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Primary Care Interventions to Prevent Child Maltreatment: An Evidence Review for the U.S. Preventive Services Task Force

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The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information (i.e., in the context of available resources and circumstances presented by individual patients).

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Structured Abstract

Purpose: To systematically review evidence on the benefits and harms of interventions provided in or referable from primary care to prevent child maltreatment for the U.S. Preventive Services Task Force (USPSTF).

Data Sources: MEDLINE®, the Cochrane Library, EMBASE, and trial registries, through December 18, 2017; reference lists of retrieved articles; outside experts; reviewers; and surveillance of literature through March 2018.

Study Selection: Two investigators independently selected studies using a priori criteria. Eligible trials (1) enrolled children (from birth through age 18 years with no known exposure to maltreatment and no signs or symptoms of current or past maltreatment) or their caregivers; (2) evaluated interventions feasible in a primary care setting or that could result from a referral by a primary care provider; and (3) reported abuse or neglect outcomes, or proxies for abuse or neglect (injury, visits to the emergency department, hospitalization).

Data Extraction: One investigator extracted data and a second checked accuracy. Two reviewers independently rated quality for included studies using predefined criteria.

Data Synthesis: Twenty-two trials provided evidence on benefits. We found no evidence of differences in reports to child protective services within a 1 year of intervention completion (pooled odds ratio [OR], 0.94, 95% CI, 0.72 to 1.23; 10.6% vs. 11.9%; 10 studies, 2444 participants) or removal of the child from the home within 1 to 3 years of followup (pooled (OR: 1.09, 95% CI, 0.16 to 7.28; 3.51% vs. 3.71%; 4 studies, 609 participants). Owing to heterogeneity of outcome measures, we could not pool other results, but the evidence either demonstrates no benefit or was inconclusive for abuse, neglect, or their sequelae. The evidence suggested no benefit for emergency department visits in the short-term (<2 years), hospitalizations, child development, school performance, and prevention of death. The evidence was inconclusive for long-term outcomes for reports to child protective services and emergency department visits (≥2 years) because results were inconsistent and imprecise. The evidence was also inconclusive for injuries, failure to thrive, failure to immunize, internalizing and externalizing behavior symptoms, school attendance, and other measures of abuse or neglect because of the limited number of trials reporting on each outcome and imprecise results. We found no results on harms.

Limitations: The scope of this review limits conclusions to children who have not experienced maltreatment and to primary-care relevant interventions. Other limitations include the heterogeneity of the interventions and outcome measures and the lack of information on harms.

Conclusions: Overall, the evidence on interventions provided in or referable from primary care to prevent child maltreatment does not consistently demonstrate benefit. We found no evidence on possible harms of these interventions. New studies that address a comprehensive array of risk factors and evaluate outcomes over the long term may help identify effective, generalizable, and acceptable interventions.

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Chapter 1. Introduction

Scope and Purpose

The U.S. Preventive Services Task Force (USPSTF) will use this report to inform an update of its 2013 recommendation on primary care interventions to prevent child maltreatment. In 2013, the USPSTF concluded that the evidence¹ was insufficient to assess the balance of benefits and harms. This report will summarize the evidence for the benefits and harms of interventions to prevent child maltreatment and identify key gaps in the scientific literature.² Evidence on interventions for children with signs and symptoms of maltreatment or known exposure to child maltreatment is outside the scope of this report.

Condition Background

Condition Definition

Child abuse and neglect, also referred to as child maltreatment, is recognized as a global problem with lifelong health and mental health consequences. From an overarching public health perspective, the World Health Organization and International Society for Prevention of Child Abuse and Neglect define child maltreatment as “all forms of physical and/or emotional ill-treatment, sexual abuse, neglect or negligent treatment or commercial or other exploitation, resulting in actual or potential harm to the child’s health, survival, development or dignity in the context of a relationship of responsibility, trust, or power.”³ In the United States, the Centers for Disease Control and Prevention (CDC) have recommended a set of uniform definitions to support public health surveillance of maltreatment.⁴ The CDC definition differentiates child abuse as “acts of commission” and child neglect as “acts of omission.” Words or actions that are deliberate and cause harm, potential harm, or threat of harm are considered acts of commission (e.g., physical, sexual, and psychological abuse). Failure to provide for a child’s basic physical, emotional, or educational needs or to protect a child from harm or potential harm constitutes an act of omission. These acts involve physical, emotional, medical and dental, and educational neglect; inadequate supervision; and exposure to violent environments. The CDC definition specifies that, in either case, harm to a child might not be the intended consequence.

From the legislative perspective, the Federal Child Abuse Prevention and Treatment Act (CAPTA) stipulates key guidance for child protection in the United States. In the most recent CAPTA reauthorization (2010), child abuse and neglect is defined as “At a minimum, any recent act or set of acts or failure to act on the part of a parent or caretaker, which results in death, serious physical or emotional harm, sexual abuse or exploitation, or an act or failure to act, which presents an imminent risk of serious harm.”⁵

The CAPTA definition provides States with minimum standards to apply in their mandatory child abuse and neglect reporting laws (both civil and criminal). This results in considerable variation across States in the statutory descriptions of what constitutes child maltreatment. This

definition landscape is further complicated by the fact that States may amend their laws frequently.

The legislative variation in definitions of maltreatment across and within individual States, along with definitional variation across social service delivery systems and sectors within and outside of the United States, has led to a lack of common operational definitions and measurement in child abuse and neglect research. These measurement challenges, in turn, continue to undermine the accuracy of case identification in research, monitoring, and assessment of the magnitude and nature of child maltreatment and impact of interventions in addressing prevention.⁶

Prevalence and Burden of Disease

Reports of child maltreatment to child protective services (CPS) are one important measure of prevalence of maltreatment. In 2015,⁷ CPS received 4 million referrals for suspected abuse or neglect, representing 7.2 million children (53.2 per 1,000 children). Among the 44 States reporting screened-in and screened-out referrals, 58.2 percent of referrals (3.4 million children) were screened in (that is, the referral was retained for further attention and received a CPS report). A subset of screened-in referrals was identified as victims of abuse or neglect: approximately 683,000 victims in 2015 (national victimization rate of 9.2/1,000). Children may have suffered multiple forms of maltreatment or may have experienced multiple instances of maltreatment. Of those with referrals, 75.3 percent experienced neglect, 17.2 percent experienced physical abuse, 8.4 percent experienced sexual abuse, 6.9 percent experienced other abuse, 6.2 percent experienced psychological abuse, and 2.2 percent experienced medical neglect.

Young children are the most vulnerable. As many as 24.2 per 1,000 children in their first year of life were identified as victimized. Rates of substantiated victimization were higher for girls (9.6/1,000) than for boys (8.8/1,000). African American children are nearly twice as likely to be substantiated victims of maltreatment reports (14.5/1,000) than whites (8.1/1,000) or Hispanics (8.4/1,000). American Indians are also at higher risk for substantiated victimization than whites (13.8/1,000).⁸ In 2015, 1,670 children died as a result of abuse or neglect (2.25 per 100,000 children).⁹

Although reports, investigations, and substantiated victims are one important way to understand the prevalence of maltreatment, not all acts of maltreatment are reported to authorities. All 50 States report cases of abuse and neglect to the National Center for Child Abuse and Neglect Data System, but definitions and rules for reporting vary by State and child protective service agency, and participation, being voluntary, is influenced by resource availability.¹⁰ The National Incidence Study, an approximately decennial sentinel respondent study last completed in 2005–2006, reported that 1.25 million victims (17/1,000) were harmed by maltreatment (harm standard), and nearly 3 million children were at risk of harm from maltreatment (40/1,000 by the endangerment standard).¹¹

In addition to concerns about underreporting, some investigators have raised concerns regarding racial bias versus higher risk in explaining the disproportionate reporting of maltreatment of African American children. Investigations that explore these competing hypotheses of racial bias and higher risk emphasize a complex pathway between child maltreatment and poverty, with

patterns varying by racial and ethnic groups, but they also note that these findings do not rule out racial bias.^{12, 13}

Ultimately, child maltreatment is often a private act known only to the perpetrator and the victim. Estimates of maltreatment can be derived from adolescent self-report, young adult self-report, or parent self-report, although surveys may yield wide variation in estimates based on the methods used such as different sampling frames, modes of assessment, and confidentiality and privacy assurances. Youth participants in the National Longitudinal Study of Adolescent Health self-reported victimization at much higher rates compared with the National Incidence Study. The former cites 28 percent reporting physical assault; 12 percent, physical neglect; 5 percent, contact sexual abuse; and 42 percent, supervision neglect. The 2013-14 National Survey of Children's Exposure to Violence, a representative sample of U.S. telephone numbers, reported that 15.2 percent of 4,000 children and adolescents reported maltreatment by a caregiver.¹⁴

Etiology and Natural History

Etiology and natural history characteristics reported below reflect only *known* cases of childhood maltreatment. Characteristics of those with maltreatment mostly have come from children in the social services system; those reported to CPS or police; or, in some instances, those who have reported maltreatment on a survey either conducted during childhood or reflecting back on child maltreatment as an adult.^{15, 16}

The etiology of childhood maltreatment can be organized into an ecological framework¹⁷ of different systems such as parent factors¹⁸ (genetic factors or social influences¹⁹), child factors viewed as bidirectional influences whereby a child's behavior shapes parental responses^{20, 21} (e.g., children with disability²²⁻²⁴), and social context factors such as attributes of the community or neighborhood that shape the way parents and children interact.²⁵⁻²⁷ Sometimes the social context factors are split into separate community and society factors.²⁸

Maltreatment in early childhood is associated with negative physical and emotional health outcomes that persist and can escalate to serious disorders throughout the life course.²⁹⁻³³ Injuries may include brain injuries, blindness, and fractures.³⁴ Injuries from abuse may lead to disability or death.³⁵ Outcomes for children with maltreatment differ by the duration and severity of the maltreatment. They also differ by child characteristics such as age when maltreated, level of resiliency, and co-occurring parental issues such as mental health problems, substance abuse, and violence.^{36, 37}

For the child victim and into adulthood, child maltreatment has been linked to numerous short- and long-term morbidities. These can include attachment and behavioral problems; cognitive impairment; mental health disorders; violence³⁸⁻⁴¹ and criminal behavior;⁴² physical health problems; and health risk behaviors such as substance use, obesity, and smoking.⁴³⁻⁴⁵ Sexual abuse can lead to sexual risk-taking behaviors that result in unplanned and unwanted pregnancy, sexually transmitted disease, and serious behavioral and emotional consequences.^{46, 47} Abuse and neglect are also associated with impairments in cognitive development, executive functioning, and school performance. Exposure to the chronic stress of maltreatment can affect brain circuitry and hormonal system balances, which is particularly harmful during early childhood, when the

brain is still developing at a rapid rate.^{48, 49}

Neglect can be as damaging as overt physical abuse.⁵⁰ Neglected infants may not receive adequate nutrition or medical care and may be at higher risk of failing to thrive and developing infections;⁵¹ neglect is involved in a majority of child maltreatment deaths.⁵² Children in foster care may experience abuse, neglect, and multiple instances of caregiver loss that can lead to serious emotional and behavioral consequences.^{53, 54} Adverse childhood experience can also have long-term negative consequences on adult education, employment, and income potential.⁵⁵

Chronic and severe abuse and neglect are recognized as forms of *complex trauma* in that they represent “multiple traumatic events, often of an invasive, interpersonal nature ... [with] wide-ranging, long-term impact ... [that] usually begin early in life and can disrupt many aspects of the child’s development and the very formation of self.”⁵⁶ As a result, children with complex trauma tend to be at higher risk for various mental and physical health problems across the life span. The total lifetime cost of all new cases of fatal and nonfatal cases of child maltreatment in the United States in 2008 was estimated to be \$124 billion.⁵⁷

Risk Factors

No single risk factor exists for maltreatment. Some children will be maltreated with only a single risk factor, and others not until several different risk factors interact. In addition, risk factors for maltreatment may vary by the age of the child. Thus, the presence of known risk factors does not guarantee that maltreatment will occur; it only increases the risk that maltreatment might occur.⁵⁸

Risk factors range from parental factors and child factors to societal factors pertinent to whole neighborhoods and communities. Parent risk factors of childhood maltreatment include domestic violence, poor parenting or communication skills, raising a child alone (single parenthood), nonbiological and transient caregivers, young age, poor educational attainment, low income, large number of children, parental history of maltreatment, substance abuse,⁵⁹ and social isolation.^{28, 60} Child risk factors include young age (less than age 4, particularly for neglect), special needs, sex, and having a history of child abuse.^{28, 61, 62} Societal factors include poverty, community and neighborhood violence, local unemployment rates, and weak social networks within communities.^{63, 64}

More recent research also has focused on the factors that prevent or mitigate the risk of childhood maltreatment. These protective factors are believed to increase child or parent resilience to risk exposure, strengthen families, strengthen connections with peers and community members, and enhance social and environmental conditions. Child protective factors include intelligence, good health and self-esteem, good relationships (peer, family, and friend) and social skills, having an optimistic disposition, good self-regulation or an easy temperament, having an active coping style, an internal locus of control, and a balance between seeking help and autonomy. Parental protective factors include nurturing caregiving; healthy parent-child attachment; parental knowledge of parenting and child development; parental coping skills; being part of a supportive, two-parent household with household rules and strong monitoring practices of children’s behavior; higher education attainment and extended family support; and making peace with their own childhood history of abuse.⁶⁵⁻⁶⁷ In addition, parents with supportive

friends who have their basic needs met are less likely to perpetrate maltreatment. Social and environmental protective factors include neighborhood-level middle to high socioeconomic status, adequate housing, good schools, easy access to health care and social services, and supportive adults outside the family who can serve as role models or mentors to children in the community.

Rationale for Intervention

Routine interventions to prevent child maltreatment could potentially reduce exposure to abuse and neglect, improve well-being, and reduce mortality. The focus of this review is on interventions relevant to primary care that are directed at the general population or at high-risk groups without signs and symptoms of maltreatment. The goal of such steps is preventing abuse or neglect from occurring.

Types of Interventions

No established taxonomy exists for interventions that focus on preventing the first incidence of abuse and are relevant to primary care (i.e., they can be conducted in primary care settings or primary care providers can refer patients to appropriate settings). Interventions often attempt to mitigate risk factors and enhance protective factors. Interventions may be implemented in different settings, including the home, newborn nursery, and primary care; school; and community-based settings. They may include parenting programs, comprehensive parent education and support programs, and psychotherapy. Some common interventions include home interventions, pediatric primary care programs, psychotherapy programs, parent education, and community-based programs (**Table 1**).

Recommendations and Clinical Practice in the United States

Existing guidelines either recommend against screening for child maltreatment because of the risk of false positives or mislabeling,⁶⁸ note insufficient evidence,⁶⁹ or make no statement on screening⁷⁰ (**Appendix A2**). Guidelines vary substantially in their confidence in interventions to prevent child maltreatment. The American Academy of Family Physicians agreed with the USPSTF's position of insufficient evidence to recommend preventive interventions in a clinical setting to prevent child maltreatment in children without signs and symptoms of maltreatment. The American Academy of Family Physicians' statement nonetheless describes a list of steps that primary care physicians can take to try to prevent maltreatment. Other guideline groups recommend home visitation programs.^{68, 70} The American Academy of Pediatrics strongly recommends physician involvement in preventing child maltreatment. No national surveys track practice patterns for preventive interventions, although a few studies address practice patterns for those treating children who have experienced maltreatment.⁷¹⁻⁷³

Although the Centers for Disease Control and Prevention's Community Guide⁷⁰ and its supporting systematic review⁷⁴ concluded that home visiting programs had strong evidence of effectiveness in preventing child maltreatment, other systematic reviews have not been as

supportive, and have cited equivocal results. Reviews cite concerns about methods, surveillance bias, selective outcome reporting, validity and reliability of outcomes, and failure to address underlying heterogeneity in programs.^{75, 76} One review that explored underlying heterogeneity of program components found that no single component predicted success.⁷⁵ However, they concluded that alignment between underlying theory and program components, combined with a match between theory and target populations, explains program success.⁷⁵

Clinical Considerations for the Update

This updated review continues to be specific to populations that have not experienced maltreatment. It does not, however, require that eligible populations be at risk for maltreatment, because of the underlying variability in and lack of strong evidence supporting risk assessment tools.

Chapter 2. Methods

Responses to Research Plan Public Comments

Numerous comments received during research plan development for the current update requested clarification on the inclusion and exclusion criteria. In response, we revised the analytic framework to specify the population of interest as “children and adolescents from birth to age 18 years”; also, the inclusion criteria no longer exclude children and adolescents with serious behavioral problems.

We clarified that the evidence review will include family-focused interventions, which may be directed at the caregiver and may not include components directed at the child. The review includes interventions thought to be feasible in primary care settings or referred away from primary care settings to specialist care or other programs and includes interventions conducted in labor and delivery settings in hospitals, home settings, and nonspecialty settings. Revisions in response to public comments resulted in the addition of two new outcomes: improved school attendance and performance and reduced risky behaviors and outcomes (e.g., sexually transmitted diseases).

Key Questions and Analytic Framework

The investigators, U.S. Preventive Services Task Force (USPSTF) members, and Agency for Healthcare Research and Quality (AHRQ) Medical Officers developed the scope, key questions (KQs), and analytic framework (**Figure 1**) that guided the literature search and review. Two KQs guide this review:

1. Do primary care feasible or referable interventions to prevent child maltreatment reduce exposure to abuse or neglect; improve behavioral, emotional, physical, or mental well-being; or reduce mortality among children and adolescents without obvious signs or symptoms of abuse or neglect?
2. What are the harms of primary care feasible or referable interventions to prevent child maltreatment?

Contextual Questions

We include two contextual questions (CQs) to help inform the report:

1. What is the validity and reliability of risk assessment tools to identify children and adolescents who are at risk of child maltreatment?
2. Do primary care–feasible or referable interventions to prevent child maltreatment reduce parent-reported measures of exposure to abuse or neglect?

These CQs were not a part of our systematic review. They are intended to provide additional

background information. Literature addressing these questions is summarized in **Appendix A**.

Search Strategies

We searched MEDLINE® (via PubMed), the Cochrane Library, and EMBASE for English-language articles published from November 1, 2011, through December 18, 2017. We used Medical Subject Headings as search terms when available and keywords when appropriate, focusing on terms to describe relevant populations, screening tests, interventions, outcomes, and study designs. **Appendix B2** describes the complete search strategies.

To supplement electronic searches, we reviewed the reference lists of pertinent review articles and studies meeting our inclusion criteria and added all previously unidentified relevant articles. We reassessed all articles in the 2013 report (**Appendix B1**). Systematic searches in the 2013 report extended through June 2012.^{1, 77} We also included articles from other systematic reviews in our hand-search yield.

We also conducted targeted searches for unpublished literature by searching ClinicalTrials.gov, Cochrane Clinical Trials Registry, and the World Health Organization International Clinical Trials Registry Platform. We continued surveillance of literature through March 2018.

Study Selection

We selected studies on the basis of inclusion and exclusion criteria developed for each KQ for identifying populations, interventions, comparators, outcomes, timing, settings, and study designs (PICOTS) (**Appendix B3**). **Appendix C** lists studies excluded at the full-stage review stage. We imported all citations identified through searches and other sources into EndNote X7.

Two investigators independently reviewed titles and abstracts. We dually and independently reviewed the full text of abstracts marked for potential inclusion by either reviewer. Two experienced team members then resolved disagreements.

Population

The focus of the review is on children and adolescents (birth through age 18 years) with no known exposure to maltreatment and no signs or symptoms of current or past maltreatment. We required included studies to have a majority of children (>50%) without known exposure to maltreatment and no signs or symptoms of current or past maltreatment. If information on the proportion with known exposure or with signs or symptoms was unavailable in the report, we sent an inquiry to the author. In cases of nonresponse or lack of clarity in the published reports, we planned to include these studies only in sensitivity analysis.

We excluded studies consisting entirely of symptomatic children and adolescents undergoing diagnostic evaluation for conditions related to abuse or neglect, asymptomatic children with known exposure to child maltreatment, children (regardless of symptomatology) who have

maltreatment perpetrated against them by a caregiver at baseline, and perpetrators of maltreatment.

Interventions

We included studies that evaluated services that were feasible in a primary care setting or could be sent as referrals by a primary care provider. These services may have been implemented by a nonclinician; they may also have included home visiting programs, primary care–based programs, respite care, parent education programs, and family support and family-strengthening programs. We excluded communitywide programs only, such as public awareness campaigns or public service announcements, without specific interventions linked to clinical settings.

Comparators

We included comparators of usual care, delayed interventions, or active interventions that allow for assessment of the independent contribution of the primary care–feasible or referable preventive intervention (e.g., clinical interventions plus media campaigns vs. media campaigns).

Outcomes

We required that all studies report direct or proxy measures of abuse or neglect. Direct measures include those reflecting physical, sexual, or emotional abuse perpetrated by a parent or caregiver; physical (e.g., failure to thrive), emotional, dental/medical (e.g., lack of immunizations or well-child visits), or educational neglect; reports to CPS; and removal of the child from the home. Proxy measures include injuries (e.g., broken bones, bruises, burns), visits to the emergency department, and hospitalizations. For studies that reported direct or proxy measures of abuse or neglect (other than self-report), we then evaluated behavioral, emotional, mental, or physical well-being.

Settings

We included studies that occurred in (1) pediatric, primary care, family medicine, or school-based clinics or (2) other settings where services are offered that could result from an assessment by a primary care clinician in a home setting or behavioral health provider’s office. We required that studies were conducted in countries categorized as “very high” on the Human Development Index.⁷⁸

Study Designs

We limited KQ 1 to randomized, controlled trials (RCTs) and systematic reviews. For KQ 2, we also searched for eligible cohort trials with a control group and case-control studies.

Studies in the 2013 USPSTF Review

We applied, dually and independently, the inclusion and exclusion criteria described above to studies included in the 2010 USPSTF review with the exception of three irretrievable government reports and gray literature (document links no longer work). We resolved disagreements by discussion and consensus; if necessary, we sought adjudication.

Data Abstraction and Quality Rating

For each included study, one investigator extracted pertinent information about the methods, populations, interventions, comparators, outcomes, timing, settings (PICOTS), and study designs (**Appendix D**). A second investigator checked all data extractions for completeness and accuracy. Among included studies from the 2013 report, one reviewer checked for errors in previously generated abstraction tables and updated them as needed.

We assessed the quality of studies as good, fair, or poor using predefined criteria (**Appendix E**). We planned to rate the outcomes for KQ 1 (benefits) and KQ 2 (harms) separately for studies as high risk of bias, low risk of bias, or some risk of bias concerns based on a tool developed by the Cochrane Collaboration for assessing the risk of bias of RCTs.⁷⁹ Two investigators independently evaluated the risk of bias of each study. We then cross walked the risk of bias criteria to USPSTF criteria for overall ratings of good, fair, or poor.⁸⁰ We checked the quality ratings of all eligible studies from 2013 to ensure that studies met our current quality rating criteria.

If we identified eligible systematic reviews, we planned to rate the quality of systematic reviews using ROBIS,^{81, 82} a tool designed to evaluate the risk of bias of systematic reviews. Using this tool, each systematic review is rated as low, unclear or some concerns, or high risk of bias. As with the Cochrane tool, low risk of bias corresponds to good quality, high to poor quality, and unclear represents uncertainty. **Appendix B4** describes the quality rating criteria for each tool.

We resolved disagreements by discussion and consensus. We rated studies as poor quality (i.e., high risk of bias) for the following reasons: groups assembled initially were not close to being comparable or were not maintained throughout the study, unreliable or invalid measurement instruments were used or not applied equally among groups (including not masking outcome assessment), and intention-to-treat analysis was lacking.

Data Synthesis and Analysis

We evaluated the findings for each outcome, first using a qualitative approach that considered the clinical and methodological characteristics of the evidence base. We paid close attention to PICOTS criteria in evaluating heterogeneity and summarize study characteristics for the evidence base for each outcome in **Appendix F**. With relatively rare outcomes such as reports to CPS, removal from the home, and hospitalizations, a longer time period for observation of outcomes allows for a greater accumulation of events, but it also increases both the likelihood of

unmeasured co-interventions that vary differentially between arms and the attenuation of intervention effects overall. Because of the potential heterogeneity of combining longer-term outcomes with studies reporting results at or close to the end of the intervention, we generally limited meta-analyses to the first report of outcomes from studies (generally within a year of study completion).

We then presented results either qualitatively or quantitatively. We generated pooled estimates when at least three similar studies were available, using the Comprehensive Meta Analysis program.⁸³ For all meta-analyses, we used random effects models and calculated the chi squared statistic and the I^2 statistic (the proportion of variation in study estimates due to heterogeneity) to assess statistical heterogeneity in effects between studies.^{84, 85} An I^2 from 0 to 40 percent might not be important, 30 percent to 60 percent may represent moderate heterogeneity, 50 percent to 90 percent may represent substantial heterogeneity, and 75 percent to 100 percent represents considerable heterogeneity.⁷⁹ The importance of the observed value of I^2 depends on the magnitude and direction of effects and on the strength of evidence for heterogeneity (e.g., p-value from the chi squared test or a confidence interval for I^2). However, as precision and the number of subjects increase, I^2 may become inflated toward 100 percent and may not reflect clinically relevant heterogeneity.⁷⁷

We presented results from fair- and good-quality studies for each outcome. We excluded poor-quality studies from the main analysis. Sensitivity analysis in **Appendix F** provide information from poor-quality studies.

USPSTF Involvement

This review was funded by AHRQ. Staff of AHRQ and members of the USPSTF participated in developing the scope of the work and reviewed draft manuscripts, but the authors are solely responsible for the content.

Chapter 3. Results

Literature Search

We identified 2,261 unique records and assessed 275 full texts for eligibility (**Figure 2**). We excluded 242 records for various reasons detailed in **Appendix C** and included 22 RCTs of good or fair quality (in 33 articles). All included trials addressed KQ 1; none addressed KQ 2. Of the 22 included trials, 12 (in 21 articles [16 previously included, 5 newly identified]) had been included in the 2013 report for the USPSTF, and 10 (in 12 articles) are newly identified.

Details of quality assessments of included studies and studies excluded based on poor quality are provided in **Appendix E**. **Appendix B1** lists the eligibility status of studies included in the previous review. **Appendix D** presents details for included studies in Evidence Tables. **Appendix F** presents sensitivity analyses to account for poor-quality studies that were excluded from the review.

Overview of Study Characteristics

Table 2 summarizes study characteristics for all trials used to answer KQ 1. Additionally, **Appendix F** provides detailed characteristics of the evidence base for each outcome. The evidence base spans more than three decades; the earliest included study recruited participants in 1976⁸⁶ and the most recent through 2010. Nearly all trials (21/22) had a home visiting component; some trials present results from attempting a similar model of home visiting interventions in different settings (e.g., the Healthy Families intervention in Alaska^{87, 88} and New York;^{89, 90} replications^{91, 92} of the Nurse Family Partnership,⁹³⁻⁹⁹). More than two-thirds of the trials recruited women who were age 20 years or older, on average. The majority of trials included a usual care comparator (19/22 trials) and were set in the United States (16/22). In other respects, however, the evidence base is heterogeneous in study populations and interventions.

Regarding enrolled populations, 13 trials enrolled mothers or mothers prenatally or immediately after birth; the mean age of infants in the 9 other trials ranged from less than 6 months to 8 years. One study enrolled fathers. Fewer than one-third of the trials reported maltreatment at baseline; other trials either did not specify or enrolled women during pregnancy.

More than one-half identified participants or infants to be at risk. Risk factors included health status of the infant, demographic and socioeconomic characteristics of the mother or family, and prior substance abuse.

Regarding treatment, as noted above, 21 of 22 included trials featured home visits. The exception was one trial focusing on behavioral therapy for male patients entering outpatient alcohol treatment who had legal guardianship of at least one child between ages 8 and 12 years.¹⁰⁰ For the trials with home visit components, the content, use of other components, personnel, intensity, and duration varied. Although the specific purpose of the home visiting program varied by trial, trials described the following activities: assessing family needs; developing a relationship

between the home visitor and the client; providing information, referral, and parent education; promoting child health, safety, and development; providing clinical care; enhancing family functioning and positive child-parent interactions; building supportive networks; and creating family plans to support parental life course development and self-sufficiency. A minority of trials featured home visit services as the sole intervention.^{87-90, 101-108} Thirteen provided home visits in the context of clinical support.^{86, 91-95, 109-117}

Fifteen trials involved clinical personnel in some capacity, which included nurses or mental health professionals sometimes serving as home visitors or providing comprehensive pediatric service as an intervention component. Of the 21 home visit trials, seven had nurses as home visitors,^{91-95, 105, 106, 110, 116} two had mental health clinicians as home visitors,^{107, 114} four had paraprofessional home visitors,^{86, 89, 104, 109} and one had peer home visitors.¹¹⁵ The remaining trials did not specify the training of the home visitors.^{87, 88, 101-103, 108, 111-113, 117} The duration of the intervention ranged from 3 months^{86, 100} to 3 years.^{105, 106, 112, 113} The planned number of sessions, when reported, ranged from 5¹¹⁶ to 41 sessions.^{101, 102}

KQ1. Benefits of Interventions to Prevent Child Maltreatment on Direct or Proxy Measures of Maltreatment

Reports to Child Protective Services

Thirteen trials (14 publications) reported on reports to CPS, and one trial reported on safeguarding actions (**Appendix D Tables 11 and 13** present data on 13 trials).^{86, 87, 89, 91, 92, 95, 100, 101, 104-106, 108, 110, 111, 114} All eligible trials reported their first results during the intervention (1 year from baseline), at the end of the intervention, or within a year of the completion of the intervention. A subset of trials reported outcomes at one or more time points after the first analysis of results. The timing of these reports varied, from within 6 months of the initial results,^{111, 189, 114} to 2 years after the initial results,¹¹⁴ or over the longer term (6 years after the initial results,⁸⁹ when the child was 7 years of age,⁹⁰ or 13 years after the initial results, when the child was 15).⁹⁷⁻⁹⁹

Results for First Followup

The pooled odds ratio (OR) from 10 trials, all having reported results within a year of completion, suggested no difference between arms (OR, 0.94; 95% confidence interval [CI], 0.72 to 1.23, I²: 6.3%; **Figure 3**). The trials suggest a trend toward lower event rates in the intervention arm (10.6% [129/1221]) when compared with the comparator arm (11.9% [145/1223]). Four trials could not contribute to the meta-analysis. One trial reported only relative risks (RR; i.e., no raw data) with asymmetric confidence intervals that we could not recalculate.¹⁰¹ A second provided counts without standard deviations or frequencies (no statistically significant differences; results not reported [not included in Appendix tables]).⁸⁶ A third trial did not specify the time period of outcome measurement, reporting only that the arms did not differ significantly, with a reported $p=0.769$.¹⁰⁴ A fourth trial reported safeguarding in the United Kingdom. We did not include this outcome in the meta-analysis because it included actions beyond reports to child protection. The outcome came from any record in general practitioner notes indicating the initiation, progression, or closure of a safeguarding process.⁹²

These records included initial assessment, being identified as a child in need, and child protection conferences. The study found higher rates of safeguarding in the intervention arm (adjusted OR [AOR], 1.85; 95% CI, 1.02 to 2.85).⁹²

Results for Subsequent Followup

Trials reporting additional results within 6 months¹¹¹ or 1 year^{89, 114} of the original results also reported no difference between the arms.

Trials measuring outcomes for later time points provided mixed results: two trials reported statistically significant differences and one reported no difference. One trial measured outcomes at 36 months from baseline and reported a statistically significant difference favoring the intervention arm; the trial reported a higher probability of *no* involvement with CPS in the intervention arm (AOR, 2.1; 95% CI, 1.0 to 4.4).¹¹⁴ A second trial reported outcomes at 7 years (5 years after the end of intervention^{89, 90}) and reported no differences between arms in the cumulative rate of the biological mother or the target child being confirmed as a subject or a victim in CPS reports through 7 years of age (27.1% vs. 29.6%; AOR, 1.13, $p>0.1$; CIs not reported [161/595 vs. 171/579; calculated OR, 1.13; 95% CI, 0.88 to 1.46]).⁹⁰ A third trial followed children through age 15 but did not provide sufficient details for independent calculation of effects. The authors noted that the intervention group had fewer child maltreatment reports involving the mother as perpetrator ($p=0.01$),⁹⁸ fewer child maltreatment reports involving the study child ($p=0.04$),⁹⁸ and fewer verified reports of parents as perpetrators of child abuse and neglect ($p<0.001$).⁹⁷ This trial also evaluated time to event and found that the treatment effect by time period was significant with longer periods of survival free of CPS reports for children ages 4 to 15 years than for children from birth to age 4 years.⁹⁹

Removal of Child from Home

Five trials^{101, 102, 109, 110, 115, 116} reported on outcomes relating to removal of the child from the home. Four trials contributed to a pooled analysis of removal of the child from the home across time points ranging from 12 months to 3 years after baseline (**Appendix D Table 14**).^{101, 102, 109, 110, 116} The results show no statistically significant differences between study arms on this outcome (3.5% [11/313] vs. 3.7% [11/296]; OR, 1.09; 95% CI, 0.16 to 7.28; I^2 , 61.8%; 4 trials; N: 609; **Figure 4**).

