weeks	0.63		0.19
5415	Oakley, A	Pregnancy/Pregnancy Outcome	harmful	Sent to Neonatal Unit		6 Weeks	0.99		0.003
5432	Sosa, R	Parenting/Parent Child Relatio	*BENEFICIAL*	Maternal Talking to Infant		0 Days	<0.002	N/A	
5432		Parenting/Parent Child Relatio	*BENEFICIAL*	Maternal Smiling at Infant		0 Days	<0.009	N/A	
5432		Parenting/Parent Child Relatio	*BENEFICIAL*	Stroking of Newborn by Mother		0 Days	<0.001	N/A	
5432		Parenting/Parent Child Relatio	*BENEFICIAL*	Simple Touching of Infant by Mother		0 Days	0.06	N/A	
5432	Sosa, R	Pregnancy/Pregnancy Outcome	*BENEFICIAL*	No Perinatal Problems		1 month	<0.001		1.83
5432		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Length of Labour		0 Days	<0.001	-1.21	
5434	Kennell, J	Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Maternal Fever	Spsis Evaluation	2 Days	0.04		-1.72
5434		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Oxytocin Use	Cesarean Section	0 Days	0.04		-1.35

TABLE 6A. OUTCOME FINDINGS FOR TRIALS WITH 5-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5434		Pregnancy/Pregnancy Outcome	*BENEFICIAL*	Usage of Epidural Anesthesia	Spontaneous Vaginal Delivery	0 Days	0.0002		-1.24
5434		Pregnancy/Pregnancy Outcome	beneficial	Sepsis Evaluations	Neonatal Abnormal Course	2 Days	0.27		-0.6
5434		Pregnancy/Pregnancy Outcome	beneficial	Neonatal Abnormal Course		2 Days	0.05		-0.57
5434		Pregnancy/Pregnancy Outcome	beneficial	Oxytocin Use		0 Days	0.13		-0.38
5434		Pregnancy/Pregnancy Outcome	beneficial	Duration of Labour		0 Days	>0.05	-0.25	
5434		Pregnancy/Pregnancy Outcome	beneficial	Duration of Labour	Vaginal birth, no forceps	0 Days	>0.05	-0.15	
5434		Pregnancy/Pregnancy Outcome	beneficial	Duration of Labour	Spontaneous Vaginal Delivery, no oxytocin	0 Days	>0.05	-0.33	
5434	Kennell, J	Pregnancy/Pregnancy Outcome	beneficial	Duration of Labour	Vaginal birth, no medications	0 Days	>0.05	-0.3	
5434		Pregnancy/Pregnancy Outcome	harmful	Oxytocin Use	Spontaneous Vaginal Birth	0 Days	0.83		0.07
5434		Pregnancy/Pregnancy Outcome	harmful	Oxytocin Use	Forceps Delivery	0 Days	0.72		0.22

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5007	Anisfeld, E	Cognitive	na	Bayley Mental Development Index		3.5 Months	>0.05	N/A	
5007	Anisfeld, E	Motor Development	na	Bayley Psychometor Development Index		3.5 Months	>0.05	N/A	
5007	Anisfeld, E	Parenting/Parent Child Relationship	*BENEFICIAL*	Above Median Looking at Mother (Videotaped)		3.5 Months	<0.05		N/A
5007		Parenting/Parent Child Relationship	*BENEFICIAL*	Maternal Responsivity		3.5 Months	<0.02	N/A	
5007		Parenting/Parent Child Relationship	*BENEFICIAL*	Secure Attachment (Ainsworth Strange Situation)		13 Months	0.019		1.93
5007		Parenting/Parent Child Relationship	beneficial	Maternal Sensitivity Crnic Global Rating		3.5 Months	0.09	N/A	
5007		Parenting/Parent Child Relationship	*HARMFUL*	Age of Onset of Social Smiling		2 Months	<0.05	0.66	
5007	Anisfeld, E	Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Infant Vocalization Alone (Videotaped)		3.5 Months	<0.01	N/A	
5007		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Regular Daily Period of Crying		2 Months	<0.05		-1.41
5007		Temperament/ Behavior/ Symptoms	beneficial	Difficult Infant Carey Scale		3.5 Months	0.94		-0.054
5016	Beeghly, M	Cognitive	beneficial	Bayley Mental Development Index		4 Months	0.46	0.13	
5016	Beeghly, M	Mother's Stress	equal	Parenting Stress from Parent-Related Sources		4 Months	>0.5	0	
5016		Mother's Stress	harmful	Parenting Stress from Child-Related Sources		4 Months	0.72	0.063	
5016	Beeghly, M	Motor Development	beneficial	Bayley Psychomotor Development Index		4 Months	>0.1	0.12	
5016	Beeghly, M	Parenting/Parent Child Relationship	beneficial	Maternal Sensitivity During Mother-Infant Interaction		4 Months	0.68	0.08	
5018	Black, MM	Cognitive	beneficial	Cognitive Development	Recruited < 1 year old	1.5 years	0.51	0.18	
5018	Black, MM	Cognitive	beneficial	Cognitive Development	Recruited 1-2 years old	2.5 years	0.76	0.079	
5018	Black, MM	Motor Development	beneficial	Motor Development	Recruited < 1 year old	1.5 years	0.91	0.03	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5018		Motor Development	beneficial	Motor Development	Recruited 1-2 years old	2.5 years	0.91	0.03	
5018	Black, MM	Parenting/ Parent Child Relationship	beneficial	Parent Negative Control	Recruited < 1 year old	1.5 years	>0.05	-0.17	
5018		Parenting/ Parent Child Relationship	beneficial	Parent Negative Control	Recruited 1-2 years old	2.5 years	>0.05	-0.17	
5018		Parenting/ Parent Child Relationship	beneficial	Parent Nurturance	Recruited < 1 year old	1.5 years	0.87	0.04	
5018		Parenting/ Parent Child Relationship	beneficial	Parent Nurturance	Recruited 1-2 years old	2.5 years	0.85	0.05	
5018		Parenting/ Parent Child Relationship	beneficial	Home Observation for Measurement of the Environment Total Score	Recruited < 1 year old	1.5 years	0.06	0.6	
5018		Parenting/ Parent Child Relationship	beneficial	Home Observation for Measurement of the Environment Total Score	Recruited 1-2 years old	2.5 years	0.2	0.39	
5018	Black, MM	Physical Health/ Growth/ Health	beneficial	Height for Age	Recruited < 1 year old	1.5 years	0.48	0.19	
5018		Physical Health/ Growth/ Health	beneficial	Height for Age	Recruited 1-2 years old	2.5 years	0.45	0.19	
5018		Physical Health/ Growth/ Health	harmful	Weight for Height	Recruited < 1 year old	1.5 years	>0.05	-0.16	
5018		Physical Health/ Growth/ Health	harmful	Weight for Height	Recruited 1-2 years old	2.5 years	>0.05	-0.36	
5018		Physical Health/ Growth/ Health	harmful	Weight for Age	Recruited 1-2 years old	2.5 years	>0.05	-0.15	
5018	Black, MM	Physical Health/ Growth/ Health	harmful	Weight for Age	Recruited < 1 year old	2.5 years	>0.05	-0.19	
5018	Black, MM	Social Relations	beneficial	Child Interactive Competence	Recruited < 1 year old	1.5 years	0.9	0.03	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5018		Social Relations	beneficial	Child Interactive Competence	Recruited 1-2 years old	2.5 years	0.9	0.03	
5018	Black, MM	Speech or Language	beneficial	Expressive Language	Recruited 1-2 years old	2.5 years	0.98	0.006	
5018		Speech or Language	beneficial	Receptive Language	Recruited < 1 year old	1.5 years	0.9	0.03	
5018		Speech or Language	beneficial	Receptive Language	Recruited 1-2 years old	2.5 years	0.89	0.03	
5018		Speech or Language	equal	Expressive Language	Recruited < 1 year old	1.5 years	>0.5	0	
5020	Blondel, B	Mother's Social Support	*BENEFICIAL*	Agree that Home Visits Provide Best Prenatal Care		0 days	0.0002		1.74
5020	Blondel, B	Pregnancy/ Pregnancy Outcome	equal	Visits to an Outpatient Clinic		0 days	>0.5	0	
5020		Pregnancy/ Pregnancy Outcome	harmful	Stay in Hospital		2 days	0.21		0.41
5020		Pregnancy/ Pregnancy Outcome	harmful	Duration of Betamimetics per os Treatment	Betamimetics per os Treatment	1 week	0.14	0.36	
5020		Pregnancy/ Pregnancy Outcome	harmful	Betamimetics per os Treatment		0 days	0.77		0.09
5020		Pregnancy/ Pregnancy Outcome	harmful	Duration of IV Betamimetics IV Treatment	Treated with Betamimetics	1 week	0.55	0.23	
5020		Pregnancy/ Pregnancy Outcome	harmful	IV Betamimetics Treatment		0 days	0.65		0.19
5020		Pregnancy/ Pregnancy Outcome	harmful	Treatment for Inhibition of Contractions		0 days	0.05		1.26
5020		Pregnancy/ Pregnancy Outcome	harmful	Admission for Threatened Preterm Delivery		0 days	0.32		0.32
5020	Blondel, B	Pregnancy/ Pregnancy Outcome	harmful	Mother's Length of Stay		0 days	0.21	0.21	
5023	Booth, CL	Mother's Mental Health	harmful	Maternal Social Skills Aggregated Score		1 year	>0.05	-0.13	
5023		Mother's Mental Health	harmful	Maternal Social Skills Adult Conversational Skill Scale		1 year	>0.05	-0.02	
5023		Mother's Mental Health	harmful	Maternal Social Skills Community Life Skills Scale		1 year	>0.05	-0.08	
5023	Booth, CL	Parenting/ Parent Child Relationship	beneficial	Mother-Child Interaction Aggregated Score		1 year	>0.05	0.14	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5023		Parenting/ Parent Child Relationship	beneficial	Mother-Child Interaction NCATS Teaching, Laboratory		1 year	>0.05	-0.2	
5023		Parenting/ Parent Child Relationship	beneficial	Mother-Child Interaction NCATS Teaching, Home		1 year	>0.05	0.13	
5023		Parenting/ Parent Child Relationship	equal	Mother-Child Interaction NCAFS Feeding, Laboratory		1 year	>0.5	0	
5026	Bryce, RL	Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Preterm Birth	Professional social class	0 days	0.025		-0.53
5026		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Preterm Birth 20-36 weeks gestation	Singleton, previous preterm birth	0 days	0.04		-0.37
5026		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Preterm Birth 20-36 weeks gestation		0 days	0.038		-0.29
5026		Pregnancy/ Pregnancy Outcome	beneficial	Preterm Birth	Living with Partner	0 days	0.059		-0.27
5026		Pregnancy/ Pregnancy Outcome	beneficial	Preterm Birth	Manual social class	0 days	0.85		-0.04
5026		Pregnancy/ Pregnancy Outcome	beneficial	Preterm Birth 20-36 weeks gestation	Multiple birth, no previous preterm	0 days	>0.05		-2.03
5026	Bryce, RL	Pregnancy/ Pregnancy Outcome	beneficial	Preterm Birth 20-36 weeks gestation	Singleton, no previous preterm birth	0 days	0.41		-0.19
5026		Pregnancy/ Pregnancy Outcome	beneficial	Preterm Birth 20-36 weeks gestation	Singleton, no previous preterm birth	0 days	0.41		-0.91
5026		Pregnancy/ Pregnancy Outcome	equal	Preterm Birth	Clerical social class	0 days	0.99		0
5026		Pregnancy/ Pregnancy Outcome	harmful	Preterm Birth	Living alone	0 days	0.72		0.16
5026		Pregnancy/ Pregnancy Outcome	harmful	Preterm Birth		0 days	0.43		0.39
5026		Pregnancy/ Pregnancy Outcome	harmful	Discharged Alive		1 week	0.22		-0.35

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5026		Pregnancy/ Pregnancy Outcome	harmful	Preterm Birth 20-36 weeks gestation	Multiple birth, no previous preterm	0 days	0.28		1.2
5027	Burchinal, M	Cognitive	*BENEFICIAL*	Stanford-Binet IQ	Intervention vs community	24 months	<0.0001	0.83	
5027		Cognitive	*BENEFICIAL*	Bayley Mental Development Index	Intervention vs community	18 months	<0.0001	1.05	
5027		Cognitive	*BENEFICIAL*	Bayley Mental Development Index	Intervention vs community	12 months	0.02	0.47	
5027		Cognitive	*BENEFICIAL*	McCarthy Scales of Children's Ability		54 months	0.014	0.5	
5027		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		48 weeks	0.004	0.5	
5027		Cognitive	*BENEFICIAL*	McCarthy Scales of Children's Ability		42 months	0.015	0.5	
5027		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		36 months	<0.0001	0.83	
5027		Cognitive	*BENEFICIAL*	McCarthy Scales of Children's Ability	Intervention vs minimal day care	54 months	<0.0001	1.47	
5027		Cognitive	*BENEFICIAL*	Stanford-Binet IQ	Intervention vs minimal day care	48 months	<0.0001	1.55	
5027		Cognitive	*BENEFICIAL*	McCarthy General Cognitive Index	Intervention vs minimal day care	42 months	<0.0001	1.4	
5027	Burchinal, M	Cognitive	*BENEFICIAL*	Stanford-Binet IQ	Intervention vs minimal day care	36 months	<0.0001	1.72	
5027		Cognitive	*BENEFICIAL*	Bayley Mental Development Index	Intervention vs minimal day care	12 months	0.02	0.62	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5027		Cognitive	*BENEFICIAL*	Bayley Mental Development Index	Intervention vs minimal day care	18 months	<0.0001	1.33	
5027		Cognitive	beneficial	Bayley Mental Development Index	Intervention vs community	6 months	0.11	0.33	
5027		Cognitive	beneficial	Bayley Mental Development Index	Intervention vs minimal day care	6 months	0.06	0.5	
5036	Connor-Kuntz, FJ	Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Very Low Birth Weight < 1.5 kgms		0 days	0.005		-2.85
5036		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Admission to Neonatal Intensive Care Unit		0 days	0.01		-0.82
5036		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Low Birth Weight < 2 kgms		0 days	0.02		-0.98
5036		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Preterm Delivery < 37 weeks		0 days	0.04		-0.65
5036		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Preterm Birth < 31 weeks		0 days	0.03		-1.61
5036		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Low Birth weight < 2.5 kgms		0 days	0.003		-0.93
5036		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Low Birth weight < 2.5 kgms		0 days	0.003		-0.93
5039	Cullen, KJ	Parenting/ Parent Child Relationship	*BENEFICIAL*	Child's Total Involvement in Family	Girls	6 years	<0.01	>0.46	
5039		Parenting/ Parent Child Relationship	*BENEFICIAL*	Child's Positive View of Family Relationships	Girls	6 years	<0.001	>0.6	
5039		Parenting/ Parent Child Relationship	*BENEFICIAL*	Child's Negative View of Family Relationship	Boys	6 years	<0.01	>0.48	
5039		Parenting/ Parent Child Relationship	*BENEFICIAL*	Child's Total Involvement in Family		6 years	<0.01	0.33	
5039	Cullen, KJ	Parenting/ Parent Child Relationship	*BENEFICIAL*	Child's Negative View of Family Relationship		6 years	<0.01	>0.33	
5039		Parenting/ Parent Child Relationship	*BENEFICIAL*	Child's Positive View of Family Relationships		6 years	<0.05	>0.25	
5039		Parenting/ Parent Child Relationship	*HARMFUL*	Ask Parents to Spend Time Doing Things with Them: Mother's Rating	Girls	6 years	<0.05	<-0.35	
5039	Cullen, KJ	Physical Health/ Growth/ Health	*BENEFICIAL*	Body Mass Index > 25	Females	28 years	0.03	-0.86	
5039		Physical Health/ Growth/ Health	beneficial	Body Mass Index > 25		28 years	0.23		-0.34
5039		Physical Health/ Growth/ Health	*BENEFICIAL*	Body Mass Index > 25	Males	28 years	0.64		0.23
5039		Pregnancy/ Pregnancy Outcome	beneficial	Smoker		28 years	0.08		-0.6
5039		Pregnancy/ Pregnancy Outcome	beneficial	Smoker	Males	28 years	0.2		-0.58
5039		Pregnancy/ Pregnancy Outcome	beneficial	Smoker	Females	28 years	0.24		-0.5
5039	Cullen, KJ	School Performance	*BENEFICIAL*	University Degree		28 years	0.01		0.83
5039		School Performance	*BENEFICIAL*	University Degree	Females	28 years	0.016		1.08

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5039		School Performance	*BENEFICIAL*	Children's School Performance, Motor Integration & Physical Development	Girls	6 years	<0.05	>0.41	
5039		School Performance	*BENEFICIAL*	Children's school Performance, Spontaneous Speech	Girls	6 years	<0.05	>0.45	
5039	Cullen, KJ	School Performance	beneficial	School of Technology		28 years	0.08		-0.67
5039		School Performance	beneficial	University Degree	Males	28 years	0.29		0.53
5039		School Performance	harmful	School of Technology	Males	28 years	0.05		-1.14
5039		School Performance	harmful	School of Technology	Females	28 years	0.55		-0.31
5039		School Performance	*HARMFUL*	Children's School Performance, Visual Discrimination	Boys	6 years	<0.01	<-0.58	
5039		School Performance	*HARMFUL*	Children's School Performance, Visual Motor Coordination	Boys	6 years	<0.05	<-0.48	
5039		School Performance	*HARMFUL*	Children's School Performance, Total Basic Learning	Boys	6 years	<0.05	<-0.435	
5039		School Performance	*HARMFUL*	Goodenough's Draw-a-Man Test	Boys	6 years	<0.05	<-0.46	
5039	Cullen, KJ	Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Depressive Symptoms	Females	28 years	0.001		-1.29
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Neurotic Symptoms	Females	28 years	0.001		-2.69
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Early School Personality Questionnaire N Scale	Boys	6 years	<0.001	>0.62	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Fears Mother's Rating		6 years	<0.01	<-0.33	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Sleep Disorders Mother's Rating		6 years	<0.05	<-0.25	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Eating Problems: Mother's Rating		6 years	<0.001	<-0.42	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Afraid of Snakes: Mother's Rating		6 years	<0.05	<-0.05	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Afraid of Blood: Mother's Rating		6 years	<0.05	<-0.25	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Gulped Food at the Table: Mother's Rating		6 years	<0.05	<-0.25	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Talked Loudly: Mother Rating		6 years	<0.05	<-0.25	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Hit or Struck Other People: Mother Rating		6 years	<0.05	<-0.25	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Eating Problems: Mother's Rating	Boys	6 years	<0.05	<-0.36	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Afraid of Needles: Mother's Rating	Boys	6 years	<0.05	<-0.36	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Sleep Disorders Mother's Rating	Girls	6 years	<0.05	<-0.35	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Fears Mother's Rating	Girls	6 years	<0.01	<-0.46	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Eating Problems: Mother's Rating	Girls	6 years	<0.01	<-0.46	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Fidgety and Restless at the Table: Mother's Rating	Girls	6 years	<0.05	<-0.35	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Afraid of Snakes: Mother's Rating	Girls	6 years	<0.05	<-0.35	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Hit or Struck Other People: Mother Rating	Girls	6 years	<0.05	<-0.35	
5039		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Exaggerated of Told Untruths: Mother's Rating	Girls	6 years	<0.05	<-0.35	
5039		Temperament/ Behavior/ Symptoms	beneficial	Neurotic Symptoms	Males	28 years	0.49		-0.18
5039		Temperament/ Behavior/ Symptoms	beneficial	Sleep Disturbances	Males	28 years	0.27		-0.45
5039		Temperament/ Behavior/ Symptoms	beneficial	Sleep Disturbances	Females	28 years	0.06		-0.83
5039		Temperament/ Behavior/ Symptoms	harmful	Depressive Symptoms	Males	28 years	0.78		0.12
5039		Temperament/ Behavior/ Symptoms	*HARMFUL*	Early School Personality Questionnaire Q Scale	Boys	6 years	<0.05	>0.36	
5039		Temperament/ Behavior/ Symptoms	*HARMFUL*	Early School Personality Questionnaire D Scale	Boys	6 years	<0.001	>0.62	
5039		Temperament/ Behavior/ Symptoms	*HARMFUL*	Early School Personality Questionnaire B Scale	Boys	6 years	<0.01	<-0.48	
5039		Temperament/ Behavior/ Symptoms	*HARMFUL*	Late for School: Mother's Rating		6 years	<0.001	>0.42	
5039		Temperament/ Behavior/ Symptoms	*HARMFUL*	Late for School: Mother's Rating	Boys	6 years	<0.01	>0.48	
5040	Cunningham, CE	Mother's Mental Health	*BENEFICIAL*	Mother's Problem Solving Skills	Community vs Control	6.5 years	0.001	0.76	
5040		Mother's Mental Health	beneficial	Mother's Problem Solving Skills	Community vs Control	6 years	0.1	0.51	
5040		Mother's Mental Health	beneficial	Mother's Problem Solving Skills	Clinic Based vs Control	6.5 years	0.08	0.45	
5040		Mother's Mental Health	beneficial	Mother's Problem Solving Skills	Clinic Based vs Control	6 years	0.379	0.2	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5040		Mother's Mental Health	beneficial	Mother's Beck Depression Inventory		6.5 years	>0.05	-0.197	
5040		Mother's Mental Health	beneficial	Mother's Beck Depression Inventory	Clinic Based vs Control	6 years	>0.05	-0.426	
5040		Mother's Mental Health	beneficial	Mother's Beck Depression Inventory	Clinic Based vs Control	6.5 years	>0.05	-0.197	
5040	Cunningham, CE	Parenting/ Parent Child Relationship	*BENEFICIAL*	Home Situation Questionnaire Z Score	Community vs Control	6.5 years	0.03	0.52	
5040		Parenting/ Parent Child Relationship	beneficial	Home Situation Questionnaire Z Score	Community vs Control	6 years	0.13	0.35	
5040		Parenting/ Parent Child Relationship	beneficial	Home Situation Questionnaire Z Score	Clinic Based vs Control	6 years	0.777	0.064	
5040		Parenting/ Parent Child Relationship	beneficial	Parent Control Home Observation	Clinic Based vs Control	6 years	0.26	0.27	
5040		Parenting/ Parent Child Relationship	beneficial	Parent Control Home Observation	Clinic Based vs Control	6.5 years	0.416	0.18	
5040		Parenting/ Parent Child Relationship	harmful	Home Situation Questionnaire Z Score	Clinic Based vs Control	6.5 years	>0.05	-0.105	
5040		Parenting/ Parent Child Relationship	harmful	Parent Control Home Observation	Community vs Control	6 years	>0.05	-0.142	
5040		Parenting/ Parent Child Relationship	harmful	Parent Control Home Observation	Community vs Control	6.5 years	>0.05	-0.09	
5040	Cunningham, CE	Temperament/ Behavior/ Symptoms	beneficial	Total Negative Child Behavior Home Observation	Community vs Control	6 years	>0.05	-0.23	
5040		Temperament/ Behavior/ Symptoms	beneficial	Total Negative Child Behavior Home Observation	Clinic Based vs Control	6 years	>0.05	-0.018	
5040		Temperament/ Behavior/ Symptoms	harmful	Total Negative Child Behavior Home Observation	Community vs Control	6.5 years	0.61	0.117	
5088	Heins, HC	Pregnancy/ Pregnancy Outcome	beneficial	Live Birth	Risk score 10-19, black, LBW	0 days	>0.05		0.74
5088		Pregnancy/ Pregnancy Outcome	beneficial	Live Birth	Rick score 10-19, white, LBW	0 days	>0.05		0.15

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5088		Pregnancy/ Pregnancy Outcome	beneficial	Live Birth	Risk score 10-19, white, VLBW	0 days	>0.05		0.18
5088		Pregnancy/ Pregnancy Outcome	beneficial	Live Birth	All risk scores, black, LBW	0 days	>0.05		-0.22
5088		Pregnancy/ Pregnancy Outcome	beneficial	Live Birth	All risk scores, white, LBW	0 days	>0.05		0.18
5088		Pregnancy/ Pregnancy Outcome	beneficial	Live Birth	All risk scores, white VLBW	0 days	>0.05		0.31
5088	Heins, HC	Pregnancy/ Pregnancy Outcome	beneficial	Very Low Birth Weight < 1.5 kgms		0 days	>0.05		-0.14
5088		Pregnancy/ Pregnancy Outcome	beneficial	Low Birth Weight < 2.5 kgms		0 days	>0.05		-0.09
5088		Pregnancy/ Pregnancy Outcome	harmful	Live Birth	All risk scores, black, LBW	0 days	>0.05		-0.46
5088		Pregnancy/ Pregnancy Outcome	*HARMFUL*	Live Birth	Risk scores 10-19, black, VLBW	0 days	<0.05		-1.05
5103	Kitzmann, H	Child Maltreatment	*BENEFICIAL*	Beliefs Associated with Child Abuse, Bavolek Total Score		2 years	0.003	NA	
5103	Kitzmann, H	Cognitive	beneficial	Bayley Mental Development Index		2 years	>0.05	NA	
5103	Kitzmann, H	Mother's Education	beneficial	Mother in School		36 weeks Gestational Age	>0.05		0.18
5103	Kitzmann, H	Mother's Education	beneficial	Number of Months Worked in 1st year		1 year	>0.05	NA	
5103		Mother's Employment	beneficial	Mother Employed		36 weeks Gestational Age	0.06		0.69
5103		Mother's Employment	equal	Number of Months Worked in 2nd year		2 years	>0.5	NA	
5103	Kitzmann, H	Mother's Mental Health	*BENEFICIAL*	Mother's Rating of Mastery		2 years	<0.01	NA	
5103		Mother's Mental Health	beneficial	Mother's Depression		2 years	>0.05	NA	
5103		Mother's Mental Health	beneficial	Mother's Anxiety		2 years	>0.05	NA	
5103		Mother's Physical Health	*BENEFICIAL*	Subsequent Pregnancy within 2 years		2 years	<0.01		-0.51

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5103		Mother's Physical Health	*HARMFUL*	Subsequent Live Birth within 2 years		2 years	<0.01		-0.51
5103	Kitzmann, H	Mother's Public Assistance	beneficial	Number of Months on AFDC 2nd year		2 years	<0.1	NA	
5103		Mother's Public Assistance	beneficial	Number of Months on AFDC 1st year		1 year	>0.05	NA	
5103	Kitzmann, H	Mother's Social Support	*BENEFICIAL*	Mother Used Other Community Services		36 weeks Gestational Age	<0.01		0.59
5103	Kitzmann, H	Parenting/ Parent Child Relationship	*BENEFICIAL*	Emotional/Cognitive Stimulational HOME Score		2 years	<0.01	NA	
5103		Parenting/ Parent Child Relationship	*BENEFICIAL*	Maternal Teaching Behavior NCAST Score		2 years	0.03	NA	
5103		Parenting/ Parent Child Relationship	beneficial	Child Responsiveness NCAST Score		2 years	>0.05	NA	
5103		Parenting/ Parent Child Relationship	beneficial	Maternal Teaching Behavior NCAST Score		2 years	>0.05	NA	
5103	Kitzmann, H	Physical Health/ Growth/ Health	beneficial	Immunizations Up to Date at 2 years		2 years	>0.05		0.095
5103		Physical Health/ Growth/ Health	harmful	Number of Well-Child Visits		2 years	>0.05	NA	
5103	Kitzmann, H	Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Mean Arterial Blood Pressure During Labor	Pregnancy-induced Hypertension	0 days	0.006		NA
5103		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Pregnancy induced Hypertension (PIH)		36 weeks Gestational Age	0.009		-0.51
5103		Pregnancy/ Pregnancy Outcome	beneficial	Therapeutic Abortion		2 years	>0.05		-0.69
5103		Pregnancy/ Pregnancy Outcome	beneficial	Number of Gardnerella Infections		36 weeks Gestational Age	>0.05	NA	
5103		Pregnancy/ Pregnancy Outcome	beneficial	Number of Visits for Obstetrical Evaluation		36 weeks Gestational Age	>0.05	NA	
5103	Kitzmann, H	Pregnancy/ Pregnancy Outcome	beneficial	Diastolic Blood Pressure at Labor Admission		36 weeks Gestational Age	>0.05	NA	
5103		Pregnancy/ Pregnancy Outcome	beneficial	Systolic Blood Pressure (labor admission)		36 weeks Gestational Age	>0.05	NA	
5103		Pregnancy/ Pregnancy Outcome	beneficial	Spontaneous Preterm Delivery		0 days	>0.05		-0.22
5103		Pregnancy/ Pregnancy Outcome	beneficial	Preterm Delivery		0 days	>0.05		-0.22

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5103		Pregnancy/ Pregnancy Outcome	equal	Indicated Preterm Delivery		0 days	>0.5		0
5103		Pregnancy/ Pregnancy Outcome	equal	Intrauterine growth retardation		0 days	>0.5		0
5103		Pregnancy/ Pregnancy Outcome	equal	Gestational Age		0 days	>0.5	0	
5103		Pregnancy/ Pregnancy Outcome	harmful	Spontaneous Abortion		2 years	>0.05		0.4
5103		Pregnancy/ Pregnancy Outcome	harmful	Number of Sexually Transmitted Diseases		36 weeks Gestational Age	>0.05	NA	
5103		Pregnancy/ Pregnancy Outcome	harmful	Number of Hospitalizations During Pregnancy		36 weeks Gestational Age	>0.05	NA	
5103		Pregnancy/ Pregnancy Outcome	harmful	Number of Prenatal Visits		36 weeks Gestational Age	>0.05	NA	
5103		Pregnancy/ Pregnancy Outcome	harmful	Gestational Weight Gain		36 weeks Gestational Age	>0.05	NA	
5103		Pregnancy/ Pregnancy Outcome	harmful	Low Birth Weight		0 days	>0.05		0.095
5103		Pregnancy/ Pregnancy Outcome	harmful	Birth Weight		0 days	>0.05	NA	
5103	Kitzmann, H	Safety or Injuries	*BENEFICIAL*	Number of Days Hospitalized for Injuries/Injestions	Mothers w/ Fewer Psychological Resources	2 years	<0.001	NA	
5103		Safety or Injuries	*BENEFICIAL*	Total Number of Health Care Encounters for Injuries/Injestions	Mothers w/ Fewer Psychological Resources	2 years	0.003	NA	
5103		Safety or Injuries	*BENEFICIAL*	Number of Days Hospitalized for Injuries/Injestions		2 years	<0.001	NA	
5103		Safety or Injuries	*BENEFICIAL*	Number of Outpatient Visits for Injuries/Injestions		2 years	0.02	NA	
5103		Safety or Injuries	beneficial	Number of Hospitalizations for Injuries/Injestions		2 years	>0.05	NA	
5103		Safety or Injuries	beneficial	Number of Emergency Visits for Injuries/Injestions		2 years	>0.05	NA	
5103		Safety or Injuries	beneficial	Total Number of Health Care Encounters for Injuries/Injestions		2 years	0.05	NA	
5103	Kitzmann, H	Temperament/ Behavior/ Symptoms	beneficial	Behavior Problems Total Score		2 years	>0.05	NA	
5117	Johnson, DL	Cognitive	beneficial	CBI Intelligent		5.5 years	0.97	0.006	
5117		Cognitive	beneficial	CBI Intelligent	Males	5.5 years	0.2	0.32	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5117		Cognitive	beneficial	CBI Task Oriented	Males	5.5 years	0.28	0.25	
5117		Cognitive	harmful	CBI Intelligent	Females	5.5 years	0.28	-0.27	
5117		Cognitive	harmful	CBI Task Oriented		5.5 years	0.66	-0.08	
5117		Cognitive	harmful	CBI Task Oriented	Females	5.5 years	0.1	-0.44	
5117	Johnson, DL	School Performance	*BENEFICIAL*	AML Learning Difficulty	Males	5.5 years	0.03	-0.55	
5117	Johnson, DL	School Performance	beneficial	AML Learning Difficulty		5.5 years	0.39	0.15	
5117		School Performance	beneficial	AML Learning Difficulty	Females	5.5 years	0.88	-0.004	
5117	Johnson, DL	Temperament/ Behavior/ Symptoms	*BENEFICIAL*	CBI Dependency	Males	5.5 years	0.03	-0.54	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	CBI Considerate	Males	5.5 years	0.03	0.56	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	CBI Hostility		5.5 years	0.01	-0.46	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	CBI Hostility		5.5 years	0.01	-0.46	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	CBI Hostility	Males	5.5 years	0.01	-0.66	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Moody		5.5 years	0.004	-0.52	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Moody	Females	5.5 years	0.01	-0.64	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Unhappy	Males	5.5 years	0.038	-0.53	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Impulse	Females	5.5 years	0.03	-0.54	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Impulse	Males	5.5 years	0.025	-0.58	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Obstinate		5.5 years	0.007	-0.48	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Obstinate	Males	5.5 years	0.018	-0.61	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Disrupts		5.5 years	0.019	-0.42	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Disrupts	Males	5.5 years	0.038	-0.53	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Restless		5.5 years	0.008	-0.47	
5117	Johnson, DL	Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Restless	Males	5.5 years	0.007	-0.7	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Fights		5.5 years	0.01	-0.46	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	AML Fights	Males	5.5 years	0.008	-0.68	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Destructive BAI	Males	5.3 years	<0.01	-1.05	
5117		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	High Activity BAI	Males	5.3 years	<0.05	-0.55	
5117		Temperament/ Behavior/ Symptoms	beneficial	CBI Dependency		5.5 years	0.68	-0.07	
5117		Temperament/ Behavior/ Symptoms	beneficial	CBI Considerate		5.5 years	0.29	0.19	
5117		Temperament/ Behavior/ Symptoms	beneficial	CBI Hostility	Females	5.5 years	0.19	-0.33	
5117		Temperament/ Behavior/ Symptoms	beneficial	CBI Distractable		5.5 years	0.4	-0.15	
5117		Temperament/ Behavior/ Symptoms	beneficial	CBI Distractable	Females	5.5 years	0.8	-0.06	
5117		Temperament/ Behavior/ Symptoms	beneficial	CBI Distractable	Males	5.5 years	0.21	-0.31	
5117		Temperament/ Behavior/ Symptoms	beneficial	CBI Introversion		5.5 years	0.47	-0.13	
5117		Temperament/ Behavior/ Symptoms	beneficial	CBI Introversion	Females	5.5 years	0.68	-0.1	
5117		Temperament/ Behavior/ Symptoms	beneficial	CBI Introversion	Males	5.5 years	0.58	-0.14	
5117		Temperament/ Behavior/ Symptoms	beneficial	CBI Extroversion		5.5 years	0.11	-0.28	
5117		Temperament/ Behavior/ Symptoms	beneficial	CBI Extroversion	Females	5.5 years	0.05	-0.5	
5117	Johnson, DL	Temperament/ Behavior/ Symptoms	beneficial	CBI Extroversion	Males	5.5 years	0.84	-0.05	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Moody	Males	5.5 years	0.06	-0.47	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Feels Hurt		5.5 years	0.14	-0.26	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Feels Hurt	Females	5.5 years	0.6	-0.13	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Feels Hurt	Males	5.5 years	0.11	-0.4	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Becomes Sick		5.5 years	0.64	-0.08	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Becomes Sick	Males	5.5 years	0.4	-0.21	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Unhappy		5.5 years	0.21	-0.22	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Coaxes		5.5 years	0.59	-0.08	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Coaxes	Females	5.5 years	0.75	-0.08	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Coaxes	Males	5.5 years	0.78	-0.07	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Obstinate	Females	5.5 years	0.11	-0.4	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Disrupts	Females	5.5 years	0.08	-0.31	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Restless	Females	5.5 years	0.15	-0.36	
5117		Temperament/ Behavior/ Symptoms	beneficial	AML Fights	Females	5.5 years	>0.05	-0.3	
5117		Temperament/ Behavior/ Symptoms	beneficial	Protective Lies BAI	Males	5.3 years	>0.05	-0.17	
5117	Johnson, DL	Temperament/ Behavior/ Symptoms	beneficial	Resistant BAI	Males	5.3 years	0.34	0.24	
5117		Temperament/ Behavior/ Symptoms	beneficial	Negative Attention-Seeking	Males	5.3 years	>0.05	-0.32	
5117		Temperament/ Behavior/ Symptoms	beneficial	Jealous of Siblings BAI	Males	5.3 years	>0.05	-0.21	
5117		Temperament/ Behavior/ Symptoms	beneficial	Extraversion BAI	Males	5.3 years	0.38	0.22	
5117		Temperament/ Behavior/ Symptoms	beneficial	Destructive BAI	Females	5.3 years	>0.05	-0.18	
5117		Temperament/ Behavior/ Symptoms	beneficial	Negative Attention-Seeking	Females	5.3 years	0.46	0.19	
5117		Temperament/ Behavior/ Symptoms	beneficial	Temper Problems BAI	Females	5.3 years	>0.05	-0.27	
5117		Temperament/ Behavior/ Symptoms	beneficial	Dependent BAI	Females	5.3 years	>0.05	-0.27	
5117		Temperament/ Behavior/ Symptoms	beneficial	Emotional Sensitivity BAI	Females	5.3 years	>0.05	-0.41	
5117		Temperament/ Behavior/ Symptoms	beneficial	Somatic Difficulties BAI	Females	5.3 years	>0.05	-0.18	
5117		Temperament/ Behavior/ Symptoms	harmful	CBI Dependency	Females	5.5 years	0.22	0.31	
5117		Temperament/ Behavior/ Symptoms	harmful	CBI Considerate	Females	5.5 years	0.68	-0.1	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5117		Temperament/ Behavior/ Symptoms	harmful	AML Becomes Sick	Females	5.5 years	0.81	0.06	
5117		Temperament/ Behavior/ Symptoms	harmful	AML Unhappy	Females	5.5 years	0.31	0.25	
5117		Temperament/ Behavior/ Symptoms	harmful	Selfish with Siblings BAI	Males	5.3 years	0.76	0.07	
5117		Temperament/ Behavior/ Symptoms	harmful	Temper Problems BAI	Males	5.3 years	0.96	0.014	
5117	Johnson, DL	Temperament/ Behavior/ Symptoms	harmful	Dependent BAI	Males	5.3 years	0.98	0.007	
5117		Temperament/ Behavior/ Symptoms	harmful	Emotional Sensitivity BAI	Males	5.3 years	0.15	0.61	
5117		Temperament/ Behavior/ Symptoms	harmful	Somiatic Difficulties BAI	Males	5.3 years	0.31	0.26	
5117		Temperament/ Behavior/ Symptoms	harmful	Protective Lies BAI		5.3 years	0.79	0.07	
5117		Temperament/ Behavior/ Symptoms	harmful	Selfish with Siblings BAI	Females	5.3 years	0.22	0.32	
5117		Temperament/ Behavior/ Symptoms	harmful	Resistant BAI	Females	5.3 years	0.71	0.1	
5117		Temperament/ Behavior/ Symptoms	harmful	Jealous of Siblings BAI	Females	5.3 years	0.6	0.14	
5117		Temperament/ Behavior/ Symptoms	harmful	High Activity BAI	Females	5.3 years	0.1	0.42	
5117		Temperament/ Behavior/ Symptoms	*HARMFUL*	Extraversion BAI	Females	5.3 years	<0.0001	1.18	
5139	Munjanja, SP	Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Preterm Delivery < 37 weeks		0 days	<0.01		-0.15
5139		Pregnancy/ Pregnancy Outcome	beneficial	Induction of Labor		0 days	0.35		-0.09
5139		Pregnancy/ Pregnancy Outcome	beneficial	Low Birth Weight < 2.5 kgms		0 days	0.49		-0.04
5139		Pregnancy/ Pregnancy Outcome	beneficial	Maternal Mortality		0 days	0.69		-0.24
5139		Pregnancy/ Pregnancy Outcome	harmful	Labor Referrals		0 days	0.26		0.05
5139		Pregnancy/ Pregnancy Outcome	harmful	Emergency Cesarian Section		0 days	0.7		0.08
5139		Pregnancy/ Pregnancy Outcome	harmful	Length of Gestation > 42 weeks		0 days	0.15		0.1
5139	Munjanja, SP	Pregnancy/ Pregnancy Outcome	harmful	Small for Gestational Age		0 days	0.34		0.09
5150	O'Sullivan, AL	Mother's Education	beneficial	Mother Return to School		18 months	0.92		0.03
5150		Mother's Education	beneficial	Mother Return to School		18 months	0.19		0.37
5150	O'Sullivan, AL	Mother's Physical Health	*BENEFICIAL*	Repeat Pregnancy	Clinic dropouts	18 months	0.02		-0.98
5150		Mother's Physical Health	*BENEFICIAL*	Repeat Pregnancy		18 months	0.003		-1.06
5150		Mother's Physical Health	beneficial	Repeat Pregnancy	Continued clinic attenders	18 months	0.49		-0.55

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5150	O'Sullivan, AL	Physical Health/ Growth/ Health	*BENEFICIAL*	Full Immunization		18 months	0.01		0.8
5150		Physical Health/ Growth/ Health	beneficial	Full Immunization	Continued clinic attenders	18 months	0.06		0.98
5150		Physical Health/ Growth/ Health	harmful	Full Immunization	Clinic Dropouts	18 months	0.83		-0.65
5150		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Attendence at Clinic		2 months	0.001		1.22
5150		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Attendence at Clinic		6 months	<0.0001		1.06
5150		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Attendence at Clinic		18 months	0.0001		1.12
5150	O'Sullivan, AL	Safety or Injuries	*BENEFICIAL*	One or More Emergency Room Visits	Continued clinic attenders	18 months	0.03		-2.38
5150		Safety or Injuries	beneficial	One or More Emergency Room Visits		18 months	0.1		-0.06
5150		Safety or Injuries	beneficial	One or More Emergency Room Visits	Dropouts	18 months	0.2		-0.5
5185	Scarr, S	Cognitive	beneficial	Stanford-Binet IQ		45 months	0.29	0.206	
5185	Scarr, S	Parenting/ Parent Child Relationship	*BENEFICIAL*	Performance on Maternal Teaching Task-Child Sorts by Color or Kind		45 months	>0.05	0.39	
5185		Parenting/ Parent Child Relationship	harmful	Performance on Mother's Teaching Task-Child's Positive Attitude		45 months	>0.05	-0.22	
5185	Scarr, S	School Performance	equal	Mother-Child Home Program Achievement Test		45 months	>0.5	0	
5185	Scarr, S	Social Relations	*BENEFICIAL*	Cain-Levine Social Competency Scale Communication Skills		45 months	0.018	0.47	
5185		Social Relations	beneficial	Cain-Levine Social Competency Scale Communication Skills		45 months	0.76	0.06	
5185	Scarr, S	Temperament/ Behavior/ Symptoms	beneficial	Childhood Personality Scale- Apathy		45 months	>0.05	-0.25	
5185		Temperament/ Behavior/ Symptoms	beneficial	Delay of Gratification		45 months	0.23	0.23	
5185		Temperament/ Behavior/ Symptoms	equal	Childhood Personality Scale- Introversion		45 months	>0.5	0	
5185		Temperament/ Behavior/ Symptoms	equal	Childhood Personality Scale- Hyperactivity		45 months	>0.5	0	
5185		Temperament/ Behavior/ Symptoms	equal	Childhood Personality Scale- Expressiveness		45 months	>0.5	0	
5185		Temperament/ Behavior/ Symptoms	equal	Childhood Personality Scale- Attention		45 months	>0.5	0	
5185		Temperament/ Behavior/ Symptoms	equal	Infant Behavior Record- Deviance		45 months	>0.5	0	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

5185		Temperament/ Behavior/ Symptoms	harmful	Infant Behavior Rating- Social Responsiveness		45 months	>0.05	-0.23
5185	Scarr, S	Temperament/ Behavior/ Symptoms	harmful	Infant Behavior Record- Coordination		45 months	>0.05	-0.15
5185		Temperament/ Behavior/ Symptoms	harmful	Infant Behavior Rating- Attention		45 months	>0.05	-0.25
5185		Temperament/ Behavior/ Symptoms	harmful	Infant Behavior Record- Activity		45 months	>0.05	-0.11
5188	Schweinhart, LJ	Cognitive	*BENEFICIAL*	Stanford-Binet IQ		4 years	<0.0001	1.91
5188		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		5 years	<0.0001	1.28
5188		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		6 years	<0.01	0.82
5188		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		7 years	0.00018	0.73
5188		Cognitive	*BENEFICIAL*	Wechsler Intelligence Scale for Children		10 years	0.0018	0.748
5188		Cognitive	beneficial	Stanford-Binet IQ		8 years	0.066	0.35
5188	Schweinhart, LJ	Legal Offenses	beneficial	Delinquency Scale	High Scope vs Nursery	15 years	>0.05	-0.19
5188		Legal Offenses	beneficial	Personal Violence Subscale	High Scope vs Nursery	15 years	>0.05	-0.15
5188		Legal Offenses	beneficial	Stealing Subscale	High Scope vs Nursery	15 years	>0.05	-0.16
5188		Legal Offenses	beneficial	Drug Abuse Substance	High Scope vs Nursery	15 years	>0.05	-0.29
5188		Legal Offenses	harmful	Status Offense Subscale	High Scope vs Nursery	15 years	>0.05	0.2
5188		Legal Offenses	harmful	Delinquency Scale	Distar vs Nursery	15 years	>0.05	0.51
5188		Legal Offenses	harmful	Personal Violence Subscale	Distar vs Nursery	15 years	>0.05	0.414
5188		Legal Offenses	harmful	Property Damage Subscale	Distar vs Nursery	15 years	>0.05	0.6
5188		Legal Offenses	harmful	Stealing Subscale	Distar vs Nursery	15 years	>0.05	0.23
5188		Legal Offenses	harmful	Drug Abuse Substance	Distar vs Nursery	15 years	>0.05	0.58

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5188		Legal Offenses	*HARMFUL*	Status Offense Subscale	Distar vs Nursery	15 years	<0.01	0.807	
5188	Schweinhart, LJ	School Performance	beneficial	School Behavior and Attitudes Learning Process Subscale	Distar vs Nursery	15 years	>0.5	0.09	
5188		School Performance	harmful	School	Behavior and Attitudes Schooling Total Scale	15 years	0.6	-0.18	
5188		School Performance	harmful	School Behavior and Attitudes Teacher Subscales	Distar vs Nursery	15 years	0.36	-0.31	
5188	Schweinhart, LJ	Temperament/ Behavior/ Symptoms	beneficial	Perceived Locus of Control Bialer Scale	Distar vs Nursery	15 years	>0.05	0.26	
5188		Temperament/ Behavior/ Symptoms	harmful	Self-Esteem Rosenberg Scale	Distar vs Nursery	15 years	>0.05	-0.375	
5234	Strayhorn, JM	Parenting/ Parent Child Relationship	*BENEFICIAL*	Parent Behavior in Play (Video)		4.1 years	<0.0001	-1.41	
5234		Parenting/ Parent Child Relationship	beneficial	Parent Practices Scale		4.1 years	0.1	-0.35	
5234		Parenting/ Parent Child Relationship	beneficial	Commands Self Report		4.1 years	0.35	-0.47	
5234		Parenting/ Parent Child Relationship	beneficial	Parent Practices Scale		5.2 years	0.14	-0.34	
5234	Strayhorn, JM	School Performance	beneficial	California Achievement Test Reading		5.2 years	0.31	0.36	
5234	Strayhorn, JM	Speech or Language	harmful	Child Verbal Ability		4.1 years	0.29	0.22	
5234	Strayhorn, JM	Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Child Behavior in Play (Video)		4.1 years	0.008	-0.58	
5234		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Parent Behar Anxious		4.1 years	0.01	-0.53	
5234		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Parent Behar Hyperactive		4.1 years	0.008	-0.059	
5234		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Frequency of Behaviors for Preschoolers		4.1 years	0.02	-0.51	
5234	Strayhorn, JM	Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Parent Responses to ADHD Symptoms DSM- III R		4.1 years	0.009	-0.56	
5234		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Teacher Behar Composite		5.2 years	0.018	-0.68	
5234		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Teacher Behar Hyperactive		5.2 years	<0.01	-0.77	
5234		Temperament/ Behavior/ Symptoms	beneficial	Parent Behar Hostile		4.1 years	0.17	-0.29	
5234		Temperament/ Behavior/ Symptoms	beneficial	Depression Items from Achenbach		4.1 years	0.63	-0.1	
5234		Temperament/ Behavior/ Symptoms	beneficial	Depression Items from Achenbach		4.1 years	0.49	0.18	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5234		Temperament/ Behavior/ Symptoms	beneficial	Teacher Behar Anxious		5.2 years	0.07	-0.51	
5234		Temperament/ Behavior/ Symptoms	beneficial	Teacher Behar Hostile		5.2 years	0.09	0.48	
5234		Temperament/ Behavior/ Symptoms	beneficial	Parent Behar Composite		5.2 years	0.05	-0.1	
5234		Temperament/ Behavior/ Symptoms	beneficial	Child Depression Parent Rating		5.2 years	0.57	-0.13	
5234		Temperament/ Behavior/ Symptoms	harmful	Parent Responses Oppositional Symptoms DSM III R		4.1 years	0.68	0.09	
5234		Temperament/ Behavior/ Symptoms	harmful	Teacher Behar Hostile		4.1 years	0.57	0.14	
5234		Temperament/ Behavior/ Symptoms	harmful	Teacher Behar Anxious		4.1 years	0.08	0.44	
5255	Tremblay, RE	Legal Offenses	*BENEFICIAL*	Self-Reported Delinquency, 10-15 years old		15 years	<0.05	NA	
5255		Legal Offenses	*BENEFICIAL*	Theft in the Home Child Report		9 years	0.02		-1.4
5255	Tremblay, PE	Legal Offenses	harmful	Theft in the Home Chid Report		8 Years	0.8		0.29
5255	Tremblay, PE	Parenting/Parent Child Relationship	beneficial	Perception of Parental Supervision		15 Years	>0.05	N/A	
5255		Parenting/Parent Child Relationship	harmful	Perception of Punishment by Parents		15 Years	>0.05	N/A	
5255	Tremblay, PE	School Performance	*BENEFICIAL*	Maintained Age Appropriate Grade Level 10, 12, 15 years old		15 Years	<0.05		N/A
5255		School Performance	*BENEFICIAL*	Held Back in School or Special Class and Highly Disruptive Teacher Rating		10 Years	0.02		-0.93
5255		School Performance	beneficial	Held Back in School or Special Class		10 Years	0.19		-0.6
5255	Tremblay, PE	Temperament/Behavior/Symptoms	*BENEFICIAL*	Fighting in the Home Child Report		9 Years	0.03		-0.82
5255		Temperament/ Behavior/ Symptoms	*BENEFICIAL*	Fighting outside the Home Child Report		9 years	0.02		-0.86
5255		Temperament/ Behavior/ Symptoms	beneficial	Teacher Rated Disruptiveness, 10-15 years old		15 years	>0.05	NA	
5255		Temperament/ Behavior/ Symptoms	beneficial	Fighting outside the Home Child Report		8 years	0.16		-0.62
5255		Temperament/ Behavior/ Symptoms	harmful	Juvenile Court Records		15 years	0.68		0.26
5255		Temperament/ Behavior/ Symptoms	harmful	Fighting in the Home Child Report		8 years	0.81		0.08
5255		Temperament/ Behavior/ Symptoms	harmful	Prosocial Mother's Rating		8 years	0.42	-0.15	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5255		Temperament/ Behavior/ Symptoms	harmful	Prosocial Mother's Rating		7 years	0.16	-0.28	
5255		Temperament/ Behavior/ Symptoms	harmful	Inattentive Mother's Rating		9 years	0.2	0.25	
5255		Temperament/ Behavior/ Symptoms	harmful	Inattentive Mother's Rating		8 years	0.13	0.29	
5255		Temperament/ Behavior/ Symptoms	harmful	Disruptive Behavior Mother's Rating		9 years	0.51	0.13	
5255		Temperament/ Behavior/ Symptoms	harmful	Disruptive Behavior Mother's Rating		8 years	0.59	0.1	
5255		Temperament/ Behavior/ Symptoms	*HARMFUL*	Prosocial Mother's Rating		9 years	0.04	-0.41	
5255		Temperament/ Behavior/ Symptoms	*HARMFUL*	Inattentive Mother's Rating		7 years	0.03	0.43	
5255		Temperament/ Behavior/ Symptoms	*HARMFUL*	Fights Mother's Rating		8 years	0.02	0.44	
5255		Temperament/ Behavior/ Symptoms	*HARMFUL*	Fights Mother's Rating		7 years	0.004	0.57	
5255		Temperament/ Behavior/ Symptoms	*HARMFUL*	Disruptive Behavior Mother's Rating		7 years	0.02	0.46	
5275	Moore, F	Physical Health/ Growth/ Health	beneficial	Kept Postpartum Appointments		10 days	>0.5		0.21
5288	Ramey, CT	Cognitive	*BENEFICIAL*	McCarthy Scales General Cognitive Index		3.5 years	0.0001	0.69	
5288		Cognitive	*BENEFICIAL*	McCarthy Scales Perceptual Performance Scale		3.5 years	0.006	0.49	
5288		Cognitive	*BENEFICIAL*	McCarthy Scales Quantitative Scale		3.5 years	0.0005	0.62	
5288		Cognitive	*BENEFICIAL*	McCarthy Scales Verbal Scale		3.5 years	0.0005	0.62	
5288		Cognitive	*BENEFICIAL*	McCarthy Scales General Cognitive Index		4.5 year	0.0003	0.65	
5288		Cognitive	*BENEFICIAL*	McCarthy Scales Memory Scale		4.5 year	0.007	0.48	
5288	Ramey, CT	Cognitive	*BENEFICIAL*	McCarthy Scales Perceptual Performance Scale		4.5 year	0.001	0.58	
5288		Cognitive	*BENEFICIAL*	McCarthy Quantitative Scale		4.5 year	0.003	0.52	
5288		Cognitive	*BENEFICIAL*	McCarthy Verbal Scale Index		4.5 year	0.0005	0.62	
5288		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		48 months	<0.001	0.82	
5288		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		36 months	<0.001	1.01	
5288		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		24 months	<0.001	1.06	
5288		Cognitive	*BENEFICIAL*	Stanford-Binet IQ		24 months	<0.001	1.06	
5288		Cognitive	*BENEFICIAL*	Bayley Mental Development Index		18 months	<0.001	1.15	
5288		Cognitive	*BENEFICIAL*	Bayley Mental Development Index		12 months	<0.01	0.46	
5288		Cognitive	*BENEFICIAL*	Bayley Mental Development Index		6 months	<0.05	0.38	

TABLE 6B. OUTCOME FINDINGS FOR TRIALS WITH 4-STAR QUALITY DESIGNS, cont'd

Trial	Lead Author First Paper	Category	Direction	Measure Name	Subgroup	Age	p-value	Effect Size	Log Odds Ratio
5288		Cognitive	beneficial	McCarthy Scales Memory Scale		3.5 years	0.05	0.35	
5288		Cognitive	*BENEFICIAL*	McCarthy Scales Motor Scale		4.5 year	0.017	0.42	
5288		Motor Development	beneficial	McCarthy Scales Motor Scale		3.5 years	0.11	0.28	
5431	Klaus, MH	Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	Duration of Labor		0 days	<0.001	-1.45	
5431		Pregnancy/ Pregnancy Outcome	*BENEFICIAL*	No Perinatal Problems		0 days	<0.001		0.31
5431		Pregnancy/ Pregnancy Outcome	beneficial	Duration of Labor	Single, cervical dilation = 3 cm	0 days	>0.05	-1.26	
5431		Pregnancy/ Pregnancy Outcome	beneficial	Duration of Labor	Single, cervical dilation = 2 cm	0 days	>0.05	-1.41	
5431		Pregnancy/ Pregnancy Outcome	beneficial	Duration of Labor	Single, cervical dilation = 1 cm	0 days >0.05	-1.23		
5431	Klaus, MH	Pregnancy/ Pregnancy Outcome	beneficial	Duration of Labor	Living Together, cervical dilation = 3 cm	0 days	>0.05	-2.33	
5431		Pregnancy/ Pregnancy Outcome	beneficial	Duration of Labor	Living Together, cervical dilation = 2 cm	0 days	>0.05	-1.43	

B. SUMMARY OF KEY RESEARCH STUDIES:

AN EVIDENCE-BASED LITERATURE REVIEW REGARDING OUTCOMES IN PSYCHOSOCIAL PREVENTION AND EARLY INTERVENTION IN YOUNG CHILDREN

Prepared for Invest in Kids
Toronto, Ontario
By Prevention Technologies, LLC
Patricia J. Mrazek, M.S.W., Ph.D. and C. Hendricks Brown, Ph.D.
Bethesda, Maryland

March 26, 1999

KEY TO THE CODES IN THE ANNOTATION:

All papers have been given a paper identification number and a trial number. The first number that is listed is the paper number. The second number that is listed is in parentheses and is the trial number. Some trials have been reported in multiple papers. In these cases, each paper will have its own number but the papers will share a trial number, e.g. 1 (5131) and 24 (5131).

auth: All authors are listed.

project title: Only some papers identify the trial by a project name.

country: This is the country where the trial took place.

N: This is the sample size at the point in time when the targeted population has been selected and randomization occurs. The number is sometimes larger than the number who actually received the intervention, and almost always larger than the sample size at follow-up evaluation.

method: This is a broad designation regarding design. (Specific quality of design measurements are included in the Final Report.)

population: This is the subject pool that was targeted. If the author specified inclusion and exclusion criteria, these are stated.

inter. type: This is the type of intervention that is targeted toward a specific population pool with various kinds of risk. The four intervention types are universal, selective, and indicated preventive intervention and treatment intervention. (A full explanation is included in the Final Report).

intervention: The experimental and comparison intervention(s) are described.

outcomes: Evidence from the trial is summarized from the author's perspective. Cost-benefit data are provided when available.

SCIENTIFIC PAPERS

This section includes the 215 relevant scientific papers which were identified in this review. There were occasions where multiple papers referred to the same trial, i.e., one paper examining short-term effects and a second paper examining longer term effects. Occasionally one paper reported the design and results of more than one trial. Thus, the number of trials described in this review, 165, is different from the number of papers in this section. Also, this section is complete -- it has embedded within it all of the scientific papers on the 5-Star and 4-Star designs, described in the previous report.

TRIAL NO.: 1 (5131)

auth: The Infant Health and Development Program
title: Enhancing the outcomes of low-birth-weight, premature infants: A multisite, randomized trial.
year: 1990
ref: JAMA
vol: 263(22)
pps: 3035-3042
project title: Infant Health and Development Program
country: USA
N: 985
method: RCT
population: See other annotations.
inter. type: Selective preventive intervention.
intervention: See other annotations.
outcomes: At 36 month follow-up (age corrected for prematurity), the experimental group had significantly higher mean IQ scores than the follow-up group (mean difference in the heavier group was 13.2 and in the lighter group 6.6), significantly fewer maternally reported behavior problems, and a small, but statistically significant, increase in maternally reported minor illnesses for the lighter-birth-weight group only, with no difference in serious health conditions.

TRIAL NO.: 5 (5005)

auth: Achenbach, T
auth: Phares, V
auth: Howell, C
auth: Rauh, V
auth: Nurcombe, B
title: Seven year outcome of the Vermont Intervention Program for Low-Birthweight Infants
year: 1990
ref: Child Development
vol: 61(6)
pps: 1672-1681
project title: Vermont Intervention Program for Low-Birthweight Infants
country: USA
N: 86
method: RCT
population: The subjects were infants weighing <2,250 grams who were free of congenital anomalies and severe neurological defects who were born in the Medical Center Hospital of Vermont between April 1980 and December 1981. The infants were randomly assigned by coin toss to an experimental or control group. An additional comparison group of infants >2,800 grams and > 37 weeks gestation was recruited from babies born after each control baby.
inter. type: Selective preventive intervention.
intervention: The Mother-Infant Transaction Program, provided by a neonatal intensive care nurse, aimed to enhance the mother's skill and confidence in caring for her low birth weight baby. There were seven daily sessions during the week prior to the infant's discharge from the hospital and four home sessions at 3, 14, 30, and 90 days after discharge.
outcomes: At seven year follow-up, the low birthweight babies in the experimental group had better cognitive scores than the no-treatment control children and had scores very similar to the scores of the normal birthweight children.

TRIAL NO.: 6 (5006)

auth: Als, H
auth: Lawhon, G
auth: Duffy, FH
auth: McAnulty, GB
auth: Gibes-Grossman, R
auth: Blickman, JG.
title: Individualized developmental care for the very low-birth-weight preterm infant: Medical and neurofunctional effects
year: 1994
ref: JAMA
vol: 272(11)
pps: 853-858
country: USA
N: 38
method: RCT
population: Subjects were newborns, consecutively admitted in a 21 month period to a newborn intensive care unit, whose birth weight was less than 1250 grams, who were between 24 and 30 weeks of gestational age at birth, whose mechanical ventilation started within the first 3 hours after birth and lasted longer than 24 hours in the fist 48 hours, who were free of known congenital abnormalities and known fetal exposure to drugs of addiction, and whose families spoke some English and had telephone access.
inter. type: Selective preventive intervention.
intervention: The experimental group received caregiving by nurses specifically trained in individualized developmental care, observation and documentation of the infants' behavior, developmental care recommendations and ongoing clinical support for the nurses and parents, and the availability of special caregiving accessories.
outcomes: The infants in the experimental group had a significantly shorter duration of mechanical ventilation and oxygen support, earlier oral feeding, improved daily weight gain, shorter hospital stays, fewer medical complications, and reduced hospital charges.

TRIAL NO.: 7 (500)

auth: Anisfeld, E
auth: Casper, V
auth: Nozyce, M
auth: Cunningham, N
title: Does infant carrying promote attachment? An experimental study of the effects of increased physical contact on the development of attachment
year: 1990
ref: Child Development
vol: 61(5)
pps: 1617-1627
country: USA
N: 49
method: RCT
population: The subjects were women who delivered their babies in a large inner-city hospital. They came from a low-income clinic that was predominantly Hispanic and black. Subjects had to be between 18 and 37 years of age, with a parity from 1 through 4. They had to have received prenatal care, have healthy infants, be enrolled in a pediatric practice for medical follow-up of the infants, planning not to return to work or school for at least 3 months after delivery, have access to a telephone, and speak conversational English. Mothers who had already decided to use a soft carrier for their infant and those who would not consider using one were eliminated.
inter. type: Selective preventive intervention.
intervention: Mothers in the experimental group were given soft baby carriers to use with their newborns (to increase physical contact); controls received infant seats.
outcomes: At 13 months, the experimental infants more securely attached to their mothers than the control infants, and experimental mothers' responsivity to their infants was increased.

TRIAL NO.: 228 (5228)

auth: Arnold, JE
auth: Levine, AG
auth: Patterson, GR
title: Changes in sibling behavior following family intervention
year: 1975
ref: Journal of Consulting and Clinical Psychology
vol: 43(5)
pps: 683-688
country: USA
N: 55 children in 27 families
method: time-series design
population: The subjects, 3 years of age and older, had siblings with severe conduct disorders and their families had received treatment in regards to those siblings. The subjects and the problem children showed no significant differences at baseline.
inter. type: Indicated preventive intervention
intervention: The families were examined to determine whether the child management techniques taught to the parents in the treatment of the older siblings later resulted in reductions in deviant behavior for the problem children's siblings.
outcomes: At the end of the treatment for the problem children, the siblings showed reduction in deviant behavior. These effects were maintained through the 6 month follow-up.

TRIAL NO.: 401 (5401)

auth: Arnold, DS
auth: Lonigan, CJ
auth: Whitehurst, GJ
auth: Epstein, JN
year: 1994
title: Accelerating language development through picture book reading: Replication and extension to a videotape training format
ref: Journal of Educational Psychology
vol: 86
pps: 235-242
country: USA
N: 64
method: RCT
population: Subjects were mother-child pairs who were recruited through advertisements in local newspapers. The children ranged in age from 24 to 34 months. All children when tested had average or above average expressive and receptive language skills. The families were middle to upper SES.
inter. type: Universal preventive intervention
intervention: The first experimental group received direct training to help parents accelerate their child's language development. The training was provided by graduate students who were trained in the dialogic reading method. The second experimental group received video training with no direct instruction. Both of these interventions occurred over a 4 week period in a laboratory. All 3 groups of parents, including the controls, were provided with audiotapes and asked to tape record at least 4 reading sessions with their child per week. The 2 experimental groups were given written instructions regarding dialogic reading techniques.

outcomes: At the end of the intervention period, there were limited effects in the direct training group (unlike the results in Whitehurst et al. 1988). However, children in the video group exhibited superior language abilities on standardized outcome measures compared to control children. The videotape method is cost-effective, and it provides a standardized means of delivering the intervention.

TRIAL NO.: 8 (5008)

auth: Barkauskas, VH
title: Effectiveness of public health nurse home visits to primarous mothers and their infants
year: 1983
ref: American Journal of Public Health
vol: 73(5)
pps: 573-580
country: USA
N: 110
method: 2 groups, random selection of each but no random assignment
population: Subjects were mother-infant pairs who delivered at the county hospital, first live birth for mother, infant 2,000 grams or larger at birth, infant living with mother, no hospitalization of infant or mother since delivery, and no separation longer than 14 days of mother and infant since delivery. Mothers were characteristically in their late teens, unmarried, and not high school graduates. Infants had no congenital anomalies noted at birth.
inter. type: Universal preventive intervention
intervention: Home visits and telephone contacts were provided by public health nurses. The intervention was the routine service provided by the public health nursing agency. The comparison group did not receive these services.
outcomes: There were no significant differences between the home-visited and the not-home-visited mother-infant pairs for the majority of health outcome variables.

TRIAL NO.: 241 (5241)

auth: Barnard, KE
auth: Hammond, MA
auth: Sumner, GA
auth: Kang, R
auth: Johnson-Crowley, N
auth: Snyder, C
auth: Spietz, A
auth: Blackburn, S
auth: Brandt, P
auth: Magyary, D
title: Helping parents with preterm infants: Field test of a protocol
year: 1987
ref: Early Child Development and Care
vol: 27(2)
pps: 256-290
country: USA
N: 76
method: no comparison group; field test of protocol
population: The subjects were mothers and their premature or low birth weight infants. The birth weight was under 2500 grams or the gestational age was less than 37 weeks.
inter. type: Selective preventive intervention.
intervention: Nurses made a maximum of eight home visits to each family, with the first visit occurring 1 week post-discharge. The nurses followed a specific protocol for each visit.
outcomes: Over 7 months, the mothers and infants showed stable or improving patterns of interaction.

TRIAL NO.: 242 (5242)

auth: Barnard, KE
auth: Magyary, D
auth: Sumner, GA
auth: Booth, CL
auth: Mitchell, SK
auth: Spieker, S
title: Prevention of parenting alterations for women with low social support
year: 1988
ref: Psychiatry
vol: 51(3)
pp: 248-253
country: USA
N: 147
method: RCT
population: Women were recruited from public health clinics if they were 22 weeks pregnant or less and had inadequate supportive networks. They tended also to reside in crowded living conditions and to move frequently, to have chaotic family lives, to experience many crises, accidents and illnesses, to have high levels of marital or partner discord, and to have difficulty in obtaining medical care.
inter. type: Selective preventive intervention
intervention: The experimental group received the Mental Health Model of intervention, focusing on a therapeutic relationship and conducted by project staff nurses. The comparison group received the Resource Utilization Model, focusing on the provision of information and the promotion of healthy lifestyle, conducted by staff nurses of the public health department. Each woman in both groups received home visits throughout pregnancy and the first year of the infant's life.
outcomes: At the end of the year of intervention, attrition was much greater in the comparison group. The experimental group had more nurse contact, achieved more of the maternal and parenting treatment goals, and had less depression. There were few differences between the 2 groups on child outcomes, and security of attachment was low in both groups.

TRIAL NO.: 240 (5240)

auth: Barnard, KE
auth: Booth, CL
auth: Mitchell, SK
auth: Telzrow, RW
title: Newborn nursing models: A test of early intervention to high-risk infants and families
year: 1988
ref: In E Hibbs (Ed.), Children and Families: Studies in Prevention and Intervention
city: Madison, CT
pub: International Universities Press
pp: 63-81
country: USA
N: 185
method: comparison groups, status of randomization unclear
population: Subjects were low-income, high-risk pregnant women who had been identified in a county health department and enrolled after the delivery of their infant.
inter. type: Selective preventive intervention.
intervention: Three different models of nursing approaches were used. Total contact time varied from 1 to 8 hours over 3 months.
outcomes: There were no significant group treatment effects.

TRIAL NO.: 290 (5009)

auth: Barnett, WS
auth: Escobar, CM
title: Economic costs and benefits of early intervention
ref: In SJ Meisels and JP Shonkoff (Eds.), Handbook of Early Childhood Intervention
year: 1990
city: New York
pub: Cambridge University Press
pps: 560-582
country: USA
outcomes: The paper reviews concepts and data, especially from the Perry Preschool Project. In cost-benefit analysis, monetary values are estimated for both the resources used and the effects produced. In cost-effectiveness analysis, programs are evaluated on the basis of program costs and effects alone (without monetary value being attached to effects). Benefits through age 19 of the Perry Preschool Project included child care, school cost savings, earnings increase, crime reduction, and welfare reduction. Benefits beyond age 19 included college costs, earnings increase, crime reduction, and welfare reduction. The investment in this fairly expensive 2 year program was not paid off until some years after the participants left school and became adults. Benefits through age 19 were sufficient to offset the cost of 1 year of preschool which may have been a sufficient dosage. Such an analysis is better at calculating costs than benefits. Benefits in the Perry Preschool Project that could not be calculated including early IQ gains, increased satisfaction with high school, reduced teenage childbearing, increased adult social competency, and an increased sense of well-being. Even very expensive programs such as the Yale Family Support program may generate long-term economic benefits, especially if there are benefits for both parents and children.

TRIAL NO.: 9 (5009)

auth: Barnett, WS
title: Benefit-cost analysis of preschool education: Findings from a 25-year follow-up
year: 1993
ref: Am J Orthopsychiatry
vol: 63(4)
pps: 500-508
project title: Perry Preschool
country: USA
N: 128
method: RCT
population: The subjects were low socio-economic status African-American children and their parents. There were 5 waves of children, born between 1958 and 1962 in a single school attendance area.
inter. type: Selective preventive intervention
intervention: The Perry Preschool program consisted of daily 2 1/2 hour classes on weekday mornings and weekly 90-minute teacher-conducted home visits with mother and child in the afternoons. The program operated 30 weeks a year. Thirteen of the children entered the preschool program at age 4 and had 1 year of intervention; the other 45 entered at age 3 and attended for 2 years.
outcomes: The economic benefits to participants and to society greatly exceeded the costs of the program. The benefit-cost ratio was in excess of 7:1.

TRIAL NO.: 12 (5011)

auth: Barrera, ME
auth: Cunningham, CE
auth: Rosenbaum, PL
title: Low birth weight and home intervention strategies: Preterm infants
year: 1986
ref: Journal of Development and Behavioral Pediatrics
vol: 7(6)
pps: 361-366
country: Canada
N: 128
method: RCT
population: Subjects were premature infants born at 1 of 3 city hospitals. Low birth weight babies weighed <1500 grams and higher birth weight babies weighed between 1500 and 2000 grams. Infants from each weight condition were block randomly assigned to a control or to 1 of 2 intervention groups.
inter. type: Selective preventive intervention
intervention: Families in both intervention groups received home visiting by a therapist: weekly for the first 3 months, every other week for the following 6 months, and once a month during the last quarter of the year. The developmental programming intervention focused on assessing and fostering development. The parent-infant intervention focused on improving the quality of the interaction between parent and child.
outcomes: The intervention was effective mainly with the low birth weight infants and their parents, but these infants also demonstrate greater vulnerability than the higher birth weight infants and thus have more room for improvement.

TRIAL NO.: 11 (5011)

auth: Barrera, ME
auth: Rosenbaum, PL
auth: Cunningham, CE
title: Early home intervention with low-birth-weight infants and their parents
year: 1986
ref: Child Development
vol: 57(1)
pps: 20-33
country: Canada
N: 111
method: RCT
population: Subjects were both preterm and full-term infants, all born at 1 of 3 city hospitals, who were matched on corrected age, sex, type of delivery, and socioeconomic status.
inter. type: Selective preventive intervention
intervention: Families in both intervention groups received home visiting by an infant-parent therapist: weekly for the first 4 months, every other week thereafter, and once a month during the last quarter of the year. The developmental programming intervention focused on fostering development in 5 domains. The parent-infant intervention focused on improving the quality of the interaction between parent and child rather than to teach specific development skills.
outcomes: At 16 months, the parent-infant intervention had the greater impact on home environment, behavior change during mother-infant interaction, and, to a lesser degree, cognitive scores.

TRIAL NO.: 267 (5267)

auth: Barth, RP
title: An experimental evaluation of in-home child abuse prevention services
ref: Child Abuse & Neglect
year: 1991
vol: 15
pps: 363-375
project title: Child Parent Enrichment Project
country: USA
N: 191
method: RCT
population: Subjects were women referred during or just after pregnancy by professionals working in 17 different agencies. All women had been screened and found to be at-risk for abusing their child. Considerable discretion for screening was granted to referrers.
inter. type: Selective preventive intervention
intervention: The control group received referrals to social and health services after an assessment. The experimental group received referrals and were home-visited for 6 months (average number of home visits 11 with a range of 5 to 20) by paraprofessionals who had received over 100 hours of training and were supervised. Assignment of a home visitor to a family was based on ethnic or geographic considerations. The focus of the intervention was on task identification and completion.
outcomes: Follow-up at an average of 3 years (with a range of 2 to 5 years) showed no difference between groups on reports of child abuse. There were no advantages of the experimental program according to self-report even though consumer satisfaction was very high.

TRIAL NO.: 14 (5014)

auth: Bass, JL
auth: Mehta, KA
auth: Ostrovsky, M
title: Childhood injury prevention in a suburban Massachusetts population
year: 1991
ref: Public Health Reports
vol: 106(4)
pps: 437-442
country: USA
N: 594
method: controlled population based trial, 4 sites
population: The subjects were parents in 3 affluent suburbs who had children between 0-5 years of age. Subjects from the control town were comparable. The children all received their pediatric care from 1 of 5 participating pediatricians. The intervention reached 29.6 percent of the 0-5 population in the intervention towns.
inter. type: Universal preventive intervention
intervention: Brief interactive physician counseling was provided to parents after parents completed the Framingham Safety Surveys and educational needs were identified. Written materials were also provided. The intervention communities also received a variety of community educational programs on safety issues. Pediatricians were trained in the use of all materials and compliance was monitored.
outcomes: The injury rate for children ages 0-5 years was decreased 15.3 percent during the intervention period. Also, population-based epidemiologic data showed a sustained decline in injury incidence.

TRIAL NO.: 16 (5016)
auth: Beeghly, M
auth: Brazelton, TB
auth: Flannery, KA
auth: Nugent, JK
auth: Barrett, DE
auth: Tronick, EZ
title: Specificity of preventative pediatric intervention effects in early infancy
year: 1995
ref: Developmental and Behavioral Pediatrics
vol: 16(3)
pps: 158-166
country: USA
N: 163
method: RCT
population: Study mothers were recruited from 2 large metropolitan teaching hospitals if they spoke English, had a telephone, lived within an hour's drive from the laboratory, and had no plans to move within 2 years. Inclusion criteria for the infants included full term delivery, "clinically normal" health status, and no more than 24 hours in neonatal special care. Two groups of infants were recruited: half were intrauterine growth retarded (small for gestational age) and half were average for gestational age.
inter. type: Selective preventive intervention
intervention: There were 2 types of short-term perinatal intervention: an infant-centered intervention which used the Brazelton Neonatal Assessment Scale to highlight newborn behavior to new mothers, and a mother-centered intervention which used in-depth interviews to focus on the mother's concerns about parenting. Both interventions used reliable protocols and were delivered by highly trained clinicians at day 3 in the hospital and at 14 and 30 days at home. Clinicians were trained in both protocols and were rechecked on reliability.
outcomes: At 4 months there were no significant differences between the 2 groups. Mothers at higher psychological risk had the poorest outcomes at 4 months and were unaffected by participation in either intervention, regardless of demographic status.

TRIAL NO.: 437 (5438)
auth: Becker, PT
auth: Grunwald, PC
auth: Moorman, J
auth: Stuhr, S
title: Outcomes of developmentally supportive nursing care for very low birth weight infants
year: 1991
ref: Nursing Research
vol: 40(3)
pps: 150-155
country: USA
N: 52
method: controlled trial, no randomization
population: Subjects were infants recruited from a nursery intensive care unit at a tertiary care center. Their birth weights were less than 1501 grams. For all infants, growth was appropriate for gestational age and there were no major chromosomal anomalies, congenital defects, or histories of maternal substance abuse.
inter. type: Selective preventive intervention
intervention: The experimental group received developmentally based nursing care that was introduced as the new standard of nursing care. Protocols were implemented using an initial education program and ongoing training and support. Nurses were taught to lower environmental stress, reduce procedural stress, and facilitate motor and sleep-wake organization.
outcomes: The educational training successfully altered nursing care. Experimental infants had more optimal respiratory and feeding status, lower levels of morbidity, shorter hospitalization, and improved behavioral organization.

TRIAL NO.: 438 (5438)
auth: Becker, PT
auth: Grunwald, PC
auth: Moorman, J
auth: Stuhr, S
title: Effects of developmental care on behavioral organization in very-low-birth-weight infants
year: 1993
ref: Nursing Research
vol: 42(4)
pps: 214-220
country: USA
N: 52
method: controlled trial
population: Subjects were infants recruited from a nursery intensive care unit at a tertiary care center. Their birth weights were less than 1501 grams. For all infants, growth was appropriate for gestational age and there were no major chromosomal anomalies, congenital defects, or histories of maternal substance abuse.
inter. type: Selective preventive intervention
intervention: The experimental group received developmentally based nursing care that was introduced as the new standard of nursing care. Protocols were implemented using an initial education program and ongoing training and support. Nurses were taught to lower environmental stress, reduce procedural stress, and facilitate motor and sleep-wake organization.
outcomes: Experimental infants showed better behavioral organization than the control infants who had received the old form of nursing care.

TRIAL NO.: 292 (5292)
auth: Beckwith, L
title: Intervention with disadvantaged parents of sick preterm infants
year: 1988
ref: Psychiatry
vol: 51
pps: 242-247
country: USA
N: 92
method: RCT
population: Subjects were infants with birthweights equal to or less than 2000 grams, born at a gestational age equal to or less than 35 weeks, and requiring more than 3 days in neonatal intensive care following birth. Their parents were selected to be English speaking and to have no more than high school education and/or neither parent to be working at more than an unskilled or semiskilled job.
inter. type: Selective preventive intervention
intervention: Experimental mother-infant dyads received weekly home visits from a pediatric nurse or an early childhood educator for the child's first year of life. The intervention began with the parents before the infant was discharged from the hospital. Primarily mothers were involved, but sometimes fathers chose to be included. The focus of the intervention was on the supportive relationship between the home visitor and the parent as well as on parent-infant interaction. No set curriculum or protocols were used.
outcomes: At the end of the intervention and at follow-up when the infants were 20 months of age (corrected for prematurity), the experimental mothers were more involved with their infants and their level of reciprocity was higher than control mothers. They also felt more satisfied with themselves and their children. However, the intervention was not associated with an increase in security of attachment or in increased mastery motivation. There was no effect on cognitive tasks until 20 months when the experimental children received higher Bayley MDI scores.

TRIAL NO.: 18 (5018)
auth: Black, MM
auth: Dubowitz, H
auth: Hutcheson, J
auth: Berenson-Howard, J
auth: Starr, RH
title: A randomized clinical trial of home intervention for children with failure to thrive
year: 1995
ref: Pediatrics
vol: 95(6)
pps: 807-814
country: USA
N: 130
method: RCT
population: The subjects were recruited from urban pediatric clinics serving low income families. The children were younger than 25 mos. (mean age 12.7 mos.), had weights for age below the 5th percentile even though their birth weights had been appropriate for gestational age (of at least 36 weeks), and had no other significant medical history. Six of the 130 children had histories of hospitalization for poor growth. Most subjects were African Americans whose mothers were single, receiving assistance, and had limited education.
inter. type: Selective preventive intervention
intervention: The experimental group received weekly home visits for 1 year from trained lay home visitors who were supervised by a community health nurse. The children also received nutrition intervention at a clinic. The home visitors focused on the parent-child relationship, including feeding, as well as on issues raised by the mothers. The cost per child for the 1 year home intervention was $2828. The control group received clinic services.
outcomes: The children's' weight improved during the 1 year study period regardless of intervention group. The experimental group had better receptive language over time and more child-oriented home environments. Only the younger children showed improvement on cognitive development.

TRIAL NO.: 19 (5131)
auth: Blair, C
auth: Ramey, CT
auth: Hardin, JM
title: Early intervention for low birthweight, premature **infants:** Participation and intellectual development
year: 1995
ref: American Journal on Mental Retardation
vol: 99(5)
pps: 542-554
project title: Infant Health and Development Program
country: USA
N: See other annotations.
method: See other annotations.
population: See other annotations.
inter. type: See other annotations.
intervention: See other annotations.
outcomes: There was improvement in IQ in years 2, 3.

TRIAL NO.: 20 (5020)
auth: Blondel, B
auth: Breart, G
auth: Llado, J
auth: Chartier, M
title: Evaluation of the home-visiting system for women with threatened preterm labor: Results of a randomized controlled trial
year: 1990
ref: European Journal of Obstetrics & Gynecology and Reproductive Biology
vol: 34(1-2)
pps: 47-58
country: France
N: 158
method: RCT, multisite
population: Subjects were women with moderate threatened preterm delivery between 26 and 36 weeks of gestation from 4 maternity units of public or private hospitals.
inter. type: Selective preventive intervention

intervention: The experimental group received 1 or 2 home visits per week by domiciliary mid-wives and had telephone contact. The focus was on medical examination and encouragement to rest and involve others in housework. Women also received prenatal care at clinics and hospitalization when necessary. The control group received clinic visits only.
outcomes: The number of days in hospital was not decreased for the experimental group but the number of prenatal visits was. The mothers' satisfaction with medical care was much greater in the experimental group.

TRIAL NO.: 21 (5021)

auth: Bloom, B
title: A Descriptive Study of Early Childhood Intervention Programs in Saskatchewan. Final Report of "The Alpern-Boll" Data, 1984-1990
year: 1991
pps: 1-135
doc: ERIC Document Number ED378748
project title: Early Childhood Intervention Programs
country: Canada
N: 788
method: pre-post descriptive
population: Subjects were young children from 12 areas within the province of Saskatchewan. They were referred to the program by their parents or professionals within the community because they had developmental delays, or were at risk for developing such delays, or had significant disabilities including Down syndrome.
inter. type: Indicated preventive intervention
intervention: Families received a systematic home-based developmental intervention following assessment. The children who received 2 assessments (N=486) had at least 6 months and often 12 months of intervention. The staff worker (training unspecified) modeled activities and the parent carried out the intervention plan.
outcomes: All children had some form of modest gain. The most improvement was seen in those children who received at least 12 months of intervention.

TRIAL NO.: 23 (5023)

auth: Booth, CL
auth: Mitchell, SK
auth: Barnard, KE
auth: Spieker, SJ
year: 1989
title: Development of maternal social skills in multiproblem families: Effects on the mother-child relationship.
ref: Developmental Psychology
vol: 25 (3)
pps: 403-412
country: USA
N: 147
method: RCT
population: Subjects were high social risk women who sought prenatal services from public health department clinics. They were 22 weeks pregnant or less and had 1 or more of the following risks: alcohol or drug addiction, psychiatric diagnosis, previous child maltreatment, both low educational level and low social support, young and low social support, low educational level and young and low income.
inter. type: Selective preventive intervention
intervention: The 2 types of intervention, both provided by nurses in home visits, lasted 18 months, from mid-pregnancy to the child's first birthday. A 1 step Information/Resource model was contrasted with a 2 step Mental Health model, focusing first on social skills and then on parenting. Both interventions had written protocols.
outcomes: Evaluations were made at the end of the intervention and 1 month later. The 2 groups did not differ in their post intervention social skills or in mother-child interaction. However, for women who began the program with low social skills, social skills and mother-child interaction were improved in the 2 step model.

TRIAL NO.: 446 (5446)

auth: Boyle, MH
auth: Cunningham, CE
auth: Heale, J
auth: Hundert, J
auth: McDonald, J
auth: Offord, DR
auth: Racine, Y
title: Helping Children Adjust - A Tri-Ministry Study: II. Evaluation methodology
status: CONCURRENT TRIAL
project title: Helping Children Adjust
country: Canada
N: 60 schools
method: RCT among participating schools
population: Subjects are children in the primary division (kindergarten to grade 3) of Ontario schools.
inter. type: Universal preventive intervention
intervention: The school-based interventions were of 3 types: parent management training, social skills training, and partner reading. There were also selected combination of these types. Their aim was to reduce and prevent problem behavior among the children by strengthening the children's relationships with parents and their interpersonal competence and academic achievement.
outcomes: Follow-up assessments have been made on 2439 children. Data not yet available.

TRIAL NO.: 75 (5075)

auth: Bradley, SJ
auth: Brody, J
auth: Landy, S
auth: Tallett, S
auth: Watson, W
auth: Stephens, D
title: Brief psychoeducational parenting program: Preliminary synopsis of pilot findings
status: CONCURRENT TRIAL
country: Canada
N: 180 to be recruited
method: RCT with wait list control condition
population: Parents are being recruiting who are having difficulties managing their 3 and 4 year old children's' behavior.
inter. type: Indicated preventive intervention
intervention: Parents are provided a 4 session parenting group in a community facility by trained community facilitators.
outcomes: After three months, the outcomes of the 70 experimental and control parents appear to be similar to the pilot findings where there were reductions in parenting stress and inappropriate parenting behavior and improvements in child behavior.

TRIAL NO.: 24 (5131)

auth: Brooks-Gunn, J
auth: McCarton, CM
auth: Casey, PH
auth: McCormick, MC
auth: Bauer, CR
auth: Bernbaum, JC
auth: Tyson, J
auth: Swanson, M
auth: Bennett, FC
auth: Scott, DT
auth: Tonascia, J
auth: Meinert, CL
title: Early intervention in low-birth-weight premature infants: Results through age 5 years from the Infant Health and Development Program
year: 1994
ref: Journal of the American Medical Association
vol: 272(16)
pps: 1257-1262
project title: Infant Health and Development Program
country: USA
N: 985
method: RCT
population: Subjects were infants weighing 2500 grams or less and whose gestational age at birth was 37 weeks or less. Siblings of eligible twins and infants with severe conditions were precluded. Non-English speaking mothers and mothers who reported drug, alcohol, or psychiatric hospitalization were also excluded. The 8 clinical sites were socioeconomically heterogeneous.
inter. type: Selective preventive intervention
intervention: The intervention was provided from neonatal discharge through age 3 years. The experimental group received home visits to age 3, 5 day per week center-based schooling from 12 months to 3 years, and pediatric surveillance; the control group received pediatric surveillance.
outcomes: The intervention effects that had been seen on IQ and vocabulary at age 3 years for the total sample and in both low birthweight groups were no longer present at 5 years, 2 years after the intervention ended. Overall IQ scores were similar in the 2 groups. However, the intervention did have positive effects on IQ and verbal performance at age 5 years for the heavier low birthweight infants. There were no differences on behavior and health measures between the experimental and control groups.

TRIAL NO.: 25 (5131)
auth: Brooks-Gunn, J
auth: McCormick, MC
auth: Shapiro, S
auth: Benasich, AA
auth: Black, GW
title: The effects of early education intervention on maternal employment, public assistance, and health insurance: The Infant Health and Development Program
year: 1994
ref: American Journal of Public Health
vol: 84(6)
pps: 924-931
project title: Infant Health and Development Program
country: USA
N: 985
method: RCT
population: Subjects were infants weighing 2500 grams or less and whose gestational age at birth was 37 weeks or less. Infants with severe conditions were precluded. The 8 clinical sites were socioeconomically heterogeneous.
inter. type: Selective preventive intervention
intervention: The intervention was provided from neonatal discharge through age 3 years. The experimental group received home visits to age 3, 5 day per week center-based schooling from 12 months to 3 years, and pediatric surveillance; the control group received pediatric surveillance.
outcomes: Effects of the intervention were on 2 generations — infants and their mothers. The intervention mothers were employed more months and returned to the work force earlier than the follow-up only group. There were no differences on subsequent fertility. Mothers with some college education as well as those who were employed received more public assistance. Use of health care services was more frequent in the experimental group.

TRIAL NO.: 257 (5247)
auth: Brugha, TS
title: NA
status: CONCURRENT TRIAL
project title: Preparing for Parenthood
country: England
N: Unknown
method: RCT
population: Subjects were pregnant women who were identified on a screening tool to be high risk for postnatal depression. When they were invited to join, they were explicitly told that the intervention was targeted to prevent postnatal depression.
inter. type: Selective preventive intervention
intervention: The experimental group received 6 antenatal and 1 postnatal group sessions at the hospital where they were receiving their antenatal care. A highly structured curriculum based on life skills training was delivered by trained therapists.
outcomes: At 3 month follow-up, there were no intervention effects. A current 12 month assessment will have both mother and child outcomes.

TRIAL NO.: 26 (5026)

auth: Bryce, RL
auth: Stanley, FJ
auth: Garner, JB
title: Randomized controlled trial of antenatal social support to prevent preterm birth
year: 1991
ref: British Journal of Obstetrics and Gynaecology
vol: 98(10)
pps: 1001-1008
country: Australia
N: 1970
method: RCT
population: Subjects were pregnant women with poor obstetric histories (prior preterm or low birthweight births, perinatal deaths, miscarriages) from 3 public antenatal clinics and the private offices of 87 obstetricians and general practitioners.
inter. type: Selective preventive intervention
intervention: Routine antenatal care was provided for the experimental and control groups. The experimental group also received expressive (emotional) social support through home visitors and telephone calls by midwives who had received extensive training in this method. Antenatal advice was not provided by the midwives.
outcomes: The observed relative reduction in preterm births in the experimental groups was 13.8 percent. The expected clinically significant reduction in preterm births was not obtained. There was no effect in the lowest social class, but there was in the highest professional social class.

TRIAL NO.: 27 (5027)

auth: Burchinal, M
auth: Lee, M
auth: Ramey, C
year: 1989
title: Type of day-care and preschool intellectual development in disadvantaged children
ref: Child Development
vol: 60
pps: 128-137
country: USA
N: 151
method: RCT
population: Subjects were infants determined to be at risk for school failure due to socioeconomic factors. Most mothers were black, single, young, and had less than a high school education. The children in the experimental group were 6 weeks to 3 months of age when they began the intervention.
inter. type: Selective preventive intervention
intervention: The experimental group attended a cognitively oriented university day care center from infancy until they entered kindergarten. Many of the control children had varying amounts of time in "quality" community day care centers. Other control children had no center-based day care.
outcomes: Assessments were made semiannually from 6 to 54 months of age. The experimental group showed higher IQs overall and less linear decline in cognitive ability between late infancy and early preschool (seemingly a vulnerable period) than the control children as a whole or than the subgroup of control children in the community day care group. However, the latter group who had at least 1 year of day care experience also showed benefits in intellectual development both in the overall level and in trends across time.

TRIAL NO.: 28 (5028)

auth: Burkett, CW
year: 1982
title: Effects of frequency of home visits on achievement of preschool students in a home-based early childhood education program.
ref: Journal of Educational Research
vol: 1
pps: 41-44
country: USA
N: 166
method: controlled trial, randomization unclear
population: Subjects were 4 and 5 year old children from disadvantaged families in 4 very rural counties. The same criteria were used that determine eligibility for Head Start. Handicapped children were included. None of the children (experimental or control) were attending any other type of formal intervention or day care program.
inter. type: Selective preventive intervention
intervention: Both experimental groups received home visits by trained paraprofessionals, written materials, and one-half day per week of classroom experience for the child under the direction of the paraprofessionals and volunteer parents for 1 year. The focus of the intervention was on assisting parents to work with their children in specified activities. One half of the group was visited weekly and the other half biweekly.
outcomes: All home visited children's' achievement scores were significantly greater those of children in the control group. However, those who were visited weekly did no better than those visited biweekly. The yearly per pupil cost for those visited biweekly was between approximately $700 in 1980 dollars.

TRIAL NO.: 29 (5029)

auth: Butz, AM
auth: Funkhouser, A
auth: Caleb, L
auth: Rosenstein, BJ
title: Infant health care utilization predicted by pattern of prenatal care
year: 1993
ref: Pediatrics
vol: 92(1)
pps: 50-54
country: USA
N: 148
method: retrospective case control
population: The subjects were those who registered for prenatal care after 28 weeks gestation or completed fewer than 4 prenatal visits. Controls were all other infants matched by date of birth.
inter. type: NA; not an intervention study
outcomes: Infants of subject mothers had significantly lower birth weight and gestational age, increased referrals to protective services, and less health care by 9 months of age. Patterns of infant health care use can be predicted before birth based on the mother's pattern of prenatal care use.

TRIAL NO.: 30 (5030)

auth: Campbell, FA
auth: Ramey, CT
title: Effects of early intervention on intellectual and academic achievement: a follow-up study of children from low-income families
year: 1994
ref: Child Development
vol: 65(2 Spec No)
pps: 684-698
project title: Carolina Abecedarian Project
country: USA
N: 120
method: RCT; random assignment at infancy and again prior to kindergarten entry at age 5
population: Subjects were full term infants, free from genetic or infectious related conditions, who were high risk on a sociodemographic index. They had been identified through social service agencies and public health clinics. Their mean age of entry was 4.4 months.
inter. type: Selective preventive intervention
intervention: There were 4 groups: preschool treatment (infancy through 5 years) plus 3 years primary school treatment (up to age 8); preschool treatment only (infancy to age 5); primary school treatment only (age 5-8 years); and untreated control group. The preschool intervention operated 8 hours per days 50 weeks per year and included an infant curriculum to enhance development and parent activities. The control preschool children were given free formula and diapers. The school age intervention included individualized educational activities taught in biweekly home visits plus referrals for community resources.
outcomes: At 4 year follow-up (children were 12 years of age), there were positive results of the preschool treatment on intellectual development and academic achievement; school-age treatment alone was less effective. The positive effects of preschool treatment on intellectual development and academic achievement were maintained through age 12 (4 years after the full experimental intervention ended).

TRIAL NO.: 32 (5131)

auth: Casey, PH
auth: Kelleher, KJ
auth: Bradley, RH
auth: Kellogg, KW
auth: Kirby, RS
auth: Whiteside, L
title: A multifaceted intervention for infants with failure to thrive: A prospective study
year: 1994
ref: Archives of Pediatric and Adolescent Medicine
vol: 148(10)
pps: 1071-1077
project title: Infant Health and Development Program
country: USA
N: 914
method: RCT
population: Subjects were infants weighing 2500 grams or less and whose gestational age at birth was 37 weeks or less. Siblings of eligible twins and infants with severe conditions were precluded. Non-English speaking mothers and mothers who reported drug, alcohol, or psychiatric hospitalization were also excluded. The 8 clinical sites were socioeconomically heterogeneous.
inter. type: Selective preventive intervention
intervention: The intervention was provided from neonatal discharge through age 3 years. The experimental group received home visits to age 3, 5 day per week center-based schooling from 12 months to 3 years, and pediatric surveillance; the control group received pediatric surveillance.
outcomes: At the end of the 3 year intervention, there were no differences in incidence of failure to thrive (FTT: defined as the failure to maintain the expected rate of weight gain over time) between the experimental and control groups. The children in the experimental group who developed FTT received less of the intervention than those who did not develop FTT. The effects of the intervention, particularly on IQ and behavior, were greater for those children with FTT whose families were the most compliant with the intervention.

TRIAL NO.: 231 (5231)

auth: Ciccetti, D
auth: Rogasch, F
title: NA
status: CONCURRENT TRIAL (soon to be published)
country: USA
method: RCT
N: 180 (approx)
population: Subjects were 18 month old children whose mothers were depressed.
intervention: Infant-parent psychotherapy was provided for the experimental mothers and their children.
inter. type: Selective preventive intervention
outcomes: The intervention is likely to show benefits at 3 years of age on child IQ scores, especially verbal, and also on mothers' ratings of attachment, i.e., the children seen as less insecure.

TRIAL NO.: 256 (5256)

auth: Cohen, NJ
auth: Muir, E
auth: Lojkasek, M
auth: Muir, R
auth: Parker, CJ
auth: Barwick, M
auth: Brown, M
title: Outcomes of two interventions to treat troubled mother-infant relationships
status: CONCURRENT TRIAL; recently completed; manuscript in preparation
country: Canada
N: 67
method: partial randomization to comparison groups, no control
population: Subjects were 12 to 30 months old infants and their mothers who attend a children's mental health center. Referrals were made by parents themselves and by the professional community. Some children had problems with feeding, sleeping, and behavioral regulation whereas in other families the concern was with factors that impeded the parent's capacity for infant care such as maternal depression and risk or allegations of abuse. Inclusion criteria included the physical capacity of mother and child to engage in play and mother's capacity to understand instructions.
inter. type: Selective and indicated preventive intervention
intervention: Two types of relatively brief psychotherapeutic interventions were provided to infants and their mothers. The first was infant-led psychotherapy called Watch, Wait, and Wonder (WWW). Each session consisted of infant centered activity on the floor with the child which was followed by discussion of how the mother experienced the session. The second was psychodynamic therapy of mother-infant problems (PPT). This could include traditional mother-infant psychotherapy, couples' therapy, individual therapy with the mother, family therapy or combined modalities. Therapists who were infant specialists with extensive experience with the interventions. The maximum number of sessions was 18. Random assignment was made to the groups whenever possible.
outcomes: At 6 month follow-up after the intervention, there were positive effects for both groups. Mothers and infants exhibited greater reciprocity in play and less conflict and mothers became significantly less intrusive. The WWW infants made significantly greater gains on the Bayley Mental Scale than infants in the PPT group. In both groups there was significant increase in satisfaction and feelings of efficacy over time, but WWW mothers reported significantly more satisfaction and less ineffectiveness in the parenting role than PPT mothers did. Mothers in the PPT group reported more depression than mothers in the WW group at the end of treatment but not at the beginning.

TRIAL NO.: 250 (5250)

auth: Cooper, PJ
auth: Murray, L
title: The impact of psychological treatments of postpartum depression on maternal mood and infant development
year: 1997
ref: In L Murray and PJ Cooper (Eds.) Postpartum Depression and Child Development
city: New York, NY
pub: The Guilford Press
pps: 201-220
country: England
method: RCT
N: 194
population: Subjects were primiparous women who had been screened for mood disturbance in the early postpartum period and had been identified as having current major depressive disorder.
inter. type: Selective preventive intervention
intervention: There were 4 intervention groups: routine primary care, nondirective counseling, cognitive-behavioral therapy, and dynamic psychotherapy. All therapy was conducted by trained therapists in the women's own homes on a weekly basis from 8 to 18 weeks postpartum.
outcomes: Follow-ups were conducted at 9 and 18 months postpartum. All 3 treatments were equally effective at speeding up the natural remission rate of postpartum depression. There was little evidence of relapse within any of the treatment conditions. By 9 months postpartum the spontaneous recovery rate within the control group had caught up with the rate achieved by treatment. Early remission from maternal depression, however it was achieved, was associated with a reduced rate of insecure attachments. However, none of the treatments were associated with a corresponding improvement in the face-to-face engagements between mother and child or in the cognitive development of the child. At 18 months mothers who had received any of the interventions reported significantly fewer infant behavioral problems than the control mothers.

TRIAL NO.: 35 (5035)

auth: Connor-Kuntz, FJ
auth: Dummer, GM
title: Teaching across the curriculum: Language-enriched physical education for preschool children
year: 1996
ref: Adapted Physical Activity Quarterly
vol: 13(3)
pps: 302-315
country: USA
N: 72
method: control
population: Subjects were 4 to 6 year old children recruited from preschool special education, Head Start, and typical preschool classes.
inter. type: Selective preventive intervention
intervention: Language instruction was added to a physical activity program for the experimental group. The control group received physical activity intervention. Both groups received 24 sessions over 8 weeks.
outcomes: At 3 month follow-up, experimental children improved their language skills regardless of whether their educational progress was characterized by a cognitive and/or language delay. Language instruction can be added without requiring additional instructional time and without compromising improvement in motor skill performance.

TRIAL NO.: 36 (5036)

auth: Corwin, MJ
auth: Mou, SM
auth: Sunderji, SG
auth: Gall, S
auth: How, H
auth: Patel, V
auth: Gray, M
title: Multicenter randomized clinical trial of home uterine activity monitoring: Pregnancy outcomes for all women randomized
year: 1996
ref: American Journal of Obstetrics and Gynecology
vol: 175(5)
pps: 1281-1285
country: USA
N: 339
method: RCT
population: Subjects were women at high risk for preterm labor at 3 centers.
inter. type: Selective preventive intervention
intervention: Experimental women received standard high risk prenatal care plus twice-daily home uterine activity monitoring without increased nursing support. The controls received standard high risk prenatal care.
outcomes: The experimental group had improved pregnancy outcomes, prolonged gestation, larger birth weight infants, and a decreased need for neonatal intensive care. These infants experienced 469 fewer days in the neonatal intensive care unit which compares favorably with the cost of the average of 49 days of monitoring per woman in this experimental group.

TRIAL NO.: 248 (5248)

auth: Cramer, B
auth: Robert-Tissot, C
auth: Stern, DN
auth: Serpa-Rusconi, S
auth: DeMuralt, M
auth: Besson, G
auth: Palacio-Espasa, F
auth: Bachmann, JP
auth: Knauer, D
auth: Berney, C
auth: D'Arcis, U
title: Outcome evaluation in brief mother-infant psychotherapy: A preliminary report
year: 1990
ref: Infant Mental Health Journal
vol: 11(3)
pps: 278-300
country: Switzerland
N: 56
method: comparative trial, non-randomized
population: Subjects were mothers with children 6 months to 2 1/2 years who were referred to a child guidance clinic for psychofunctional problems (sleeping, feeding, or attachment difficulties). The experimental group was selected on the basis of a judgment of suitability for this form of clinical management
inter. type: Indicated preventive intervention
intervention: Experimental mothers were provided brief psychotherapy which focused on the mothers' representation of her infant and her projections dating to unresolved conflicts from her own childhood. No direct advice was given. Videotapes of the mother-infant interaction are used to guide and modify inappropriate patterns that relate to the infant's symptoms. The sessions occurred weekly for a maximum of 10 sessions. The therapists (who were also the authors) developed this form of intervention based on the Fraiberg model of mother-infant therapy.
outcomes: There was marked improvement in the experimental mothers' representations, the mother-infant interactions, and in the symptoms for which the child was referred.

TRIAL NO.: 37 (5037)

auth: Cronan, TA
auth: Cruz, SG
auth: Arriaga, RI
auth: Sarkin, AJ
title: The effects of a community-based literacy program on young children's language and conceptual development
year: 1996
ref: American Journal of Community Psychology
vol: 24(2)
pps: 251-272
project title: Project PRIMER
country: USA
method: RCT
N: 289
population: Subjects were Head Start families with 1 child in Head Start and another child who was 1,2, or 3 years of age. Head Start is designed for children of low income families.
inter. type: Selective preventive intervention
intervention: University students were trained for 8 weeks to teach Head Start parents effective methods for reading to their children. The curriculum that was used was Project PRIMER. Families received 18, 3, or 0 instructional home visits. On 3 visits the instructional sessions were videotaped to ensure that the intervention was uniformly conducted.
outcomes: Parents who received 18 visits increased their participation in appropriate literacy behaviors more than the control parents. Children in the 18 session experimental group showed greater gains in language and conceptual development than children in the control group. There were few differences between the children in the 3 visit and control groups.

TRIAL NO.: 38 (5037)

auth: Cronan, TA
auth: Walen, HR
auth: Cruz, SG
title: The effects of community-based literacy training on Head Start parents
year: 1994
ref: Journal of Community Psychology
vol: 22(3)
pps: 248-258
project title: Project PRIMER
country: USA
method: RCT
N: 143
population: Subjects were Head Start families with 1 child in Head Start and another child who was 1,2, or 3 years of age. Head Start is designed for children of low income families.
inter. type: Selective preventive intervention
intervention: University students were trained to teach Head Start parents effective methods for reading to their children. The curriculum that was used was Project PRIMER. Families received 18, 3, or 0 instructional home visits. On 3 visits the instructional sessions were videotaped to ensure that the intervention was uniformly conducted.
outcomes: Mothers in the 18 visit and 3 visit experimental groups were more likely to increase behaviors thought to increase reading readiness and concept learning than the control mothers. The effects were strongest for the 18 visit group. There were no child outcomes.

TRIAL NO.: 405 (5039)

auth: Cullen, KJ
year: 1976
title: A six-year controlled trial of prevention of children's behavioral disorders
ref: Journal of Pediatrics
vol: 88(4)
pps: 662-667
project title: Busselton study
country: Australia
N: 246
method: controlled trial
population: From 1964 to 1967, children were recruited by allotment of alternate births in the local hospital into experimental and control groups with prior stratification according to the child's sex and position in the family.
inter. type: Universal preventive intervention
intervention: In the child's first year of life, 4 counseling sessions, 20 to 30 minutes in length, were conducted by the family's general practitioner. This was followed by 2 interviews per year for the next 4 years. One general practitioner provided all the intervention counseling, which aimed to enhance the self worth of the mother, foster gentle physical interaction with the child, and to encourage the mother to adopt a positive attitude about modifying the child's behavior. Control parents were interviewed annually by the secretary of the study, and pictures of the children were taken at 6 month intervals.
outcomes: The experimental children had significantly fewer fears, sleep disorders, eating problems, loud modes of speech, and aggression toward others than did the controls. Generally the results were more positive for experimental girls than boys. The experimental girls revealed signficantly more positive feelings toward their mothers than did the controls, but the boys revealed significantly more negative feelings. Overall, the results were modest.

TRIAL NO.: 39 (5039)

auth: Cullen, KJ
auth: Cullen, AM
title: Long-term follow-up of the Busselton six-year controlled trial of prevention of children's behavior disorders
year: 1996
ref: The Journal of Pediatrics
vol: 129(1)
pps: 136-139
project title: Busselton study
country: Australia
N: 246
method: controlled trial
population: From 1964 to 1967, children were recruited by allotment of alternate births in the local hospital into experimental and control groups with prior stratification according to the child's sex and position in the family.
inter. type: Universal preventive intervention
intervention: In the child's first year of life, 4 counseling sessions, 20 to 30 minutes in length, were conducted by the family's general practitioner. This was followed by 2 interviews per year for the next 4 years. One general practitioner provided all the intervention counseling, which aimed to enhance the self worth of the mother, foster gentle physical interaction with the child, and to encourage the mother to adopt a positive attitude about modifying the child's behavior. Control parents were interviewed annually by the secretary of the study, and pictures of the children were taken at 6 month intervals.
outcomes: Initial benefits at 6 years of age appear to have lasted to ages 27-29. On self report, there were significantly fewer neurotic symptoms, and the women had significantly fewer depressive symptoms. More intervention subjects had received university degrees. Intervention women were less obese, and there was somewhat less smoking in the whole intervention group.

TRIAL NO.: 40 (5040)

auth: Cunningham, CE
auth: Bremner, R
auth: Boyle, M
title: Large group community-based parenting programs for families of preschoolers at risk for disruptive behavior disorders: Utilization, cost effectiveness, and outcome
year: 1995
ref: Journal of Child Psychology and Psychiatry
vol: 36(7)
pp: 1141-1159
country: Canada
N: 150
method: RCT
population: Subjects were junior kindergartners who had been identified through universal screening of all public and separate schools in one community. Screening questionnaires for behavior problems had been sent home by teachers to parents. If the children rated at least 1.5 standard deviations above the mean on the screening tool, they were considered high risk for later disruptive behaviour disorders, and their parents were offered the intervention.
inter. type: Indicated prevenive intervention
intervention: Parents were randomly assigned to 1 of 3 groups: a 11-12 session clinic-based parenting course for individual families; a 11-12 session large group community-based parenting course; or a waiting list control condition. Both interventions employed a coping modelling problem solving model. The large community-based groups devoted time to informal supportive interaction and personal network building. Monthly booster sessions were offered in both types of intervention. The professional group leaders received extensive training and monitoring. Parents in both interventions were able to enroll their children in an activity-based social skills program which was conducted conjointly with parenting sessions.

outcomes: Parents in the large community groups reported greater improvements in behavior problems at home and better maintenance of these gains at 6 month follow-up. Immigrant families, those using English as a second language, and parents of children with severe behavior problems were significantly more likely to enroll in the community groups than in the clinic based individual parent training. With groups of 18 families, the community group intervention was more than 6 times as cost effective as the clinic/individual program.

TRIAL NO.: 41 (5041)

auth: Dawson, P.
auth: vanDoorninck, WJ
auth: Robinson, JL
title: Effects of home-based, informal social support on child health
year: 1989
ref: Developmental and Behavioral Pediatrics
vol: 10(2)
pps: 63-67
country: USA
N: ?
method: RCT
population: Subjects were pregnant women expecting their first or second child, 20-26 weeks pregnant, at least 16 years of age at expected date of delivery, not planning to move away, and able to speak English. They were recruited from 3 clinics in a maternity and infant care project of a local health department. They were not selected for psychosocial risk, but all had low incomes.
inter. type: Universal preventive intervention
intervention: Control mothers received routine maternity and pediatric care, including social and nutrition services, occasional home visits by public health nurses, and delivery at the university hospital. The first experimental group received these same services plus weekly home visits. The second experimental group received the routine services and weekly home visits, and was invited to parent groups which met every 2 weeks. All services began by the 30th week of pregnancy. Paraprofessional home visitors provided parents with emotional support, information, and help in using community resources during pregnancy and throughout the infants' first 14 months. The home visitors received 30 hours of training and on-going supervision.
outcomes: There were no differences between treatment and control groups in perinatal outcomes for mothers. For newborns, birth weight and gestational age did not differ significantly. Both home-visited women and controls made good us of well-child care. Home-visited women made greater use of sick-child care, most of which was appropriate. The greater use of sick-child care was concentrated among mothers with moderate or high family stress, with whom home visitors had closer relationships. No differences were found across groups in the occurrence of accidents, ingestions, poor weight gain, or hospitalization. There were also no differences in the use of contraception or in subsequent child-bearing. The cost of home visiting was $1224
per family per year. (The home visitors received $3.69/hour.) The cost of the parent group was approximately the same.

TRIAL NO.: 43 (5043)

auth: Dickens, WJ
auth: Loeppky, C
auth: Rodniski, M
auth: Seiler, K
title: The Early School Years Project: Early Childhood Intervention in the Inner City
year: 1988
pps: 1-38
doc: ERIC Document Number ED293661
project title: Early School Year's Project
country: Canada
N: 537
method: controlled trial, no randomization

population: Subjects were parents and their nursery and kindergarten children. All families in designated classrooms are eligible to participate. The classrooms were in 3 schools categorized as having low income families, high unemployment rates, high numbers of English as second language families, parents with low education levels, high transiency , and a high number of single parent families. The 2 control schools were also categorized this way. There were 2 cohorts of children.
inter. type: Selective preventive intervention
intervention: Winnipeg, Manitoba's Early School Years Project provided a school-year's worth of educational enrichment with 4 components: the Early Childhood classroom; the Home Learning program; the Parent program; and the Parent/Child Centres. A teacher and a well-trained language development aide (with training spread out over 2 years) provided the classroom intervention and a home visitor established the link between home and school by providing support and resources for parents to use with their children. The Centres were drop-in facilities with a play area, libarary, parent resource centre, workshops and special events.
outcomes: At the end of the intervention all students from all 5 schools demonstrated academic progress. For the 1st cohort, the experimental children had higher self-esteem than control students, but at 1 year follow-up this difference was marginal. The positive effects on the 2nd cohort were somewhat stronger. There were no significant effects of the intervention on cohort one students' language skills but there were on cohort two students. Over the course of the project parents did become more involved with the school and they learned skills that they used with all their children.

TRIAL NO.: 44 (5044)
auth: Dihoff, RE
auth: McEwan, M
auth: Farrelly, M
auth: Brosvic, GM
auth: Carpenter, L
auth: Anderson, J
auth: Kafer, LB
auth: Rizzuto, GE
auth: Bloszinsky, S
year: 1994
title: Efficacy of part- and full-time early intervention.
ref: Perceptual and Motor Skills
vol: 79
pps: 907
country: USA
N: study 1, 87? ; study 2, 36
method: 2 studies; matching of comparison groups in study 1; no comparison group in study 2
population: Subjects were children from birth to age 3 with developmental disabilities and their parents.
inter. type: Indicated preventive intervention
intervention: There were 2 intervention groups in **study 1:** a part-time and a full-time group experience aimed toward remediating the developmental delays in the children. In the part-time intervention, program therapists provided group activities for 2 hours once a week. In the full-time intervention, the children received a complete day of educational and therapy activities conducted by the program's speech-language therapist/teacher. In study the parents received a bimonthly parent group meeting.
outcomes: In study 1, subjects in both intervention groups had significant improvements in development, with the greatest gains being in the full time group. In study 2, there were reductions in parental stress levels and in dysfunctional parenting skills.

TRIAL NO.: 406 (5406)

auth: Donachy, W
title: Parent participation in pre-school education
year: 1976
ref: British Journal of Educational Psychology
vol: 46
pps: 31-39
country: Scotland
N: 96
method: controlled, nonrandomized
population: Subjects were 3 and 4 year old children and their mothers from 2 urban areas, each of which included a district which was considered to be an Educational Priority Area.
inter. type: Universal and selective preventive intervention
intervention: There were 4 experimental groups (2 preschool-based and 2 nursery-based) and 2 control groups from another geographic area. Two preschool-based groups received a weekly program for 5 months. The children played under supervision and the mothers were in a teacher-led discussion group focused on story books and other activities the mothers could do at home with their children. In 1 nursery-based program the children attended nursery school in the afternoons for 5 months and the mothers received the same discussion program as the mothers in the preschool-based program. In the other nursery-based program the children attended nursery school in the mornings for 5 months, but there was no other intervention component. The controls were not offered any intervention.
outcomes: All parent programme groups demonstrated significant gains in the children's Stanford-Binet scores. Children in all social classes made gains of about the same size .

TRIAL NO.: 49 (5049)

auth: Dunkley, J
title: Training midwives to help pregnant women stop smoking
year: 1997
ref: Nursing-Times
vol: 93(5)
pp: 64-66
country: England
N: 100
method: RCT
population: Subjects were women who were no more than 18 weeks pregnant and smoked one or more cigarettes daily. They were recruited from a maternity unit at a teaching hospital.
inter. type: Selective preventive intervention
intervention: Midwives received special training in smoking cessation and intervention techniques. In the experimental group midwives applied these techniques to help pregnant women stop smoking.
outcomes: There were no significant differences between the experimental and control groups in the number of women who gave up smoking. Overall the quit rate was 10 percent. However, women in the experimental group significantly reduced the number of cigarettes they smoked compared to the control group.
result: minimal effect

TRIAL NO.: 50 (5050)
auth: Dworkin, PH
auth: Allen, D
auth: Geertsma, MA
auth: Solkoske, L
auth: Cullina, J
title: Does developmental content influence the effectiveness of anticipatory guidance?
year: 1987
ref: Pediatrics
vol: 80(2)
pps: 196-202
country: USA
N: 128
method: RCT
population: Subjects were inner city mothers and their first-born infants, born at a large, urban medical center. Mothers had to speak English, had to have enrolled to receive pediatric care through the hospital clinic, and the baby had to be in good health.
inter. type: Universal preventive intervention (bordering on selective)
intervention: All mother-infant pairs were seen by the same pediatric provider (doctors and nurse practitioners) for health maintenance visits at 2 weeks and 2, 4, and 6 months of age. Age-appropriate issues were discussed and anticipatory guidance was provided using flow sheets and a manual. For the experimental group the basis for such information was also explained through age-specific discussions of affective, cognitive, and physical development. Training sessions for the intervenors were provided prior to the start of the study, and reliability was assessed by the study coordinator observing visits.
outcomes: There was no significant effect on any of the outcome measures, suggesting that specific, age-appropriate issues may be discussed without emphasizing the developmental basis for such information.

TRIAL NO.: 54 (5054)
auth: Ershoff, DH
auth: Quinn, VP
auth: Mullen, PD
title: Relapse prevention among women who stop smoking early in pregnancy: A randomized clinical trial of a self-help intervention
year: 1995
ref: American Journal of Preventive Medicine
vol: 11(3)
pps: 178-184
country: USA
N: 218
method: RCT
population: Subjects were an ethnically diverse group of pregnant women enrolled in a large health maintenance organization. They were less than 18 weeks pregnant and identified themselves as prepregnancy smokers. They indicated on a form that they had quit smoking since becoming pregnant (spontaneous quitters).
inter. type: Selective preventive intervention
intervention: All women received a 45 minute smoking-related interview conducted by a health educator when they began their prenatal care. They also received a 2 page pamphlet on the hazards of smoking during pregnancy. The health educator reinforced the written information in a 2 minute discussion. The experimental group then received 4 of 8 self-help booklets, together with a 3 minute overview of the program. The remaining 4 booklets were mailed thereafter at weekly intervals. They contained a step-by-step program to increase motivation for quitting smoking and taught behavioral strategies for cessation and relapse prevention. Controls were given a 1 page tip sheet on behavioral techniques to help avoid relapse.

outcomes: Biochemical confirmation of continuous abstinence through delivery revealed that 16 percent of the women in the experimental group relapsed compared with 20 percent of usual care controls. The program was equally ineffective among all subgroups including women at highest risk for relapse. There was a relatively high rate of deception in self-reported smoking status.