One trial, reporting on removals at birth, included CPS-involved placements and informal care arrangements (type of placement by study group not specified).¹¹⁵ The trial also collected data on the percentage of children in out-of-home care at followup but did not differentiate new removals from placements at the time of birth. Because of measurement issues with the followup outcome, we focused on removal rates only at birth and did not include results in the pooled analysis above. This trial reported results with a different direction of effect but no statistically significant difference between study arms; 9 percent of the intervention group and 4 percent of the control group had been placed in out-of-home care at birth (the intervention began during pregnancy) (N=187/225; OR, 1.55; 95% CI, 0.61 to 3.94).

Other Measures of Abuse or Neglect

Two RCTs^{103, 109} reported on study-specific measures of abuse (**Appendix D Tables 16 and 17**). These measures included physical abuse (hitting with the hand or objects, biting, burning with objects or by immersion, twisting, shaking, throwing or pushing so as to cause a fall, or hair pulling; identified from review of public agency documents from the Tennessee Department of Human Services)¹⁰⁹ and neglect (abandonment, leaving a child with an inappropriate caretaker, gross failure to seek medical care, failure to provide shelter or nutrition, or gross failure to provide for normal intellectual development; identified from review of public agency documents from the Tennessee Department of Human Services,¹⁰⁹ and results from the Framingham Safety Survey about household hazards¹⁰³). One trial reported no differences, finding 13/141 cases (9.2%) of physical abuse in the intervention arm vs. 8/122 (6.6%) in the comparator arm (RR, 1.4 [95% CI, 0.58 to 3.62]). The same study¹⁰⁹ reported 15/141 cases (10.6%) cases of neglect in the intervention arm vs. 5/122 (4.1%) in the comparator arm (RR, 2.79 [95% CI, 0.98 to 7.91]).¹⁰⁹ The second reported a statistically significant difference, but the clinical importance of the effect is unclear. The trial reported mean values on the Framingham Safety score of 1.72 (intervention) vs. 1.68 (comparator); higher scores represent greater safety. The trial noted a p-value of 0.03 for this outcome but provided no measures of dispersion for us to calculate mean differences independently.¹⁰³

Injuries With a High Specificity for Abuse or Neglect

One trial found no statistically significant differences in the rates of nonaccidental injuries (0/64 vs. 1/71; calculated RR, 0.37; 95% CI, 0.015 to 8.91) (**Appendix D Table 18**).¹¹⁶

Emergency Room Visits: Findings

Eleven trials reported on emergency room (ER) visits (**Appendix D Tables 20 and 22**).^{86-88, 92-99, 101, 102, 105-107, 110-113, 117, 118} The timing and type of outcome measurement varied substantially across trials; several trials presented outcomes at multiple time periods. To ensure that we captured all the evidence without inappropriately combining different periods of followup, we present the results by timing of outcome measurement first and then by type of outcome measurement for each time period. The results were generally inconsistent in direction of effect.

Results for Followup <1 Year

Two trials reported outcomes at 6 months of corrected gestational age and found no statistically significant difference in the percentage of infants in each of four arms who used the ER from age 0 to 6 months (p=0.637) in one study¹¹¹ and AOR: 1.52; 95% CI, 0.86 to 2.70 in the second study.⁹²

Results for Followup From 1 to <2 Years

Of these 10 trials, six reported ER visit outcomes at between 1 and 2 years after enrollment or recruitment.^{86, 95-99, 101, 102, 107, 111, 117, 118} Measurement of outcomes varied and included (1) mean number of all-cause ER visits, (2) mean number of ER visits for accidents and injuries, (3)

number of children using the ER for any reason, and (4) total ER visits. Overall, the results are inconsistent in demonstrating benefit.

Because three of five trials reporting on mean number of all-cause ER visits do not provide measures of dispersion, the results cannot be pooled.^{95, 102, 107} Three trials reported no statistically significant differences.^{102, 107, 117, 118} Two trials reported statistically significant differences at or near the $p=0.05$ level.^{95, 111}

One trial, which reported the mean number of ER visits at 12 months specifically for accidents and injuries, showed no statistically significant difference between study arms.⁹⁵⁻⁹⁹

Two trials reported the number of children in each group who used the ER for any reason; calculated RRs indicate no differences for intervention arms compared with usual care at either 12 months or 18 months.^{111, 117, 118}

One trial of extended contact between mothers and neonates with or without home visits, when compared with usual care, reported on total number of ER visits per arm (rather than means; no standard deviations were reported). The study authors noted a lack of statistical significance.⁸⁶

Results for Followup From 2 to <4 Years

Of these 11 trials, six reported ER visit outcomes at 2 to >4 years of followup.^{87, 88, 92-99, 105, 106, 112, 113} Variations in the type of outcome reported again precluded pooling. Outcomes included (1) mean number of all-cause ER visits; (2) mean number of ER visits for accidents, injuries, and ingestions; (3) number of children seen in the ER; (4) number of children seen for accidents or injuries; and (5) number of children seen for injuries or ingestions. Overall, the results are inconsistent in demonstrating benefit.

Two trials reported the mean number of all-cause ER visits over the 2-year study period.^{87, 95} One trial reported a statistically significant difference;⁹⁵ the second reported no statistically significant differences.⁸⁷

Two trials reported the mean number of ER visits specifically for accidents, injuries, or ingestions.⁹³⁻⁹⁹ One reported no difference;⁹³ the other reported a statistically significant reduction in mean number of ER visits for the nurse-visited arm compared with the control arm ($p=0.03$).⁹⁵

Two trials^{87, 88, 112} reported the number of children seen in the ER but found no statistically significant difference between study arms (AOR, 1.23; 95% CI, 0.74 to 2.05;^{87, 88} AOR, 1.21 95% CI, 0.96 to 1.52¹¹²).

Two trials reported the number of children seen specifically for accidents or injuries.^{105, 106, 112, 113} One study found a statistically significant difference (OR, 0.59; 95% CI, 0.36 to 0.98),^{105, 106} and the other found no statistically significant difference (AOR, 0.94; 95% CI, 0.65 to 1.34).^{112, 113}

One trial found no statistically significant difference in the proportion of children seen

specifically for injuries and ingestions (AOR, 1.16; 95% CI, 0.92 to 1.46).⁹² This study also combined emergency department visits and hospitalizations and did not find any statistically significant differences (AOR, 1.32; 97.5% CI, 0.99 to 1.76).

Long-Term Followup (≥4 Years)

Two trials reported long-term outcomes at 4⁹⁶ and 5 to 5.5 years;¹¹³ they yielded mixed results. One trial, which evaluated outcomes at 4 years for three groups,⁹⁶ reported a 35 percent reduction in ER visits of all types for children in the nurse-visited group ($p=0.0008$) compared with rates for the control group but no difference in the number of ER visits for injuries or ingestions ($p>0.05$); the trial did not report raw numbers, RRs, or CIs. One trial, which reported the proportion of children who had used the ER in the past year at the 5- to 5.5-year followup,¹¹³ showed no statistically significant difference between groups (10% vs. 9.2%; AOR, 0.96; 95% CI, 0.73 to 1.27).

Hospitalization: Findings

Twelve trials reported on hospitalization outcomes (**Appendix D Tables 24 and 26**).^{86-88, 92, 93, 96, 101, 105, 106, 110, 111, 113, 116, 118} Because of substantial heterogeneity in outcome definitions and time periods of interest, results could not be pooled.

Outcomes varied in their degree of specificity to child abuse and neglect. They included (1) number of children with hospital admission as a result of an injury that was referred for independent investigation by the Family and Children's Services staff and was concluded to have arisen as a result of a nonaccidental injury to the neonate,¹¹⁶ (2) number of children hospitalized because of child abuse and neglect,¹⁰⁵ (3) proportion of children hospitalized because of injury or ingestion,⁹² (4) number of children hospitalized for ambulatory-care sensitive conditions, (5) number of children rehospitalized, (6) number of children with all-cause hospitalization, (7) mean number of all-cause hospitalizations, (8) total counts of hospital visits, (9) mean number of hospital days, and (10) types of injuries reported among those hospitalized. In general, the evidence does not demonstrate benefit for the active intervention arm(s).

One trial of a postnatal home visitation program led by nurse-midwives found no differences in hospital admissions at 18 months resulting from injury referred for independent investigation by the Family and Children's Services staff and concluded to have arisen as a result of a nonaccidental injury to the neonate.¹¹⁶

One trial each found no difference in the number of children hospitalized because of child abuse and neglect,¹⁰⁵ the number of children hospitalized for ambulatory-care sensitive conditions,⁸⁷ and the number of children rehospitalized at 14 days and 18 months (the original cause was not specified).¹¹⁰

One trial found no statistically significant differences in the proportion of children hospitalized because of injury or ingestion at 6 or 24 months.⁹² As noted above, the study did not report any significant differences after pooling emergency department visits and hospitalizations.

Four of five trials reporting on the number of children hospitalized found no differences.^{88, 101, 102, 113, 117} One trial reported four outcomes for the number of children hospitalized (6 months followup, 12 months followup, less than 24 hours stay, more than 24 hours stay); the investigators reported no statistically significant differences for three of these outcomes. The exception was the number of children hospitalized for more than 24 hours at 6 months (lower numbers in the intervention arm when compared with the control arm, $p=0.017$).¹¹¹

One trial found that the home visitation group had lower overall rates of hospital admission for unintentional injury than the control group at the 9-year followup (28.3% vs. 42.1%, $p<0.05$).^{105, 106}

Three trials found no statistically significant differences in the mean number of all-cause hospitalization.^{93, 96, 117} One trial reported no differences in total counts of hospital visits (measures of dispersion not reported).⁸⁶

With respect to other hospitalization outcomes, one trial found significantly fewer mean hospital days for nurse-visited children in a home health program than for children in the usual care arm (log incidence difference=-0.66; 95% CI, -1.21 to -0.13; $p<0.05$).⁹⁶ Other home visitation trials did not find between-group differences in hospital days.^{101, 117}

One trial also reported differences in the severity of injuries between home visitation program groups.⁹³ The three nurse-visited children from this trial who were hospitalized had burns to the face, coin ingestion, and ingestion of iron medication; the 13 children in the control group were hospitalized for fractures (fibula, tibia, skull [two children]), head trauma without skull fracture [three children]), strangulated hernia with delay in care, coin ingestion, suspected child abuse and neglect, burns (face and neck, both legs), and finger injury with osteomyelitis.⁹³

Failure to Thrive

One trial reported on failure to thrive. It found no statistically significant differences between study arms for this outcome (0% [0/39] vs. 2.5% [1/40]; RR, 0.34, 95% CI, 0.01 to 8.14) (**Appendix D Table 28**).¹¹⁰

Failure to Immunize

One trial reported on failure to immunize. It found no statistically significant differences between study arms in the rate of *no* vaccinations at 6 months (calculated RR, 0.49; 95% CI, 0.16 to 1.52) (**Appendix D Table 30**).¹¹⁶

KQ1. Benefits of Interventions to Prevent Child Maltreatment on Other Outcomes

Internalizing and Externalizing Behavior

Six trials reported on internalizing (depression, anxiety) and externalizing (disruptive, aggressive, or delinquent) behavioral outcomes in children (**Appendix D Tables 32 and 34**).⁸⁷⁻⁹⁰

93, 94, 101, 105, 106, 112-114 As with other outcomes, the evidence included substantial heterogeneity in the timing and type of outcome measurement. Overall, the findings are inconsistent. Overall, three of six trials found a reduction in behavior difficulties in children in primary care interventions to prevent child maltreatment.^{87, 88, 105, 106, 114}

Results for Followup ≤2 Years

One trial¹¹⁴ reported behavior outcomes at 6 months and 12 months¹¹⁴ on the Internalizing and Externalizing scales of the Infant Toddler Social Emotional Adjustment Scale (ITSEA). The study presented results that adjusted for baseline values and repeated measures and found a significant effect of the intervention on the proportion of children with ITSEA externalizing behaviors ($p < 0.05$) and mean ITSEA externalizing behaviors at 12 months (mean score: 13.8 vs. 18.4, effect size 0.094) but not at 6 months. The study found no statistically significant differences between arms for proportion of children with ITSEA internalizing behaviors or mean ITSEA internalizing behavior scores at 6 months or at 12 months.

Results for Followup for 2 to <4 Years

Five trials reported outcomes between 2 and 4 years of followup; three found no differences and two found statistically significant differences. One trial^{93, 94} of nurse home visits examining child behavior outcomes at 2 years of age using the Child Behavior Checklist (CBCL) found no difference between arms at age 2 years. A second trial examined outcomes of a paraprofessional home visitation program at age 7 years on five subscales of the CBCL measuring rule-breaking, aggressive behaviors, social problems, anxious depressed, and withdrawn depressed behaviors but found no significant differences between arms.^{89, 90} One trial reported outcomes at 30 to 33 months^{112, 113} and found that no statistically significant differences between intervention and control arms for the proportion or mean scores of children with aggressive behavior problems or anxious or depressed problems based on CBCL scores (although trends favored the control arm).

One trial^{87, 88} found that children in the intervention group were more likely to have a higher percentage of participants with a normal CBCL internalizing score at age 2 years (87% vs. 79%; AOR, 2.06; 95% CI, 1.31 to 3.25) and they had significantly lower mean scores of internalizing behavior problems on the CBCL than usual care (48.2 vs. 51.0, mean difference: -2.8; 95% CI, -4.2 to -1.5). More participants in the intervention group were found to have CBCL externalizing scores in the normal range (82% vs. 77%; AOR, 1.48; 95% CI, 1.14 to 1.94) but no statistically significant differences were found for externalizing behavior problems on the mean CBCL score.

One trial examined outcomes at 36 months.^{105, 106} At 36 months of age, the study reported lower mean scores and rates of internalizing problems (mean score: 9.86 vs. 10.12; OR, 0.13; 95% CI, 0.03 to 0.23; Cohen's d, 0.26; 95% CI, 0.06 to 0.47; $p < 0.01$) and lower overall mean scores and rates of behavior problems on the ITSEA (mean score: 9.87 vs. 10.11; OR, 0.12; 95% CI, 0.02 to 0.22; Cohen's d, 0.24; 95% CI, 0.04 to 0.44) but no differences for mean scores for externalizing behaviors as assessed by the ITSEA.

Long-Term Followup (≥ 4 Years)

Three trials evaluated long-term outcomes. One trial reported fewer issues of concern in the intervention when compared with the control arm, one reported no effects, and one reported more issues of concern in the intervention arm.

One trial that reported outcomes at 36 months reported outcomes again at ages 5, 6, and 9 years.^{105, 106} Behavioral outcomes were assessed again at ages 5, 6, and 9 years using the Strengths and Difficulties Questionnaire, and at age 9 years, the intervention group demonstrated fewer overall behavior problems (mean score: 9.91 vs. 10.08, Cohen's d , 0.17; 95% CI, 0.06 to 0.29; $p < .05$).

One trial reported on child internalizing and externalizing behavior problems outcomes at age 9 years, 7 years after the intervention ended, using the Computerized Diagnostic Interview Schedule for Children and found no statistically significant differences between arms for mother or teacher reports of behavior problems.^{93, 94}

In one trial (with trends favoring the control arm at 30 to 33 months) at 5.5 years,^{112, 113} mothers in the intervention group reported more borderline or clinical behavioral concerns on the CBCL (18.1 vs. 14.8%; OR, 1.35; 95% CI, 1.10 to 1.64).

Social, Emotional, and Other Developmental Outcomes Not Otherwise Categorized

Five trials evaluated discrete social, emotional, or other developmental outcomes separately from overall measures of externalizing or internalizing problems (**Appendix D Tables 36 and 37**).^{90, 94, 101, 102, 112-114} The heterogeneity of outcomes precluded meta-analysis, but all trials reported results that were not statistically significant.

One trial evaluated dysregulation midway through the intervention period and at intervention completion and found no significant difference between study arms at 6 or 12 months post-baseline.¹¹⁴

Another trial¹¹² reported sleep problems as an outcome, assessed toward the end of the intervention period when the children were 30 to 33 months of age.¹¹² The mean scores were not significantly different between the intervention group and control group. Longer-term outcomes from this same trial examined children's social skills when the children were 5 to 5.5 years of age, again finding no difference between the intervention and control groups ($p = 0.40$).¹¹³

In a third trial,⁹⁰ researchers assessed attention and social problems using subscales of the CBCL when children were 7 years of age, at 5 years after the intervention had been completed.⁹⁰ The trial demonstrated no significant differences between the intervention and control groups for either attention or social problems.

A fourth trial found no significant differences between study arms in a few school-related outcomes (conduct, antisocial behavior, academically focused behavior, and peer affiliation) at a followup 7 years after the intervention had been completed, when children were 9 years of age.

One trial assessed but did not report infant or toddler social and emotional adjustment outcomes.¹⁰¹ A subsequent cost evaluation alluded to the results not being significant but did not report specific outcome data.¹⁰²

Child Development as Measured by the Bayley Development Scales

Four trials^{87, 88, 93-99, 101} reported on child development as measured by the Bayley Scales of Child Development (**Appendix D Tables 38 and 39**). The results generally indicated no differences between intervention and control groups, with the exception of some results from one trial.⁸⁸

Two trials reported Bayley Scale outcomes at 1 year of age; both reported no statistically significant differences.^{95, 101}

Two trials reported on Bayley scale outcomes when children were 2 years of age.^{88, 93} One trial reported no difference in the Bayley mental index at 2 years of age.⁹³ The other evaluated the Bayley mental and psychomotor indices at 2 years of age and found a significant difference in the Bayley mental development index with those in the experimental group having a 3.2-point higher mean score (mean score: 88 vs. 84.8 [<85 is the threshold for mild delay]; 95% CI, 1.2 to 5.2).⁸⁸ The mean difference between the two groups was not significant for the psychomotor index.

One of these two trials (above) also reported the proportion of children in each group with an index score greater than 85 (i.e., in the normal range).⁸⁸ The experimental group had higher adjusted odds of being in the normal range on the mental index. For the mental index, 58 percent of the experimental group and 48 percent of the control group were in the normal range, with an AOR, of 1.55 (95% CI, 1.01 to 2.37). The unadjusted odds were not statistically significant (calculated OR, 1.50; 95% CI, 0.91 to 2.47). The groups were more similar for the psychomotor index, with 85 percent of the experimental group and 80 percent of the control group in the normal range; the differences were not statistically significant (adjusted OR, 1.36; 95% CI, 0.72 to 2.58).

Other Development Outcomes

Three trials reported on other outcome measures (**Appendix D Tables 41 and 43**).^{92, 95, 113} One trial reported no measures of variance but noted that the overall results for a group of infant development tests was not statistically significant.⁹⁵ Another trial found no statistically significant differences in the proportion of parents with a significant concern regarding the child's development on the Parents' Evaluation of Development Status (calculated RR, 0.94; 95% CI, 0.76 to 1.16).¹¹³ A third trial found no statistically significant differences between study arms in maternal concerns regarding cognitive development at 12 months.⁹² Subsequent measures showed fewer concerns in the intervention arm by 24 months. The same study demonstrated better early language scores (the Early Language Milestone Scale score) at 24 months and fewer language concerns at 12 and 18 months in the intervention arm.

School Performance: Findings

One trial⁹³ found no statistically significant differences between the intervention and control arms for mental development at 24 months (**Appendix D Tables 44 and 45**). At 9 years of age, the same study found no differences on grade point averages averaged across reading and math. The study also found no differences on math and reading achievement test scores in grades 1 through 3.⁹⁴

School Attendance: Findings

One trial⁹⁰ reported on school attendance and found that children at age 7 years in the intervention group reported skipping school significantly less often than children in the usual-care group (2.35% [9/388] vs. 6.47% [26/405]; RR, 0.36; 95% CI, 0.17 to 0.76) (**Appendix D Tables 44 and 45**). The same study reported no statistically significant differences using maternal reports of skipping school.

Death

Four trials of fair quality reported on the outcome of child death (**Appendix D Table 46**).^{93, 94, 101, 110, 116} Variations in the timing and outcome specifications preclude quantitative synthesis. One trial reported mortality at the 6-month followup,¹¹⁶ one at 12 months,¹⁰¹ and one¹⁰¹ at 18 months.¹¹⁰ Yet another trial reported child deaths at the 9-year followup.^{93, 94} One trial included deaths attributed to sudden infant death syndrome.¹¹⁰ One trial included only those deaths for which a child protection concern was known and an open verdict was reached.¹⁰¹ The other two trials included all deaths in the period specified for followup.

No study reported statistically significant differences in the rates of child death between intervention and usual-care groups. Three trials reported a lower but nonsignificant rate of child death among children in their intervention groups.^{93, 94, 101, 116} One trial reported a higher but nonsignificant rate of death among children in the intervention group.¹¹⁰ In the longest study (9 years of followup),^{93, 94} 1 death occurred in the intervention group (222 subjects) and 10 deaths in the control group (of 498 subjects). The OR favoring the intervention group was 0.22 (95% CI, 0.03 to 1.74).^{93, 94} Overall rates of death were low (0 to 3%). These were rare events even among these mostly high-risk children.

Composite Outcome

One trial reported on a composite outcome comprising infant death, severe nonaccidental injury, and involuntary foster care placement (**Appendix D Table 48**).¹¹⁶ The investigators found a lower but not statistically significant risk for this measure outcome in the intervention group (3% [2/65] vs. 12.7% [9/71] in the usual-care group; RR, 0.24; 95% CI, 0.05 to 1.08). When adjusted for baseline covariates, the RR, was 0.22, 95% CI, 0.02 to 0.98.¹¹⁶

KQ2. Harms of Interventions to Prevent Child Maltreatment

We did not find any trials reporting harms of interventions to prevent child maltreatment.

Chapter 4. Discussion

This chapter begins with a summary of review findings for each KQ; **Table 2** provides additional details. We then present limitations of the evidence and our update review and end with conclusions and recommendations for future research.

Summary of Review Findings

Benefits of Interventions (KQ1)

The evidence on the effect of interventions that are feasible in or referable from primary care settings on short-term outcomes for interventions to prevent child maltreatment, reports to CPS, ER visits, and hospitalizations suggests no benefit (**Table 3**). Long-term results of the same outcomes are not consistent. Results from the Nurse Family Partnership generally demonstrate benefit and the other trials do not. Other systematic reviews also found inconsistent evidence of benefits for trials other than the Nurse Family Partnership.⁷⁵ At or beyond the 3-year followup, two trials reported fewer CPS reports,^{97, 98, 114} and one did not.^{89, 90} One⁹⁶ of two trials^{96, 113} reporting on ER visits at or beyond the 4-year followup found lower rates of ED visits in the intervention arm. Other concerns with long-term outcomes include risks of contamination or unmeasured co-interventions. Additionally, interpretation of some outcomes can be challenging. Lower rates of all-cause ER visits or hospitalizations may represent markers of health care utilization rather than abuse or neglect. Long-term results, therefore, are not conclusive across the entire body of evidence. Sensitivity analyses that include poor-quality studies did not change our conclusions (**Appendix F2**). The evidence was also inconclusive for other outcomes, based primarily on the limited number of trials reporting on each outcome and lack of statistically significant results. These include injuries, failure to thrive, failure to immunize, internalizing and externalizing behavior symptoms, school attendance, and other measures of abuse or neglect. The evidence also suggests no benefit for removal of the child from the home, child development, school performance, and prevention of death.

Our evidence consisted entirely of RCTs and almost entirely of interventions that included home visits. Trials generally focused on young mothers and drew from vulnerable populations. Some interventions, such as the Nurse Family Partnership and Healthy Families, were tested in multiple settings. Nevertheless, the 21 included trials differed substantially in other respects, such as the populations of interest, baseline risk of maltreatment, intervention intensity and duration, and outcomes measured. These underlying characteristics may explain variations in the effectiveness of the intervention, but the evidence base for each outcome was not extensive enough to identify any patterns.

Harms of Interventions (KQ2)

We did not find any trials reporting harms of interventions to prevent child maltreatment. We had prespecified harms to include stigma, labeling, legal risks, risk of further harm to the child, and dissolution of the family, but we also intended to include other harms as reported. We did

not find any trials or observational studies on harms of these interventions.

Limitations of the Review

As with the previous review for the USPSTF, we restricted inclusion to studies focused on preventive interventions for children who had not yet experienced maltreatment. Therefore, we are unable to determine whether child maltreatment prevention interventions are effective for children who have experienced maltreatment.

Limitations of the evidence relate primarily to the considerable diversity of the interventions and the uncertainties stemming from such heterogeneity. Although nearly all included trials had a home visiting component, several aspects of this particular activity differed. These included the nature and theoretical basis of the interventions delivered during the home visits, credentials of the home visiting staff, and intensity and duration of the intervention.

In addition, all trials involved implementing multiple components. Complex, multicomponent interventions need to report the theoretical foundation for the intervention to help interpret the results and reproduce successful interventions.¹¹⁹ Study authors generally did not provide a theory of change or logic model that identified components essential to the success of the intervention. Without theoretical or contextual information on critical intervention components, we cannot determine how successful interventions are different from unsuccessful interventions. This lack of information limits our ability to understand when and how interventions work.

Additionally, the question of applicability of the findings to other pediatric or caregiver populations (e.g., with lower or higher risk profiles) and other settings (e.g., with fewer resources) remains uncertain.

Studies focusing on short-term outcomes of relatively rare events such as hospitalizations, removal from the home, and reports to CPS generally did not find statistically significant results. The few trials that did assess measures over the long term reported mixed results. The extent to which positive results in long-term trials can be attributed to the interventions themselves, to contextual factors such as the resources and abilities of the investigators and sponsoring institutions, or to intervening factors is unclear.

Notably, we found no evidence on harms of child maltreatment interventions. We also did not find any evidence on risky behaviors or outcomes, self-injurious behaviors, or suicidality. We limited our evaluation to direct or proxy measures of abuse or neglect and their sequelae. We have not evaluated the effectiveness of home visiting and other interventions for their many other potential outcomes (e.g., maternal outcomes, family functioning, long-term functioning of the child).

Finally, we did not examine the effects of changes in national, state, county, or municipal laws or regulations. We also did not evaluate the effect of universal interventions that might be delivered in communities rather than to individuals. Although prevention of child maltreatment can be undertaken through changes in policy and through community interventions, these activities lie

outside the purview of the USPSTF.

Future Research Needs

Significant uncertainties in the evidence on interventions that are feasible in or referable from primary care settings on benefits for maltreatment prevention and the absence of information on harms point to the need for further research on child maltreatment preventive interventions.

Funders of new studies need to consider the benefits of investing in entirely new and unproven interventions versus reproducing interventions with some evidence of effectiveness. The latter option would include evaluating interventions modified to address lessons learned in an initial efficacy study or programs adapted to the needs of somewhat different settings or populations.

Reproducing studies of successful interventions requires that investigators clearly identify which intervention components are critical, which also means describing all parts of the intervention or program in considerable detail. Researchers should also specify the degree of fidelity to those components that is needed or expected and comment on the deviations from fidelity that were necessary in earlier studies and, thus, should be evaluated in further research.

Additionally, efforts to test interventions in new settings will need to address issues of applicability and acceptability. New settings may not have the personnel, resources, or organizational commitment found in the original trials. These settings may need adaptations for specific demographic traits and risk factors in the new community. Acceptability in new settings requires stakeholder buy-in. Effective implementation requires a commitment of resources in the short and long term if evidence-based interventions are to be sustained in a clinical practice setting.

Community-based participatory research, when applied in trial designs, can help address the relevance of an intervention for the community. These approaches, for existing interventions, can also inform how the intervention might be tailored, while still preserving its essential elements. They also enhance rigor, for example, by increasing family engagement and exposure to the intervention and reducing attrition.

Future intervention studies are needed with families where known risk factors for child maltreatment, particularly substance abuse and domestic violence, are present. Interventions with these highly vulnerable and challenging-to-serve populations necessitate multifaceted and innovative interventions. These should be integrated into the existing community-based service infrastructure, be trauma informed and culturally sensitive,¹²⁰ and address known protective factors that reduce the likelihood of maltreatment (e.g., reducing social isolation, strengthening household financial security, family planning/birth spacing).^{3, 121}

Interventions that attempt to address root causes of family violence will have to address multiple risk factors and may require structural changes in the community to provide greater family support. Such complex interventions should be evaluated on a broad set of outcomes that include child-, parent-, and family-level outcomes. However, studies that evaluate long-term and broadly

defined outcomes have a greater opportunity for bias and confounding by secular factors and trends that may not be measured concurrently. For that reason, new studies will need to carefully measure and control for co-interventions and contamination over the long term.

Studies should also account for the family's engagement (or lack thereof) in community-based services. Such programs may be able to bolster short-term gains from participation in a time-limited intervention and sustain a positive trajectory for the family.

To address the intervention needs of high-risk families, researchers should consider adapting successful interventions from relevant studies that examine prevention of maltreatment recurrence. Future studies could adapt such successful interventions, particularly for children known to be in a high-risk pool (e.g., children referred to the child welfare system without substantiated maltreatment).

Although clinicians may perceive a need for better risk assessment instruments, studies thus far have not demonstrated high sensitivity or specificity for such tools. Poor accuracy of instruments, when coupled with the potential harms of screening—particularly removal of the child from the home, stigma, and erosion of trust and communication between the health care provider and the family—raises concerns about any prevention approach that is based on screening for risk.

Investigators of new studies will need to consider the intensity of planned interventions. Intensity can reflect numerous program characteristics: overall length of the program; number, duration, and nature of interactions (e.g., face-to-face, telephone); and training of intervention staff. New studies that implement *low*-intensity interventions should clarify how such interventions are anticipated to have long-term effects on caregiver behavior. New studies implementing *high*-intensity interventions will additionally need to account for the potential effects of a long-term therapeutic relationship between the primary care provider and family that is independent of the intervention.

Given the current state of home visiting programs and the benefits in other outcome areas, we acknowledge the challenges of new studies to determine effectiveness of various approaches (such as the need for larger sample size, higher fidelity and theoretical basis, and possibly more intense services).

Recruitment of participants in these trials can be challenging. Some direct and proxy measures of child abuse and neglect are rare. A combination of small sample sizes and rare outcomes contribute to lack of precision in results. Greater support of pragmatic designs can increase the evidence base. A variety of policy and analytic techniques that allow for rigorous evaluation using quasi-experimental designs and a broader set of data collection and analytic techniques can be used to strengthen inference about causality. Funders of child maltreatment prevention efforts and other home visiting interventions should consider common measures of intervention fidelity; common outcome assessments; and data sharing recommendations, incentives, or requirements. Further, funders should consider supporting robust analyses that take advantage of implementation and evaluation of programs at the individual and jurisdictional levels.

Ongoing and Unpublished Studies

We identified four ongoing trials that are potentially relevant to this topic. One is a Canadian trial¹²² of the Nurse-Family Partnership model; two trials testing this model in Elmira, New York,⁹⁵⁻⁹⁹ and Memphis, Tennessee,^{93, 94} have been included in this review. A second trial¹²³ presented preliminary results from brief universal nurse home-visiting program, Durham Connects, but did not report on child maltreatment outcomes.¹²⁴ A third trial is enrolling families of children with special healthcare needs and provides a behavioral intervention intended to improve parenting skills and prevent child neglect.¹²⁵ Finally, a fourth trial aims to enhance coping and resilience by improving the quality of the parent-child relationship.¹²⁶ It includes families with young children aged 2 to 36 months at risk for maltreatment. Because recruitment is ongoing and draws from referrals from child welfare, family court, primary care, and preventive agencies, the final proportion of children with signs, symptoms, or prior experience of maltreatment is not known (and therefore the study's relevance to our review is not yet known).

Conclusions

On the whole, the evidence base on interventions feasible in or referable from primary care settings to prevent child maltreatment does not consistently demonstrate benefit. No information was available about possible harms of these interventions. Additional research on interventions that address a comprehensive array of risk factors and evaluate outcomes over the long term may help identify effective, generalizable, and acceptable interventions.