Trial No.: 55 (5055)

auth: Ershoff, DH
auth: Mullen, PD
auth: Quinn, VP
title: A randomized trial of a serialized self-help smoking cessation program for pregnant women in an HMO
year: 1989
ref: American Journal of Public Health
vol: 79(2)
pps: 182-187
country: USA
method: RCT
N: 242
population: Subjects were English-speaking women who were less than 18 weeks pregnant who obtained prenatal care in 1 of 5 health centers of a large multispecialty group affiliated with a health maintenance organization (HMO). The women were socioeconomically and ethnically diverse. At the time of their first prenatal visit they reported that they were smoking.
inter. type: Selective preventive intervention
intervention: All women received a 45 minute smoking-related interview conducted by a health educator when they began their prenatal care. They also received a 2 page pamphlet on the hazards of smoking during pregnancy. The health educator reinforced the written information in a 2 minute discussion and advised patients of a 5 session smoking cessation class available free through the HMO. The experimental group then received the first of 8 self-help booklets, together with a 3 minute overview of the program. The remaining 7 booklets were mailed thereafter at weekly intervals. They contained a step-by-step program to increase motivation for quitting smoking and taught behavioral strategies for cessation and relapse prevention.
outcomes: Biochemical confirmation of continuous abstinence achieved prior to the 20th completed week of pregnancy and lasting through delivery revealed 22.2 percent of the women in the 3 week serialized program quite versus 8.6 percent of controls with usual care. The total costs of the intervention were approximately $11 per patient.

TRIAL NO.: 56 (5056)

auth: Ershoff, DH
auth: Aaronson, NK
auth: Danaher, BG
auth: Wasserman, FW
title: Behavioral, health, and cost outcomes of an HMO-based prenatal health education program
year: 1983
ref: Public Health Reports
vol: 98(6)
pps: 536-547
country: USA
method: control group without randomization
N: 129
population: Subjects were English-speaking women who presented themselves for prenatal care to a large health center before they were 24 weeks pregnant and delivered their baby as a member of the health maintenance organization. They were all smokers at the time of pregnancy testing, but some reported they had stopped by the time the intervention began. Controls were obtained from 2 sources: a random sample of women enrolled at the same facility who began their prenatal care during a 4 month period preceding the experimental program and a random sample of women who began their prenatal care during the same period as the experimental group but who were enrolled at other facilities of the same HMO. Other criteria were the same but the women were identified as smokers at any time during their pregnancy, including those who had stopped when they first learned that they were pregnant.
inter. type: Selective preventive intervention
intervention: The experimental group received nutrition counseling (2 45-minute individual counseling sessions with a nutritionist and a follow-up session 3 months later) and an 8 week home-correspondence smoking cessation program including a brief introduction by a health educator. The control group received standard prenatal care.
outcomes: At 2 months postpartum, follow-up data showed that a greater percentage of women in the experimental group quit smoking during pregnancy than in the control group (49.1 percent vs. 37.5 percent). Of those who smoked through their pregnancy, experimental women had a greater reduction in their mean rate of daily smoking. A significantly greater percentage of experimental group women adjusted their diets during the prenatal period (91 percent vs. 68 percent). Experimental infants had a significantly higher mean birth weight than controls, and there were fewer low birth weight infants. Hospital treatment cost savings associated with the reduced incidence of low birth weight infants among experimental women yielded an overall benefit-cost ratio for the prenatal program of approximately 2:1.

TRIAL NO.: 258 (5054)

auth: Ershoff, DH
auth: Quinn, VP
auth: Mullen, PD
auth: Lairson, DR
title: Pregnancy and medical cost outcomes of a self-help prenatal smoking cessation program in a HMO
year: 1990
ref: Public Health Reports
vol: 105
pps: 340-347
country: USA
N: 323
method: RCT
population: Subjects were the socioeconomically and ethnically diverse English-speaking pr members of a large health maintenance organization who reported that they were smoking at the time of their first prenatal visit. They were less than 18 weeks pregnant at intake.
inter. type: Selective preventive intervention
intervention: At the first prenatal visit, a health educator conducted a 45 minute interview with all the patients and they then were given a pamphlet on the hazards of cigarette smoking during pregnancy and the importance of quitting. The health educator reinforced this in a 2 minute discussion. The experimental group then received a serialized cessation program including 8 booklets on a weekly basis.
outcomes: The experimental women were more likely to achieve smoking cessation for the majority of their pregnancy (22.2 percent vs. 8.6 percent), gave birth to infants weighing on average 57 grams more, and were 45 percent less likely to deliver a low birth weight infant. The intervention had a benefit-cost ratio of 2.8:1.

TRIAL NO.: 57 (5057)

auth: Esdaile, SA
title: A play-focused intervention involving mothers of preschoolers
year: 1996
ref: American Journal of Occupational Therapy
vol: 50(2)
pps: 113-123
country: Australia
N: 38
method: controlled trial without randomization
population: Subjects were mothers of preschoolers, ages 2 to 3.5, living in a multiethnic, industrial area of a large city with a high incidence of child abuse. They were recruited through maternal and child health centers. After recruitment, the mothers were asked to assess their child's temperament on a screening instrument. Children with the most difficult temperaments and others with the easiest of temperaments were allocated in 2 experimental and 1 wait-list control groups.
inter. type: Universal preventive intervention (subjects were not recruited because of child behavior problems)
intervention: The intervention was designed to enhance mother-child interaction through play, reduce mothers' perceived stress, and increase mothers' knowledge about child development. The experimental mothers were given 10 weeks of a structured activity-based program involving toy making (for 1 experimental group only) and toy demonstrations (both experimental groups). The children were provided for in adjacent playgroups with trained caregivers. The sessions were conducted by an occupational therapist. Transportation to the sessions was provided if necessary.
outcomes: At the end of the intervention and at the 18 month follow-up, there were no significant changes in any of the variables, including temperament, behavior, and parenting concept. This is in spite of the fact that the subjects were quite positive about the intervention.

TRIAL NO.: 58 (5058)

auth: Eyberg, SM
auth: Boggs, SR
auth: Algina, J
title: Parent-child interaction therapy: A psychosocial model for the treatment of young children with conduct problem behavior and their families
year: 1995
ref: Psychopharmacol Bull
vol: 31(1)
pps: 83-91
country: USA
method: RCT
N: 50
population: Subjects are families of 3 to 6 year old children referred for treatment of conduct problem behavior and screened for inclusion during clinic visits and in a school observation. Controls are wait-listed.
inter. type: Indicated preventive intervention
intervention: Experimental families received an average of 13 sessions of Parent-Child Interaction Therapy which focuses on changing the quality of the parent-child relationship and on increasing the child's compliance. Graduate student therapists follow a p rocedural outline for each treatment session. Undergraduate research assistants use videotapes of the therapy sessions to record treatment integrity data.
outcomes: Data is preliminary because only 19 subjects have completed the intervention. Outcomes at 4 months after baseline assessment (soon after completion of the intervention), comparing treated families with wait-list controls, show significant differences. The number of problem areas and the frequency of conduct problem behaviors decreased; parents believe they had more in influence on their child's behavior.

TRIAL NO.: 61 (5061)

auth: Field, T
auth: Widamayer, S
auth: Greenberg, R
auth: Stoller, S
title: Effects of parent training on teenage mothers and their infants
year: 1982
ref: Pediatrics
vol: 69(6)
pps: 703-707
country: USA
method: RCT
N: 120
population: Subjects were teenage mother and their infants who had been recruited at the neonatal stage from a large university hospital neonatal nursery. The mothers were black teenagers ranging in age from 13 to 19 year, and they were of lower SES. Their infants were delivered at term without perinatal complications.
inter. type: Selective preventive intervention
intervention: The experimental mothers were trained as CETA (Comprehensive Employment Training ACT)- paid teacher's aides in a medical school infant nursery that provided care for their infants and infants of medical faculty. They received parent training, job training, and an income for 4 hours per day for 6 months. The comparison group mothers received parent training through 6 months of biweekly home visits. The home visits were made by a psychology graduate student and a training CETA aide (black teenager). The mothers were instructed in caregiving and in sensorimotor and interactions exercises. The control group received neither of these interventions.
outcomes: At 2 years of age the infants of both intervention groups weighed more than the control infants and the infants in the nursery group received better Bayley mental and motor scores than the home-visited group who, in turn, received better scores on those scales than the control infants. Mothers in the nursery intervention had a greater rate of return to work or school and fewer repeat pregnancies.

TRIAL NO.: 62 (5062)
auth: Field, TM
auth: Widmayer, SM
auth: Stringer, S
auth: Ignatoff, E
year: 1980
title: Teenage, lower-class black mothers and their preterm infants: An intervention and developmental follow-up
ref: Child Development
vol: 51
pps: 426-436
country: USA
N: 150
method: RCT
population: Subjects included 5 groups of lower-class, black mothers and their infants: 60 preterm and their teenage mothers (half assigned to experimental and half to control), 30 full-term and their teenage mothers, 30 preterm and their adult mothers, and 30 full-term and their adult mothers. Preterm infants were required to be less than 37 weeks gestation, under 2500 grams, and without serious neonatal complications. Full-term infants were required to be 40 weeks gestation and more than 2500 grams.
inter. type: Selective preventive intervention
intervention: The experimental group received biweekly home visits by 2 person teams, a trained interventionist and a teenage, black, female work/study student, to educate mothers on child development, teach exercise and stimulation for facilitating development, and facilitate mother-infant interactions. The visits were twice per month for the first 4 months and monthly thereafter for the next 8 months.
outcomes: Outcomes are reported while the intervention is still occurring. At 4 month assessment, the experimental infants showed more optimal growth, Denver scores, and face-to face interactions. Their mothers rated their infants' temperaments more optimally, expressed more realistic developmental milestones and child-rearing attitudes, and received higher ratings on face-to-face interactions. At 8 month assessment, the experimental group received superior Bayley mental, Caldwell, and infant temperament scores.

TRIAL NO.: 63 (5063)
auth: Field, TM
auth: Schanberg, SM
auth: Scafidi, F
auth: Bauer, CR
auth: Vega-Lahr, N
auth: Garcia, R
auth: Nystrom, J
auth: **Kuhn, CM**
year: 1986
title: Tactile/kinesthetic stimulation effects on preterm neonates
ref: Pediatrics
vol: 77 (5)
pps: 654-658
country: USA
N: 40
method: RCT
population: Subjects were preterm neonates from an intensive care unit who were less than 36 weeks gestation and weighed less than 1500 grams but had no congenital anomalies or maternal drug addiction and whose weight upon admission to the transitional care nursery was between 1100 and 1650 grams.
inter. type: Selective preventive intervention
intervention: The experimental infants received tactile/kinesthetic stimulation consisting of body stroking and passive movement of the limbs for 3, 15-minute periods per day for 10 days. A protocol was

used but it is unclear who provided the stimulation.
outcomes: The experimental infants averaged a 47 percent greater weight gain per day, were more active and alert during sleep-wake behavior observations, and showed more more behavior on the Brazelton scale than the control infants. Their hospital stay was 6 days shorter, yielding a cost saving of approximately $3000 per infant.

TRIAL NO.: 251 (5251)

auth: Field, T
title: The treatment of depressed mothers and their infants
year: 1997
ref: In L Murray and PJ Cooper (Eds.) Postpartum Depression and Child Development.
city: New York
pub: The Guilford Press
pps: 221-236
country: USA
N: 120
method: depressed and nondepressed control groups; randomization?
population: Subjects were chronically depressed mothers (identified through biological markers for continuing depression) and their infants.
inter. type: Selective preventive intervention
intervention: The experimental mothers and infants received 3 months of comprehensive services, including free all-day care in a model infant nursery in a local public vocational high school. The mothers attended vocational high school in the mornings and participated in social and vocational rehabilitation activities and aerobics in the afternoon. The mothers also spent approximately 1 hour per day in the infant nursery helping the teachers take care of their infants. Music mood induction, relaxation therapy, massage therapy, infant massage, and interactive coaching with the mothers and infants together were also provided.
outcomes: At 6 months, the experimental infants showed more positive interaction behavior, better growth, fewer pediatric complications, normalized biochemical values, and by year 1 superior Bayley Mental and Motor scores. Their mothers continued to have higher depression scores than did the nondepressed mothers, but their interaction behavior became significantly more positive and their biochemical values and vagal tone normalized or approximated the values of the nondepressed control group.

TRIAL NO.: 253 (5253)

auth: Field, T
auth: Grizzle, N
auth: Scafidi, F
auth: Abrams, S
title: Massage therapy for infants of depressed mothers
year: 1996
ref: Infant Behavior and Development
ref: 19
pps: 107-112
country: USA
N: 32
method: 2 intervention groups
population: Subjects were full-term, normal birthweight infants and their depressed adolescent mothers. The infants had had normal Apgar scores. The mothers were low SES, single, and on public assistance. They had been classified as depressed because they were diagnosed as dysthymic on the Diagnostic Interview Schedule and had high scores on the Beck. The infants were recruited at birth and attended a daycare nursery from birth and during the time they participated in the study.
inter. type: Selective prevenive intervention
intervention: The experimental infants were provided 15 minutes of massage therapy between morning feedings 2 days per week for a 6 week period. The massage was administered by a researcher who was trained on the procedure. The control infants were rocked for 15 minutes between morning feedings 2 days per week over the same 6 week period.

outcomes: There were positive benefits for both interventions, but the effects were more dramatic for the experimental group. Over the 6 week period, the experimental infants were first more alert and then showed less stress, and their sleep was enhanced. They gained more weight, showed greater improvement on emotionality, sociabiliy, and soothability temperament dimensions, and had greater decreases in uriary stress catecholamines/hormones.

TRIAL NO.: 254 (5254)

auth: Field, TM
title: Effects of early separation, interactive deficits, and experimental manipulations on infant-mother face-to-face interaction
year: 1977
ref: Child Development
vol: 48
pps: 763-771
country: USA
N: 36
method: comparison groups, non-randomized
population: Subjects were mother-infant dyads. There were 3 groups of subjects: babies with premature, respiratory distress syndrome who had been separated from their mothers after birth and who received low Brazelton interaction scores; babies who were postterm and postmature who received low Brazelton scores; and babies who were healthy and term.
inter. type: Indicated preventive intervention
intervention: All dyads received a 15 minute intervention which included an experimental manipulation of the mother trying to keep her infant's attention and the mother imitating her infant's behaviors.
outcomes: Altering the mother's amount of activity modified considerably the face-to-face interactions of the dyads.

TRIAL NO.: 65 (5065)

auth: Finney, JW
auth: Brophy, CJ
auth: Friman, PC
auth: Golden, AS
auth: Richman, GS
auth: Ross, AF
title: Promoting parent-provider interaction during young children's health-supervision visits
year: 1990
ref: Journal of Applied Behavioral Analysis
vol: 23(2)
pps: 207-213
country: USA
N: 32
method: RCT
population: Mother-child pairs were recruited from a community health center serving a low SES population in a large city. They were selected unsystematically from those mothers who had previously scheduled visits with their regular health-care providers.
inter. type: Universal preventive intervention
intervention: All mothers identified questions about their children that they wished to ask the providers during the appointments. The experimental mothers were prompted and encouraged to ask these questions and any others they thought of during the health visit. The controls received brief contacts with the researcher, but there were no further discussions of the parents' questions.
outcomes: There was more interaction between parents and health -care providers and more discussion of behavioral topics in the experimental group. Both groups reported satisfaction with their health-care services.

TRIAL NO.: 439 (5439)
auth: Fleisher, BE
auth: VandenBerg, K
auth: Constantinou, J
auth: Heller, C
auth: Benitz, WE
auth: Johnson, A
auth: Rosenthal, A
auth: Stevenson, DK
title: Individualized developmental care for very-low-birth-weight premature infants
year: 1995
ref: Clinical Pediatrics
vol: 34(10)
pps: 523-529
country: USA
N: 40
method: RCT
population: Subjects were infants with birth weights less than 1250 grams and gestational ages less than 30 weeks. Potential subjects were excluded for these reasons: multiple gestation; mechanical ventilation not begun in the first 3 hours or continued for more than 24 of the first 48 hours of life; chromosomal abnormalities, congenital anomalies or infection; parents lived beyond a predesignated catchment area; parents were non-English speaking; and enrollment in other research studies with conflicting goals.
inter. type: Selective preventive intervention
intervention: Infants in the control group received routine care. Experimental infants were evaluated by certified developmental specialists within 24 hours of admission and weekly thereafter. Individualized care plans were developed and were implemented by highly trained and specialized nurses.
outcomes: Experimental babies required fewer days of intermittent mandatory ventilation and continuous positive airway pressure and achieved full enteral feedings sooner. Length of hospital stay and hospital charges were less for experimental than control infants. There was an average reduction of charges of $128,670 per experimental infant. The saving was approximately 10 times the cost of the developmental service component of the program. There were favorable effects on experimental infants' behavioral performance at 42 weeks' postconceptional age.
inter: developmentally oriented NICU care
result: shorter length of stay and better behavioral performance

TRIAL NO.: 67 (5067)
auth: Forgatch, MS
auth: Toobert, DJ
title: A cost-effective parent training program for use with normal preschool children
year: 1979
ref: Journal of Pediatric Psychology
vol: 4(2)
pps: 129-145
country: USA
N: exp #1 = 12; exp #2 = 15
method: RCT
population: exp # 1: Subjects were children and mothers who had been recruited through the local newspaper seeking normal (defined as not currently involved in psychological treatment) preschoolers who whine at high rates. exp # 2: Recruitment was the same, but the target behavior was noncompliance.
inter. type: Indicated preventive intervention
intervention: The experimental subjects in both experiments were given brief parent training with supplemental written materials and telephone calls. The wait list controls received the same intervention later.

outcomes: At 1 month follow-up: exp #1: In the experimental group the mean rate of whining incidents significantly decreased from base line to termination, but both groups showed a significant decrease in whining from base line to follow-up. exp #2: The findings were similar to the first experiment.

TRIAL NO.: 69 (5069)

auth: Fox, NL
auth: Sexton, MJ
auth: Hebel, JR
title: Alcohol consumption among pregnant smokers: Effects of a smoking cessation intervention program
year: 1987
ref: American Journal of Public Health
vol: 77(2)
pps: 211-213
country: USA
N: 935
method: RCT
population: Subjects were women who smoked 10 or more cigarettes per day at the beginning of pregnancy, had not yet passed the 18th week of gestation, and who registered for prenatal care through private obstetricians or a large university obstetrics clinic.
inter. type: Selective preventive intervention
intervention: The experimental group received assistance with smoking cessation, including information, support, practical guidance, and behavioral strategies. The smoking cessation counselors did not make recommendations regarding intake of alcohol or other health-related behaviors. No contact was made with the controls until follow-up.
outcomes: At follow-up during the 8th month of pregnancy, the experimental women had decreased their smoking during pregnancy, but there were no effects on alcohol intake, suggesting that interventions for 1 habit are not extended to other behaviors by the women themselves.

TRIAL NO.: 70 (5070)

auth: Gelfand, DM
auth: Teti, DM
auth: Seiner, SA
auth: Jameson, PB
title: Helping mothers fight depression: Evaluation of a home-based intervention program for depressed mothers and their infants
year: 1996
ref: Journal of Clinical Child Psychology
vol: 25(4)
pps: 406-422
country: USA
N: 148
method: controlled trial without randomization
population: Subjects were mothers who were clinically depressed with infants between 3 and 13 months of age. They were referred to the study by their therapists except for 3 who self-referred. They had a diagnosis of depression or dysthymia but no other known major psychiatric or substance abuse disorder. Most reported at least 1 previous depressive episode. Controls were non-depressed mothers with the same age infants who were recruited through birth-registry records or newspaper announcements in similar geographic areas. Most subjects were married, middle- or lower-middle class, had a high school degree, and were Mormons.
inter. type: Selective preventive intervention
intervention: The experimental mothers received 29 home visits at 1 to 3 week intervals from 1 of 6 nurses who had been trained in mother-infant and public health nursing. Individualized intervention programs, developed in consultation with the project supervisors, aimed to enhance parenting skills and counteract the effects of the mothers' depressed affect. The nurses acted as the mothers' advocates and information sources. Nurses' verbal and written reports of their visits provide checks on the fidelity of intervention delivery.

outcomes: At 1 month follow-up, experimental mothers improved significantly more in reported depression and daily hassles than the controls. Better maternal and child adjustment accompanied decreased depression.

TRIAL NO.: 71 (5071)

auth: Girolametto, L
auth: Pearce, PS
auth: Weitzman, E
title: Interactive focused stimulation for toddlers with expressive vocabulary delays
year: 1996
ref: Journal of Speech and Hearing Research
vol: 39
pps: 1274-1283
country: Canada
method: RCT
N: 25
population: All families were recruited from waiting lists for parent-focused language intervention programs offered at 2 agencies in a metropolitan city. Only self-referrals from these lists were accepted. The children were late-talking toddlers between 23 and 33 months of age at entry into the study. None had major sensory impairments, oral motor problems, frank neurological problems, or autism. English was the only language spoken in the home.
prev. type: Indicated preventive intervention (bordering on selective)
intervention: The intervention aimed to teach parents to teach specific target words to their toddlers with expressive vocabulary delays. The Hanen Program for Parents was administered to families by 2 experienced speech-language pathologists who were certified by The Hanen Centre to administer this program and a parent associate who had a child with language delay and had completed a program. The 11 week intervention included 8 evening sessions to teach program strategies and 3 home visits to provide parents with individual feedback regarding their own and their child's progress. The home visits were conducted by the speech-language pathologist and the parent associate. Videotapes were used to provide feedback, and home practice was assigned. Intervention fidelity was monitored by examining parent attendance at sessions the observing parent-child interaction during the home visits.
outcomes: At the completion of the intervention (4 months after the pretest), the experimental children made developmental gains in vocabulary, in the use of multiword phrases, and in grammatical complexity that were over and above the maturational changes made by the wait-list control group. (These children already had good cognitive and receptive language skills.) The experimental mothers' language input was slower, less complex, and more focused than control mothers.

TRIAL NO.: 72 (5072)

auth: Girolametto, L
auth: Verbey, M
auth: Tannock, R
title: Improving joint engagement in parent-child interaction: An intervention study
year: 1994
ref: Journal of Early Intervention
vol: 18(2)
pps: 155-167
country: Canada
N: 14
method: controlled trial
population: Subjects were preschoolers with developmental delays and their mothers. The sample was drawn from a larger data pool of another study that had been randomized. A matching procedure from those experimental and control groups was utilized.
inter. type: Indicated preventive intervention
intervention: The experimental group received the Hanen Early Language Program; it was latter delivered to the wait list control 4 months later. The program, which trains mothers to increase the child's social interaction in naturally occurring events, lasted 12 weeks and consisted of 9 group sessions and 3 home visits. A speech-language pathologist with extensive training and experience in using the Hanen conducted the group sessions. A trained parent-assistant, who was herself a graduate of the program, conducted the home visits an assisted in the group sessions. Written materials and videotape feedback were used.
outcomes: The experimental group demonstrated increases in interactive engagement between mothers and their children.

TRIAL NO.: 76 (5076)

auth: Gomes-Pedro, J
auth: Patricio, M
auth: Carvalho, A
auth: Goldschmidt, T
auth: Torgal-Garcia, F
auth: Monteiro, MB
title: Early intervention with Portuguese mothers: A 2-year follow-up
year: 1995
ref: Development and Behavioral Pediatrics
vol: 16(1)
pps: 21-28
country: Portugal
N: 60
method: RCT
population: Subjects were primiparious, Portuguese, Casucasian low-middle class mothers between the ages of 18 and 35. All had been living with their baby's father for at least 1 year. All intended to breast-feed their newborn. None intended to work during the first 3 months after delivery. Only mothers with an uncomplicated pregnancy were included. Mothers who had addictive behaviors or who had participated in prenatal classes, where mothers are taught about babies' competencies, were not included. Gestational age had to be between 37 and 42 weeks. Labor could not last for more than 24 hours and had to be experienced with no or mild anesthesia. Deliveries had to be vaginal with cephalic presentation.
inter. type: Universal preventive intervention
intervention: On the 3rd day of the infant's life, the experimental mothers underwent a 7 minute structured intervention with a pediatrician who used selected items of the Brazelton Neonatal Behavioral Assessment Scale (NBAS) to the assess the newborns. The mothers were shown how the baby demonstrated sensory orientation, cuddliness, and consolability, as well as how to elicit competencies from the baby.

outcomes: There were follow-up pediatric assessments in the presence of the mothers at 8 and 28 days, 3, 6, 9, 12, 15, 18, and 24 months. There were no significant differences between the 2 groups on day 3, but on day 28 the experimental babies obtained better scores in 5 of the 28 behavioral items on the NBAS, and there were positive effects on neurobehavioral development and mother-infant interaction. Control mothers tended to overstimulate their babies whereas the experimental mothers did a better job of adjusting their behavior to help the baby. By 2 years the benefits were less clear, but there were better interactive patterns among the dyads in the experimental group.

TRIAL NO.: 77 (5077)

auth: Gotts, EE
title: Parent training, home environment, and early childhood development: A long-term follow-up study
year: 1987
ref: Early Child Development and Care
vol: 27
pps: 359-372
project title: Home-Oriented Preschool Education Program (HOPE)
country: USA
N: 703
method: RCT
population: All preschool children within randomly selected sites within an isolated rural area of Central Appalachia were invited to participate.
inter. type: Universal preventive intervention
intervention: There were 4 groups: an outside control; television only, which was a daily educational television series for preschoolers; television plus weekly home visits by a paraprofessional; television plus home visits plus a weekly one-half group experience for the children with a teacher and an aide. Families participated in this intervention from 1 to 3 years.
outcomes: At 10 year follow-up, no attempt was made to locate the outside controls, and the 2 groups who had received home visitation were combined. Participation in the home enrichment program appeared to attenuate the effects of a child's family background on the child's performance in school and to reduce the relationship between social class and the quality of home learning environment provided.

TRIAL NO.: 78 (7077)

auth: Gotts, EE
title: Home-based early intervention
year: 1983
ref: In AW Childs and GB Melton (Eds.), Rural Psychology
city: New York
pub: Plenum Publishing Company
project title: Home-Oriented Preschool Education (HOPE)
country: USA
N: See annotation #77
method: See annotation # 77
population: See annotation #77
inter. type: See annotation #77
intervention: See annotation #77
outcomes: This paper reports on secondary analyses of the original HOPE data. The children were divided into groups of differing ability levels (IQ). The intervention seemed to have stabilized the below average (IQ 91.5 and below) children relative to their peers with lower average and higher average IQs. Home visitation seemed to have reduced the rate of retention in grade from about 25 percent in the group who received the television (TV) only intervention to 5 percent by the addition of home visitation. Home-visited children were significantly lower on personal disorganization and symptoms of depression that the TV only children.

TRIAL NO.: 80 (5079)
auth: Grantham-McGregor, S
auth: Schofield, W
auth: Harris, L
title: Effect of psychosocial stimulation on mental development of severely malnourished children: An interim report
year: 1983
ref: Pediatrics
vol: 72(2)
pps: 239-243
project title: The Jamaican Study
country: Jamaica
N: 54
method: controlled trial, not randomized
population: Subjects were severely malnourished children, between the ages of 6 and 24 months, who were inpatients at a university hospital. The first cohort of children served as the comparison group, and the second cohort received the intervention. Control children were also recruited. These children had been adequately nourished but were ill with acute diseases and were hospitalized during the same period as the first cohort of malnourished children. All children had birthweights over 2.4 kg. Twins, children with physical handicaps or who had been previously admitted to the hospital, and those living in residential children's home were excluded.
inter. type: Selective preventive intervention
intervention: The experimental children received structured play sessions in the hospital and weekly paraprofessional home visits with toy demonstrations for 2 years after hospitalization. The home visitors showed mothers how to continue structured play. The comparison children, also severely malnourished, received standard hospital care. The control children received no follow-up intervention.
outcomes: At 2 year follow-up since they left the hospital, the experimental children had developmental gains superior to the comparison group who received standard hospital care, but on nutrition and locomotor development they were still behind the normal controls.

TRIAL NO.: 79 (5079)
auth: Grantham-McGregor, S
auth: Powell, C
auth: Walker, S
auth: Chang, S
auth: Fletcher, P
title: The long-term follow-up of severely malnourished children who participated in an intervention program
year: 1994
ref: Child Development
vol: 65(2)
pps: 428-439
project title: The Jamaican Study
country: Jamaica
N: 54
method: controlled trial, not randomized
population: Subjects were severely malnourished children, between the ages of 6 and 24 months, who were inpatients at a university hospital. The first cohort of children served as the comparison group, and the second cohort received the intervention. Control children were also recruited. These children had been adequately nourished but were ill with acute diseases and were hospitalized during the same period as the first cohort of malnourished children. All children had birthweights over 2.4 kg. Twins, children with physical handicaps or who had been previously admitted to the hospital, and those living in residential children's home were excluded.
inter. type: Selective preventive intervention

intervention: The experimental children received structured play sessions in the hospital and weekly or 2 weekly paraprofessional home visits with toy demonstrations for 3 years after hospitalization. The home visitors showed mothers how to continue structured play. The comparison children, also severely malnourished, received standard hospital care. The control children received no follow-up intervention.
outcomes: At 7, 8, 9, and 14 years after leaving the hospital, the 3 groups were compared on tests of school achievement and IQ. The comparison children showed no sign of reducing their deficits, and at the 14-year follow-up had markedly lower scores. The experimental children were intermediate between the comparison children and control children on scores on every test. At 14 year follow-up post hospitalization (11 years since the intervention ended), the experimental children's scores were significantly higher than those of the comparison children in the WISC full and verbal scales. However, all groups had very low scores on the IQ test and the WRAT achievement test.

TRIAL NO.: 268 (5268)

auth: Gray, JD
auth: Cutler, CA
auth: Dean, JG
auth: Kempe, CH
title: Prediction and prevention of child abuse and neglect
ref: Journal of Social Issues
year: 1979
vol: 35(2)
pps: 127-139
country: USA
N: 150
method: RCT
population: Subjects were mothers randomly drawn from the total pool of women who had their first or second child at a large city hospital in a 17 month period. Mothers of infants with neonatal conditions severe enough to require transfer to the neonatal intensive care unit were excluded. These women were then screened for their parenting potential and assigned to a high-risk or low-risk group.
inter. type: Selective preventive intervention
intervention: The high-risk experimental group received pediatric care by 1 pediatrician at the hospital where the child was born; weekly home visits by public health nurses; referrals to other medical facilities or mental health clinics; and coordination of care and emotional support from lay persons. The high-risk experimental group and the low-risk group received standard care.
outcomes: At follow-up when the child was between 17 and 35 months of age, 25 randomly selected families in each of the 3 groups were assessed. There were no significant differences between the high-risk experimental and high-risk comparison groups in the number of child abuse reports, indications of abnormal parenting, accidents, immunizations, or in scores on the Denver Developmental Screening Test. However, there were differences in the number of injuries serious enough to require hospitalization. Information from observations of labor as well as from delivery room interactions correctly predicted 76.5 percent of the abnormal parenting potential.

TRIAL NO.: 83 (5083)

auth: Gutelius, MF
auth: Kirsch, AD
auth: MacDonald, S
auth: Brooks, MR
auth: McErlean, T
title: Controlled study of child health supervision: Behavioral results
year: 1977
ref: Pediatrics
vol: 60 (3)
pps: 294-304
country: USA
N: 119
method: RCT
population: Subjects were unmarried primigravidas between 15 and 18 years of age who lived in low-income census tracts in a large city. They were identified in schools and prenatal clinics by at least the seventh month of pregnancy. Other inclusion criteria included an IQ of 70 or above, no evidence of chronic physical disease, and no sign of major emotional pathology as determined by a short interview with a psychiatrist. These mothers were randomly assigned, and then there was a second screening. Infants with birth weights under 2500 grams or congenital anomalies were eliminated, plus 8 infants died at birth or shortly thereafter.
inter. type: Selective preventive intervention
intervention: The experimental group received routine health care and counseling from a nurse (master's degree in public health nursing) beginning by the seventh month of pregnancy. After birth, the experimental infants received complete well-baby care for the first 3 years of life from the same pediatrician and nurse. Care was provided by appointment in a mobile coach parked in front of the mother's home. A second set of home visits was made by the nurse for a cognitive stimulation program. The 2 sets of home visits made a total of at least 18, 12, and 8 visits in the first, second, and third years of life, respectively. During the first year, there were 16 additional events, including group discussion meetings on child rearing. The counseling that was provided was mostly unstructured, direct, and full of advice to the mothers on their personal lives. The control group was referred to local clinics for prenatal and well-child care.
outcomes: During the 3 years of the intervention plus 3 years follow-up, positive effects were evident in improved diet and feeding habits, sleeping patterns, and child rearing practices such as toilet training. On developmental and intelligence tests, there were significant differences between the experimental and control children through 3 years of age, with decreasing differences in the following years. Experimental children had fewer behavior problems than control children at 5 and 6 years, and more experimental mothers persevered in efforts to continue their education.

TRIAL NO.: 87 (5131)

auth: Haas, JS
auth: McCormick, MC
title: Hospital use and health status of women during the 5 years following the birth of a premature, low-birthweight infant
year: 1997
ref: The American Journal of Public Health
vol: 87(7)
pps: 1151-1155
country: USA
project title: Infant Health and Development Program
N: 985
method: RCT
population: Subjects were infants weighing 2500 grams or less and whose gestational age at birth was 37 weeks or less. Siblings of eligible twins and infants with severe conditions were precluded. Non-English speaking mothers and mothers who reported drug, alcohol, or psychiatric hospitalization were also excluded. The 8 clinical sites were socioeconomically heterogeneous.
inter. type: Selective preventive intervention
intervention: The intervention was provided from neonatal discharge through age 3 years. The experimental group received home visits to age 3, 5 day per week center-based schooling from 12 months to 3 years, and pediatric surveillance; the control group received pediatric surveillance.
outcomes: Women who have had a premature, low-birthweight infant experience substantial morbidity that continues for at least 5 years following the birth of the child. Almost 60 percent of the women required hospitalization during this 5 year period. While pregnancy accounted for approximately half of these hospitalizations, the remainder were unrelated to pregnancy. Almost 20 percent of these women reported themselves to be in poor to fair health.

TRIAL NO.: 409 (5409)

auth: Hall, LA
title: Effect of teaching on primiparas' perceptions of their newborn
year: 1980
ref: Nursing Research
vol: 29(5)
pps: 317-322
country: USA
N: 30
method: RCT
population: Subjects were primiparous mothers between 18 and 30 years of age who were married, had no chronic disease, had had a normal pregnancy, labor, delivery, and postpartal course, and had delivered at 1 community teaching hospital.
inter. type: Universal preventive intervention
intervention: The first contact with all subjects took place at the hospital 1 to 2 days postpartum; this was for data collection purposes. The experimental mothers then received a home visit by a nurse 2 to 4 days post-discharge that consisted of structured, informative teaching concerning infant behavior. The final data collection for all subjects was in the home.
outcomes: At one month the experimental mothers had a significantly more positive perception of their infants than control mothers did.

TRIAL NO.: 84 (5084)

auth: Hanks, C
auth: Kitzman, H
auth: Milligan, R
title: Implementing the COACH Relationship Model: Health promotion for mothers and children
year: 1995
ref: Advances in Nursing Science
vol: 18(2)
pps: 57-66
project title: COACH
country: USA
N: Not stated
method: clinical trial
population: Subjects were low-income mothers.
inter. type: Universal preventive intervention
intervention: A nurse home visitation program developed and utilized the COACH Relationship Model to help subjects change health-related behaviors as part of a clinical trial conducted from 1990 to 1994.
outcomes: No data was provided.

TRIAL NO.: 85 (5085)

auth: Hansen, K
auth: Wong, D
auth: Young, PC
title: Do the Framingham Safety Surveys improve injury prevention counseling during pediatric health supervision visits?
year: 1996
ref: The Journal of Pediatrics
vol: 129(4)
pps: 494-498
project title: Framington Safety Surveys
country: USA
N: 312
method: non-random, pre-post
population: Subjects were parents with young children coming for health supervision visits at a hospital-based pediatric clinic or a private group practice.
inter. type: Universal preventive intervention
intervention: Parents filled out the Framingham Safety Survey before the visit with the physician. The survey checklist was placed with the child's record for the physician to review if he chose to do so. He was unaware that the checklist was a research tool.
outcomes: Most physicians believed the FSS was useful. However, introduction of the survey did not improve injury prevention counseling. 47 percent of the high-risk behaviors identified on the checklists for children under 2 years of age were not discussed by the physician.

TRIAL NO.: 86 (5086)

auth: Hardy, JB
auth: Streett, R
title: Family support and parenting education in the **home:** An effective extension of clinic- based preventive health care services for poor children
year: 1989
ref: The Journal of Pediatrics
vol: 115(6)
pps: 927-931
country: USA
N: 263
method: RCT
population: Subjects were healthy neonates weighing more than 2000 grams and born to black inner-city women aged 18 years and older.
inter. type: Selective preventive intervention
intervention: Home visitation began 7 to 10 days after birth and continued for almost 2 years on a schedule of every 2-3 months with additional discretionary visits. The home visitor was a college-educated black woman who had previously lived in the community. After limited training, she worked under the supervision of an educator and a social worker. She used a parenting education curriculum, including educational booklets and a calendar. If she encountered difficult psychosocial problems, mothers were referred to the social worker or educator. Routine home visits were scheduled to occur in such a way as to encourage compliance with well-child clinic visits. The home visitor was also available by telephone.
outcomes: At the completion of the intervention, the experimental group compared to the control group demonstrated many benefits: better compliance with well-child care including immunizations, fewer illness visits to the outpatient clinic, fewer hospitalizations, and fewer suspicions and no cases of neglect or abuse. Substantial costs were averted ink the experimental group.

TRIAL NO.: 88 (5088)

auth: Heins, HC
auth: Nance, NW
auth: McCarthy, BJ
auth: Efird, CM
title: A randomized trial of nurse-midwifery prenatal care to reduce low birth weight
year: 1990
ref: Obstetrics & Gynecology
vol: 75 (3 Pt 1)
pps: 341-345
country: USA
N: 1458
method: RCT
population: Subjects were women at high risk for low birth weight outcome according to a risk factor scale or delivery of a low birth weight baby in their last pregnancy. The women were free of known medical or pregnancy complications.
inter. type: Selective preventive intervention
intervention: The experimental group received nurse-midwifery care in a separate low birth weight prevention clinic. In addition to medical care, they received stress reduction counseling, social support, and substance abuse counseling. They were seen in the clinic at 1-2 week intervals. The control group attended the regular high-risk obstetric clinic.
outcomes: There were few differences between the groups. There was some indication that black women at high statistical risk of giving birth to a low birth weight infant may have derived some benefit from the program.

TRIAL NO.: 89 (5089)

auth: Herman, AA
auth: Berendes, HW
auth: Yu, KF
auth: Cooper, LC
auth: Overpeck, MD
auth: Rhoads, G
auth: Maxwell, JP
auth: Kinney, BA
auth: Koslowe, JP
auth: Coates, DL
title: Evaluation of the effectiveness of a community-based enriched model prenatal intervention project in the District of Columbia
year: 1996
ref: Health Services Research
vol: 31(5)
pps: 609-621
project title: Better Babies Project
country: USA
N: 943
method: comparison census tracts, not randomized
population: Subjects were women less than 29 weeks pregnant who lived in the study neighborhood which had high low-birthweight and infant mortality rates. Controls were pregnant women who lived in neighborhoods with similar rates of poverty.
inter. type: Selective preventive intervention
intervention: The experimental group received an enriched freestanding prenatal intervention program designed to prevent low birthweight. Services were delivered until 6 weeks postpartum by paraprofessional lay health workers, supervised by a community health nurse and a social worker. Services included referrals to other community resources, a weight gain program for women with low prepregnant weight and/or poor pregnancy weight gain; an alcohol and drug abuse education program; referral of women with alcohol and drug abuse problems; information on how to identify early signs of labor; a drop-in center; and after-hour assistance available by telephone by the Visiting Nurse Association. The lay workers were expected to recruit 4 new subjects every month.
outcomes: There was no effect on overall low- and very low birthweight rates in the experimental group. Participation was low, and mobility was high. The authors highlight the similarity of their approach to the Health Start Project.

TRIAL NO.: 433 (5433)

auth: Hofmeyr, GJ
auth: Nikodem, VC
auth: Wolman, WL
auth: Chalmers, BE
auth: Kramer, T
title: Companionship to modify the clinical birth environment: Effects on progress and perceptions of labor, and breastfeeding
year: 1991
ref: British Journal of Obstetrics and Gynaecology
vol: 98
pps: 756-764
country: South Africa
N: 189
method: RCT
population: Subjects were nulliparous women in established labour at a community hospital serving a low income urban population. The women were without significant obstetric complications whose cervices were less than 6 cm dilated and who had no supportive companion with them.
inter. type: Selective preventive intervention
intervention: The experimental mothers received supportive companionship from volunteer from the community, concentrating on comfort, reassurance, and praise. The volunteers had no medical or nursing experience. They were carefully selected but were trained very minimally.
outcomes: The experimental intervention had no measurable effect on the progress of labour. Diastolic blood pressure and use of analgesia were modestly but significantly reduced. The experimental mothers were significantly more likely to report that they felt that they had coped well during labour, and their mean labour pain scores and state anxiety scores were significantly lower than those of the control group. At 6 weeks the experimental women were more likely to be breastfeeding exclusively and to be feeding at flexible intervals.

TRIAL NO.: 246 (5246)

auth: Holden, JM
auth: Sagovsky, R
auth: Cox, JL
title: Counselling in a general practice setting: Controlled study of health visitor intervention in treatment of postnatal depression
year: 1989
ref: British Medical Journal
vol: 298
pps: 223-226
country: Scotland
N: 55
method: control group received routine primary care
population: Subjects were women attending child health clinics at 5 centers who had been screened for postnatal depression about 6 weeks after delivery. Those found to be positive on a screening instrument were screened again at home by a psychiatrist about 12 weeks after delivery. Those women found to still be depressed but non-psychotic were randomized into experimental and control groups.
inter type: Selective preventive intervention
intervention: The experimental group received a mean of 8.8 weekly in-home counseling sessions by professional health visitors who were trained in nondirective counseling techniques.
outcomes: After 3 months, 69 percent of the experimental mothers had completely recovered compared with 38 percent of the control mothers. No child outcomes were reported.

TRIAL NO.: 90 (5090)

auth: Honig, AS
auth: Lally, JR
auth: Mathieson, DH
year: 1982
title: Personal-social adjustment of school children after five years in a family enrichment program
ref: Child Care Quarterly
vol: 11(2)
pps: 138-146
country: USA
N: 57
method:
population: Subjects were children who had graduated from 5 years of participation in a family enrichment program that provided developmental day care for the children and a home visitation program with the families. All families were low-income and 85 percent were single-parent families. Contrast children were selected within the 15 schools where program graduates were enrolled. They were matched on age, sex, race, SES, classroom, and teacher.
inter. type: Selective preventive intervention
intervention: The home visitation program supported positive family social and learning experiences for the children. The day care program, which had a 1 to 4 adult-child ratio, focused on learning and positive social experiences.
outcomes: After graduation from the family enrichment program, two groups were followed up: 37 kindergarten children and 20 first grade children. The positive social skills in both groups were not maintained into first grade. The transition from the highly supportive day-care learning environment to public school classrooms with low adult-to-child ratios presented problems for some of the children.

TRIAL NO.: 91 (5030)

auth: Horacek, HJ
auth: Ramey, CT
auth: Campbell, FA
auth: Hoffman, KP
auth: Fletcher, RH
title: Predicting school failure and assessing early intervention with high-risk children
year: 1987
ref: Journal of the American Academy of Child and Adolescent Psychiatry
vol: 26
pps: 758-763
project title: The Carolina Abecedarian Project (second intervention)
country: USA
N: 111
method: RCT
population: Subjects were children identified at birth as being at high risk for school failure based on social and economic variables (see earlier annotations). These children who had been assigned to experimental and control groups were again randomly assigned at kindergarten to a school-age intervention or control group. Also, an average-risk group was recruited as a comparison group from the same schools as the high-risk children.
inter. type: Selective preventive intervention
intervention: The experimental kindergarten children received 15 home visits per year for 3 years from a teacher who prepared a home program to supplement the school's basic curriculum. The teacher also consulted with the regular classroom teacher, averaging 18 school visits per family per year.
outcomes: High-risk children experienced 3.8 times the rate of grade failure (50 percent) of their average-risk peers (13 percent). The double educational intervention — preschool and elementary school — reduced the incidence of grade failure to 16 percent.

TRIAL NO.: 94 (5117)

auth: Johnson, DL

title: Primary prevention of behavior problems in young children: The Houston Parent-Child Development Center

year: 1991

ref: In R Price, EL Cowen, RP Lorion, and J Ramos-McKay (Eds.), Fourteen Ounces of Prevention: A Casebook for Practitioners

city: Washington, DC

pub: American Psychological Association

pps: 44-52

project title: Houston Parent-Child Development Center

country: USA

N: 800 (approx.)

method: RCT

population: Subjects were 1 year old children whose Mexican-American families were impoverished. Families were excluded if the child had a neurological impairment or was chronically ill or the mother was employed in ways that would interfere with participation.

inter. type: Selective preventive intervention

intervention: The intervention was specifically designed for this minority group and therefore had its first year in the home, included fathers, and conducted much of its verbal interactions in Spanish. The program began when the children were 1 and ended when they were 3, totaling approximately 550 hours of family involvement. The 25 home visits were conducted by paraprofessional women from the barrios who had been trained as resource persons, bringing information to the mother about child development and child training. There were also several family workshops held on weekends for whole families. Mothers also participated in English-language classes. The second year consisted by 4 mornings a week at the project Center where the children were in nursery school, the mothers attended classes, and videotaping of mother-child interaction was used as a teaching tool. Both professionals and paraprofessionals were involved.

outcomes: At the end of the program, experimental mothers demonstrated better interactive skills with their child and provided a more educationally stimulating environment. The children demonstrated small but significantly better IQ scores. When the children were 4 to 7 years, boys in the control group demonstrated the most behavior problems. When the children were 5 to 8 years, control children had more behavior problems and significantly lower cognitive scores.

TRIAL NO.: 117 (5117)
auth: Johnson, DL
auth: Breckenridge, JN
title: The Houston Parent-Child Development Center and the primary prevention of behavior problems in young children
year: 1982
ref: American Journal of Community Psychology
vol: 10(3)
pps: 305-316
project title: Houston Parent-Child Development Center
country: USA
N: 458
method: RCT
population: Subjects were 1 year old children whose Mexican-American families were impoverished. Families were excluded if the child had a neurological impairment or was chronically ill or the mother was employed in ways that would interfere with participation.
inter. type: Selective preventive intervention
intervention: The intervention was specifically designed for this minority group and therefore had its first year in the home, included fathers, and conducted much of its verbal interactions in Spanish. The program began when the children were 1 and ended when they were 3, totaling approximately 500 hours of family involvement. The 25 home visits were conducted by paraprofessional women from the barrios who had been trained as resource persons, bringing information to the mother about child development and child training. There were also several family workshops held on weekends for whole families. Mothers also participated in English-language classes. The second year consisted by 4 mornings a week at the project Center where the children were in nursery school, the mothers attended classes, and videotaping of mother-child interaction was used as a teaching tool. Both professionals and paraprofessionals were involved.
outcomes: A follow-up of part of the sample 1-4 years after the program was completed (when the children averaged 5 1/2 years) showed, according to mothers' reports, that experimental boys and girls presented very few problems and control girls were not too different from them. Control boys were more destructive, overactive, negative attention-seeking, and less emotionally sensitive than program boys and girls and control girls.

TRIAL NO.: 233 (5117)
auth: Johnson, DL
auth: Walker, T
title: Primary prevention of behavior problems in Mexican-American children
year: 1987
ref: American Journal of Community Psychology
vol: 15(4)
pps: 375-385
project title: Houston Parent-Child Development Center
country: USA
N: 458
method: RCT
population: See earlier annotation.
inter. type: Selective preventive intervention
method: See earlier annotation.
outcomes: A second follow-up 5 to 8 years after the program's completion was based on teachers' ratings. The frequency of behavior problems, including acting-out, aggressive behaviors, in the experimental children was significantly less than in the control children. Differences between groups on moody, withdrawn behaviors approached but did not achieve significance. Experimental boys were less dependent than control boys. Although there were no teacher-reported group differences on learning problems, the experimental children obtained significantly higher Iowa Test of Basic Skills Composite scores. The authors note that this appears to be the first primary prevention program to have demonstrated effectiveness in reducing behavior problems over such a long time.

TRIAL NO.: 269 (5269)

auth: Johnson, Z
auth: Howell, F
auth: Molloy, B
title: Community mothers' programme: Randomised controlled trial of non-professional intervention in parenting
year: 1993
ref: British Medical Journal
vol: 306
pps: 1449-1452
country: Ireland
N: 262
method: RCT
population: Subjects were first time mothers who were delivered their babies during a 6 month period in a deprived area of a Dublin.
inter. type: Selective preventive intervention
intervention: The experimental group of mothers were home visited once a month for the first year of the child's life by experienced volunteer community mothers who delivered a child development programme with specific modules but did not give advice. The home visitors received 4 weeks of training and worked under the supervision of a nurse. Both the experimental and control groups received standard support from their own local public health nurse, which consisted of visits at birth and 6 weeks and at other times as required. Both groups received offers for an infant developmental assessment and immunisations.
outcomes: At the end of the study, experimental children had received more immunisations, had been read to more frequently, played more cognitive games, were less likely to be given cows' milk before 26 weeks or other inappropriate foods. The children were less likely to be tired or miserable and were less likely to display negative feelings.

TRIAL NO.: 96 (5096)

auth: Jones, ME
auth: Mondy, LW
title: Lessons for prevention and intervention in adolescent pregnancy: A five-year comparison of outcomes of two programs for school-aged pregnant adolescents
year: 1994
ref: Journal of Pediatric Health Care
vol: 8(4)
pps: 152-159
project title: Lifespan Program
country: USA
N: 216
method: retrospective comparison group, not randomized
population: All subjects were African American, single women who were younger than 18 years of age at the time of the birth of the index birth, which was their first birth. All were of low SES, and their care was subsidized by the county. The first experimental group had received the Lifespan Program, and the other experimental group received prenatal care and educational programming through the school district's alternative school. The comparison sample received their care at the same clinic as the Lifespan group but this was prior to the Lifespan Program being initiated.
inter. type: Selective preventive intervention
intervention: The Lifespan Program utilizes trained volunteers to teach prenatal education in community-based prenatal clinics. Incentives are provided if participants attend 8 or more lessons. Also, there is 1 hospital visitation during the postpartum period to assess needs and make referrals.
outcomes: No differences were found on gestational age or mean birth weights of the infants.

TRIAL NO.: 97 (5097)

auth: Jordan, TJ
auth: Grallo, R
auth: Deutsch, M
auth: Deutsch, CP
year: 1985
title: Long-term effects of early enrichment: A 20-year perspective on persistence and change
ref: American Journal of Community Psychology
vol: 13(4)
pps: 393-415
project title: Institute for Developmental Studies early enrichment program
country: USA
N: 1200
method: RCT
population: Subjects were 4 year old children from Harlem families who had volunteered for participation. There was individual randomization to classrooms.
inter. type: Selective preventive intervention
intervention: The experimental and comparison interventions occurred from age 4 through the third grade. The experimental classrooms sought to maximize the opportunities for positive cognitive, social, and emotional development; the emphasis was on "learning to learn". Children in the comparison classrooms received instruction according to the regularly scheduled school curriculum without special attempts at enrichment.
outcomes: Follow-up of 154 subjects was approximately 20 years, occurring when the subjects were 17 to 22 years of age. The experimental intervention exerted sustained, positive influence in later life on males but not females. For the males gains were made in employment status, educational attainment, vocabulary skills, academic self-concept, and sense of control.

TRIAL NO.: 232 (5232)

auth: Kagitcibasi, C
title: Is psychology relevant to global human development issues? Experience from Turkey
year: 1995
ref: American Psychologist
vol: 50(4)
pps: 293-300
project title: Turkish Early Enrichment Project
country: Turkey
N: 280
method: RCT
population: The subjects were 3 and 5 year old children and their mothers, all of whom were from low-incomes areas of Istanbul. Two-thirds of the children attended 1 of 6 child care centers provided by factories where their mothers were employed as semiskilled or unskilled workers. One-third were children of nonworking mothers from homes in the same neighborhoods.
inter. type: Selective preventive intervention (bordering on universal)

intervention: In the 1st year of the study, extensive assessments were carried out on all children and mothers. In the 2nd year the families were assigned to experimental and control groups. In the 2nd and 3rd years, the experimental group received their intervention. In the 4th year assessments were made of all families. The experimental group received a 2-component intervention: cognitive training to support the cognitive development of the child and mother enrichment designed to support the socioemotional development of the child. The cognitive component was delivered at home and in groups settings at a community center or the workplace in alternate weeks. The mothers were trained to work on cognitive materials at home with their children. The paraprofessional trainers were middle-class women with at least a high school education, whereas most mothers had only a primary school education or less. They received training from the research team. The mother enrichment program was conducted in biweekly group discussion sessions. The topics ranged from health to the psychological needs of children to a focus on mothers' own needs.

outcomes: The 4th year assessments (at the end of the intervention), showed that there were positive effects on the children's overall development and school achievement as well as positive changes in the mothers. The experimental children passed the control children on most of the cognitive measures. The experimental mothers were more accepting of their children's antonomy and had higher aspirations for their children. A follow-up study 6 years after the end of the original study (7 years after the end of the mother training), these results were sustained. Significantly more experimental children were still in school and had better academic performance. They also had better WISC-R vocabulary scores, better social adjustment, greater autonomy, and remembered their mothers to be more nurturant and more responsive. The experimental group had better family relations; there was less physical punishment; and the parents had higher educational expectations for their children. Trouble with the law was rare among all subjects, but the few who had problems with the law (6 percent) were all from the control group.

TRIAL NO.: 98 (5098)

auth: Kang, R
auth: Barnard, K
auth: Hammond, M
auth: Oshio, S
auth: Spencer, C
auth: Thibodeaux, B
auth: Williams, J
title: Preterm infant follow-up project: A multi-site field experiment of hospital and home intervention programs for mothers and preterm infants
year: 1995
ref: Public Health Nursing
vol: 12(3)
pps: 171-180
country: USA
N: 327
method: assignment first made according to mother's level of education, then randomization
population: Subjects were mothers and their preterm infants who were less than 36 weeks of gestational age at hospital discharge, were without central nervous system disorders and congenital anomalies, and had not been exposed to illicit drugs prenatally. Subjects were recruited from tertiary and secondary neonatal care centers at three sites in large cities. Mothers had to live within the catchment area and speak English.
inter. type: Selective preventive intervention
intervention: The first experimental intervention was a hospital based State Modulation (SM) treatment, focused on teaching mothers to read the behavioral cues and modulate the states of consciousness of the infants during feedings. The second experimental intervention included both the SM treatment and a nurse home visitation program using a field tested curriculum called the Nursing Systems for Effective Parenting-Preterm (NSEP-P). Home visitation lasted 5 months following discharge from the hospital. A hospital program on car seats and standard public health nursing home visits served as comparison interventions. High-education mothers were only assigned to SM or car seat groups. Low education mothers were only assigned to combinations of hospital and home visit interventions.
outcomes: State Modulation treatment was effective in influencing positive social interaction of infants regardless of level of maternal education. SM combined with NSEP-P was most effective in improving the social interaction between babies and mothers with limited formal education.

TRIAL NO.: 99 (5099)

auth: Karnes, MB
auth: Johnson, LJ
title: Bringing out Head Start talents: Findings from the field
year: 1987
ref: Gifted Child Quarterly
vol: 31(4)
pps: 174-179
project title: Bringing Out Head Start Talents
country: USA
N: 446
method: controlled trial, no randomization
population: Subjects were Head Start children, including some who were identified as potentially gifted, from 2 different counties.
inter. type: Selective preventive intervention
intervention: Some classrooms received the intervention; other classrooms did not. There were some children in both sets of classrooms who had been identified as potentially gifted. Teachers in the experimental classrooms were taught to enhance the higher-level thinking skills of all the children in the classroom and to utilize a manualized program to develop specific talents in the children. Special programming was provided by the teachers to all the parents as well as specifically to the children potentially gifted. Transition to public school was facilitated by the teacher through an end-of-the-year talent report on the children.
outcomes: All children in the experimental classrooms made significant gains in cognitive and creative functioning compared to children in the control classrooms. The largest gains were made by children who had not been identified as potentially gifted. The teachers in the experimental classrooms became significantly more positive toward their classes than teachers in the control classrooms.

TRIAL NO.: 434 (5434)

auth: Kennell, J
auth: Klaus, M
auth: McGrath, S
auth: Robertson, S
auth: Hinkley, C
title: Continuous emotional support during labor in a US hospital: A randomized controlled trial
year: 1991
ref: JAMA
vol: 265(17)
pps: 2197-2201
country: United States
N: 412
method: RCT
population: Subjects were nulliparous women ranging in age from 13 to 34 years, with single-gestation, term, uncomplicated pregnancies. They were admitted to the study after they were admitted to the hospital and were in active labor, with initial cervical dilatation of 3 or 4 cm. and without high risk medical conditions including history of drug or alcohol abuse. Women were assigned to experimental or observation groups; a control group was assigned after delivery.
inter. type: Universal preventive intervention
intervention: The experimental group received continuous support during labor from a doula, a nonprofessional woman who had received 3 weeks of training and ongoing supervision in ways to physically and emotionally comfort the patients. The doula and the pregnant woman met for the first time during labor. The observation group received routine care, and an observer kept records of all that happened.
outcomes: Continuous labor support from the doula significantly reduced the rate of cesarean section deliveries and reduced the use of epidural anesthesia for spontaneous vaginal deliveries. Oxytocin use, duration of labor, prolonged infant hospitalization, and maternal fever followed a similar pattern. Medical costs were reduced, especially from the decrease in cesarean deliveries, but no dollar figures are given.

TRIAL NO.: 101 (5101)

auth: Kerr, SM
auth: Jowett, SA
auth: Smith, LN
title: Preventing sleep problems in infants: A randomized controlled trial
year: 1996
ref: Journal of Advanced Nursing
vol: 24(5)
pps: 938-942
country: Scotland
N: 202
method: RCT
population: All parents of infants born in the area during December, 1993 were invited to join the study. Infants were excluded if they had been born before the end of 37 weeks gestation or if they had identified moderate-severe physical or mental disability.
inter. type: Universal preventive intervention
intervention: The experimental group was home visited one time only by the nurse-researcher. A health education approach was use to increase parental knowledge of sleep and settling behavior. Discussion was consolidated with written material.
outcomes: At 6 month follow-up, when the children were 9 months old, a significantly smaller percentage of babies in the experimental group had settling and night-waking difficulties than in the control group.

TRIAL NO.: 102 (5131)

auth: Kirby, RS
auth: Swanson, ME
auth: Kelleher, JK
auth: Bradley, RH
auth: Casey, PH
title: Identifying at-risk children for early intervention services: Lessons from the Infant Health and Development Program
year: 1993
ref: Journal of Pediatrics
vol: 122(5 Pt 1)
pps: 680-686
project title: Infant Health and Development Program
country: USA
N: NA
method: NA
population: NA
inter. type: NA
intervention: NA
outcomes: This is not an intervention study. Rather, it reviews risk factors that have been identified by participating states who are trying to meet Public Law 99-457 and develop early intervention services for infants and young children who have, or are at risk for, developmental problems. The states' risk factors are compared to the risk factors and 36 month development outcomes obtained in the IHDP. Few of the individual risk factors identified by the states were associated with poor developmental outcomes, and the composites lacked specificity (yielding positive predictive values of 25 to 35 percent, with poor specificities ranging from 12 to 40 percent).