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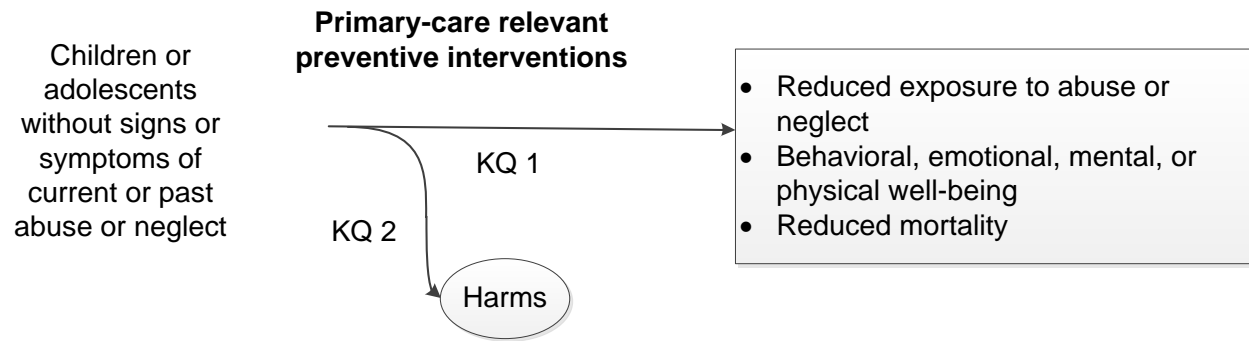
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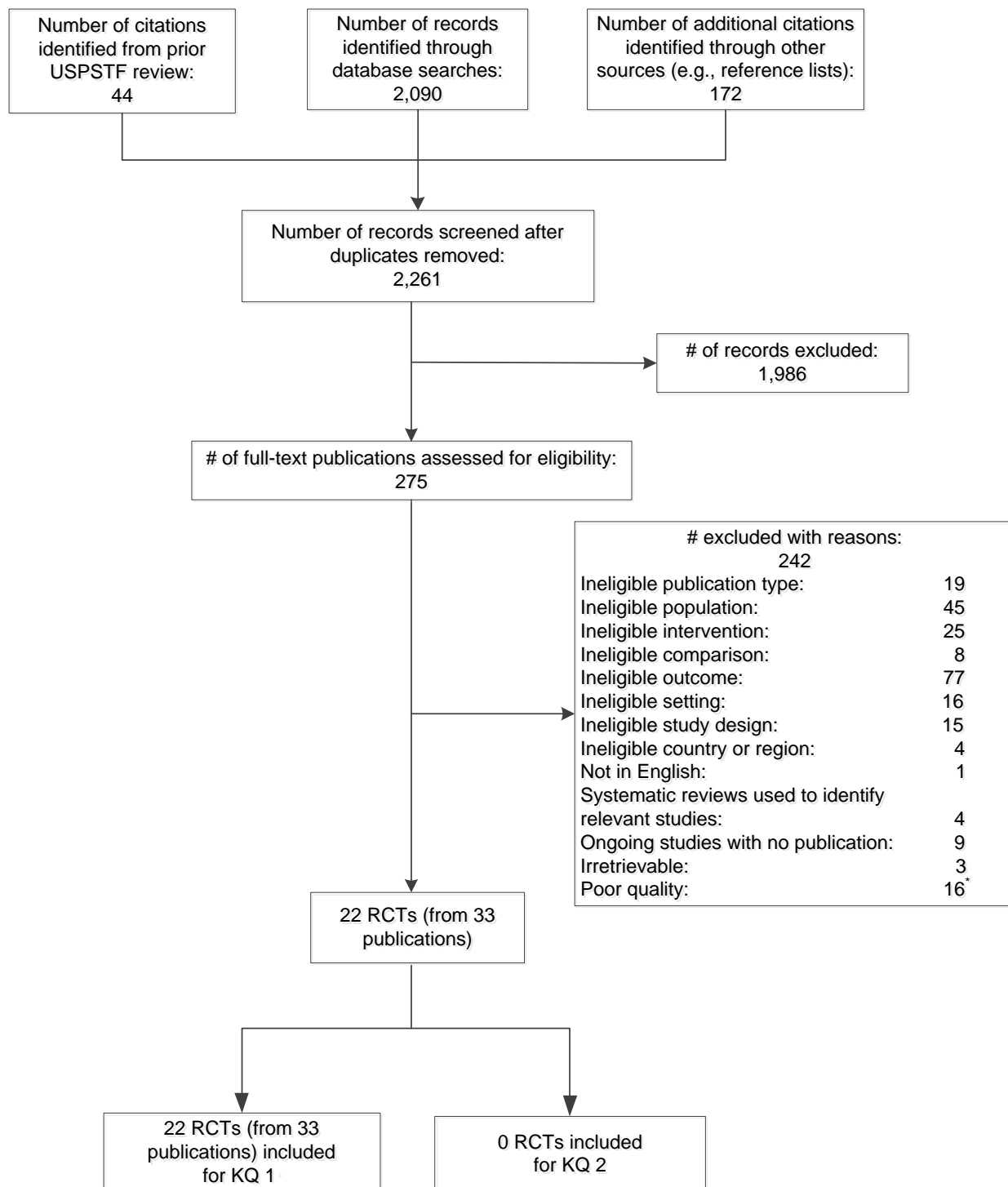
Figure 1. Analytic Framework



*The World Health Organization and International Society for Prevention of Child Abuse and Neglect define child maltreatment as including “all forms of physical and/or emotional ill-treatment, sexual abuse, neglect, or negligent treatment or commercial or other exploitation, resulting in actual or potential harm to the child’s health, survival, development, or dignity in the context of a relationship of responsibility, trust, or power” (1). Maltreatment includes physical abuse, neglect, sexual abuse/exploitation, emotional abuse, parental substance abuse, and abandonment.”³

Abbreviations: KQ=key question.

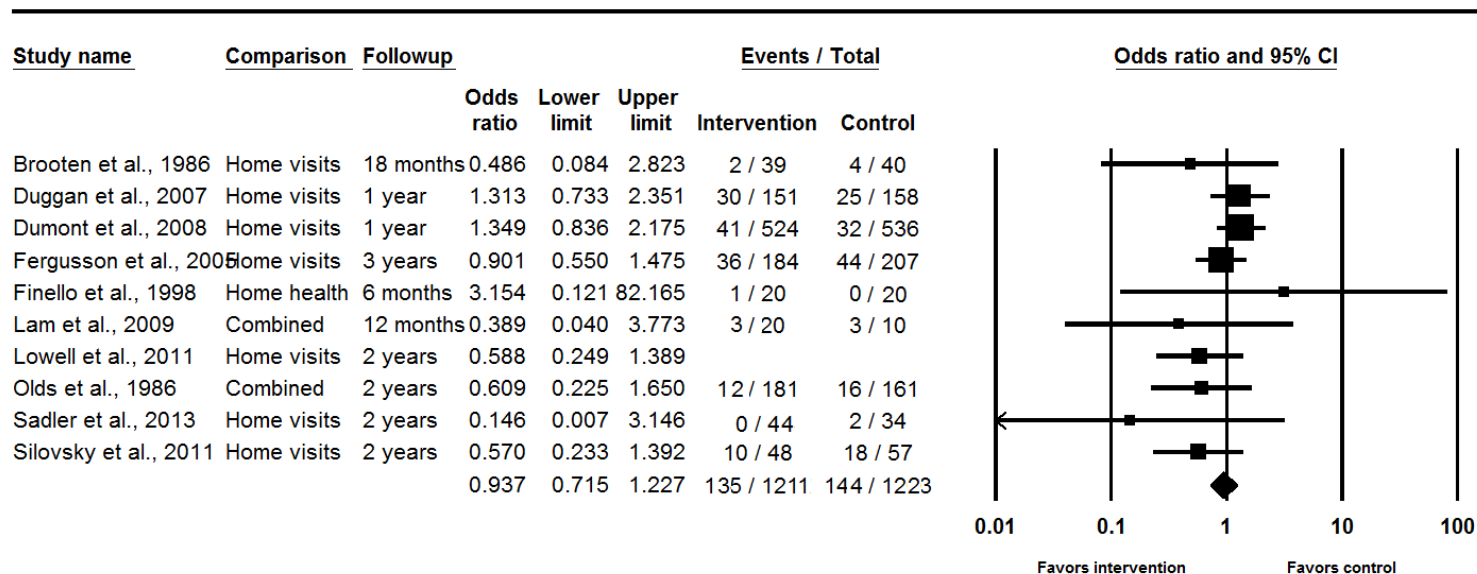
Figure 2. Summary of Evidence Search and Selection



* Thirteen RCTs (in 16 publications) were excluded for poor quality and used in sensitivity analyses for KQ 1.

Abbreviations: KQ=key question; RCTs=randomized, controlled trials; USPSTF=US Preventive Services Task Force.

Figure 3. Child Protective Services Reports: Pooled Results

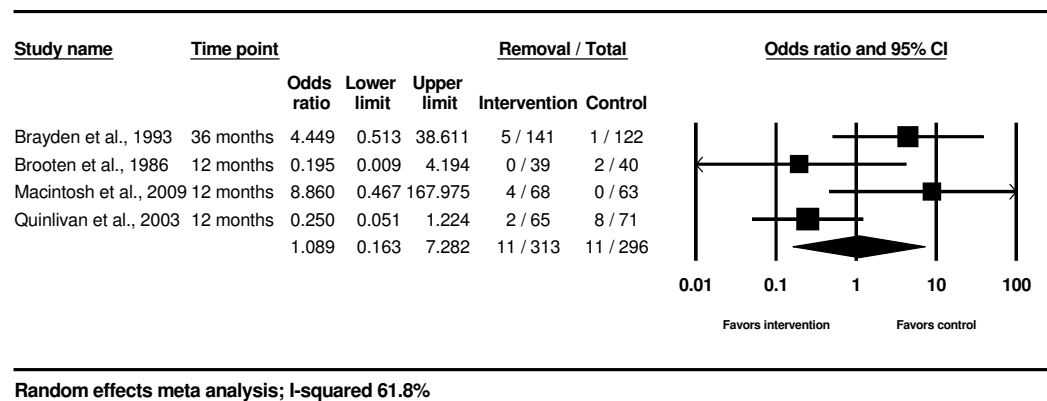


I-squared: 6.3%

For studies with multiple arms, the pooled estimates averages the treatment effect from active arms and is presented as a “combined arm.” Finello et al present results from a combination of home health and home visits, home health alone, and home visits alone. Because the trial reports cases only for the home health arm, the pooled analysis includes the home health arm only. Lowell et al did not report number of events per arm, the total N analyzed for both arms is 117.

Abbreviation: CI=confidence interval.

Figure 4. Removal of the Child From the Home: Pooled Results



Abbreviation: CI=confidence interval.

Table 1. Types of Child Maltreatment Prevention Programs

Type of Program	Description of Program
Home visitation programs	<ul style="list-style-type: none"> • Aim to improve parenting and parent-child relationships by building positive parent-child relationships and attachment, reducing harsh parenting, increasing nurturing parenting, and improving safety in the home. • Components may support parents in meeting basic needs (e.g., employment) and help them gain access to social support and community services.
Pediatric primary care programs	<ul style="list-style-type: none"> • Train health professionals to identify risk factors placing infants or children at high risk for maltreatment or neglect and to make referrals to community resources. • Components include comprehensive parent education and support interventions.
Psychotherapy interventions	<ul style="list-style-type: none"> • May target high-risk groups. • May focus on improving the parent's mood and coping skills, using cognitive behavioral therapy strategies. • Components include strengthening the parent-child relationship and addressing attachment problems between caregiver and child. • May be offered in the home as a home visiting service, included as a component of a home visitation program, or be clinic-based.
Respite care programs	<ul style="list-style-type: none"> • Offer short-term, temporary relief to families caring for children with developmental disabilities or serious emotional disturbances that place them at risk for maltreatment or neglect. • Offer families a break while providing a safe environment for the child. • May be provided for several hours, overnight, or for a few weeks at a time and may be provided in the home, a foster home, or a facility in the community.
Parent education programs	<ul style="list-style-type: none"> • Improve parents' understanding of children's developmental needs and normal developmental behaviors, improving their capacity to provide nurturing care and increasing the use of positive discipline strategies. • Are often didactic and delivered via parent groups.
Community-based programs	<ul style="list-style-type: none"> • Aim to reduce barriers created by a lack of community support and other negative forces within a community by both reducing risks and enhancing protective factors. • Components include fostering partnerships with other local programs serving young children and working to create more supportive relationships among community residents. • May also include achieving policy-level changes that increase resources available at the level of clinical care.

Table 2. Characteristics of Interventions to Prevent Child Maltreatment

Study Characteristics*	Subcharacteristics	Number of Studies	Percent
Study quality	Good-quality studies	4	12%
	Fair-quality studies	18	50%
	Poor-quality studies	13	38%
Population characteristics: Enrollment	Enrolled in prenatal period or immediately after birth	13	59%
	Mixed enrolment	1	5%
	Enrolled after the perinatal period	8	36%
Population characteristics: Maltreatment reported at baseline	Reported maltreatment at baseline	6	27%
	Did not report maltreatment at baseline	16	73%
Population characteristics: Risk status	Parent identified to be at risk	12	55%
	Child identified to be at risk because of birth status (premature or low birthweight)	2	9%
	Participants not specifically identified to be at risk	7	32%
Population characteristics: Age of mother	Most or all mothers under age 20 years	7	32%
	Mothers age 20 years or older on average	15	68%
Intervention characteristics: Home visits	Home visit component	21	95%
	No home visit component	1	5%
Intervention characteristics: Personnel	Clinical personnel involved in care	15	68%
	No clinical personnel	7	32%
Comparator	Usual care comparator	19	86%
	No usual care comparator	3	14%
Geographic setting	United States of America	16	73%
	United Kingdom	3	14%
	Canada	1	5%
	Australia	1	5%
	New Zealand	1	5%

* For all characteristics other than study quality, the table presents data from good- or fair-quality studies only.

† We limited inclusion to studies reporting less than 50 percent of cases experiencing maltreatment at baseline.

Table 3. Summary of Evidence of Interventions to Prevent Child Maltreatment

Key Question	Population, Intervention	No. of Studies; No. of Observations	Summary of Findings by Outcome	Consistency/Precision	Reporting Bias	Overall Quality of Studies	Body of Evidence Limitations	EPC Assessment of Strength of Evidence: For Outcome	Applicability
KQ 1: Reports to CPS	Caregivers of children at risk of maltreatment	14; 4,958	CPS reports at or within 1 year of trial completion: OR, 0.94, 95% CI, 0.72 to 1.23, I^2 : 6.3%, 10.6% vs. 11.9% (k=10, 2,444 participants) Mixed results for long-term follow up*	Consistent/imprecise short-term outcomes; inconsistent/imprecise for long-term outcomes	No evidence of reporting bias	Fair	Heterogeneity across studies in type of intervention	Low for no benefit for short-term outcomes, insufficient for long-term outcomes	Unclear whether findings apply to subgroups defined by parent risk factors
KQ 1: Removal of the child from home	Infants/toddlers age ≤ 3 years	5; 885	Removals 0–3 years: 11/313 (3.51%) vs. 11/296 (3.71%); OR, 1.09; 95% CI, 0.16 to 7.28, I^2 : 61.8% (k=4, 609 participants) Removals at birth (for intervention started in pregnancy) in one study: calculated OR, [†] 1.55; 95% CI, 0.61 to 3.94, 225 participants	Inconsistent/imprecise	No evidence of reporting bias	Fair	Heterogeneity across studies in timing of outcome	Low for no benefit	Unclear whether findings apply to subgroups defined by parent risk factors
KQ 1: Other measures of abuse or neglect	Caregivers (mothers or families)	2; 461	Abuse: [‡] 13/141 (9.2%) vs. 8/122 (6.6%); RR, 1.4, 95% CI, 0.58 to 3.62; k=1, 263 participants Neglect: [§] 15/141 (10.6%) vs. 5/122 (4.1%); RR, 2.79, 95% CI, 0.98 to 7.91; 1 trial, 263 participants Significantly higher safety scores in the intervention arm; 1 trial, 147 participants	Inconsistent/imprecise	No evidence of reporting bias	Fair	Heterogeneity across studies in outcome measure	Insufficient	Unclear whether findings apply to subgroups defined by parent risk factors

Table 3. Summary of Evidence of Interventions to Prevent Child Maltreatment

Key Question	Population, Intervention	No. of Studies; No. of Observations	Summary of Findings by Outcome	Consistency/Precision	Reporting Bias	Overall Quality of Studies	Body of Evidence Limitations	EPC Assessment of Strength of Evidence: For Outcome	Applicability
KQ 1: Injuries with a high specificity for abuse	Adolescent mothers	1; 136	Nonaccidental injuries: 0/64 (0) vs. 1/71 (1.4%), calculated RR: 0.37, 95% CI, 0.015 to 8.91	Consistency unknown (single trial)/imprecise	No evidence of reporting bias	Fair	Single small trial	Insufficient	Unclear whether findings apply to subgroups defined by parent risk factors`
KQ 1: Visits to the ER	Children	11; 5,732	<p>2 of 7 studies reported a statistically significant difference in mean number of all-cause ER visits the first 2 years of follow up; all other studies report results that are not statistically significant[¶]</p> <p>1 of 2 studies reported statistically significant results at the 2- to 4-year follow up for each of the following: mean number of all-cause ER visits; mean number of ER visits for accidents, injuries, and ingestions; and number of children seen for accidents or injuries; 2 studies found no differences for number of children seen in the ER; 1 study found no difference in the proportion of children seen for injuries and ingestions</p> <p>1 of 2 studies reported statistically significant differences at long-term follow up</p>	Inconsistent/imprecise	No evidence of reporting bias	Fair	Heterogeneity across studies in outcome measures	Low for no benefit for short-term outcomes, insufficient for long-term outcomes	Unclear whether findings apply to subgroups defined by parent risk factors`

Table 3. Summary of Evidence of Interventions to Prevent Child Maltreatment

Key Question	Population, Intervention	No. of Studies; No. of Observations	Summary of Findings by Outcome	Consistency/Precision	Reporting Bias	Overall Quality of Studies	Body of Evidence Limitations	EPC Assessment of Strength of Evidence: For Outcome	Applicability
KQ 1: Hospitalization	Infants	12; 5,491	<p>1 of 5 studies showed a reduction in number of children with all-cause hospitalization, but only for 1 of 4 outcome measures</p> <p>1 of 2 studies found a lower mean number of hospital days</p> <p>1 trial found lower overall rates of hospital admission for unintentional injury at a 9-year follow up</p> <p>All other outcomes not statistically significantly different[¶]</p>	Consistent/imprecise for results under 3 years; inconsistent/imprecise for long-term follow up	No evidence of reporting bias	Fair	Heterogeneity outcome measures; each outcome/timing only presented in a single study	Low strength of evidence of no benefit	Unclear whether findings apply to subgroups defined by parent risk factors
KQ 1: Failure to thrive	Infants	1; 79	0% (0/39) vs. 2.5% (1/40), RR: 0.34, 95% CI, 0.01 to 8.14	Consistency unknown (single trial)/imprecise	No evidence of reporting bias	Fair	Single small trial	Insufficient	Unclear whether findings apply to subgroups defined by parent risk factors
KQ 1: Failure to immunize	Adolescent mothers	1; 136	No vaccinations at 6 months: 4/71 (5.6%) vs. 9/65 (13.8%), calculated RR: 0.49, 95% CI, 0.16 to 1.52	Consistency unknown (single trial)/imprecise	No evidence of reporting bias	Fair	Single small trial	Insufficient	Unclear whether findings apply to subgroups defined by parent risk factors [`]

Table 3. Summary of Evidence of Interventions to Prevent Child Maltreatment

Key Question	Population, Intervention	No. of Studies; No. of Observations	Summary of Findings by Outcome	Consistency/Precision	Reporting Bias	Overall Quality of Studies	Body of Evidence Limitations	EPC Assessment of Strength of Evidence: For Outcome	Applicability
KQ 1: Internalizing and externalizing behavior symptoms	Caregivers of children at risk of maltreatment	6; 5,529	3 of 6 trials reported reductions in behavior difficulties [#] 1 study reported greater clinical problems in the intervention arm Other outcomes are not statistically significantly different ^{**}	Inconsistent/imprecise	No evidence of reporting bias	Fair	Small number of trials; heterogeneity of outcome measures	Insufficient	Home-based intervention targeting high-risk families may be effective in decreasing behavior problems
KQ 1: Other social, emotional, and developmental outcomes	Infants/toddlers ≤ 3 years of age	4; 3,965 children	0 of 5 studies reported statistically significant differences on a variety of social, emotional, and developmental measures ^{††}	Consistent/imprecise	No evidence of reporting bias	Fair	Heterogeneity outcome measures; each outcome/timing only presented in a single study	Low strength of evidence of no benefit for children ≤ 3 years	Unclear whether findings apply to subgroups defined by parent risk factors; one intervention may not be readily generalizable to other (pediatric practice) settings
KQ 1: Bayley Scales of Development	Caregivers and families	4; 1,638 caregivers and families	1 of 4 trials reported higher scores in the intervention arm (mean difference between arms: 3.2; 95% CI, 1.2 to 5.2)	Consistent/imprecise	No evidence of reporting bias	Fair	Outcomes measured at different ages	Low for no benefit	All studies focused on at-risk caregivers and families
KQ 1: Other measures of development	Pregnant mothers	3; 3,204	1 of 3 trials reported statistically significant differences on other development outcomes, but for subset of reported outcome measures and timing	Consistent/imprecise	No evidence of reporting bias	Fair	Heterogeneity in outcome measures	Low for no benefit	Unclear whether findings apply to subgroups defined by parent risk factors`

Table 3. Summary of Evidence of Interventions to Prevent Child Maltreatment

Key Question	Population, Intervention	No. of Studies; No. of Observations	Summary of Findings by Outcome	Consistency/Precision	Reporting Bias	Overall Quality of Studies	Body of Evidence Limitations	EPC Assessment of Strength of Evidence: For Outcome	Applicability
KQ 1: School performance	School-age children	1, 1,139	1 study found no difference on various school performance measures	Consistency unknown n (single trial)/Imprecise	No evidence of reporting bias	Fair	Single trial	Low for no benefit	Single study, applicability to other settings and ages unclear
KQ 1: School attendance	School-age children/families	1, 1,184	Self-reported school attendance at age 7: 9/388 (2.35%) vs. 26/405 (6.47%); RR: 0.36, 95% CI, 0.17 to 0.76 No difference in maternal reports of skipping school	Consistency unknown n (single trial)/imprecise	No evidence of reporting bias	Fair	Single trial; inconsistent self-report and maternal report	Insufficient	Single study, applicability to other settings and ages unclear
KQ 1: Death	Pregnant or post partum women, 3 studies included only women at risk for maltreatment, all studies included home visitng	4; 1,065	0 of 4 trials reported statistically significant differences in death	Consistent/imprecise	No evidence of reporting bias	Fair	Heterogeneity in included studies	Low for lack of effect on outcome of death	Unclear whether findings apply to subgroups defined by parent risk factors
KQ 1: Composite maltreatment outcome**	Mothers of new borns	1; 136 mothers	2/65 (3.1%) vs. 9/71 (12.7%); RR: 0.24, 95% CI, 0.05 to 1.08 Adjusted RR _c =0.22 (95% CI, 0.02 to 0.98, p=0.04)	Consistency unknown n (single trial)/imprecise	No evidence of reporting bias	Fair	Single small trial	Insufficient	Unclear whether findings apply to subgroups other than teenage first-time mothers
KQ 2: Harms	NA	0; 0	No eligible studies	NA	NA	NA	NA	Insufficient	NA

* Long-term CPS reports: adjusted OR, 0.48, 95% CI, 0.23 to 1.0, in one study (3 year-followup, 157 participants); AOR:1.13, p>0.1 in second study (5-year-followup, 1,174 participants); p=0.04 in another study (13-year followup, 216 participants, no effect size provided).

† Calculations based on N randomized.

‡ Defined as hitting with the hand or objects, biting, burning with objects or by immersion, twisting, shaking, throwing or pushing so as to cause a fall, or hair pulling; identified from review of public agency documents from the Tennessee Department of Human Services.

Table 3. Summary of Evidence of Interventions to Prevent Child Maltreatment

[§] Defined as abandonment, leaving a child with an inappropriate caretaker, gross failure to seek medical care, failure to provide shelter or nutrition, or gross failure to provide for normal intellectual development; identified from review of public agency documents from the Tennessee Department of Human Services.

[†] Outcomes with no statistically significant results include mean number of ER visits for accidents and injuries (1 study), proportion of children with ER visits for injuries and ingestions (1 study), number of children using the ER (2 studies), and total ER visits (1 study).

[¶] Outcomes with no statistically significant results include number of hospitalizations due to nonaccidental injury to the neonate (1 study), number of children hospitalized because of child abuse and neglect (1 study), proportion of children hospitalized for injuries and ingestions (1 study), number of children hospitalized for ambulatory-care sensitive conditions (1 study), number of children rehospitalized (1 study), mean number of all-cause hospitalizations (3 studies), and total count of hospital stays (1 study).

[#] One study reported statistically significant differences on each of the following: mean and proportion of children with higher externalizing behaviors at 12 months; internalizing behaviors at 2 years and 3 years; behavior problems at 5, 6, and 9 years; and more maternal concerns on the child behavior checklist.

^{**} Outcomes with no statistically significant results include internalizing behaviors at 6 and 12 months (1 study); child behavior at 2 years (1 study), 30 to 33 months (1 study), and 7 years (1 study); and internalizing and externalizing behaviors at 9 years (1 study).

^{††} Outcomes included dysregulation, sleep problems, social skills, attention and social problems, school-related conduct outcomes, and infant social and emotional adjustment.

[#] Defined as infant death, severe nonaccidental injury, and involuntary foster care placement.

Abbreviations: AOR=adjusted odds ratio; CI=confidence interval; CPS=child protective services; EPC=Evidence-based Practice Center; ER=emergency room; KQ=key question; NA=not applicable; OR=odds ratio; RR=relative risk; vs.=versus.

Appendix A1. Types of Abuse and Neglect

The Child Welfare Information Gateway, a service of the Children's Bureau of the U.S. Department of Health and Human Services, Administration for Children and Families, provides a summary of State civil definitions of child abuse and neglect that determine the grounds for intervention by State child protective agencies.¹²⁷ These definitions address the following types of maltreatment:

Physical Abuse

Physical abuse includes any nonaccidental physical injury to the child and can include striking, kicking, burning, or biting the child or any action that results in physical harm of the child. As of April 2016, in 38 States, the definition includes acts or circumstances that threaten the child with harm or create a substantial risk of harm to the child's health or welfare.¹²⁷ Seven States include in their definitions of physical abuse the crime of human trafficking, including labor trafficking, involuntary servitude, and trafficking of minors.¹²⁷ Physical abuse does not include physical discipline, as long as it does not cause bodily injury to the child.¹²⁸

Neglect

Neglect is the failure of a parent or other person with responsibility for the child to provide needed food, clothing, shelter, medical care, or supervision to the degree that the child's health, safety, and well-being are threatened with harm. Half the States include failure to educate the child as required by law in their definition of neglect. Ten States specifically define medical neglect as failing to provide any special medical treatment or mental health care needed by the child, and four define it as withholding medical treatment or nutrition from disabled infants with life-threatening conditions.¹²⁷

Sexual Abuse or Exploitation

The Federal CAPTA specifies a definition of sexual abuse as:

"The employment, use, persuasion, inducement, enticement, or coercion of any child to engage in, or assist any other person to engage in, any sexually explicit conduct or simulation of such conduct for the purpose of producing a visual depiction of such conduct; or

"The rape, and in cases of caretaker or interfamilial relationships, statutory rape, molestation, prostitution, or other form of sexual exploitation of children, or incest with children."⁵, p. 2

CAPTA offers a relatively specific definition as guidance to the States; however, some States provide further specification of sexual abuse in their statutes. Most States include sexual exploitation in their definition, which includes allowing the child to engage in prostitution or in the production of child pornography.¹²⁷ Twenty-one States specify human trafficking, including sex trafficking or trafficking of children for sexual purposes, in their definition of sexual abuse.¹²⁷

Emotional Abuse

Nearly all States include emotional maltreatment in their definitions of abuse and neglect. Emotional abuse can include inattention to child's emotional needs, failure to provide

Appendix A1. Types of Abuse and Neglect

psychological care, or permitting the child to use alcohol or drugs.¹²⁷ Emotional injury is often defined as “injury to the psychological capacity or emotional stability of the child as evidenced by an observable or substantial change in behavior, emotional response, or cognition” and injury as evidenced by “anxiety, depression, withdrawal, or aggressive behavior.”¹²⁷

Parental Substance Abuse

Many States include parental substance abuse as an element of their definitions of child abuse and neglect.¹²⁷ Exposures considered to be maltreatment include prenatal exposure of a child to harm because of the mother’s use of an illegal drug or other substance; manufacture of a controlled substance in the presence of a child or on the premises occupied by a child; allowing a child to be present where the chemicals or equipment for the manufacture of controlled substances are used or stored; selling, distributing, or giving drugs or alcohol to a child; and use of a controlled substance by a caregiver that impairs the caregiver’s ability to adequately care for the child.

Abandonment

Seventeen States include abandonment in their definitions of abuse and neglect as a type of neglect.¹²⁷ Nineteen define it as separate from neglect.¹²⁷ Abandonment of the child occurs when the parent’s identity or whereabouts are unknown, the child has been left by the parent in circumstances in which the child suffers serious harm, or the parent has failed to maintain contact with the child or to provide reasonable support for a specified period of time.

Domestic Violence

Some States include exposure to domestic violence (DV) as a form of abuse or neglect in their legislation.¹²⁸ Domestic violence and child maltreatment, particularly physical and emotional abuse, are known to have high rates of co-occurrence.¹²⁹ Additionally, CAPTA promotes the use of differential response for child exposure to domestic violence (e.g., offering timely services without a formal determination or substantiation of child abuse or neglect) to avoid separating the child from the nonperpetrating parent (usually the mother). The 2010 reauthorization of CAPTA calls attention to the need for a more comprehensive and collaborative approach across CPS and domestic violence services that addresses the safety of both child and adult victims.

Appendix A2. Current Recommendations From Various Professional Organizations on Prevention of Child Maltreatment

Organization, Year	Recommendation
American Academy of Family Physicians 2013 ⁶⁹	<p>Screening/Intervention Notes that there is insufficient evidence that any specific screening strategy or behavioral intervention produces better health outcomes than clinician awareness and evaluation of potential signs of abuse.</p> <p>Nonetheless provides a list of steps primary care physicians can take to prevent child abuse, which includes screening for risk factors or problems, with a link to the American Academy of Pediatrics' recommendations.</p>
American Academy of Pediatrics 2010, ¹³⁰ 2015 ¹³¹	<p>Screening/Intervention No statement on screening or intervention</p> <p>Universal prevention 2014 (published in October 2010, reaffirmed in January 2014) Strongly recommends physician involvement in preventing child maltreatment.¹³⁰</p> <p>Notes that universal prevention of child maltreatment must begin with an approach that assesses the caregivers' strengths and deficits and connects the family with community resources that will protect the dependent children before abuse or neglect occurs.</p> <p>2015 (published in April 2015)¹³¹</p> <p>Focuses on management of suspected physical abuse.</p> <p>Notes that "Child abuse prevention is important but difficult and requires efforts that are broad and sustained. The pediatrician, as a trusted advisor to parents, caregivers, and families about health, development, and discipline, can play an important role in abuse prevention by assessing caregivers' strengths and deficits, providing education to enhance parenting skills, connecting families with supportive community resources that address parent and family needs, and promoting evidence-based parenting practices that are nurturing and positive." This statement cites the 2010 clinical statement.</p>
Canadian Task Force on Preventive Health Care 2000 ⁶⁸	<p>Screening Unacceptable rate of predictive value (e.g., positive predictive value of 6.6% and a sensitivity of 55.6% for physical abuse in one study).</p> <p>D recommendation for screening: "because of the high false-positive rates of screening tests for child maltreatment and the potential for mislabeling people as potential child abusers, the possible harms associated with these screening maneuvers outweigh the benefits."</p> <p>Interventions Good evidence to include referral in the periodic health examination for home visitation by nurses (A).</p> <p>Insufficient evidence to include referral in the periodic health examination for prevention of child maltreatment (C) for comprehensive health care; parent education and support; or home-based services, including case management, education, and psychotherapy. No additional evidence to alter recommendation (C) in 1993 update for programs for children aimed at preventing sexual abuse and abduction.</p>
Community Preventive Services Task Force ⁷⁰	<p>Screening None</p> <p>Interventions Noted strong evidence of effectiveness for early childhood home visitation to prevent violence against the child (maltreatment): recommended.</p> <p>Also noted that "programs delivered by professional visitors (i.e., nurses or mental health workers) seem more effective than programs delivered by paraprofessionals, although programs delivered by paraprofessionals for 2 years also appear to be effective in reducing child maltreatment."</p>

Appendix A3. Contextual Question 1: What is the validity and reliability of risk-assessment tools to identify children and adolescents at risk of child maltreatment?