TRIAL NO.: 103 (5103)

auth: Kitzman, H
auth: Olds, DL
auth: Henderson, CR
auth: Hanks, C
auth: Cole, R
auth: Tatelbaum, R
auth: McConnochie, KM
auth: Sidora, K
auth: Luckey, DW
auth: Shaver, D
auth: Engelhardt, K
auth: James, D
auth: Barnard, K
title: Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing: A randomized controlled trial
year: 1997
ref: The Journal of the American Medical Association
vol: 278(8)
pps: 644-649
project title: Prenatal/Early Infancy: Memphis
country: USA
N: 1139
method: RCT
population: Subjects were women less than 29 weeks pregnant who were being seen at an obstetrical clinic at a regional medical center in a large city. Subjects were required to have had no previous live births, no specific chronic illnesses thought to contribute to fetal growth retardation or preterm delivery, and at least 2 of the following risk conditions: unmarried, less than 12 years of education, and unemployed. Most subjects were African American.
inter. type: Selective preventive intervention
intervention: There were 4 intervention conditions: 1) free round-trip taxicab transportation for scheduled prenatal care appointments; 2) free transportation plus developmental screening and referral services for the child at 6,12, and 24 months of age; 3) free transportation and screening plus intensive nurse home-visitation services during pregnancy, 1 postpartum visit in the hospital, and 1 postpartum visit at home; 4) same as #3 plus continued nurse home visits throughout he child's second birthday.
outcomes: During the first 2 years of the child's life, there were no intervention effects on birth weight, length of gestation, low birth weight, preterm delivery, Apgar scores, duration of breast-feeding, immunization rates, mental development, behavioral problems, or mothers' education and employment. There were intervention effects on pregnancy-induced hypertension, frequency of health care encounters for children in which injuries or ingestions were detected, and second pregnancies.

TRIAL NO.: 431 (5431)

auth: Klaus, MH
auth: Kennell, JH
auth: Robertson, SS
auth: Sosa, R
title: Effects of social support during parturition on maternal and infant morbidity
year: 1986
ref: British Medical Journal
vol: 293
pps: 585-587
country: Guatemala
N: 465
method: RCT
population: Subjects were full term healthy primigravidous women in early labour who had a cervical dilatation of 3 cm or less and were without medical problems. Mother-infant pairs were excluded from the study if they developed a complication during labour, delivery, or post partum that required special care.

inter. type: Universal preventive intervention
intervention: The control group received the usual hospital routines. The experimental group received that same care plus constant support and companionship from 1 of 3 lay women with no obstetric training, known as a doula. The support was both emotional and physical, and included rubbing the patient's back, holding her hands, and providing explanation and encouragement. The patient was told that she would never be left alone.
outcomes: Experimental mothers had significantly fewer perinatal complications, including caesarean sections, and fewer infants who were admitted to neonatal intensive care. Of the women who had an uncomplicated labour and delivery, those with a doula had a significantly shorter duration of labour.

TRIAL NO.: 235 (5131)

auth: Kraemer, HC
auth: Fendt, KH
title: Random assignment in clinical trials: Issues in planning (Infant Health and Development Program)
year: 1990
ref: Journal of Clinical Epidemiology
vol: 43(11)
pps: 1157-1167
project title: Infant Health and Development Program
country: USA
N: See earlier annotation.
method: RCT; this paper discusses options available for the randomization of subjects into groups in a clinical trial and uses the IHDP as an example; of special note are the mid-course changes in randomization procedures that were necesary in IHDP to procure an adequate sample size
population: See earlier annotation
inter. type: See earlier annotation
intervention: See earlier annotation
outcomes: See earlier annotation.

TRIAL NO.: 243 (5243)

auth: Kronqvist, EL
auth: Koivisto, M
auth: Oksanen, R
auth: Saukkonen, AL
auth: Forsius, H
title: Preventive aspects of family health care service in Finland: A comparative study
year: 1988
ref: In EC Hibbs (Ed.) Children and Families: Studies in Prevention and Intervention
city: Madison, CT
pub: International Universities Press
pps: 263-279
country: Finland
N: 240
method: nonrandomized control group
population: Subjects were families with their first pregnancy.
inter. type: Universal preventive intervention
intervention: The experimental families received services from a team of professionals at the Child Health Care Center 10 times during the first year of the child's life, and 6 times each year thereafter until the child was age 7 (although the visits became less frequent). They received psychological counseling which focused on their current problems with child rearing. They also attended an average of 15-20 group sessions with other families; a professional presented a topic related to child rearing for discussion. The control families attended the same Center 7 times in the first year and once a year thereafter.
outcomes: At 4 and 8 year follow-up, there were not any significant differences between the groups concerning child rearing practices. However, teachers scored the children in the experimental group significantly higher than those in the control group in the areas of both cognitive development and emotional and social behavior. Experimental children expressed less positive feelings toward their parents than did the control children.

TRIAL NO.: 245 (5245)

auth: Landy, S
auth: Peters, RD
auth: Arnold, R
auth: Allen, AB
auth: Brookes, F
auth: Jewell, S
title: Evaluation of "Staying on Track": An early identification, tracking, and referral system
year: 1998
ref: Infant Mental Health Journal
vol: 19(1)
pps: 34-58
project title: Staying on Track
country: Canada
N: 427
method: longitudinal sequential cohort design plus comparison group, nonrandomized
population: Subjects included children from 1 month of age to 5 1/2 years who lived within a designated geographical area (a stable, rural part of Ontario). All children within this area were eligible to participate.
inter. type: Universal preventive intervention
intervention: Public health nurses at preassigned intervals provided information and counseling for families and made referrals to other agencies if necessary as part of a community-wide system for the early identification, tracking, and referral of infants from 1 month of age to school entry at 5.5 year of age Cohorts received different amounts of intervention: cohort 1 received at least 4 home visits; cohort 2 received 3 clinic visits; cohort 3 received 1 clinic visit; and the comparison group received no special services. No set curriculum was used for the visits.
outcomes: Significant effects in self-regulatory behavior, developmental level, and social competence were found at 18 months when comparing cohorts 1 and 2. The less intensive intervention provided for cohort 3 was less sussessful at 5 1/2 years than the comparison group. The cost per child per annum was $454 in 1997 Canadian dollars.

TRIAL NO.: 410 (5410)

auth: Larson, CP
title: Efficacy of prenatal and postpartum home visits on child health and development
year: 1980
ref: Pediatrics
vol: 66(2)
pps: 191-197
country: Canada
N: 115
method: partial RCT
population: All pregnant women attending the private offices of obstetricians who delivered babies at a large urban teaching hospital were screened. Maternal criteria for inclusion were French-Canadian or English-Canadian ethnicity, between 18 and 35 years of age, working class income, high school graduation or less, no significant illness during pregnancy, and no prior history of psychiatric hospitalization. Additional criteria were the normal delivery of a full-term healthy newborn discharged from the hospital within 5 days of birth without major congenital defects.
inter. type: Universal preventive intervention
intervention: Experimental group 1 received a prenatal home visit during the 7th month of pregnancy, a postpartum hospital visit, and home visits until the child was 15 months of age (4 visits from 1 to 6 weeks of age and 5 visits from 6 weeks to 15 months of age). Experimental group 2 received home visits beginning during the child's 6th week and continuing until 15 months of age (7 visits from 6 weeks to 6 months of age and 3 visits from 6 to 15 months of age. In both groups the status of the mother was the initial focus of the visit, and her needs were given priority. The control group received no visits. The 2 home visitors for the study had undergraduate degrees in child psychology. They were bilingual and of middle-class background. They received extensive training throughout a 6 month pilot study and follow-up of those families until the child's 18th month. They had an equal distribution of group 1 and group 2 families.

outcomes: Significant differences favoring group 1 were found at each evaluation period during the intervention and at 18 months (3 months after the intervention ended). There was a reduced accident rate; higher scores on assessments of home environment and maternal behavior; lower prevalence of mother-infant interaction or feeding problems and of non-participant fathers. The accident rate for the controls was quadruple that of group 1 at 6 months and double at 12 months. There was only 1 suspected case of child abuse, and that was in group 2. The authors conclude that the timing of the visits may be a critical factor in the efficacy of a home visitor program and that the content of the program is dependent upon the timing and cannot be assessed independently.

TRIAL NO.: 111 (5111)
auth: Lee, VE
auth: Brooks-Gunn, J
auth: Schnur, E
auth: Liaw, F
title: Are Head Start effects sustained? A longitudinal follow-up comparison of disadvantaged children attending Head Start, no preschool, and other preschool programs
year: 1990
ref: Child Development
vol: 61
pps: 495-507
reprinted in 1991
ref: Annual Progress in Child Psychiatry & Child Development
vol: 61(2)
pps: 600-618
project title: Project Head Start
country: USA
N: 969
method: group assignment by family choice, not randomized
population: Subjects were disadvantaged black 4 and 5 year old children who participated in generic Head Start programs compared to others who had no preschool and others who had preschool experiences of another kind in 2 American cities. Children from families speaking a foreign language and those with severe handicaps were excluded. In 1969, the Head Start poverty eligibility guidelines were $3000 for a family of 3, with an increment of $600 for each additional person.
inter. type: Selective preventive intervention
intervention: Both Head Start and non-Head Start programs were standard preschools (not day-care) and were at least 8 to 9 months in duration.
outcomes: The follow-up occurred when the children were in kindergarten and first grade. Children who attended Head Start maintained educationally substantive gains in general cognitive/analytic ability, especially when compared to children without preschool experience. These effects were not as large as those found immediately following the Head Start intervention. Findings suggest an effect of preschool rather than of Head Start per se.

TRIAL NO.: 112 (5112)

auth: Leib, SA
auth: Benfield, G
auth: Guidubaldi, J
title: Effects of early intervention and stimulation on the preterm infant
year: 1980
ref: Pediatrics
vol: 66(1)
pps: 83-90
country: USA
N: 28
method: pre-post population design
population: Subjects were infants with birth weights between 1200 and 1800 grams, head circumference, length, and weight on admission between the 10th and 90th percentile for gestational age, and without major congenital problems, history of seizures, or multiple births, and 2 parents living at home. Although not required, the families were all white and predominantly middle class.
inter. type: Selective preventive intervention
intervention: A prescribed sensory enrichment program within the neonatal intensive care unit was provided to the experimental infants by nurses during feeding times in addition to standard preterm nursery care. The control infants received the standard care only.
outcomes: Mean weight gain per day and mean total weight gain during the hospitalization were not significantly different for the 2 groups nor was the length of hospitalization. At 6 month follow-up, the experimental infants had significantly higher developmental status than control infants on both the mental and motor scales of the Bayley.

TRIAL NO.: 113 (5113)

auth: Levenstein, P
title: Cognitive growth in preschoolers through verbal interaction with mothers
year: 1970
ref: American Journal of Orthopsychiatry
vol: 40(3)
pps: 426-432
project title: Mother-Child Home Program
country: USA
N: 54
method: before-after design with three geographically separated groups equated for housing and SES
population: The subjects were low income preschoolers and their mothers.
inter. type: Selective preventive intervention
intervention: The experimental group received an average of 32.4 home visits over the course of 7 months by social case workers who called themselves Toy Demonstrators. With toys and books, the home visitors stimulated verbally oriented play in the dyad by acting as a model for the mother. The first comparison group received an average of 24 home visits by social workers, including the gifts, but the visits were non-verbally stimulating. The second comparison group received no intervention beyond the testing.
outcomes: The experimental group made highly significant cognitive gains (17 IQ points) in contrast to the 2 comparison groups (1 and 2 points). There was almost no change in the similar and relatively low verbal IQ's of mothers in the 3 groups.

TRIAL NO.: 115 (5113)

auth: Levenstein, P
title: Which homes? A response to Scarr and McCartney (1988)
year: 1989
ref: Child Development
vol: 60(2)
pps: 514-518
project title: Home-Child Home Program
country: USA
N: NA
method: NA
population: NA
inter. type: NA
intervention: NA
outcomes: No original data are presented. This is a discussion paper only. Scarr and McCartney's Bermudian study shows the futility of using the Mother-Child Home Program to prevent later educational disadvantage in preschoolers who are not at risk for such disadvantage. Levenstein highlights the significant positive school effects through 8th grade that were reported for a Massachusetts preschool sample who were socioeconomically at risk for educational disadvantage and were of lower SES than the advantaged Bermudian children.

TRIAL NO.: 116 (5126)

auth: Levenstein, P
title: The Mother-Child Home Program: Research methodology and the real world
year: 1992
ref: In J McCord and RE Tremblay (Eds.), Preventing Antisocial Behavior Interventions from Birth Through Adolescence
city: New York
pub: Guilford Press
pps: 43-66
country: USA
project title: Verbal Interaction Project: Mother-Child Home Program
N: 151
method: RCT, unit randomization
population: See earlier annotation.
inter. type: Selective preventive intervention
intervention: See earlier annotation.
outcomes: The short-term and long-range outcome IQ scores for all 6 cohorts of the 1967 to 1972 unit-randomized program graduates were consistently superior to the untreated or placebo-treated control groups and to their own pretest IQ scores. The postprogram scores endured into fifth and eighth grades. Some positive effects were seen on the IQs of younger siblings, suggesting carryover effects of mothers' parenting skills. Other replication data is provided to suggest that the program is most effective with the most disadvantaged children.

TRIAL NO.: 444 (5444)

auth: Levenstein, P
title: The Mother-Child Home Program: Research methodology and the real world
year: 1992
ref: In J McCord and RE Tremblay, (Eds.), Preventing Antisocial Behavior Interventions from Birth Through Adolescence
city: New York
pub: Guilford Press
pps: 43-66
project title: Verbal Interaction Project: Mother-Child Home Program
country: USA
N: 127
method: RCT, subject randomization
population: See earlier annotation.
inter. type: Selective preventive intervention
intervention: See earlier annotation.
outcomes: Subject-randomized cohorts did not show the same positive effects as unit-randomized cohorts had shown, but their initial IQs were at or above the national norms and were higher than those of the unit-randomized children.

TRIAL NO.: 119 (5119)

auth: Lieberman, AF
auth: Pawl, JH
title: Infant-parent psychotherapy
year: 1993
ref: In CH Zeanah, Jr (Eds.), Handbook of Infant Mental Health
city: New York
pub: The Guilford Press
pps: 427-442
country: Unknown
N: 100
method: RCT
population: The subjects were low-socioeconomic, Spanish-speaking 12-month old infants and their mothers. Anxiously attached dyads were randomly assigned to an intervention or a control group. Securely attached dyads comprised a second control group.
inter. type: Indicated preventive intervention (bordering on selective)
intervention: The experimental group received infant-parent psychotherapy for 1 year, beginning at 12 months of age. The therapy consisted by weekly visits with each mother and baby, which lasted 1 1/2 hours and took place at the home or in the office playroom, as preferred by the mother. All intervenors were bilingual, bicultural women with master's degrees in psychology or social work. The focus was on increasing the mother's empathic responses to her child, improving negotiations over disagreements, and decreasing the child's avoidance and angry behavior directed at the mother.
outcomes: The experimental group performed significantly better than the anxious controls in measures of maternal empathy, infant security of attachment, and mother-child partnership and was indistinguishable from the secure control group. The most important treatment variable was the mother's ability to use the therapy to explore her feelings toward herself and toward her child.
note: describes RCT published by Lieberman, Weston, and Pawl, 1991

TRIAL NO.: 122 (5122)

auth: Lovell, ML
auth: Richey, CA
title: The impact of social support skill training on daily interactions among parents at risk for child maltreatment
ref: Children and Youth Services Review
year: 1997
vol: 19(4)
pps: 221-251
country: Canada
N: 38
method: controlled trial without randomization
population: Subjects were high-risk parents with preschool-aged children who had been mandated for comprehensive agency treatment by child protection officials. Parents were excluded if they were unwilling to participate or if they were severely disruptive.
inter. type: Treatment intervention
intervention: Experimental and comparison sites were selected from two non-profit agencies offering similar child management programs. There were 2 cohorts of subjects. All families received all agency services and attended a weekly parent group. For the experimental parents, the group was Social Support Skill Training, a 17 week structured intervention with a curriculum and led by a family worker from the agency and a group worker hired by the project. The group worker met weekly with the project coordinator to ensure that the intervention complied with training protocol.
outcomes: At 5 month follow-up, there were few differences between the experimental and control groups. The experimental parents did report significantly higher proportions of contacts with formal service providers.

TRIAL NO.: 411 (5411)

auth: Lowe, ML
year: 1970
title: Effectiveness of teaching as measured by compliance with medical recommendations
ref: Nursing Research
vol: 19(1)
pps: 59-63
country: USA
N: 80
method: RCT
population: Subjects were black primigravidas who sought care at 1 medical center prior to the end of the 16th week of pregnancy. It is implied but not stated that the women were of low SES.
inter. type: Universal preventive intervention
intervention: The control group received only routine care and instructions. The experimental group was referred to the local public health nursing service for instructions in addition to their clinic care.
Dietary habits and weight control were the primary foci of the instructions.
outcomes: There were no significant differences between the 2 groups in compliance with medical recommendations. Despite viewing excess weight gain as a negative, 73 percent of the controls and 53 percent of the experimental women gained more weight during pregnancy than their doctors recommended.

TRIAL NO.: 120 (5120)

auth: Lyons-Ruth, K
auth: Connell, DB
auth: Grunebaum, HU
auth: Botein, S
title: Infants at social risk: Maternal depression and family support services as mediators of infant development and security of attachment
year: 1990
ref: Child Development
vol: 61
pps: 85-98
country: USA
N: 80
method: comparison, not randomized
population: Subjects were referred from health, educational, and social service agencies serving low income families because of staff concerns about the quality of the caregiving environment for the infant. No family was rejected because of the degree of caretaking disturbance. Two families self-referred. Infants were between birth and 9 months at study entry. The first comparison group was identified at 18 months of age through the same clinical referral process used to identify the high-risk infants. The second comparison group was a matched group of mothers and infants from the same neighborhoods who had never sought or received social services directed at parenting skills, had never been identified as maltreating, and had never undergone extensive psychiatric treatment. The mothers were individually matched to high-risk mothers on per-person family income, education, age, race, child's age, sex, and birth-order.
inter. type: Selective preventive intervention
intervention: Weekly hour-long home visiting services were provided by experienced staff to the experimental group. Some home visitors were lay people and others were professionals. (These 2 groups originally were separate but they were combined for analysis.) The focus was on family health and social service needs. A weekly group meeting was also provided.
outcomes: At 18 months of age, the experimental infants were no different from the comparison children on infant mental development scores. However, the experimental children of depressed mothers outperformed unserved infants of depressed mothers by an average of 10 points on the Bayley Mental Scale and were twice as likely to be classified as securely attached. Overall, there were no significant effects of treatment on maternal behavior. Findings suggest that current maternal depression, history of psychiatric hospitalization, and child maltreatment, in addition to low SES, are specific predictors of unfavorable infant social and cognitive development.

TRIAL NO.: 126 (5126)

auth: Madden, J
auth: Levenstein, P
auth: Levenstein, S
title: Longitudinal IQ outcomes of the Mother-Child Home Program
year: 1976
ref: Child Development
vol: 47
pps: 1015-1025
project title: Verbal Interaction Project
country: USA
N: 151, the original sample N is not stated
method: comparison group, no randomization
population: Subjects were 2 to 4 year old children from low-income families who were eligible for low-income housing.
inter. type: Selective preventive intervention

intervention: The Mother-Child Home Program was delivered to mother-child dyads. There were 52 semiweekly home visits by master's degree social workers (called Toy Demonstrators) over a 7-month period. During the second year of the program the number of home visits was changed to 46; the time period was changed to 10 months; and non-social workers were introduced as the intervenors. The visits began when the children were 2 years of age and continued through the following year. The goal of the intervention was to involve the mother in promoting, through the use of books and toys, the child's social and emotional development and learning readiness.
outcomes: Follow-up data were gathered when the children were 4 to 6 years old. Satisfactory IQ scores were retained by program graduates at least into first grade when the program was expanded to 2 full years instead of the original 1 year. When the program was expanded to the 2 year format, non-social worker Toy Demonstrators were introduced as interveners. The estimated annual unit cost in the 2 year non-social worker model program was $400 in 1976 dollars.

TRIAL NO.: 127 (5127)
auth: Madden, J
auth: O'Hara, J
auth: Levenstein, S
title: Home again: Effects of the Mother-Child Home Program on mother and child
year: 1984
ref: Child Development
vol: 55
pps: 636-647
project title: Mother-Child Home Program
country: USA
N: 160
method: See earlier annotation
population: See earlier annotation
inter. type: See earlier annotation
intervention: See earlier annotation
outcomes: Follow- up occurred 3 years after the program ended, when the children should have been in first grade. There were no detectable effects in achievement or IQ tests or in first grade teachers' ratings of school adjustment and performance, but IQ and achievement were near national norms. Mothers were able to increase the interactive behavior modeled for them. These follow-up results were unexpected because earlier evaluations demonstrated positive results.

TRIAL NO.: 412 (5412)

auth: Main, DM
auth: Gabbe, SG
auth: Richardson, D
auth: Strong, S
title: Can preterm deliveries be prevented?
year: 1985
ref: American Journal of Obstetrics and Gynecology
vol: 151
pps: 892-898
country: USA
N: 132
method: RCT
population: Subjects were black indigent inner-city women who were less than 18 weeks gestation when they sought prenatal care at a university hospital in a large city. The Creasy method was used to identify women who were at high risk for preterm labor.
inter. type: Selective preventive intervention
intervention: The experimental women received care in the Preterm Labor Prevention Clinic on a weekly or biweekly basis by 1 of 2 doctors. In addition to high risk medical care and patient education about the subtle signs of preterm labor, a 24 hour hot line was provided to assure easy access to care. The high risk controls were followed up by the obstetric residents in routine or high risk clinics.
outcomes: There were no significant differences in percentages of preterm infants, mean gestational age, or birth weight. This was a medical, not a psychosocial, intervention. The risk index had low sensitivity (48 percent), and only 30 of 62 patients who experienced preterm deliveries were correctly classified. The experimental women had come for their appointments and had developed strong relationships with the medical staff, yet the intervention was not effective. The authors speculate that the risk factors for preterm deliveries are so complex in this particular population that conventional medical therapy alone cannot be effective.

TRIAL NO.: 247 (5247)

auth: Malphurs, JE
auth: Field, TM
auth: Larrain, C
auth: Pickens, J
auth: Pelaez-Nogueras, M
auth: Yando, R
auth: Bendell, D
title: Altering withdrawn and intrusive interaction behaviors of depressed mothers
year: 1996
ref: Infant Mental Health Journal
vol: 17(2)
pps: 152-160
country: USA
N: 44
method: Not a trial; no control or comparison group
population: Subjects were mother-baby dyads recruited from a well-baby clinic. Mothers were depressed (on the Beck Depression Inventory), low SES, teenagers from 3 ethnic groups.
inter. type: Selective preventive intervention
intervention: Specific types of interaction coaching was given to the mothers according to their interaction style with their infants (imitation for intrusive mothers and attention-getting for the withdrawn mothers).
outcomes: The data suggested that mothers can be taught a variety of techniques to improve the quality of mother-infant interactions

TRIAL NO.: 128 (5128)
auth: Marcenko, MO
auth: Spence, M
title: Home visitation services for at-risk pregnant and postpartum women: A randomized trial
year: 1994
method: RCT
ref: American Journal of Orthopsychiatry
vol: 64(3)
pps: 468-478
country: USA
N: 225
method: RCT
population: Subjects were pregnant women who were at risk for out-of-home placement of their newborns. They were recruited from an inner-city hospital outpatient obstetrics clinic during their first or second prenatal visit. Inclusion criteria were at least 1 of the following histories: substance abuse, homelessness, domestic violence, psychiatric illness, incarceration, HIV infection, or lack of social support.
inter. type: Selective preventive intervention
intervention: The control women received normal prenatal services including social service assessment, referral and short-term individual counseling. The experimental mothers received home visits from paraprofessional women from the same community who had received 1 month of intensive training. During the first 6 weeks postpartum, visits were weekly; based on a risk assessments the visits might have been reduced to every 2 weeks and then eventually to 1 per month. The mothers also received social work services, including referrals for other services and individual/family/group counseling, and nursing services focusing on health care needs.
outcomes: After 10 months exposure to the intervention, there was no indication that the intervention had been successful in preventing out-of-home placement, and in fact more experimental women had children in care. Also the quality of the home environment was not different between the 2 groups. Experimental women did report increased social support, especially from friends, greater access to services, and decreased psychological distress.

TRIAL NO.: 129 (5030)

auth: Martin, SL
auth: Ramey, CT
auth: Ramey, S
title: The prevention of intellectual impairment in children of impoverished families: Findings of a randomized trial of educational day care
year: 1990
ref: American Journal of Public Health
vol: 80 (7)
pps: 844-847
project title: Carolina Abecedarian Project
country: USA
N: 86
method: RCT
population: Pregnant women whose unborn children were at high-risk for intellectual impairment were identified by public health agencies and hospitals. Study families were primarily black, low-income, single parent families. Mothers tended to be young and to have low IQs and low education levels. Target children were predominantly firstborns.
inter. type: Selective preventive intervention
intervention: Experimental children entered day care between 6 and 12 weeks of age, and remained in care for 5 days a week, 50 weeks a year. The program was designed to promote social and cognitive growth in an orderly, friendly environment.
outcomes: The experimental group had higher IQs from 6 months through this most recent assessment at 54 months than those of the control children when maternal mental retardation and home environment effects were controlled. At every age, a greater proportion of the experimental program children had normal range IQs.

TRIAL NO.: 131 (5131)

auth: McCarton, CM
auth: Brooks-Gunn, J
auth: Wallace, IF
auth: Bauer, CR
auth: Bennett, FC
auth: Bernbaum, JC
auth: Broyles, RS
auth: Casey, PH
auth: McCormick MC
auth: Scott, DT
auth: Tyson, J
auth: Tonascia, J
auth: Meinert, CL
title: Results at age 8 years of early intervention for low-birth-weight premature infants: The Infant Health and Development Program
year: 1997
ref: Journal of the American Medical Association
vol: 277(2)
pps: 126-132
project title: Infant Health and Development Program
country: USA
N: 874
method: RCT
population: See earlier annotation
inter. type: See earlier annotation
intervention: See earlier annotation
outcomes: At 5 years follow-up when the subjects were 8 years of age, attenuation of the large favorable effects seen at 3 years was observed in both the heavier and lighter LBW groups. The experimental and control groups were similar on all primary outcome measures. There were modest intervention-related differences in cognitive and academic skills of heavier LBW premature children. A higher-than-average (i.e., compared to the standardized sample) rate of behavioral difficulties was found on the Child Behavior Checklist for both the heavier and lighter low birth weight groups in the total study population. The cost of delivering the 3 programmatic components of the full intervention was estimated at $15,146 per year per child.

TRIAL NO.: 130 (5130)

auth: McDuffie, RS
auth: Beck, A
auth: Bischoff, K
auth: Cross, J
auth: Orleans, M
title: Effect of frequency of prenatal care visits on perinatal outcome among low-risk women: A randomized controlled trial
year: 1996
ref: JAMA
vol: 275(11)
pps: 847-851
country: USA
N: 2764
method: RCT
population: Subjects were women in the first trimester of their pregnancies who presented for the intake visit at a group-model health maintenance organization. They were between 18 and 39 years of age, had completed less than 13 weeks of gestation, had no history of obstetrical risk or current medical condition, were English-speaking, and were not planning to change insurance carriers during the pregnancy.
inter. type: Universal preventive intervention
intervention: Following risk assessment, experimental subjects received 9 prenatal visits and controls received 14. Additional visits were available as indicated or as desired by the patients in both groups. The study was a test of the 1989 Expert Panel on the Content of Prenatal Care guidelines on the timing and content of prenatal care, including a schedule consisting of fewer prenatal visits than traditionally provided for women at low risk of adverse perinatal outcomes.
outcomes: On average, there were 2.7 fewer visits observed in the experimental group than in the control group. There were no significant increases in the main outcomes of the experimental group: preterm delivery, preeclampsia, cesarean delivery, low birth weight or patients' satisfaction with quality of prenatal care. There were more provider visits in the experimental group than predicted (10.3 vs. 9.0). The mean difference of 2.7 in the number of visits between the 2 groups could result in substantial savings in direct medical costs for the 2 million low-risk pregnant women who receive care each year in the US.
inter: fewer prenatal visits for low risk women
results: good perinatal outcome and patient satisfaction

TRIAL NO.: 135 (5135)

auth: Messimer, SR
auth: Hickner, JM
auth: Henry, RC
title: A comparison of two antismoking interventions among pregnant women in eleven private primary care practices
year: 1989
ref: Journal of Family Practice
vol: 28(3)
pps: 283-288
country: USA
N: 137
method: RCT
population: Subjects were pregnant women in 11 private primary care obstetrical practices. All self-reported that they smoked.
inter. type: Selective preventive intervention
intervention: Study practices were randomized. Physicians in the control practices used a protocol to counsel the women at 3 prenatal care visits regarding the harmful effects of nicotine and recommended quitting smoking at each of these visits. The physicians in the experimental practices used the American Lung Association's (ALA) Because You Love Your Baby smoking cessation program and counseled women at each prenatal visit, monitored smoking at each visit, and recommended patient quit smoking at each visit. Additional educational materials were provided. In both groups, ashtrays were removed from waiting rooms and staff were not allowed to smoke in view of the patients. Training was provided to both groups of physicians and their staff, and compliance was checked at the midpoint using a chart review.
outcomes: The ALA protocol was not significantly better in achieving self-reported rates of smoking cessation than the comparison protocol at 32 to 36 week visits (28 vs. 16 percent). Cigarette consumption in both groups had decreased by one half at the time of the first obstetric visit. Also, 34 percent of the originally identified smokers quit smoking entirely by the time of the first prenatal visit prior to any physician intervention. The mean decrease following intervention was about 2 cigarettes in each group. The vast majority of women cited pregnancy as the reason they cut back or quit, not what they learned at the physician's office.

TRIAL NO.: 414 (5414)

auth: Minde, K
auth: Shosenberg, N
auth: Marton, P
auth: Thompson, J
auth: Ripley, J
auth: Burns, S
title: Self-help groups in a premature infancy: A controlled evaluation
year: 1980
ref: The Journal of Pediatrics
vol: 96(5)
pps: 933-940
country: Canada
N: 60
method: RCT (alternate assignment)
population: Subjects were premature infants and their parents. Inclusion required that the parents live within 15 miles of the hospital, speak English, and intend to keep the baby. The infant had to have a birthweight below 1501 grams, be without physical abnormalities, be a singleton birth, and at 72 hours have an absence of complication seriously compromising his chance of survival and/or normal cerebral functioning.

inter. type: Selective preventive intervention
intervention: The experimental group participated in weekly group meetings beginning while the infants were still in the neonatal nursery. The sessions were led by a "veteran mother", who had had a similar small baby in the same nursery within the prior year, and a senior nurse coordinator who also was available to the parents at any time. The groups met for 7 to 12 weeks. The groups focused on parents' feelings about having such a small baby, on strategies for coping, and on the developmental needs of the infants.
outcomes: Experimental parents visited their infants in the hospital significantly more often and looked at, touched, and talked to their infants more frequently. At 3 months after hospital discharge, experimental mothers were more interactive with their babies. However, total sleep time and weight was not different between the groups.

TRIAL NO.: 136 (5416)
auth: Minde, K
auth: Faucon, A
auth: Falkner, S
year: 1994
title: Sleep problems in toddlers: Effects of treatment on their daytime behavior
ref: Journal of the American Academy of Child and Adolescent Psychiatry
vol: 33(8)
pps: 1114-1121
country: Canada
method: matched control group
N: 58
population: Experimental subjects 12 to 36 month old children with moderate to serious sleep problems of at least 3 months' duration. Referrals came from 8 community doctors in a small town. All subjects had to show good overall cognitive development and no physical abnormality. To quality for inclusion, parents had to fill out a sleep diary for 2 weeks and the children had to have a composite sleep score of 9. Controls were recruited from advertisements posted in the waiting rooms of the same doctors who referred the experimental subjects. None of them had ever been considered to have a sleep problem, and on the sleep diary they were required to have a composite sleep score of less than 6.
inter. type: Treatment intervention
intervention: Experimental families were offered up to 6 counseling sessions with a senior social worker who used a dynamically oriented behavior approach in working with the families. In 2 parent families, the sessions included both parents.
outcomes: At the end of the intervention period, there was a significant decrease of the sleep problems in the experimental children. There were also improvements in their daytime interactions with key caretakers.

TRIAL NO.: 275 (5275)

auth: Moore, FI
auth: Ballinger, P
auth: Beasley, JD
title: The influence of postpartum home visits on postpartum clinic attendance
ref: Public Health Reports
year: 1974
vol: 89(4)
pps: 360-364
country: USA
N: 1800
method: RCT
population: Subjects were medically indigent residents who delivered at a charity hospital.
inter. type: Selective preventive intervention
intervention: Each woman in the study was contacted on the maternity ward and given an appointment for a postpartum examination at 1 of the family planning clinics. Experimental women in group 1 were home visited by paraprofessional family health counselors 1 time postpartum to provide information on child care and self-care as well as encouragement to keep the postpartum appointment. The 6 counselors received a 3 week training program developed by a multidisciplinary team. Experimental women in group 2 were home visited by a different 6 paraprofessional health counselors who had received a 3 day training program. Their only role was to encourage the women to attend the clinic for postpartum examination. Both home visited groups received the contact within 10 days after hospital discharge. The control group women were not visited at home.
outcomes: The percentages of kept appointments was 79.4 for group 1, 83.5 for group 2, and 75.8 for controls. The difference between group 1 and the controls was not significant, whereas the difference between group 2 and the controls was. Within each of the 3 groups, the percentage of kept appointments decreased as the number of pregnancies increased.

TRIAL NO.: 133 (5133)

auth: Moxley-Haegert, L
auth: Serbin, LA
title: Developmental education for parents of delayed infants: Effects on parental motivation and children's development
year: 1983
ref: Child Development
vol: 54(5)
pps: 1324-1331
country: Canada
N: 39
method: RCT
population: Subjects were 39 caregiver-child pairs referred by 1 of 2 outpatient pediatric services located in a large city. All children referred were under 36 months of age and had demonstrated delayed development. The caregiver was the person most likely to be involved in carrying out the home treatment program prescribed for the child.
inter. type: Treatment intervention
intervention: A home treatment program of 5 skill-building exercises suitable for the specific problems of the child was provided for all children. The experimental group of parents received a brief course in developmental education from an educator who visited the home weekly for 3 weeks. The course consisted of training in observing and recognizing developmental progress in the child. The first control condition received parent education in child management, including reading materials and visits from an educator for 3 weeks to provide reinforcement for following the home program. The no-education control group received not visits or reading materials to supplement the home program but they did get reminder phone calls.
outcomes: At 1 year follow-up, the developmental education parents continued to participate more in their children's treatment program than the parents of either control group. The children in the developmental education group gained a greater number of skills that were the focus of the home treatment program.

TRIAL NO.: 139 (5139)

auth: Munjanja, SP
auth: Lindmark, G
auth: Nystrom, L
title: Randomised controlled trial of a reduced-visits programme of antenatal care in Harare, Zimbabwe
year: 1996
ref: The Lancet
vol: 348(9024)
pps: 364-369
country: Zimbabwe
N: 15,994
method: RCT (7 primary care clinics were randomized to experimental and control conditions)
population: Subjects were middle to low income pregnant women from the townships of a large region.
inter. type: Universal preventive intervention
intervention: All women were exposed to a mass media campaign that lasted for 6 months prior to the start of the trial. The campaign's aim was to encourage early booking of antenatal care. Before the trial began, training of staff was started in the clinics with the experimental program, and staff workshops were held throughout the 2 years of the study. Research staff also visited control clinics to be sure they were adhering to the standard programme of antenatal care. The experimental clinics provided fewer but more objectively oriented prenatal visits and fewer procedures per visit than the control clinics.
outcomes: Experimental women made fewer prenatal visits and had significantly fewer referrals for pregnancy-induced hypertension or eclampsia than controls. The risk for preterm delivery was significantly lower for experimental women. There were no other significant differences between the groups in other major indices of pregnancy outcomes, including obstetric interventions, low birthweight, and perinatal and maternal mortality and morbidity. There were no adverse effects on the main intermediate outcome pregnancy variables.

TRIAL NO.: 134 (5134)

auth: Neuman, SB
title: Children engaging in storybook reading: The influence of access to print resources, opportunity, and parental interaction
year: 1996
ref: Early Childhood Research Quarterly
vol: 11(4)
pps: 495-513
country: USA
N: 41
method: controlled trial (?)
population: Subjects were parents and children from 3 Head Start classrooms located in 3 Title 1 elementary schools in a large, urban area. Recruitment was conducted by teachers at each site.
inter. type: Selective preventive intervention
intervention: The experimental mothers attended a weekly club over a 12-week period designed to talk about and receive free children's books.
outcomes: By self-report almost half of the mothers had significant reading difficulties and were enrolled in literacy programs. Text type affected patterns of interaction; parents' reading proficiency influenced conversational interactions. Regardless of parental reading proficiency, however, children's receptive language and concepts of print improved significantly.

TRIAL NO.: 415 (5415)

auth: Oakley, A
auth: Rajan, L
auth: Grant, A
title: Social support and pregnancy outcome
year: 1990
ref: British Journal of Obstetrics and Gynaecology
vol: 97
pps: 155-162
country: England
N: 509
method: RCT
population: Subjects, recruited from the antenatal clinics of 4 hospitals, were eligible provided they had had at least 1 previous normally formed baby weighing under 2500 grams following spontaneous onset of labour, were less than 24 weeks gestation with a singleton pregnancy, and were fluent in English. All of the mothers were socially disadvantaged, and 41 percent were smoking at the time of booking.
inter. type: Selective preventive intervention
intervention: The control group received standard antenatal care. The experimental group received that same care plus a midwife social support intervention which included at a minimum 3 home visits at 14, 29, and 28 weeks gestation, plus 2 telephone contacts or brief home visits in between these times. The midwives were also available by phone 24 hours a day. They followed a semi-structured interview schedule and gave advice only if requested to do so. They did not give any clinical care. Forms and audiotapes provided some monitoring of the intervention.
outcomes: Babies of the experimental mothers had a mean birthweight 38 grams higher than those of control mothers. Experimental group mothers were significantly healthier in the early weeks than those in the control group as judged by reported physical and psychosocial health and use of health services. Women's attitudes to the social support intervention were very positive.

TRIAL NO.: 143 (5143)

auth: Olds, DL
auth: Henderson, CR
auth: Chamberlin, R
auth: Tatelbaum, R
title: Preventing child abuse and neglect: A randomized trial of nurse home visitation
year: 1986
ref: Pediatrics
vol: 78(1)
pps: 65-78
project title: Prenatal/Early Infancy Project
country: USA
N: See earlier annotation.
method: See earlier annotation.
population: See earlier annotation.
inter. type: Selective preventive intervention
intervention: See earlier annotation.
outcomes: Among the women at highest risk for care-giving dysfunction, those who were visited by a nurse had fewer instances of verified child abuse and neglect during the first 2 years of their children's lives. They were observed in their homes to restrict and punish their children less frequently, and they provided more appropriate play materials. Their babies were seen in the emergency room less frequently during the first year of life. During the second year of life, the babies of all nurse-visited women, regardless of the families' risk status, were seen in the emergency room fewer times, and they were seen by physicians less frequently for accidents and poisonings than comparison group babies.

TRIAL NO.: 252 (5143)

auth: Olds, DL
auth: Henderson, CR
auth: Phelps, C
auth: Kitzman, H
auth: Hanks, C
title: Effect of prenatal and infancy nurse home visitation on government spending
year: 1993
ref: Medical Care
vol: 31(2)
pps: 155-174
project title: Prenatal/Early Infancy Project
country: USA
N: See earlier annotations
method: See earlier annotations
population: See earlier annotations
inter. type: See earlier annotations
intervention: See earlier annotations
outcomes: A cost-benefit analysis estimated program costs (direct costs of nurse-visitation, costs of services to which nurses linked families, and costs of the taxicab service); benefits (cost outcomes presumed to be affected by the program through improved maternal and child functioning such as AFCD, Medicaid, Food Stamps, Child Protective Services, and tax revenues generated by women's working); and discounts of savings across time (used a 3 percent discounting rate). Within 2 years after the program ended, the net cost of the program for the sample as a whole was $1,582 per family. For low-income families, the cost of the program was recovered with a dividend of $180 per family.

TRIAL NO.: 144 (5143)

auth: Olds, D
auth: Henderson, CR
auth: Kitzman, H
auth: Cole, R
title: Effects of prenatal and infancy nurse home visitation on surveillance of child maltreatment
year: 1995
ref: Pediatrics
vol: 95(3)
pps: 365-372
project title: Prenatal/Early Infancy Project
country: USA
N: 400
method: RCT
population: See other annotations.
inter. type: Selective preventive intervention
intervention: See other annotations for full description of the nurse home visitation.
outcomes: Outcomes pertain to a subsample of maltreated children from 56 families. All of these children had a state-verified report of child abuse or neglect during the first 4 years of the child's life. Of the maltreated children, those who had been nurse home visited for the first 2 years of the child's life had less serious expressions of caregiving dysfunction. They also had 87 percent fewer visits to the physician for injuries or ingestions and 38 percent fewer visits to the emergency department.

TRIAL NO.: 145 (5143)

auth: Olds, DL
auth: Henderson, CR
auth: Tatelbaum, R
auth: Chamberlin, R
title: Improving the life-course development of socially disadvantaged mothers: A randomized trial of nurse home visitation
year: 1988
ref: American Journal of Public Health
vol: 78(11)
pps: 1436-1445
country: USA
N: See earlier annotation.
method: See earlier annotation.
population: See earlier annotation.
inter. type: Selective preventive intervention
intervention: See earlier annotation.
outcomes: During the first 4 years after delivery of their first child, in contrast to the comparison group, nurse-visited white women who had not graduated from high school when they registered in the study returned to school more rapidly. Nurse-visited, poor, unmarried white women showed an 82 percent increase in the number of months they were employed, had 43 percent fewer subsequent pregnancies, and postponed the birth of second children an average of 12 months longer.

TRIAL NO.: 147 (5143)

auth: Olds, DL
auth: Eckenrode, J
auth: Henderson, CR
auth: Kitzman, H
auth: Powers, J
auth: Cole, R
auth: Sidora, K
auth: Morris, P
auth: Pettitt, LM
auth: Luckey, D
year: 1997
title: Long-term effects of home visitation on maternal life course and child abuse and neglect: Fifteen-year follow-up of a randomized trial
ref: JAMA
vol: 278 (8)
pps: 637-643
country: USA
N: 400
method: RCT
population: See earlier annotation.
inter. type: See earlier annotation.
intervention: See earlier annotation.
outcomes: At 15 years after the birth of the child (13 years since termination of the intervention), women who were visited by nurses during pregnancy and infancy had significantly fewer subsequent pregnancies, less use of welfare, fewer verified reports of abuse and neglect, fewer behavioral impairments due to use of alcohol and other drugs, and fewer arrests.

TRIAL NO.: 236 (5143)
auth: Olds, DL
auth: Henderson, CR
auth: Tatelbaum, R
auth: Chamberlin, R
title: Improving the delivery of prenatal care and outcomes of pregnancy: A randomized trial of nurse home visitation
year: 1986
ref: Pediatrics
vol: 77(1)
pps: 16-28
project title: Prenatal/Early Infancy Project
country: USA
N: 400
method: RCT
population: Subjects were pregnant women living in a small, semirural county. They had had no previous live births and had any one of the following characteristics that predispose to infant health and development problems: young age (less than 19 years), single-parent status, or low SES. The design, however, allowed any woman who asked to participate and who was bearing a first child to be enrolled. Women more than 25 weeks pregnant were to be excluded but 30 women were between the 26th and 29th week of pregnancy due to difficulty in estimating length of gestation.
inter. type: Selective preventive intervention
intervention: There were 4 conditions: developmental screening at ages 1 and 2; screening and free transportation to health care; screening, transportation, and nurse home-visitation once every 2 weeks during pregnancy; and all the above plus continued nurse home-visitation on a diminishing schedule until the infants were 24 months of age. The nurses followed protocols and record-keeping and reviews were used to monitor implementation. The intervention focused on parent education, enhancement of the women's informal support systems, and linkage of the parents with community services.
outcomes: Women who were nurse-visited had many positive behavioral and health outcomes compared to the control group combined with the group who received only transportation. Although there were no overall main intervention effects for birth weight or length of gestation, there were positive effects of the program on birth weight and length of gestation for the offspring of young adolescents and smokers. In contrast to their comparison-group counterparts, young adolescents who were visited by nurses gave birth to newborns who were an average of 395 grams heavier, and women who smoked and were visited by nurses exhibited a 75 percent reduction in the incidence of preterm delivery.

TRIAL NO.: 237 (5143)
auth: Olds, DL
auth: Henderson, CR
auth: Tatelbaum, R
title: Prevention of intellectual impairment in children of women who smoke cigarettes during pregnancy
year: 1994
ref: Pediatrics
vol: 93(2)
pps: 228-233
project title: Prenatal/Early Infancy Project
country: USA
N: See earlier annotation.
method: See earlier annotation.
population: See earlier annotation.
inter. type: See earlier annotation.
intervention: See earlier annotation.
outcomes: Children born to women who smoked 10 or more cigarettes per day at registration during pregnancy and who were nurse-visited had IQs at 3 and 4 years of age that were 4.86 points higher after adjustment for covariates than did children born to women who smoked 10 or more cigarettes per day and who were not home-visited. The improvement seems to be associated with a reduction in maternal smoking and improvements in diet during pregnancy.

TRIAL NO.: 238 (5143)

auth: Olds, DL
auth: Henderson, CR
auth: Kitzman, H
title: Does prenatal and infancy nurse home visitation have enduring effects on qualities of parental caregiving and child health at 25-50 months of life?
year: 1994
ref: Pediatrics
vol: 93(1)
pps: 89-98
project title: Prenatal/Early Infancy Project
country: USA
N: See earlier annotation.
method: See earlier annotation.
population: See earlier annotation.
inter. type: See earlier annotation.
intervention: See earlier annotation.
outcomes: There were no differences between the experimental and comparison groups in the rates of new cases of child abuse and neglect or in the children's intellectual function in the period when the children were 25 to 48 months of age. However, nurse-visited children had fewer injuries and ingestions, fewer behavioral and parental coping problems (as noted in the physician record), and made fewer visits to the emergency department. Nurse-visited mothers were observed to be more involved with and to punish their children to a greater extent than were mothers in the comparison groups.

TRIAL NO.: 239 (5143)

auth: Olds, D
title: The Prenatal/Early Infancy Project
year: 1988
ref: In R Price, E Cowen, R Lorion, and J Ramos-McKay (Eds.), Fourteen Ounces of Prevention: A Casebook for Practitioners
city: Washington, DC
pub: American Psychological Association
project title: Prenatal Early Infancy Project
country: USA
note: See earlier annotations.

150 (5150)
auth: O'Sullivan, AL
auth: Jacobsen, BS
title: A randomized trial of a health care program for first-time adolescent mothers and their infants
year: 1992
ref: Nursing Research
vol: 41(4)
pps: 210-215
country: USA
N: 243
method: RCT
population: Subjects were first time mothers who were 17 years of age or under who delivered a well baby at a large urban teaching hospital and intended to keep the baby. All of the mothers were unwed, on Medicaid, and black.
inter. type: Selective preventive intervention
intervention: The experimental mothers received routine well-baby care plus special services in a teen baby clinic in the same hospital. A pediatrician, a nurse practitioner, a social worker, and trained volunteers provided rigorous follow-up, discussions with the mother about her plans for return to school and use of family planning methods, and extra health teaching including videotapes. The control mothers received routine well-baby care. Both groups received services for 18 months.
outcomes: At 18 months when the intervention ended, the experimental mothers showed significant differences in repeat pregnancy rates, but no differences in return to school rates. Their infants were more likely to have full immunization status, but there was no difference on the rate of use of the emergency room for infant care.
note: comment from Mackey included as separate paper

TRIAL NO.: 152 (5152)
auth: Parush, S
auth: Hahn-Markowitz, J
title: The efficacy of an early prevention program facilitated by occupational therapists: A follow-up study
year: 1997
ref: American Journal of Occupational Therapy
vol: 51(4)
pps: 247-251
country: Israel
N: 109
method: controlled trial, subjects drawn randomly from 6 health centers (3 which offered the intervention and 3 which did not)
population: Subjects were mothers of 3 to 3.5 year old children who were healthy and developmentally normal. The families were from lower class neighborhoods in a large city. All mothers spoke and read Hebrew on at least the 6th-grade level and were not mentally retarded or mentally ill, and the infants were at healthy and without disability.
inter. type: Universal preventive intervention
intervention: The experimental mothers received .5 hours of intervention at the health care center once every 8 weeks during the infants' first year of life. The sessions involved the mother, infant, and an occupational therapist, and the focus was improving the mother's sensitivity to the infant's needs and increasing the mother's awareness of the importance of her role in her child's early development. Developmental information and modeling techniques were used. The controls did not receive the intervention.
outcomes: At 18 months follow-up after the intervention ended, the mothers had acquired greater knowledge and more appropriate attitudes and practices about child development. There was no direct assessment of the children's development.

TRIAL NO.: 153 (5153)

auth: Pelaez-Nogueras, M
auth: Field, TM
auth: Hossain, Z
auth: Pickens, J
title: Depressed mothers' touching increases infants' positive affect and attention in still-face interactions
year: 1996
ref: Child Development
vol: 67(4)
pps: 1780-1792
country: USA
N: 48
method: RCT
population: Subjects were 3 month old infants and their mothers. All infants were healthy, born at gestational age, were of normal birthweight, and had no history of medical complications. They were recruited from a longitudinal study sample of low socioeconomic status families. The mothers were primarily black or Hispanic and most were single adolescents. The Beck Depression Inventory was used to identify a subgroup of mothers with depression.
inter. type: Selective preventive intervention
intervention: The experimental mothers (both depressed and non-depressed) were instructed and shown how to provide touch for their infants during a 8 minute standardized paradigm. The control mothers did not receive the intervention.
outcomes: The infants of depressed mothers showed more positive affect during the experimental paradigm than the infants of nondepressed mothers, but the mothers themselves showed no significant differences in their own behavior. This suggests that the infants' behavior may reflect their histories of interaction with their mothers and that by providing touch stimulation for their infants, the depressed mothers can increase infant positive affect and attention and in this way compensate for negative effects often resulting from their typical lack of affectivity during interactions.

TRIAL NO.: 155 (5155)

auth: Peters, R
title: The Better Beginnings, Better Futures Project: Research Overview
status: CONCURRENT TRIAL
project title: The Better Beginnings, Better Futures Project
country: Canada
N: Not yet available.
method: comparison communities, nonrandomized
population: Subjects are children from birth to 4 years of age in the younger cohort and 4 to 8 years in the older cohort. They are from 8 low-income communities within Ontario. Comparison data are being collected from children and families living in communities which are similar to those involved in the funded project.
inter. type: Selective preventive intervention
intervention: The communities are funded to provide services tailored to local circumstances for the children. The goals are to prevent problems and promote development in social, emotional, behavioral, physical, and cognitive domains.
outcomes: Not yet available.

TRIAL NO.: 417 (5417)

auth: Petersen, L
auth: Handel, J
auth: Kotch, J
auth: Podedworny, T
auth: Rosen, A
title: Smoking reduction during pregnancy by a program of self-help and clinical support
year: 1992
ref: Obstetrics & Gynecology
vol: 79
pps: 924-930
country: USA
N: 317
method: RCT
population: Subjects were literate, English-speaking pregnant women who enrolled into prenatal care at 1 of 4 multi-specialty health centers within a large health maintenance organization.
inter. type: Selective preventive intervention
intervention: Experimental group 1 were mailed a pregnancy-specific self-help manual and audiocassette tape designed to help the women quit smoking. Experimental group 2 received the same materials plus extra attention on the subject from obstetricians and nurse practitioners who had been trained on smoking cessation counseling techniques. The controls received routine obstetric care and were mailed a list of community-based smoking-cessation resources.
outcomes: At 6 months gestation among smokers at baseline, there were no statistically significant differences between groups. For subjects who had quit smoking at baseline, the data showed little difference between groups; 87 percent of the spontaneous quitters reported nonsmoking at 6 months' gestation.

TRIAL NO.: 159 (5159)

auth: Piper, MC
auth: Pless, IB
title: Early intervention for infants with Down syndrome: A controlled trial
year: 1980
ref: Pediatrics
vol: 65(3)
pps: 463-468
country: Canada
N: 37
method: controlled trial
population: Subjects were infants with Down syndrome, all under 24 months of age.
inter. type: Treatment intervention
intervention: The experimental group received center-based biweekly 1 hour therapy sessions for 6 months. The goal was to encourage the child's acquisition of successive developmental levels. The professional therapist was 1 of 6 members of a multidisciplinary team. Written instructions were given to the parents to follow between therapy sessions. The control group did not receive the intervention.
outcomes: No significant difference was found between the experimental and control groups. The intervention did not alter the pattern of mental development in these Down syndrome infants.

TRIAL NO.: 160 (5160)

auth: Poland, ML
auth: Giblen, PT
auth: Waller, JB
auth: Hankin, J
title: Effects of a home visiting program on prenatal care and birthweight: A case comparison study
year: 1992
ref: Journal of Community Health
vol: 17(4)
pps: 221-229
country: USA
N: 761
method: comparison group, non-randomized
population: The subjects were randomly selected from low-income women enrolled at a public health prenatal clinic, but many of them refused or discontinued service. A comparison sample matched on parity, race, and the trimester they entered prenatal care was selected from the same clinic.
inter. type: Selective preventive intervention
intervention: The experimental group received social support services from paraprofessionals who had been on public assistance and had successfully attained health and human services for themselves and their infants. The paraprofessionals received 6 weeks of training and were supervised by a nurse or social worker. Their tasks were to offer information, provide support and counseling for feelings of insecurity, depression, fear of medical procedures and other problems, and make referrals to health and human service agencies.
outcomes: The experimental group had significantly more prenatal appointments, and their babies had significantly higher birthweights (although data in abstract contradicts this). The greater the intensity of contact, the more prenatal care. However, the amount of prenatal care itself did not contribute significantly to differences in birthweight.

TRIAL NO.: 161 (5161)

auth: Powell, C
auth: Grantham-McGregor, S
title: Home visiting of varying frequency and child development
year: 1989
ref: Pediatrics
vol: 84 (1)
pps: 157-164
country: Jamaica
N: 152
method: control
population: Subjects were children between 6 and 30 months in 2 poor city neighborhoods. Exclusions included twins, children with obvious physical or mental handicaps, those with birth weights less than 2.5 kg or those who had not been weighed at birth but had a history of being small, and half of those who had a sibling in this age group (only 1 child per family) was accepted.
inter. type: Selective preventive intervention
intervention: In Jamaica primary health care services include home visits by community health aides who provide health and nutritional advice. This intervention added a structured curriculum of psychosocial stimulation to the home visitors' agenda. The new aims were to improve child development, make the mothers more effective teachers, and improve maternal-child interaction and the self-esteem of both. The paraprofessional home visitors had previously received 8 hours of training for their original task; they received another 8 specifically on the new task. There was some on-going monitoring of the delivery of the intervention, including observation by a nurse supervisor. The experimental group received home visits twice a month for 2 years; the comparison group was visited once a month for 2 years; and the control group received no visits.
outcomes: The experimental children showed small but significant increases in scores on the Griffiths Mental Development Scales (developmental quotient) and performance subscale when compared to the monthly and control groups. The monthly group showed no benefit.

TRIAL NO.: 442 (5442)

auth: Powell, C
auth: Grantham-McGregor, S
title: Home visiting of varying frequency and child development
year: 1989
ref: Pediatrics
vol: 84 (1)
pps: 157-164
country: Jamaica
N: 58
method: RCT
population: Subjects were children between 6 and 30 months in 2 poor city neighborhoods. Exclusions included twins, children with obvious physical or mental handicaps, and those with birth weights less than 2.5 kg or those who had not been weighed at birth but had a history of being small. The study was directed toward families not already participating in the earlier trial of this intervention.
inter. type: Selective preventive intervention
intervention: In Jamaica primary health care services include home visits by community health aides who provide health and nutritional advice. This intervention added a structured curriculum of psychosocial stimulation to the home visitors' agenda. The new aims were to improve child development, make the mothers more effective teachers, and improve maternal-child interaction and the self-esteem of both. The paraprofessional home visitors had previously received 8 hours of training for their original task; they received another 8 specifically on the new task. There was some ongoing monitoring of the delivery of the intervention, including observation by a nurse supervisor. The experimental group weekly home visits for 2 years and the control group received no visits.
outcomes: The experimental children showed marked improvements in performance and hearing and speech subscales as well as the developmental quotient scores. The results of this trial combined with the earlier trial indicate that as the frequency of visiting increases so do the benefits.

TRIAL NO.: 164 (5164)

auth: Radin, N
title: Three degrees of maternal involvement in a preschool program: Impact on mothers and children
year: 1972
ref: Child Development
vol: 43
pps: 1355-1364
country: USA
N: 80
method: matched control groups
population: Subjects were 4 year old lower social class children in a compensatory preschool program.
inter. type: Selective preventive intervention
intervention: The experimental mothers were offered intense involvement in the preschool program; the comparison mothers were offered a moderate level of involvement; the control mothers had no involvement.
outcomes: At the end of 1 year of intervention, there were no significant differences in intellectual growth or behavior among the children in the 3 groups, but there were changes in attitudes in mothers with involvement in the preschool. At 1 year follow-up, children whose mothers had been involved in the preschool showed a significantly greater gain in Peabody IQ than the control children.

TRIAL NO.: 288 (5288)

auth: Ramey, CT
auth: Bryant, DM
auth: Campbell, FA
auth: Sparling, JJ
auth: Wasik, BH
year: 1988
title: Early intervention for high-risk children: The Carolina Early Intervention Program
ref: In RH Price, EL Cowen, RP Lorion, and J Ramos-McKay (Eds.), Fourteen Ounces of Prevention: A Casebook for Practitioners
pps: 32-43
city: Washington, DC

pub: American Psychological Association
project title: The Carolina Early Intervention Program
country: USA
population: Subjects were infants with mothers who tended to be young, Black, poor, single and with less than a high school education. The children were considered at high risk for delayed intellectual development and poor readiness for public school success.
inter. type: Selective preventive intervention
intervention: There were 4 components: developmental day care at a child development child beginning when the infant was between 6 and 12 weeks of age and continuing through 54 months of age; a toy lending library; a home visiting program by the teachers; and a parent group program. Specific curriculum are used in each component.
outcomes: The intervention had a measurable impact on cognition in the first year of life and this impact was sustained over the preschool period. Compared to the average performance of the control group on the Stanford-Binet at 2, 3, and 4 years of age, the intervention group had a significant impact. (The mean percentage of the control group who scored 84 or below was 39.6 percent and of the intervention children it was 8.3 percent.) If the performance of the control group indicates risk during this developmental period, then the early intervention program reduced the risk for borderline or lower intellectual functioning by a total of 79 percent.