Among the 21 good or fair quality trials and the 13 poor quality trials evaluating the effectiveness of interventions to prevent child maltreatment, six used screening instruments to identify children and adolescents at risk of maltreatment for inclusion in prevention trials. The six studies used one of five screening instruments: Kempe Family Stress Checklist (KFSI), the Maternal History Interview (MHI-2), the Parent Screening Questionnaire (PSQ) within the SEEK Model, the Brief Infant-Toddler Social and Emotional Assessment (BITSEA), and the Parent Risk Questionnaire (PRQ). *Appendix A3 Table 1* presents information on reliability and validity of these instruments. We found reports of screening test accuracy^{132, 133} for two of five instruments. The results from one screening test accuracy study indicate high sensitivity and specificity (80% and 89.4% respectively) for KFSI but the method of validation has serious flaws because it appears to exclude participants with intermediate risk.¹³² A second study reported relatively lower rates of sensitivity and specificity (65% and 81.3% respectively) for MHI-2 but a very low positive predictive value (5.5%) and high false positive and false negative rates.¹³³

Three additional included studies used screening instruments adapted from the KFSI and examined specific areas of parent and family functioning including age of parents, social support, planning of pregnancy, parental substance use, family financial situation, maternal use of needed services, maternal intelligence or health, difficulty of child-caring, maternal exposure to abuse, and other history of family violence as well as criminal or mentally ill behavior. We did not find studies evaluating the reliability or validity of these adapted instruments.^{105, 106, 134-136}

Among the 1,850 records excluded from this review, six studies used one of four additional screening instruments to identify children at risk of maltreatment. These include the BabyFirst Screen, the Brisbane Evaluation of Needs Questionnaire, and the Child Abuse Potential Inventory (CAPI). *Appendix A3 Table 2* presents information on reliability and validity of these instruments. The BabyFirst Screen was the only instrument for which we found statistics on validity, specifically out-of-home placements. Similar to the MHI-2 instrument, the positive predictive value is low, and the false positive and negative rates are relatively high. Authors of studies evaluating the Child Abuse Potential Inventory (CAPI) instrument did not report measures such as sensitivity and specificity.^{137, 138} We did not find validations of other instruments in a population with a wide spectrum of risk. The California Family Risk Assessment was evaluated for predictive validity of new reports in a sample of already identified cases.¹³⁹ The Clinical Prediction Tool evaluated the risk of referral to child protection referrals among children with scalds or burns.¹⁴⁰ One study of an instrument, the Parenting Profile Assessment, did not measure validity against an external measure. The authors reported sensitivity and specificity against a combination of parental self-report of abuse and agency reports.¹⁴¹ In general, the instruments described above have poor accuracy. Instruments to predict physical child abuse in emergency room settings may not have relevance to the primary care context and have a high false-positive rate.^{142, 143}

Appendix A3 Table 1. Reliability and Validity of Risk Screening Instruments Used in Included Studies

Instrument	Study using the Instrument	Description	Reliability	Validity*
Kempe Family Stress Checklist (KFS) ^{132, 144}	Caldera et al, 2007, ⁸⁸ Duggan et al, 2007, ⁸⁷ DuMont et al, 2008, ⁸⁹ DuMont et al, 2010, ⁹⁰ Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶	<ul style="list-style-type: none"> • 10-item rating scale • Items include psychiatric and criminal history, childhood history of care, emotional functioning, attitudes towards and perception of children, discipline of children, and level of stress in parent's life • Original checklist developed to evaluate parents with known abuse or neglect 	<ul style="list-style-type: none"> • High reliability reported in HFA sites in Oregon for classifying parents on individual characteristics in terms of levels of risk ($r=0.93$) but does not provide answer to whether families would receive the same score by independent evaluations.¹⁴⁴ 	<ul style="list-style-type: none"> • Validated in a sample, in 197 women 2 to 2.5 years after baseline measure.¹³² • Validated against identified abuse, neglect, or failure to thrive (from chart review, specifics not defined) • Validation of 38 with positive scores (possibly scores ≥ 40, not clearly specified) and 157 without positive scores (threshold not specified; possibly includes 100 women with scores 0-10 and 25-35) • 80% sensitivity and 89.4% specificity, sample appears to exclude intermediate risk category • Reported 52.5% positive predictive value, 96.8% negative predictive value.¹³²
Maternal History Interview (MHI-2) ^{109, 133}	Brayden et al, 1993 ¹⁰⁹	<ul style="list-style-type: none"> • Series of open-ended questions that are designed to predict abuse, neglect, or nonorganic failure to thrive • Participant answers are scored by best fit into predetermined categories • Subscale scores are developed for knowledge of parenting skills and philosophy about discipline, personality (extroversion, aggressiveness, dependency, and self-image), positive and negative feelings about the pregnancy, the mother's perception of her nurture as a child, a truncated version of the Life Stress Inventory for both mother and father, and a "lie" scale (to detect attempts to respond only with socially appropriate answers). 	<ul style="list-style-type: none"> • 90% or greater interobserver agreement among four trained interviewers.¹⁰⁹ 	<ul style="list-style-type: none"> • Validation study on 1400 expectant mothers screened¹³³ • Target children and siblings followed through 36 months for reports of abuse (excluding "unsubstantiated reports, grudge or crank reports, and those without evidence of trauma." Siblings were included only if their first abuse report occurred after the interview • Based on reported data,[†] calculated sensitivity: 65%; calculated specificity: 81.3%, positive predictive value: 5.5%, calculated negative predictive value: 99.3%; calculated false positive rate: 34.8%, calculated false negative rate: 18.7%

Appendix A3 Table 1. Reliability and Validity of Risk Screening Instruments Used in Included Studies

Instrument	Study using the Instrument	Description	Reliability	Validity*
Parent Screening Questionnaire (PSQ) ^{147, 148}	Dubowitz et al, 2009, ¹⁴⁸ Dubowitz et al, 2012 ¹⁴⁷	<ul style="list-style-type: none"> • 20-item self-report questionnaire • Screens for risk factors for maltreatment: parental depression, substance abuse, major stress, intimate partner violence, food insecurity, and harsh punishment. 	<ul style="list-style-type: none"> • Not reported 	<ul style="list-style-type: none"> • Not reported
Brief Infant-Toddler Social and Emotional Assessment (BITSEA) ^{114, 149}	Lowell et al, 2011 ¹¹⁴	<ul style="list-style-type: none"> • 42-item screener for parents and child-care providers • Measures both problems (problem scale, including items associating with externalizing and internalizing behaviors and dysregulation) and delays in the acquisition of competencies (competence scale, including competence, social relatedness, maladaptiveness, and atypicality) in 1- to 3-year-olds, also consists of items designed to measure symptoms of autism spectrum disorders. Intended to identify children “at risk” for or currently experiencing social-emotional/behavioral problems. 	<ul style="list-style-type: none"> • 10-to-45-day test-retest reliability (intraclass correlation coefficient) 0.87 for the problem scale; 0.85 for the competence scale, n=119).¹¹⁴ 	<ul style="list-style-type: none"> • Not reported
Parent Risk Questionnaire (PRQ) ¹¹⁴	Lowell et al, 2011 ¹¹⁴	<ul style="list-style-type: none"> • Developed for intervention (Lowell et al, 2011¹¹⁴): • 25-item parent-report screener Assessing risk in 12 areas including depression, domestic violence, substance use, homelessness, incarceration, isolation, single and teen parenthood, education, and employment. 	<ul style="list-style-type: none"> • Not reported 	<ul style="list-style-type: none"> • Not reported

* Specifically, we evaluated tests of validity against an external measure of abuse or neglect (not self-report), and included measures such as sensitivity, specificity, negative or positive predictive values, false negatives or positive, and area under the curve, when reported.

† By including subjective comments from the screening, 273 women would have been identified as high risk, with 15 being reported subsequently for abuse; 1127 women would have been identified as not being at high risk, with 8 being reported subsequently for abuse¹³³

Appendix A3 Table 2. Reliability and Validity of Additional Risk Screening Instruments

Instrument	Description	Reliability	Validity*
BabyFirst Screen ¹⁵⁰	<ul style="list-style-type: none"> • 23 weighted items relating to biological, psychological, and social risk factors for maltreatment. • One item about congenital anomaly or acquired disability, four items about developmental risk factors such as low birth weight and complications of pregnancy and delivery. • 8 items on family interaction risk factors such as age of mother, single parent households with or without social support, parent education status. • 10 items of other risk factors including relationship distress, multiple births, prenatal class attendance, maternal smoking during pregnancy, harsh discipline, existing involvement with child protective service, anxiety disorder, parent's criminal history or exposure to child abuse/neglect 	<ul style="list-style-type: none"> • Not reported 	<ul style="list-style-type: none"> • BabyFirst Screen administered at birth to parents of infants born in Manitoba, Canada between 2000 to 2002, followed for reports of out-of-home placement through 2004 • 5,563 (14.9%) screened "at risk," 24,923 (66.7%) screened "not at risk," 6,859 (18.3%) not screened¹⁵⁰ • 3% placed in out-of-home care at least once during the study period. • Reported sensitivity: 77.6%; specificity: 83.3%; positive predictive value: 10.9%, negative predictive value: 99.3%; false positive rate: 16.7%; false negative rate: 22.4%
Brisbane Evaluation of Needs Questionnaire ¹⁵¹	<ul style="list-style-type: none"> • Study-developed questionnaire designed to identify adverse family characteristics • The first tier included physical forms of domestic violence, childhood abuse of either parent, sole parenthood and ambivalence to the pregnancy (sought termination, no antenatal care) • Second tier included less definitive risk factors: maternal age less than 18 years, unstable housing, financial stress, less than 10 years of maternal education, low family income, social isolation, history of mental health disorder (either parent), alcohol or drug abuse, and domestic violence other than physical violence 	<ul style="list-style-type: none"> • Not reported 	<ul style="list-style-type: none"> • Not reported
Child Abuse Potential Inventory (CAPI) ^{138, 152}	<ul style="list-style-type: none"> • 160-item self-report measure consisting of a primary clinical scale containing a 77-item Physical Abuse Scale with eight subscales: distress, rigidity, unhappiness, ego, loneliness, problem with child and self, problem with family, and problem with others. 	<ul style="list-style-type: none"> • Split-half and Kuder-Richardson-20 reliability coefficients range from 0.92 to 0.98¹³⁸ 	<ul style="list-style-type: none"> • Not reported

* Specifically, we evaluated tests of validity against an external measure of abuse or neglect (not self-report), and included measures such as sensitivity, specificity, negative or positive predictive values, false negatives or positive, and area under the curve, when reported.

Appendix B1. Relationship of Current Included Studies to Previous AHRQ Evidence Reviews

Included in Nelson et al, 2013 and/or Nelson et al, 2004		Included in Viswanathan et al, 2018		
Records excluded in Viswanathan et al, 2018, with reason	Records included in Viswanathan et al, 2018 (11 RCTs in 16 publications)	New studies identified from electronic search (1 RCT in 1 publication)	New studies identified from hand search (2 RCTs in 2 publications)	Old studies identified from our hand search not captured in prior review (7 RCTs in 9 publications)
<p><i>Ineligible or no population:</i> Olds et al, 1995¹⁵³ Olds et al, 2007¹⁵⁴ Taylor et al, 2010¹⁵⁵</p> <p><i>Ineligible or no intervention:</i> Anderson, 1993¹⁴¹ Cerny and Inouye, 2001¹³⁸ Korfmaier, 2000¹⁴⁴ Stevens-Simon and Barrett, 2001¹⁵⁶</p> <p><i>Ineligible or no outcome:</i> Armstrong et al, 1999¹⁵¹ Black et al, 1994¹⁵⁷ Bugental et al, 2002¹⁵⁸ Duggan et al, 2000¹⁵⁹ El-Mohandes et al, 2003¹⁶⁰ Fraser et al, 2000¹⁶¹ El-Mohandes et al, 2010¹⁶² Kiely et al, 2010¹⁶³ Olds et al, 2004¹⁶⁴</p> <p><i>Ineligible study design:</i> Dawson et al, 1989¹⁶⁵ Flynn, 1999¹⁶⁶ Leventhal et al, 1996¹⁶⁷ McGuigan et al, 2000¹⁶⁸</p> <p><i>Irretrievable:</i> Katsev et al, 1999¹⁶⁹ CCAPR, 1996¹⁷⁰</p> <p><i>Poor quality:</i> Barth, 1991¹³⁴ Dubowitz et al, 2009¹⁴⁸ Duggan et al, 1999¹⁴⁵ Duggan et al, 2004¹⁴⁶ Gray et al, 1979¹³⁵ Koniak-Griffin et al, 2003¹⁷¹</p>	<p>Lowell et al, 2011¹¹⁴ Barlow et al, 2007¹⁰¹ Fergusson et al, 2005¹⁰⁵ Brayden et al, 1993¹⁰⁹ Brooten et al, 1986¹¹⁰ Bugental and Schwartz, 2009¹⁰³ Duggan et al, 2007⁸⁷ DuMont et al, 2008⁸⁹ Marcenko and Spence, 1994¹¹⁵ Kitzman et al, 1997⁹³ Olds et al, 2007⁹⁴ Olds et al, 1986⁹⁵ Olds et al, 1994⁹⁶ Olds et al, 1997⁹⁷ Eckenrode et al, 2000⁹⁸ Siegel et al, 1980⁸⁶</p>	Easterbrooks et al, 2013 ¹⁰⁴	<p>Sadler et al, 2013⁹¹ Robling et al, 2016⁹²</p>	<p>Lam et al, 2009¹⁰⁰ Silovsky et al, 2011¹⁰⁸ Guyer et al, 2003¹¹² Minkovitz et al, 2007¹¹³ Finello et al, 1998¹¹¹ Wiggins et al, 2005¹¹⁸ Wiggins et al, 2004¹¹⁷ Larson, 1980¹⁰⁷ Quinlivan et al, 2003¹¹⁶</p>

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; CCAPR=Center on Child Abuse Prevention Research; RCT=randomized, controlled trial.

Appendix B2. Search Strategies

KQ 1 and KQ 2 PubMed (January 1, 2011, through August 2, 2016)

	Terms	Results
#4	Search ("Child Abuse"[Mesh]) OR "Shaken Baby Syndrome"[Mesh]	26291
#6	Search "Child, Abandoned"[Mesh] OR "emotional abuse"[tw]	1762
#8	Search "Domestic Violence"[Mesh]	38014
#9	Search "Domestic Violence"[Mesh] Filters: Child: birth-18 years	28626
#11	Search (#4 OR#6 OR#9)	30620
#12	Search (((("Single-Blind Method"[Mesh]) OR "Double-Blind Method"[Mesh]) OR "Random Allocation"[Mesh]) OR ("Randomized Controlled Trials as Topic"[Mesh] OR "Randomized Controlled Trial" [Publication Type])	610171
#14	Search (#11 AND#12)	605
#17	Search ("Cohort Studies"[Mesh]) OR "Prospective Studies"[Mesh] OR (prospective AND cohort)	1559045
#18	Search (#11 AND#17)	3746
#19	Search (#4 OR#6 OR#9) Filters: Systematic Review s	638
#20	Search (#19 OR#18 OR#14) Filters: Systematic Review s	638
#21	Search (#19 OR#18 OR#14)	4771
#22	Search (#19 OR#18 OR#14) Filters: Child: birth-18 years	4697
#23	Search (#19 OR#18 OR#14) Filters: Humans; Child: birth-18 years	4695
#24	Search (#19 OR#18 OR#14) Filters: Humans; English; Child: birth-18 years	4476
#25	Search (#19 OR#18 OR#14) Filters: Publication date from 2011/01/01; Humans; English; Child: birth-18 years	1447

PubMed=1447

Cochrane

Child AND (abuse OR neglect OR maltreatment)=9=0 New

EMBASE

Child AND (abuse OR neglect OR maltreatment)=305=197 New

ClinicalTrials.gov

Child AND (abuse OR neglect OR maltreatment)=25

HSRProj

Child AND (abuse OR neglect OR maltreatment)=9

Cochrane Clinical Trials Registry

Child AND (abuse OR neglect OR maltreatment)=37=8 New

WHO ICTRP

Child AND (abuse OR neglect OR maltreatment)=8=0 New

Total Database=1661

Both Databases KQ 1 and KQ 2=1661

Appendix B2. Search Strategies

KQ 1 and KQ 2 PubMed (August 3, 2016, through December 18, 2017)

	Terms	Results
#1	Search ("Child Abuse"[Mesh]) OR "Shaken Baby Syndrome"[Mesh]	27580
#2	Search "Child, Abandoned"[Mesh] OR "emotional abuse"[tw]	2022
#3	Search "Domestic Violence"[Mesh]	39977
#4	Search "Domestic Violence"[Mesh] Filters: Child: birth-18 years	30107
#5	Search (#1 OR #2 OR #4)	32294
#6	Search (((("Single-Blind Method"[Mesh]) OR "Double-Blind Method"[Mesh]) OR "Random Allocation"[Mesh]) OR ("Randomized Controlled Trials as Topic"[Mesh] OR "Randomized Controlled Trial" [Publication Type])	659186
#7	Search (#5 AND #6)	660
#8	Search ("Cohort Studies"[Mesh]) OR "Prospective Studies"[Mesh] OR (prospective AND cohort)	1715795
#9	Search (#5 AND #8)	4044
#10	Search (#1 OR #2 OR #4) Filters: Systematic Reviews	733
#11	Search (#7 OR #9 OR #10)	5204
#12	Search (#7 OR #9 OR #10) Filters: Child: birth-18 years	5102
#13	Search (#7 OR #9 OR #10) Filters: Humans; Child: birth-18 years	5100
#14	Search (#7 OR #9 OR #10) Filters: Humans; English; Child: birth-18 years	4867
#15	Search (#7 OR #9 OR #10) Filters: Publication date from 2016/01/01; Humans; English; Child: birth-18 years	325

PubMed=325=306 New

Cochrane

Child AND (abuse OR neglect OR maltreatment)=4=3 New

EMBASE

Child AND (abuse OR neglect OR maltreatment)=76=24 New

ClinicalTrials.gov

Child AND (abuse OR neglect OR maltreatment)=32 =27 New

HSRProj

Child AND (abuse OR neglect OR maltreatment)=1

Cochrane Clinical Trials Registry

Child AND (abuse OR neglect OR maltreatment)=29=18 New

WHO ICTRP

Child AND (abuse OR neglect OR maltreatment)=2=2 New

Total Database=381 New

Appendix B3. Eligibility Criteria for Study Selection

Include or Exclude Question	Exclusion Code	Reason for Exclusion	Inclusion Criteria	Exclusion Criteria
1. Does the article represent original research?	X1	Ineligible publication type	Original research and systematic reviews	Editorials, commentaries, or narrative reviews
2. Does the study report on the population of interest?	X2	Ineligible or no population	Children and adolescents (birth through age 18 years) with no known exposure to maltreatment and no signs or symptoms of current or past maltreatment (but may have known risk factors that lead to inclusion in trials)	Symptomatic children and adolescents undergoing diagnostic evaluation for conditions related to abuse or neglect (e.g., those presenting with a broken bone or other signs of physical abuse or neglect, trauma symptoms associated with domestic violence exposure), asymptomatic children with known exposure to child maltreatment, perpetrators of maltreatment, and children who have maltreatment perpetrated against them by a caregiver
3. Does the study include an intervention of interest?	X3	Ineligible or no intervention	Services that could result from a referral by a primary care provider; services may be implemented by a nonclinician and may include home visiting programs, primary care-based programs, respite care, parent education programs, and family support and family strengthening programs Family-focused interventions may be directed at the caregiver and may or may not include components directed at the child	Community-wide interventions only, such as public awareness campaigns or public service announcements, without specific interventions linked to clinical settings
4. Does the study use a comparator of interest?	X4	Ineligible or no comparison	Usual care, delayed intervention, or active interventions that allow for assessment of the independent contribution of the primary care–feasible or referable preventive intervention (e.g., clinical interventions plus media campaigns vs. media campaigns)	Comparators that do not allow for assessment of the independent contribution of the primary-care–feasible or referable preventive intervention (e.g., clinical interventions plus media campaigns vs. usual care)

Appendix B3. Eligibility Criteria for Study Selection

Include or Exclude Question	Exclusion Code	Reason for Exclusion	Inclusion Criteria	Exclusion Criteria
5. Does the study report on outcomes of interest?	X5	Ineligible or no outcome	<p>KQ 1: Direct or proxy measures of abuse or neglect (required):</p> <ul style="list-style-type: none"> Physical, sexual, or emotional abuse perpetrated by a parent or caregiver against a child* Physical (e.g., failure to thrive), emotional, dental/medical (e.g., lack of immunizations or well-child visits), or educational neglect Reports to child protective services Removal of the child from the home Injuries such as broken bones, bruises, burns, and other injuries with a high specificity for abuse Visits to the emergency department Hospitalizations <p>Behavioral, emotional, mental, or physical well-being:</p> <ul style="list-style-type: none"> Decreased internalizing behaviors (depression, anxiety) Decreased externalizing behaviors (disruptive, aggressive, or delinquent behavior) Healthy social-emotional development (e.g., attachment problems, peer relationships); reduced developmental delays (language, cognitive) Decreased incidence of reactive attachment disorder, disinhibited social engagement disorder, acute stress disorder, or posttraumatic stress disorder 	<p>KQ 1: Outcomes not otherwise specified; studies without direct or proxy measures of abuse or neglect</p> <p>KQ 2: None</p> <p><i>*Note: Studies reporting behavioral, emotional, mental, or physical well-being outcomes included on the left for KQ 1 that do not also report at least one child maltreatment outcomes will be excluded.</i></p>
5. Does the study report on outcomes of interest? (continued)			<ul style="list-style-type: none"> Decreased incidence of traumatic stress symptoms, such as impairments in attachment, self-regulation, under- or overcontrolling behaviors (e.g., irritable/angry outbursts, self-destructive behavior, food hoarding), executive functioning, and self-concept; hypervigilance; exaggerated startle response; dissociation; concentration problems; somatic problems (e.g., headaches, gastrointestinal problems); sleep disturbances; and nightmares Decreased suicidality and self-injurious behaviors Improved school attendance and performance Reduced risky behaviors and outcomes (e.g., sexually transmitted diseases) Mortality <p>KQ 2: Any harms that result as an effect of the intervention (e.g., stigma, labeling, legal risks, risk of further harm to the child, dissolution of the family); worsening of outcomes listed for KQ 1</p>	

Appendix B3. Eligibility Criteria for Study Selection

Include or Exclude Question	Exclusion Code	Reason for Exclusion	Inclusion Criteria	Exclusion Criteria
6. Is the study conducted in a clinical setting of interest?	X4	Ineligible or nonclinical setting	Primary-care feasible or referable: pediatric, primary care, family medicine, school-based clinic, or other settings where primary care services are offered; services that could result from an assessment by a clinician (including delivery hospitals, in-home settings, and nonspecialist settings)	Not a primary-care feasible or referable setting; populations or services/interventions that are not applicable to U.S. practice
7. Does the study use a study design of interest?	X7	Ineligible study design	KQ 1: Randomized, controlled trials; systematic reviews KQ 2: Randomized, controlled trials, controlled clinical trials, systematic reviews, cohort trials with a control group; and case-control studies	KQ 1: Nonrandomized cohort trials, case-control studies, case series, or case studies KQ 2: Case series or case studies
8. Does the study include countries with an HDI similar to the United States?	X8	Ineligible country or region	Research conducted in the United States or in populations similar to U.S. populations, with services and interventions applicable to U.S. practice (i.e., conducted in countries categorized as “very high” on the Human Development Index [as defined by the United Nations Development Programme])	Research not relevant to the United States (i.e., conducted in countries not categorized as “very high” on the Human Development Index)
9. Is article published in English?	X9	Not published in English	Studies published in English	Studies published in any language other than English

Note: Four additional exclusion codes not specified in the work plan were later applied to studies for systematic reviews that were used in hand search, ongoing studies with no publication, publications that were irretrievable, and studies that were rated poor in quality.

* Self-reported measures of child abuse or neglect are not included in the report as eligible outcomes. They are summarized in a contextual question.

Abbreviations: HDI=Human Development Index; KQ=key question; U.S.=United States.

Appendix B4. USPSTF Quality Rating Criteria

RCTs and Cohort Studies

- Initial assembly of comparable groups:
 - For RCTs: Adequate randomization, including first concealment and whether potential confounders were distributed equally among groups
 - For cohort studies: Consideration of potential confounders, with either restriction or measurement for adjustment in the analysis; consideration of inception cohorts
- Maintenance of comparable groups (includes attrition, cross-overs, adherence, contamination)
- Important differential loss to followup or overall high loss to followup
- Measurements: Equal, reliable, and valid (includes masking of outcome assessment)
- Clear definition of interventions
- All important outcomes considered
- Analysis: Adjustment for potential confounders for cohort studies or intention-to-treat analysis for RCTs

Definition of ratings based on above criteria:

Good: Meets all criteria: Comparable groups are assembled initially and maintained throughout the study (followup $\geq 80\%$); reliable and valid measurement instruments are used and applied equally to all groups; interventions are spelled out clearly; all important outcomes are considered; and appropriate attention is given to confounders in analysis. In addition, intention-to-treat analysis is used for RCTs.

Fair: Studies are graded “fair” if any or all of the following problems occur, without the fatal flaws noted in the “poor” category below: Generally comparable groups are assembled initially, but some question remains whether some (although not major) differences occurred with followup; measurement instruments are acceptable (although not the best) and generally applied equally; some but not all important outcomes are considered; and some but not all potential confounders are accounted for. Intention-to-treat analysis is used for RCTs.

Poor: Studies are graded “poor” if any of the following fatal flaws exists: Groups assembled initially are not close to being comparable or maintained throughout the study; unreliable or invalid measurement instruments are used or not applied equally among groups (including not masking outcome assessment); and key confounders are given little or no attention. Intention-to-treat analysis is lacking for RCTs.

Source: U.S. Preventive Services Task Force Procedure Manual, Appendix VI. Criteria for Assessing Internal Validity of Individual Studies. Available at: <https://www.uspreventiveservicestaskforce.org/Page/Name/methods-and-processes>

Appendix B5. Risk of Bias Assessment Form

Domain	Domain-Specific Question	Assessment
Bias arising from randomization	1. Was method of randomization adequate? (e.g., random number table, computer-generated randomization)? Mark no if they used alternate days/times, etc.	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias arising from randomization	2. Was allocation concealment adequate? (e.g., pharmacy-controlled randomization or use of sequentially numbered sealed envelopes)?	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias arising from randomization	3. Were group characteristics balanced at baseline? Not all imbalances matter—some could occur by chance. Answer “no” only if the differences appear to be the result of poor or failed randomization	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias arising from randomization	Bias arising from randomization or selection? (If all or most items in this domain were answered as “Yes” or “Probably Yes,” then this domain should be rated as “Low.”)	<input type="checkbox"/> High <input type="checkbox"/> Some concerns <input type="checkbox"/> Low <input type="checkbox"/> Uncertain because no information
Bias arising from randomization	Comments (Provide justification for a “high” or “some concern” ROB rating.)	Enter text
Bias due to missing outcome data	4. What was the overall attrition? (# not included at follow up/# at baseline) What was the attrition by group? Did attrition vary for different outcomes?	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias due to missing outcome data	5. Did the study have low attrition? (i.e., ≤20% for overall attrition or ≤15% for differential attrition [this refers to an absolute difference in the attrition rate of 15% or more between groups])	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias due to missing outcome data	6. Are the proportion of participants and reasons for missing data similar across interventions?	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias due to missing outcome data	7. For benefits outcomes, was intent-to-treat analysis used?	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias due to missing outcome data	8. Were appropriate statistical methods used to account for missing data? Extrapolation of last observation carried forward (LOCF) may be appropriate as long as there is not a lot of change over time that is expected.	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA

Appendix B5. Risk of Bias Assessment Form

Domain	Domain-Specific Question	Assessment
Bias due to missing outcome data	Bias arising from missing outcome data? (If all or most items in this domain were answered as "Yes" or "Probably Yes," then this domain should be rated as "Low.")	<input type="checkbox"/> High <input type="checkbox"/> Some concerns <input type="checkbox"/> Low <input type="checkbox"/> Uncertain because no information
Bias due to missing outcome data	Comments (Provide justification for a "high" or "some concern" ROB rating.)	Enter text
Bias due to departures from intended intervention	9. Were the patients unaware of their intervention status of participants? This refers to "masking" or "blinding."	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias due to departures from intended intervention	10. Were the trial personnel and clinicians unaware of the intervention status of participants? This refers to the "masking" or "blinding" of the clinicians/researchers administering the intervention.	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias due to departures from intended intervention	11. Were outcome assessors unaware of the intervention status of participants? This refers to the "masking" or "blinding" of the researchers performing the outcome assessment.	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias due to departures from intended intervention	12. Was intervention fidelity adequate? (e.g., Did researchers rule out any impact from a concurrent intervention or an unintended exposure that might bias results? Was adherence adequate?)	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias due to departures from intended intervention	13. Were cross-overs or contamination minimal such that it would not raise concern for bias?	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias due to departures from intended intervention	Bias arising from departures from intended interventions? (If all or most items in this domain were answered as "Yes" or "Probably Yes," then this domain should be rated as "Low.")	<input type="checkbox"/> High <input type="checkbox"/> Some concerns <input type="checkbox"/> Low <input type="checkbox"/> Uncertain because no information
Bias due to departures from intended intervention	Comments (Provide justification for a "high" or "some concern" ROB rating.)	Enter text
Bias from measurement of outcomes	14. Were benefit outcomes (e.g., abuse) adequately described, prespecified, valid, and reliable? If this varied by outcome, please answer for the "main" or "primary" outcome here and then describe which is the main outcome in the comment and provide information on this item for any other outcomes we are likely to report from this study.	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias from measurement of outcomes	15. Were similar techniques used among groups to ascertain benefit outcomes?	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA

Appendix B5. Risk of Bias Assessment Form

Domain	Domain-Specific Question	Assessment
Bias from measurement of outcomes	16. Was the duration of follow up adequate to assess benefit outcomes?	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias from measurement of outcomes	Bias arising from measurement of benefit outcomes? (If all or most items in this domain were answered as “Yes” or “Probably Yes,” then this domain should be rated as “Low.”)	<input type="checkbox"/> High <input type="checkbox"/> Some concerns <input type="checkbox"/> Low <input type="checkbox"/> Uncertain because no information
Bias from measurement of outcomes	Comments (Provide justification for a “high” or “some concern” ROB rating.)	Enter text
Bias from measurement of outcomes	17. Were harm outcomes adequately described, valid and reliable?*	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias from measurement of outcomes	If this varied by outcome, please answer for the “main” or “primary” outcome here and then describe which is the main outcome in the comment and provide information on this item for any other outcomes we are likely to report from this study.	
Bias from measurement of outcomes	18. Were similar techniques used among groups to ascertain harm outcomes? [†]	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias from measurement of outcomes	19. Was the duration of follow up adequate to assess harm outcomes? [†]	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias from measurement of outcomes	Bias arising from measurement of harm outcomes? [†] (If all or most items in this domain were answered as “Yes” or “Probably Yes,” then this domain should be rated as “Low.”)	<input type="checkbox"/> High <input type="checkbox"/> Some concerns <input type="checkbox"/> Low <input type="checkbox"/> Uncertain because no information
Bias from measurement of outcomes	Comments [†] (Provide justification for a “high” or “some concern” ROB rating.)	Enter text
Bias in selection of the reported result	20. Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?	<input type="checkbox"/> Yes <input type="checkbox"/> Probably yes <input type="checkbox"/> Probably no <input type="checkbox"/> No <input type="checkbox"/> No information <input type="checkbox"/> NA
Bias in selection of the reported result	Bias arising from selection of reported results? (If all or most items in this domain were answered as “Yes” or “Probably Yes,” then this domain should be rated as “Low.”)	<input type="checkbox"/> High <input type="checkbox"/> Some concerns <input type="checkbox"/> Low <input type="checkbox"/> Uncertain because no information
Bias in selection of the reported result	Comments (Provide justification for a “high” or “some concern” ROB rating.)	Enter text
Study quality—Benefits	What is the overall quality of the study?	<input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> NA

Appendix B5. Risk of Bias Assessment Form

Domain	Domain-Specific Question	Assessment
Study quality—Benefits	Overall rating justification or comments	Enter text
Study quality—Benefits	Does ROB rating of study vary by benefits outcome?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Study quality—Benefits	Study quality ratings by benefits outcome	Enter text
Study quality—Harms	What is the overall quality of the study? [†]	<input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> NA
Study quality—Harms	Overall rating justification or comments [†]	Enter text
Study quality—Harms	Does ROB rating of study vary by harms outcome? [†]	<input type="checkbox"/> Yes <input type="checkbox"/> No
Study quality—Harms	Study quality ratings by harms outcome [†]	Enter text

[†] None of the included studies in this review reported on harms outcomes. Risk of bias ratings for harms outcomes were not included in Appendix E because they were not applicable to all included studies.