TRIAL NO.: 166 (5131)
auth: Ramey, CT
auth: Bryant, DM
auth: Wasik, BH
auth: Sparling, JJ
auth: Fendt, KH
auth: LaVange, LM
title: Infant Health and Development Program for low birth weight, premature infants: Program elements, family participation, and child intelligence
year: 1992
ref: Pediatrics
vol: 3
pps: 454-465
project title: Infant Health and Development Program
country: USA
N: 985
method: RCT
population: See earlier annotation.
inter. type: Selective preventive intervention
intervention: The experimental group received intervention from birth to 3 years, including pediatric follow-up, home visits, parent support groups, and a systematic educational program provided in specialized child development centers. The control group received the same pediatric follow-up and referral services.
outcomes: A Family Participation Index showed that program implementation was not different across the 8 sites. High levels of participation were linked to positive cognitive outcomes at age 3 in the children in the experimental group.

TRIAL NO.: 169 (5030)

auth: Ramey, CT
auth: Yeates, KO
auth: Short, EJ
title: The plasticity of intellectual development: Insights from preventive intervention
year: 1984
ref: Child Development
vol: 55(5)
pps: 1913-1925
country: USA
project title: Carolina Abecedarian Project
N: See earlier annotation.
method: See earlier annotation.
population: See earlier annotation.
inter. type: See earlier annotation.
intervention: See earlier annotation.
outcomes: IQ differences are not significant at 6 and 12 months of age but are significant and favor the experimental group children at 18, 24, 36, and 48 months. These findings lend some support to the notion that IQ is not fixed and can be influenced by early intervention.

TRIAL NO.: 170 (5030)

auth: Ramey, CT
auth: Campbell, FA
title: Preventive education for high-risk children: Cognitive consequences of the Carolina Abecedarian Project
year: 1984
ref: American Journal on Mental Deficiency
vol: 88(5)
pps: 515-523
country: USA
project title: Carolina Abecedarian Project
N: 122
method: RCT
population: Subjects were high risk mothers and their newborn infants. High risk indicators included a lack of parental education and income, a history of mild retardation or school failure in family members, and psychopathology or social maladaptation. All mothers were given a standardized intelligence to help determine eligibility. The index children were determined to be at high-risk for nonbiologically based mild mental retardation.
inter. type: Selective preventive intervention
intervention: The experimental children were treated in a child-centered prevention-oriented intervention program delivered in a daycare setting from infancy to age 5. Language, cognitive, perceptual-motor, and social development were stressed.
outcomes: The children were examined with age-appropriate tests of development at 6, 12, 18, 24, 30, 42,48, and 54 months of age. Beginning at 18 months, and on every test thereafter, the experimental children outscored control children on mental tests. Experimental children consistently scored at the national average whereas control children's scores declined from the average level at 12 months to below average at 18 months and thereafter.

TRIAL NO.: 171 (5171)

auth: Ramey, CT
auth: Smith, BJ
title: Assessing the intellectual consequences of early intervention with high-risk infants
year: 1976
ref: American Journal of Mental Deficiency
vol: 81(4)
pps: 318-324
country: USA
project title: Carolina Abecedarian Project
N: 50
method: RCT
population: Subjects were infants from lower socioeconomic homes whose families had been identified prenatally through prenatal clinics and social services.
inter. type: Selective preventive intervention
intervention: All families received family support social work services, nutritional supplements, and medical care, but the form this took varied between the experimental and control groups. The experimental group received educational day care at a center 8 hours per day, 5 days a week while the control group remained at home.
outcomes: At 7 and 18 months, the experimental infants' performance on the Bayley was superior to that of the control group.

TRIAL NO.: 173 (5173)

auth: Ramey, CT
auth: Farran, DC
auth: Campbell, FA
title: Predicting IQ from mother-infant interactions
year: 1979
ref: Child Development
vol: 50(3)
pps: 804-814
country: USA
N: 57
method: RCT
population: Subjects were children identified as belonging to families at high risk for producing children who would become labeled as mentally retarded during the school years. Identification of these children was made prenatally with the use of a High Risk Index administered to their mothers. The Index included such factors as parental education, income, maternal IQ, history of social or emotional problems, evidence of sociocultural retardation in other family members, intactness of the family, and need for public assistance. These children were randomized into experimental and control groups. In addition to the control children, a non-equivalent comparison group was recruited.
inter. type: Selective preventive intervention
intervention: The experimental children received 8-hour-per-day, 5-days-per-week, center-based day-care from the time they were 3 months old.
outcomes: Early day care altered the predictiveness of some maternal factors including IQ. Maternal IQ was a significant predictor variable only for the control children.

TRIAL NO.: 418 (5418)

auth: Rauh, VA
auth: Achenbach, TM
auth: Nurcombe, B
auth: Howell, CT
auth: Teti, DM
title: Minimizing adverse effects of low birthweight: Four year results of an early intervention program
year: 1988
ref: Child Development
vol: 59
pps: 544-553
project title: Mother-Infant Transaction Program
country: USA
N: 119
method: RCT
population: Subjects were infants whose birthweight was below 2250 grams and gestational age under 37 weeks, and who were hospitalized in the intensive care nursery for at least 10 days. Exclusion criteria included multiple births, congenital anomalies and/or severe neurological defects, and single mothers. A comparison group of infants with birthweights over 2800 grams and more than 37 weeks gestation was recruited from the normal nursery.
inter. type: Selective preventive intervention
intervention: The experimental group received 11 sessions from a nurse, beginning during the final week of hospitalization and extending into the home over a 3-month period. Each session involved the mother, father, infant and nurse and had a specific focus. The overall emphasis was on helping parents in their adjustment to the birth and care of a low birthweight baby. The nurses were monitored on the content and delivery of the intervention.
outcomes: At 4 year follow-up, the experimental mothers reported significantly greater self-confidence and satisfaction with mothering and more favorable perceptions of infant temperament than control mothers. There were significant group differences in cognitive abilities as measured by the McCarthy at 36 and 48 months. These differences had not been present for the experimental children at earlier ages.

TRIAL NO.: 174 (5174)

auth: Resnick, MB
auth: Armstrong, S
auth: Carter, RL
title: Developmental intervention program for high-risk premature infants: Effects on development and parent-infant interactions
year: 1988
ref: Journal of Development and Behavioral Pediatrics
vol: 9(2)
pps: 73-78
country: USA
N: 41
method: RCT
population: Subjects were premature infants, weighing less than 1800 grams at birth, who had been admitted to a regional neonatal intensive care unit within 24 hours of birth.
inter. type: Selective preventive intervention
intervention: All experimental children received a minimum of 2 developmental interventions per day while they were in the neonatal intensive care unit. The interventions were administered by postmaster's level graduate students specializing in early childhood development and trained in the intervention techniques. Protocols were adapted to each infant's medical condition. After discharge from the hospital, a pediatric nurse practitioner made home visits weekly until the infant reached his or her adjusted birth date. Thereafter, a home-based early childhood developmental specialist (post-master's professional) visited the infant and caregiver twice monthly through 12 months' adjusted age. During the visits, the intervention staff evaluated the child's development and modeled intervention activities for the parents using a sequential curriculum. Control infants received traditional, remedially oriented care.
outcomes: At 6 months and 12 months (which was the end of the intervention period), the experimental group demonstrated significant positive effects on mental development and on the quality of caregiver-infant interactions.

TRIAL NO.: 175 (5175)

auth: Reynolds, AJ
title: One year of preschool intervention or two: Does it matter?
ref: Early Childhood Research Quarterly
year: 1995
vol: 10(1)
pps: 1-31
project title: Child Parent Center Preschool Program
country: USA
N: 887
method: comparison groups without randomization
population: Subjects were low income black 3 and 4 year old children from the inner city. They were part of the Longitudinal Study of Children at Risk, in which the effects of the federally-funded Child Parent Center (CPC) preschool program was one major question.
inter. type: Selective preventive intervention
intervention: One intervention group received 2 years of CPC, a Head Start-type program, while the other intervention group received only 1 year. The comparison group from similar neighborhoods entered kindergarten without any preschool experience.
outcomes: The children with the preschool intervention were significantly more academically competent than the no-preschool children when measured in the 6th grade. While the 2-year participants began and ended kindergarten more academically competent than 1-year participants, through the elementary grades these children did not significantly or meaningfully differ from one another on any academic measure. If the study had stopped in Grade 3, it would have been concluded that the effects of preschool participation faded to the level of nonsignificance. Instead, cognitive effects reasserted themselves in Grade 4 and then stabilized. By Grade 6, differences between preschool and no-preschool groups were of similar magnitude as in Grade 1. However, achievement test scores of all groups were well below national averages.

TRIAL NO.: 176 (5176)

auth: Richman, N
auth: Douglas, J
auth: Hunt, H
auth: Lansdown, R
auth: Levere, R
title: Behavioral methods in the treatment of sleep disorders: A pilot study
year: 1985
ref: Journal of Child Psychology and Psychiatry
vol: 26(4)
pps: 581-590
country: England
N: 35
method: pilot; no control
population: Subjects were children between the ages of 1 and 5 with severe sleep disorders lasting more than 6 months. Families were referred by health care providers but were excluded if they were so disturbed that it was inappropriate to focus on the sleep alone.
inter. type: Treatment intervention
intervention: Families were provided a maximum of 6 sessions over a maximum of 6 months. Families were randomly assigned to 1 of 6 therapists (psychologists and a psychiatrist). The therapists recommended behavioral methods for the parents to use at home.
outcomes: There were some improvement in 77% of children.

TRIAL NO.: 177 (5177)

auth: Rickel, AU
auth: Lampi, L
title: A two-year follow-up study of a preventive mental health program for preschoolers
year: 1981
ref: Journal of Abnormal Child Psychology
vol: 9(4)
pps: 455-464
project title: Preschool Mental Health Project
country: USA
N: 70 at follow-up; original N not specified
method: control and comparison groups; no mention of randomization
population: Subjects were first grade children enrolled in Title 1 programs housed in 3 elementary public schools of a large metropolitan city. All children were black and came from lower income homes. All of the children had attended the Preschool Mental Health Project's preschool program where they had been screened for school adaptation problems and had been divided into high-risk and low-risk groups.
inter. type: Indicated preventive intervention
intervention: The high-risk children in the experimental intervention received a year of preschool with a program utilizing behaviorally specific prescriptions for learning problems, acting-out behaviors, and shy, withdrawn behaviors. College undergraduates tailored individual sessions to the needs of the individual children. High-risk control children received placebo attention activities differing in content but not quantity in comparison to the experimental group.
outcomes: This paper is the 2 year follow-up of the preschool intervention. The experimental group was superior to that of the placebo control group at follow-up on measures of behavioral adjustment and achievement. The intervention boosted the high-risk experimental children to the point where their performance was comparable to that of children who had not experienced behavioral or learning difficulties.

TRIAL NO.: 230 (5177)

auth: Rickel, AU
auth: Smith, RL
auth: Sharp, KC
title: Description and evaluation of a preventive mental health program for preschoolers
year: 1979
ref: Journal of Abnormal Child Psychology
vol: 7(1)
pps: 101-112
project title: Preschool Mental Health Project
country: USA
N: 64
method: RCT
population: Subjects were first grade children enrolled in Title 1 programs housed in 3 elementary public schools of a large metropolitan city. All children were black and came from lower income homes. All of the children had attended the Preschool Mental Health Project's preschool program where they had been screened for school adaptation problems and had been divided into high-risk and low-risk groups.
inter type: Indicated preventive intervention
intervention: The high-risk children in the experimental intervention received a year of preschool with a program utilizing behaviorally specific prescriptions for learning problems, acting-out behaviors, and shy, withdrawn behaviors. College undergraduates tailored individual sessions to the needs of the individual children. High-risk control children received placebo attention activities differing in content but not quantity in comparison to the experimental group.
outcomes: The learning and behavior of the experimental children significantly improved in contrast to the control group.

TRIAL NO.: 178 (5178)

auth: Rickert, VI

auth: Johnson, CM

title: Reducing nocturnal awakening and crying episodes in infants and young childreN: A comparison between scheduled awakenings and systematic ignoring

year: 1988

ref: Pediatrics

vol: 81(2)

pps: 203-212

country: USA

N: 33

method: RCT

population: Subjects were families with children between 6 and 54 months of age who exhibited spontaneous awakening and crying episodes during the night at least 1 time per night for the last 4 weeks. The parents were recruited through local newspaper advertisements.

inter. type: Indicated preventive intervention

intervention: During a single home visits, all parents were interviewed and instructed to keep home records about the night awakenings. The control parents were told that some children "grow-out" of awakening spontaneously at night. They were told to keep records for 8 weeks and at 3 and 6 weeks afterward. They were also told that further intervention would be offered if necessary. The first intervention group was instructed over the telephone by the researcher/psychologist to awaken their child at scheduled times 15 to 60 minutes before typical spontaneous awakenings and to do the things they normally did if the child had awakened them, including feeding and consoling. The second intervention group was told over the telephone by the researcher/psychologist to respond to the night awakenings by being sure there were no physical reasons for the child's crying and then to respond to the crying in a stereotypic, mechanical manner without any soothing, letting the child "cry it out".

outcomes: During the 8 week intervention and at 3 and 6 week follow-ups, children in both intervention groups awoke and cried less frequently than children in the control group. The children left to cry it out responded more quickly. There was some improvement in the control group, suggesting that some sleep problems resolve with time.

TRIAL NO.: 443 (5248)

auth: Robert-Tissot, C
auth: Cramer, B
auth: Stern, DN
auth: Serpa, SR
auth: Bachmann, JP
auth: Palacio-Espasa, F
auth: Knauer, D
auth: De Muralt, M
auth: Berney, C
auth: Mendiguren, G
title: Outcome evaluation in brief mother-infant psychotherapies: Report on 75 cases
year: 1996
ref: Infant Mental Health Journal
vol: 17(2)
pps: 97-114
country: Switzerland
N: 84
method: RCT
population: Subjects were children under 30 months of age were who referred to a child guidance clinic for sleep, feeding, and behavioral disorders (mostly crying fits, aggression, and temper tantrums). After a pre-intervention assessment, 84 parents agreed to be in the study.
inter. type: Indicated preventive intervention
intervention: Two types of intervention were provided in the clinic on a weekly basis: interaction guidance therapy (provided by a psychologist and a speech therapist) and psychodynamic therapy (provided by 4 psychiatrists who were also psychoanalysts). The interaction guidance approach was originally designed for families who could or would not cooperate with other therapies. The focus is on encouraging positive family interactions through the use of video-assisted coaching methods. The psychodynamic model is based on Fraiberg's work, and it aims at uncovering the impact of maternal conflict on the perceptions the mother has of the child. Mother and child are both present in the sessions in both types of intervention. The actual number of sessions attended ranged from 1 to 12 with the average number being 6.1 over 9.3 weeks. There was no control group.
outcomes: At 6 month follow-up, there were no major differences in the 2 forms of intervention. All referral symptoms were improved, with a significant decrease in symptoms for sleep problems. Behavior problems showed less marked improvement at the end of the intervention and tended to increase by 6 month follow-up. There was significant improvement in mother-infant interactions, but the authors had expected an even larger positive effect.

TRIAL NO.: 181 (5181)

auth: Rogers, MM
auth: Peoples-Sheps, MD
auth: Suchindran, C
title: Impact of a social support program on teenage prenatal care use and pregnancy outcomes
year: 1996
ref: Journal of Adolescent Health
vol: 19(2)
pps: 132-140
project title: Resource Mothers and Pregnant Teens Project
country: USA
N: 6514
method: comparison group from counties in which program was not offered; retrospective analysis
population: Subjects were primiparous teenagers (under 18 years of age). Referrals came from a variety of sources, such as human service agencies, churches, and teenagers already in the program, in 13 rural and 3 moderately urban counties. Teenagers could enter at any point in their pregnancies, but efforts were made to enroll them early. The program reached a large percentage of young, unmarried, black teenagers.
inter. type: Selective preventive intervention
intervention: The Resource Mothers Program was modeled after the Rural Infant Care Project which had demonstrated a reduction in the incidence of low birthweight infants to adolescent mothers. The RMP used paraprofessional women to provide social support to pregnant teenagers through home visiting. The women had 3 weeks of intensive training. Home visits were provided monthly during pregnancy; a visit was made at the hospital at the time of delivery; and home visits continued regularly for the first year after delivery. Extra visits could be added as needed. The average caseload of a resource mother was between 50 and 65 teenagers.
outcomes: The intervention had no significant effect on low birth weight. However, the teenagers receiving the intervention were more likely to initiate prenatal care early and to receive adequate prenatal care, and they were less likely to have a preterm birth.

TRIAL NO.: 277 (5277)

auth: Ross, M
title: The Promoting Parenthood Project
status: CONCURRENT TRIAL
project title: The Promoting Parenthood Project
country: Scotland
N: 123 couples
method: RCT
population: Subjects were couples, married or cohabiting, who attended "parentcraft" classes which is the formal antenatal education offered through the National Health Service. The couples were expecting their first child.
inter. type: Universal preventive intervention
intervention: There were 4 conditions in addition to the parentcraft classes: directed anticipatory guidance (two 1-hour lectures); non-directed anticipatory guidance (two 1-hour discussion groups); workbook-only; and control. The intervenor was the psychologist who designed the intervention. The interventions were antenatal only and focused on issues involved in transitioning to parenthood.
outcomes: There were no significant differences among conditions on standard measures. There were differences across the entire sample indicating decrasing anxious/depressive symptomatology between baseline and follow-up and decreases in affectional expression and increases in relationship consensus.

TRIAL NO.: 244 (5244)

auth: Ross, S
title: Building Blocks
status: CONCURRENT TRIAL
project title: Building Blocks
country: Canada (Vancouver)
method: study in design phase, may use comparison communities
N: 10 individual projects
population: Subjects are an immigrant population.
inter. type: Selective preventive intervention
intervention: The intervention is based on Hawaii Healthy Start. There will be 3 component areas from which projects can choose: home visitation, fetal alcohol focus, and community capacity building and integration.

TRIAL NO.: 183 (5143)

auth: Samples, FL
title: The differential impact of a comprehensive early intervention program on the level of support received by African-American and white adolescent mothers
year: 1996
doc: ERIC Document Number ED402059
pps: 1-18
project title: Prenatal/Early Infancy Project
country: USA
N: 141
method: secondary analysis of data from the original project
population: See earlier annotation.
inter. type: See earlier annotation.
intervention: See earlier annotation.
outcomes: A sample of 141 primiparous women was selected from the original data set for inclusion. Nurse-visited mothers were more likely than control group mothers to expect high levels of social support from significant others with child care and household chores. Black mothers in the control group reported more support for chores during pregnancy and in the postpartum period than did black or white mothers in the nurse-visited group.

TRIAL NO.: 184 (5184)

auth: Sankey, CG
auth: Elmer, E
auth: Halechko, AD
auth: Schulberg, P
title: The development of abused and high-risk infants in different treatment modalities: Residential versus in-home care
year: 1985
ref: Child Abuse and Neglect
vol: 9(2)
pps: 237-243
country: USA
N: 60
method: matched comparison groups
population: Subjects were infants from birth to 6 months of age who had been adjudicated as deprived (high risk or abused) by the juvenile court. Their parents agreed to placement of the infants in the residential unit rather than in a foster or relative home.
inter. type: Selective preventive intervention
intervention: The experimental children were admitted to an experimental residential treatment program for abused and high risk infants. Parents were offered help on an outpatient basis. One comparison group was infants who were not admitted to the unit because of space limitations or parental opposition to admission. The second control group consisted of healthy infants with no history of abuse/neglect. All comparison infants lived with the birth mother or a foster mother.
outcomes: The babies in residential care, who had multiple caregivers, kept pace developmentally with the comparison babies.

TRIAL NO.: 185 (5185)

auth: Scarr, S
auth: McCartney, K
title: Far from home: An experimental evaluation of the Mother-Child Home Program in Bermuda.
year: 1988
ref: Child Development
vol: 59(3)
pps: 531-543
project title: Bermuda Mother-Child Home Program
country: Bermuda
N: 125
method: RCT
population: Subjects were 24 to 30 month old children and their mothers. Only 33 to 58 percent of the families could be considered disadvantaged. Nearly half the children were attending group care programs on a full-time basis from ages 2 to 4, the period in which the intervention took place.
inter. type: Universal preventive intervention
intervention: The experimental group received the Mother-Child Home Program, consisting of 46 semi-weekly visits by paraprofessional "toy demonstrators" over each of 2 years. The aim was to affect cognition, social behavior, and emotion. The home visitors were extensively trained and supervised. The control group did not receive a home-visiting program.
outcomes: The experimental intervention had few demonstrable effects on any segment of the sample, even the socioeconomically disadvantaged. On average, children in Bermuda score above US norms on cognitive tests and are functioning well in the preschool period.

TRIAL NO.: 186 (5186)

auth: Scarr-Salapatek, S
auth: Williams, ML
title: The effects of early stimulation on low-birth-weight infants
year: 1973
ref: Child Development
vol: 44
pps: 94-101
country: USA
N: 30
method: RCT; assignment based on birth order
population: Subjects were infants who weighed between 1300 and 1800 grams at birth. They were all born to black mothers, typically young and unmarried. The families came from the lowest SES group in a large city, and the mothers initiated prenatal care late in their pregnancies.
inter. type: Selective preventive intervention
intervention: The experimental group received a stimulation program to enhance sensorimotor development for the first year of life: 6 weeks in the nursery and weekly home visits thereafter to improve maternal care. The nursery staff were trained to provide stimulation that approximated good home conditions for normal newborns. The control infants received standard pediatric care for low-birth-weight infants. The home visits were conducted by social workers highly trained in child development and casework. All mothers in both groups were seen by a psychiatrist before discharge from the hospital.
outcomes: At 1 year when the intervention ended the experimental infants had significantly higher developmental status than the control group with an average difference of nearly 10 IQ points. The intervention had brought the experimental group to nearly normal levels of behavioral development.

TRIAL NO.: 188 (5188)

auth: Schweinhart, LJ
auth: Weikart, DP
auth: Larner, MB
title: Consequences of three preschool curriculum models through age 15
year: 1986
ref: Early Childhood Research Quarterly
vol: 1
pps: 15-45
country: USA
project title: High/Scope Preschool Curriculum Study
N: 68
method: RCT
population: Subjects were 3 and 4 year old children who lived in families of low socioeconomic status and who, according to test scores, were at risk of failing in school.
inter. type: Selective preventive intervention
intervention: Three preschool curriculum, all part of the same research project, were compared. The High/Scope model used an open-framework approach in which teacher and child both planned and initiated activities and actively worked together. The Distar model used a programmed-learning approach in which the teacher initiated activities and the child responded to them. The model in the nursery school tradition used a child-centered approach in which the child initiated and the teacher responded. All 3 approaches had two components in common: classroom sessions lasting 2 1/2 hours 5 days a week and home visits by a teacher lasting 90 minutes once every 2 weeks with both the parent and child present.

outcomes: Data was collected at age 15 for youngsters who had attended 1 of 3 preschool programs at ages 3 and 4: the High/Scope model, the Distar model, and a model in the nursery school tradition. The mean IQ of the children who had attended these 3 high-quality preschool programs rose 27 points during the first year of the program, from 78 to 105 and at age 10 was 92. The 3 preschool curriculum groups differed little in their patterns of IQ and school achievement over time. According to self-reports at age 15, the group that had attended the Distar preschool program engaged in twice as many delinquent acts as did the other 2 curriculum groups, including 5 times as many acts of property violence. The Distar group also reported relatively poor relations with their families, less participation in sports, fewer school job appointments, and less reaching out to others for help with personal problems. However, there is no evidence that the Distar group engaged in more delinquency than they would have if they had not attended the preschool program. It is clear that the other 2 models had a more favorable effect on social behavior.

TRIAL NO.: 216 (5009)

auth: Schweinhart, LJ
auth: Weikart, DB
title: The High/Scope Perry Preschool Program
year: 1988
ref: In R Price, EL Cowen, RP Lorion and J Ramos-McKay (Eds.), Fourteen Ounces of Prevention: A Casebook for Practitioners
city: Washington, DC
pub: American Psychological Association
pps: 53-65
project title: High/Scope Perry Preschool Program
country: USA
method: RCT
N: 123
population: See earlier annotation.
inter. type: See earlier annotation.
intervention: See earlier annotation.

outcomes: The long-term follow-ups of this sample had minimal attrition and demonstrate effects on children's school success and later on socioeconomic success and social responsibility as young adults. Although early significant effects on IQ diminished over time and were no longer significant by 2nd grade, experimental children had increased academic achievement, as measured by standardized tests, throughout the elementary and middle-school grades. Teacher ratings of children's social and emotional maturity after kindergarten significantly favored the experimental children. By age 15, these children placed a higher value on schooling and had stronger commitments to school than did the control group. They also had better grades and fewer failing grades. At age 19, they had higher scores than the controls on a measure of literacy and competence in skills of everyday life. They also expressed more favorable attitudes toward high school. By age 19, they had better jobs, higher earnings and job satisfaction, less unemployment, and less public assistance. Fewer of the experimental subjects had ever been arrested, and they had less self-reported delinquent behavior. At age 19, female experimental subjects reported fewer pregnancies and births than did the control women. A cost-benefit analysis and its long-term effects revealed that there was a return of $6 for every dollar invested in the 1-year program and $3 for every dollar invested in the 2-year program. The annual cost per child was $5000 (1981 dollars).

TRIAL NO.: 189 (5189)

auth: Seifert, H
auth: Schwarz, I
title: Treatment effectiveness of large group basic concept instruction with Head Start students
year: 1991
ref: Language, Speech, and Hearing Services in Schools
vol: 22(2)
pps: 60-64
N: 57
country: USA
method: control
population: Subjects were children between 3 and 6 years of age in 4 Head Start classrooms. All children in Head Start classroom whose second language was English or who had a known cognitive deficit were excluded from the data analysis; however, if they were in the experimental classroom, they received the intervention with the rest of their classmates.
inter. type: Selective preventive intervention
intervention: The experimental classroom received direct instruction from a speech-language pathologist on basic concept knowledge 30 minutes a day, twice a week for 7 consecutive weeks. An explicit sequence of concepts was taught to the children, and this was followed by interactive instruction.
outcomes: The basic concepts scores of the experimental group were significantly improved.

TRIAL NO.: 190 (5190)

auth: Seitz, V
auth: Rosenbaum, LK
auth: Apfel, NH
title: Effects of family support intervention: A ten-year follow-up
year: 1985
ref: Child Development
vol: 56(2)
pps: 376-391
project title: Yale Child Welfare Project
country: USA
N: 36
method: quasi-experiment, control group recruited 2 years later
population: Subjects were families who resided in a depressed inner-city area. Mothers were recruited at a clinic when they registered for obstetrical care. They were eligible if this was their first child, there were no serious complications of pregnancy, if they resided in the inner city and had incomes below the federal poverty level, and if the mothers were not markedly retarded or acutely psychotic.
inter. type: Selective preventive intervention
intervention: The experimental mothers were provided a coordinated set of medical and social services including day-care, 28 home visits by a social worker, house calls by a pediatrician, and well-baby visits. The program, known as the Provence approach to family support, began during the mother's pregnancy and continued to 30 months postpartum.
outcomes: The 10 year follow-up results support the conclusions of the 5 year follow-up. Experimental mothers were more self-supporting, had achieved a higher level of education, and had smaller family sizes than control mothers. The experimental children had better school attendance, and the boys were less likely to require costly special school services than control children. There were no lasting effects on children's IQ. The control families required $40,000 in extra welfare and school services in the single year that the 10 year follow-up data were gathered.

TRIAL NO.: 191 (5190)

auth: Seitz, V
auth: Apfel, NH
title: Parent-focused intervention: Diffusion effects on siblings
year: 1994
ref: Child Development
vol: 65(2)
pps: 677-683
project title: Yale Child Welfare Project
country: USA
N: See earlier annotation.
method: See earlier annotation.
population: See earlier annotation.
inter. type: See earlier annotation.
intervention: See earlier annotation.
outcomes: Family support services provided to families of firstborn children produced delayed benefits for later-born children. As was true for the older experimental children, siblings had better school attendance than did control group siblings, were less likely to need supportive or remedial services, and were more likely to be making normal school progress.

TRIAL NO.: 154 (5154)

auth: Seymour, FW
auth: Brock, P
auth: During, M
auth: Poole, G
title: Reducing sleep disruptions in young children: Evaluation of therapist-guided and written information approaches: A brief report
year: 1989
ref: Journal of Child Psychology and Psychiatry
vol: 30(6)
pps: 913-918
country: New Zealand
N: 45
method: RCT
population: Subjects were families who attended a community-oriented, family counselling agency and their children, who were between 9 months and 5 years of age, who had problems with sleep.
inter. type: Indicated preventive intervention
intervention: The experimental group received a standardized night waking program that was therapist-guided in an hour long interview and used written materials and follow-up telephone calls. The comparison group received written information only. The control group was wait listed.
outcomes: There was similar significant improvement in sleeping in both intervention groups compared to the control group.

TRIAL NO.: 192 (5192)

auth: Shapiro, C
title: Shortened hospital stay for low-birth-weight infants: Nuts and bolts of a nursing intervention project
year: 1995
ref: Journal of Obstetric, Gynecologic and Neonatal Nursing
vol: 24(1)
pps: 56-62
country: Canada
N:?
method: RCT
population: Subjects were newborns with a birth weight of less than 2000 grams and their families who had to live within the boundaries of the city. Parents were first approached in the hospital after the infants had stabilized.
inter. type: Selective preventive intervention
intervention: The experimental early discharge group received community-based, in-home, public-health nursing and homemaker services on an individualized basis according to assessed need. The homemakers, who were required to have a minimum of a 10th grade education, had completed a 6 week training program with a curriculum. Control infants received routine medical and nursing care, were kept in the hospital until they reached a weight of at least 2000 grams, and families were referred to the existing public health nursing services at discharge.
outcomes: A significantly higher number of nurse home visits and telephone contacts were made to experimental group than to the controls. One of the most identified needs was assistance with breastfeeding.

TRIAL NO.: 193 (5193)

auth: Sheeber, LB
auth: Johnson, JH
title: Evaluation of a temperament-focused, parent-training program
year: 1994
ref: Journal of Clinical Child Psychology
vol: 23(3)
pps: 249-259
country: USA
N: 40
method: RCT
population: Subjects were mothers of 3 to 5 year old children who showed evidence of a difficult temperament and whose families had parenting problems. Screening instruments were used to identify the risk group. The sample was primarily Caucasian married women, mean age 34, and middle class. They were recruited through preschools and advertisements in local publications. Families were screened out if behavior problems were suggestive of psychopathology or appeared to have developed in response to a recent or severe stress, or if the mother or child were currently receiving mental health treatment, or if medication to control hyperactivity or other behaviors had previously been tried.
inter. type: Indicated preventive intervention
intervention: Experimental mothers were provided a temperament-focused, psychoeducational group intervention for 9 weeks. The intervention was theory-based and manualized, and the sessions were led by a psychologist. Implementation was verified through checklists and observations by an undergraduate research assistant. The control group was wait-listed to receive the intervention 4 months later. Subjects agreed not to participate in alternative treatment or parenting groups in the interim.

outcomes: At post-intervention and 2 month follow-up, experimental mothers demonstrated increased satisfaction with parent-child relationships and perceived parenting competence, as well as improved affect. In addition, reductions in mother-rated child behavior problems and disruptions in family lifestyle were observed. However, spousal relationships did not improve in the experimental group, and there was a lack of change in father ratings of maternal parenting skill.

TRIAL NO.: 291 (5195)

auth: Shure, MB
auth: Spivack, G
title: Interpersonal cognitive problem solving and primary prevention: Programming for preschool and kindergarten children
year: 1979
ref: Journal of Clinical Child Psychology
vol: 8(2)
pps: 89-94
project title: I Can Problem Solve
country: USA
N: 131
method: RCT
population: Subjects were black inner-city nursery and kindergarten children. By chance, the group included some children who had impulsive and inhibited behaviors.
inter. type: Selective preventive intervention
intervention: The I Can Problem Solve curriculum, which focuses on how children think, was taught by teachers in a standardized curriculum of daily 20 minute sessions to 3 groups of children: those who were trained in nursery school and kindergarten; those trained in nursery school only; and those trained in kindergarten only. There also was a control group.
outcomes: At 1 year follow-up after the intervention, there were lasting benefits of the intervention in terms of increased alternative solution thinking, consequential thinking, and improved behavior of impulsive and inhibited children. For youngster not trained in nursery school, training can still be successful in kindergarten.

TRIAL NO.: 194 (5105)

auth: Shure, MB
auth: Spivack, G
year: 1980
title: Interpersonal problem solving as a mediator of behavioral adjustment in preschool and kindergarten children
ref: Journal of Applied Developmental Psychology
vol: 1
pps: 29-44
project title: I Can Problem Solve
country: USA
N: 219
method: control
population: Subjects were black children attending federally funded day care.
inter. type: Selective preventive intervention (bordering on universal)
intervention: See earlier annotation.
outcomes: In both the nursery trained and kindergarten trained groups, increased ability to conceptualize alternative solutions to interpersonal problems was significantly related to improved social adjustment.

TRIAL NO.: 195 (5195)

auth: Shure, MB
auth: Spivack, G
title: Interpersonal problem-solving in young children: A cognitive approach to prevention
year: 1982
ref: American Journal of Community Psychology
vol: 10(3)
pps: 341-356
project title: I Can Problem Solve
country: USA
N: 219
method: RCT
population: Subjects were black inner-city 4 and 5 year old children.
inter. type: Selective preventive intervention
intervention: An interpersonal cognitive problem-solving intervention was implemented with the aim of reducing and preventing impulsive and inhibited behaviors. Children received the intervention only in preschool or only in kindergarten or in preschool and in kindergarten or not at all. The children received 12 weeks of formal scripted sessions, implemented by the teachers in groups of 6 to 9 children, plus gradual incorporation of the problem solving techniques into the regular school day.
outcomes: The impact of the intervention lasted at least a full year. Training was as effective in kindergarten as in preschool. One year of intervention had the same immediate behavior impact as 2 years. Well-adjusted children trained in preschool were less likely to begin showing behavioral difficulties over the 2 year period than were comparable controls.

TRIAL NO.: 196 (5195)

auth: Shure, MB
title: Training children to solve interpersonal problems: A preventive mental health program
year: 1979
ref: In RF Munoz, LR Snowden & JG Kelly (Eds.), Social and Psychological Research in Community Settings
city: San Francisco, CA
pub: Jossey-Bass Publishers
pps: 30-68
project title: I Can Problem Solve
country: USA
note: Reviews earlier work

TRIAL NO.: 289 (5195)

auth: Shure, MB
auth: Spivack, G
year: 1988
title: Interpersonal cognitive problem solving
ref: In RH Price, EL Cowen, RP Lorion, and J Ramos-McKay (Eds.), Fourteen Ounces of Prevention: A Casebook for Practitioners
pps: 69-82
city: Washington, DC
pub: American Psychological Association
note: reviews prior published work

TRIAL NO.: 432 (5431)

auth: Sosa, R
auth: Kennell, J
auth: Klaus, M
auth: Robertson, S
auth: Urrutia, J
title: The effect of a supportive companion on perinatal problems, length of labor and mother-infant interaction
year: 1980
ref: The New England Journal of Medicine
vol: 303(11)
pps: 597-600
country: Guatemala
N: 136
method: RCT
population: Subjects were primigravid mothers in early labor with cervical dilatation of 1 to 2 cm and no known medical problems.
inter. type: Universal preventive intervention
intervention: The experimental mothers received constant support from untrained lay women (doulas) whom the mothers had never met before going into labor. One doula was present during the day and another at night. She provided support consisting of physical contact, conversation, and the presence of a friendly companion.
outcomes: The length of time from admission to delivery was significantly shorter in the experimental group. Mothers who had a doula present during labor were awake more after delivery, stroked, smiled at, and talked to their babies more than the control mothers (all at high levels of significance).

TRIAL NO.: 198 (5030)

auth: Spitz, HH
title: Does the Carolina Abecedarian early intervention project prevent sociocultural mental retardation?
ref: Intelligence
year: 1992
vol: 16 (2)
pps: 225-237
project title: Carolina Abecedarian Project
country: USA
N: NA
method: NA
population: NA
population type: NA
intervention: NA
outcomes: This paper is a critical analysis and commentary on whether the claim that the Carolina Abecedarian Project produced and maintained higher IQs in experimental children at risk for mild mental retardation than control children is indeed true. Four cohorts were recruited over a 5-year period. The experimental groups in cohorts 3 and 4 produced unusually high scores on the Bayley, but these scores were never reported separately, only as part of all 4 cohorts combined. Therefore, the overall IQ for the intervention groups was raised. The author questions whether the difference in cohorts 3 and 4 might be explained by chance allocation of brighter children to the experimental group. Also, unexpectedly the total group of control children did quite well cognitively. Although they were behind the experimental children at 6 months, they recovered by 54 and 60 months of age.

TRIAL NO.: 199 (5009)

auth: Spitz, HH
title: Were children randomly assigned in the Perry Preschool Project? (Comment on an article by E. Zigler, C. Taussig and K. Black, American Psychologist, no. 47, pp. 997, 1992)
year: 1993
ref: American Psychologist
vol: 48(8)
pps: 915
project title: Perry Preschool Project
country: USA
N: NA
method: commentary on the interferences in random assignment in this project
population: NA
inter. type: NA
intervention: NA
outcomes: NA

TRIAL NO.: 203 (5234)

auth: Strayhorn, JM
auth: Weidman, CS
title: Follow-up one year after parent-child interaction training: Effects on behavior of preschool children
year: 1991
ref: Journal of the American Academy of Child and Adolescent Psychiatry
vol: 30(1)
pps: 138-143
country: USA
N: 98 parents with 105 children
method: RCT
population: Subjects were low income parents who complained of at least 1 behavioral or emotional problem in their 2 to 5 year old children. Families whose primary language was not English or whose children had low vocabulary test scores were excluded.
inter. type: Indicated preventive intervention
intervention: The experimental group received group training involving instruction and role-playing practice and individual sessions involving modeling and written materials. The intervention was delivered to parents by research assistant paraprofessionals. The average amount of training received was 12.5 hours. The parent training was supervised by a psychiatrist. The control group received a pamphlet on parenting and watched 2 videotapes on the use of time-out and positive reinforcement.
outcomes: At 1 year follow-up after completion of the intervention, parent ratings and child achievement test scores showed no difference between the experimental and control groups. However, teacher ratings of child behavior, including attention deficit and hyperactivity symptoms, significantly favored the experimental group. Children's improvements in classroom behavior were significantly correlated with improvements parents had shown during the intervention in their behavior toward the children.

TRIAL NO.: 234 (5234)

auth: Strayhorn, JM
auth: Weidman, CS
title: Reduction of attention-deficit and internalizing symptoms in preschoolers through Parent-Child Interaction Training
year: 1989
ref: Journal of the American Academy of Child and Adolescent Psychiatry
vol: 28
pps: 888-896
country: USA
N: 98 parents with 105 children
method: RCT
population: Subjects were low income parents who complained of at least 1 behavioral or emotional problem in their 2 to 5 year old children. Families whose primary language was not English or whose children had low vocabulary test scores were excluded.
inter. type: Indicated preventive intervention
intervention: The experimental group received group training involving instruction and role-playing practice and individual sessions involving modeling and written materials. The intervention was delivered to parents by research assistant paraprofessionals. The average amount of training received was 12.5 hours. The parent training was supervised by a psychiatrist. The control group received a pamphlet on parenting and watched 2 videotapes on the use of time-out and positive reinforcement.
outcomes: The results constitute a mix between posttest results and follow-up (33 to 139 days after the last contact). The experimental parents reported significantly more improvement in their children's symptoms of attention deficit and internalizing symptoms. Both groups improved with respect to parents' ratings of children's oppositional symptoms. A blind measure of videotaped interaction between parent and child demonstrated significantly more improvement in the experimental group.

TRIAL NO.: 66 (5066)

auth: Thomas, PB
title: Florida First Start Program: Program Planning and Implementation Guide
year: 1992
pps: 1-83
doc: ERIC Document Number ED374895, Florida State Department of Education, Office of Early Intervention and School Readiness
project title: Florida First Start Program
country: USA
N: Not given
method: program evaluation, no control or comparison groups
population: Subjects were handicapped children or children at risk of future school failure from birth to 4 years of age (or 3 years if enrolled in full-time preschool). Handicapped status was established by State Board of Education rules for preschool special education services or a written report by a licensed professional. At-risk status included a wide range of conditions: victim of child abuse or sibling of child abused, graduate of perinatal intensive care, mother under age 18, developmental delay, survivor of a major illness or accident resulting in developmental delay, parent who is developmentally delayed or severely emotionally disturbed or drug or alcohol dependent or incarcerated, victim of substance-exposure prenatally.
inter. type: Selective and indicated preventive intervention
intervention: The families and children received comprehensive education and support services, including home visits at least once a month by a trained paraprofessional; developmental screenings; health screenings; family group meetings at least once a month; and access to a parent resource center. Additionally, there was a community-wide public awareness component.
outcomes: No data was reported. Program evaluation is more focused on participation rates than outcomes.

TRIAL NO.: 255 (5255)
auth: Tremblay, RE
auth: McCord, J
auth: Boileau, H
auth: Charlebois, P
auth: Gagnon, C
auth: LeBlanc, M
auth: Larivee, S
title: Can disruptive boys be helped to become competent?
year: 1991
ref: Psychiatry
vol: 54
pps: 148-161
project title: Trial within the Montreal Longitudinal Experimental Study
country: Canada
N: 319
method: RCT
population: Subjects were kindergarten boys who were considered to be disruptive by their teachers and their families. The boys were from 53 schools in low SES areas of a large metropolitan city. Inclusion criteria included: both biological parents were born in Canada and their mother-tongue was French; neither parent had more than 14 years of schooling; the "at risk" boys had disruptive scores above the 70th percentile on screening questionnaires which were completed by teachers when the boys finished kindergarten (mean age 6). Subjects knew they were involved in a study on children's development, but they did not know they had been identified as being at-risk for antisocial behavior.
inter. type: Indicated preventive intervention
intervention: The experimental group received 2 school years of intervention (when the boys averaged 7 to 9 years of age). The intervention included parent training, based on the Patterson model for family intervention; social skills training with the boys; and teaching the boys to use fantasy and be critical of television. Two university-trained child care workers, a psychologist, and a social worker carried out the program with parents and teachers. On average parents averaged 17.4 sessions, with a maximum of 46. The social skills program involved prosocial skills training the 1st year and a program aimed at self-control the 2nd year. Another set of professionals provided this intervention. Graduate students provided 12 home sessions to the child and his siblings on fantasies and alternative to the expression of aggression and 9 sessions in a television training program. However, only half of the experimental children received the home visits by the graduate students because of lack of funds. The observation group received almost as much attention as the experimental group, but no effort was made to change the children or their families. The control group received no special attention or intervention. All 3 groups were free to seek additional interventions in the community.
outcomes: Assessments were made at the end of the intervention and at 1 and 2 years follow-up. At the end of the intervention, there were no differences between groups on the teacher ratings for disruptive behavior, anxiety, inattentiveness, or prosocial behavior, and the experimental mothers were more likely than the other mothers to perceive their sons as disruptive. Two years later experimental mothers gave reliably lower ratings to their sons for prosocial behavior. At 1 year follow-up, all the boys were similar in the amount of misbehavior they reported. However, at 2 year follow-up, the experimental boys reported that during the prior year they were less likely to be fighting outside the home and at home and were less likely to be stealing at home. All disruptive boys from all groups were increasingly placed in special classrooms or held back in school, but the experimental boys were less likely to also be rated as highly disruptive by a teacher or by peers.

TRIAL NO.: 266 (5255)

auth: Tremblay, RE
auth: Pagani-Kurtz, L
auth: Masse, LC
auth: Vitaro, F
auth: Pihl, RO
title: A bimodal preventive intervention for disruptive kindergarten boys: Its impact through mid-adolescence
year: 1995
ref: Journal of Consulting and Clinical Psychology
vol: 63(4)
pps: 560-568
project title: Trial within the Montreal Longitudinal-Experimental Study
country: Canada
N: 319
method: RCT
population: Subjects were disruptive kindergarten boys from inner-city low socioeconomic neighborhood schools. Teacher ratings identified boys at-risk for later antisocial behavior. After randomization, children were included only if both parents were Canadian-born whose first language was French and if the parents had 14 years or less of schooling.
inter. type: Indicated preventive intervention
intervention: Experimental parents received training every other week over a 2 year period, with a maximum number of 46 sessions. The training was based on the Oregon social Leaning Center Model. The experimental children received 19 school-based social skills training sessions over the same 2 year period.
outcomes: At long-term follow-up when the boys were in mid-adolescence, the experimental group was significantly less delinquent on self-report. However, court records did not reveal any significant differences between the groups. A significantly greater percentage of experimental boys remained in age-appropriate regular classrooms up to the end of elementary school. However, this impact disappeared by age 15; by this age 59.3 percent were not in an age-appropriate regular classroom.

TRIAL NO.: 207 (5207)

auth: Valdez-Menchaca, MC
auth: Whitehurst, GJ
title: Accelerating language development through picture book reading: A systematic extension to Mexican day care
year: 1992
ref: Developmental Psychology
vol: 28(6)
pps: 1106-1114
country: Mexico
N: 20
method: RCT
population: Subjects were working class, Spanish-speaking 27 to 35 month old children attending a public day-care center. They had been attending the center an average of 15 months. All children were developmentally normal as measured on the DDST, but their linguistic ability was low which was an inclusion criteria.
inter. type: Indicated preventive intervention
intervention: The experimental group received 30 10 to 12 minute individual training sessions carried out every weekday during the children's preschool schedule. The intervention was delivered by a graduate student using a variation of Whitehurst's dialogic-reading parent-training program which includes the use of picture books to improve the 2 year olds' language skills. Children in the control group received one to one interaction with the graduate student in activities designed to foster perceptual and fine motor skills, but no specific language stimulation was provided.
outcomes: Immediately following the intervention, differences favoring the experimental group were found on all standardized language posttests and on some measures of language production.

TRIAL NO.: 208 (5208)

auth: van den Boom, DC
title: The influence of temperament and mothering on attachment and exploratioN: An experimental manipulation of sensitive responsiveness among lower-class mothers with irritable infants
year: 1994
ref: Child Development
vol: 65(5)
pps: 1457-1477
country: The Netherlands
N: 100
method: RCT
population: Subjects were infants selected for irritability on the 10th and 15th day after birth with the Neonatal Behavioral Assessment Scale. All infants were Caucasian, firstborn, and from low SES families. All infants were carried to term and weighed more than 2500 grams at birth. Pregnancies and deliveries were uncomplicated. Mothers did not receive more than routine medication during delivery. Apgar scores were at least 7 at 1 minute and 8 at 5 minutes.
inter. type: Indicated preventive intervention
intervention: The experimental group received intervention beginning when the infants were 6 months old and ending when the infants were 9 months. The mothers were asked if they would like to participate in a program for first time mothers. They were not told of the irritability assessments. The home-based intervention, conducted by a psychologist, focused on enhancing maternal sensitive responsiveness. Specific interventions were tailored to each infant and mother.
outcomes: At the end of the intervention, the experimental mothers were significantly more responsive, stimulating, visually attentive, and controlling of their infant's behavior than control mothers. Experimental infants had higher scores than control infants on sociability, self-soothing, and exploration, and they cried less. At 12 months of age, significantly more intervention group dyads were securely attached than control group dyads.

TRIAL NO.: 229 (5208)

auth: van den Boom, DC
title: Do first-year intervention effects endure? Follow-up during toddlerhood of a sample of Dutch irritable infants
year: 1995
ref: Child Development
vol: 66
pps: 1798-1816
country: The Netherlands
N: See earlier annotation.
method: See earlier annotation.
population: See earlier annotation.
inter. type: See earlier annotation.
intervention: See earlier annotation.
outcomes: When the children were 3.5 years of age, experimental mothers were more responsive to their toddlers, and the husbands of mothers who participated in the intervention exhibited this responsive attitude as well. Experimental children continued to be more secure in their relationship with the mother, exhibited fewer problem behaviors, and were better able to maintain a positive relationship with peers than control children.

TRIAL NO.: 210 (5210)

auth: Villar, J
auth: Farnot, U
auth: Barros, F
auth: Victora, C
auth: Langer, A
auth: Belizan, JM
title: A randomized trial of psychosocial support during high-risk pregnancies. The Latin American Network for Perinatal and Reproductive Research
year: 1992
ref: The New England Journal of Medicine
vol: 327(18)
pps: 1266-1271
project title: Latin American Multicenter Trial
country: Argentina
N: 2235
method: RCT
population: Subjects were women at 4 centers in Latin America who were at higher-than-average risk for delivering a low-birth-weight infant and were recruited before the 20th week of pregnancy.
inter. type: Selective preventive intervention
intervention: The experimental group received 4-6 home visits by nurses or social workers in addition to routine prenatal care. The control group received only routine prenatal care.
outcomes: There were few differences in outcomes between the experimental and control groups, even among the mothers at highest risk.

TRIAL NO.: 125 (5125)

auth: Walsh, CA
auth: MacMillan, HL
auth: Thomas, BH
title: The Family Connections Study: A randomized controlled trial to evaluate the effectiveness of home visitation in preventing the recurrence of child physical abuse and neglect
status: CONCURRENT TRIAL
project title: Family Connections Study
country: Canada
N: 163
method: RCT
population: Subjects were consecutive clients referred to regional child protective agencies with an episode of physical abuse or neglect confirmed by the respective agency. Families were excluded if they were non-English speaking, the child was over 12 years of age, not living at home, or the victim of sexual abuse, or the abuse had been committed by a foster parent or person living outside the home.
inter. type: Treatment intervention (aiming to reduce recurrence)
intervention: The experimental group received intensive home visitation and the routine clinical follow-up by the respective agency caseworker and the standard services arranged by the agency. The home visitors were trained public health nurses who visited 1.5 hours per week for 6 months, followed by every 2 weeks for 6 months, followed by monthly for 12 months. The focus was on intensive family support, parent education, and linkage of family members with other health services. The nurses were supervised bi-weekly in groups in addition to supervision within their teams. The control group received the routine caseworker follow-up and services.
outcomes: The third year interviews are in process. The main outcome to be measured is subsequent physical abuse and neglect to any child in the family.

TRIAL NO.: 213 (5213)
auth: Wasik, BH
auth: Ramey, CT
auth: Bryant, DM
auth: Sparling, JJ
title: A longitudinal study of two early intervention strategies: Project CARE
year: 1990
ref: Child Development
vol: 61(6)
pps: 1682-1696
project title: Project CARE
country: USA
N: 65
method: RCT
population: Subjects were families whose infants were judged to be at elevated risk for delayed development because of the disadvantaged educational or social circumstances of the parents.
inter. type: Selective preventive intervention
intervention: There were 2 experimental groups — home-based family education plus center-based educational day care or home-based family education only. The center based program was designed to address both cognitive and social domains of development using a systematic development curriculum. The children could attend day care all day. The teachers ranged in their level of formal training from high school graduates to master teachers. Intensive staff training was conducted. The home-based program, consisting of weekly home visits for the first 3 years of the child's life, was designed to help the parent foster the cognitive and social development of the child. The home visitors' backgrounds varied similar to the teachers. The control group received free formula and diapers as did the children in the home-based program only. A social worker was available to all families in all 3 groups for crisis intervention.
outcomes: The children were tested repeatedly between 6 and 54 months of age. On each test after the 6 month assessment, scores of the experimental children in the full 2 component intervention had the best standardized cognitive test results. No cognitive intervention effects were obtained for the family education home visitation group. Group effects were not obtained for measures of either the quality of the home environment or parent attention.

TRIAL NO.: 436 (5436)

auth: Webster-Stratton, C
title: Teaching mothers through videotape modeling to change their children's behavior
year: 1982
ref: Journal of Pediatric Psychology
vol: 17(3)
pps: 279-294
country: USA
N: 35
method: RCT
population: The subjects were mothers and their 3 to 5 year old children. They were recruited by a flyer announcing a parent-training program. SES ranged from lower middle to upper middle class. 75 percent of the mothers had taken some form of parenting program before.
inter. type: Universal preventive intervention
intervention: Experimental mothers attended a series of 4 weekly 2-hour videotape modeling group sessions. The groups, comprising 8 or 9 parents, were led by a graduate student therapist with extensive group work training. The therapist used a prepared script for each vignette to facilitate group discussion. There was no opportunity for the parents to practice directly under supervision what they had observed on the videotapes.
outcomes: At the end of treatment, there was a significant decrease in experimental children's negative affect behaviors and submissive behaviors and a significant increase in children's positive affect behaviors when compared to control children. The experimental mothers reported significantly fewer and less intense behavior problems than the control mothers. Two months after the program ended, the children's behavior continued to improve.

TRIAL NO.: 260 (5260)

auth: Webster-Stratton, C
title: Randomized trial of two parent-training programs for families with conduct-disordered children
year: 1984
ref: Journal of Consulting and Clinical Psychology
vol: 52(4)
pps: 666-678
country: USA
N: 40
method: RCT
population: Subjects were 3 to 8 year old children without debilitating physical impairment, intellectual deficit, or history of psychosis. The primary referral problem to the psychiatric and behavioral clinic in a pediatric hospital was the child's oppositional behavior. Parents had to be willing to pay clinic fees for the intervention, depending upon family income.
inter. type: Indicated preventive intervention (bordering on treatment intervention)
intervention: There were 2 intervention groups: 1) 9 weeks of individual therapy or 2) 9 weeks of therapist-led group therapy based on standardized videotape modeling. There was also a wait list control group. The content and sequencing of training were comparable for both interventions, but the process of training differed. In the individual therapy, one-to-one sessions, using role playing the modeling, occurred between the therapist, parent, and target child. In the group therapy 8 to 10 parents met with a therapist and reviewed 180 videotape vignettes of parent-child interaction. Two psychologists with parent training experience provided all the interventions to both groups.
outcomes: At 1 month and 1 year follow-up, there were significant behavioral improvements in both experimental groups. Although both interventions seemed to offer equivalent and sustained improvements in the families, there were majors differences in total therapist time, so the videotape modeling format was more cost-effective.

TRIAL NO.: 261 (5261)

auth: Webster-Stratton, C
title: Enhancing the effectiveness of self-administered videotape parent training for families with conduct-problem children
year: 1990
ref: Journal of Abnormal Child Psychology
vol: 18(5)
pps: 479-492
country: USA
N: 47
method: RCT
population: Subjects were children between 3 and 8 years of age without debilitating physical impairment, intellectual deficit, or history of psychosis and receiving no treatment at the time of referral. The children's primary referral problem had to be child misconduct that had been occurring for more than 6 months, and parents had to rate their child as having a clinically significant number of behavior problems on a screening checklist.
inter. type: Indicated preventive intervention
intervention: There were 2 interventions: 1) a 10-week standardized individually self-administered videotape modeling program (IVM) and 2) IVM plus two 1-hour therapist consultations (IVMC). There was also a wait list control group. One clinical child psychologist who had received intensive training delivered all the IVMC interventions. All consultation sessions were audiotaped and analyzed.
outcomes: At 1 month follow-up, both experimental groups of mothers reported significantly fewer child behavior problems, reduced stress levels, and less use of spanking. Home visit data indicated that both experimental groups exhibited significant behavioral changes. Although there were few differences between the experimental groups, the IVMC children were significantly less deviant that the IVM children.

TRIAL NO.: 262 (5264)

auth: Webster-Stratton, C
title: Long-term follow-up of families with young conduct-problem childreN: From preschool to grade school
year: 1990
ref: Journal of Clinical Child Psychology
vol: 19(2)
pps: 144-149
country: USA
N: See annotation #264.
method: See annotation #264.
population: See annotation #264.
inter. type: See annotation #264.
intervention: See annotation #264.
outcomes: This is a 3 year follow-up by which time all the subjects were enrolled in school. Only the intervention that combined videotape modeling with therapist-led group discussion achieved stable improvements. Even though all of the children had received 1 of the 2 types of intervention, after 3 years 25 to 46 percent of parents and 26 percent of teachers reported significant child behavior problems.

TRIAL NO.: 263 (5263)

auth: Webster-Stratton, C
title: Advancing videotape parent training: A comparison study
year: 1994
ref: Journal of Consulting and Clinical Psychology
vol: 62(3)
pps: 583-593
project title: ADVANCE
country: USA
N: 85
method: RCT
population: Subjects were children between 3 and 8 years of age without debilitating physical impairment, intellectual deficit, or history of psychosis. They were not receiving any treatment at the time of referral. Their primary referral problem was child misconduct that had been occurring for more than 6 months; their parents rated them on a screening instrument as having a clinically significant number of behavior problems. The children met the criteria for a DSM-III-R diagnosis of oppositional defiant disorder, conduct disorder, or both.
inter. type: Treatment intervention
intervention: All families received basic parent training in the clinic for 12 to 13 2-hour sessions. Groups of 10 to 15 parents met to view videotapes of parenting skills and participate in a therapist-led discussion. The experimental parents also received the ADVANCE program consisting of 14 additional clinic 2-hour sessions of videotapes and therapist-led discussion, but this extra program provided broader based training on how to deal with interpersonal distress through improved communication, problem solving, and self-control skills.
outcomes: At short term follow-up, both groups significantly improved. The experimental group also significantly improved in parents' communication, problem-solving skills, and consumer satisfaction and in children's increased knowledge of prosocial solutions.

TRIAL NO.: 264 (5264)

auth: Webster-Stratton, C
auth: Kolpacoff, M
auth: Hollinsworth, T
title: Self-administered videotape therapy for families with conduct-problem childreN: Comparison with two cost-effective treatments and a control group
year: 1988
ref: Journal of Consulting and Clinical Psychology
vol: 56(4)
pps: 558-566
country: USA
N: 114
method: RCT
population: Subjects were children between 3 and 8 years of age without debilitating physical impairment, intellectual deficit, or history of psychosis. They were not receiving any treatment at the time of referral. Their primary referral problem was child misconduct that had been occurring for more than 6 months; their parents rated them on a screening instrument as having a clinically significant number of behavior problems. The families were either self-referred or professionally referred.
inter. type: Indicated preventive intervention
intervention: There were 3 experimental groups, all with the same goals, content, sequencing, and number of treatment sessions. They differed on the methods of training. All parents were provided 10 to 12 2-hour sessions at the clinic; the focus was on teaching parents how to reduce their children's behavior problems, particularly aggression and noncompliance, and how to increase their children's prosocial behaviors. The 3 methods were: videotape modeling followed by therapist-led group discussion; individually administered videotape modeling; and group discussion with videotapes. The intervenors were psychologists and a social worker, all of whom had received intensive training. They used intervention manuals and were supervised and observed .

outcomes: At 1 month follow-up, all 3 experimental groups of mothers reported significantly fewer child behavior problems, more prosocial behaviors, and less spanking compared with the control group. Home visit observation data indicated that all experimental groups exhibited significant behavioral changes. There were relatively few differences between experimental groups on most outcomes, but cost effectiveness favored the individually administered program.

TRIAL NO.: 265 (5264)

auth: Webster-Stratton, C
auth: Hollinsworth, T
auth: Kolpacoff, M
title: The long-term effectiveness and clinical significance of three cost-effective training programs for families with conduct-problem children
year: 1989
ref: Journal of Consulting and Clinical Psychology
vol: 57(4)
pps: 550-553
country: USA
N: See annotation # 264
method: See annotation #264
population: See annotation #264
inter. type: See annotation #264
intervention: See annotation #264
outcomes: At 1 year post-intervention, all the significant improvements reported immediately post-intervention had been maintained for two thirds of the sample. Consumer satisfaction was highest for the intervention combining group discussion and videotape modeling. The most cost-effective intervention — videotape modeling only— had sustained its effectiveness over time.