Appendix C. Reasons for Exclusion

Exclusion Codes:

EX1: Ineligible publication type
 EX 2: Ineligible population
 EX 3: Ineligible/no intervention
 EX 4: Ineligible/no comparison
 EX 5: Ineligible/no outcomes
 EX 6: Ineligible/nonclinical setting
 EX 7: Ineligible study design
 EX 8: Ineligible country/region
 EX 9: Not in English
 EX 10: Systematic reviews used for handsearch
 EX 11: Ongoing studies with no publications
 EX 12: Irretrievable
 EX 13: Poor quality

1. Allen KA. The neonatal nurse's role in preventing abusive head trauma. *Adv Neonatal Care*. 2014 Oct;14(5):336-42. doi: 10.1097/ANC.0000000000000117. PMID: 25137601. Exclusion Code: X4.
2. Altman RL, Canter J, Patrick PA, et al. Parent education by maternity nurses and prevention of abusive head trauma. *Pediatrics*. 2011 Nov;128(5):e1164-72. doi: 10.1542/peds.2010-3260. PMID: 22025587. Exclusion Code: X7.
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Appendix D Table 1. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Program Name, Funding Source, and Design

Author, Year	Program/ Trial Name	Country	Funding Source	Study Date Range	Study Design	No. of Study Arms	Total N	Duration
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰²	Family Partnership Model	United Kingdom	Nuffield Foundation, Department of Health	2003 to 2004*	Parallel group RCT	2	131 caregivers [†]	18 months
Brayden et al, 1993 ¹⁰⁹	NA	United States	National Institute of Mental Health and National Institute of Child Health and Human Development	1984 to 1988	Parallel group RCT	3	314 mothers at high risk	2 years
Brooten et al, 1986 ¹¹⁰	NA	United States	Robert Wood Johnson Foundation and the Division of Nursing, Health Resources Administration, U.S. Department of Health and Human Services	1982 to 1987	Parallel group RCT	2	79 infants	18 months
Bugental and Schwartz, 2009 ¹⁰³	Healthy Start+	United States	National Institutes of Health; National Science Foundation	NR	Parallel group RCT	2	147 caretakers randomized, 110 agreed to participate	1 year
Caldera et al, 2007 ⁸⁸ Duggan et al, 2007 ⁸⁷	Healthy Families Alaska	United States	Alaska Mental Health Trust Authority and Alaska State Department of Health and Social Services	2000 to 2003	Parallel group RCT	2	364 families randomized	2 years
DuMont et al, 2008 ⁸⁹ DuMont et al, 2010 ⁹⁰	Healthy Families New York	United States	Department of Health and Human Services Office on Child Abuse and Neglect, follow up funded by National Institute of Justice	Recruitment: March 2000 to August 2001	Parallel group RCT	2	1,173 mothers	Original study: 2 years Follow up: 7 years
Easterbrooks et al, 2013 ¹⁰⁴	Healthy Families Massachusetts	United States	The Massachusetts Children's Trust Fund; Pew Center for the States	NR	Parallel group RCT	2	707 caregivers [‡]	24 months
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶	Early Start Program	New Zealand	The Health Research Council of New Zealand, the National Child Health Research Foundation, the Canterbury Medical Research Foundation, and the New Zealand Lottery Grants Board	Recruitment: January 2000 to July 2001 [§]	Parallel group RCT	2	443 families	Up to 36 months; average 24 months

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Author, Year	Program/ Trial Name	Country	Funding Source	Study Date Range	Study Design	No. of Study Arms	Total N	Duration
Finello et al, 1998 ¹¹¹	NA	United States	PAIDOS Healthcare, Hastings Foundation, State of California Department of Health Services	NR	Parallel group RCT	4	81 infants	24 months
Guyer et al, 2003 ¹¹² Minkovitz et al, 2007 ¹¹³	Heathy Steps for Young Children	United States	Agency for Healthcare Research and Quality; the Commonwealth Fund and over 60 national and local sponsors	Enrollment: September 1996 to November 1998	Parallel group RCT	2	2,584 children randomized (randomization occurred at birth before enrollment or checks for eligibility), 2,235 children enrolled (RCT design only)	3 years
Kitzman et al, 1997 ⁹³ Olds et al, 2007 ⁹⁴	The Memphis Trial	United States (TN)	National Institute of Nursing Research, the Bureau of Maternal and Child Health, the Administration for Children and Families, the Office of the Assistant Secretary for Planning and Evaluation, the National Center for Child Abuse and Neglect	Participants recruited from Jun 1990–Aug 1991	Parallel group RCT	4	1,139 caregivers ^l randomized during the prenatal phase of the study, 743 enrolled for follow up in the postnatal phase	24 months
Lam et al, 2009 ¹⁰⁰	NA	United States	National Institute on Alcohol Abuse and Alcoholism	NR	Parallel group RCT	3	30 male patients (w ith their female partners and custodial children)	12 weeks
Larson, 1980 ¹⁰⁷	NA	Canada	National Health and Welfare Canada, Health Programs Branch	NR	Parallel group RCT	3 ^{fl}	115 mother-infant pairs	G1: 0 months G2: approximately 13.5 months
Low ell et al, 2011 ¹¹⁴	Child and Family Interagency, Resource, Support, and Training	United States	The Starting Early Starting Smart Prototype (Substance Abuse and Mental Health Services Administration) and the Robert Wood Johnson Foundation	NR	Parallel group RCT	2	157 families	Mean 22.1 weeks [#]

Appendix D Table 1. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Program Name, Funding Source, and Design

Author, Year	Program/ Trial Name	Country	Funding Source	Study Date Range	Study Design	No. of Study Arms	Total N	Duration
Marcenko and Spence, 1994 ¹¹⁵	NA	United States	A grant from the Department of Health and Human Services (90CB004-01) under the Abandoned Infants Assistance Program.	NR	Parallel group RCT	2	225 mothers	Pregnancy through 12 months of age
Olds et al, 1986 ⁹⁵ Olds et al, 1994 ⁹⁶ Olds et al, 1997 ⁹⁷ Eckenrode et al, 2000 ⁹⁸ Zielinski et al, 2009 ⁹⁹	The Elmira Trial	United States	Bureau of Community Health Services, Robert Wood Johnson Foundation, W. T. Grant Foundation	1981 to 1996	Parallel group RCT	4 ^{**}	400 families	Pregnancy through 2 years of age
Quinlivan and Street, 2003 ¹¹⁶	NA	Australia	Health Department of Australia	July 1998–December 2000	Parallel group RCT	2	136 pregnant adolescents	6 months
Robling et al, 2016 ⁹²	Family Nurse Partnership	United Kingdom	Policy Research Programme, Department of Health (England)	June 2009 (screening of women began)-April 2014 (all follow up data collected)	Parallel group RCT	2	1,645 mothers	~27-33 months (home visits from early pregnancy [eligible women were of <25 weeks gestation] until child's second birthday)
Sadler et al, 2013 ⁹¹	Minding the Baby	United States	National Institutes of Health, several foundations (Irving B. Harris, FAR, Annie E. Casey, Pritzker Early Childhood, Seedlings, Edlow Family, Schneider family)	NR	Cluster group RCT	2	105 families	27 months
Siegel et al, 1980 ⁸⁶	NA	United States (NC)	National Institute of Child Health and Human Development, the William T. Grant Foundation	Participants recruited from Jan 1976–Oct 1977	Parallel group RCT	6 ^{††}	321 caregiver ^{**}	3 months
Silovsky et al, 2011 ¹⁰⁸	SafeCare+	United States	U.S. Department of Justice, Oklahoma Department of Human Services	March 2007–May 2009	Parallel group RCT	2	105 caregivers	NR ^{§§}

Appendix D Table 1. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Program Name, Funding Source, and Design

Author, Year	Program/ Trial Name	Country	Funding Source	Study Date Range	Study Design	No. of Study Arms	Total N	Duration
Wiggins et al, 2005 ¹¹⁸ Wiggins et al, 2004 ¹¹⁷	The Social Support and Family Health Study	United Kingdom	Health Technology Assessment Programme of the National Health Service Research and Development Programme and the Camden and Islington Health Authority	Recruitment in 1999	Parallel group RCT	3	731 women and their infants	1 year

* Based on cost analysis results reported in McIntosh et al, 2009.¹⁰²

† Randomized subjects were vulnerable pregnant women.

‡ Randomized subjects were first-time mothers.

§ The 19-month recruitment period was from January 1, 2000 to July 31, 2001, so although it was not reported, the dates of the original study are likely to be 2001-2004, and the dates of the followup study are likely to be 2004-2010.

‖ Randomized subjects were pregnant women.

¶ The study included a nonrandomized arm not further described in the evidence tables.

Treatment duration was individualized; Mean 22.1 weeks (SD=14.5, median=18.7).

** Intervention and baseline characteristics only reported for three of the study groups (Treatments 1 and 2 were combined for purposes of analysis after it was determined that there were no differences between the group). See comments in *Appendix D Table 3* for detailed explanation.

†† The study stratified the design to account for neonates who needed observation nursery in the first 24 hours. The remainder of the evidence tables combine the two usual-care arms and the two intensive-intervention arms. See *Appendix D Table 3* for detailed explanation.

Randomized subjects were pregnant women.

§§ Post-service time point is no earlier than 6 months after the pre-service interview.

Abbreviations: FAR=the FAR fund from New York City ; G=group; KQ=key question; NA=not applicable; NC=North Carolina; NR=not reported; PAIDOS=PAIDOS Healthcare, Inc.; RCT=randomized, controlled trials; SD=standard deviation; TN=Tennessee.

Appendix D Table 2. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰² (Family Partnership Model)	Parents in both arms continued to receive the standard help then available to such families	Control, n=63 pregnant women*	Standard services available for vulnerable families	Women in the control group had a mean of 9.2 visits by health visitors	Intervention, n=68† pregnant women*	18 months of weekly visits from a health visitor trained in understanding the processes of helping, skills of relating to parents effectively, and methods of promoting parent-infant interaction using the Family Partnership Model.	The intervention group received, on average, two-thirds (41.2) of the total possible number of 72 intervention visits
Brayden et al, 1993 ¹⁰⁹	NR	HR control group, n=154 mothers	Standard of care for prenatal, postnatal, and pediatric services	Some women who were predicted to be at high risk were assigned to the HR control group to receive the standard of care. Standard prenatal, postnatal, and pediatric care was provided to participants and consisted of routine medical services provided by the obstetric and pediatric residents of the hospital in outpatient clinics. Medical care was supervised by hospital attending physicians.	HRI group, n=160 mothers	A comprehensive, medically based maternal and child health program	Prenatal, postnatal, and pediatric care was provided until children were 2 years of age. Care was provided by a multidisciplinary team of nurses, midwives, nurse practitioners, social workers, paraprofessional home visitors, a nutritionist, and a psychologist. Psychological support, education about self-care, and promotion of health behaviors during pregnancy and early parenthood were provided. Telephone calls, mailings, and, in some cases, home visits followed each missed appointment. Participants were assigned to a main support person from the clinical staff. Individual appointments with the psychologist were provided to mothers until 28 weeks of gestation. Support groups also met twice a month until children were 22 months of age. The intervention program had a lower patient-to-staff ratio and provided greater continuity of care.

Appendix D Table 2. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Brooten et al, 1986 ¹¹⁰	Long-term medical follow up care was provided to infants in both groups by the hospital's HR follow up clinic or by private pediatricians.	Routine care, n=40 infants [§]	Routine care	Infants were discharged from neonatal care units per routine nursery policy, which required that the infant be clinically well, feeding well, and weigh approximately 2,200 g. Although parents received support and instruction from nursery nurses about their infant and his or her care discharge, no routine home follow up care by nurses was provided.	Early discharge, n=39 infants	NR	Infants were discharged before they weighed 2,200 g so long as they were clinically well and able to feed by nipple every 4 hours, were able to maintain their body temperature in an open crib in room air, had no evidence of sleep apnea or bradycardia in a 12-hour recording of the infant's heart rate and respiration, their mother or other caregiver demonstrated satisfactory care-taking skills, and the physical home environment and facilities for the care of the infant were adequate. The early-discharge group received home follow up care provided by a nurse who promoted parental interaction with the infant, evaluated parental perception and concerns, taught parents how to take care of their infant, and at times provided routine medical care. Nurses had weekly contact with parents via phone. Home visits were conducted the first week and at 1, 9, 12, and 18 months.

Appendix D Table 2. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Bugental and Schwartz, 2009 ¹⁰³ (Healthy Start+)	Healthy Start home visitation program	Standard home visit, n=59 mothers	Standard HSP home visitation program	NR	Intervention, n=51 mothers	Cognitive-based extension of HSP home visitation program: Additional cognitive appraisal component was designed to enhance parents' perceptions of power and competence and included reframing in primary and secondary appraisals. Specifically, parents were assisted in acquiring skills in reading children's cues of distress and countering misattributional processes and provided with problem-solving training in which they define the problem, brainstorm possible solutions, evaluate possible consequences, develop an action plan, and observe and evaluate the success of their efforts. Home visitors were matched to participants' cultural backgrounds. Weekly supervision and monitoring occurred from a licensed clinical psychologist. Over the 1st year of life of the child, there were 17 home visits.	Briefly, the key distinction between groups was the facilitation of mothers' own problem-solving and information search in G2 vs. the provision of ideas on how to solve problems along with relevant information in G1.
Caldera et al, 2007 ⁸⁸ Duggan et al, 2007 ⁸⁷ (Healthy Families Alaska)	NA	Control, n=185 randomized, 163 randomized and completed baseline interview	Referral to other community services	NR	HFAK Intervention, n=179 randomized, 162 randomized and completed baseline interview	Home visiting offered for 3–5 years, offered weekly for the first 6–9 months; families are promoted to service levels with less frequent visits as family functioning improves. Home visitation includes information, referrals, preparation of parents for developmental milestones, promotion of child environmental safety, and encouragement of positive parent-child interaction.	NR

Appendix D Table 2. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
DuMont et al, 2008 ⁸⁹ DuMont et al, 2010 ⁹⁰ (Healthy Families New York)	NR	Control, n=594 mothers	Mothers in the control group were provided with only research and information regarding other service providers. Frequency and duration are not reported.	NR	Intervention, n=579 mothers	Participant was assigned a home visitor who contacted her to set up initial home visit. Families were offered HFNY services: Home visits by trained paraprofessionals. Visits were scheduled biweekly during pregnancy and increase to once a week after mother gives birth. Prenatal visits focus on promoting healthy behaviors, discouraging risky behaviors, coping with stress, encouraging compliance with prenatal appointments and medical advice, and educating expectant mother about development of the fetus. Following birth of child, home visits concentrate on 1) improving parent-child relationship through instruction, reinforcement, modeling, and parent-child activities; 2) helping parents understand child development and age-appropriate behaviors; 3) promoting optimal health and development by supporting healthy behaviors, improving compliance with scheduled immunizations and well-	Families who enrolled in HFNY received an average of nearly 22 visits between BL and 1Y, with almost 30% receiving >30 visits. Only 8% of families received just 1 or 2 visits. Families who were still participating in the program between 1Y and 2Y received average of 14 visits, with 42% receiving between 11 and 20 visits in that year.

Appendix D Table 2. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
DuMont et al, 2008 ⁸⁹ DuMont et al, 2010 ⁹⁰ (continued)						child visits, facilitating linkages to and encouraging appropriate use of healthcare, and connecting families with Food Stamps, housing assistance, or other community resources; and 4) enhancing parental life course development and self-sufficiency by developing Individual Family Support Plans.	
Easterbrooks et al, 2013 ¹⁰⁴ (Healthy Families Massachusetts)	NR	Control, n=NR	Resource and information only	NR	HV (Home Visiting Services) Group, n=NR	Statewide paraprofessional child maltreatment prevention home visit program in which young, first-time mothers and their children received visits from paraprofessional home visitors. Frequency and duration are not reported.	NR
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ (Early Start Program)	NR	Control, n=223 families randomized, 221 families agreed to participate	NR	NR	Early Start Program, n=220 families randomized, 206 families agreed to participate	Assess needs and resources, encourage positive partnership, provide support and problem solving for up to 36 months	Services received for a mean of 24 months
Finello et al, 1998 ¹¹¹	Enrollment in appropriate hospital follow up clinic for well-baby care, formal developmental assessment, immunizations, and general health care	Control group, n=20 infants	NR	The control group received no formal in-home assistance.	HH group, n=21 infants	The “home health care (HH)” system was a short-term intervention that provided critical care in family homes during the first 1–4 weeks after discharge. Physician consultation was available 24 hours on-call.	NR

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Guyer et al, 2003 Minkovitz et al, 2007 ¹¹³ (Healthy Steps)	All families received standard pediatric care.	Control, n=1,102 families	Control families were provided with information and referral to other appropriate services in the community	NR	Intervention, n=1,133 families	Intervention families also received HS program components, including contact with developmental specialists and 7 services: enhanced well-child care, up to 6 home visits in first 3 years, phone line for nonemergency developmental concerns, developmental assessments, written materials, parent groups, and linkages to community resources	NR
Kitzman et al, 1997 ⁹³ Olds et al, 2007 ⁹⁴ (The Memphis Trial)	Transportation to clinic	Transportation, n=166 women	Free round-trip taxicab transportation for scheduled prenatal care appointments	NR	Screening, n=515 women	Free round-trip taxi transportation for scheduled prenatal care appointments and developmental screening and referral services for the child at age 6, 12, and 24 months of age	NR

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Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Lam et al, 2009 ¹⁰⁰	Standard individual CBT session conducted weekly, alternating with weekly study sessions; drawn from the Cognitive-Behavioral Coping Skills Therapy Manual for alcohol treatment (Project Match Research Group 1994)	Traditional individual-based treatment (IBT), n=10 men, their partners, and one child per participant	Consisted of 24 sessions, with 2 60-min sessions per week for 12 weeks (study therapy session and standard individual treatment session were conducted in an alternating, yet interleaved manner); study sessions: attended only by male participants, included 12 individual-based coping skills sessions (modified from Moti, Abrams, Kadden, Cooney's CBT for alcoholism, 1989)	83% attendance rate for the 24 sessions	Standard behavioral couples therapy (BCT), 10 men, their partners, and one child per participant	Consisted of 24 sessions, with two 60-min sessions per week for 12 weeks (a study therapy session and a standard individual treatment session were conducted in an alternating, yet interleaved manner); study sessions: attended by both partners, included urine screens, reviewing previous week's homework, improving communication and problem-solving skills, reinforcing sobriety (O'Farrell & Fals-Stewart 2006) (no parent-skills training provided)	86% attendance rate for the 24 sessions
Larson, 1980 ¹⁰⁷	NR	Control for intervention, n=44 mother-child pairs	No home visits or other forms of intervention	No home visits or other forms of intervention	Postpartum home visits, n=36 mother-child pairs	Postpartum home visits (seven visits from 6 weeks to 6 months of age and five visits from 6 to 15 months of age) covered general caretaking, mother-infant interaction, social status, and child development.	NR

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Lowell et al, 2011 ¹¹⁴ (Child FIRST)	NA	Usual care, n=79 mothers	NR	NR	Child FIRST, n=78 mothers	Children age 6 to 36 months enrolled. Each family was assigned a clinical team consisting of a master's-level developmental/mental health clinician and an associate- or BA-level care coordinator/case manager who usually reflected the ethnic and cultural diversity of the family. The family was the target of the intervention to build supportive networks. Therapeutic services were delivered predominantly in the home. Comprehensive assessments of parent factors and child developmental and behavioral status were completed by clinician and care coordinator with parents. Family-driven plans were developed to integrate supports.	Weekly visits of 45–90 minutes were made jointly or individually by the clinician and/or case manager as needed by the family. Although many appointments were missed or canceled, nonjudgmental and client-centered outreach continued. A parent-child psychotherapeutic and psychoeducational approach was used, guided by family-driven issues. A Child FIRST Assessment and Intervention manual was used to teach and guide the delivery of the intervention; a fidelity checklist was completed by the clinician after each visit with a family and used in clinical supervision to maintain intervention fidelity.

Appendix D Table 2. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Marcenko and Spence, 1994 ¹¹⁵	NR	Control, n=100 mothers	Normal facility-based services of the outpatient obstetrics and gynecology clinic were provided, including comprehensive prenatal, postpartum, family-planning, and gynecological services; on-site anonymous HIV testing; and social services. Home visitation services were not available through this facility. Social services consisted of service assessment and referral and short-term individual counseling. However, women were free to access any other community social services.	NR	Home visitation, n=125 mothers	<p>All services included in the control intervention were provided, but social services were provided through the experimental intervention. Indigenous home visitors provided peer support, modeled appropriate parenting, and helped families overcome barriers to services.</p> <p>Social workers assessed the psychosocial needs of families and implemented plans to address these needs. Nurses were responsible primarily for addressing health care needs.</p> <p>Families received services from the time of the mother's first prenatal visit through the child's first birthday. During the prenatal period, families were visited at least every 2 weeks, with weekly visits during times of unusual stress. During the first 6 weeks postpartum, families received a weekly</p>	NR

Appendix D Table 2. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Marcenko and Spence, 1994 ¹¹⁵ (continued)						home visit. At the end of this 6-week period, a risk assessment was conducted and, if indicated, the visits were reduced to 2-week intervals. The schedule was re-evaluated at 6 months postpartum, and visits were made as necessary, but in no case less frequently than once a month.	
Olds et al, 1986 ⁹⁵ Olds et al, 1994 ⁹⁶ Olds et al, 1997 ⁹⁷ Eckenrode et al, 2000 ⁹⁸ Zielinski et al, 2009 ⁹⁹ (The Elmira Trial)	NR	Comparison, n=184 [†] families	Original study group 1: No services provided during pregnancy. Sensory and developmental screening by infant specialist at age 1 and 2. Original Study Group 2: Free transformation for regular prenatal and well-child care. Sensory and developmental screening by infant specialist at age 1 and 2.	NR	Nurse-visited: pregnancy, n=100 families	Transportation plus nurse home visits every 2 weeks during pregnancy	Average of nine visits during pregnancy lasting 1.25 hours per visit

Appendix D Table 2. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Quinlivan and Streett, 2003 ¹¹⁶	NR	Control, n=71 mothers	No home visits	NR	Home visits, n=65 mothers	Five structured postnatal home visits by nurse-midwives at 1 week, 2 weeks, 1 month, 2 months, and 4 months after birth. Each visit lasted 1–4 h. Nurse-midwives could contact the participant's OB if needed or make appointments/referrals on behalf of the mother or child.	NR
Robling et al, 2016 ⁹² (Nurse Family Partnership)	All participants got publicly funded health and social care	Usual care; n=822 randomized (2 assessed as ineligible, 10 withdrew consent for use of their data)	Publicly funded health and social care services, including the Health Child Programme (universally offered screening, education, immunization, and support from birth to child's second birthday) delivered by specialist community public health nurses and maternity care appropriate to clinical need	Mean visits over the study period: 10.4 visits from community midwives; 16.2 from community health visitors	Family Nurse Partnership + usual care; 823 randomized (3 assessed as ineligible, 12 withdrew consent for use of their data)	64 structured home visits from early pregnancy (ideally, early in second trimester) until child's second birthday by specially recruited and trained family nurses; 14 visits targeted during pregnancy, 28 during infancy, and 22 during toddlerhood but actual number received can vary by individual need, engagement, and gestational age at enrollment; visits had a target minimum duration of 60 minutes	The mean number of valid visits received by phase (pregnancy, infancy, toddlerhood) was 9.71, 18.63, and 13.22, respectively, with 54.7% of participants who completed the program meeting or exceeding target rates of expected visits for the pregnancy phase, 53.0% for the infancy phase, and 43.6% for the toddlerhood phase; visits had an average duration of 79.14 minutes; nurse-reported program content was broadly in line with prescribed targets, but with a greater emphasis on environmental health. Additionally, mean visits over the study period: 10.4 visits from community midwives; 16.2 from community health visitors

Appendix D Table 2. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Sadler et al, 2013 ⁹¹ (Minding the Baby)	NR	Control, n=45 families	Routine pre- and postnatal well-woman and well-baby health visits per clinical guidelines and immunization schedules. Monthly mailed information sheets from Healthy Steps about child rearing and health, and birthday and holiday cards.	Usual care at an urban community health center	Intervention group (MTB), n=60 families	Master's-level clinicians (a team of nurse and social worker) conducted weekly home visits from late pregnancy through child's first birthday, then every other week visits until child's second birthday. Home visitors reviewed content on child health and development, maternal mental health, parenting, social support, maternal life course, maternal health, infant mental health, environment and safety. MTB model is based on Nurse-Family Partnership and Infant-Parent Psychotherapy approaches.	Visits lasted approximately 1 hour but varied based on the family's needs. Mean number of home visits per month was 3.4 (SD: 1.5), lasting 45–90 minutes.
Siegel et al, 1980 ⁸⁶	NR	Control, n=111 mothers	Usual care (combines 2 arms, [1] infants with complicated labor or delivery who required observation nursery stay and did not receive early contact, and [2] infants with uncomplicated labor and delivery who did not require observation nursery stay who received early contact)	Mothers with uncomplicated labor and delivery had traditional, brief contact with infants following delivery and ~2.5 hours of routine contact each day of hospital stay; mothers with complicated labor delivery received extended but not early contact	Hospital contact only, n=50 mothers	Early and extended hospital contact only, which comprised at least 45 minutes of mother-infant contact during the first 3 hours after delivery and at least 5 additional hours each day during hospital stay	NR

Appendix D Table 2. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Silovsky et al, 2011 ¹⁰⁸ (SafeCare+)	NR	Services as usual (SAU), n=57 parents	SAU used standard community mental health program approaches to enroll families in services, given their fee for services billing arrangements. A variety of services were offered, including individual and family therapy as well as case management services. Goal setting and treatment planning varied among families and was designed to fit the specific family's needs, such as parenting, anger management, substance abuse, depression, and anxiety.		SafeCare Plus (SC+), n=48 parents	SafeCare is a home-based model using a skills-based approach to changing those parenting behaviors most proximal to child maltreatment. SafeCare+(SC+) consists of SC with the addition of motivational interviewing as well as training of the home visitors on identification and response to imminent child maltreatment and risk factors of substance abuse, depression, and IPV. Further, for the current project, SC+ was adapted for high-risk rural communities.	

Appendix D Table 2. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Wiggins et al, 2005 ¹¹⁸ Wiggins et al, 2004 ¹¹⁷ (The Social Support and Family Health Study)	Routine NHS health visiting services	Standard health visitor services, n=364 mother-child pairs	Routine NHS health visiting services: one postnatal home visit when the baby was 10–15 days old and clinic support thereafter; subsequent home visits not routinely made except for women deemed to be at risk.	NR	Support Health Visitor (SHV) Intervention, n=183 mother-child pairs	1 year of monthly supportive listening visits in the woman's home, beginning when the baby is about 10 weeks old; SHVs also provide practical support and information on request.	Intervention was carried out by five very experienced health visitors who underwent 2 days of additional training by NHS. Interpreters available to SHVs during home visits. 94% participating women had at least one visit. Average 10 hours of support provided in seven home visits and additional telephone contacts.

* 59 randomized subjects remained at 6-month followup. 58 randomized subjects remained at 12-month followup. However, authors reported that intent-to-treat analysis was used.

† N analyzed=67 in McIntosh et al, 2009¹⁰²

‡ 58 program completers remained at 6-month followup. 62 program completers remained at 12-month followup. However, authors reported that intent-to-treat analysis was used.

§ Including 4 sets of twins.

|| Including 3 sets of twins.

¶ 90 in original G1 + 94 in original G2

Abbreviations: BA=bachelor of arts; BCT=behavioral couples therapy; BL=baseline CBT=cognitive behavioral therapy; G=group; HFAK=Healthy Families Alaska; HFNY=Healthy Families New York; HH=Home Health; HR=High Risk; HRI=high-risk intervention; HS=Healthy Steps; HSP=Healthy Start Home visitation program; HV=home visiting; IBT=individual based therapy; IPV=intimate partner violence; KQ=key question; MTB=Minding the Baby; N/n=number; NA=not applicable; NHS=National Health Service; NR=not reported; OB=obstetrician; SAU=services as usual; SC+=SafeCare Plus; SD=standard deviation; SHV=Support Health Visitor; vs.=versus; Y=year.

Appendix D Table 3. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰² (Family Partnership Model)	NA	NA	NA	NA	NA	NA	None
Brayden et al, 1993 ¹⁰⁹	Standard care, n=295 mothers	Standard prenatal, postnatal, and pediatric care	Standard prenatal, postnatal, and pediatric care consisted of routine medical services provided by the obstetric and pediatric residents of the hospital in outpatient clinic. Medical care was supervised by hospital attending physicians.	NA	NA	NA	Although three groups were compared in the study, only the results from the HR intervention and group controls were used to assess prevention of child maltreatment. As such, baseline characteristics and study outcomes were only reported for G1 and G2 in subsequent tables in this Appendix.
Brooten et al, 1986 ¹¹⁰	NA	NA	NA	NA	NA	NA	Children were the unit of recruitment (with parental consent) and the unit of analysis.
Bugental and Schwartz, 2009 ¹⁰³ (Healthy Start+)	NA	NA	NA	NA	NA	NA	Study design is “comparative intervention trial (no control group).” Groups were randomly assigned.
Caldera et al, 2007 ⁸⁸ Duggan et al, 2007 ⁸⁷ (Healthy Families Alaska)	NA	NA	NA	NA	NA	NA	Unit of recruitment was mothers. Outcome measures were self- reported on behalf of the mother on outcomes inflicted on children.

Appendix D Table 3. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
DePanfilis and Dubowitz, 2005 ¹⁷² (Family Connections)	Family connections for 9 mo. (FC9), n=63 families	Community-based service program that works with families in their homes and in the context of their neighborhoods; core components included emergency assistance (e.g., when eviction notice received), home-based family intervention (family assessment, outcome-driven service plans, individual and family counseling), service coordination with referrals targeted toward risk (e.g., substance abuse treatment) and protective factors (e.g., mentoring program), and multifamily supportive recreational activities (e.g., dinner gatherings, museum trips); direct services were expected to be provided for a minimum of 1 hr/week	Most families received a minimum of 1 hr/week of direct services during the first 3 months; 47 of 63 (75%) families completed the intervention; families served for 9 months were less likely to receive the same intensity of services for the full-service period due to less engagement of families after 6 months; families received an average of 31 hours of total direct service hours (average 0.9 hr/week)	Family connections for 9 mo. enhanced with group intervention (FC9+g), n=NR	Not described/presented in article due to poor compliance	Only 32% of caregivers assigned to a group intervention attended any session, and very few actually graduated from the full group program.	Article only reports on a comparison of 70 families who were assigned to FC intervention for 3 months versus 84 families assigned to receive FC intervention for 9 months, combining those with and without the group intervention. Outcomes are reported on smaller numbers of participants because data were not available for the full sample for all measures and time points.

Appendix D Table 3. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
DuMont et al, 2008 ⁸⁹ DuMont et al, 2010 ⁹⁰ (Healthy Families New York)	NA	NA	NA	NA	NA	NA	942 mothers and 800 children out of the original 1,173 dyads were able to be interviewed for the 7-year follow up; report includes subgroup analyses for groups named RRO (recurrence reduction opportunity, n=104) and HPO (high prevention opportunity, n=179). The RRO group was mothers who had been found to be the perpetrators of abuse against a different child. The HPO mothers were young, first-time mothers who initiated visits early.
Easterbrooks et al, 2013 ¹⁰⁴ (Healthy Families Massachusetts)	NA	NA	NA	NA	NA	NA	Study duration reflects the last time point at which mothers completed interviews after enrollment, not necessarily the length of the intervention.
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ (Early Start Program)	NA	NA	NA	NA	NA	NA	Just under 60% of Early Start families received 3 or more years of service.

Appendix D Table 3. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Finello et al, 1998 ¹¹¹	HV group	The HV system provided prevention and intervention services focused on developmental and health monitoring, parent support, and health and social service linkages for the first 2 years after discharge.	NR	HH/HV group	The HH/HV group received both the short-term intervention (HH) and the long-term support via home visits (HV).	NR	None
Guyer et al, 2003 ¹¹² Minkovitz et al, 2007 ¹¹³ (Healthy Steps)	NA	NA	NA	NA	NA	NA	Healthy Steps was a clinical trial at 15 pediatric sites, 6 of which delivered the intervention and control to randomized families, and 9 of which were quasi-experimental (entire site delivered intervention or control). This review only included data from the randomized, controlled portion of the original study.

Appendix D Table 3. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Kitzman et al, 1997 ⁹³ Olds et al, 2007 ⁹⁴ (The Memphis Trial)	Home visits, n=230 women	Free round-trip taxicab transportation for scheduled prenatal care appointments; developmental screening and referral services for the child at 6, 12, and 24 months of age; and intensive nurse home visitation services during pregnancy, 1 postpartum visit in the hospital before discharge, and 1 postpartum visit in the home	Mean of 7 completed prenatal visits (range 0–18)	Extended home visits, n=228 women	Free round-trip taxicab transportation for scheduled prenatal care appointments; developmental screening and referral services for the child at 6, 12, and 24 months of age; intensive nurse home-visitation services during pregnancy, 1 postpartum visit in the hospital before discharge, and 1 postpartum visit in the home; and continued visitation by nurses through the child's second birthday	Mean of seven completed prenatal visits (range 0–18); mean of 26 completed postnatal visits (range 0–71)	To reduce cost of the study, only G2 and G4 were evaluated for postnatal outcomes and reported.

Appendix D Table 3. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Lam et al, 2009 ¹⁰⁰	Combined parent skills and behavioral couples therapy (PSBCT)	Consisted of 24 sessions, with two 60-min sessions per week for 12 weeks (a study therapy session and a standard individual treatment session were conducted in an alternating, yet interleaved manner); study sessions: attended by both partners, 6 core BCT sessions (included urine screens, reviewing previous week's homework, improving communication and problem-solving skills, reinforcing sobriety) and 6 parent-skills training sessions (adapted from "Helping the noncompliant child," Forehand & Long 2002/McMahon & Forehand 2003)	84% attendance rate for the 24 sessions	NA	NA	NA	None

Appendix D Table 3. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Larson, 1980 ¹⁰⁷	NA	NA	NA	NA	NA	NA	Original study included 3 study groups. Assignment to groups B (G2) and C (G1) was random and ended when 80 subjects were entered. Group A mothers were then entered into the study until a predetermined date. Results from Group A are not included in our analysis and not entered into the evidence tables in this appendix.
Lowell et al, 2011 ¹¹⁴ (Child FIRST)	NA	NA	NA	NA	NA	NA	Intent-to-treat analytic approach. Several measures were used to assess abuse and behavioral outcomes, some of which required responses from parents and others, such as the Infant-Toddler Social and Emotional Assessment, which asks parents to report on child social-emotional/behavioral problems. CPS records were used to assess CPS involvement prior to (or at) baseline and at any time from baseline to 3 years post-baseline (study/data collection period).
Marcenko and Spence, 1994 ¹¹⁵	NA	NA	NA	NA	NA	NA	Women in the sample suspected that they were pregnant an average of 140 days (20 weeks, 4.5 months) prior to their first or second prenatal visit.

Appendix D Table 3. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Olds et al, 1986 ⁹⁵ Olds et al, 1994 ⁹⁶ Olds et al, 1997 ⁹⁷ Eckenrode et al, 2000 ⁹⁸ Zielinski et al, 2009 ⁹⁹ (The Elmira Trial)	Nurse visited: infancy, n=116 families	Nurse home visits every 2 weeks during pregnancy until child is age 2 years. Nurse home visitation included parent education, enhancement of informal support systems, and linkage with community services.	Visit frequency diminished over time unless predetermined crisis conditions existed. Each visit lasts about 1.25 hours.	NA	NA	NA	Four treatment conditions by design. Model of analysis was 3x2x2x2 factorial design. Treatments 1 and 2 were combined for purposes of analysis after it was determined that there were no differences between the groups in their use of routine prenatal and well-child care, the primary means by which transportation was hypothesized to affect pregnancy and infancy outcomes. Planned comparisons focused on the contrast of the nurse-visited (infancy) group vs. the comparison group. 46 nonwhite women were removed from the analysis because the sample of nonwhite women was too small to cross-classify race with other variables of importance.
Quinlivan and Streett, 2003 ¹¹⁶	NA	NA	NA	NA	NA	NA	It is unclear whether any intervention activities were performed at the 6 months study visit for G2. Authors listed the 6-month follow up as an intervention visit but described the content of the visit as "assessment visit" in Panel 1.

Appendix D Table 3. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Robling et al, 2016 ⁹² (Nurse Family Partnership)	NA	NA	NA	NA	NA	NA	Women assigned to the intervention arm had an average of 39 specialist nurse visits, each lasting on average longer than 1 hour. They also had fewer health visitor interactions than usual care arm (usual care arm saw “health visitors eight more times than did those in the FNP group”).
Sadler et al, 2013 ⁹¹ (Minding the Baby)	NA	NA	NA	NA	NA	NA	None
Siegel et al, 1980 ⁸⁶	Home visits only, n=53 mothers	First visit with mother in hospital, then 9 home visits from paraprofessionals during first 3 months after discharge	NR	Combined intervention, n=107 mothers	Combines two groups (combines 2 arms, (1) infants with complicated labor or delivery who required observation nursery stay and received extended hospital contact and home visits from paraprofessionals, but not early contact, and (2) infants with uncomplicated labor or delivery who received early and extended hospital contact and home visits)	NR	None
Silovsky et al, 2011 ¹⁰⁸ (SafeCare+)	NA	NA	NA	NA	NA	NA	None

Appendix D Table 3. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Wiggins et al, 2005 ¹¹⁸ Wiggins et al, 2004 ¹¹⁷ (The Social Support and Family Health Study)	CGS Intervention, n=184 mother-child pairs	Participants were assigned to 1 of 8 community groups that offered services for mothers with children less than 5 years in the study area. Groups offered a combination of services: drop-in sessions, home visiting, and/or telephone support. Standard package of services was available to participating women for 1 year.	Community groups encouraged to take the initiative to contact the women assigned to them but otherwise provide their normal service. Uptake was 19% and highest among community groups that offered home visiting as at least part of their service. Average 1.5 hours of support.	NA	NA	NA	None

Abbreviations: BCT=behavioral couples therapy; CGS=Community Group Support; CPS=child protective services; FC=family connections; FC9=family connections for 9 months; G=group; HH=home health; HPO=high prevention opportunity; HR=high risk; HV=home visiting; KQ=key question; N/n=number; NA=not applicable; NR=not reported; PSBCT=parent skills and behavioral couples therapy; RRO=recurrence reduction opportunity.

Appendix D Table 4. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Population, Inclusion and Exclusion, and Risk Factors

Author, Year (Program/Trial Name)	Target Population	Inclusion Criteria	Exclusion Criteria	Risk Factors
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰² (Family Partnership Model)	Parents who have been identified prenatally as being at high risk for poor parenting	Community midwives in United Kingdom attached to 40 participating general practitioner practices across two counties screened women using a range of demographic and psychosocial criteria (including financial, housing, and mental health problems) for risk of infant abuse and neglect	Women without a working understanding of English or not wishing to be randomized	Age <17 years; serious housing problems or no accommodation; serious financial difficulties; isolated with no support network; history of psychiatric illness; learning problems; serious drug or alcohol problems in the past; serious parenting difficulties or had a previous child on the child protection register; domestic violence; and been referred to social services
Brayden et al, 1993 ¹⁰⁹	Pregnant women seen for prenatal care at Metropolitan Nashville General Hospital and their infants when delivered	Women receiving prenatal care between December 1984 and November 1986 and income less than 200% of the Federal poverty guideline	Women at >28 weeks of gestation were excluded; income greater than 200% of the Federal poverty guideline; other NR ineligibility reasons	Risk assignment was determined using a structured interview, MHI-2; subscale scores developed on following categories: knowledge of parenting skills, philosophy about discipline, personality, positive and negative feelings about pregnancy, mother's perception of her nurture as a child, truncated version of Life Stress Inventory for mother and father, "lie" scale to detect attempts to answer only in a socially appropriate way. Items included changing residences more than 12 times in the previous year, previous removal of children by protective services, maternal comment or behavior suggesting abusive tendencies, or gross untruthfulness in the interview.*

Appendix D Table 4. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Population, Inclusion and Exclusion, and Risk Factors

Author, Year (Program/Trial Name)	Target Population	Inclusion Criteria	Exclusion Criteria	Risk Factors
Brooten et al, 1986 ¹¹⁰	Infants with birth weights of 1,500 g or less who were born at the Hospital of the University of Pennsylvania	Infants who are clinically well, able to feed by nipple every 4 hours, able to maintain body temp in open crib in room air, has no evidence of serious apnea or bradycardia in 12 hours recording of heart rate and respiration rate; mother or caretaker must demonstrate satisfactory care-taking skills, physical home environment and facilities for care of infant were adequate	Infants with life-threatening congenital anomalies; grade 4 intraventricular hemorrhage, extensive surgical intervention, oxygen dependence for a period of more than 10 weeks or a combination of these factors were excluded from the study.	Prolonged hospitalization is associated with failure to thrive, child abuse, and parental feelings of inadequacy. Infants in the routine discharge group were thought to be at increased risk due to prolonged hospitalization.
Bugental and Schwartz, 2009 ¹⁰³ (Healthy Start+)	Families of children born at a medical risk	Presence of a medical risk factor for the infant: preterm status <36 weeks gestational age, medical problem (e.g., respiratory or cardiac problems), other reason (e.g., Cesarean delivery). Families were eligible for inclusion for children up to 6 months of age.	NR	Participants were at relatively low risk for child maltreatment as indicated by their mean score (M=19) on the Family Stress Checklist. [†]
Caldera et al, 2007 ⁸⁸ Duggan et al, 2007 ⁸⁷ (Healthy Families Alaska)	Families at risk of child maltreatment	Scoring ≥25 on the Kempe Family Stress Checklist	Families who were previously enrolled in HFAK and mothers who did not speak English well enough to complete study activities	Kempe Family Stress Checklist used to identify family at high risk of child abuse ¹⁴⁴
DuMont et al, 2008 ⁸⁹ DuMont et al, 2010 ⁹⁰ (Healthy Families New York)	Expectant parents and parents with an infant under 3 months of age who are deemed to be at risk for child abuse or neglect and live in communities that have high rates of teen pregnancy, infant mortality, welfare receipt, and late or no prenatal care.	Scoring ≥25 on the Kempe Family Stress Checklist	Residing outside catchment area, non-English or Spanish speaking	Kempe Family Stress Checklist used to identify parents at high risk of abuse

Appendix D Table 4. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Population, Inclusion and Exclusion, and Risk Factors

Author, Year (Program/Trial Name)	Target Population	Inclusion Criteria	Exclusion Criteria	Risk Factors
Easterbrooks et al, 2013 ¹⁰⁴ (Healthy Families Massachusetts)	Of the intervention: Young, first-time mothers in Massachusetts (ages 16–20 years at childbirth) Of the desired outcome: Young, first-time mothers in Massachusetts (ages 16–20 years at childbirth) and their first-born infants/toddlers (average age 1 year, prenatal to age 3)	Females age 16 years or older, have never received HFM services before, speak either English or Spanish, cognitively able to provide informed consent	NR	No explicit risk identification offered, but authors noted that children born to adolescent mothers are generally at risk for maltreatment.
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ (Early Start Program)	Families in New Zealand facing stress and difficulty, with at least one new infant <3 months of age.	Families exhibiting two or more of the following parent and family functioning risk factors: age of parents, social support, planning of pregnancy, parental substance use, family financial situation, and family violence [‡] ; any family in which serious concerns about the family's capacity to care for the child were identified by a community nurse.	NR	Risk factors listed in inclusion criteria; based on an 11-point screening instrument developed from the measure used in the Hawaii Healthy Start Program.
Finello et al, 1998 ¹¹¹	Very low birthweight infants (<1,750 g) following neonatal intensive care unit discharge in Los Angeles	Infants between 750 and <1,750 g birthweight discharged from SCN at LA Co./USC Women's hospital or Hospital of the Good Samaritan; no gross abnormality at discharge.	Birthweight <750 g or 1,750 g and over; gross abnormality at discharge	Study participants were enrolled based on health and developmental risks associated with very low birthweight and were not identified a priori as being at risk per se for child abuse and neglect. [§]
Guyer et al, 2003 ¹¹² Minkovitz et al, 2007 ¹¹³ (Healthy Steps)	Families of new borns up to 4 weeks of age.	Consecutive new borns up to 4 weeks of age were enrolled at birth or their first office visit.	New borns were excluded if they were to be adopted or placed in foster care, they were too ill to make an office visit by 4 weeks, their mother did not speak English or Spanish, or the family intended to leave the practice within 6 months.	NR

Appendix D Table 4. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Population, Inclusion and Exclusion, and Risk Factors

Author, Year (Program/Trial Name)	Target Population	Inclusion Criteria	Exclusion Criteria	Risk Factors
Kitzman et al, 1997 ⁹³ Olds et al, 2007 ⁹⁴ (The Memphis Trial)	Women <29 weeks pregnant with no previous live births, visiting the Regional Medical Center in Memphis for obstetrical care	Eligibility determined at the obstetric care clinic: pregnant women <29 weeks' gestation, no previous live births, no chronic illnesses, at least 2 sociodemographic risk characteristics (unmarried, <12 years of education, unemployment status)	NR	Sociodemographic risk conditions: unmarried, less than 12 years of education, and unemployed
Lam et al, 2009 ¹⁰⁰	Heterosexual married or cohabiting male patients voluntarily entering outpatient treatment for an alcohol use disorder	Men at least 18 years of age; met DSM-IV criteria for alcohol abuse or dependence, were married (≥1 year) or cohabitating (≥2 years) with an intimate female partner at the time of admission and the female partner did not meet DSM-IV criteria for substance abuse or dependence; had legal guardianship of at least one child between 8 and 12 years of age, inclusive, who was living in the home. If the couple had more than one child in the target age range, one child was randomly selected for participation.	See inclusion criteria	Parental substance abuse
Larson, 1980 ¹⁰⁷	Pregnant women attending private OB offices who deliver at a large urban teaching hospital in Montreal	French-Canadian or English-Canadian ethnicity, 18–35 years old, working class income (less than 1977 Montreal poverty line plus \$10K/year), HS grad or less education, no significant illness during pregnancy, no prior history of psychiatric hospitalization, normal delivery of full-term healthy newborn discharged within 5 days of birth without major congenital defects	NR	NR

Appendix D Table 4. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Population, Inclusion and Exclusion, and Risk Factors

Author, Year (Program/Trial Name)	Target Population	Inclusion Criteria	Exclusion Criteria	Risk Factors
Lowell et al, 2011 ¹¹⁴ (Child FIRST)	Families with children ages 6–36 months living in families at psychosocial risk and/or manifesting social-emotional/behavioral problems	Eligible families had a child ages 6–36 months, where child was living in a permanent caregiving environment and had a positive screen for social-emotional/behavioral problems on the Brief Infant-Toddler Social and Emotional Assessment and/or their parent screened high for psychosocial risk on the Parent Risk Questionnaire were eligible. Families recruited from sites serving predominantly inner-city families in Bridgeport, Connecticut: the Bridgeport Hospital Pediatric Primary Care Center and the Supplementary Nutrition Program for Women, Infants, and Children.	Children referred directly from community providers.	The study defined eligibility based on the results of screening for presence of “psychosocial risk,” not for exposure to neglect or abuse; the risk assessment covered 12 areas including depression, domestic violence, substance use, homelessness, incarceration, isolation, single and teen parenthood, education, and employment.
Marcenko and Spence, 1994 ¹¹⁵	Pregnant women visiting an inner-city hospital outpatient obstetrics clinic in Philadelphia for their first or second prenatal visit	At least one of the following histories: substance abuse, homelessness, domestic violence, psychiatric illness, incarceration, HIV infection, or lack of social support.	NR	Family history listed as inclusion criteria were identified as risk factors for child out-of-home placement.
Olds et al, 1986 ⁹⁵ Olds et al, 1994 ⁹⁶ Olds et al, 1997 ⁹⁷ Eckenrode et al, 2000 ⁹⁸ Zielinski et al, 2009 ⁹⁹ (The Elmira Trial)	Pregnant women with no previous live births and one of the below risk factors: <19 years of age, single-parent status, low socioeconomic status	Pregnant women who, at intake, had no previous live births, were less than 26 weeks of gestation, and had any of the three characteristics predisposed to infant health and developmental problems. However, any women who asked to participate were enrolled regardless of their age, marital status, and SES.	49 mother-child pairs were ineligible at the 15-year follow up due to child death (n=26), mother death (n=2), child adopted (n=15), and refusal to participate (n=6); 81% of the original sample included and 92% of those eligible for follow up ⁹⁸	Mother age <19 years, single-parent status, low SES

Appendix D Table 4. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Population, Inclusion and Exclusion, and Risk Factors

Author, Year (Program/Trial Name)	Target Population	Inclusion Criteria	Exclusion Criteria	Risk Factors
Quinlivan and Streett, 2003 ¹¹⁶	Teenagers attending their first antenatal appointment at an Australian public care teenage pregnancy clinic for first-time mothers	Age <18, ability to speak English, intention to continue with the pregnancy and not to relinquish their infant	Residence >150 km from hospital, known fetal abnormality	NR
Robling et al, 2016 ⁹² (Nurse Family Partnership)	First-time teenage mothers	Nulliparous women age 19 years or younger, living within the catchment area of a local FNP team, of less than 25 weeks' gestation, and able to provide consent and speak English; women expecting multiple births and those with a previous pregnancy ending in miscarriage, stillbirth, or termination were still eligible	Women planning to have their child adopted or to move outside of the FNP catchment area for longer than 3 months	NR
Sadler et al, 2013 ⁹¹ (Minding the Baby)	Primiparous women attending nurse-midwifery group prenatal care sessions at the study site	Able to speak and understand English; 14–25 years of age; having a first child; no active heroin or cocaine use (prescreened by the Community Health Center as criteria for entry into group prenatal care); no DSM-IV psychotic disorder; no major or terminal chronic condition in the mother (AIDS, cancer, etc.; prescreened by the study site)	NR	NR
Siegel et al, 1980 ⁸⁶	Pregnant women in their third trimester receiving care at the public prenatal clinic and delivered at the community hospital in Greensboro, NC	Women who had uncomplicated pregnancy, no previous delivery of nonviable infant; not expecting twins; intended to stay in the area for ≥1 year; did not have a family member in the study	NR	NR

Appendix D Table 4. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Population, Inclusion and Exclusion, and Risk Factors

Author, Year (Program/Trial Name)	Target Population	Inclusion Criteria	Exclusion Criteria	Risk Factors
Silovsky et al, 2011 ¹⁰⁸ (SafeCare+)	Families at high risk of child maltreatment in rural communities	Families with a caregiver at least 16 years old, at least one child 5 years old, and at least one of the following risk factors: parental substance abuse, mental health issues, or IPV per preservice evaluation results [¶]	A current child welfare case or service involvement due to a recent child welfare case or a history of more than two prior child welfare referrals (regardless of substantiation status); the primary caretaker has a substantiated report of perpetrating child sexual abuse; any conditions that would prevent the primary caregiver from providing valid self-report data (e.g., severe psychosis, severe mental retardation)	Parental substance abuse, mental health issues, or IPV
Wiggins et al, 2005 ¹¹⁸ Wiggins et al, 2004 ¹¹⁷ (The Social Support and Family Health Study)	Women living in deprived enumeration districts	Women who gave birth in the first 9 months of 1999	Women whose babies had died, were seriously ill, or had been placed in foster care	NR

* Threshold values designating high risk were 15th percentile for the Nurture scale, 5th percentile for the Life Stress scale, and 1st percentile in other subscales. Scores of the first 200 subjects were used to determine the actual scores used for risk assessment.

† The checklist makes use of a structured interview. Scores (0, 5 or 10) are made by the rater on 10 items potentially predictive of abuse (e.g. history of drug use, unrealistic caregiving expectations, past involvement with child protective services). The scoring system reflects the extent to which these scores (obtained during the mother's pregnancy) predict later neglect or abuse by the time children were toddlers.¹³²

‡ The Hawaii Healthy Start Program family violence measure that was used in the original trial appears to be measuring partner violence. All families in Plunket, New Zealand, received a free home visit by a community nurse within 3 months of the birth of a child. Nurses were asked to refer any family where 2 or more risk factors were present or where there were serious concerns about the family's capacity to care for the child. The followup trial likewise defined its family violence measure as IPV assessed using the Revised Conflict Tactics Scale.

§ The children were not specifically identified as being at risk for maltreatment. 38% of the sample were "small for gestational age," meaning they were at risk for health and developmental problems. 82% of families had environmental risk factors. The authors reported sociodemographic data (educational level, maternal age, and environmental risk. Environmental risk referred to an MCH HV program assessment that evaluated maternal risk factors such as alcohol or drug abuse, below 18 years, housing, and parent-infant interaction problems)—these risk factors are assumed to be for poor child health and developmental outcomes, which may include CAN, but that was not specified in the article.

|| At the time of the 5.5-year followup, 2 of 6 randomization sites and 4 of 9 quasi-experimental sites continued to operate HS targeted to children 0 to 3 years of age.

¶ i.e., Child Abuse Potential Inventory >165; Beck Depression Inventory II >19; reports of partner-initiated assault, injury, sexual coercion, or psychological aggression on the Conflict Tactic Scale 2; or scores consistent with a substance abuse disorder on the Diagnostic Interview Scale

Abbreviations: CAN=child abuse and neglect, DSM-IV=Diagnostic and Statistical Manual of Mental Disorders, 4th; HFAK=Healthy Families Alaska; HFM=Healthy Families Massachusetts; HS=Healthy Start; HV=home visit; IPV=intimate partner violence; KQ=key question; LA=Los Angeles; MCH=maternal and child health; MHI=Maternal History Interview; NC=North Carolina; NR=not reported; OB=obstetrician; SCN=Special Care Nursery; SES=socioeconomic status; USC=University of Southern California.

Appendix D Table 5. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰² (Family Partnership Model)	NR*	Caregiver 100	Caregiver (Mother) Overall: White: 94 Black: 2 Asian: 2 Other: 3	NR	NR	Other relevant maternal characteristics at baseline: 30% no higher educational/vocational qualifications 61% poverty 61% history of mental health issues 52% housing concerns 35% unwanted pregnancy 17% working
Brayden et al, 1993 ¹⁰⁹	Caregiver (Mother) [†] G1: 22.4 (NR) G2: 21.2 (NR) Child, gestation at prenatal entry: G1: 16.0 weeks G2: 17.0 weeks	Caregiver 100	Caregiver (Mother) G1: White: 73 Nonwhite: 27* G2: White: 66.7 Nonwhite: 33.3*	Previous removal of child by protective services: G1 and G2 combined: 14 (4.5) [§]	NR	Other relevant maternal baseline characteristics: Maternal marital status, single: G1: 57.4% G2: 64.5% Medicaid eligibility: G1: 83% G2: 85%
Brooten et al, 1986 ¹¹⁰	Caregiver (Mother): G1: 23 years (6) (Range: 12–38 years) G2: 24 years (7) (Range: 16–44 years) Child, gestational age at birth: G1: 30 weeks (2) G2: 30 weeks (2) Child, gestational age at discharge: G1: 38 weeks (2) G2: 36 weeks (2)	Caregiver 100 Children NR	Caregiver (Mother) G1: Black: 78 White: 22 G2: Black: 83 White: 17	NR	NR	Other relevant maternal baseline characteristics: Maternal marital status, unmarried: G1: 67% G2: 69% Family on Medicaid: G1: 56% G2: 75%

Appendix D Table 5. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Bugental and Schw artz, 2009 ¹⁰³ (Healthy Start+)	Child Overall: 9.37 weeks (5.50) Mother G1: 27.3 years (6.4) G2: 27.1 years (7.0)	Caregiver NR Child* G1: 41 G2: 43	% of Latino children Overall: 87 G1: 91 G2: 83	NR	NR	Child by type of medical risk factor: Preterm status: 48 Medical problem: 59 Other reasons: 40
Caldera et al, 2007 ⁸⁸ Duggan et al, 2007 ⁸⁷ (Healthy Families Alaska)	Caregiver (Mother) [¶] G1: 23.7 (5.7) G2: 23.4 (5.7)	Caregiver [¶] 100 Children NR	Caregiver (Mother) [¶] G1: Alaska Native: 20 Caucasian: 56 Multiracial: 7 Other: 17 G2: Alaska Native: 23 Caucasian: 54 Multiracial: 10 Other: 13	NR	NR	Other maternal characteristics at baseline: [¶] Graduated from high school: 58% Below poverty level: 58% Physical assault by mother on partner (excludes mothers without a partner): 49% Poor psychological resources: 44% Depressive symptoms: 57% Maternal substance use: 56%
DuMont et al, 2008 ⁸⁹ DuMont et al, 2010 ⁹⁰ (Healthy Families New York)	Caregiver (Mother) Overall: 22.5 years (5.5) G1: 22.5 years (5.4) G2: 22.4 years (5.6)	Caregiver 100 Child NR	Caregiver (Mother) Overall: White, non-Latina: 34.4 African American, non-Latina: 45.4 Latina: 18.0 G1: White, non-Latina: 34.3 African American, non-Latina: 46.5 Latina: 17.7 G2: White, nont-Latina: 34.4 African American, non-Latina: 44.4 Latina: 18.3	Prior substantiated or unsubstantiated child abuse or neglect reports at baseline: Overall: 20.2 [#] G1: 20.7 G2: 19.7 Prior substantiated child abuse or neglect reports at baseline: Overall: 9.0 G1: 8.9 G2: 9.0	NR	Other relevant maternal characteristics: Mother's childhood history of child maltreatment: Overall: 48.7% G1: 48.1% G2: 49.2% Family received cash assistance from welfare: Overall: 29.2% G1: 27.4% G2: 31.1% First-time mother: Overall: 54.2% G1: 53.2% G2: 55.3% % of mother <19 years old: Overall: 31.0% G1: 29.8% G2: 32.3% % never married: Overall: 82%

Appendix D Table 5. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Easterbrooks et al, 2013 ¹⁰⁴ (Healthy Families Massachusetts)	Child, 12 months after enrollment G1: 11.75 months (5.65) G2: 12.05 months (5.27) Caretaker (Mother) G1: 18.78 years (1.23) G2: 18.69 years (1.28)	Caregiver NR Child G1: 45.6 G2: 47.1	Caregiver (Mother) G1: White: 41.4 African American (non-Hispanic): 17.7 Hispanic: 30.5 Other (non-Hispanic): 10.5 G2: White: 34.2 African American (non-Hispanic): 20.6 Hispanic: 38.3 Other (non-Hispanic): 6.9	NR	NR	Other relevant maternal characteristics at baseline: Single: G1: 34.1% G2: 34.1% Welfare recipient: G1: 55.3% G2: 60.1% Some and major financial difficulties: G1: 64.7% G2: 62.5%
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ (Early Start Program)	Mother G1: 24.4 years (NR) G2: 24.6 years (NR) Biological father G1: 26.6 years (NR) G2: 27.3 years (NR)	NR	Mother, Maori: G1: 26.7 G2: 24.8 Biological father, Maori: G1: 25.4 G2: 30.7	NR	NR	Other relevant family characteristics at baseline: Single-parent family: G1: 63.8% G2: 64.6% Pregnancy unplanned: G1: 82.3% G2: 80.1% Welfare dependent: G1: 90.1% G2: 88.4%
Finello et al, 1998 ¹¹¹	Caregiver (Mother) Overall: 28.21 years (7.14) (Range: 14–41 years) G1: 26.2 years (6.8) G2: 28.8 years (6.8) G3: 27.9 years (7.5) G4: 29.8 years (7.5) Child, gestational age at time of enrollment G1: 31.9 weeks (2.8) G2: 29.8 weeks (3.1) G3: 30.4 weeks (3.0) G4: 30.5 weeks (2.0)	Caregiver 100 Child G1: 70 G2: 29 G3: 45 G4: 30	Caregiver (Mother) Overall: Latino: 9 African American: 3 Other: 2	NR	NR	Other relevant maternal characteristics at baseline: Firstborn child: 30.5% Mean no. of live births: 2.6 (SD=1.6) Mean no. of children in the household: 2.5 (SD=1.5) Mean no. of children under the age of 5 in the household: 0.99 (SD=1.2)

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Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Guyer et al, 2003 ¹¹² Minkovitz et al, 2007 ¹¹³ (Healthy Steps)	Caregiver (Mother) Overall: * ≤19 years: 13.6% 20–29 years: 51.0% ≥30 years: 35.4% Child, age at 5- to 5.5-year interview *§ Overall: 5.22 years	Caregiver 100 Child NR	Caregiver (Mother) Overall: † White: 57.9 Black: 24.4 Asian/Native American: 4.5 Hispanic: 20.2 Other: 13.2	NR	NR	Other relevant maternal characteristics at baseline: Not married: 35.8% First live birth: 46.4% Medicaid during pregnancy: 31.8%
Kitzman et al, 1997 ⁹³ Olds et al, 2007 ⁹⁴ (The Memphis Trial)	Caregiver (Mother) G1: 18.0 years (3.3) G2: 18.1 years (3.2) G3: 17.9 years (2.8) G4: 18.1 years (3.3) Child, gestational stage at enrollment G1: 16.4 weeks (6.0) G2: 16.4 weeks (5.8) G3: 16.3 weeks (5.5) G4: 16.5 weeks (5.6)	Caregiver 100 Child NR	Caregiver (Mother) White: G1: 4 G2: 8 G3: 7 G4: 11 African American: Overall enrolled: 92	NR	NR	Other relevant maternal characteristics at baseline: Unmarried: 98% <18 years of age: 64% Below the Federal poverty level: 85%

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Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Lam et al, 2009 ¹⁰⁰	Child G1: 8.8 (2.2) G2: 9.0 (2.0) G3T: 8.9 (2.1) Caregiver (Father) G1: 34.2 (4.4) G2: 34.6 (4.9) G3: 33.4 (5.1)	Child ⁺ G1: 50 G2: 50 G3: 40	Caregiver (Father) G1: White: 60 Black: 20 Hispanic: 10 Other: 10 G2: White: 60 Black: 30 Hispanic: 0 Other: 10 G3: White: 70 Black: 20 Hispanic: 10 Other: 10	Open cases with CPS at baseline G1: 30 G2: 40 G3: 40	NR	Other relevant baseline characteristics for father's female partner: Female partner's age in years: M (SD) G1: 33.1 (5.2) G2: 32.8 (5.4) G3: 33.2 (5.4) Female partner's ethnicity: N (%) G1: White: 60 Black: 20 Hispanic: 10 Other: 10 G2: White: 70 Black: 10 Hispanic: 10 Other: 10 G3: White: 70 Black: 10 Hispanic: 0 Other: 20
Larson, 1980 ¹⁰⁷	NR	Caregiver 100 Child ⁺⁺ Overall: 50.4 G1: 50.0 G2: 60.0 G3: 41.7	NR	NR	NR	Other relevant family characteristics at baseline** : Single-parent household: Overall: 52.2% G1: 45.5% G2: 65.7% G3: 47.2%

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Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Lowell et al, 2011 ¹¹⁴ (Child FIRST)	Child G1: 18 months (8.8) G2: 19 months (9.2) Caregiver (Mother) G1: 26.9 (6.9) G2: 27.7 (7.0)	Caregiver 100 Child G1: 54.4 G2: 57.7	Caregiver (Mother) G1: Latino: 57.0 Black: 32.9 White: 8.9 Other: 1.3 G2: Latino: 60.3 Black: 26.9 White: 6.4 Other: 6.4	Prior or current involvement with CPS G1: 39.2 G2: 28.2	Proportion with clinically concerning problems at baseline: G1: Language development: 21.9 Any ITSEA domain: 48.1 ITSEA externalizing: 36.5 ITSEA internalizing: 13.5 ITSEA dysregulation: 32.7 G2: Language development: 17.1 Any ITSEA domain: 56.6 ITSEA externalizing: 43.3 ITSEA internalizing: 9.4 ITSEA dysregulation: 28.3	Other relevant family characteristics at baseline: Single, never married: G1: 57.7% G2: 59.7% Teenage mother: G1: 10.1% G2: 9.1% Receiving public assistance: G1: 92.4% G2: 92.9%
Marcenko and Spence, 1994 ¹¹⁵	Caregiver (Mother) G1: 23.08 years (NR) (Range: 13.21–41.48 years) G2: 23.23 years (NR) (Range: 13.48–39.08 years)	Caregiver 100 Child NR	Caregiver (Mother) Overall: Black: 94 Hispanic: 4 White: 2 G1: Black: 93.5 Hispanic: 2.6 White: 2.6 Other: 1.3 G2: Black: 94.5 Hispanic: 3.6 White: 0.9 Other: --	Prior family involvement with CPS: G1: 31.6 G2: 34.9	Caregiver (Mother) G1: 23.08 years (NR) (Range: 13.21–41.48 years) G2: 23.23 years (NR) (Range: 13.48–39.08 years)	Other relevant maternal characteristics at baseline: Never married: G1: 89.6% G2: 88.2% Public welfare benefits as usual source of financial support: Overall: 79%

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Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Olds et al, 1986 ⁹⁵ Olds et al, 1994 ⁹⁶ Olds et al, 1997 ⁹⁷ Eckenrode et al, 2000 ⁹⁸ Zielinski et al, 2009 ⁹⁹ (The Elmira Trial)	Caregiver (Mother) ^{††§} G1: 19.3 years (2.9) G2: 19.5 years (3.1) G3: 19.4 years (3.7)	Caregiver 100 Child ^{§§} G1: 45 G2: 56 G3: 45	Caregiver (Mother) Overall: White: 89 Black: 11 ^{†††}	NR	NR	Other relevant maternal characteristics at baseline: Overall: <19 years of age: 47% Unmarried: 62% Semiskilled and unskilled laborers: 61% Poor, unmarried teenagers: 23%
Quinlivan and Streett, 2003 ¹¹⁶	Caregiver (Mother): G1: 16.6 years (0.90) G2: 16.4 years (0.96)	Caregiver 100 Child* G1: 55 G2: 43	Caregiver (Mother) Indigenous Australian: G1: 18 G2: 30	NR	NR	Other relevant maternal characteristics at baseline: Low or destitute socioeconomic status score: G1: 85% G2: 88%
Robling et al, 2016 ⁹² (Nurse Family Partnership)	Caregiver (Mother): G1: 17.9 yrs (16.9-18.8) G2: 17.9 yrs (17.0-18.8)	Caregiver 100	Caregiver (Mother) G1: White: 88 Mixed: 5 Asian: 1 Black: 5 Other: <1 G2: White: 88 Mixed: 6 Asian: 2 Black: 4 Other: <1	NR	NR	NR

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Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Sadler et al, 2013 ⁹¹ (Minding the Baby)	Caregiver (Mother) Overall: 19.6 years (2.9) G1: 19.7 years (2.8) G2: 19.5 years (2.6) Child, gestational age at enrollment: Overall: 39 weeks (2.4) G1: 39 weeks (2.0) G2: 39 weeks (2.6)	Caregiver 100 Children Overall: 48 G1: 48 G2: 49	Caregiver (Mother): Overall: Latina: 62 African American or Caribbean: 28 Mixed ethnicity: 10 G1: Latina: 58 African American or Caribbean: 35 mixed ethnicity: 6.7 G2: Latina: 67 African American or Caribbean: 22 Mixed ethnicity: 11.7	Active CPS case at time of enrollment:## Overall: 6 G1: 4 G2: 7	NR	Other relevant maternal characteristics at baseline: Single/never married: Overall: 83.8% G1: 88.6% G2: 80.3%
Siegel et al, 1980 ⁸⁶	Caregiver (Mother) Overall: 21 years (NR)	Caregiver 100 Child NR	Caregiver (Mother) Overall: 25***	NR	NR	"Other relevant maternal characteristics at baseline: Average no. of babies before the index pregnancy: 0.8 Currently married: 33% ^{†††} Mean years of education: 11"
Silovsky et al, 2011 ¹⁰⁸ (SafeCare+)	Caregiver (Unspecified): Overall: 27 years (9) G1: 27.7 years (8.7) G2: 25.9 years (6.8)	Caregiver 99 Child NR	Caregiver (Unspecified):*** G1: White: 74 Black or African American: 14 Hispanic or Latino: 4 American Indian or Alaska Native: 7 Asian: 1 G2: White: 68 Black of African American: 15 Hispanic or Latino: 2 American Indian or Alaska Native: 15 Asian: NR	NR	NR	Other relevant family characteristics at baseline: Average no. of children: 2 Median income per month: \$700 Never married: 32.4% [‡]

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Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Wiggins et al, 2005 ¹¹⁸ Wiggins et al, 2004 ¹¹⁷ (The Social Support and Family Health Study)	Child G1: 9.2 weeks (3.2) G2: 9.0 weeks (3.5) G3: 9.6 weeks (3.8) Caregiver (Mother), age at birth of index child: G1: 29.6 years (5.8) G2: 29.5 years (5.9) G3: 29.7 years (5.9)	Caregiver (Mother) 100	Mother defines ethnicity as "white" G1: 60 G2: 54 G3: 57	NR	NR	Other relevant maternal characteristics at baseline: Study child is mother's first baby: N (%) G1: 176 (48) G2: 87 (48) G3: 92 (50) English not mother's first language: N (%) G1: 139 (38) G2: 73 (40) G3: 70 (38) Mother is a lone parent: N (%) G1: 89 (25) G2: 53 (29) G3: 47 (26) Family lives in "public" housing: N (%) G1: 257 (71) G2: 127 (69) G3: 126 (69) Weekly household income <£200: N (%) G1: 169 (54) G2: 90 (56) G3: 95 (56) Mother had "no support" in past month G1: 17 (5) G2: 11 (6) G3: 9 (5)

* Proportion of mothers <17 years old at baseline: G1: 14%, G2: 12%.