TRIAL NO.: 435 (5435)

auth: Webster-Stratton, C
auth: Hammond, M
title: Treating children with early-onset conduct problems: A comparison of child and parent training programs
year: 1997
ref: Journal of Consulting and Clinical Psychology
vol: 65(1)
pps: 93-109
country: USA
N: 97
method: RCT
population: Subjects were families of 4 to 8 year old children with early onset conduct problems that met DSM criteria for oppositional disorder and conduct disorder.
inter. type: Treatment intervention
intervention: There were 4 intervention groups: a parent training treatment group, a child training group, a combined child and parent training group, and a waiting-list control group.
outcomes: Immediately post-treatment, all 3 treatments resulted in significant improvements in comparison with controls, and the improvements were maintained at 1 year follow-up. The combined child and parent training group produced the most significant improvements in child behavior at the 1 year follow-up.

TRIAL NO.: 440 (5440)

auth: Webster-Stratton, C
title: Preventing conduct problems in Head-Start children: Strengthening parenting competencies
year: 1996
ref: University of Washington Technical Report, presented at the American Public Health Association Pre-conference Workshop, November 16, 1996
project title: PARTNERS; Head Start
country: USA
N: 362
method: RCT
population: Subjects were Head Start mothers and their 4 year old children.
inter. type: Selective preventive intervention
intervention: Eight Head Start centers were randomly assigned. In the experimental group, parents, teachers, and family service workers participated together in the new intervention called PARTNERS while in the control condition parents, teachers, and family service workers participated in the regular center-based Head Start program. Teachers and family service workers from the experimental centers underwent 2-3 day training workshops. The parents had a 8-9 week program with PARTNERS. The primary aim of the program was to strengthen protective factors — namely parenting competence, child social competence, and home-school connections as these are seen as the most proximal links in the chain leading to the prevention of conduct problems.
outcomes: At post-intervention and at 1 year follow-up, there were improvements in the experimental mothers' parenting, in their children's affect and behavior, and in the relationship between the mothers and the Head Start family service workers. The only variable related to a family's inability to benefit from the intervention was a history of mother psychiatric illness.

TRIAL NO.: 220 (5220)

auth: Whitehurst, GJ
auth: Epstein, JN
auth: Angell, AL
auth: Payne, AC
auth: Crone, DA
auth: Fischel, JE
title: Outcomes of an emergent literacy intervention in Head Start
year: 1994
ref: Journal of Educational Psychology
vol: 86(4)
pps: 542-555
country: USA
N: 207
method: RCT
population: Subjects were 4-year-olds who attended classrooms in 4 Head Start centers that were geographically close to the university conducting the research.
inter. type: Selective preventive intervention
intervention: The children in the experimental classrooms received an add-on emergent literacy curriculum to their Head Start curriculum. The add-on curriculum had 2 components: dialogic reading, which is an interactive style of adult-child shared picture book reading, and a program to teach children about the phonemic structure of language. The dialogic reading program took place at school with the teachers and at home with the parents. Teachers and parents were trained by means of a 20 minute video, brief role-playing, and discussion. The program continued over the course of the school year, one book per week. The phonics program was conducted in the classroom on 3 days per week for 5 months. There was some on-going monitoring of teachers and parent trainers. A child who participated maximally over the course of the school year would have invested about 42 hours of time in the classroom program. The control children received the typical Head Start curriculum.

outcomes: Effects on language were large but only for those children whose primary caregivers had been actively involved in the at-home component of the program (perhaps because of frequency of exposure). The classroom-based interactive reading did not, by itself, generate increases in children's language skills. Despite the gains in emergent literacy skills, the curriculum did not bring these children up to the typical level of performance of children of their age.

TRIAL NO.: 221 (5221)

auth: Whitehurst, GJ
auth: Falco, FL
auth: Lonigan, CJ
auth: Fischel, JE
auth: DeBaryshe, BD
auth: Valdez-Menchaca, MC
auth: Caulfield, M
title: Accelerating language development through picture book reading
year: 1988
ref: Developmental Psychology
vol: 24(4)
pps: 552-559
country: USA
N: 30
method: RCT
population: Subjects were children between 21 and 35 months of age and their intact middle-class families. On screening tests, the children had normal developmental and linguistic status. Families volunteered as a result of newspaper reports of the project in l ocal newspapers.
inter. type: Universal preventive intervention
intervention: Parents in the experimental group participated in two 25- to 30-minute training sessions at the university over the course of the 4 week intervention. They received instructions to alter the frequency and timing of various aspects of their child-directed speech during picture book reading sessions with their child. They audiotaped some of the sessions for review, and they received weekly reminder telephone calls. Control parents were instructed to read to their children in their customary fashion.
outcomes: Outcomes were assessed at the end of the 4 week intervention and at 9 months following posttesting. Analysis of the tapes demonstrated that the experimental parents complied with the intervention instructions. Experimental children scored significantly higher than control children on standardized posttest of expressive language ability. Because of the small sample size and attrition, these results, which appeared to continue to 9 months, were no longer statistically significant.

TRIAL NO.: 223 (5223)

auth: Widmayer, SM
auth: Field, TM
title: Effects of Brazelton demonstrations for mothers on the development of preterm infants
year: 1981
ref: Pediatrics
vol: 67(5)
pps: 711-714
N: 30
method: RCT
country: USA
population: Subjects were healthy, preterm (less than 37 weeks) neonates born to teen-aged, lower SES status, black mothers.

inter. type: Selective preventive intervention
intervention: Mothers of the first experimental group were present during an administration of the Brazelton Neonatal Behavioral Assessment Scale on their infants and were asked to complete the Mother's Assessment of the Behavior of Her Infant Scale (MABI) at birth and weekly for 4 weeks after discharge of the infant from the hospital. The mothers of the second experimental group were not present for the Brazelton scale, but were asked to complete the MABI scale for the same period of time. The control mothers were not present for the Brazelton, did not complete the MABI, but did complete a questionnaire on their infants' developmental milestones.
outcomes: Assessments were made at the end of the intervention (when the infants were 1 month of age), and at 4 and 12 months of age. Experimental infants and their mothers had more responsive interactions at 1 and 4 months, and by 12 months had significantly higher scores on the Bayley Mental Development Scale.

TRIAL NO.: 259 (5259)

auth: Windsor, RA
auth: Lowe, JB
auth: Perkins, LL
auth: Smith-Yoder, D
auth: Artz, L
auth: Crawford, M
auth: Ambrugy, K
auth: Boyd, NR
title: Health education for pregnant smokers: Its behavioral impact and cost benefit
year: 1993
ref: American Journal of Public Health
vol: 83(2)
pps: 201-206
country: USA
N: 994
method: RCT
population: Women were identified as current smokers through screening interviews at their first prenatal visit at 1 of 4 maternity clinics in a public health department. They were included in the study if they were eligible for care, sought care before 32 weeks gestation, returned for a second visit, were not prisoners, and could read the baseline questionnaire.
inter. type: Selective preventive intervention
intervention: The experimental group received a 15 minute behavioral intervention from a trained health counselor during the first visit; this included standardized cessation skills and risk counseling plus self-help materials (component 1). In component 2, a chart reminder was put in the medical record and a letter sent to the patient. In component 3, social support methods were provided in the form of a "buddy" letter, contract, and tip sheet. Both the experimental and control groups received 2 pamphlets urging them to quit smoking and 2 minutes discussion from a nurse during a prenatal education class at the first visit.
outcomes: Significantly more experimental mothers quit smoking than control mothers. The intervention increased quit rates by 7.4 percent among black patients and 4.9 percent among white patients. Of the women who quit or significantly reduced, a 200 gram and a 92 gram difference, respectively, was observed when birthweights were compared with those of smokers. Detailed cost-benefit data are provided. The cost-benefit ratio low estimate is $1:$17.93 and high estimate is $1:$45.83. The number of pregnant smokers in the US annually is estimated to be more than 1 million.

TRIAL NO.: 224 (5224)

auth: Wolfe, DA
auth: Edwards, B
auth: Manion, I
auth: Koverola, D
title: Early intervention for parents at risk of child abuse and neglect: A preliminary investigation
year: 1988
ref: Journal of Consulting and Clinical Psychology
vol: 56(1)
pps: 40-47
country: Canada
N: 53
method: RCT
population: Subjects were parents and children under supervision from a child protective service agency. The parents had to be younger than 25 years old and have a child between the ages of 9 months and 5 years. At screening, the mother had to have an identified major problem in the parenting role and score within the at-risk range on the Child Abuse Potential Inventory. Home observation had to confirm the need for child-rearing assistance. Exclusion criteria included evidence of major addiction or psychopathology, major developmental disorders, higher intervention priorities (e.g. violence between adult partners, unsuitable housing), or involvement in other treatment services.
inter. type: Selective preventive intervention
intervention: Behavioral training was provided for the experimental parents because their children were at high risk of maltreatment. The therapists were graduate students in psychology who were trained in an apprenticeship and were supervised biweekly, including videotaped and live training sessions. Both the experimental and control parents received an information group offered by the child protection agency.
outcomes: At 3 month follow-up, experimental mothers reported fewer and less-intense child behavior problems than the control mothers did. At 1 year follow-up, caseworkers reported greater improvement and lower risk of maltreatment among experimental families. However, home observations of target behavior did not confirm the gains reported by mothers and caseworkers but rather showed few changes in either parent or child behavior over time. (No attempt was made to document injuries or incidents of suspected abuse.)

TRIAL NO.: 225 (5225)

auth: Zeskind, PS
auth: Ramey, CT
title: Preventing intellectual and interactional sequelae of fetal malnutrition: A longitudinal, transactional, and synergistic approach to development
year: 1981
ref: Child Development
vol: 52(1)
pps: 213-218
N: ?
method: RCT
population: Subjects were black, low-SES children who had previously been randomly assigned before 3 months of age to an instructional day-care center program designed to prevent socioculturally caused mental retardation or to a nonattending home control group. Five of these children were later identified as having low PI which has been used in the diagnosis of fetal malnutrition. Despite the low PI diagnosis, the infants had been full birth weight, full term, appropriate weight for gestational age, and showed no abnormalities at birth. The 5 children, found in both the experimental and control groups, were compared to 17 and 15 healthy average PI infants with the respective experimental and control groups.
inter. type: Selective preventive intervention
intervention: See earlier annotation.
outcomes: At 36 months, the low PI infants in the control group continued to show detrimental effects on intellectual, behavioral, and social-interactional development while there was continued amelioration of those effects in the supportive day-care center environment.

TRIAL NO.: 226 (5226)

auth: Zucker, RA
auth: Maguin, ET
auth: Noll, RB
auth: Fitzgerald, HE
auth: Klinger, MT
title: A prevention program for preschool c.o.a.s: Design and early effects
year: 1990
doc: ERIC Document Number ED327331. Paper presented at the Annual Meeting of the American Psychological Association (Boston, MA, August 10-14, 1990).
pps: 1-15
project title: Michigan State University Multiple Risk Outreach Program (MROP)
country: USA
N: 104
method: RCT
population: Families were recruited by screening all drunk driving arrests in all district courts in a 3 county area. Inclusion criteria included father's blood alcohol level at least 0.15 percent, male child age 3 to 6 years, father living with the child's biological mother, and residence in a 30 mile service area. After randomization, there was an 8 session assessment schedule with both parents and the target child. Then the intervention began.
inter. type: Selective preventive intervention
intervention: There were 2 experimental 28-session interventions — mother-only and both-parents — and 1 control group. The interventions were based on Social Learning Therapy developed by Patterson and colleagues. Behavioral modification strategies were combined with additional attention to parents' alcohol and drug problems, marital functioning, and other parent issues.
outcomes: At 6 month follow-up, ratings of child behavior in control families remained unchanged whereas the ratings of prosocial behavior and undesirable behavior showed improvement for the 2 experimental groups combined.

REVIEWS

7001
auth:
title: Meeting Basic Learning Needs through Programmes of Early Childhood Care and Development.
year: 1993
pps: 1-31
doc: ERIC Document Number ED383401
country: Colombia, Nepal, India, Peru, Brazil, Indonesia, China, Jamaica, Thailand, Chile

7002
auth: Alexander, GR
auth: et al
title: Preterm birth prevention: An evaluation of programs in the United States
year: 1991
ref: Birth
vol: 18(3)
pps: 160-169
country: USA
method: RCTs and other
outcomes: studies with historical controls found positive results, but RCTs did not; positive results for low risk populations but not high risk

7409
auth: Barnard, JE
auth: Martell, LK
title: Mothering
year: 1995
ref: In MH Bornstein (Ed.), Handbook of Parenting, Volume 3 Status and social conditions of parenting
city: Hove, UK
pub: Lawrence Erlbaum Associates
pps: 3-26

7003
auth: Barnes, HV
auth: Goodson, BD
auth: Layzer, JI
title: Review of research on supportive interventions for children and families: Volumes I and II
year: 1996
ref: National Evaluation of Family Support Programs, unpublished final report from Abt Associates for Administration on Children, Youth and Families, Contract No. 105-94-1925

7060
auth: Barnett, S
title: Long-term effects of early childhood programs on cognitive and social outcomes
year: 1995
ref: In The Future of Child: Long Term Outcomes of Early Childhood Programs
city: Los Altos, CA
pub: The Center for the Future of Children, The David and Lucile Packard Foundation
pps: 25-50

7053
auth: Barnett, WS
title: Benefits of compensatory preschool education
year: 1990
ref: Journal of Human Resources
vol: 27
pps: 279-312
note: review of 14 programs

7004
auth: Bass, JL
auth: Christoffel, KK
auth: Widome, M
auth: Boyle, W
auth: Scheidt, P
auth: Stanwick, R
auth: Roberts, K
title: Childhood injury prevention counseling in primary care settings: A critical review of the literature
year: 1993
ref: Pediatrics
vol: 92(4)
pps: 544-550
country: USA
method: review of 20 studies (5 RCT, 10 nonRCT, 2 multiple time series, 1 descriptive, and 2 no positive effects)
intervention: physician counseling
outcomes: 18 of 20 had positive results; injury prevention counseling should be part of routine health supervision

7005
auth: Blondel, B
auth: Breart, G
title: Home visits during pregnancy: consequences on pregnancy outcome, use of health services, and women's situations
year: 1995
ref: Semin Perinatol
vol: 19(4)
pps: 263-271
country: France
method: review of 8 RCTs, meta-analysis
intervention: 2 types of home visits: social support vrs. medical care for women with complications
outcomes: no effects on pregnancy outcome but some effects on women in other areas

7056
auth: Boocock, SS
title: Early childhood programs in other nations: Goals and outcomes
year: 1995
ref: Future of Children
vol: 5
pps: 94-114
note: review of research on programs in 13 countries

7415
auth: Olds, D
auth: Kitzman, H
auth: Cole, R
auth: Robinson, J
title: Theoretical foundations of a program of home visitation for pregnant women and parents of young children
year: 1997
ref: Journal of Community Psychology
vol: 25(1)
pps: 9-25

7006
auth: Brown, B
title: Head Start: How research changed public policy.
ref: Young Children
year: 1985
vol: 40(5)
pps: 9-13

7007
auth: Brown, SA
auth: Grimes, DE
title: A meta-analysis of nurse practitioners and nurse midwives in primary care
year: 1995
ref: Nursing-Research
vol: 44(6)
pps: 332-9
outcomes: unclear what the 33 outcomes are; discussion of cost analysis

7064
auth: Brust, J
auth: Heins, J
auth: Rheinberger, M
title: A review of the research on home visiting: A strategy for preventing child maltreatment
year: 1998
ref: Health Care Coalition on Violence Publication

7009
auth: Chalmers, I
auth: Hetherington, J
auth: Newdick, M
auth: Mutch, L
auth: Grant, A
auth: Enkin, M
auth: Enkin, E
auth: Dickersin, K
title: The Oxford Database of Perinatal Trials: Developing a register of published reports of controlled trials
year: 1986
ref: Controlled Clinical Trials
vol: 7(4)
pps: 306-324

7010
auth: Chalmers, I
title: A register of controlled trials in perinatal medicine.
year: 1986
ref: WHO Chron (XNQ)
vol: 40(2)
pps: 61-65

7008
auth: Cole, JO
title: A critical analysis of the assessment of the effects of Head Start on minority children
year: 1986
ref: Journal of Negro Education
vol: 55(1)
pps: 91-106
note: Reviews the general findings of Head Start evaluation efforts, examines some of the issues raised by national surveys of the effectiveness of the Head Start program (e.g., the Westinghouse Learning Corporation's 1969 report)

7011
auth: Collins, RC
auth: Kinney, PF
title: Head Start Research and Evaluation: Background and Overview.
ref: Technical Paper prepared for the Head Start Evaluation Design Project.
year: 1989
pps: 1-39
doc: ERIC Document Number ED315158
note: includes the Consortium for Longitudinal Studies, the Perry Preschool Project, the Syracuse Study, and the Abecedarian Project

7012
auth: Cusson, RM
auth: Lee, AL
title: Parental interventions and the development of the preterm infant
year: 1994
ref: Journal of Obstetric Gynecologic and Neonatal Nursing
vol: 23(1)
pps: 60-68
note: reviews 29 studies

7013
auth: Darlington, RB
title: The long-term effects of model preschool programs.
year: 1991
ref: In L Okagaki and RJ Sternberg (Eds.), Directors of development: Influences on the development of children's thinking
city: Hillsdale, NJ
pub: Lawrence Erlbaum Associates
pps: 203-215
note: review of Consortium for Longitudinal Studies 11 preschool programs

7066
auth: Deal, LW
title: The effectiveness of community health nursing interventions: A literature review year: 1994
ref: Public-Health-Nursing
vol: 11(5)
pps: 315-323

7402
auth: Dolan-Mullen, P
auth: Ramirez, G
auth: Groff, JY
year: 1994
title: A meta-analysis of randomized trials of prenatal smoking cessation intervention
ref: American Journal of Obstetrics and Gynecology
vol: 171
pps: 1328-1334

7410
auth: Dryfoos, JG
title: Adolescents at risk: Prevalence and prevention
year: 1990
city: New York
pub: Oxford University Press

7014
auth: Durlak, JA
auth: Wells, AM
year: 1997
title: Primary prevention mental health programs for children and adolescents: A meta- analytic review
ref: American Journal of Community Psychology
vol: 25(2)
pps: 115-52
note: review of 177 programs

7401
auth: Elbourne, D
auth: Oakley, A
auth: Chalmers, I
title: Social and psychological support during pregnancy
year: 1989
ref: In I Chalmers, M Enkin, and MJNC Keirse (Eds.), Effective Care in Pregnancy and Childbirth
city: Oxford
pub: Oxford University Press
pps: 221-236
method: review of RCT's and meta-analysis

7416
auth: Farrington, D
title: Intensive health visiting and the prevention of juvenile crime
year: 1995
ref: Health-Visitor
vol: 68(3)
pps: 100-10
note: discusses long term outcomes of home visitation programs

7015
auth: Feldman, MA
auth: NA
title: Parenting education for parents with intellectual **disabilities:** A review of outcome studies
year: 1994
ref: Res Dev Disabil
vol: 15(4)
pps: 299-332
country: Canada
note: review of 20 studies, meta-analysis
intervention: parenting education programs, mostly behavioral
outcomes: encouraging

7057
auth: Gomby, DS
title: Home Visiting: Analysis and Recommendations.
year: 1993
ref: Future of Children
vol: 3
pps: 6-22
doc: ERIC Document Number EJ476485

7061
auth: Gomby, D
auth: Larner, M
auth: Stevenson, C
auth: Lewit, E
auth: Behrman, R
title: Long term outcomes of early childhood programs: Analysis and recommendations
year: 1995
ref: In The Future of Child: Long Term Outcomes of Early Childhood Programs
city: Los Altos, CA
pub: The Center for the Future of Children, The David and Lucile Packard Foundation
pps: 6-24

7016
auth: Halpern, R
title: Lack of effects for home-based early intervention? Some possible explanations
year: 1984
ref: American Journal of Orthopsychiatry
vol: 54(1)
outcomes: statistical evidence is lacking

7065
auth: Helfer, R
title: A review of the literature on the prevention of child abuse and neglect
year: 1982
ref: Child Abuse and Neglect
vol: 6
pps: 251-261

7018
auth: Hoag, MJ
auth: Burlingame, GM
title: Evaluating the effectiveness of child and adolescent group treatment: A meta-analytic review
year: 1997
ref: Journal of Clinical and Child Psychology
vol: 26(3)
pps: 234-246
note: review of 56 outcome studies, including ages 4 to 18

7017
auth: Hodgson, R
auth: Abassi, T
auth: Clarkson, J
title: Effective mental health promotion: a literature review
year: 1996
ref: Health-Education-Journal 1996
vol: 55(1)
pps: 55-74

7420
auth: Hodnett, ED
auth: Roberts, I
title: Home-based social support for socially disadvantaged mothers. (Cochrane Review) year: 1998
ref: In The Cochrane Library, Issue 2.
city: Oxford

7019
auth: Jason, L
auth: NA
title: Early secondary prevention with disadvantaged preschool children
year: 1975
ref: American Journal of Community Psychology
vol: 3(1)
pps: 33-46
country: USA
note: review of programs for infants, toddlers, and preschoolers
outcomes: reduction in intellectual and linguistic problems

7412
auth: Joyner, CC
title: Head Start: Research insufficient to assess program impact
year: 1998
ref: Testimony before the Subcommittee on Children and Families, Committee on Labor and Human Resources, U.S. Senate, and the Subcommittee on Early Childhood, Youth and Families, Committee on Education and the Workforce, House of Representatives, March 26, 1998

7020
auth: Kamerman, SB
auth: Kahn, AJ
title: Home Health Visiting in Europe
year: 1993
doc: ERIC Document Number EJ476487
ref: Future of Children
vol: 3(3)
pps: 39-52

7059
auth: Karoly, L
auth: Greenwood, P
auth: et al
title: Investing in our children: What we know and don't know about the costs and benefits of early childhood interventions
year: 1998
ref: RAND

7021
auth: Kazdin, AE
title: Parent management training: Evidence, outcomes, and issues
year: 1997
ref: Journal of the American Academy of Child and Adolescent Psychiatry
vol: 36(10)
pps: 1349-1356
intervention: treatment technique for oppositional and aggressive behavior in children

7022
auth: Kim, YW
title: When Should We Begin? A Comprehensive Review of Age at Start in Early Intervention
year: 1996
pps: 1-21
doc: ERIC Document Number ED403725

7403
auth: Klaus, MH
auth: Kennell, JH
title: The doula: An essential ingredient of childbirth rediscovered
year: 1997
ref: Acta Paediatrica
vol: 86
pps: 1034-1036

7405
auth: Korner, AF
year: 1987
title: Preventive interventions with high-risk newborns: Theoretical, conceptual, and methodologic perspectives
ref: In JD Osofsky (Ed.), Handbook of Infant Development, Second edition
city: New York
pub: John Wiley
pps: 1006-1036

7023
auth: Lazar, I
auth: Darlington, R
title: Lasting effects of early education: A report from the Consortium of Longitudinal Studies
year: 1982
ref: Monographs of the Society for Research in Child Development,
vol: 47(2-3)
pps: 1-151

7024
auth: Locurto, C
title: Beyond IQ in preschool programs?
year: 1991
ref: Intelligence
vol: 15(3)
pps: 295-312
note: examines extent of outcomes for pre-school programs

7025
auth: MacMillan, HL
auth: MacMillan, JH
auth: Offord, DR
auth: Griffith, L
auth: MacMillan, A
title: Primary prevention of child physical abuse and neglect: A critical review Part I.
year: 1994
ref: Journal of Child Psychology and Psychiatry
vol: 35(5)
pps: 835-856

7026
auth: McCarton, CM
auth: Wallace, IF
auth: Bennett, FC
title: Early intervention for low-birth-weight premature infants: What can we achieve?
year: 1996
ref: Ann Med
vol: 28(3)
pps: 221-225
country: USA
note: review with emphasis on the Infant Health and Development Program
intervention: various programs designed to prevent disabilities
outcomes: only modest success

7499
auth: McKey, RH
auth: Condelli, L
auth: Granson, H
auth: Barrett, B
auth: McConkey, C
auth: Platz, M
year: 1985
title: The impact of Head Start on children, families and communities
ref: Final report of the Head Start Evaluation, Synthesis, and Utilization Project
city: Washington, DC

7062
auth: Miller, LB
auth: Dyer, J
title: Four preschool programs: Their dimensions and effects
year: 1975
ref: Monographs of the Society for Research on Child Development
vol: 40(5,6), Serial No. 162

7027
auth: Oakley, A
title: Social support in pregnancy: The soft way to increase birthweight?
year: 1985
ref: Soc Sci Med
vol: 21(11)
pps: 1259-1268
country: England
method: review of RCTs, nonrandomized studies, and observational studies
outcomes: considerable positive evidence

7029
auth: Ochiltree, G
title: Effects of child care on young children: Forty years of research. Early childhood study paper no. 5
year: 1994
pps: 153
doc: ERIC Document Number ED376987
country: Australia

7418
auth: Olds, D
auth: Korfmacher, J
title: The evolution of a program of research on prenatal and early childhood home visitation: Special issue introduction
year: 1997
ref: Journal of Community Psychology
vol: 25(1)
pps: 1-7

7030
auth: Olds, DL
title: Review of research on home visiting for pregnant women and parents of young children
year: 1993
ref: Future of Children
vol: 3 (3)
pps: 53-92

7417
auth: Olds, DL
auth: Kitzman, H
title: Can home visitation improve the health of women and children at environmental risk?
year: 1990
ref: Pediatrics
vol: 86(1)
pps: 108-116

7068
auth: Olds, D
auth: Pettitt, LM
auth: Robinson, J
auth: Henderson, C
auth: Eckenrode, J
auth: Cole, B
auth: Powers, J
title: Reducing risks for antisocial-behavior with a program of prenatal and early-childhood home visitation
year: 1998
ref: Journal of Community Psychology
vol: 26(1)
pps: 65-83

7408
auth: Olds, DL
auth: Henderson, CR Jr
auth: Kitzman, H
auth: Eckenrode, J
auth: Cole, R
auth: Tatelbaum, R
auth: Robinson, J
auth: Pettitt, LM
auth: O'Brian, R
auth: Hill, P
year: 1998
title: Prenatal and infancy home visitation by nurses: A program of research
ref: Technical Report, Prevention Research Center, Family and Child Home Visitation Program 2000

7028
auth: Organization for Economic Cooperation & Development
title: Our Children at Risk.
year: 1995
pps: 2-149
doc: ERIC Document Number ED393586
city: Paris
pub: Centre for Educational Research and Development
country: 17 countries

7031
auth: Panitch, M
title: A literature review of early intervention
year: 1993
pps: 1-64
doc: ERIC Document Number ED390199
country: Canada

7404
auth: Parke, RD
auth: Tinsley, BJ
year: 1987
title: Family interaction in infancy
ref: In JD Osofsky (Ed.), Handbook of Infant Development, Second edition
city: New York
pub: John Wiley
pps: 579-641

7407
auth: Patterson, GR
title: Performance models for parenting: A social interactional perspective
year: 1997
ref: In JE Grusec and L Kuczynski (Eds.), Parenting and Children's Internalization of Values: A Handbook of Contemporary Theory
city: New York
pub: John Wiley
pps: 193-225

7032
auth: Paul, AS
title: Two decades of early childhood intervention
year: 1992
ref: The intergenerational transfer of cognitive skills
vol: 1&2
pps: 32-40

7413
auth: Powell, DR
title: Evaluating family support programs: Are we making progress?
year: 1994
ref: In SL Kagan and B Weissbourd (Eds.), Putting Families First: America's Family Support Movement and the Challenge of Change
city: San Francisco
pub: Jossey-Bass Inc, Publishers

7033
auth: Provence, S
title: On the efficacy of early intervention programs.
year: 1987
ref: Annual progress in child psychiatry and child development, 1986. (Stella Chess, Alexander Thomas, Eds.) pp. 678-685 Reprinted from "Developmental and Behavioral Pediatrics
vol: 6
pps: 363-366
note: summarizes some of the literature on early intervention programs and their short and long-term results, including Head Start, The Perry Preschool Program, and the Yale Child Welfare Program

7034
auth: Ramey, CT
auth: Bryant, DM
auth: Suarez, TM
title: Early intervention: Why, for whom, how, and at what cost?
year: 1990
ref: Clinical Perinatology
vol: 17(1)
pps: 47-55
note: review of knowledge base of early educational intervention

7167
auth: Ramey, CT
auth: Ramey, SL
title: Effective early intervention
year: 1992
ref: Mental Retardation
vol: 30(6)
pps: 337-345
country: USA
intervention: summary of 3 early education intervention programs for children with low IQ mothers
outcomes: benefits of continuous educational intervention over the first 5 years of life last at least until early adolescence

7172
auth: Ramey, CT
auth: Ramey, SL
title: Which children benefit the most from early intervention?
year: 1994
ref: Pediatrics
vol: 6 Pt 2
pps: 1064-1066
note: review of findings from three separate studies intervention: intensive early intervention programs for children of low-income and undereducated families

7035
auth: Rivara, FP
auth: Grossman, DC
title: Prevention of traumatic deaths to children in the United States: How far have we come and where do we need to go?
year: 1996
ref: Pediatrics
vol: 97 (6 Pt 1)
pps: 791-797
country: USA
note: review of preventive strategies
outcomes: great decrease in nonintentional injury offset by increase in intentional injury

7036
auth: Roberts, I
auth: Kramer, MS
auth: Suizza, S
title: Does home visiting prevent childhood injury? A systematic review of randomized controlled trials
year: 1996
ref: BMJ
vol: 312(7022)
pps: 29-33
country: Canada
method: 11 RCTs, meta-analysis
outcomes: good potential, but surveillance complications in child abuse

7037
auth: Samuels, SC
title: Long term effects of early childhood educational enrichment programs: Preventive implications
year: 1981
ref: Journal of Preventive Psychiatry
vol: 1(1)
pps: 57-75

7038
auth: Schorling, JB
title: The prevention of prenatal alcohol use: A critical analysis of intervention studies
year: 1993
ref: Journal of Studies on Alcohol
vol: 54(3)
pps: 261-267
country: USA
method: 5 studies (2 with treatment/control groups, no RCTs)
intervention: prenatal education and counseling re: alcohol use
outcomes: no intervention superior to routine prenatal care

7039
auth: Scott-Jones, D
title: Family and community interventions affecting the development of cognitive skills in children
year: 1992
ref: The intergenerational transfer of cognitive skills
vol: 1&2
pps: 84-108

7040
auth: Shonkoff, JP
auth: Hauser-Cram, P
title: Early intervention for disabled infants and their families: A quantitative analysis
year: 1987
ref: Pediatrics
vol: 80(5)
pps: 650-658
country: USA
note: review of 31 studies
outcomes: positive effects on developmental progress tempered by restrictive range of measured outcomes, nature of the services, and description of sample

7041
auth: Spitz, HH
title: The raising of intelligence: A selected history of attempts to raise retarded intelligence
year: 1986
city: Hillsdale, NJ
pub: Lawrence Erlbaum Associate
note: history of procedures

7042
auth: Stagner, MW
auth: Duran, MA
title: Comprehensive community initiatives principles, practice, and lessons learned
year: 1997
ref: Future of Children
vol: 7(2)
pps: 132-140

7043
auth: Stevens, JH
year: 1982
title: Research in review. From 3 to 20: The Early Training Project
ref: Journal of the National Association for the Education of Young Children
vol: 37(6)

7044
auth: St. Pierre, RG
auth: Layzer, JI
auth: Barnes, HV
title: Two-generation programs: Design, cost, and short-term effectiveness
year: 1995
ref: Future Child
vol: 3
pps: 76-93
method: review of six programs
outcomes: mixed and modest results in promoting the development of children and improving the parenting skills and economic self-sufficiency of parents

7045
auth: Szabo, RM
auth: NA
title: Prevention of unintentional injuries in children
year: 1997
ref: Journal of South Orthopedic Association
vol: 6(1)
pps: 17-24
country: USA

7067
auth: Szatmari, P
auth: Nagy, J
title: Children of schizophrenic parents: A critical review of issues in prevention
year: 1990
ref: Journal of Preventive Psychiatry and Allied Disciplines
vol: 4(4)
pps: 311-327

7046
auth: Taylor, RL
title: Psychological intervention with mildly retarded children: Prevention and remediation of cognitive deficits
year: 1988
ref: Handbook of Special Education: Research and Practice
vol: 2
pps: 59-75
note: reviews a number of Head Start and early Head Start programs

7058
auth: US General Accounting Office
title: Head Start: Research provides little information on impact of current program
year: 1997
method: review of 22 programs (of 600 located and screened)

7047
auth: Washington, V
auth: Bailey, U
title: Project Head Start: Models and strategies for the twenty-first century
year: 1995
ref: Garland Reference Library of Social Science. Source Books on Education
vol: 38
pps: 202
doc: ERIC Document Number ED386322
pps: 1682-1696

7406
auth: Webster-Stratton, C
year: 1997
title: Early intervention for families of preschool children with conduct problems
ref: In MJ Guralnick (Ed.), The Effectiveness of Early Intervention: Second Generation Research
city: Baltimore, MD
pub: Paul Brookes
method: review
pps: 429-453

7414
auth: Webster-Stratton, C
title: Parent training with low-income families: Promoting parental engagement through a collaborative approach
ref: In JR Lutzker (Ed.), Handbook of Child Abuse Research and Treatment
city: New York
pub: Plenum Press
year: 1998
pps: 183-210

7049
auth: Wu, P
auth: Campbell, DT
title: Extending latent variable LISREL analyses of the 1969 Westinghouse Head Start Evaluation to blacks and full year whites
year: 1996
doc: ERIC Document Number EJ533547
ref: Evaluation and Program Planning
vol: 19(3)
pps: 183-191
method: secondary data analysis

7063
auth: Yoshikawa, H
title: Prevention as cumulative protection: Effects of early family support and education on chronic delinquency and its risks
year: 1994
ref: Psychological Bulletin
vol: 115
pps: 28-54

7055
auth: Yoshikawa, H
title: Long-term effects of early childhood programs on social outcomes and delinquency
year: 1995
ref: The Future of Children
vol: 5
pps: 51-75
outcomes: early childhood programs have resulted in long-term reductions in serious acting out behavior

7050
auth: Zahr, L
title: An integrative research review of intervention studies with premature infants from disadvantaged backgrounds
year: 1994
ref: Maternal Child Nursing Journal
vol: 22(3)
pps: 90-101
note: includes 13 studies

7051
auth: Zigler, E
auth: Styfco, SJ
auth: Gilman, E
title: The national Head Start program for disadvantaged preschoolers
year: 1993
ref: In E Zigler and SJ Styfco (Eds.), Head Start and beyond: A national plan for extended childhood intervention
pps: 1-41
project title: Head Start

7052
auth: Zigler, E
auth: Berman, W
title: Discerning the future of early childhood intervention
year: 1983
ref: American Psychologist
vol: 38(8)
pps: 894-906
note: historical about Head Start

C. SEVERAL METHODS OF SUMMARIZING OUTCOME FINDINGS

SEVERAL METHODS OF SUMMARIZING OUTCOME FINDINGS FROM MRAZEK & BROWN'S EVIDENCE-BASED LITERATURE REVIEW OF PSYCHOSOCIAL PREVENTION AND EARLY INTERVENTION PROGRAMS FOR YOUNG CHILDREN

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Mrazek and Brown's report to Invest in Kids represents a valuable and comprehensive review of the evidence-based literature regarding outcomes in prevention and early intervention projects for young children from birth to six years of age. The paper provides extensive information on a wide variety of trials, organizing the information into types of outcome within each project. In addition, what may be the most original characteristic of this review compared with other recent reviews, the authors propose a number of dimensions upon which the merit of the design and implementation of a program can be judged, thus providing a context within which to consider the validity of the reported results. Finally, Mrazek and Brown have also calculated and reported effect sizes, where possible, for every statistically significant effect in the top 34 projects in their review. This was an extremely labour intensive undertaking, but the resulting information greatly increases the value of the database.

There are, however, a number of limitations to the report being utilized for the purpose for which it was commissioned, i.e., to aid policy-making decisions regarding supporting prevention and early intervention projects that are both well-designed and efficacious. These limitations of the paper include:

1. The paper emphasizes the development and application of criteria by which to evaluate program design and implementation and pays less attention to the actual outcomes produced by the programs.
2. The section that does document program outcomes is presented in an extensively long table format which precludes the reader from easily summarizing the information.
3. There are no clear summary measures evaluating proportion of beneficial, harmful or non-significant outcomes for any given trial. There are no summary indices of average effect sizes for different projects, different types of outcome (child, parent or community), or as a function of outcome duration (short, medium, or long-term). Such summary measures might make the results easier to understand in terms of conclusions and implications for future practice and research.

Our goal was to generate a variety of summary measures that would address these aforementioned shortcomings, and which may enhance the usefulness of the report provided by Mrazek and Brown.

POINTS TO CONSIDER WHEN REVIEWING THE FOLLOWING SUMMARIES

Significant Effects and Effect Sizes

The designation regarding whether an outcome is considered significant (in either the beneficial or harmful direction) is the conventional .05 cut-off. This practice means that there is a 5% chance that a non-significant finding will be reported as significant. It is worth considering that if this 5% chance is extrapolated to a project that examine an extremely large number of comparisons, then one would expect an increasing number of significant findings appearing simply by chance. For example, there are 239 outcomes examined in project # 5143 (Prenatal / Early Infancy Project - Elmira); thus, as a function of the number of variables, one would expect twelve results significant at the .05 level by chance. Although there are statistical corrections available to account for multiple comparisons, it is not clear from the Mrazek and Brown report whether or not this was actually carried out either in the original study, or subsequently by Mrazek and Brown.

In the Appendices of this report, the direction is reported for non-significant findings. It is important that these directions only be considered as part of the larger picture - that is, within the context of the signifi-

cant findings. While non-significant effects may be part of a larger pattern, in and of themselves they can not be interpreted reliably.

In a few of the summary charts, we grouped the magnitude of effects into Negligible, Small, Medium, Large, and NR (not reported). The purpose of these groupings was to enable the reader to combine effect sizes and log odds ratios into a composite comparison. The effect sizes are grouped into categories on the basis of Cohen's recommendations, which are generally accepted in the field. As no similar well-publicized convention exists for log odds ratios, the cut-offs reported in Mrazek and Brown were used. The following table indicates the categorization rules.

Category	Effect Size	Log Odds Ratio
Negligible	under 0.20	under 0.30
Small	0.20 - 0.49	0.30-0.74
Medium	0.50-0.79	0.75-1.49
Large	0.80 or greater	1.50 or greater
NR	not reported	not reported

Confusing Trajectories with Large Numbers of Comparisons

One convention in Mrazek and Brown's report that could potentially result is misinterpretation, is that a number of projects report multiple points along a trajectory as different outcomes. Thus, one outcome analyzed as several points in time for the same groups of children are reported as numerous outcomes. For example project #5027 (Burchinal) reports 13 significant, beneficial cognitive outcomes. However, upon inspection it appears that there are three between group comparisons being made at several points in time. It may be more accurate to construe this type of result as a trajectory or growth curve, rather than as independent outcomes. A growth curve analysis would indicate whether rates of change were different between groups over time, or conversely, whether a difference arising between Time 1 and Time 2 was merely being maintained over subsequent data points. Projects #5143 (Prenatal / Early Infancy Project — Elmira) and #5030 (Carolina Abecedarian Project) should both be evaluated carefully, as they too report multiple data points for a given comparison group and outcome.

Quality of Outcome Measure

It should also be noted that in the type of summaries reported here, each step further removed from the data is a trade-off in terms of summarizing large amounts of data at the expense of detail. In particular, the quality of the outcome measure gets obscured in this type of presentation. For example, with Trial #5020, there is one reported significant beneficial effect. This beneficial Mother's Social Support outcome is reported as "Agree that Home Visits Provide Best Prenatal Care". It is not clear that a global consumer satisfaction rating is a particularly valid outcome. If this outcome is considered in the context of the other nine outcomes reported for that study, all of which were objective indicators of distress directly prior to, during, or after delivery, it is the only outcome that even goes in the right direction. The other nine are all non-significant, but with the exception of one equal one, go in a harmful direction.

SUMMARIES OF PROJECT FINDINGS

An important contribution that Mrazek and Brown's review has made to the early intervention / prevention literature is their documentation of all outcome effects measured in each of the thirty-four projects receiving five and four star ratings (see Tables 6a and 6b in Mrazek and Brown's report). For each outcome the direction of the difference is indicated, as well as whether or not the effect is statistically significant, the

size of the effect (effect size or log odds ratio) and the type of outcome measure using 20 categories of child and parent / family outcomes. Mrazek and Brown summarize these outcome effects in tabular form in their report. Although they also list the age of the child when each outcome measure was collected, in tables 6a and 6b, they do not summarize the outcome effects in terms of how long after the intervention ceased the measures were collected.

Duration of Effects

Since the duration of outcome effects is an important issue in evaluating the effectiveness of intervention programs, we summarized Mrazek and Brown's results in terms of whether each reported outcome effect was short-term (i.e., the measure was collected during or immediately after the intervention period), intermediate (i.e., collected up to 2.5 years after the intervention period) or long-term (i.e., collected more than 2.5 years after the intervention period). We also categorized each measure employing the 20 types of outcomes used by Mrazek and Brown, presenting the child outcome categories in Table 1, parent / family measures in Table 2, and government cost outcomes in Table 3.

What is immediately apparent from Tables 1-3 is that most of the outcome effects reported in the 34 studies in Mrazek and Brown's review are short term: 55% of child outcomes and 77% of parent outcomes. Only 20% of the child outcomes and 7% of the parent outcomes measured were long term, i.e., collected more than 2.5 years after the intervention ended.

It is also interesting to note in Table 1, that of the 100 long-term child outcome measures reported, only 18 were significantly beneficial and 13 of these 18 were cognitive or school performance outcomes. For the parent measures in Table 2, only 33 long-term outcome measures are reported with 13 being beneficial.

We have included a series of Tables as Appendices which present for each of the 34 projects presented in Mrazek and Brown's Tables 6a and 6b: 1) The type and number of each child outcome and parent outcome measures, 2) The number of outcomes which are significantly beneficial, significantly harmful or not significant, 3) The direction of all non significant effects, and 4) Information about effect sizes / log odds ratios for measures when calculated. We present this information by project for all child measures in Table 10, and then separately for short-term, intermediate and long-term child measures in Tables 11, 12 and 13 respectively. Table 14 presents the same type of outcome information for all the parent measures and then separately for short-term, intermediate, and long-term parent measures in Tables 15, 16 and 17.

By referring to Appendix Table 13 it can be seen that of the 34 projects, only five reported long-term child outcomes:
1) #5030, The Carolina Abecedarian Project; 2) #5039, The Busselton Study; 3) #5131, The Infant Health and Development Project (IHDP); 4) #5188, The High / Scope Preschool Curriculum Study; and 5) #5255, The Montreal Longitudinal Experiment. Note that #5188 is not the High/Scope Perry Preschool Project. That study is #5009 (Barnett, 1993) in Mrazek and Brown's review, and received a rating of three stars. Therefore the outcomes of the High/Scope Perry Preschool Study were not included in Tables 6a and 6b and are not presented here, even though the long-term outcome results of that study are likely the most widely cited in the early intervention literature.

To review briefly the long-term child outcome analyses of these five studies which yielded significantly beneficial results, the Abecedarian Project reported 2 of 3 cognitive measures and 2 of 4 school performance measures as significantly beneficial; the Busselton Study 2 of 6 behavioural outcomes, 1 of 6 physical health

outcomes and 2 of 12 school performance outcomes; IHDP reported 0 of 9 behavioural outcomes, 1 of 9 social relations, 4 of 12 cognitive, 0 of 15 physical health and 0 of 7 school performance outcomes as significantly beneficial. In the High / Scope Perry Curriculum Study, 0 of 2 behavioural, 2 of 3 cognitive, 0 of 3 school performance and 0 of 11 legal offence outcomes were reported as beneficial. Finally, the Montreal Longitudinal Study reported 0 of 2 behavioural measures, 1 of 1 school performance and 1 of 3 legal offence measures as significantly beneficial. These results indicate that the evidence for the long-term positive outcomes is in the areas of cognitive (3 studies, 8 of 18 analyses significant) and school performance measures (3 studies with a total of 5 of 16 significant outcomes and 2 studies with 0 of 10 outcomes significant). Only one study, the Busselton Study, showed significant long-term beneficial effects on children's behaviour (2 of 6 outcomes analysed), while three other studies found no significant effects on behavioural outcomes (0 of 13 outcomes analysed).

Table 17 shows that only 2 studies of the 34 analysed by Mrazek and Brown reported long term outcomes on parent measures. The Elmira PEIP home visiting program resulted in significant positive long-term outcomes on child maltreatment (2 of 2 outcomes analysed), mother's physical health (3 of 6 analysed) and mothers being on public assistance (8 of 19 analysed). No beneficial effects were found on mother's education / employment in the Elmira Study. The Montreal Study reported only two parent outcome analyses of parenting behaviour and both were insignificant. Thus, the Elmira home visiting program is the only one of the 34 in this review to show positive long-term effects on parent.

TABLE I. SUMMARY TABLE OF CHILD OUTCOMES ACROSS PROJECTS

CHILD OUTCOMES ACROSS PROJECTS					
Outcome	**Short-term** (during or immediately after intervention)	**Intermediate** (up to 2.5 years after intervention)	**Long-term** (more than 2.5 years after intervention)	TOTALS	% of All Outcomes
Temperament/Behaviour/Symptoms	**N=81** 30 Beneficial 12 Harmful 39 Not Significant	**N=82** 22 Beneficial 1 Harmful 59 Not Significant	**N=19** 2 Beneficial 0 Harmful 17 Not Significant	**N=182** 54 Beneficial 13 Harmful 115 Not Significant	35.69%
Social Relations	**N=4** 1 Beneficial 0 Harmful 3 Not Significant		**N=9** 1 Beneficial 0 Harmful 8 Not Significant	**N=13** 2 Beneficial 0 Harmful 11 Not Significant	2.55%
Cognitive	**N=96** 66 Beneficial 0 Harmful 30 Not Significant	**N=17** 3 Beneficial 0 Harmful 14 Not Significant	**N=18** 8 Beneficial 0 Harmful 10 Not Significant	**N=131** 77 Beneficial 0 Harmful 54 Not Significant	25.69%
Speech and Language	**N=10** 1 Beneficial 0 Harmful 9 Not Significant	**N=6** 1 Beneficial 0 Harmful 5 Not Significant		**N=16** 2 Beneficial 0 Harmful 14 Not Significant	3.14%
Motor Development	**N=10** 1 Beneficial 0 Harmful 9 Not Significant	**N=1** 0 Beneficial 0 Harmful 1 Not Significant		**N=11** 1 Beneficial 0 Harmful 10 Not Significant	2.16%
Physical Health/Growth/Health	**N=27** 3 Beneficial 2 Harmful 22 Not Significant		**N=21** 1 Beneficial 1 Harmful 19 Not Significant	**N=48** 4 Beneficial 3 Harmful 41 Not Significant	9.41%
Safety or Injuries	**N=18** 10 Beneficial 0 Harmful 8 Not Significant	**N=20** 8 Beneficial 2 Harmful 10 Not Significant		**N=38** 18 Beneficial 2 Harmful 18 Not Significant	7.45%
School Performance	**N=30** 13 Beneficial 4 Harmful 13 Not Significant	**N=6** 2 Beneficial 0 Harmful 4 Not Significant	**N=21** 5 Beneficial 0 Harmful 16 Not Significant	**N=57** 20 Beneficial 4 Harmful 33Not Significant	11.18%
Legal Offences	**N=2** 1 Beneficial 0 Harmful 1 Not Significant		**N=12** 1 Beneficial 0 Harmful 11 Not Significant	**N=14** 2 Beneficial 0 Harmful 12Not Significant	2.75%
Column Total (%of total outcomes measured)	278 (54.51%)	132 (25.88%)	100 (19.61%)	510	

TABLE 2. SUMMARY TABLE OF PARENT AND FAMILY OUTCOMES ACROSS PROJECTS

PARENT AND FAMILY OUTCOMES ACROSS PROJECTS					
Outcome	**Short-term** (during or immediately after intervention)	**Intermediate** (up to 2.5 years after intervention)	**Long-term** (more than 2.5 years after intervention)	TOTALS	% of All Outcomes
Parenting/ Parent-Child Relationship	**N=47** 20 Beneficial 2 Harmful 25 Not Significant	**N=22** 3 Beneficial 0 Harmful 19 Not Significant.	**N=2** 0 Beneficial 0 Harmful 2 Not Significant	**N=71** 23 Beneficial 2 Harmful 46 Not Significant	15.67%
Child Maltreatment	**N=14** 2 Beneficial 0 Harmful 12 Not Significant	**N=20** 0 Beneficial 1 Harmful 19 Not Significant	**N=2** 2 Beneficial 0 Harmful 0 Not Significant	**N=36** 4 Beneficial 1 Harmful 21 Not Significant	7.94%
Pregnancy/ Pregnancy-Outcomes	**N=214** 38 Beneficial 3 Harmful 173 Not Significant			**N=214** 38 Beneficial 3 Harmful 163 Not Significant	47.24%
Motherís Stress		**N=2** 0 Beneficial 0 Harmful 2 Not Significant		**N=2** 0 Beneficial 0 Harmful 2 Not Significant	0.44%
Motherís Social Support	**N=17** 7 Beneficial 0 Harmful 10 Not Significant	**N=3** 0 Beneficial 0 Harmful 3 Not Significant		**N=20** 7 Beneficial 0 Harmful 13 Not Significant	4.41%
Motherís Mental Health	**N=9** 1 Beneficial 0 Harmful 8 Not Significant	**N=7** 1 Beneficial 0 Harmful 6 Not Significant		**N=16** 2 Beneficial 0 Harmful 14 Not Significant	3.53%
Motherís Physical Health	**N=11** 5 Beneficial 1 Harmful 5 Not Significant	**N=10** 2 Beneficial 0 Harmful 8 Not Significant	**N=6** 3 Beneficial 0 Harmful 3 Not Significant	**N=27** 10 Beneficial 1 Harmful 16 Not Significant	5.96%
Motherís Education/Employment	**N=27** 4 Beneficial 1 Harmful 22 Not Significant	**N=3** 0 Beneficial 0 Harmful 3 Not Significant	**N=4** 0 Beneficial 0 Harmful 4 Not Significant	**N=34** 4 Beneficial 1 Harmful 29 Not Significant	7.51%
Motherís Public Assistance	**N=11** 0 Beneficial 1 Harmful 10 Not Significant	**N=3** 0 Beneficial 0 Harmful 3 Not Significant	**N=19** 8 Beneficial 0 Harmful 11 Not Significant	**N=33** 8 Beneficial 1 Harmful 24 Not Significant	7.28%
Column Total (% of total outcomes measured)	350 (77.26%)	70 (15.45%)	33 (7.28%)	453	

TABLE 3. STATUS OF COMMUNITY OUTCOMES

Despite the prevailing theory of child development which recognizes the importance of an ecological context, only one of the projects that met the inclusion criteria for the Mrazek and Brown report included any measure of community outcome. In addition, the outcome that was included (i.e., Government Cost) can be considered a distal indicator, and would not be expected to disentangle the relationship between community (or neighbourhood) and child development. In comparison, a factor such as sense of community safety might facilitate a better understanding of the relationship.

Having identified Government Cost as a somewhat uninformative outcome for child development, it was nonetheless measured by the Prenatal/ Early Infancy Project. Government Cost savings were calculated as a composite factor reflecting expenses associated with reduction in health services, taxes from increased employment, reduction in welfare cost, and reduction in criminal justice cost. The following summarizes the findings:

#5143 Prenatal / Early Infancy Project -- Elmira Reported Government Cost Outcomes		
Short-term	Intermediate (<2.5 years)	Long-term (>2.5 years)
N=2 0 Beneficial 0 Harmful 2 not sig. (2+, 0=, 0-)	**N=4** 3 Beneficial (0.38; n.a.) range 0.29-0.46 0 Harmful 1 not sig. (1+, 0=, 0-)	0

Further Summaries of Project Characteristics and Outcomes

In Table 4 we present a summary of several other interesting characteristics for each of the 34 five and four star rated programs from the information in Mrazek and Brown's review. Of particular note here is the wide range of sample sizes among the programs and also the breadth of outcome measures employed in each project. The last two columns in Table 4 present the number of categories of child and parent / family outcome measures in each study. The nine child categories and nine parent / family categories are those previously presented in Tables 1 and 2.

TABLE 4. PROJECT CHARACTERISTICS: ONSET, DURATION, SAMPLE SIZE, NUMBER OF OUTCOMES CATEGORIES INCLUDED, AND PERCENTAGE OF BENEFICIAL EFFECTS

Project #	Title or Authour	Developmental Period of Onset	Duration or (Number of Contacts if Pertinent)	Sample Size	Number of Child Outcome Categories (/9) % of total child outcomes that are beneficial % of total child outcomes with medium or large effect sizes	Number of Family Outcome Categories (/9) % of total parent outcomes that are beneficial % of total parent outcomes with medium or large effect sizes
5431	Klaus, MH	PARTUITION	Delivery	465	**N=0**	**N=1** 29% Beneficial 14% Medium or Large Effect Sizes
5434	Kennell, J	PARTUITION	Delivery	412	**N=0**	**N=1 Category (12 total comparisons)** 25% Beneficial 25% Medium or Large Effect Sizes
5020	Blondel, B	PRENATAL	Not specified, but entirely prenatal	158	**N=0**	**N=2** 10% Beneficial 10% Medium or Large Effect Sizes
5023	Booth, CL	PRENATAL	18 months	147	**N=0**	**N=2** 0% Beneficial 0% Medium or Large Effect Sizes
5026	Bryce, RL	PRENATAL	Not specified, but entirely prenatal	1970	**N=0**	**N=1** 23% Beneficial 0% Medium or Large Effect Sizes
5036	Connor-Kuntz, FJ	PRENATAL	Not specified, but entirely prenatal	339	**N=0**	**N=1** **100% Beneficial** 86% Medium or Large Effect Sizes
5054	Ershoff, DH	PRENATAL	8 weeks prenatal	323	**N=0**	**N=1 Category (7 total comparisons)** 43% Beneficial 29% Medium or Large Effect Sizes
5088	Heins, HC	PRENATAL	Not specified, entirely prenatal	1458	**N=0**	**N=1** 0% Beneficial 0% Medium or Large Effect Sizes
5103	Prenatal / Early Infancy Project ñ Memphis	PRENATAL	2 years (prenatal care, then screening at 6, 12, and 24 months)	1139	**N=4** 36% Beneficial NR% Medium or Large Effect Sizes	**N=8** 22% Beneficial 3% Medium or Large Effect Sizes (many NR)
5130	McDuffie, RS	PRENATAL	9 visits prenatal	2764	**N=0**	**N=3 Categories (27 total comparisons)** 4% Beneficial 0% Medium or Large Effect Sizes
5139	Munjanja, SP	PRENATAL	Not specified, but entirely prenatal	15994	**N=0**	**N=1** 13% Beneficial 0% Medium or Large Effect Sizes
5143	Prenatal / Early Infancy	PRENATAL	Prenatal plus two years	400	**N=6 Categories (150 total comparisons)** 31% Beneficial	**N=7 Categories (83 total comparisons)** 19% Beneficial
	Project ñ Elmira				17% Medium or Large Effect Sizes	13% Medium or Large Effect Sizes

TABLE 4. PROJECT CHARACTERISTICS: ONSET, DURATION, SAMPLE SIZE, NUMBER OF OUTCOMES CATEGORIES INCLUDED, AND PERCENTAGE OF BENEFICIAL EFFECTS, cont'd

Project #	Title or Authour	Developmental Period of Onset	Duration or (Number of Contacts if Pertinent)	Sample Size	Number of Child Outcome Categories (/9) % of total child outcomes that are beneficial % of total child outcomes with medium or large effect sizes	Number of Family Outcome Categories (/9) % of total parent outcomes that are beneficial % of total parent outcomes with medium or large effect sizes
5210	The Latin America Multicenter Trial	PRENATAL	4-6 visits prenatal	2235	**N=0**	**N=1 Category (21 total comparisons)** 0% Beneficial 0% Medium or Large Effect Sizes
5259	Windsor, RA	PRENATAL	Not specified, but entirely prenatal	994	**N=0**	**N=1 Category (4 total comparisons)** 25% Beneficial 25% Medium or Large Effect Sizes
5415	Oakley, A	PRENATAL	5 contacts prenatal	509	**N=1 Category (1 total comparison)** 100% Beneficial 0% Medium or Large Effect Sizes	**N=5 Categories (39 total comparisons)** 13% Beneficial 3% Medium or Large Effect Sizes
5007	Anisfield, E	INFANCY	3 months	49	**N=3 Categories (5 total comparisons)** 40% Beneficial 40% Medium or Large Effect Sizes	**N=1 Category (5 total comparisons)** 60% Beneficial 60% Medium or Large Effect Sizes
5016	Beeghly, M	INFANCY	1 month (3 visits total)	163	**N=2 Categories (2 total comparisons)** 0% Beneficial 0% Medium or Large Effect Sizes	**N=2 Categories (3 total comparisons)** 0% Beneficial 0% Medium or Large Effect Sizes
5018	Black, MM	INFANCY	1 year (weekly home visit)	150	**N=5 Categories (16 total comparisons)** 0% Beneficial 0% Medium or Large Effect Sizes	**N=1 Category (6 total comparisons)** 0% Beneficial 0% Medium or Large Effect Sizes
5027	Burchinal, M	INFANCY	5 years	151	**N=1 Category (15 total comparisons)** 87% Beneficial 80% Medium or Large Effect Sizes	**N=0**
5030	Carolina Abecedarian Project	INFANCY	5 years	122	**N=3 Categories (59 total comparisons)** 61% Beneficial 61% Medium or Large Effect Sizes	**N=1 Categories (4 total comparisons)** 0% Beneficial 0% Medium or Large Effect Sizes
5039	The Busselton Study	INFANCY	5 years (4 contacts during first year, two for each subsequent year)	246	**N=3 Categories (44 total comparisons)** 53% Beneficial 21% Medium or Large Effect Sizes	**N=1 Category (10 total comparisons)** 86% Beneficial 14% Medium or Large Effect Sizes
5117	Houston Parent-Child Development Center	INFANCY	2 years	458	**N=3 Categories (80 total comparisons)** 25% Beneficial 19% Medium or Large Effect Sizes	**N=0**
5131	Infant Health and Development Program	INFANCY	3 years	895	**N=5 Categories (73 total comparisons)** 16% Beneficial 4% Medium or Large Effect Sizes	**N=3 Categories (19 total comparisons)** 22% Beneficial 0% Medium or Large Effect Sizes
5150	OíSullivan, AL	INFANCY	18 months	243	**N=2 Categories (6 total comparisons)** 33% Beneficial 33% Medium or Large Effect Sizes	**N=3 Categories (8 total comparisons)** 63% Beneficial 63% Medium or Large Effect Sizes

TABLE 4. PROJECT CHARACTERISTICS: ONSET, DURATION, SAMPLE SIZE, NUMBER OF OUTCOMES CATEGORIES INCLUDED, AND PERCENTAGE OF BENEFICIAL EFFECTS, cont'd

Project #	Title or Authour	Developmental Period of Onset	Duration or (Number of Contacts if Pertinent)	Sample Size	Number of Child Outcome Categories (/9) % of total child outcomes that are beneficial % of total child outcomes with medium or large effect sizes	Number of Family Outcome Categories (/9) % of total parent outcomes that are beneficial % of total parent outcomes with medium or large effect sizes
5275	Moore, F	INFANCY	One contact w/I ten days of birth	1800	**N=1 Category (1 total comparison)** 0% Beneficial 0% Medium or Large Effect Sizes	**N=0**
5288	Carolina Early Intervention Project	INFANCY	4.5 years	NR	**N=2 Categories (19 total comparisons)** 89% Beneficial 63% Medium or Large Effect Sizes	**N=0**
5185	Bermuda Mother-Child Home Program	TODDLER	2 years	125	**N=4 Categories (15 total comparisons)** 7% Beneficial 0% Medium or Large Effect Sizes	**N=1 Category (2 total comparisons)** 50% Beneficial 0% Medium or Large Effect Sizes
5040	Cunningham, CE	PRESCHOOL	1 year (11 or 12 sessions)	150	**N=1 Category (3 total comparisons)** 0% Beneficial 0% Medium or Large Effect Sizes	**N=2 Categories (15 total comparisons)** 7% Beneficial 7% Medium or Large Effect Sizes
5188	High / Scope Preschool Curriculum Study	PRESCHOOL	1 year	68	**N=4 Categories (22 total comparisons)** 23% Beneficial 23% Medium or Large Effect Sizes	**N=0**
5189	Seifert, H	PRESCHOOL	1 year (only 7 hours of contact)	57	**N=1 Category (3 total comparisons)** 67% Beneficial 67% Medium or Large Effect Sizes	**N=0**
5220	Whitehurst, GJ	PRESCHOOL	1 school year (42 hours of contact)	207	**N=3 Categories (20 total comparisons)** 35% Beneficial 5% Medium or Large Effect Sizes	**N=0**
5234	Strayhorn, JM	PRESCHOOL	1 year (only 12.5 hours of contact)	98	**N=3 Categories (19 total comparisons)** 37% Beneficial 32% Medium or Large Effect Sizes	**N=1 Category (4 total comparisons)** 25% Beneficial 25% Medium or Large Effect Sizes
5255	Montreal Longitudinal Experimental Study	SCHOOL	2 years	319	**N=3 Categories (23 total comparisons)** 26% Beneficial 17% Medium or Large Effect Sizes (some NR)	**N=1 Category (2 total comparisons)** 0% Beneficial 0% Medium or Large Effect Sizes
5432	Sosa, R	NR in Mrazek and Brown	???	???	**N=0**	**N=2 Categories (6 total comparisons)** 83% Beneficial 33% Medium or Large Effect Sizes (rest NR)

TABLE 5. SUMMARY AND COMMENTS REGARDING AGE OF ONSET AND SAMPLE SIZE

Age of Onset	N of 4 and 5 Star Projects	N in Literature Search
PRENATAL	13	34
PARTUITION	2	3
INFANCY	11	75
TODDLER	1	14
PRESCHOOL	5	34
EARLY SCHOOL AGED	1	3
NOT SPECIFIED	1	2
TOTAL	34 Projects	165 Projects

Comment:

It is understandably easier to do a controlled, randomized trial that is limited in scope (i.e., a discrete number of prenatal visits), then a more complex multidimensional intervention. However, based on the relative difficulty of carrying out a limited prenatal intervention compared to a comprehensive, multi-year child development intervention, it may be unreasonable to hold the two types of research to the same standard. Using the criteria that were outlined by Mrazek and Brown, 38% of the PRENATAL interventions and 67% of the PARTUITION interventions were included in the report. In comparison, only 15% of the TODDLER and PRESCHOOL commenced interventions, and 7% of the INFANCY interventions met the criteria for inclusion in the report. It may be valuable in the future to evaluate projects in comparison to other research designs of similar scope in order to develop an appreciation of the unique challenges faced by complex, multi-year, multidimensional interventions. The following summaries of sample size and breadth of measures are related to this issue.

Sample Size	Number of Projects
Under 200	12
200-499	10
500-799	1
800-1099	2
1100+	7
Not specified	2
Total	34

Comment:

The function of sample size across projects has a somewhat bimodal distribution. Similar to the issue research design, short-term prenatal and partuition interventions are more amenable to large numbers of subjects. Indeed, of the seven projects in the 1100+ category, six are prenatal interventions, and the seventh is a infancy intervention consisting of one home visit within the first ten days of life. While these interventions may have merit in their own right, it is not necessarily appropriate to compare them to more comprehensive efforts.

Table 6. Project Comprehensiveness and Reflected by Breadth of Measures

		Number of Child Outcomes Measured (maximum = 9)				
		0	1	2-3	4-5	6-9
Number of Parent and Family Outcomes Measured (maximum = 9)	0	--	3	3	1	0
	1	9	0	5	2	0
	2-3	4	1	2	1	0
	4-5	0	1	0	0	0
	6-9	0	0	0	1	1

Note: Mother's Education and Mother's Employment are combined for consistency with this summary report although they constitute separate categories in the Mrazek and Brown report.

Comment:

The chart above reinforces the notion that when extremely stringent methodology standards are employed, then projects with a more narrow focus are included. The shaded area represents the number of projects included in Mrazek and Brown (35% of total) that used only one child outcome measure and no family measures OR, conversely, one family measure and no child outcome measures. Such a narrow focus is not congruent with the theoretical shift to more comprehensive, ecologically based models of child development, yet these more comprehensive projects were rejected for inclusion in the current study based on perceived methodological flaws.

SUMMARIES OF SIZE OF EFFECTS FOR BENEFICIAL OUTCOMES

A final set of summary tables and figures are designed to identify where beneficial outcome effects have been found and which show substantial (i.e., medium or large) sizes of effect. Tables 7, 8 and 9 present the number of statistically significant outcomes and those with medium or large effect sizes for short, intermediate and long-term outcomes. It can be seen that for both child and parent / family outcomes, by far the greatest number of outcomes are short-term (i.e., collected during or immediately after the intervention). For child measures, short-term effects account for 70% of the beneficial outcomes (126 of a total of 180), and also 70% of outcomes with medium or large effect sizes (79 of 113). For the parent and family measures, short-term effects account for 80% of the beneficial outcomes (77 of 96) and 70% of the medium or large effect sizes (37 of 53). Clearly, the great majority of outcome effects in these 34 projects are short-term.

When looking at the types or categories of outcome measures that have received the greatest attention and those that have yielded the most beneficial results, Figures 1 and 2 present relevant information for the child outcome measures. As shown in Figure 1, behavioural, cognitive and school outcome measures account for 73% of all those reported in Mrazek and Brown's review. In Figure 2, cognitive and school outcomes account for over half of all beneficial child outcomes, with behavioural measures accounting for 30%.

Similar summaries for the parent and family outcome measures are presented in Figures 3 and 4. It is interesting to note in Figure 3 the relative dearth of family or parent outcomes that measure characteristics of the family or the parenting relationship. For the most part, family or parent outcomes tend to focus on the parent as an individual - there is very little in the way of interactions at the family level / family functioning. Thus, when considering the large number of "family and parent" outcomes reported in this document, it should be remembered that only 16% of the measured outcomes relate to parenting or parent-child relationships, another 8% measure child maltreatment, and the rest focus solely on the parent.

Clearly, the largest category of measures entails pregnancy outcomes for the mother. This reflects the fact that prenatal and partuition programs account for 15 of 34 five and four star projects in Mrazek and Brown's review suggesting that these programs may be easier to design and implement methodologically than those including children at older ages.

Finally, to summarize the types of child and parent measures which have yielded the strongest outcome effects, Figure 5 presents the percentage of all outcome measures in each category which show statistically significant beneficial effects and also the percentage yielding medium or large effect sizes. These percentages were calculated from out Tables 7 and 8. Thus, for child behaviour outcome measures, 54 out of 182 were significantly beneficial (30%) while 26 out of 182 showed medium or large effects (14%).

What Figure 5 indicates is that for child outcomes, the highest percentage of beneficial results occurs within the cognitive category, followed by safety, school and behaviour categories. However, when looking at the percentage of all outcome measures that yielded medium or large effect sizes, the cognitive category at 50% if far and away the highest percentage, with school performance measures being the next highest at 20%. In order to place these results in the proper context, it is necessary to refer back to Figure 1, which presents of the percentages of all child measures which were for example cognitive (26%), behavioural (30%), school (11%), and safety (7%). Thus, cognitive measures seem to reflect the greatest impact of early intervention,

since they have been collected frequently and have most consistently yielded positive and substantially strong outcomes. Child behavioural measures, though collected frequently, have yielded half the percentage (30%) of beneficial outcomes compared with cognitive measures, and a substantially lower percentage of medium and large effect sizes than cognitive measures (14% vs. 50%).

For the parenting measures presented in Figure 5, mothers' physical health, social support and parenting measures show the highest percentages of beneficial effects, while physical health, public assistance, legal offences and social support categories show the highest percentages of medium or large size effects. It is important to remember, however, from Figure 4, that mothers' physical health, public assistance / legal offences and social support account for only 6%, 7% and 4% of all parent measures respectively. Pregnancy outcomes, though by far the largest category of all parent measures reported in the viewed studies at 47%, showed comparatively low rates of beneficial effects (18%) and also low rates of medium or larges size effects (10%). Three of six measures of government costs from the Elmira PEIP yielded significantly beneficial effects, but effect sizes were not calculated.

TABLE 7. SIZE OF EFFECTS FOR BENEFICIAL CHILD OUTCOMES ACROSS PROJECTS

CHILD OUTCOMES ACROSS PROJECTS				
Outcome	**Short-term** (during or immediately after intervention)	**Intermediate** (up to 2.5 years after intervention)	**Long-term** (more than 2.5 years after intervention)	MAGNITUDE TOTALS FOR CATEGORY
Temperament/Behaviour/Symptoms	**N=30 (out of 81)** 3 Negligible 18 Small 6 Medium 2 Large 1 Not reported	**N=22 (out of 82)** 6 Small 15 Medium 1 Large	**N=2 (out of 19)** 1 Medium 1 Large	**N=54 (out of 182)** 3 Negligible 24 Small 22 Medium 4 Large 1 Not reported
Social Relations	**N=1 (out of 4)** 1 Small		**N=1 (out of 9)** 1 Small	**N=2 (out of 13)** 2 Small
Cognitive	**N=66 (out of 96)** 6 Small 25 Medium 35 Large	**N=3 (out of 17)** 1 Small 2 Large	**N=8 (out of 18)** 4 Small 4 Medium	**N=77 (out of 131)** 11 Small 29 Medium 37 Large
Speech and Language	**N=1 (out of 10)** 1 Small	**N=1 (out of 6)** 1 Large		**N=2 (out of 16)** 1 Small 1 Large
Motor Development	**N=1 (out of 10)** 1 Small	**N=0 (out of 1)**		**N=1 (out of 11)** 1 Small
Physical Health/Growth/Health	**N=3 (out of 27)** 2 Small 1 Large		**N=1 (out of 21)** 1 Large	**N=4 (out of 48)** 2 Small 2 Large
Safety or Injuries	**N=10 (out of 18)** 3 Small 2 Medium 1 Large 4 Not reported	**N=8 (out of 20)** 5 Small 1 Medium 2 Large		**N=18 (out of 38)** 8 Small 3 Medium 3 Large 4 Not reported
School Performance	**N=13 (out of 30)** 7 Small 4 Medium 2 Large	**N=2 (out of 6)** 2 Medium	**N=5 (out of 21)** 1 Small 3 Medium 1 Not reported	**N=20 (out of 57)** 8 Small 9 Medium 2 Large 1 Not reported
Legal Offences	**N=1 (out of 2)** 1 Medium		**N=1 (out of 12)** 1 Not reported	**N=2 (out of 14)** 1 Medium 1 Not reported
Total	N = 126 significant beneficial 45.32% of short-term outcomes	N = 36 significant beneficial 27.27% of intermediate outcomes	N = 18 significant beneficial 16.82% of long-term outcomes	N = 180 significant beneficial 35.29% of all outcomes

Table 8. SIZE OF EFFECTS FOR BENEFICIAL PARENT AND FAMILY OUTCOMES ACROSS PROJECTS

PARENT AND FAMILY OUTCOMES ACROSS PROJECTS				
Outcome	**Short-term** (during or immediately after intervention)	**Intermediate** (up to 2.5 years after intervention)	**Long-term** (more than 2.5 years after intervention)	MAGNITUDE TOTALS FOR CATEGORY
Parenting/ Parent-Child Relationship	**N=20 (out of 47)** 8 Small 1 Medium 4 Large 7 Not reported	**N=3 (out of 22)** 2 Medium 1 Large	**N=0 (out of 2)**	**N=23 (out of 71)** 8 Small 3 Medium 5 Large 7 Not reported
Child Maltreatment	**N=2 (out of 14)** 1 Large 1 Not reported	**N=0 (out of 20)**	**N=2 (out of 2)** 1 Medium 1 Large	**N=4 (out of 36)** 1 Medium 2 Large 1 Not reported
Pregnancy/ Pregnancy-Outcomes	**N=38 (out of 214)** 1 Negligible 13 Small 13 Medium 9 Large 2 Not reported			**N=38 (out of 214)** 1 Negligible 13 Small 13 Medium 9 Large 2 Not reported
Mother's Stress		**N=0 (out of 2)**		**N=0 (out of 2)**
Mother's Social Support	**N=7 (out of 17)** 3 Small 2 Medium 2 Large	**N=0 (out of 3)**		**N=7 (out of 20)** 3 Small 2 Medium 2 Large
Mother's Mental Health	**N=1 (out of 9)** 1 Not reported	**N=1 (out of 7)** 1 Medium		**N=2 (out of 16)** 1 Medium 1 Not reported
Mother's Physical Health	**N=5 (out of 11)** 1 Small 4 Medium	**N=2 (out of 10)** 1 Small 1 Medium	**N=3 (out of 6)** 1 Small 2 Medium	**N=10 (out of 27)** 3 Small 7 Medium
Mother's Education/Employment	**N=4 (out of 27)** 2 Negligible 1 Small 1 Medium	**N=0 (out of 3)**	**N=0 (out of 4)**	**N=4 (out of 34)** 2 Negligible 1 Small 1 Medium
Mother's Public Assistance	**N=0 (out of 11)**	**N=0 (out of 3)**	**N=8 (out of 19)** 1 Small 4 Medium 3 Large	**N=8 (out of 33)** 1 Small 4 Medium 3 Large
Total	N = 77 significant beneficial 22.1% of short-term outcomes	N = 6 significant beneficial 8.57% of intermediate outcomes	N = 13 significant beneficial 39.39% of long-term outcomes	N = 96 significant beneficial 21.29% of all outcomes

Table 9. SUMMARY OF SIZE OF EFFECTS FOR SIGNIFICANT BENEFICIAL RESULTS

CATEGORY	NUMBER OF SIGNIFICANT BENEFICIAL OUTCOMES COMPARED TO TOTAL OUTCOMES	NUMBER OF SHORT-TERM OUTCOMES WITH MEDIUM OR LARGE EFFECT SIZES	NUMBER OF INTERMEDIATE OUTCOMES WITH MEDIUM OR LARGE EFFECT SIZES	NUMBER OF LONG-TERM OUTCOMES WITH MEDIUM OR LARGE EFFECT SIZES	NUMBER OF TOTAL OUTCOMES WITH MEDIUM OR LARGE EFFECT SIZES
Child	186 (out of 523) 36%	79 (out of 278 outcomes) 28.42%	24 (out of 132 outcomes) 18.18%	10 (out of 100 outcomes) 10.00%	113 (out of 510 outcomes) 22.16%
Parent and Family	96 (out of 453) 21%	37 (out of 350 outcomes) 10.57%	5 (out of 70 outcomes) 7.14%	11 (out of 33 outcomes) 33.33%	53 (out of 453 outcomes) 11.70%
Community	3 (out of 6) 50%	0 (out of 2 outcomes) 0%	0 (out of 4 outcomes) 0%		0 (out of 6 outcomes) 0%

FIGURE 1. PERCENTAGE OF TOTAL MEASURED CHILD OUTCOMES ACROSS PROJECTS

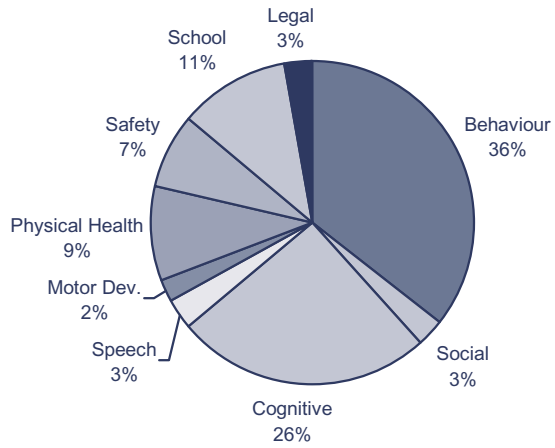

FIGURE 2. PERCENTAGE OF TOTAL BENEFICIAL CHILD OUTCOME FROM EACH CATEGORY

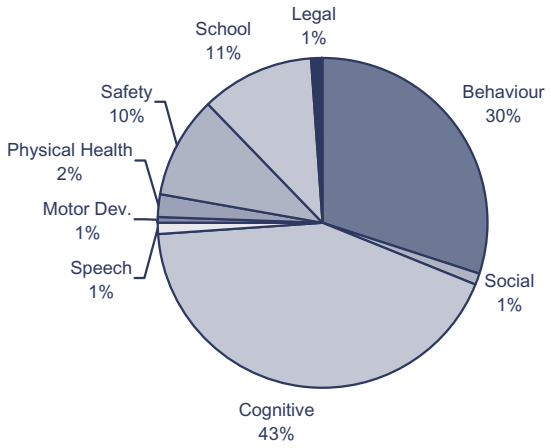

FIGURE 3. PERCENTAGE OF TOTAL MEASURED FAMILY OUTCOME FROM EACH CATEGORY

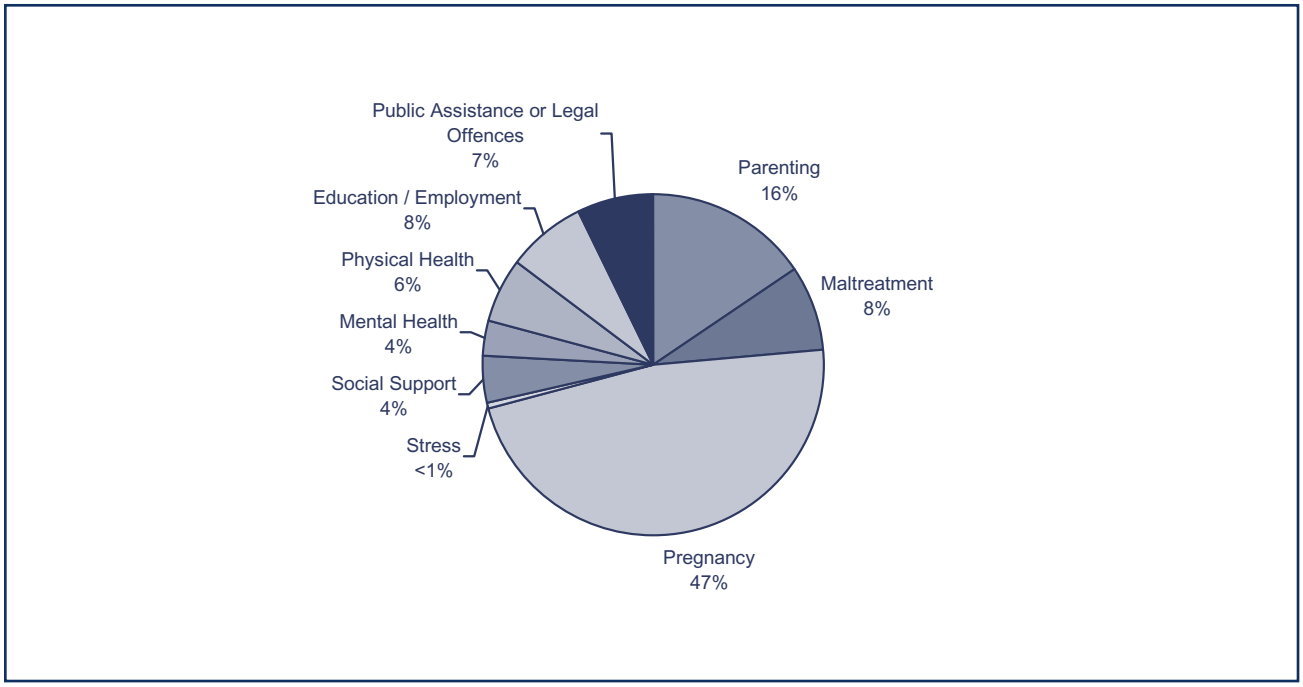

FIGURE 4. PERCENTAGE OF TOTAL BENEFICIAL FAMILY OUTCOME FROM EACH CATEGORY

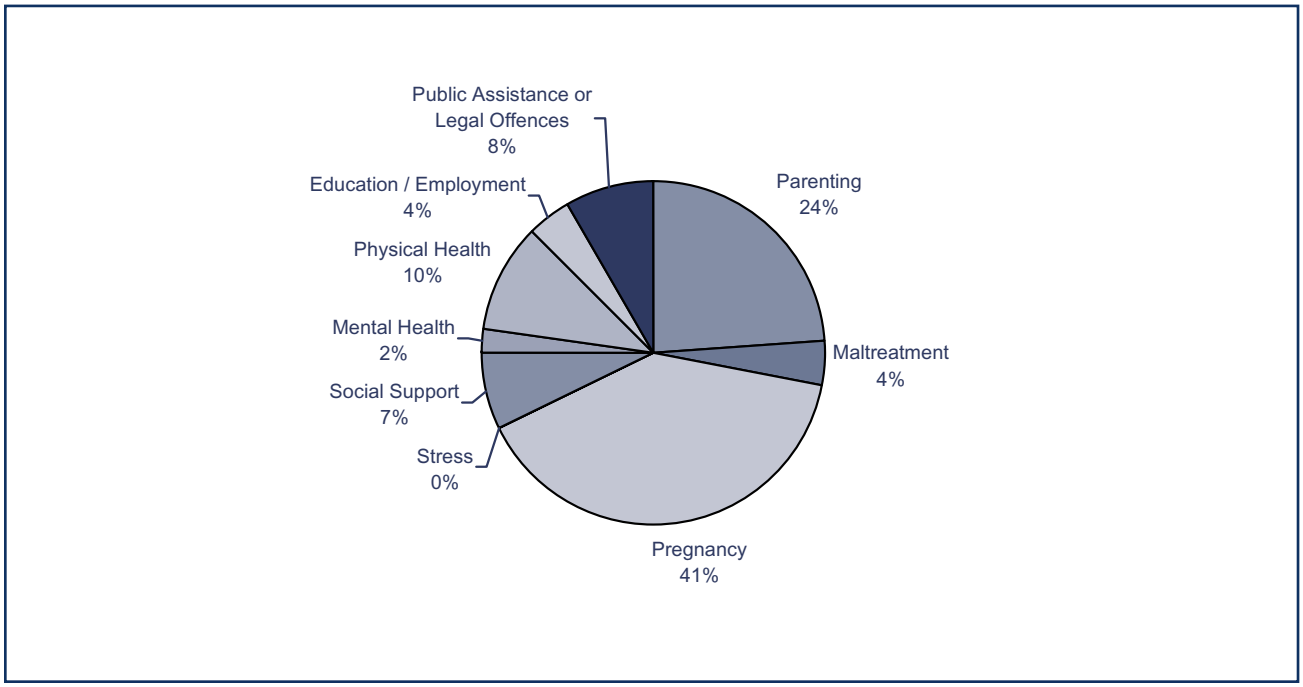

FIGURE 5: THE PERCENTAGE OF OUTCOME MEASURES WITHIN EACH CATEGORY THAT YIELDED 1) STATISTICALLY SIGNIFICANT BENEFICIAL EFFECTS AND 2) MEDIUM OR LARGE EFFECT SIZES

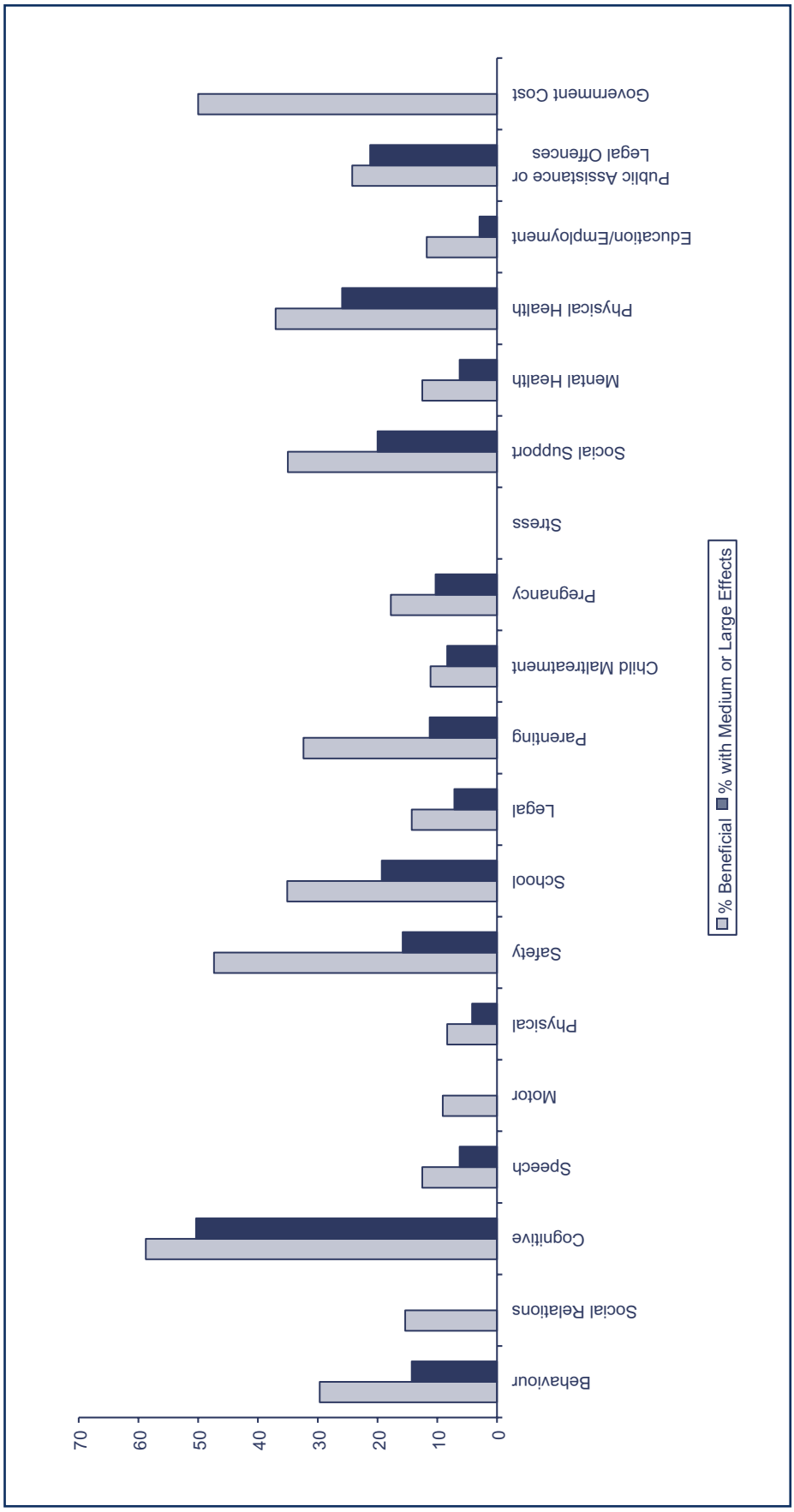

TABLE 10. SUMMARY OF ALL REPORTED CHILD OUTCOMES BY PROJECT

IDENTIFYING TRIAL INFORMATION		NUMBER OF OUTCOMES REPORTED FOR EACH TYPE Number of Beneficial and Harmful Effects (Mean effect size; Mean log odds ratio for categorical outcomes) Range of effect sizes; Range of log odds ratios Number of Non-Significant effects and Direction (+;=;--)								
Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5007	Anisfield, E *No project title*	**N=3** 2 Beneficial (n.a., 1.41) (no range) 0 Harmful 1 Not sig. (1+, 0=, 0-)		**N=1** 0 Beneficial 0 Harmful 1 Not sig. (NR)		**N=1** 0 Beneficial 0 Harmful 1 Not sig. (NR)				
5016	Beeghly, M *No project title*			**N=1** 0 Beneficial 0 Harmful 1 Not sig. (1+, 0=, 0-)		**N=1** 0 Beneficial 0 Harmful 1 Not sig. (1+, 0=, 0-)				
5018	Black, MM *No project title*		**N=2** 0 Beneficial 0 Harmful 2 Not sig. (2+, 0=, 0-)	**N=2** 0 Beneficial 0 Harmful 2 Not sig. (2+, 0=, 0-)	**N=4** 0 Beneficial 0 Harmful 4 Not sig. (3+, 1=, 0-)	**N=2** 0 Beneficial 0 Harmful 2 Not sig. (2+, 0=, 0-)	**N=6** 0 Beneficial 0 Harmful 2 Not sig. (2+, 0=, 4-)			

TABLE 10. SUMMARY OF ALL REPORTED CHILD OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5027	Burchinal, M *No project title*			**N=15** 13 Beneficial (0.98; n.a.) range 0.47-1.72 0 Harmful 2 not sig. (2+, 0=, 0-)						
5030	Carolina Abecedarian Project			**N = 50** 34 Beneficial (0.92; 2.37) range 0.50-1.49; 1.72-2.67 0 Harmful 16 Not sig. (15+; 1=; 0-)		**N=5** 0 Beneficial 0 Harmful 5 Not sig. (5+; 0=; 1-)			**N=4** 2 Beneficial (0.53; n.a.) range 0.43-0.62 0 Harmful 2 Not sig. (2+; 0=; 0-)	
5039	The Busselton Study	**N=29** 20 Beneficial (0.34; 1.99) range 0.25 - 0.62; 1.29 - 2.69 5 Harmful (0.47; n.a.) range 0.36 ñ 0.62 4 Not sig. (3+, 0=. 1-)					**N=6** 1 Beneficial (n.a.; 0.86) 0 Harmful 5 Not sig. (4+, 0=, 1-) * incl. pregnancy outcome as it refers to the focal children, not the original parent		**N=12** 4 Beneficial (0.43; 0.96) range 0.41-0.45 0.83-1.08 4 Harmful (0.49; n.a.) range 0.44-0.58 4 Not sig. (2+, 0=, 2-)	

TABLE 10. SUMMARY OF ALL REPORTED CHILD OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5040	Cunningham, CE *No project title*	**N=3** 0 Beneficial 0 Harmful 3 Not sig. (2+, 1=, 0-)								
5103	Prenatal/ Early Infancy - Memphis	**N=1** 0 Beneficial 0 Harmful 1 Not sig. (1+, 0=, 0-)		**N=1** 0 Beneficial 0 Harmful 1 Not sig. (1+, 0=, 0-)			**N=2** 0 Beneficial 0 Harmful 2 Not sig. (2+, 0=, 0-)	**N=7** 4 Beneficial (N.R) 0 Harmful 3 Not sig. (3+, 0=, 3-)		
5117	Houston Parent-Child Development Center	**N=71** 19 Beneficial (0.58; n.a.) range 0.42-1.05 1 Harmful (1.80; n.a.) 51 not sig. (37+, 0=, 14-)		**N=6** 0 Beneficial 0 Harmful 6 not sig. (3+, 0=, 3-)					**N=3** 1 Beneficial (0.55; n.a.) no range 0 Harmful 2 not sig. (2+, 0=, 0-)	
5131	Infant Health and Development Program	**N=12** 2 Beneficial (0.19; n.a) range 0.18-0.20 0 Harmful 10 Not sig. (4+; 1=; 5--)	**N=9** 1 Beneficial (0.2; n.a.) 0 Harmful 8 Not sig. (6+; 0=; 2--)	**N= 16** 8 Beneficial (0.58; n.a) range 0.27-1.79 0 Harmful 8 Not sig. (3+; 1=; 4--)			**N=29** 1 Beneficial (0.4; n.a.) 3 Harmful (0.23; n.a.) 0.15-0.27 25 Not sig. (18+; 1=; 6--)		**N=7** 0 Beneficial 0 Harmful 7 Not sig. (6+; 0=; 1--)	

TABLE 10. SUMMARY OF ALL REPORTED CHILD OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5143	Prenatal/ Early Infancy Project ñ Elmira	**N=16** 2 Beneficial (0.29; n.a.) range 0.27-0.31 2 Harmful (0.37, n.a) range 0.33-0.41 12 not sig. (7+, 0=, 5-)		**N=14** 1 Beneficial (0.44, n.a.) 0 Harmful 13 not sig. (13+, 0=, 0-)	**N=6** 1 Beneficial (0.84,; n.a.) 0 Harmful 5 not sig. (5+, 0=, 0-)			**N=28** 13 Beneficial (0.49; n.a.) range 0.27-0.89 2 Harmful (0.57, n.a.) range 0.33-0.81 3 not sig. (2+; 0=, 1-)	**N=6** 3 Beneficial (n.a.; 1.29) range 1.14-1.40 0 Harmful 3 not sig. (3+, 0=, 0-)	
5150	OíSullivan AL *No project title*						**N=3** 1 Beneficial (n.a.; 0.80) 0 Harmful 2 not sig. (1+, 0=, 1-)	**N=3** 1 Beneficial (n.a.; 2.38) 0 Harmful 2 not sig. (2+, 0=, 0-)		
5185	Bermuda Mother-Child Home Program	**N=11** 0 Beneficial 0 Harmful 11 not sig. (2+, 5=, 4-)	**N=2** 1 Beneficial (0.47; n.a.) 0 Harmful 1 not sig. (1+, 0=, 0-)	**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)					**N=1** 0 Beneficial 0 Harmful 1 not sig. (0+, 1=, 1-)	
5188	High/Scope Preschool Curriculum Study	**N=2** 0 Beneficial 0 Harmful 2 not sig. (1+, 0=, 1-)		**N=6** 5 Beneficial (1.10; n.a.) range 0.73-1.91 0 Harmful 1 not sig. (1+, 0=, 0-)					**N=3** 0 Beneficial 0 Harmful 3 not sig. (1+, 0=, 2-)	**N=11** 0 Beneficial 1 Harmful (0.81; n.a.) 10 not sig. (4+, 0=, 6-)

TABLE 10. SUMMARY OF ALL REPORTED CHILD OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5189	Seifert, H *No project title*								**N=3** 2 Beneficial (0.97; n.a.) range 0.91-1.03 0 Harmful 1 not sig. (1+, 0=, 0-)	
5220	Whitehurst, GJ *No project title*			**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)	**N=5** 1 Beneficial (0.39; n.a.) 0 Harmful 4 Not sig. (3+, 0=, 1-)				**N=14** 6 Beneficial (0.42; n.a.) range 0.33-0.56 0 Harmful 8 not sig. (6+, 0=, 2-)	
5234	Strayhorn, JM *No project title*	**N=17** 7 Beneficial (0.53; n.a.) range 0.059-0.77 0 Harmful 10 not sig. (7+, 0=, 3-)			**N=1** 0 Beneficial 0 Harmful 1 not sig. (0+, 0=, 0-)				**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)	
5255	Montreal Longitudinal Experimental Study	**N=17** 2 Beneficial (n.a.; 0.84) range 0.82-0.86 5 Harmful (0.46; n.a.) range 0.41-0.57 10 not sig. (2+, 0=, 8-)							**N=3** 2 Beneficial (n.a.; 0.93) 0 Harmful 1 not sig. (1+, 0=, 0-)	**N= 3** 2 Beneficial (n.a.; 1.40) 0 Harmful 1 not sig. (0+, 0=, 1-)

TABLE 10. SUMMARY OF ALL REPORTED CHILD OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5275	Moore, F *No project title*						**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)			
5288	Carolina Early Intervention Project			**N=17** 16 Beneficial (0.70; n.a.) range 0.38-1.15 0 Harmful 1 not sig. (1+, 0=, 0-)		**N=2** 1 Beneficial (0.42; n.a.) 0 Harmful 1 not sig. (1+, 0=, 0-)				
5415	Oakley, A *No project title*						**N=1** 1 Beneficial (0.40; n.a.) 0 Harmful O not sig.			

Legend for Outcome Cells

N = number of reported outcomes under the specific category
n Beneficial = number of outcomes with a significant beneficial effect
(mean effect size)
range of effect sizes; range of log odds ratio
n Harmful = number of outcomes with a significant harmful effect
(mean effect size)
range of effect sizes; range of log odds ratio
n Not sig. = number of outcomes without significant effect size
(n+ denotes number of non-sig. findings in beneficial direction/
n= denotes number with no direction/
--denotes number of non-sig. findings in harmful)

A designation of ìn.a.î means that the information is not applicable ñ for example, if effect sizes were calculated, but not log odds ratios, then the means would have a value for the effect size mean and n.a. for log odds ratio. In comparison, a designation of ìNRî means that the information was not reported in Mrazek and Brown.

TABLE 11. SUMMARY OF REPORTED SHORT-TERM CHILD OUTCOMES BY PROJECT

IDENTIFYING TRIAL INFORMATION		NUMBER OF OUTCOMES REPORTED FOR EACH TYPE Number of Beneficial and Harmful Effects (Mean effect size; Mean log odds ratio for categorical outcomes) Range of effect sizes; Range of log odds ratios Number of Non-Significant effects and Direction (+;=;--)								
Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5007	Anisfield, E *No project title*	**N=3** 2 Beneficial (n.a., 1.41) (no range) 0 Harmful 1 Not sig. (1+, 0=, 0-)		**N=1** 0 Beneficial 0 Harmful 1 Not sig. (NR)		**N=1** 0 Beneficial 0 Harmful 1 Not sig. (NR)				
5018	Black, MM *No project title*		**N=2** 0 Beneficial 0 Harmful 2 Not sig. (2+, 0=, 0-)	**N=2** 0 Beneficial 0 Harmful 2 Not sig. (2+, 0=, 0-)	**N=4** 0 Beneficial 0 Harmful 4 Not sig. (3+, 1=, 0-)	**N=2** 0 Beneficial 0 Harmful 2 Not sig. (2+, 0=, 0-)	**N=6** 0 Beneficial 0 Harmful 6 Not sig. (2+, 0=, 4-)			
5027	Burchinal, M *No project title*			**N=15** 13 Beneficial (0.98; n.a.) range 0.47-1.72 0 Harmful 2 not sig. (2+, 0=, 0-)						

TABLE 11. SUMMARY OF REPORTED SHORT-TERM CHILD OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5030	Carolina Abecedarian Project			**N = 47** 32 Beneficial (0.92; 2.37) range 0.27-1.79; 1.72-2.67 0 Harmful 15 Not sig. (14+; 1=; 0-)		**N=5** 0 Beneficial 0 Harmful 5 Not sig. (5+; 0=; 1-)				
5039	The Busselton Study	**N=29** 18 Beneficial (0.34; n.a.) range 0.25 - 0.62; 5 Harmful (0.47; n.a.) range 0.36 ñ 0.62 0 Not sig.							**N=6** 2 Beneficial (0.96) range 0.83-1.08 4 Harmful (0.49; n.a.) range 0.44-0.58 0 not sig.	
5103	Prenatal/ Early Infancy - Memphis	**N=1** 0 Beneficial 0 Harmful 1 Not sig. (1+, 0=, 0-)		**N=1** 0 Beneficial 0 Harmful 1 Not sig. (1+, 0=, 0-)			**N=2** 0 Beneficial 0 Harmful 2 Not sig. (2+, 0=, 0-)	**N=7** 4 Beneficial (N.R) 3 Not sig. (3+, 0=, 3-)		
5131	Infant Health and Development Program	**N=3** 2 Beneficial (0.19; n.a) range 0.18-0.20 0 Harmful 1 not sig. (1+; 0=; 0--)		**N= 4** 4 Beneficial (0.85; n.a) range 0.33-1.79 0 Harmful 0 Not sig.			**N=14** 1 Beneficial (0.4; n.a.) 2 Harmful (0.27; n.a.) 11 Not sig. (10+; 0=; 1--)			

TABLE 11. SUMMARY OF REPORTED SHORT-TERM CHILD OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5143	Prenatal/ Early Infancy Project ñ Elmira	**N=14** 1 Beneficial (0.31; n.a.) 2 Harmful (0.37, n.a) range 0.33-0.41 11 not sig. (7+, 0=, 4-)		**N=6** 0 Beneficial 0 Harmful 6 not sig. (6+, 0=, 0-)				**N=8** 5 Beneficial (0.44; n.a.) range 0.32-0.62 0 Harmful 3 not sig. (2+; 0=, 1-)	**N=6** 3 Beneficial (n.a.; 1.29) range 1.14-1.40 0 Harmful 3 not sig. (3+, 0=, 0-)	
5150	OíSullivan AL *No project title*						**N=3** 1 Beneficial (n.a.; 0.80) 0 Harmful 2 not sig. (1+, 0=, 1-)	**N=3** 1 Beneficial (n.a.; 2.38) 0 Harmful 2 not sig. (2+, 0=, 0-)		
5185	Bermuda Mother-Child Home Program	**N=11** 0 Beneficial 0 Harmful 11 not sig. (2+, 5=, 4-)	**N=2** 1 Beneficial (0.47; n.a.) 0 Harmful 1 not sig. (1+, 0=, 0-)	**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)					**N=1** 0 Beneficial 0 Harmful 1 not sig. (0+, 1=, 1-)	
5188	High/Scope Preschool Curriculum Study			**N=1** 1 Beneficial (1.91; n.a.) 0 Harmful 0 not sig.						

TABLE 11. SUMMARY OF REPORTED SHORT-TERM CHILD OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5189	Seifert, H *No project title*								**N=3** 2 Beneficial (0.97; n.a.) range 0.91-1.03 0 Harmful 1 not sig. (1+, 0=, 0-)	
5220	Whitehurst, GJ *No project title*			**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)	**N=5** 1 Beneficial (0.39; n.a.) 0 Harmful 4 Not sig. (3+, 0=, 1-)				**N=14** 6 Beneficial (0.42; n.a.) range 0.33-0.56 0 Harmful 8 not sig. (6+, 0=, 2-)	
5234	Strayhorn, JM *No project title*	**N=11** 5 Beneficial (0.45; n.a.) range 0.059-0.58 0 Harmful 6 not sig. (3+, 0=, 3-)			**N=1** 0 Beneficial 0 Harmful 1 not sig. (0+, 0=, 0-)					
5255	Montreal Longitudinal Experimental Study	**N=15** 2 Beneficial (n.a.; 0.84) range 0.82-0.86 5 Harmful (0.46; n.a.) range 0.41-0.57 8 not sig. (1+, 0=, 7-)								**N= 2** 1 Beneficial (n.a.; 1.40) 0 Harmful 1 not sig. (0+, 0=, 1-)

TABLE 11. SUMMARY OF REPORTED SHORT-TERM CHILD OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5275	Moore, F *No project title*						**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)			
5288	Carolina Early Intervention Project			**N=17** 16 Beneficial (0.70; n.a.) range 0.38-1.15 0 Harmful 1 not sig. (1+, 0=, 0-)		**N=2** 1 Beneficial (0.42; n.a.) 0 Harmful 1 not sig. (1+, 0=, 0-)				
5415	Oakley, A *No project title*						**N=1** 1 Beneficial (0.40; n.a.) 0 Harmful 0 not sig.			

TABLE 12. SUMMARY OF REPORTED INTERMEDIATE PARENT AND FAMILY OUTCOMES BY PROJECT

IDENTIFYING TRIAL INFORMATION		NUMBER OF OUTCOMES REPORTED FOR EACH TYPE Number of Beneficial and Harmful Effects (Mean effect size; Mean log odds ratio for categorical outcomes) Range of effect sizes; Range of log odds ratios Number of Non-Significant effects and Direction (+;=;--)								
Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5016	Beeghly, M *No project title*			**N=1** 0 Beneficial 0 Harmful 1 Not sig. (1+, 0=, 0-)		**N=1** 0 Beneficial 0 Harmful 1 Not sig. (1+, 0=, 0-)				
5040	Cunningham, CE *No project title*	**N=3** 0 Beneficial 0 Harmful 3 Not sig. (2+, 1=, 0-)								
5117	Houston Parent-Child Development Center	**N=71** 19 Beneficial (0.58; n.a.) range 0.42-1.05 1 Harmful (1.80; n.a.) 51 not sig. (37+, 0=, 14-)		**N=6** 0 Beneficial 0 Harmful 6 not sig. (3+, 0=, 3-)					**N=3** 1 Beneficial (0.55; n.a.) no range 0 Harmful 2 not sig. (2+, 0=, 0-)	

TABLE 12. SUMMARY OF REPORTED INTERMEDIATE PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5143	Prenatal/ Early Infancy Project ñ Elmira	**N=2** 1 Beneficial (0.27; n.a.) 0 Harmful 1 not sig. (0+, 0=, 1-)		**N=8** 1 Beneficial (0.44; n.a.) 0 Harmful 7 not sig. (7+, 0=, 0-)	**N=6** 1 Beneficial (0.84; n.a.) 0 Harmful 5 not sig. (5+, 0=, 0-)			**N=20** 8 Beneficial (0.51; n.a.) range 0.27-0.89 2 Harmful (0.57; n.a.) range 0.33-0.81 10 not sig. (8+; 0=, 2-)		
5188	High/Scope Preschool Curriculum Study			**N=2** 2 Beneficial (1.05; n.a.) range 0.82-1.28 0 Harmful 0 not sig. (0+, 0=, 0-)						
5234	Strayhorn, JM *No project title*	**N=6** 2 Beneficial (0.73; n.a.) range 0.68-0.77 0 Harmful 4 not sig. (4+, 0=, 0-)							**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)	
5255	Montreal Longitudinal Experimental Study								**N=2** 1 Beneficial (n.a.; 0.93) 0 Harmful 1 not sig. (1+, 0=, 0-)	

TABLE 13. SUMMARY OF REPORTED LONG-TERM PARENT AND FAMILY OUTCOMES BY PROJECT

IDENTIFYING TRIAL INFORMATION		NUMBER OF OUTCOMES REPORTED FOR EACH TYPE Number of Beneficial and Harmful Effects (Mean effect size; Mean log odds ratio for categorical outcomes) Range of effect sizes; Range of log odds ratios Number of Non-Significant effects and Direction (+;=;--)								
Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5030	Carolina Abecedarian Project			**N = 3** 2 Beneficial (0.55; n.a.) range 0.50-0.59 0 Harmful 1 Not sig. (1+; 0=; 0-)					**N=4** 2 Beneficial (0.53; n.a.) 0 Harmful 2 Not sig. (2+; 0=; 0-)	
5039	The Busselton Study	**N=6** 2 Beneficial (n.a.; 1.99) range 1.29 - 2.69 0 Harmful 4 Not sig. (3+, 0=. 1-)					**N=6** 1 Beneficial (n.a.; 0.86) 0 Harmful 5 Not sig. (4+, 0=, 1-) * incl. pregnancy outcome as it refers to the focal children, not the original parent		**N=12** 2 Beneficial (0.43; n.a.) range 0.41-0.45 0 Harmful 4 Not sig. (2+, 0=, 2-)	

TABLE 13. SUMMARY OF REPORTED LONG-TERM PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Temperament/ Behaviour/ Symptoms	Social Relations	Cognitive	Speech / Language	Motor Development	Physical/ Growth	Safety or Injuries	School Performance	Legal Offences
5131	Infant Health and Development Program	**N=9** 0 Beneficial 0 Harmful 9 Not sig. (4+; 1=; 5--)	**N=9** 1 Beneficial (0.2; n.a.) 0 Harmful 8 Not sig. (6+; 0=; 2--)	**N= 12** 4 Beneficial (0.32; n.a) range 0.27-0.39 0 Harmful 8 Not sig. (3+; 1=; 4--)			**N=15** 0 Beneficial 1 Harmful (0.15; n.a.) 14 Not sig. (8+; 1=; 5--)		**N=7** 0 Beneficial 0 Harmful 7 Not sig. (6+; 0=; 1--)	
5188	High/Scope Preschool Curriculum Study	**N=2** 0 Beneficial 0 Harmful 2 not sig. (1+, 0=, 1-)		**N=3** 2 Beneficial (0.74; n.a.) range 0.73-0.75 0 Harmful 1 not sig. (1+, 0=, 0-)					**N=3** 0 Beneficial 0 Harmful 3 not sig. (1+, 0=, 2-)	**N=11** 0 Beneficial 1 Harmful (0.81; n.a.) 10 not sig. (4+, 0=, 6-)
5255	Montreal Longitudinal Experimental Study	**N=2** 0 Beneficial 0 Harmful 2 not sig. (1+, 0=, 1-)							**N=1** 1 Beneficial (NR) 0 Harmful 0 not sig.	**N= 3** 1 Beneficial (NR) 0 Harmful 0 not sig.

TABLE 14. SUMMARY OF ALL REPORTED PARENT AND FAMILY OUTCOMES BY PROJECT

IDENTIFYING TRIAL INFORMATION		NUMBER OF OUTCOMES REPORTED FOR EACH TYPE Number of Beneficial and Harmful Effects (Mean effect size; Mean log odds ratio for categorical outcomes) Range of effect sizes; Range of log odds ratios Number of Non-Significant effects and Direction (+;=;--)								
Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5007	Anisfield, E *No project title*	**N=5** 3 Beneficial (n.a., 1.93) 1 Harmful (0.66; n.a.) 1 not sig. (1+, 0=, 0-)								
5016	Beeghly, M *No project title*	**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)			**N=2** 0 Beneficial 0 Harmful 2 not sig. (0+, 1=, 1-)					
5018	Black, MM *No project title*	**N=6** 0 Beneficial 0 Harmful 6 not sig. (6+, 0=, 0-)								
5020	Blondel, B *No project title*			**N=9** 0 Beneficial 0 Harmful 9 not sig. (0+, 1-, 8-)		**N=1** 1 Beneficial (n.a.; 1.74) 0 Harmful 0 not sig.				

TABLE 14. SUMMARY OF ALL REPORTED PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5023	Booth, CL *No project title*	**N=4** 0 Beneficial 0 Harmful 4 not sig. (3+, 1=, 0-)					**N= 3** 0 Beneficial 0 Harmful 3 not sig. (0+, 0=. 3-)			
5026	Bryce, RL *No project title*			**N=13** 3 Beneficial (n.a.; 0.397) range 0.29-0.40 0 Harmful 10 not sig. (5+, 1=, 4-)						
5030	Carolina Abecedarian Project	**N=4** 0 Beneficial 0 Harmful 4 Not sig. (3+, 0=, 1-)								
5036	Connor-Kuntz, FJ *No project title*			**N=7** 7 Beneficial (n.a.; 1.25) range 0.65-2.85 0 Harmful 0 not sig.						
5039	The Busselton Study	**N=7** 6 Beneficial (0.41; n.a.) range 0.25-0.60 1 Harmful (0.35; n.a.) 0 not sig.								

TABLE 14. SUMMARY OF ALL REPORTED PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5040	Cunningham, CE *No project title*	**N=8** 1 Beneficial (0.52; n.a.) 0 Harmful 7 not sig. (4+, 0=, 3-)					**N=7** 1 Beneficial (0.76; n.a.) 0 Harmful 6 not sig. (6+, 0=, 0-)			
5054	Ershoff, DH *No project title*			**N=7** 3 Beneficial (n.a.; 1.07) range 0.66-1.52 0 Harmful 4 not sig. (4+, 0=, 0-)						
5088	Heins, HC *No project title*			**N=10** 0 Beneficial 1 Harmful (n.a.; 1.05) 9 not sig. (8+, 0=, 1-)						
5103	Prenatal / Early Infancy Project	**N=4** 2 Beneficial (NR) 0 Harmful 2 not sig. (2+, 0=, 0-)	**N=1** 1 Beneficial (NR) 0 Harmful 0 not sig.	**N=20** 2 Beneficial (NR) 0 Harmful 18 not sig. (7+, 3=, 8-)		**N=1** 1 Beneficial (n.a.; 0.59) 0 Harmful 0 not sig.	**N=3** 1 Beneficial (NR) 0 Harmful 2 not sig. (2+, 0=, 0-)	**N=2** 1 Beneficial (0.51; n.a.) 1 Harmful (0.51; n.a.) 0 not sig.	**N=4** 0 Beneficial 0 Harmful 4 not sig. (3+, 1=, 0-)	**N=2** 0 Beneficial 0 Harmful 2 not sig. (2+, 0=, 0-)

TABLE 14. SUMMARY OF ALL REPORTED PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5130	McDuffie, RS *No project title*			**N=25** 1 Beneficial (n.a.; 0.33) 0 Harmful 24 not sig. (11+, 2=, 11-)		**N=1** 0 Beneficial 0 Harmful 1 not sig. (0+, 0=, 1-)		**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)		
5131	Infant Health and Development Project	**N=1** 1 Beneficial (0.40; n.a.) 0 Harmful 0 not sig.							**N=12** 3 Beneficial (0.18; n.a.) range 0.08-0.31 0 Harmful 9 not sig. (5+, 0=, 4-)	**N=6** 0 Beneficial 1 Harmful (0.35; n.a.) 5 not sig. (1+, 0=, 3-)
5139	Munjanja, SP *No project title*			**N=8** 1 Beneficial (n.a.; 0.15) 0 Harmful 7 not sig. (3+, 0=, 4-)						
5143	Prenatal / Early Infancy Project - Elmira	**N=18** 4 Beneficial (0.89; n.a.) range 0.67-1.01 0 Harmful 14 not sig. (11+, 1=, 2-)	**N=35** 3 Beneficial (0.73; n.a.) range 0.46-0.89 1 Harmful (0.37; n.a.) 31 not significant (21+, 0=, 10-)	**N=36** 7 Beneficial (0.78; 1.53) ranges 0.23-1.55; 0.67-2.38 1 Harmful (0.51; n.a.) 28 not sig. (14+, 1=, 13-)		**N=15** 5 Beneficial (0.60; 1.09) ranges 0.27-0.99; n.a. 0 Harmful 10 not sig. (7+, 0=, 3-)		**N=18** 6 Beneficial (0.58; n.a.) range 0.46-0.79 0 Harmful 12 not sig. (11+, 0=, 1-)	**N=16** 1 Beneficial (0.80; n.a.) 1 Harmful (0.80; n.a.) 14 not-sig (10+, 0=, 4-)	**N=25** 8 Beneficial (0.74; n.a.) range 0.45-1.18 0 Harmful 17 not sig. (14+, 0=, 3-)

TABLE 14. SUMMARY OF ALL REPORTED PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5150	OíSullivan *No project title*			**N=3** 3 Beneficial (n.a.; 1.12) range 1.06-1.22 0 Harmful 0 not sig.				**N=3** 2 Beneficial (n.a.; 1.02) range 0.98-1.06 0 Harmful 1 not sig. (1+, 0=, 0-)	**N=2** 0 Beneficial 0 Harmful 2 not sig. (2+, 0=, 0-)	
5185	Bermuda Mother-Child Home Program	**N=2** 1 Beneficial (0.39; n.a.) 0 Harmful 1 not sig. (0+, 0=, 1-)								
5210	The Latin America Multicenter Trial			**N=21** 0 Beneficial 1 Harmful (n.a.; 0.28) 20 not sig. (17+, 0=, 3-)						
5234	Strayhorn, JM *No project title*	**N=4** 1 Beneficial (1.41; n.a.) 0 Harmful 3 not sig. (3+, 0=, 0-)								
5255	Montreal Longitudinal Experimental Trial	**N=2** 0 Beneficial 0 Harmful 2 not sig. (1+, 0=, 1-)								

TABLE 14. SUMMARY OF ALL REPORTED PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5259	Windsor, RA *No project title*			**N=4** 1 Beneficial (0.61; n.a.) 0 Harmful 3 not sig. (3+, 0=, 0-)						
5415	Oakley, A *No project title*	**N=1** 1 Beneficial (n.a.; 0.73) 0 Harmful		**N=30** 3 Beneficial (1.0; 0.41) ranges n.a.; 0.37-0.45 0 Harmful 27 not sig. (23+, 2=, 2-)		**N=2** 0 Beneficial 0 Harmful 2 not sig. (2+, 0=, 0-)	**N=3** 0 Beneficial 0 Harmful 3 not sig. (3+, 0=, 0-)	**N=3** 1 Beneficial (0.42; n.a.) 0 Harmful 2 not sig. (2+, 0=, 0-)		
5431	Klaus, MH *No project title*			**N=7** 2 Beneficial (1.45; 0.31) 0 Harmful 5 not sig. (5+, 0=, 0-)						
5432	Sosa, R *No project title*	**N=4** 3 Beneficial (NR) 0 Harmful 1 not sig. (1+, 0=, 0-)		**N=2** 2 Beneficial (1.21; 1.83) 0 Harmful 0 not sig.						

TABLE 14. SUMMARY OF ALL REPORTED PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5434	Kennell, J *No project title*			**N=12** 3 Beneficial (n.a.; 1.437) range 1.24-1.72 0 Harmful 9 not sig. (7+, 0=, 2-)						

Legend for Outcome Cells

N = number of reported outcomes under the specific category
n Beneficial = number of outcomes with a significant beneficial effect
(mean effect size)
range of effect sizes; range of log odds ratio
n Harmful = number of outcomes with a significant harmful effect
(mean effect size)
range of effect sizes; range of log odds ratio
n Not sig. = number of outcomes without significant effect size
(n+ denotes number of non-sig. findings in beneficial direction/
n= denotes number with no direction/
--denotes number of non-sig. findings in harmful)

TABLE 15. SUMMARY OF REPORTED SHORT-TERM PARENT AND FAMILY OUTCOMES BY PROJECT

IDENTIFYING TRIAL INFORMATION		NUMBER OF OUTCOMES REPORTED FOR EACH TYPE Number of Beneficial and Harmful Effects (Mean effect size; Mean log odds ratio for categorical outcomes) Range of effect sizes; Range of log odds ratios Number of Non-Significant effects and Direction (+;=;--)								
Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5007	Anisfield, E *No project title*	**N=5** 3 Beneficial (n.a., 1.93) 1 Harmful (0.66; n.a.) 1 not sig. (1+, 0=, 0-)								
5018	Black, MM *No project title*	**N=6** 0 Beneficial 0 Harmful 6 not sig. (6+, 0=, 0-)								
5020	Blondel, B *No project title*			**N=9** 0 Beneficial 0 Harmful 9 not sig. (0+, 1-, 8-)		**N=1** 1 Beneficial (n.a.; 1.74) 0 Harmful 0 not sig.				
5023	Booth, CL *No project title*	**N=4** 0 Beneficial 0 Harmful 4 not sig. (3+, 1=, 0-)					**N= 3** 0 Beneficial 0 Harmful 3 not sig. (0+, 0=. 3-)			

TABLE 15. SUMMARY OF REPORTED SHORT-TERM PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5026	Bryce, RL *No project title*			**N=13** 3 Beneficial (n.a.; 0.397) range 0.29-0.40 0 Harmful 10 not sig. (5+, 1=, 4-)						
5030	Carolina Abecedarian Project	**N=4** 0 Beneficial 0 Harmful 4 Not sig. (3+, 0=, 1-)								
5036	Connor-Kuntz, FJ *No project title*			**N=7** 7 Beneficial (n.a.; 1.25) range 0.65-2.85 0 Harmful 0 not sig.						
5039	The Busselton Study	**N=7** 6 Beneficial (0.41; n.a.) range 0.25-0.60 1 Harmful (0.35; n.a.) 0 not sig.								