† Authors reported $p < 0.05$ for G2 vs. G1.

‡ Calculated.

§ Authors reported 14 cases of previous removal of child by protective services among the 314 HR participants at baseline. Among the 14 cases, 29% were physical abuse and 21% were neglect.

¹ Based on 36 mothers in G1 and 36 mothers in G2.

[¶] Based on 325 families (163 in G1, 162 in G2) of those randomized who were interviewed at baseline.

[#] Over 40% of the prior CPS reports were still open at the time of random assignment.

^{**} Calculated based on 115 participating mother-infant dyads.

^{††} Reported by authors based on the remaining 324 participants at the 15-year followup.⁹⁷

^{§§} Calculated based on the remaining 324 participants at the 15-year followup.⁹⁷

Appendix D Table 5. Characteristic of RCTs Included in the Main Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

|| At the 15-year followup, percentage of white participants among the 324 remaining participants changed to 90% for G1, 91% for G2, and 86% for G3.

¶¶ These participants are excluded from the analysis.

All cases involved charges of abuse or neglect against the parents of the participant mothers in this study.

*** Authors reported approximately one-quarter of the 321 women participating in the study were white.

††† Authors reported approximately one-third of the participants were married at baseline.

‡‡ Authors noted that overrepresentation of American Indian families compared with the general population in the county might be due to specific recruitment efforts.

Abbreviations: CPS=child protective services; G=group; HR=high risk; ITSEA=Infant Toddler Social Emotional Adjustment Scale; KQ=key question; NR=not reported; SD=standard deviation.

Appendix D Table 6. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Program Name, Funding Source, and Design

Author, Year	Program/ Trial Name	Country	Funding Source	Study Date Range	Study Design	No. of Study Arms	Total N	Duration
Barth, 1991 ¹³⁴	Child Parent Enrichment Program	United States	Biomedical research support grant from the Division of Research, National Institutes of Health; California Office of Child Abuse Prevention grant; Department of Health and Human Services Administration on Children, Youth, and Families grants	NR	Parallel group RCT	2	191 caregivers*	Approximately 6 months
DePanfilis and Dubowitz, 2005 ¹⁷²	Family Connections	United States	Children's Bureau, U.S. Department of Health and Human Services	Participants screened and recruited from 1997–2001	Parallel group RCT	4	154 caregivers, 473 children	United States
Dubowitz et al, 2009 ¹⁴⁸	Safe Environment for Every Kid (SEEK) Model	United States	Department of Health and Human Services Office on Child Abuse and Neglect	June 2002 to November 2005 (duration of sampling) June 1, 2002– January 31, 2006 (intervention period of observation)	Cluster group RCT	2	729 caregivers enrolled	NR
Dubowitz et al, 2012 ¹⁴⁷	Safe Environment for Every Kid (SEEK) Model	United States	CDC and Doris Duke Charitable Foundation	June 2006 to April 2009	Cluster group RCT	2	1,119 families	12 months
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶	Hawaii Healthy Start Program	United States	Hawaii State Department of Health (program funding); HRSA/MCHB; RWJ Foundation; Annie E. Casey Foundation; The David and Lucile Packard Foundation; National Institutes of Mental Health, Epidemiological Center for Early Risk Behaviors	1994 to 1999 [†]	Parallel group RCT	2	730 families randomized, 684 interviewed at baseline, 643 families analyzed	3 years

Appendix D Table 6. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Program Name, Funding Source, and Design

Author, Year	Program/ Trial Name	Country	Funding Source	Study Date Range	Study Design	No. of Study Arms	Total N	Duration
Gray et al, 1977 ¹³⁶ Gray et al, 1979 ¹³⁵	NA	United States	Grant Foundation, Inc.	1971 to 1975	Parallel group RCT	3 [†]	100 families randomized	NR
Hardy and Streett, 1989 ¹⁷³	Child and Youth Program	United States	Study supported in part by Morris Goldseker Foundation of Maryland, Inc.; C&Y services supported by Federal Maternal and Child Health Program funds	1983 to 1987	Parallel group RCT	2	290 infants	2 years
Infante-Rivard et al, 1989 ¹⁷⁴	NA	Canada	Fonds de la Recherche en Sante du Quebec	NR	Parallel group RCT	2	47 mother-child dyads	NR
Koniak-Griffin et al, 2002 ¹⁷⁵ Koniak-Griffin et al, 2003 ¹⁷¹	Early Intervention Program	United States (CA)	National Institute on Nursing Research and Office of Research on Women's Health	NR	Parallel group RCT	2	144 caregivers [§] randomized, 102 enrolled	24 months
Mejdoubi et al, 2015 ¹⁷⁶	VoorZorg	Netherlands	Netherlands Organization for Health Research and Development (ZonMw)	Recruitment occurred January 2007– April 2009 Follow up began in March 2007	Parallel group RCT	2	460 caregivers [*]	Pregnancy through 2 years of age
Norr et al, 2003 ¹⁷⁷	Resources, Education and Care in the Home (REACH)– Futures	United States	Agency for Health Care and Policy Research, National Center for Nursing Research, Dean's Fund from the College of Nursing at University of Illinois at Chicago	NR	Parallel group RCT	2	588 recruited, number randomized NR, 447 families retained at 12 months	12 months
Paradis et al, 2013 ¹⁷⁸	Building Healthy Children	United States	New York State Department of Health, Monroe County Department of Human Services, United Way of Greater Rochester	NR	Parallel group RCT	2	497 families	NR
Wagner and Clayton, 1999 ¹⁷⁹	PAT: Salinas Valley	United States	U.S. Department of Education, Robert Wood Johnson Foundation, Smith Richardson Foundation	1992–1996	Parallel group RCT	2	497	3 years

Appendix D Table 6. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Program Name, Funding Source, and Design

Author, Year	Program/ Trial Name	Country	Funding Source	Study Date Range	Study Design	No. of Study Arms	Total N	Duration
Wagner and Clayton, 1999 ¹⁷⁹	PAT: Teen	United States	U.S. Department of Education, Robert Wood Johnson Foundation, Smith Richardson Foundation	Initiated in 1991	Parallel group RCT	4	704	2 years

* Randomized subjects were pregnant women.

† Recruitment ended in December 1995.

‡ The study recruited participants into three arms: two randomized arms for high-risk participants, and one nonrandomized arm for low-risk participants. The evidence table does not present results from the nonrandomized arm.

§ Randomized subjects were pregnant adolescents.

|| Authors reported on data collected during 2012 while the evaluation was still ongoing.

¶ Unclear but appears to start between birth and age 2, and home visits continue until the child turns 3 or until familial goals are reached.

Abbreviations: CA=California; CDC=Centers for Disease Control and Prevention; C&Y=children and youth; HRSA=Health Resources and Services Administration; KQ=key question; MCHB=Maternal and Child Health Bureau; NA=not available; NR=not reported; PAT=Parents as Teachers; REACH=Resources, Education and Care in the Home; RCT=randomized, controlled trials; RWJ=Robert Wood Johnson; SEEK=Safe Environment for Every Kid.

Appendix D Table 7. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Barth, 1991 ¹³⁴ (Child Parent Enrichment Program)	NR	Control, n=94 pregnant women	Referral to social and health services	Control group received referrals to social and health services indicated by a 2-hour assessment interview. In a few cases, a second interview was needed to complete the assessment and referral process. When families assigned to G2 refused services or accepted fewer than 5 visits (there were only 6 such families, and their mean number of visits was 2.1), they were reassigned to the control group.	Intervention, n=97 pregnant women	Intervention was provided by lay person paraprofessionals known as parenting consultants who were recruited to represent ethnic and geographic communities in the service region. They participated in a 9-week training course (over 100 hours). Assignment of a parenting consultant to a client was based on ethnic or geographic considerations. Home visits using task-centered approach to reduce the risk of parenting problems. Tasks included those done by the parenting consultant alone (e.g., providing transportation, advocating on client's behalf), the client alone (e.g., attending prenatal care, eating two good meals per day), or conjointly (e.g., driving together to pick up food).	Average: 11 visits (range: 5–20). Parenting consultant and client completed an average of 17 tasks per case.

Appendix D Table 7. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
DePanfilis and Dubowitz, 2005 ¹⁷² (Family Connections)	The intervention (Family Connections) is provided to all arms, for different durations and with or without an added group element	Family connections for 3 months, n=62 families*	Community-based service program that works with families in their homes and in the context of their neighborhoods; core components included emergency assistance (e.g., when eviction notice received), home-based family intervention (family assessment, outcome-driven service plans, individual and family counseling), service coordination with referrals targeted toward risk (e.g., substance abuse treatment) and protective factors (e.g., mentoring program), and multifamily supportive recreational activities (e.g., dinner gatherings, museum trips); direct services were expected to be provided for a minimum of 1 hr/week	Most families received a minimum of 1 hr/week of direct services; 59 of 62 (95%) families completed the intervention; families received an average of 17 hours of total direct services (average 1.4 hr/week)	Family connections for 3 mo. enhanced with group intervention (FC3+g), n=NR	Not described/presented in article due to poor compliance	Only 32% of caregivers assigned to a group intervention attended any session, and very few graduated from the full group program

Appendix D Table 7. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Dubowitz et al, 2009 ¹⁴⁸ (SEEK Model)	NR	Control, n=323 caregivers	Residents in the control group did not receive the training, did not use the PSQ, and provided standard pediatric care and an on-site human services worker with similar responsibilities as the social worker for the intervention group.	NR	Intervention, n=406 caregivers	SEEK Model care consisted of: 1) specially trained residents who were trained over 2 half-days to address targeted risk factors for maltreatment such as maternal depression, substance use, etc., and to understand the relevance of these problems to children's health; booster trainings were conducted every 6 months; 2) pocket cards were available for doctors containing salient information and a handbook of local resources and user-friendly parent handouts 3) administration of the PSQ 4) a social worker who worked closely with residents and families if the residents/families chose to involve them. Management often involved guidance and support in the clinic and referrals to community agencies.	NR

Appendix D Table 7. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Dubowitz et al, 2012 ¹⁴⁷ (SEEK Model)	NA	Standard care, n=524 families	Standard care	Health professionals at pediatric practices in the control group received no special training and provided standard pediatric primary care. Control practices did not receive SEEK materials or social work support.	A SEEK group, n=595 families	The SEEK model of enhanced pediatric primary care, delivered by health professionals in pediatric practices, is intended to identify and help address the impact of parental depression, substance abuse, major stress, and intimate partner violence on children's health, development, and safety; how to briefly identify problems; and how to address them.	Health professionals in SEEK pediatric practices attended 4-hour, small group training conducted by pediatricians, a social worker, and a psychologist. Trainings emphasized the use of a PSQ, a 20-item self-report questionnaire screening for targeted problems administered during the child's checkup. Parents are given handouts for each problem and customized local agency listings. A social worker was available at each SEEK practice 1 day per week and by phone for health professionals and parents. The social worker provided crisis intervention and facility referrals.

Appendix D Table 7. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ (Hawaii Healthy Start Program)	NR	Control, n=290 families randomized, 270 families analyzed	Provided with information and referral to other appropriate services in the community	NR	HSP, n=395 families randomized, 373 families included	Home visits for 3–5 years by trained paraprofessionals to provide assistance, education, and services; model effective parent-child interaction; ensure child has medical home. Participants progress through stepped levels of care, decreasing in intensity as families achieve milestones in healthy functioning as followed: Level 1: visited weekly; Level 2: biweekly; Level 3: monthly; Level 4: quarterly, with explicit criteria for promotion; intervention was for 1, 2, or 3 years.	HSP home visitors delivered service to 373 families, among them 184 families were considered active by their respective program sites. Home visitors developed individual service plans for 71% of families, screened 55% of the index children, and assessed parent-child interactions in 47% of all referred families. In the infant's first year, all families: Mean number of visits during the infant's first year: 13 12 or more visits during the first year: 45% Frequency of visits: At least weekly: 1% Every 8–14 days: 28% Every 15–21 days: 22% Every 22–31 days: 11% Less than monthly: 25% No visits: 12%

Appendix D Table 7. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Gray et al, 1977 ¹³⁶ Gray et al, 1979 ¹³⁵	1 home visit when child was ages 17 to 35 months (mean: 26.8 months): mother interviewed; medical and social information involving entire family collected; mother-child interaction observed; Denver Developmental Screening Test administered to child	HRN group, n=25 families	All families received standard pediatric care.	Investigators did nothing directly for the participating high-risk families assigned to the HRN group after discharge. However, all the available information was routinely shared with attending hospital staff, community agencies such as visiting nurse services, and the family physician or clinic.	HRI group, n=25 families	Provision of pediatric care by one pediatrician at the Medical Center where the child is born.	Special well-child care for high-risk families included promotion of maternal attachment to the new born; contact with the mother by telephone on the second day after discharge; provision of more frequent office visits; giving more attention to the mother;
Hardy and Streett, 1989 ¹⁷³ (Child and Youth Program)	NA	Control, n=147 infants	NR	NR	Home visits, n=143 infants	Home visiting services, entirely delivered by a single home visitor (college-educated, former resident of community), starting when child was 7–10 days old and provided routinely at 2–3 weeks before C&Y visits (occurs at child age 2, 4, 6, 9, 12, 15, 18, 21, and 24 months). Additional visits made at discretion of staff members. Home visitor was also available to families by phone. Program was extension of pediatric primary care services provided in the clinics of a Federally funded (MCHB) Children and Youth Program.	Routine visits lasted 40–60 minutes.

Appendix D Table 7. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Infante-Rivard et al, 1989 ¹⁷⁴	NR	Control group, n=26 mother-child dyad	Single postnatal visit at 2 to 4 weeks after birth by experienced public health nurses per a routine procedure.	NR	Experimental group, n=21 mother-child dyad	Subjects receive tree prenatal visits at 28, 30, and 36 weeks of gestation, and five postnatal visits at 1, 2, 5, 12, and 30 weeks. Content involves teaching and counseling.	NR
Koniak-Griffin et al, 2002 ¹⁷⁵ Koniak-Griffin et al, 2003 ¹⁷¹ (Early Intervention Program)	NA	Control, n=45 mothers	Traditional public health nursing care: one prenatal home visit made shortly after the participant's entry into the study, and a second during the third trimester (visits focused on assessment and counseling related to prenatal health care, self-care, preparation for childbirth, education planning, and well-baby care [including immunizations]); additional home visit within 6 weeks postpartum to provide general information about child care, postpartum recovery, maternal and infant nutrition, home safety, community resources, and family planning	Mean (SD) number of home visits actually made ¹⁷¹ Prenatal period: 1.02 (0.26) Postpartum period: 1.09 (0.42)	Early intervention, n=56 mothers	Care by public health nurses using a case management approach with one nurse providing continuous care from pregnancy through 1 year postpartum: 4 "preparation for motherhood" classes, counseling, and a maximum of 17 1.5- to 2-hour home visits (2 prenatal and 15 postpartum)	Mean number of home visits, intervention vs. control: ¹⁷¹ 2.13 (prenatal) and 10.35 (postpartum) vs. 1.02 (prenatal) and 1.09 (postpartum)

Appendix D Table 7. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Mejdoubi et al, 2015 ¹⁷⁶ (The VoorZorg Study)	NR	Usual care, n=223 mothers	During pregnancy, women visited a midwife an average of 4 times for health education and physical exams. After birth, Youth Health Care nurses visited parent and baby week 1 (between 4–7 days) and week 2 after birth. In total, 9–11 check-ups are performed until the child's second birthday. Consults were available and proceeded less frequently until the child's 19th birthday.	NR	VoorZorg and usual care, n=237 mothers	In addition to usual care (see column N), trained and experienced VoorZorg nurses provided 10 home visits during pregnancy, 20 during the first, and 20 during the second year of life of the child. Each visit was between 1 hour and 1.5 hour. The purpose of the visits was effecting structured behavioral changes, conducting health education, discussing questions of expectant mother, setting and maintaining realistic achievable goals, increasing the mother's self-efficacy, and involving the mother's social network.	On average, VoorZorg participants were included at 20 weeks of pregnancy and received an average of nine home visits during pregnancy. The average number of visitations after birth was not reported. VoorZorg nurses also communicated with participants via text message, telephone, and social media.
Norr et al, 2003 ¹⁷⁷ (REACH-Futures)	NR	Standard care, n=219 families	Standard routine well-child visits at the clinic or provider of their choice	NR	REACH-F (Home visits by nurse-health advocate team), n=258 families	Community workers contact/conduct home visits with families within 2 weeks after initial discharge (following birth) monthly and more frequently if necessary. Nurse and community worker conduct home visits at 1, 6, and 12 months.	Average client received around five home visits and seven contacts over the first 12 months.

Appendix D Table 7. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Paradis et al, 2013 ¹⁷⁸ (Building Healthy Children)	NR	Control, 227 families	Families randomized to the control group are screened and referred to clinic staff to receive community referrals and other support based on identified need.		Treatment group, n=270 families	3 evidence-based services (PAT, CPP, interpersonal psychotherapy) delivered via home visits. Outreach nurses also assisted with concrete needs such as transportation to medical visits. EMR communications and intervention social workers ensured full integration with the medical home.	Mothers who screen positively for depressive symptoms are engaged into interpersonal depression treatment as soon as possible. Once depressive symptoms improve, families are transitioned into PAT or CPP services.
Wagner and Clayton, 1999 ¹⁷⁹ (Salinas Valley PAT)	NR	Control, n=199 families	Evaluation team periodically sent toys to the control group as a method of tracking their location and encouraging participation in the assessment. If annual assessments for the study revealed significant developmental delays or other problems, families were referred to appropriate services.	NR	PAT, n=298 families	Offered monthly home visits for as long as the families chose to remain in the program, up to the child's third birthday. Home visits were conducted by a trained parent educator and covered lessons from the national PAT curriculum. Parent educators modeled appropriate ways of interacting with the children, left supplemental materials for parents to read, and conducted periodic screenings of child's hearing, vision, and general development and made referrals as appropriate. Voluntary group meetings were offered periodically during which parents discussed issues and received social support from other parents and parent educators.	Received an average of 20 visits over 3 years. Visits were planned to last 45–60 minutes but actually lasted 28–50 minutes. Only 15% of participant group families attended any group meeting.

Appendix D Table 7. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 1 and Study Arm 2

Author, Year (Program/Trial Name)	Co-Intervention	Group 1 (G1) Intervention Name, N	Group 1 Intended Intervention	Group 1 Actual Intervention Received	Group 2 (G2) Intervention Name, N	Group 2 Intended Intervention	Group 2 Actual Intervention Received
Wagner and Clayton, 1999 ¹⁷⁹ (Teen PAT)	NR	Control, n=178 mothers	Evaluation team periodically sent toys to the control group as a method of tracking their location and encouraging participation in the assessment. If annual assessments for the study revealed significant developmental delays or other problems, families were referred to appropriate services.	Only services received were those the participants sought on their own from existing community health and human services providers, except the toys sent and annual assessments with referrals to appropriate services	Teen PAT program services alone, n=177 mothers	Offered monthly home visits and PAT group meetings through the children's second birthdays. On average, participants received 10 visits during the 2 -year period. Trained parent educators covered lessons from the national PAT curriculum.	Received an average of 10 visits over 2 years. Visits were planned to last 45–60 minutes but actual length was not measured. Group meeting attendance was low (average two meetings for G2 families). Also received an average of six additional telephone contacts.

*154 families originally randomized. Only 125 families had data at all three timepoints.

Abbreviations: CPP=child-parent psychotherapy; C&Y=children and youth; EMR=electronic medical record; FC=Family Connections program; G=group; HRI=high-risk intervention; HRN=high-risk nonintervention; HSP=Healthy Start Home visitation program; KQ=key question; MCBH=Maternal and Child Health Bureau; N/n=sample size; NA=not applicable; NR=not reported; PAT=Parents as Teachers; PSQ=Parent Screening Questionnaire; REACH=Resources, Education and Care in the Home; SD=standard deviation; SEEK=Safe Environment for Every Kid.

Appendix D Table 8. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Barth, 1991 ¹³⁴ (Child Parent Enrichment Program)	NA	NA	NA	NA	NA	NA	None
DePanfilis and Dubowitz, 2005 ¹⁷² (Family Connections)	Family connections for 9 mo. (FC9), n=63 families	Community-based service program that works with families in their homes and in the context of their neighborhoods; core components included emergency assistance (e.g., when eviction notice received), home-based family intervention (family assessment, outcome-driven service plans, individual and family counseling), service coordination with referrals targeted toward risk (e.g., substance abuse treatment) and protective factors (e.g., mentoring program), and multifamily supportive recreational activities (e.g., dinner gatherings, museum trips); direct services were expected to be provided for a minimum of 1 hr/week	Most families received a minimum of 1 hr/week of direct services during the first 3 months; 47 of 63 (75%) families completed the intervention; families served for 9 months were less likely to receive the same intensity of services for the full-service period due to less engagement of families after 6 months; families received an average of 31 hours of total direct service hours (average 0.9 hr/week)	Family connections for 9 mo. enhanced with group intervention (FC9+g), n=NR	Not described/presented in article due to poor compliance	Only 32% of caregivers assigned to a group intervention attended any session, and very few actually graduated from the full group program	Article only reports on a comparison of 70 families who were assigned to FC intervention for 3 months vs. 84 families assigned to receive FC intervention for 9 months, combining those with and without the group intervention. Outcomes are reported on smaller numbers of participants because data were not available for the full sample for all measures and time points.

Appendix D Table 8. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Dubowitz et al, 2009 ¹⁴⁸ (SEEK Model)	NA	NA	NA	NA	NA	NA	PSQ was not used as a screening instrument in this study. It was administered to intervention families only.
Dubowitz et al, 2012 ¹⁴⁷ (SEEK Model)	NA	NA	NA	NA	NA	NA	In this cluster group RCT, pediatric primary care practices were targeted and randomly assigned to the control or SEEK group. Eighteen private practices were randomized, 7 to SEEK and 11 to the control group. 595 families were recruited from SEEK practices to receive SEEK pediatric care and 524 families were recruited from control practices to receive usual care.
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ (Hawaii Healthy Start Program)	See comment	NR	NR	NA	NA	NA	The study had a third study group (the testing control group, followed only at 3 years, n=45 families randomized) due to funder interest in possible impact of repeated study follow up interviews on outcomes. It was not included in the analysis reported in either publications.

Appendix D Table 8. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Gray et al, 1977 ¹³⁶ Gray et al, 1979 ¹³⁵	NR	NR	NR	NA	NA	NA	Investigators recruited mothers and their infants. Information was collected about both, and mother-child dyads (families) were classified as low or high risk. Unit of analysis was children. Analyses were conducted on a random selection of 25 children from the high-risk intervention group and 25 from the high-risk nonintervention group.
Hardy and Streett, 1989 ¹⁷³ (Child and Youth Program)	NA	NA	NA	NA	NA	NA	The Federal Children and Youth Projects (funded under Title V of the Social Security Act) was intended to provide comprehensive health care to children and youth, including health supervision, screening, medical care, nutrition, and social services.
Infante-Rivard et al, 1989 ¹⁷⁴	NA	NA	NA	NA	NA	NA	None

Appendix D Table 8. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Koniak-Griffin et al, 2002 ¹⁷⁵ Koniak-Griffin et al, 2003 ¹⁷¹ (Early Intervention Program)	NA	NA	NA	NA	NA	NA	Both study groups had regular telephone calls with public health nurses for scheduling and encouraging continued participation in the study. There was no difference between the two groups, but the extra phone calls to the control group may have served as a sort of intervention. Sample size analyzed for 2-year follow up is 101 due to attrition. ¹⁷¹
Mejdoubi et al, 2015 ¹⁷⁶ (The VoorZorg Study)	NA	NA	NA	NA	NA	NA	Unit of recruitment is female caregiver (pregnant women). Unit of analyses for CPS reports is child.
Norr et al, 2003 ¹⁷⁷ (REACH-Futures)	NA	NA	NA	NA	NA	NA	The study was not restricted to African Americans but did initially recruit from a predominately African American clinic. The sample of Mexican Americans was added on; they were recruited into the program later. Community workers conducting home visits for Mexican American participants are bilingual, and are African American for African Americans.

Appendix D Table 8. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Paradis et al, 2013 ¹⁷⁸ (Building Healthy Children)	NA	NA	NA	NA	NA	NA	None
Wagner and Clayton, 1999 ¹⁷⁹ (Salinas Valley PAT)	NA	NA	NA	NA	NA	NA	None

Appendix D Table 8. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Study Arm 3 and Study Arm 4

Author, Year (Program/Trial Name)	Group 3 (G3) Intervention Name, N	Group 3 Intended Intervention	Group 3 Actual Intervention Received	Group 4 (G4) Intervention Name, N	Group 4 Intended Intervention	Group 4 Actual Intervention Received	Comments
Wagner and Clayton, 1999 ¹⁷⁹ (Teen PAT)	Case management services alone, n=174 mothers	Offered comprehensive case management services modeled after those provided through CA's Adolescent Family Life Program, with face-to-face contacts provided as often as teens needed but at least quarterly. Case managers provided referrals as needed.	Also received an average of 8 additional telephone contacts	PAT services plus case management, n=175 mothers	Offered monthly home visits and PAT group meetings through child's 2nd birthday. Participants received avg 10 visits during the 2-year period. Trained parent educators covered lessons from national PAT curriculum. Also offered comprehensive case management services modeled after those provided through CA's Adolescent Family Life Program, with face-to-face contact provided as often as teens needed but at least quarterly. Case managers provided referrals as needed. Case management contacts could occur at home or elsewhere and were separate from PAT program visits.	Received an average of 10 PAT visits over 2 years. PAT visits were planned to last 45–60 minutes but actual length was not measured. PAT group meeting attendance was low (average three meetings for G4 families). Participants received an average of 10 case management contacts in 2 years. (Total visits=20 for G4 participants). Also received an average of 17 additional telephone contacts.	None

Abbreviations: CA=California; CPS=child protective services; FC=family connections; KQ=key question; N/n=sample size; NA=not applicable; NR=not reported; PAT=Parents as Teachers; PSQ=Parent Screening Questionnaire; RCT=randomized, controlled trial; SEEK=Safe Environment for Every Kid; vs.=versus.

Appendix D Table 9. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Population, Inclusion and Exclusion, and Risk Factors

Author, Year (Program/Trial Name)	Target Population	Inclusion Criteria	Exclusion Criteria	Risk Factors
Barth, 1991 ¹³⁴ (Child Parent Enrichment Program)	Pregnant women in CA referred to the program by public health, education, or social service professionals working in 17 different agencies.	Professionals screened clients on conditions that may presage child abuse (e.g., underuse of needed community services, criminal or mental illness record, suspicion of previous abuse by mother).	NR	Mother is underusing needed services, has history of criminal or mentally ill behavior, suspected of physical abuse in the past, has low self-esteem/is socially depressed or isolated, has generally chaotic life; there is a lack of support from father and/or family; mother's intelligence or health is not good; baby was not planned or wanted; mother was or is abused; child is difficult to care for. Typical participant had more than four risk factors. When referrers determined that clients might benefit from program services, they referred them to the project.
DePanfilis and Dubowitz, 2005 ¹⁷² (Family Connections)	Families residing in Baltimore's Westside Empowerment Zone (urban area with extreme poverty, unemployment, and general economic distress) that had at least one child between the ages of 5 and 11	Referrer concern that at least one of 19 neglect subtypes, which were operationally defined (e.g., unsafe housing conditions, inadequate supervision, inadequate/delayed health care) was occurring at a low level (not yet reportable to CPS) or a perceived risk for one of these subtypes; at least two additional risk factors for neglect related to the child (e.g., behavior problem; physical, developmental, or learning disability; more than three children) or the caregiver/family (e.g., unemployment/overemployment, mental health problem, drug or alcohol problem, domestic violence, homelessness); and willingness to participate in the program. [†]	Current CPS involvement*	See inclusion criteria. The most frequent neglect concerns identified at intake were delay getting mental health care for a child (32%) and inadequate supervision (22%). For example, because schools made the largest number of referrals, a teacher could have called because a child was acting out in school and a parent may have refused to sign permission for a psychological evaluation. These concerns would not constitute mental injury reportable to CPS but may suggest that a child's basic needs were at risk of not being met.

Appendix D Table 9. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Population, Inclusion and Exclusion, and Risk Factors

Author, Year (Program/Trial Name)	Target Population	Inclusion Criteria	Exclusion Criteria	Risk Factors
Dubowitz et al, 2009 ¹⁴⁸ (SEEK Model)	Parents of children aged 0–5 years brought in for health supervision at a university-based pediatric primary care resident continuity clinic serving a low-income urban population in Baltimore	Parents who brought their child ages 0–5 years to a health supervision visit, spoke English	Had another child in the study, or had the child in foster care	Study participants were not recruited based on risk factors.
Dubowitz et al, 2012 ¹⁴⁷ (SEEK Model)	Predominantly middle income suburban family with child <5 years old	NR	Children >5 years old. In families with more than one child <5 years, the youngest was selected as the study index child.	Participants were identified as a relatively low-risk population.
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ (Hawaii Healthy Start Program)	At-risk families living in the HSP target community on Oahu and who were not already known to CPS.	HSP staff or hospital staff review the mother's medical record and if it suggests risk (or there is too little information to assess risk), staff conduct a semistructured interview with the mother using Kempe's Family Stress Checklist (positive score ≥ 25). If HSP home visiting intake is open in the family's community, the family is invited to enroll. If intake is closed, the family is referred to other community resources.	NR	Based on the Family Stress Checklist, risk factors for child abuse: parental substance use, poor mental health, domestic violence, history of abuse as a child, unrealistic expectations of the child, unwanted child, risk of poor bonding.
Gray et al, 1977 ¹³⁶ Gray et al, 1979 ¹³⁵	Mothers having their first or second child at Colorado General Hospital, along with their infants once delivered	NR	Infants with neonatal conditions severe enough to require transfer to the neonatal intensive care unit were excluded from the study along with their mothers	Mothers were assessed for psychologic, interactional, and lifestyle dynamics that might result in "abnormal parenting practices," including child abuse and neglect. The following screening procedures were used to determine predictive behaviors: collection of parental information, administration of a questionnaire, assessment of labor and delivery room information, observation and/or interview during the postpartum period. Investigators were trained to identify warning signs during the prenatal period, delivery, and postpartum

Appendix D Table 9. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Population, Inclusion and Exclusion, and Risk Factors

Author, Year (Program/Trial Name)	Target Population	Inclusion Criteria	Exclusion Criteria	Risk Factors
Hardy and Streett, 1989 ¹⁷³ (Child and Youth Program)	Healthy black neonates weighing more than 2,000 g born between August 1983 and April 1985 to mothers age 18 years or older	Infant must make at least one visit to the C&Y clinic within the first 3 months of life and followed for a minimum of 10 months.	NR	C&Y staff members, basing on their observations and knowledge of the family, check a box on the medical record of each child believed to be at particularly high risk for illness, developmental problems, neglect or other abuse, or any combination thereof.
Infante-Rivard et al, 1989 ¹⁷⁴	Canadian mothers of low socioeconomic status	Mothers with <12 years of schooling and/or living below the poverty level according to the Canadian criteria at the time of the study (Conseil National du Bien-Etre Social, 1984), Canadian nationality, French or English speaking, absence of a chronic or psychiatrically treated illness, and absence of alcohol or drug abuse.	After the child was born, a hospital stay longer than a week for either the mother or the child, congenital malformation or disease of the child requiring regular medical care, occurrence of maternal postpartum depression	Not reported. All are of low socioeconomic status
Koniak-Griffin et al, 2002 ¹⁷⁵ , Koniak-Griffin et al, 2003 ¹⁷¹ (Early Intervention Program)	Adolescent mothers from referrals to the Community Health Services Division of the County Health Department in San Bernardino, California	Adolescents ages 14–19 years, ≤26 weeks' gestation, having their first child, planning to keep the child	Narcotic or injection drug dependent, having a documented serious medical or obstetric problem	NR
Mejdoubi et al, 2015 ¹⁷⁶ (The VoorZorg Study)	First-time mothers <26 years of age along with their first-born infants (prenatal to 2 years), recruited by general practitioners, midwives, gynecologists, and others in 20 municipalities in the Netherlands who have at least one risk factor	Under 26 years of age, low educational level, first-time pregnancy, maximum 28 weeks of gestation, some understanding of the Dutch language, have at least one of the following: being single, a history or present situation of domestic violence, psychosocial symptoms, unwanted pregnancy, financial problems, housing difficulties, no employment and/or education, or alcohol and/or drug abuse.	NR	Single, a history or present situation of domestic violence, psychosocial symptoms, unwanted pregnancy, financial problems, housing difficulties, no employment and/or education, or alcohol and/or drug abuse

Appendix D Table 9. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Population, Inclusion and Exclusion, and Risk Factors

Author, Year (Program/Trial Name)	Target Population	Inclusion Criteria	Exclusion Criteria	Risk Factors
Norr et al, 2003 ¹⁷⁷ (REACH-Futures)	Low-income, inner-city pregnant women who self-identified as African American or Mexican American	Medicaid or state supplemental health insurance eligibility (income under 150% FPL), address in a Chicago neighborhood with high infant mortality, medically and obstetrically low risk, no evidence of current drug use	NR	NR
Paradis et al, 2013 ¹⁷⁸ (Building Healthy Children)	Families of new borns and children up to age 2 years who are patients at three primary care practices	No previous CPS indication, maternal age <21 years at first delivery, and ≤2 children younger than age 3	NR	Maternal history of abuse/neglect in their own childhood, elevated depressive symptoms, exposure to domestic violence
Wagner and Clayton, 1999 ¹⁷⁹ (Salinas Valley PAT)	Families with children ≤6 months old that were recruited from WIC office, medical clinics, and school districts	Same as target population	NR	NR
Wagner and Clayton, 1999 ¹⁷⁹ (Teen PAT)	Teens with children <6 months old that were recruited from PAT demonstration sites	Teens <19 years old, either pregnant or had babies <6 months old	NR	NR

* Prior involvement with the agency was not ground for exclusion.