TABLE 15. SUMMARY OF REPORTED SHORT-TERM PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5054	Ershoff, DH *No project title*			**N=7** 3 Beneficial (n.a.; 1.07) range 0.66-1.52 0 Harmful 4 not sig. (4+, 0=, 0-)						
5088	Heins, HC *No project title*			**N=10** 0 Beneficial 1 Harmful (n.a.; 1.05) 9 not sig. (8+, 0=, 1-)						
5103	Prenatal / Early Infancy Project	**N=4** 2 Beneficial (NR) 0 Harmful 2 not sig. (2+, 0=, 0-)	**N=1** 1 Beneficial (NR) 0 Harmful 0 not sig.	**N=20** 2 Beneficial (NR) 0 Harmful 18 not sig. (7+, 3=, 8-)		**N=1** 1 Beneficial (n.a.; 0.59) 0 Harmful 0 not sig.	**N=3** 1 Beneficial (NR) 0 Harmful 2 not sig. (2+, 0=, 0-)	**N=2** 1 Beneficial (0.51; n.a.) 1 Harmful (0.51; n.a.) 0 not sig.	**N=4** 0 Beneficial 0 Harmful 4 not sig. (3+, 1=, 0-)	**N=2** 0 Beneficial 0 Harmful 2 not sig. (2+, 0=, 0-)
5130	McDuffie, RS *No project title*			**N=25** 1 Beneficial (n.a.; 0.33) 0 Harmful 24 not sig. (11+, 2=, 11-)		**N=1** 0 Beneficial 0 Harmful 1 not sig. (0+, 0=, 1-)		**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)		

TABLE 15. SUMMARY OF REPORTED SHORT-TERM PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5131	Infant Health and Development Project	**N=1** 1 Beneficial (0.40; n.a.) 0 Harmful 0 not sig.							**N=12** 3 Beneficial (0.18; n.a.) range 0.08-0.31 0 Harmful 9 not sig. (5+, 0=, 4-)	**N=6** 0 Beneficial 1 Harmful (0.35; n.a.) 5 not sig. (1+, 0=, 3-)
5139	Munjanja, SP *No project title*			**N=8** 1 Beneficial (n.a.; 0.15) 0 Harmful 7 not sig. (3+, 0=, 4-)						
5143	Prenatal / Early Infancy Project - Elmira	**N=6** 2 Beneficial (0.95; n.a.) range 0.89-1.01 0 Harmful 4 not sig. (4+, 0=, 0-)	**N=13** 1 Beneficial (0.85; n.a.) 0 Harmful 12 not significant (9+, 0=, 3-)	**N=36** 7 Beneficial (0.78; 1.53) ranges 0.23-1.55; 0.67-2.38 1 Harmful (0.51; n.a.) 28 not sig. (14+, 1=, 13-)		**N=12** 5 Beneficial (0.60; 1.09) ranges 0.27-0.99; n.a. 0 Harmful 7 not sig. (5+, 0=, 2-)		**N=2** 1 Beneficial (0.56; n.a.) 0 Harmful 1 not sig. (1+, 0=, 0-)	**N=9** 1 Beneficial (0.80; n.a.) 1 Harmful (0.80; n.a.) 7 not-sig (3+, 0=, 4-)	**N=3** 0 Beneficial 0 Harmful 3 not sig. (2+, 0=, 1-)
5150	OíSullivan *No project title*			**N=3** 3 Beneficial (n.a.; 1.12) range 1.06-1.22 0 Harmful 0 not sig.				**N=3** 2 Beneficial (n.a.; 1.02) range 0.98-1.06 0 Harmful 1 not sig. (1+, 0=, 0-)	**N=2** 0 Beneficial 0 Harmful 2 not sig. (2+, 0=, 0-)	

TABLE 15. SUMMARY OF REPORTED SHORT-TERM PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5185	Bermuda Mother-Child Home Program	**N=2** 1 Beneficial (0.39; n.a.) 0 Harmful 1 not sig. (0+, 0=, 1-)								
5210	The Latin America Multicenter Trial			**N=21** 0 Beneficial 1 Harmful (n.a.; 0.28) 20 not sig. (17+, 0=, 3-)						
5234	Strayhorn, JM *No project title*	**N=3** 1 Beneficial (1.41; n.a.) 0 Harmful 2 not sig. (2+, 0=, 0-)								
5259	Windsor, RA *No project title*			**N=4** 1 Beneficial (0.61; n.a.) 0 Harmful 3 not sig. (3+, 0=, 0-)						

TABLE 15. SUMMARY OF REPORTED SHORT-TERM PARENT AND FAMILY OUTCOMES BY PROJECT, cont'd

Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5415	Oakley, A *No project title*	**N=1** 1 Beneficial (n.a.; 0.73) 0 Harmful 0 not sig.		**N=30** 3 Beneficial (1.0; 0.41) ranges n.a.; 0.37-0.45 0 Harmful 27 not sig. (23+, 2=, 2-)		**N=2** 0 Beneficial 0 Harmful 2 not sig. (2+, 0=, 0-)	**N=3** 0 Beneficial 0 Harmful 3 not sig. (3+, 0=, 0-)	**N=3** 1 Beneficial (0.42; n.a.) 0 Harmful 2 not sig. (2+, 0=, 0-)		
5431	Klaus, MH *No project title*			**N=7** 2 Beneficial (1.45; 0.31) 0 Harmful 5 not sig. (5+, 0=, 0-)						
5432	Sosa, R *No project title*	**N=4** 3 Beneficial (NR) 0 Harmful 1 not sig. (1+, 0=, 0-)		**N=2** 2 Beneficial (1.21; 1.83) 0 Harmful 0 not sig.						
5434	Kennell, J *No project title*			**N=12** 3 Beneficial (n.a.; 1.437) range 1.24-1.72 0 Harmful 9 not sig. (7+, 0=, 2-)						

TABLE 16. SUMMARY OF REPORTED INTERMEDIATE PARENT AND FAMILY OUTCOMES BY PROJECT

IDENTIFYING TRIAL INFORMATION		NUMBER OF OUTCOMES REPORTED FOR EACH TYPE Number of Beneficial and Harmful Effects (Mean effect size; Mean log odds ratio for categorical outcomes) Range of effect sizes; Range of log odds ratios Number of Non-Significant effects and Direction (+;=;--)								
Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5016	Beeghly, M *No project title*	**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)			**N=2** 0 Beneficial 0 Harmful 2 not sig. (0+, 1=, 1-)					
5040	Cunningham, CE *No project title*	**N=8** 1 Beneficial (0.52; n.a.) 0 Harmful 7 not sig. (4+, 0=, 3-)					**N=7** 1 Beneficial (0.76; n.a.) 0 Harmful 6 not sig. (6+, 0=, 0-)			
5143	Prenatal / Early Infancy Project - Elmira	**N=12** 2 Beneficial (0.84; n.a.) range 0.67-1.00 0 Harmful 10 not sig. (7+, 1=, 2-)	**N=20** 0 Beneficial 1 Harmful (0.37; n.a.) 19 not significant (12+, 0=, 7-)			**N=3** 0 Beneficial 0 Harmful 3 not sig. (2+, 0=, 1-)		**N=10** 2 Beneficial (0.59; n.a.) range 0.49-0.69 0 Harmful 8 not sig. (7+, 0=, 1-)	**N=3** 0 Beneficial 0 Harmful 3 not-sig (3+, 0=, 0-)	**N=3** 0 Beneficial 0 Harmful 3 not sig. (2+, 0=, 1-)
5234	Strayhorn, JM *No project title*	**N=1** 0 Beneficial 0 Harmful 1 not sig. (1+, 0=, 0-)								

TABLE 17. SUMMARY OF REPORTED LONG-TERM PARENT AND FAMILY OUTCOMES BY PROJECT

IDENTIFYING TRIAL INFORMATION		NUMBER OF OUTCOMES REPORTED FOR EACH TYPE Number of Beneficial and Harmful Effects (Mean effect size; Mean log odds ratio for categorical outcomes) Range of effect sizes; Range of log odds ratios Number of Non-Significant effects and Direction (+;=;--)								
Trial #	Trial Name or Lead Author First Paper	Parenting or Parent-Child Relationship	Maltreatment	Pregnancy or Pregnancy Outcome	Motherís Stress	Motherís Social Support	Motherís Mental Health	Motherís Physical Health	Motherís Education and Employment	Motherís Public Assistance or Legal Offences
5143	Prenatal / Early Infancy Project - Elmira		**N=2** 2 Beneficial (0.68; n.a.) range 0.46-0.89 0 Harmful 0 not significant					**N=6** 3 Beneficial (0.58; n.a.) range 0.46-0.79 0 Harmful 3 not sig. (3+, 0=, 0-)	**N=4** 0 Beneficial 0 Harmful 4 not-sig (4+, 0=, 0-)	**N=19** 8 Beneficial (0.74; n.a.) range 0.45-1.18 0 Harmful 11 not sig. (10+, 0=, 1-)
5255	Montreal Longitudinal Experimental Trial	**N=2** 0 Beneficial 0 Harmful 2 not sig. (1+, 0=, 1-)								

D. PEER REVIEWS

The Mrazek and Brown reports and the Crooks and Peters report were peer reviewed by:

- Dr. Michael Boyle, a Professor in the Department of Psychiatry and Behavioural Neuroscience, Associate Member Department of Clinical Epidemiology and Biostatistics, and Member of the Center for Studies of Children at Risk, McMaster University, Hamilton, Ontario. He was engaged to provide reactions to the methodology of the review.

- Dr. Clyde Hertzman, a professor in the Department of Health Care and Epidemiology and Associate Director of the Centre for Health Services and Policy Research at the University of British Columbia. He is also a Fellow in the Human Development Program, as well as Director of the Population Health Program of the Canadian Institute for Advanced Research. Dr. Hertzman was asked to evaluate the methods and findings of the Mrazek and Brown report and the Crooks and Peters analysis against the early childhood intervention field as a whole.

- Dr. Susan Bradley, a Professor in the Department of Psychiatry, University of Toronto, formerly Head of the Division of Child Psychiatry and Psychiatrist-in-Chief at the Hospital for Sick Children. Dr. Bradley was selected to provide a perspective of a front-line administrator who relies on research to guide service planning.

PEER REVIEWS

A REVIEW OF TWO RESEARCH REPORTS

by Michael H. Boyle

(1) AN EVIDENCED-BASED LITERATURE REVIEW REGARDING OUTCOMES IN PSYCHOSOCIAL PREVENTION AND EARLY INTERVENTION IN YOUNG CHILDREN, PREPARED BY PATRICIA J. MRAZEK AND C. HENDRICKS BROWN

(2) SEVERAL METHODS OF SUMMARIZING OUTCOME FINDINGS FROM MRAZEK & BROWN'S EVIDENCED-BASED LITERATURE REVIEW OF PSYCHOSOCIAL PREVENTION AND EARLY INTERVENTION PROGRAMS FOR YOUNG CHILDREN, PREPARED BY CLAIRE CROOKS AND RAY DEV. PETERS

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September 26, 2000

INTRODUCTION

Invest in Kids has contracted two research reports to review the evidence on programs designed to enrich the trajectories of healthy development and psychosocial adjustment among young children exposed to prevention and early intervention initiatives. The author of this paper has been asked to assess both reports with special attention to the methodology used and its usefulness for improving the knowledge base about healthy child development in Canada and for helping policy analysts and decision makers to identify programs and strategies likely to have a positive impact on children.

The assessment is divided into three parts. Part I critiques the review methods of Mrazek and Brown using evaluative criteria developed to help clinicians assess the validity, relevance and implications of systematic overviews of the medical literature (Oxman, Cook & Guyatt, 1994; Oxman & Guyatt, 1988). The evaluative criteria take the form of questions, modified by the author to acknowledge the broader decision-making context of the policy analyst. Part II discusses the methodological issues raised by Crooks and Peters in response to the review by Mrazek and Brown. Special attention is given to issues associated with the interpretation of effect sizes and the approach used by the authors to combine standard effects sizes across studies. Part III presents summary comments and recommendations for the review process that might increase its relevance and usefulness to policy analysts.

PART I: Mrazek and Brown

This is an ambitious project which attempts to identify, evaluate and report on a wide range of interventions assessed for their ability to improve the development, adjustment and life quality of young children from birth to age 6. The methodology of the report and inferences of the authors are examined through a series of questions.

1. Did the review address a clear, focused question?

Questions bearing on the usefulness of prevention/intervention initiatives have of a number of important elements. These elements consist of the population, the program and the target outcome. The population identifies intended beneficiaries; the program, the means to attain benefits for exposed individuals; and the target outcome, the sought after improvements in functioning and quality of life. Clarity and precision in the definition of these elements are important for three reasons: (1) to serve as inclusion/exclusion criteria for determining study eligibility; (2) to reduce the undesirable effects of study-to-study heterogeneity which serve to undermine the appropriate use of statistical methods for combining study results ; and (3) to facilitate generalizability and take-up of results. A clear focused question might examine the extent to which parent management training (program) reduces aggressive, antisocial behaviour (target outcome) in boys aged 6 to 12 years referred to clinic for conduct problems (population).

The report by Mrazek and Brown was an "evidenced-based literature review regarding the outcomes in psychosocial prevention and early intervention in young children". A number of target "areas" were identified, including: the parents during the prenatal period; the parent-child relationship from zero through six; the

cognitive, language and social development of the child; the broader community; and medical conditions that overlap substantially with psychosocial conditions (p. 1). The population of interest was all encompassing from conception to children six years of age taken from general, high risk and clinical samples.

The point of departure for the review is not an answerable question, clear and focused in scope, but a very broad objective conceived at a high level of abstraction. Unless the authors and funders are prepared to classify the elements of the review with greater specificity - population, program and target outcomes - and link these elements into individual questions, it is difficult to envision this work issuing concrete recommendations about programs and policies. The problem arises from excessive heterogeneity. The review includes a large number of individual elements whose combinations and permutations make it difficult, if not impossible, to understand and attribute program effects.

One of the purposes of a review is to test the replicability of program effects through the integration of multiple studies. The abstraction of relevant data from eligible studies is an arduous task. The task can become too large if too many studies are identified, a potential problem when the study question or objective is defined broadly. Inclusion and exclusion criteria provide the means for limiting the study pool to manageable numbers. This strategy should be used to increase study homogeneity and the potential for replication. If the strategy serves to increase study heterogeneity then the inferential advantages of testing replicability are lost and the review will be reduced necessarily to the study of individual reports.

2. Were the appropriate criteria identified and operationalized to select articles for inclusion?

The criteria for selecting relevant articles arise from the three elements identified above - population, program and target outcomes - along with a set of methodological standards to help eliminate studies that may be biased or invalid. The criteria must be "appropriate" in the sense that they are linked directly to the central question or objective of the review and "operationalized" in such a way to permit independent replication.

The authors note that studies for inclusion should be focused on children from conception to six years of age; include a "central psychosocial component"; be targeted at one of five different areas (see above); and achieve a minimum Grade IV standard of evidence based on the hierarchy of evidence used in the report issued by the Institute of Medicine Committee on Prevention of Mental Disorders (Mrazek & Haggerty, 1994). (Grade IV evidence is obtainable from "well-designed controlled trials without randomization".)

The criteria identified by Mrazek and Brown to select articles correspond to the general objective cited for their review. With exception of the methodological standards for inclusion which are very specific, the other criteria are broadly stated. The population is, or should be, easily identified for any given study. The programs and target outcomes that might be included are very general in their specification and less easily identified. Differences in opinion about what constitutes a program with a psychosocial component and what constitutes a relevant outcome for this review could, on replication, lead to differences in the selection of studies for review.

3. Were comprehensive search methods used to locate relevant articles? Is it unlikely that important articles were missed?

Comprehensive search strategies are needed to insure that all relevant studies are included in the review. These search strategies should include the use of appropriate bibliographic data bases, the development and use of specific key words that link the population, program and target outcomes, checking the reference lists of retrieved articles, investigating government documents and personal contact with experts working in the field of inquiry. Studies reported in peer-reviewed publications are the easiest to locate and retrieve unless they are in press or not yet indexed. Unpublished studies including government funded evaluation projects are less accessible and their exclusion could lead to a distortion in the studies located for review, called "publication bias" - the higher likelihood for studies with positive results to be published (Dickersin, 1990).

The authors report searching through "Medline, PsychInfo, ERIC, Current Contents, CINAHL and other data bases...using that data bases's standard subject headings...with no specific lower limit to the year searched or the language of the article". Specific details are not forthcoming on the other data bases searched, key words used to identify articles and reported access to studies through contacts with agencies, institutes, and key scientific leaders in the field.
To select relevant articles, the authors developed a three-stage process to winnow out studies with inadequate design. Each stage involved increasing the data for review (e.g., abstract to full paper) and the comprehensiveness of the evaluation (e.g., abbreviated to full assessment of the design). A step-wise accounting of the studies reviewed at each stage is not presented. It appears that the search procedure led to the identification of 165 studies in 215 papers that met basic research design criteria. In assessing program effects, these 165 studies were reduced further to the 34 "best-designed trials" on the grounds that the "...validity of outcomes in poorer designed trials would be questionable".

Overall, there is too little detail provided on the search methods used in the review to comment on their adequacy. In systematic reviews, a reasonable standard is to expect enough information on these methods to permit replication. The use of more stringent methodologic criteria to identify the subset of 34 studies that form the basis for the review has the potential to create two substantial problems. First of all, it favours the inclusion of populations, programs and target outcomes that are most amenable to trial methodology conducted in laboratory like settings. This could mean the systematic exclusion of prevention and intervention initiatives in natural settings that are difficult to implement and evaluate. Second, the small number of studies selected and broad scope of the review will lead almost invariably to large study-to-study variation or heterogeneity. This could make it impossible to summarize the findings of the review in anything other than a study-by-study basis.

4. Was the validity of the included studies assessed?

The validity of a study is assessed by the extent to which it is free from error, both systematic and random. Past research has shown that studies using weaker methodology, and therefore vulnerable to error, tend to report larger intervention effects (Chalmers et al., 1983). Accordingly, the concern is that the evidence for program effects is less convincing if it arises from studies that are weak methodologically.

The authors use two classification systems to assess the quality of research design for the studies included in

their report: the Trial Elements Score developed by Oakley and colleagues (1995); and a system developed by the authors themselves which they call the Threats to Trial Integrity Score. The system proposed by the authors appears to be very promising: the dimensions of the system along with the scoring key are given in the report. All 165 studies identified for the review were rated using the system; threshold values were applied to the scoring system so that five groupings emerged from low to high which the authors associated with stars; studies grouped as 4-or 5 stars (N=34) were retained for detailed evaluation of their program effects.

5. Were assessments of the studies free of potential bias and reproducible?

The concern for quality of measurement in the assessment of studies for a review article is directly analogous to observer ratings of subject behaviour in primary studies. In review articles, rater knowledge about key features of individual studies such as the authors, their affiliations and source of support as well as the results of the study itself can influence the search, identification and interpretation of relevant data. This, in turn, can influence the inclusion of studies for review, the classification of important study parameters, the assessment of methodologic quality and the interpretation of the results. The potential for bias can be avoided by eliminating information that might distort rater assessments or by using "naive"assessors for whom such information is not meaningful. There is no indication in the review that these procedures were followed.

Quality of measurement is not just a function of bias but also patternless mistakes or random error that accrues in data collection. Random error attenuates associations between measured variables; it is minimized by efforts to standardize the collection of information through the use of explicit criteria, sound instruments and adequate training; and it is assessed empirically by replication studies. Assessments in review studies are "reproducible" when different raters exposed to the same data and naive to each other's findings provide the same or similar results. In the report, the authors note that they had "...10% disagreement..." when they initially classified their intervention types. (There were four intervention types in their classification system). No other information is provided about the reproducibility of the ratings obtained in the review.

6. Was there significant variation in results and methods of included studies?

As noted earlier, large variation in the results and methods of included studies makes it difficult, if not impossible, to combine studies meaningfully. Indeed, no attempt is made in the review to aggregate studies or to examine study heterogeneity empirically. The 34 studies presented in depth shared similar 4-or 5 star ratings for quality design using the Threats to Trial Integrity measure developed by the authors. However, similarity among the studies on other important parameters is limited. There appear to be large differences in effects attributable to programs both between studies and within studies on different outcomes. Overlap among the 34 studies in any of the important design parameters such as population, intervention and targeted outcomes is minimal. Indeed, the authors of the review had to process 969 outcomes from the 62 papers written about the 34 studies. As a consequence, the studies reviewed are not drawn from a sample that can be used to make generalizations about programs and strategies likely to have a positive impact on healthy child development. Rather, inferences from the review must be drawn on a study-by-study basis.

7. What are the overall results of the study?

The results of the study are presented in a series of tables and graphs that either describe individual details of each study (e.g., country, author, publication year, study population, general intervention type and Threats to Trial Integrity Score) or collapse over one of these variables. A general summary is provided of the 165 studies included in the review and more specific details, including standardized effects, is tabled for the 34 studies given 4-or 5 stars for design quality. There is one summary table (Table 5) for effects classified as significant beneficial, significant harmful and non significant for each targeted outcome category (N=20) among the 34 best designed trials. For the most part, the "overall" results, as measured by the effectiveness of evaluated programs, are indistinguishable from individual study results. There are, however, some summary comments and these are listed below.

1. The intervention methods beginning prenatally and continuing past infancy such as the ones used in the study by Gutelius (1977) warrant consideration in a new trial (p 14).

2. The results for educational day care programs delivered during infancy are very strong, particularly when they are placed in a comprehensive setting (p 15).

3. Intervention trials for toddlers have provided relatively small increments to the knowledge base (p 15).

4. Parent training programs and preschool education programs initiated in the preschool/kindergarten period show "clear evidence of beginning effects on oppositional-defiant disorder" (p 15).

5. Universal intervention trials should be implemented to examine the trade-offs in costs and effects associated with intervention intensity, timing and training in home visiting programs (p 16).

6. 280 (30%) of the 969 outcome measures in the 34 trials meeting 4-or 5-star quality ratings showed significant improvement for the intervention group compared to control; and 32 (10%) of the significant findings have large magnitudes. 3% of the 969 outcome measures showed harm (p 17).

8. What are the reviewers' inferences and do the results of the study support them?

The concluding comments are brief and grouped in three sections: (1) a comparison between the review and a RAND report which also looked at early childhood interventions; (2) a list of 10 gaps or unanswered questions in the research data base arising from the reviewers' perceptions of limitations associated with the content and methods of available studies; and (3) concluding comments. In brief, there is concern about the quality of available studies which is well documented in the review and a specific recommendation that additional effectiveness trials be done testing some of the intervention strategies used by Gutelius, Ramey and Olds.

PART II: CROOKS AND PETERS

The report by Crook and Peters extends the review of Mrazek and Brown by subgrouping standardized effects and creating numerical averages among the 969 outcomes culled from the 34 studies meeting the 4-or 5 star quality standards. The authors of this report compute summary indices of average effect sizes for different projects, types of outcomes and follow-up durations. They also draw attention to a number of unresolved methodological and statistical issues applicable to the review by Mrazek and Brown. These include:

1. The impact of multiple testing (i.e., the use of more than one outcome to evaluate program effects) on nominal significance levels. Mrazek and Brown worked with 969 "outcomes" from 34 studies, and there is no indication of any attempt to adjust significance levels within individual studies using multiple outcomes. This problem extends to the treatment of serial measures (i.e., assessments repeated over time on the same individual). Mrazek and Brown treated serial measures as independent outcomes. Crook and Peters argued that serial measures should be viewed as growth curves.

2. The classification of effect sizes according to perceived importance. Mrazek and Brown used three categories of effects - significantly beneficial, nonsignificant, and significantly harmful - where significance was defined as statistically significant. Crook and Peters made a distinction between statistical significance and magnitude of effect by using the cut-offs proposed by Cohen for standardized effects: negligible (<0.20), small (0.20-0.40), medium (0.50-0.79) and large (>0.79).

3. The distinction between outcome measures in their relevance and quality. Mrazek and Brown treated all outcome measures in the same way. Crook and Peters argued that there are distinctions in quality that should be made.

Some of the highlights from the report that reflect on methodological/statistical issues are the following: most of the outcome effects reported in the 34 studies reviewed by Mrazek and Brown are short term - collected during or immediately after the intervention period; and the subsample of 34 studies selected for review from the 165 meeting inclusion were skewed towards singular focus programs delivered early-on (e.g., prenatal programs) and away from multi-focus programs delivered later on (e.g., infant programs).

Combining Effects Across Studies

As noted by the authors, combining effects from different studies to produce summary measures is intended make the results of a review easier to understand. The alternative is to examine each study on a case-by-case basis and, using consensus and normative judgements, come to some conclusions about the relative merit of individual programs.

In the medical literature, effects observed in different studies are combined to increase the precision with which outcomes are estimated. There are a number of issues associated with the construction of summary estimates, and one of the most contentious focuses on the constraints imposed by study heterogeneity. Although "standards" have not been developed, trialists refrain from combining effect sizes when large variation exists in the magnitude of these effects or the study elements associated with them. When large study-to-study variation exists in estimated effects, then it is extremely important to analyse this variation in an effort to

understand its methodological or substantive origins. If the variation can be explained, then the summary estimates of effects can be put into proper context.

The Determinants and Interpretation of Effect Sizes

In addition to program ingredients, there are a variety of factors which determine program effects in evaluation studies. These include: the relevance of the (outcome) concept to program objective, its sensitivity to change, systematic measurement error, random error and the timing and number of assessments. All of these factors reflect on measurement quality and most of them are considered in Mrazek and Brown's Threats to Trial Integrity Score under dimension VII: Measurement Threat. Although all of these factors introduce bias in the estimation of program effects, there are some important distinctions to be made among them in the direction and magnitude of this bias. For example, only one of these factors - systematic measurement error - is likely to exaggerate program effects on a regular basis and make them look bigger than they really are. Assessments timed to occur during or near the end of the intervention period in most cases, but not all cases, provide stronger estimates of effect than assessments timed at successively longer follow-up after the intervention period is over. This, of course, can be accounted for in any analysis just as Crooks and Peters have done. Most importantly, the dominant impact of the other factors is to place upper limits on the ascertainment of program effects, in other words to make program effects look smaller than they really are. For example, random measurement error can have a dramatic impact on effect sizes as indicated by the large increases in effect size estimates that accompany efforts to reduce or eliminate measurement error by statistical and analytical means (Boyle & Pickles, 1998; Stoolmiller, Eddy & Reid, 2000). There are two reasons for drawing attention to this: (1) for the most part, actual program effects will be underestimated not overestimated; and (2) including studies with less than 4-or 5-star quality ratings is unlikely to lead to any substantial overestimation of program effects.

The effect size conventions developed by Cohen have drawn attention appropriately to the importance of looking at the magnitude of effects produced in research studies and have stimulated investigators to consider statistical power when planning their investigations. However, these conventions ignore extremely important contextual factors that need to be taken into account when assigning social value and practical worth to program benefits. McCartney and Rosenthal (2000) give the example of how an effect size of r=0.03 in a randomized double-blind trial of the effects of aspirin on reducing heart attacks was considered large enough to terminate the study prematurely on ethical grounds so that the control group could be advised of the benefits of aspirin. Arbitrary cut points with names like negligible, small, medium and large ignore the inherent worth of particular outcomes and their value to society. In addition to the inherent value assigned to outcomes are other considerations that play an important role in their valuation. One, the costs and side effects, if any, of achieving effects need to be considered. Effects of comparable intrinsic worth but less expensive to achieve and with positive rather than negative side effects exhibit more practical value. Two, outcomes that are intermediate in a causal chain or process variables expected to bring about positive outcomes have less practical value than targeted outcomes that specifically represent desirable change in functioning or quality of life. Three, outcomes that are short lived have less practical value than outcomes that are longer lived.

Multiple Outcomes in Individual Studies and Serial Measurement of the Same Outcome

Crooks and Peters raise a central issue when they comment on the treatment of multiple outcomes and serial measurements in the review by Mrazek and Hendricks. The issue has two primary components: (1) the misspecification of nominal significance levels when groups are compared on different outcomes and/or the same outcome repeatedly assessed; and (2) the differential weighting of studies according to the number of assessments they have collected. This latter problem is particularly insidious because it means that a handful of studies will dictate overall perceptions about program benefits.

In my view, there is an urgent need in both reports to "level of the playing field" among selected studies. This would necessitate the development and testing of a data reduction strategy applicable to all studies and the computation of summary measures of effects within studies which could, in turn, be analysed across studies. In developing such a strategy, the criteria would need to focus on the nature, relevance and quality of measurement applicable to target outcomes. Also, decision rules and a step-by-step methodology would have to be constructed.

Data Limitations and Constraints

The summary efforts of Crooks and Peters are a valuable extension to the review document produced by Mrazek and Brown. However, it is important to note that the data limitations and constraints of the review apply to the summary. The three issues of concern to this reviewer are: (1) study heterogeneity that may compromise efforts to combine study results in a meaningful way; (2) potential sampling biases associated with the inclusion of only 4-or 5-star quality designs; and (3) the enormous array of multiple outcomes and serial measurements that have been treated as independent effects.

PART III: SUMMARY COMMENTS

In my view, Mrazek and Brown have created a data base that has considerable potential for aiding policy analysts in the search for programs and strategies likely to benefit healthy child development. This data base is very much analogous to a survey whose usefulness and impact needs to be mined through additional analysis aimed at addressing specific questions. There are, however, some issues to consider, and a summary of them are presented briefly below.

Methodological Quality of the Review

The methodology of the review was assessed through a series of standard questions. In a number of instances, lack of information prevented adequate assessment. This same problem - the incomplete reporting of methods in the studies included in the review - was addressed by Mrazek and Brown in a single strategy: assume the worst. Studies which failed to provide sufficient information to assess a methodological criterion were scored poorly. This will lead inevitably to some downward bias in quality ratings.

Methodological Assessments of Papers in the Review

A variety of checklists have been available for some time to assess the integrity of clinical trials (see the review by Moher, Jadad & Tugwell, 1996). Given the availability of these instruments, the rational for creating a new instrument, as useful and comprehensive as it appears to be, is not entirely clear. There are some other considerations to take into account. One, the Threats to Trial Integrity Score was used as a screening instrument to identify a subset of "high quality" trials among a much larger number of trials that met methodological criteria for inclusion. As noted earlier, this led to a distortion or bias in the studies selected for detailed assessment. Furthermore, Juni, Witschi, Bloch and Egger (1999) have shown that the direction and magnitude of associations are variable between effect size estimates obtained in the same studies and summary scores derived from different instruments used to assess the quality of those trials. The authors write that, "...the use of summary scores to identify trials of high quality is problematic..." (p. 1054). The difficulty is that the effect sizes observed among high and low quality trials as scored by these instruments can be reversed in the same group of studies. Two, the scale was not used for the purpose it might best serve, to evaluate the extent to which study-to-study variability in program effects might be accounted for by methodological differences in these same studies. Concentrating on studies with 4-or 5 star quality ratings eliminates the opportunity to assess the importance of quality to the ascertainment of effects.

Including More Studies in the Review of Program Effects

The scope of the review was very wide, and there's little question that its breadth created formidable challenges for the reviewers to use standard, evaluable methods for identifying, selecting and assessing relevant articles. The formation of the question/objective is the key element for any research endeavour. To be useful, a research question must be answerable within available resources and existing methodologies. It is easy to underestimate the exacting requirements and difficulty of carrying-out a sophisticated review of high methodological integrity. Given the breadth of the question/objective, I think that it was a mistake to focus on 4-or 5-star quality design studies. If the inclusion criteria used to identify relevant articles are meaningful, then extending the assessment of program effects to studies excluded because of low ratings will increase the meaningfulness of the review and provide an opportunity to study important factors which might contribute to variations in program outcomes. The problems identified in the previous paragraph can be addressed in this way. Of course, extending the review to excluded studies is not without cost. Accordingly, a discussion of the costs and benefits associated with this recommendation is warranted.

Interpretation of Effects

A variety of issues associated with the interpretation of program effects have been discussed in previous sections. These issues include: (1) consolidating multiple outcomes within individual studies to reduce the number of comparisons; (2) estimating net overall effects from serial measures of the same outcome taken within individual studies; (3) contextualizing program effects by assigning practical value to outcomes; and (4) quantifying and modelling study-to-study variation in program effects. Once again these issues can be addressed but it will take resources to do so. Accordingly, a discussion of this recommendation in view of the feasibility of successfully addressing the issues and the cost of doing so might be the focus of discussion.

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PEER REVIEWS

A REVIEW OF TWO RESEARCH REPORTS

by Susan J. Bradley

(1) AN EVIDENCED-BASED LITERATURE REVIEW REGARDING OUTCOMES IN PSYCHOSOCIAL PREVENTION AND EARLY INTERVENTION IN YOUNG CHILDREN, PREPARED BY PATRICIA J. MRAZEK AND C. HENDRICKS BROWN

(2) SEVERAL METHODS OF SUMMARIZING OUTCOME FINDINGS FROM MRAZEK & BROWN'S EVIDENCED-BASED LITERATURE REVIEW OF PSYCHOSOCIAL PREVENTION AND EARLY INTERVENTION PROGRAMS FOR YOUNG CHILDREN, PREPARED BY CLAIRE CROOKS AND RAY DEV. PETERS

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Should we be dismayed by what seems to be a dearth of positive, robust long-term effects from this review of early intervention studies? I think not and will argue why this is a very good beginning which should enable us to improve the state of our science in this area and to ensure that we are able to deliver programs that work.

Mrazek and Brown have provided a model for assessing the research literature in early intervention for young children but also in any other area of scientific inquiry. They have helped us see that the information, which many of us have taken at face value, should be regarded more cautiously. These cautions are so imperative, and the implications for supporting an across-the-board increase in the rigour of future research are so clear, that I am simply going to let them stand on their own. Although the Mrazek and Brown approach worries some child development specialists, because they fear research funders may constrain their funds to simplistic and quantitative intervention models favored in most existing randomized control trials, I do not share those reservations. Certainly, here in Canada, we have seen Ray Peters and his Better Beginnings Research Coordination Unit undertake a large-scale comparison-group study of an ecological prevention model, which is not at all simplistic, and which employs both quantitative and qualitative research methods. We also are aware that Harriet MacMillan has an RCT underway of an intervention model focusing on mothers who have abused their children at least once, to prevent a re-occurrence of child maltreatment. Her example shows we can successfully implement an RCT with even very high risk families.

Thus, we should encourage funders to provide the level of resources required to increase the rigour of all our research, always remembering that providing adequate control groups and comparison groups doubles the research costs. We must improve the standards of scientific rigour, so we can know what works for Canadian families with young children.

That being said, I will concentrate the rest of my peer review on what we as clinicians and program administrators need in terms of future studies which will take us to the next level of knowing what works in terms of programming for families with young children.

I believe that Mrazek and Brown have shown that our programs for young children have limited evidence of robust, long-term benefits. However, being unable to prove something does not disprove it. For me this means that we should not stop doing what we think is useful. However, if we are running programs that have not been evaluated:

1. We must develop ways of evaluating what we are doing and we must always be prepared to modify our interventions in light of our findings, and

2. We must also incorporate into our programs the elements that have been validated or for which the evidence suggests promise.

Crooks and Peters have pointed out the limitations of Mrazek and Brown's report, particularly that many of the studies showing beneficial effects were short-term studies delivered in the pregnancy and early post partum period. Indeed, most of us would not advocate that we invest the bulk of our funds in such interventions, as opposed to programs that target families in the later infancy to early childhood period of life. Their analysis does make us realize, however, that our literature will most frequently present studies on programs that are "manageable," (which is often a code word that means "short term and highly focused"), but which may not answer the more relevant or important questions about what is really needed.

Crooks and Peters have also clearly pointed out how most of the studies in any age range are short term and collectively the benefits for children and parents are in the modest range. The types of gains that appear to be most robust for children are in the realm of cognitive development. This is very important, as intelligence is a strong predictor of later outcomes in a number of domains. However, for those of us who are mental health professionals it seems a bit disappointing that the gains in behavior and emotional development are not so robust. This apparent lack may be related to at least two different issues. We still do not know what are the most important components or contents of programs. Further, our capacity to measure many aspects of child and parent behaviour is less than satisfactory. I am thinking of the constant dilemma about discrepancies between parent and child report and about whether independent observation of behaviour (often the gold standard) is in fact a better measure of child outcomes than parent perception. Clearly there is room for good research to develop and validate instruments which predict to later outcomes.

Nonetheless, it is also clear that school readiness programs should be widely available to those at risk families most likely to be unable to ensure that their children will develop optimally in the preschool period. What is equally important if we provide such programs is that we ensure the fidelity of their implementation. The great variation in outcomes related to the Head Start programs is most likely explained by the lack of fidelity, possibly because of a dilution of resources. These results are good evidence that efforts to cut corners in program implementation may significantly reduce the effectiveness of the intervention.

The David Olds PEIP Elmyra study demonstrates that nurse home visiting works, and to date his intervention model of nurse home visiting appears to be the best intervention to prevent child maltreatment. The fact that Olds discontinued his lay home visiting program because of lack of efficacy is also interesting. However, I don't believe that we know enough about the overall comparison between nurse home visiting and lay home visiting to warrant abandoning lay home visiting programs or programs that attempt to provide a culturally sensitive version of the Olds model using trained workers backed up by skilled professionals.

I am reminded here of Multisystemic Treatment (MST) model of intervention developed by Stephen Henggeler (1999) for young offenders. In this highly successful intervention the frontline workers are trained and backed up by skilled professionals. Many of the families involved in the MSST programs are the same types of families we try to reach in our lay/nurse home visiting programs. What Henggeler insists on is a support system which promotes 24 hour backup to families, as well as intensive training and backup to workers.

The other factor in home visiting interventions that needs to be examined is what is being done in the actual face-to-face work with these families. As I discuss below we need to understand how much of the documented changes can be attributed to the relationship and support provided by the home visitors as opposed to the information and direction disseminated by them. Nurses, because of their training, are likely to be more expert in all of these domains than even highly trained lay home visitors, but we must determine what is the most critical element of this type of intervention in the eyes of the families we wish to help.

Others today, who are far more expert than I, will address ways in which our methodologies have advanced so that we may now design studies that overcome some of the deficits in the studies reviewed by Mrazek and Brown. The only point I would like to emphasize is that we need to define as clearly as we can what early markers are the best predictors of later out-

comes. This is critically important because many programs will never be able to do the sophisticated long-term follow-up studies which are required to provide definitive evidence of outcomes. Many studies can and should, in my opinion, be attempting to identify specific behaviours which may predict better than others to later positive outcomes for parents and children. For example, in parenting programs, can we devise indicators of "good enough" parenting to suggest that children exposed to such parenting behaviour will be relatively likely to develop normally? In the same vein, can we uncover particular child characteristics, such as high levels of reward seeking, or children with high levels of sensitivity or inhibition which predict worse outcomes and which require more focused or specific interventions?

Although we clinicians and administrators realize that the most important outcomes are long term, I strongly suggest that we should not dismiss the importance of short and medium term benefits. For example, it would be hard to argue that we should abandon a program that improves parenting skills in the short term. Clearly, we also need to explore what happens to those children who show improvement, but who appear to lose those gains with time. But I would also like to suggest that it is particularly important to pair long-term quantitative research with more in-depth and qualitative work. Such a joint methodological approach may help us understand the different trajectories followed by our families, and the factors which affect those paths. I suspect those of us developing research intervention models may end up borrowing from the therapy literature, which is showing that many individuals need boosters over a prolonged period to maintain their short-term gains.

For the most part when we limit our examination of child outcomes to the most rigourous studies surfaced by the Mrazek and Brown methodology it seems clear that with good programs we can improve children's cognitive skills, and also but to a lesser extent their socio-emotional development. On the other hand, the small effects associated with changes in parenting behaviours from the Mrazek and Brown report suggest that it is harder to help parents alter their behaviour. This makes me think that we have to re-examine our approaches, perhaps learning from the therapy and adult learning literatures. Before I discuss what I think are promising possibilities I would like to examine what I believe we are trying to change.

I would argue that in order for children to grow optimally they need a parent who can respond sensitively to the child's needs and can help the child learn to self-regulate. To accomplish this, a parent needs to have knowledge about the child's needs and how they change with growth and development. The parent also needs attitudes and skills which enable them to interact with their child in a way that makes the child feel supported and encouraged to grow.

Some would also argue that we need to modify the parents' internal working models, especially as they relate to their child. These internal structures appear to facilitate automatic reactions. If such automatic patterns or reactions are maladaptive they can be presumed to interfere with adaptive attitudes and behaviours. Within the cognitive behavioural literature there has been a debate for a number of years about whether it is optimal to strive to change schemas or internal working models (which are presumed to direct attitudes) as opposed to just changing thoughts or behaviours (Jacobson et al., 1996). Although many of us would argue that such changes may go in both directions, we would probably acknowledge that ultimately, we want a parent to have an inner schema which allows her to perceive her child and his behaviour in ways that maintain a positive relationship between the two of them. Currently, we know more about disseminating

knowledge than we do about changing attitudes and skills and particularly changing schemas.

Therapists have been exploring these domains and can tell us that change does seem to occur in the context of a positive and accepting relationship that permits exploration of behaviours, beliefs and attitudes. Such changes are more likely to occur within the context of a therapeutic or caring relationship than in a teaching relationship. That is, we change our behaviours, beliefs and attitudes because those we care about and who care about us, encourage and support us to do so. This may be where our models of early intervention need to acknowledge that many of our parents may need more than what we can offer in the less intensive and population based approaches. Further we may need to develop sophisticated assessment approaches to enable us to refine what type of intervention may be most suitable for which parent. This may involve using some of the newer approaches to assessing mother's internal working models of her child and of her own relationship with care-taking figures. Such assessments could allow us to tailor interventions to the parent's need.

Another approach, which may be useful, is to explore non-verbal models. I am thinking here of the approach used by Carolyn Webster-Stratton in her parenting group programs. These parenting programs are among the best validated interventions in the literature. I believe we may be able to learn more from examining some of the components which appear to be central to her approach. Webster-Stratton (1997) uses video vignettes which demonstrate positive ways to interact with children. In contrast to some programs which show positive and negative interactions she emphasizes only the positive behaviours and uses the vignettes to reinforce, in a non-verbal way, what the group has been covering in a more traditional or didactic fashion. Given that many at-risk parents have poorly developed verbal skills and may even have significant language related problems finding ways that convey messages in non-verbal ways seems very relevant. Further rehearsing and practicing positive behaviours may ultimately change maladaptive inner schemas and attitudes.

The other domain, which is current in the therapy literature, is assessment of a client's readiness for change (Prochaska et al., 1992). We know that many of the individuals whom we try to help in our programs appear to be demoralized and unable to benefit from the intervention. We need to examine whether some individuals may need help which promotes their understanding and which moves them into a state of "readiness to change".

Lastly, the relationship between a depressed parent and young child is an area requiring a great deal more study. Many of the at risk families we attempt to help have parents who are depressed. Although as a psychiatrist I would clearly argue for the importance of treating the parent's depression, such treatment does not seem to address many of the interactive mis-attunements that appear to affect young children. We need to find ways of helping such mothers respond more contingently to their infants before the impact of their lack of response has embedded itself in the infant's internal working model. Unfortunately, we have seen that this seems to happen if the mother's depression continues into the child's second year (Field, 1989).

In summary, I believe that we have the evidence that good "Head Start" type programs work if they are properly resourced and can maintain good fidelity to the original intervention models. This means such strategies as 1) having a good child to adult ratio with trained workers, 2) providing support to parents and 3) continuing for at least two years. These Head Start type programs should be available to the most at risk families and might also be available to others on a paying basis. Dan Offord has argued for years that if middle

class parents get involved they insist on good quality programs and by including them on a paying basis it may help to ensure the quality of the programs.

I also believe that Olds has shown the efficacy of nurse home visiting and that we need to provide nurse home visiting. However, the Olds nurse home visiting model should be considered the "gold standard" against which we examine other intervention models, such as lay home visiting to clarify whether we can achieve comparable gains in different, perhaps more economic, but also culturally sensitive ways.

I want to thank Pat Mrazek and Hendricks Brown for stimulating this debate, and Claire Crooks and Ray deV. Peters for enlarging the issues and helping us to more clearly see the "forest from the trees". I want further to thank Invest in Kids for initiating this process and along with Human Resources Development Canada and Health Canada pushing us all to practical resolutions of these interesting but complex findings.

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PEER REVIEWS

A REVIEW OF TWO RESEARCH REPORTS

by Clyde Hertzman

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Background

As requested, this review focuses on the advantages and disadvantages of using the Mrazek and Brown type of methodology, from the perspective of improving child development in Canada and providing policy-makers with the information they need to identify programs or approaches with the largest probability of positively affecting healthy child development in Canada. Since the Prime Minister and the Premiers have recently signed an agreement on early child development, I have focused, in particular, on the degree to which this review might help those in the public sector and in local communities fulfill the objectives of that agreement.

I would suggest that those seeking to improve early child development in Canada would confront 9 significant complicating realities when trying to use a review such as this:

1. Child development, unlike most of the 'conditions' for which intervention trials are reviewed, is not a disease or, for that matter, a discrete condition in any sense. Instead, children's development exists on a continuum and, in Canada, as many as 25 - 30% of children find themselves on developmental trajectories that will likely not lead to competent adulthood. Thus, the key issue is how to shift the population distribution of child development in Canada, no how to 'treat' individuals.

2. Child developmental status is a result of the interaction of children's age-specific emerging competencies with the total environment in which they grow up, live and learn. Thus, day-to-day experiences are a continuous, uncontrolled 'developmental trial.' This, too, makes child development unlike most of the conditions addressed in clinical epidemiology, which tend to be 'detachable' from daily life. This reality makes the identification of every intervention and control group semi-fictional in child development.

3. Canada has just committed itself to collective responsibility-taking for early child development among all Canadian children. This means that the chances that any group of children will be valid 'controls' in the future is even lower than it was in the past, when the above 2 objections already applied. In other words, child development is part of a multi-sectoral movement for social change. We have few, if any precedents to support the notion that summary evaluations of discrete programs is relevant for managing broad social change. An analogy can be made here to the fiasco of the MRFIT trial; wherein the effects of the broad social movement for cardiac risk factor reduction swamped the effect of the discrete intervention, rendering a $150 million trial fundamentally inconclusive.

4. In Canada, evidence from the NLSCY and other sources shows those compositional effects such as neighbourhood character and socioeconomic ghettoization affect early child development above and beyond individual factors. Thus, changing the social ecology of early childhood, by means of remote as residential zoning reform, may be of greater significance than interventions that can be feasibly evaluated by clinical trials, and the readiness-to-learn of the group may be more important than the status of specific individuals. In fact, Early Development Indicator data from whole communities strongly suggests that child development may be subject to an 'ecological reality' and an 'individualistic fallacy,' rather than the reverse. If so, evidence from trials where the unit of observation is the individual may be fundamentally irrelevant to the outcome of interest over time. The

best example of this may be the idea of a 'tipping point.' That is, the proportion of vulnerable children in a community may rise to a point where vulnerability becomes the norm and colours the developmental experience of most children, even those not thought to be vulnerable on an individual basis. Below that point, invulnerability may be the norm, such that vulnerable children move to the norm of invulnerability.

5. Longitudinal studies show that early childhood experiences may affect later health, well-being, and competence through a mixture of latent, pathway, and cumulative effects unfolding over years and decades. Because of the complexities of these effects, short-term clinical trials will be highly vulnerable to both false negatives and false positives whereas long-term trials will face problems of feasibility, cost and attrition.

6. A compelling case has been made that the sustainability and effectiveness of many programs for young children depend upon intangibles, such as the orientation and commitment of those delivering the program, and the capacity of 'civil society' to assimilate the program. The elements that can fairly be generalized from clinical trials rarely include these factors.

7. Exceedingly high levels of residential transiency in Canada are a fundamental threat to many programs, both individual and community-based, that are based upon continuous involvement of children and families.

8. Large scale changes in social conditions over time (such as the closure of industry in a one industry town, or the conclusion of a significant Aboriginal land claim) could affect child development outcomes in ways that obviate discrete interventions running concurrent to the change.

9. Biological understandings of the nature of early child development are in a rapid state of flux. For instance, new understandings of the timing and nature of forms of stimulation that might make a difference, or new knowledge regarding the prospects for strengthened competence in one domain crossing over and strengthening competence in other domains, have the capacity to fundamentally change where we look for effective early interventions. This is particularly important, because we do not, at present, have a credible understanding of the biology of compositional effects (see point 4 above), despite their undoubted importance.

Concerns about the Review

Because of the realities described above, it cannot be assumed that trials are exclusively the method of choice for understanding what can be done to improve early child development in Canada. A more reasonable attitude would be, following the words of former Prime Minister MacKenzie-King, "trials if necessary, but not necessarily trials." In other words, it would be much more useful to include a broader range of study designs, examining EACH study for threats to validity, rather than pre-empting all non-trials and only beginning the evaluation among them. After all, most of the useful information will be found among Grade 5 or 6 studies (according to the Mrazek and Brown classification scheme). Over all, the most important criterion for interpretation is consistency. The investigators used this, as is shown in Table 5 and their comments. It could, however, be just as easily used with a mixture of trial and non-trial designs.

A further concern in this regard is the doctrine that "absence of evidence is evidence of absence" when it comes to threats to validity of a specific study design. Often, the reason for not mentioning a design feature in the scientific literature is space constraint, oversight, or mention in a previous paper. Thus, it is possible that, lurking among the "1 to 3 Star" papers is a lot of valid information being ignored. It is difficult to hold a review such as this to the expectation that it will look behind the published documents, yet it can be argued that there is no substitute for understanding all the features of a study before evaluating it. This point also relates to Crooks/Peters important observation that children develop along trajectories. Thus, understanding a study from a longitudinal perspective, rather than from a "specific paper/specific outcome" perspective, would probably give a more valid understanding of whether or not the intervention had actually brought about an important shift in child development.

Another valid point made by Crooks/Peters is the way in which the validity criteria allow certain types of studies to pass muster more easily than others. They point out that only one ecological study makes it into the review. Moreover, in their Tables 5 and 6 they show that narrowly focused studies pas muster more than broadly focused ones; and that studies at very young ages outperform studies at older ages. I would add to that, that selective studies clearly fared better than universal ones. This is troubling, since the changes that will be made in the conditions of child development in Canada over time will tend to be broad rather than narrow; universal rather than targeted; and cutting across ages, rather than confined to labour, delivery and infancy. An argument could be made that what we need, from the standpoint of the Federal-Provincial agreement, is something I would call "policy Bayesianism," after Bayes' notion of successive probabilities. The point here is that, among those who are empowered to take action to improve child development in Canada, a specific range of initiatives is available to them. If they follow gut instinct, stakeholder pressure and political expediency, the probability that they will do the right thing may be give and "X," such that "X" will likely be a low probability. Next, in consideration of the evaluations of the available initiatives, it should be possible to add "evidence of effectiveness" into the mix. When this is added to the traditional criteria for decision-making, the probability of doing the right thing will be "Y." If Y>X, then the review process will have been helpful, and will have contributed to the well-being of Canadian children. Needless to say, a review process like this would look much different from the one under consideration here.

Despite the clear importance of changes that affect the whole "ecosystem" of early childhood, evidence regarding such changes is hard to classify within the intervention framework. Ecosystem change studies do not fit neatly even within 'universal prevention' category. The significance of this can be seen in conjunction with the point made above regarding the range of study designs under consideration. The "one-two epistemological punch" of limiting the review to trials and using clinical prevention framework for a social change activity would, for instance, exclude from consideration comparison studies of changes in children's readiness for school, over time, among different communities engaging in the Children's Agenda in different ways. Yet, in the end, it is evidence like this which would be most important for judging the success of our initiatives overall. In this respect, it is analogous to following infant morality rates among defined subpopulations (e.g., aboriginals) to determine if "things are going in the right direction."

This reviewer was not in a position to carefully check how well the paper selection strategy did in picking up all the relevant studies. However, a few key omissions did stick out. Given the importance of long-term

effects, I found it particularly disturbing that the 27 year follow-up of the Perry pre-school project did not find its way into the review. This was published several years ago, as a free-standing monograph in the High-Scope series. It is among the most important outcome studies to date, because it shows growing effect sizes between age 19 and 27, with a broadening range of welfare and economic outcomes. This study amply illustrates Crooks/Peters points about how outcomes should be understood along trajectories, and the potential for long-term results to differ in substance and direction from the short-term. I am not sure why it was missed. As the authors show in their review, the design of the study itself did pass peer review, so the fact that the 27 year follow-up was published in a "house journal" should not affect its acceptability for review. If, according to the reviewers, it was consciously rejected, then this reinforces my point above that the criteria were too restrictive.

From the standpoint of improving child development in Canada, one of the most significant difficulties in this review is the classification of effect sizes. The Mrazek/Brown schema is also supported by Crooks/Peters as "generally accepted in the field." Thus, my objection is pointed in both directions. I have 3 objections to using a generic effect size criterion here. First, as Rose pointed out in his paper, "Sick individuals and sick populations," a small effect on the distribution of an outcome in the total population may have larger overall benefits than a large effect on a target population. Thus, a reasonable cut-off point for studies of individual effects may be needlessly ambitious for community and population effects. Second, given that we are dealing with developmental trajectories, it is not clear how much of a boost in one developmental domain may be needed to make a long-term difference of importance. For instance, the best example of this is the observation, from the Perry pre-school project, was that the principal value of the early intervention was not in its direct impact on cognitive development. Rather, its benefit came from the fact the intervention children had a more positive experience of transition to school than the controls. Third, if we are dealing with "tipping point" phenomena, the original problem size may be more important than the effect size. Consider the following example ...an enriched pre-school program is put in 2 schools to reduce the number of children going into Grade 1 who will require extra help form the teacher. In the first school, 30% of the pre-school children are "at risk" and the intervention reduces this to 15% needing extra help in Grade 1. In the second school, 15% of the pre-school children are "at risk," and the intervention reduces this to 10% needing extra help in Grade 1. According to the reviewers' criteria, the program at the first school would be more effective than at the second. From the perspective of the Grade 1 teachers, however, the teacher in the first school will have 5/30 kids to divide her attention, while the teacher in the second school will have only 3/30. From what primary school teachers say, such differences as this make a large difference to their overall classroom effectiveness. Thus, from the teachers' perspective, the program at the second school has been more effective than at the first! Thus, evidence of effectiveness that cannot be explained away by bias or chance is much more important than judgments about the adequacy of effect sizes.

It is clear from the NLSCY and inter-jurisdictional comparisons that many of the important determinants of healthy child development are a function of community and family conditions that are strongly "influenceable" by policies coming from far outside the realm of child development interventions. Housing and workplace flexibility policies are but two examples of this. Moreover, Canada is in a period when public agencies across a wide spectrum are being asked to participate in improving the conditions of early childhood. Thus, I

found it disturbing that the review did not include the Self-sufficiency Project, even as a study in progress. The Self-sufficiency Project is a randomized controlled trial of income supplementation for welfare mothers seeking work in two places in Canada: New Brunswick and Vancouver. A collaboration between the Centre for Studies of Children at Risk, Statistics Canada and HRDC has lead to a child development supplement being added to it. The early results concerning labour force activities are rich in information about the program's effectiveness (as it is an effectiveness trial), much of which is promising. Studies like this get directly at the sort of changes public agencies can make to improve child development. Even though the results on child development are not yet available, it is disturbing that this study, and others like it (for instance, the study of moving ghetto families to middle-class neighbourhoods in the US) did not get through the screens for inclusion. In the "not quite a trial" category, the same can be said for Better Beginnings, Better Futures study in Ontario; which is a great example of the risks and benefits of "government funded community development" as a strategy for improving child outcomes.

One of the most important things from the standpoint of improving child development in Canada is knowing whether we have the knowledge to act or not. Thus, it was most disturbing to see the document TOTALLY CONTRADICTED ITSELF on this point. Summary assessments are expressed twice in the document, once on page 17 and once on page 42. This is what is said on page 17:

> "...as a whole, the 11 trials with 5-Star designs and the 23 trials with 4-Star designs show substantial benefit in particular categories of outcome....while 657 or two-thirds of the outcomes were not found to be significant, 280 or approximately 30% of the results showed significant improvement for the intervention group, compared to control. In contrast only 32, or about 3% showed significant harm...."

This, clearly, is a positive assessment, and one that is well-supported by the summary information in Table 5. Moreover, Tables 1 and 2 in Crooks/Peters re-express these data in categories that better show the range of benefits by intervention type and domain of outcome. However, page 42 gives and entirely different spin:

> "...most of the outcomes of the trials with 5-Star and 4_Star designs are not overly impressive. Only 10 percent of the significant findings have strong magnitude of effect. Rarely have these outcomes been replicated, and there have been few, if any, effectiveness trials."

The statement on page 17 says "go" to the policymaker, while the statement on page 42 says, "stop." There is really no point to a structured, disciplined review of this sort if, in the end, the policy conclusions are all a matter of spin. Notwithstanding this contradiction, I believe the conclusion on page 17 is much more useful than the one on page 42. In part, this is because of what I have said about effect sizes above. Since I do not accept their criteria for adequate effects, I am much more convinced by validity of effects. The statement on page 17, which makes less reference to their criteria for effect sizes is, thus, more useful.

In general, more thought needs to be given to the forms in which information from reviews of this nature is summarized for policy consumption. For instance, a particularly good example of this is found on page 15, where it says "the results for educational day care programs are very strong, particularly when they are placed in a comprehensive setting..." This is useful, because it is expressed in terms of a commonly understood and prevalent institutional form (educational day care) and

is expressed at a level of generality that is easily translated from context-to-context (a comprehensive setting). Unfortunately, it is one of the few statements of its type in the review. What is needed is an activity which starts with the information in Crooks/Peters Tables 1 and 2; calculates the ratio of helpful to harmful interventions by domain; identifies the domains where it is very high (e.g., the cognitive domain); identifies the common features of the interventions in this domain; and states them in transferable form, like the example given above. Also, what is needed, and what Crooks/Peters do not provide, is a longitudinal interpretation of studies to complement the domain specific interpretations. The outcome here would be evidence of improvement of developmental trajectories across any and all domains over time. The character of the interventions leading to these results could then be stated in transferable form as described above.

Notwithstanding all that has been said above, the forms of expression in Table 5 (and its successor tables in Crooks/Peters) are very helpful. That is, summarizing the ratio of helpful to harmful studies by domain is very useful, and fits very well into the "policy Bayesian" framework I described above.

Finally, the section of the review on "gaps in research" is very helpful. I especially agree with suggestions number 1, 4, 5, 9 and 10.

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