† Families were referred to the program by schools (30%), community-based agencies (22%), health care clinics (21%), self (16%), or public social services (12%).

Abbreviations: CA=California; CPS=child protective services; C&Y=Child & Youth Program; FPL=Federal poverty level; HSP=Healthy Start Home visitation program; KQ=key question; NR=not reported; PAT=Parents as Teachers; REACH=Resources, Education and Care in the Home; SEEK=Safe Environment for Every Kid; WIC=Women's, Infant, and Children.

Appendix D Table 10. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and Ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Barth, 1991 ¹³⁴ (Child Parent Enrichment Program)	Caregiver (Mother) Overall median: 23.5 years (NR)	Caregiver 100	Caregiver (Mother) White: 45 Latino: 31 Black: 17 Other: 7	NR*	NR	Other relevant maternal characteristics at baseline: 70% of participants had family incomes <\$10,000 90% scored above the mean on CAPI 44% primiparas 56% had one or more children [†] 40% had supportive relationship with father [†]
DePanfilis and Dubowitz, 2005 ¹⁷² (Family Connections)	Child Overall: 8.3 years (4) (Range: new born–20 years) Caregiver (Unspecified) Overall: 36.9 years (12.2) (Range: 19–72 years)	Caregiver 98.1 Child NR	Child Black: 84.6 Caregiver (Unspecified) Black: 86.4 Hispanic: NR	History of unsubstantiated CPS report [‡] : 56.5% History of substantiated CPS report [‡] : 38.3%	Families with child behavior problems: 66%	Other relevant family characteristics at baseline: Children living with their mothers: 77.8% Children per family: 3.0 (1.6), range: 1–9 Families had unemployment: 71%
Dubowitz et al, 2009 ¹⁴⁸ (SEEK Model)	Child, median age G1: 8.0 months (IQR 17) G2: 6.0 months (IQR 13) Caregiver (Mother, Father, Other) G1: 25.3 years (7.3) G2: 25.3 years (6.8)	Caregiver (Mother) G1: 93 G2: 92 Child Overall: 48	Child Overall: Black: 93	CPS involvement: G1: 12 [§] G2: 12 [§]	NR	Other relevant parental factors at baseline: Caregiver relationship, n (%): Mother: G1: 287 (93) G2: 231 (92) Father: G1: 15 (6) G2: 13 (4) Other: G1: 4 (2) G2: 8 (3) Marital status, single, n (%) G1: 216 (86) G2: 268 (87) Medicaid, n (%) G1: 224 (92) G2: 270 (93)

Appendix D Table 10. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and Ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Dubowitz et al, 2012 ¹⁴⁷ (SEEK Model)	Child G1: 26.7 months (20.1) G2: 25.0 months (19.5) Caregiver (Mother) G1: 34.5 years (5.2) G2: 33.4 years (5.7)	Caregiver 100 Child G1: 47 G2: 50	Child G1: Asian: 5 Black: 7 White: 75 Latino: 1 Bi- or multiracial/other: 12 G2: Asian: 2 Black: 4 White: 86 Latino: 1 Bi- or multiracial/other: 8	CPS Reports (Pre-SEEK only): G1: 7 (1) G2: 16 (3)	NR	Other relevant family characteristics at baseline: Child on medical assistance, n (%): G1: 33 (6) G2: 69 (12) Maternal marital status, single and never married, n (%): G1: 26 (5) G2: 52 (9) Pre-SEEK CTSPC score psychological aggression subscale, mean (SD): [¶] G1: 7.8 (11.4) G2: 6.2 (10.0) Minor physical assault subscale, mean (SD): [¶] G1: 3.4 (6.8) G2: 2.7 (6.7)

Appendix D Table 10. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and Ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ (Hawaii Healthy Start Program)	Caregiver (Mother): G1: 23.3 years (5.8) G2: 23.7 years (5.8)	NR	Caregiver (Mother): G1: Native Hawaiian or Pacific Islander: 33 Asian or Filipino: 28 White: 14 No primary ethnicity or unknown: 26 G2: Native Hawaiian or Pacific Islander: 34 Asian or Filipino: 28 White: 10 No primary ethnicity or unknown: 27	NA [#]	NA	Other characteristics (of participating families) at baseline: Household income below poverty level: G1: 67% G2: 63% Poor maternal general mental health: G1: 50% G2: 43% Maternal substance use: G1: 23% G2: 19% Partner violence: p=0.02 G1: 52% G2: 43% Very high risk (≥45 on Kempe's Family Stress Checklist) - Mother: G1: 25% G2: 23% Very high risk (≥45 on Kempe's Family Stress Checklist) - Father: G1: 40% G2: 35% Partner's relationship: G1: None: 13% Friends or going together: 37% Living together: 29% Married: 21% G2: None: 11% Friends or going together: 35% Living together: 29% Married: 26%
Gray et al, 1977 ¹³⁶ , Gray et al, 1979 ¹³⁵	Child, during follow up Overall: 26.8 months (NR)	Caregiver 100 Child NR	NR	NR	NR	NR

Appendix D Table 10. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and Ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Hardy and Streett, 1989 ¹⁷³ (Child and Youth Program)	Caregiver (Mother): Overall: 22.6 years (Range: 18-33 years)	NR	Child Black: 100**	NR	NR	Other relevant family characteristics at baseline: Single mothers: 78% Families with no prior children: 23% “High-risk” family: G1: 26% G2: 28%
Infante-Rivard et al, 1989 ¹⁷⁴	Caregiver (Mother) ^{††} G1: 23.5 years (3.8) G2: 25.3 years (5.7)	Caregiver (Mother) ^{††} 100	NR	NR	NR	Other relevant maternal characteristics at baseline ^{††,‡} % living alone: G1: 7.7 G2: 9.5 % having no other children at home: G1: 50.0 G2: 61.9 % mother with less than 10 years of schooling: G1: 26.9 G2: 9.5 % under poverty level: G1: 65.4 G2: 33.3 % single or separated: G1: 19.2 G2: 9.5

Appendix D Table 10. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and Ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Koniak-Griffin et al, 2002 ¹⁷⁵ , Koniak-Griffin et al, 2003 ¹⁷¹ (Early Intervention Program)	Caregiver (Mother) Overall: 16.79 years (1.13) G1: 16.84 years (1.00) G2: 16.75 years (1.24) Child, gestational stage at enrollment Overall: 20.48 weeks (5.54) G1: 20.25 weeks (5.12) G2: 20.67 weeks (5.92)	Caregiver 100 Child NR	Caregiver (Mother) Overall: Latina: 62 African American: 13 Non-Hispanic White: 18 Other (mixed ethnicity): 4 G1: Latina: 60 African American: 16 Non-Hispanic White: 18 Other (mixed ethnicity): 2 G2: Latina: 64 African American: 11 Non-Hispanic White: 18 Other (mixed ethnicity): 5	NR	NR	Baseline characteristics reported on the remaining 101 participants analyzed at the 2-year follow up ¹⁷¹ Other relevant maternal characteristics at baseline: Hollingshead 4-Factor Index of Socioeconomic Status Overall: 22.90 (10.24) G1: 20.98 (10.19) G2: 24.43 (10.12) Marital status, single: Overall: 92% G1: 87% G2: 96%
Mejdoubi et al, 2015 ¹⁷⁶ (The VoorZorg Study)	Caregiver (Mother) G1: 19.1 years (2.3) G2: 19.4 years (2.6)	Caregiver 100	Caregiver (Mother) G1: Dutch: 49% Turkish/Moroccan: 6% Surinamese/Antillean: 26% Other: 19% G2: Dutch: 49% Turkish/Moroccan: 6% Surinamese/Antillean: 27% Other: 19%	NR	NR	Other relevant maternal characteristics at baseline: Weeks of gestation: M (SD) G1: 19.8 weeks (5.7) G2: 19.5 weeks (6.0) Married/living together: N (%) G1: 36 (22) G2: 46 (24)

Appendix D Table 10. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and Ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Norr et al, 2003 ¹⁷⁷ (REACH-Futures)	NR	Caregiver 100 Child NR	Caregiver (Mother) Overall:†† African American: 68 Mexican American: 32	NR	NR	Significant difference between African American and Mexican American mothers in the following characteristics at baseline: African Americans: <20 years old: G1: 44.0%, G2: 42.3% Primiparas: G1: 60.3%, G2: 58.8% Employed or in school: G1: 42.1%, G2: 43.6% High school graduates: G1: 58.9%, G2: 54.9% Living with own mother or mother figure: G1: 61.0%, G2: 64.3% Living with male partner: G1: 13.5%, G2: 13.7% Lived in a household where someone is currently employed: G1: 50.0%, G2: 53.3% Mexican Americans: <20 years old: G1: 29.5%, G2: 36.8% Primiparas: G1: 47.4%, G2: 42.1% Employed or in school: G1: 29.5%, G2: 30.3% High school graduates: G1: 34.6%, G2: 42.1% Living with own mother or mother figure: G1: 26.9%, G2: 31.6% Living with male partner: G1: 66.7%, G2: 52.6% Lived in a household where someone is currently employed: G1: 79.5%, G2: 68.4%

Appendix D Table 10. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and Ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Paradis et al, 2013 ¹⁷⁸ (Building Healthy Children)	Child, age at enrollment Overall: 6.34 months (NR) (Range: 1–26 months) G1: 6.40 months (NR) G2: 6.29 months (NR) Caregiver (Mother) Overall: 18.9 years (NR) (Range: 14–23 years) G1: 19.1 years (NR) G2: 18.9 years (NR)	Caregiver NR Child Overall: 48 G1: 53 G2: 44	Caregiver (Mother) Overall: White: 20 African American: 68 Biracial or other: 11 Hispanic: 19 G1: White: 24 African American: 61 Biracial or other: 13 Hispanic: 23 G2: White: 17 African American: 74 Biracial or other: 9 Hispanic: 15	NR	NR	59% of children exposed to domestic violence including bidirectional violence involving both mothers and fathers, based on maternal report. Other relevant maternal characteristics at baseline: Mean annual income, in thousands: Overall: 10.9 G1: 11.6 G2: 10.4
Wagner and Clayton, 1999 ¹⁷⁹ (Salinas Valley PAT)	Caregiver (Mother) G1: 25.9 years (NR) G2: 25.3 years (NR)	Caregiver 100 ^{§§} Child NR	Caregiver (Mother) G1: Latina: 76.9 Non-Latina: 23.1 G2: Latina: 83.6 Non-Latina: 16.5	NR	NR	Other relevant family characteristics at baseline: ^{¶¶} Mother was married: 57.0% Father lived in the household: 72.4% Mother was only adult in household: 10.9% Child had siblings: 52.9% Household received AFDC: 20.5% Household had Medi-Cal: 60.8% Family enrolled while pregnant: G1: 46.9% G2: 59.8%

Appendix D Table 10. Characteristic of RCTs Included in the Sensitivity Analysis for Child Maltreatment Prevention Benefits and Harms (KQs 1 and 2): Demographics

Author, Year (Program/Trial Name)	Age Mean (SD)	Female No. (%)	Race and Ethnicity No. (%)	Maltreated No. (%)	Symptoms No. (%)	Other Relevant Baseline Characteristics
Wagner and Clayton, 1999 ¹⁷⁹ (Teen PAT)	Caregiver (Mother) G1: 16.8 years (NR) G2: 16.6 years (NR) G3: 16.6 years (NR) G4: 16.6 years (NR) (Range: 15–18 years)	Caregiver 100 Child NR	Caregiver (Mother) G1: Latina: 55.1 Caucasian: 19.1 African American: 24.2 Other: 1.7 G2: Latina: 57.1 Caucasian: 20.3 African American: 18.1 Other: 4.5 G3: Latina: 52.6 Caucasian: 25.4 African American: 17.9 Other: 4.0 G4: Latina: 59.4 Caucasian: 18.3 African American: 21.1 Other: 1.1	NR	NR	Other relevant maternal characteristics at baseline:## Mother was married: 12.4% Mother was only adult in household: 1.1% Household received AFDC: 31.4%

* Typical participant had more than four risk factors (e.g., underuse of needed community services, criminal or mental illness record, suspicion of previous abuse by mother).

† Calculated.

‡ Indicated/substantiated and unsubstantiated child abuse and neglect reports were not a factor of selection into the study. Percentage reported based on N=154 participants.

§ Before the study, 12% in both study arms had CPS involvement.

‖ Based on 506 families in G1 and 577 families in G2 interviewed at baseline. $p=0.006$.

¶ Based on 502 families in G1 and 583 families in G2 who were interviewed at baseline. $p=0.019$.

Subjects with prior or current CPS involvement were excluded from the study by design.

** By design

†† Based on 47 (26 in G1, 21 in G2) participants who completed the study.

‡‡ Based on the 477 participants remaining in the study at 12-month followup.

§§ Authors reported 495 mothers and 433 fathers among the 495 families participating in the Salinas Valley PAT Demonstration.

|| Majority of whom were Caucasian.

¶¶ Calculated based on information reported by ethnicity of mothers.

Calculated based on information reported by study arm.

Abbreviations: AFDC=Aid to Families with Dependent Children; CAPI=Child Abuse Potential Inventory; CPS=child protective services; CTSPC=Conflict Tactic Scales: Parent to Child; G=group; IQR=interquartile range; KQ=key question; N/n=sample size; NA=not available; NR=not reported; PAT=Parents as Teachers; REACH=Resources, Education and Care in the Home; SD=standard deviation; SEEK=Safe Environment for Every Kid.

Appendix D Table 11. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Barlow et al, 2007 ¹⁰¹ Fair Total N=131 caregivers randomized (N analyzed=131)	Placement on child protection register or care proceedings; ascertained by health visitors	12 months*	NR (15)	NR (17)	NA	NA	RR 2.02 (95% CI, 0.46–2.54, p=NS) [†]
Brooten et al, 1986 ¹¹⁰ Fair Total N=79 infants randomized (N analyzed=79)	Number of infants placed in foster care; data source not reported	18 months [‡]	4 (10)	2 (5.1)	NA	NA	Calculated RR, 0.51 (95% CI, 0.10 to 2.64)
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=309)	Substantiated CPS reports for all types of maltreatment, provided through the Alaska Office of Children's Services	After year 1 of age only	NR (10)	NR (12)	NA	NA	No difference [§] , p=0.53
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=297)	Substantiated CPS reports for all types of maltreatment provided through the Alaska Office of Children's Services	After year 2 of age only	NR (9)	NR (9)	NA	NA	No difference, p=0.89
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=297)	Substantiated CPS reports for all types of maltreatment provided through the Alaska Office of Children's Services	2 years of age	NR (17)	NR (16)	NA	NA	No difference, p=0.71

Appendix D Table 11. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=309)	Substantiated and unsubstantiated CPS reports for all types of maltreatment, provided through the Alaska Office of Children's Services ^{III}	After year 1 of age only	NR (16)	NR (20)	NA	NA	No difference, p=0.48
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=297)	Substantiated and unsubstantiated CPS reports for all types of maltreatment, provided through the Alaska Office of Children's Services ^{II}	After year 2 of age only	NR (23)	NR (18)	NA	NA	No difference, p=0.39
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=297)	Substantiated and unsubstantiated CPS reports for all types of maltreatment, provided through the Alaska Office of Children's Services ^{III}	2 years of age	NR (33)	NR (30)	NA	NA	Calculated RR, 0.91 (95% CI, 0.65 to 1.27); reported p=0.59
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=309)	Substantiated and CPS reports for neglect, provided through the Alaska Office of Children's Services ^{II}	After year 1 of age only	NR (6)	NR (10)	NA	NA	No difference, p=0.32

**Appendix D Table 11. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–
Child Protective Services Reports and Actions, Categorical Outcomes**

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=297)	Substantiated and CPS reports for neglect, provided through the Alaska Office of Children's Services ^{II}	After year 2 of age only	NR (7)	NR (6)	NA	NA	No difference, p=0.58
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=297)	Substantiated and CPS reports for neglect, provided through the Alaska Office of Children's Services ^{III}	2 years of age	NR (13)	NR (12)	NA	NA	No difference, p=0.81
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=309)	Substantiated and unsubstantiated CPS reports for neglect, provided through the Alaska Office of Children's Services ^{II}	After year 1 of age only	NR (13)	NR (16)	NA	NA	No difference, p=0.66
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=297)	Substantiated and unsubstantiated CPS reports for neglect, provided through the Alaska Office of Children's Services ^{II}	After year 2 of age only	NR (18)	NR (16)	NA	NA	No difference, p=0.55
Duggan et al, 2007 ⁸⁷ , Good Total N=364 families randomized (N analyzed=297)	Substantiated and unsubstantiated CPS reports for neglect, provided through the Alaska Office of Children's Services ^{II}	2 years of age	NR (27)	NR (26)	NA	NA	No difference, p=0.87

Appendix D Table 11. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=1,060)	Prevalence of substantiated CPS reports at Year 1 of age, defined as percentage of women with a substantiated report; obtained from review of CPS records of child abuse and neglect reports	1 year of age	NR (5.98)	NR (7.90)	NA	NA	Calculated RR, 1.32 (95% CI, 0.85 to 2.06)
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Prevalence of substantiated CPS reports at Year 2 of age, defined as percentage of women with a substantiated report; obtained from review of CPS records of child abuse and neglect reports	2 years of age	NR (4.8)	NR (5.08)	NA	NA	Calculated RR, 1.06 (95% CI, 0.612 to 1.83)
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=1,173)	Cumulative rate of biological mom or target child confirmed as subject or victim of CPS report; based on NYS Statewide Automated Child Welfare Information System database search. [¶]	Target child's 7 th birthday	NR (27.10)	NR (29.55)	NA	NA	AOR, 1.13 (95% CI, NR, p=NS)

Appendix D Table 11. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Easterbrooks et al, 2013 ¹⁰⁴ Fair Total N=707 caregivers randomized (N analyzed=707)	Rate of maltreatment; based on DCF records covering only the time period after participants enrolled in the study. Children were classified as maltreated if there were CPS reports of neglect, physical abuse, or a combination occurring after participants enrolled into the study, regardless of report resolution (substantiated or unsubstantiated) or the identity of the perpetrator (mother or other person). Children were classified as not maltreated if there were no such reports. [#]	NR	NR (NR)**	NR (NR)**†	NA	NA	G2 vs. G1: p=0.769
Fergusson et al, 2005 ¹⁰⁵ , Fergusson et al, 2013 ¹⁰⁶ Fair Total N=443 families randomized (N analyzed=391)	Parent report of contact with Child, Youth, and Family Service	36 months of age	NR (21.3)	NR (19.6)	NA	NA	OR 0.91 (95% CI, 0.55 to 1.48) Cohen's d 0.04 (95% CI, -0.15 to 0.25) p=0.39

Appendix D Table 11. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=69)	Reported child abuse cases; based on hospital and project charts as well as parent report	12 months	0 (0)	0 (0)	0 (0)	0 (0)	p=0.331
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=80)	Reported child abuse cases; based on hospital and project charts as well as parent report	6 months	0 (0)	0 (0)	0 (0)	0 (0)	p=0.408
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=69)	Reported child neglect cases; based on hospital and project charts as well as parent report	12 months	0 (0)	0 (0)	0 (0)	0 (0)	p=0.331
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=80)	Reported child neglect cases; based on hospital and project charts as well as parent report	6 months	0 (0)	1 (0.05)	0 (0)	0 (0)	p=0.439
Lam et al, 2009 ¹⁰⁰ Fair Total N=30 male patients with their female partners and custodial children randomized (N analyzed=30)	Parent's report of active involvement with CPS ^{††} ; not verified or confirmed with CPS.	12 months	NR (30)	NR (20)	NR (10)	NA	NR ^{††}

**Appendix D Table 11. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–
Child Protective Services Reports and Actions, Categorical Outcomes**

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Low ell et al, 2011 ¹¹⁴ Good Total N=157 families randomized (N analyzed=117)	Family's prior or current involvement with child protective services at 36 months; based on interview with mother. State of Connecticut CPS records were abstracted upon receiving parental consent. ^{§§II}	36 months	NR (NR)	NR (NR)	NA	NA	Reported OR, for no CPS involvement 2.1 (95% CI, 1.0 to 4.4, p<0.05) ^{III} Calculated OR, for CPS involvement 0.48 (95% CI, 0.23 to 1.0)
Low ell et al, 2011 ¹¹⁴ Good Total N=157 families randomized (N analyzed=117)	Family's prior or current involvement with child protective services at 24 months; based on interview with mother. State of Connecticut CPS records were abstracted upon receiving parental consent. ^{§§}	24 months	NR (NR)	NR (NR)	NA	NA	Reported OR, for no CPS involvement 1.9 (95% CI, 0.9 to 4.2) Calculated OR, for CPS involvement 0.53 (95% CI, 0.24 to 1.11)
Low ell et al, 2011 ¹¹⁴ Good Total N=157 families randomized (N analyzed=117)	Family's prior or current involvement with child protective services at 12 months; based on interview with mother. State of Connecticut CPS records were abstracted upon receiving parental consent. ^{§§#}	12 months	NR (NR)	NR (NR)	NA	NA	Reported OR, for no CPS involvement 1.7 (95% CI, 0.7 to 3.9) Calculated OR, for CPS involvement 0.59 (95% CI, 0.26 to 1.43)

**Appendix D Table 11. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–
Child Protective Services Reports and Actions, Categorical Outcomes**

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Lowell et al, 2011 ¹⁴ Good Total N=157 families randomized (N analyzed=117)	Family's prior or current involvement with child protective services at 6 months; based on interview with mother. State of Connecticut CPS records were abstracted upon receiving parental consent. ^{§§}	6 months	NR (NR)	NR (NR)	NA	NA	Reported OR, for no CPS involvement 1.7 (95% CI, 0.7 to 3.9) Calculated OR, for CPS involvement 0.59 (95% CI, 0.26 to 1.43)
Olds et al, 1986 ⁹⁵ Fair Total N=400 families randomized (N analyzed=342)	Reports of child abuse and neglect; determined by review of medical and CAN registry records (from all 15 states across which the families spread) for the presence of verified cases of abuse or neglect from the Department of Social Services, emergency room visits, and other medical visits until the child reached the age of 4 years.	2 years of age	NR (10)	NR (8)	NR (5)	NA	Calculated RR, for G3 vs. G1: 0.47 (95% CI, 0.16 to 1.36) ^{¶¶} Calculated RR, for G2 vs. G1: 0.78 (95% CI, 0.31 to 1.99)

Appendix D Table 11. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Olds et al, 1986 ⁹⁵ Fair Total N=400 families randomized (N analyzed=NR)	Verified reports in which parents are perpetrators of child abuse and neglect; determined by review of CPS records from states in which the mothers and target children resided during the interval from the birth of their first child (focal child) to the child's 15th birthday.	15 years	NR (NR)	NR (NR)	NR (NR)	NA	Parents in the nurse-visited group were perpetrators of child abuse and neglect in fewer verified reports. (p<0.001). ^{##}
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=948)	Safeguarding was counted as any record in GP notes indicating the initiation, progression, or closure of a safeguarding process (e.g., initial assessment, being identified as a child in need, child protection conference) ^{***}	2 years	38 (8.0)	64 (13.6)	NA	NA	Adjusted OR: 1.85 (95% CI, 1.02-2.85) p=0.005
Sadler et al, 2013 ⁹¹ Fair Total N=105 families randomized (N analyzed=78)	Open cases with CPS	24 months	2 (5)	0 (0)	NA	NA	p=0.1

Appendix D Table 11. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Silovsky et al, 2011 ¹⁰⁸ Fair Total N=105 caregivers randomized (N analyzed=105)	Caregiver had a referral to child welfare of participant as a perpetrator of any type of abuse or neglect. A computerized sequential strategy was used to match research and child welfare database cases on Social Security numbers and combinations of name, gender, and date of birth (including similar names and spellings).	Average 716 days ^{†††}	18 (31.5)	10 (20.8)	NA	NA	NR

* Assessed for time period between 6 months and 12 months of age.

† Author-reported confidence intervals are asymmetric. Data were not sufficient to recalculate.

‡ Subjects randomized were newborns, so age at followup is likely 18 months.

§ Using CPS reports, pediatric medical records, interviews with primary caregiver, observation of the home environment, and interaction with the child: no difference in HV and control groups in rates for substantiated or overall reports of child maltreatment.

‡ Excludes three families with a fetal or infant death and families known to be out of town for >6 months in Year 2

¶ Analyses control for female target child, count of moderate to severe Kempe items, annual earnings at random assignment, and having at least a GED or high school diploma.

Categories of maltreatment included physical abuse, sexual abuse, neglect, and congenital drug addiction. Reports of congenital drug addiction were recoded as child neglect. A “case” of child maltreatment referred to a child who had one or more reports of child maltreatment. That is, the child may have had a single report at one time or more than one report at multiple points in time. A single report connoted a single instance of child maltreatment regardless of how many individuals contacted child protective services.

** The number of mothers and/or children in each group was not reported. The number of maltreated children in each group was also not reported. 204 children had DCF maltreatment reports, among them, 145 were substantiated by DCF and 84% of the 204 reports concerned neglect.

†† Outcome is assessed at each interview by asking each parent separately the following single-item (yes/no) question: Do you currently have an open case with CPS regarding the target child? If either parent answered yes, the couple was counted as having an open CPS case at that assessment period. In cases in which only one parent’s report was available, that report was used.

The study also reports numbers pretreatment, post-treatment, and at 6 months. The analysis here is restricted to 12 months (reports at earlier times may not represent program effects). The proportion of PSBCT participants with an open CPS case on the target child showed clinically meaningful effects at posttreatment and 6 months ($r > .20$), with stronger effects at 12 months ($r > .30$). Although BCT showed no meaningful change in the proportion of CPS-involved participants at posttreatment and 6-month followup, clinically meaningful effects emerged at 12 months.

§§ There was not sufficient information detailed in the reports to establish the duration of involvement or active involvement with CPS at baseline.

¶¶ Analyses assessed the effect of the intervention on no involvement with CPS between intervention groups at 36 months. Analyses adjusted for history of involvement at baseline.

Appendix D Table 11. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Child Protective Services Reports and Actions, Categorical Outcomes

^{¶¶} Higher risk subgroup (poor, unmarried teenagers): G1: 19% vs. G3: 4% confirmed reports of abuse or neglect, $p=0.07$.

^{###} The effect was greater for women who were unmarried and had low SES ($p<0.001$), who also reported less impairment by alcohol or other drugs ($p=0.005$), fewer arrests ($p<0.001$), fewer convictions ($p<0.008$), and less jail time ($p<0.001$) than those in the control group. The effect of the program on the number of verified child abuse reports was especially strong for the 4- to 15-year period after the birth of the child (no data given).

^{***} Conducted in the United Kingdom, so safeguarding is not identical to reports to CPS.

^{†††} All participants were followed up for child welfare referrals from enrollment through January 2010. Average length of followup was 716 days ($SD=213$); children under 5 years of age.

Abbreviations: AOR=adjusted odds ratio; CAN=child abuse and neglect; CI=confidence interval; CPS=child protective services; DCF=(Massachusetts) Department of Children and Families G=group; KQ=key question; NA=not applicable; NR=not reported; NYS=New York state; OR=odds ratio; RR=relative risk; SD=standard deviation; vs.=versus.

Appendix D Table 12. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Barth, 1991 ¹³⁴ Poor Total N=191 caregiver randomized (N analyzed=191)	Reports of child abuse and removal from home obtained from county social service records	3 years (Range 2-5 years)	9 (9.6)	11 (10.3)	NA	NA	Authors reported no statistically significant differences in numbers of families reporting child abuse or neglect, child welfare, or court-ordered in-home or out-of-home services, or other health outcomes.
DePanfilis et al, 2005 ¹⁷² Poor Total N=154 families* randomized (N analyzed=111)	Indicated/substantiated reports of child abuse or neglect; assessed by computerized searches of official reports from birth until 6 months after the intervention ended [†]	6 months after intervention termination [‡]	4 (5.7)	NR	1 (1.4)	NR	Calculated RR, for G3 vs. G1: 0.284 (95% CI, 0.03 to 2.46) Reported Chi-square=1.823, p=0.177
DePanfilis et al, 2005 ¹⁷² Poor Total N=154 families* randomized (N analyzed=139)	All reports of child abuse or neglect; assessed by computerized searches of official reports from birth until 6 months after the intervention ended	6 months after intervention termination [‡]	5 (7.1)	NR	6 (8.7)	NR	Calculated RR, for G3 vs. G1: 1.22 (95% CI, 0.39 to 3.80) Reported Chi-square=0.115, p=0.735
Dubowitz et al, 2009 ¹⁴⁸ Poor Total N=729 parents randomized (N analyzed=558)	At least one report to child protective services, including substantiated and unsubstantiated reports but excluding “ruled-out” reports. Analysis controlled for the number of children.	42 months after study onset [§]	48 (19.2)	41 (13.3)	NA	NA	Calculated RR, 1.44 (95% CI, 0.98 to 2.11)

Appendix D Table 12. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)—Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Dubowitz et al, 2012 ¹⁴⁷ Poor Total N=1,119 families randomized (N analyzed=1,119)	State child protective services reports involving study families were obtained. Reports after June 2006 were considered during SEEK. Ruled-out reports (i.e., reports investigated, but with no supporting evidence of maltreatment) were excluded.	NR ^{II}	2 (0.4)	8 (1)	NA	NA	Calculated OR, 3.52 (95% CI, 0.75 to 16.51), reported p=0.69 ^{II}
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=643)	Number and percentage of families with all substantiated child protective service reports in the index child's first 3 years of life; verified by matching study sample with Department of Human Services (HDHS) records. Excluded substantiated CPS reports that were based on toxicology screens at the time of the child's birth.	3 years of age	11 (4.1)	12 (3.2)	NA	NA	No significant difference, p=0.56
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=643)	Number and percentage of families with all substantiated child protective service reports in the index child's third year of life; verified by matching study sample with HDHS records. Excluded substantiated CPS reports that were based on toxicology screens at the time of the child's birth.	3 years of age	2 (0.7)	4 (1.1)	NA	NA	NR

Appendix D Table 12. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)—Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=643)	Number and percentage of families with all substantiated child protective service reports in the index child's second year of life; verified by matching study sample with HDHS records. Excluded substantiated CPS reports that were based on toxicology screens at the time of the child's birth.	2 years of age	6 (2.2)	5 (1.3)	NA	NA	NR
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=643)	Number and percentage of families with all substantiated child protective service reports in the index child's first year of life; verified by matching study sample with HDHS records. Excluded substantiated CPS reports that were based on toxicology screens at the time of the child's birth.	1 year of age	3 (1.1)	3 (0.8)	NA	NA	NR

Appendix D Table 12. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=643)	Number and percentage of families with substantiated child protective service reports of abuse or neglect (excludes threats) in the index child's first 3 years of life; verified by matching study sample with HDHS records. Excluded substantiated CPS reports that were based on toxicology screens at the time of the child's birth.	3 years of age	4 (1.5)	4 (1.1)	NA	NA	No difference, p=0.55
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=643)	Number and percentage of families with substantiated child protective service reports of abuse or neglect (excludes threats) in the index child's third year of life; verified by matching study sample with HDHS records. Excluded substantiated CPS reports that were based on toxicology screens at the time of the child's birth.	3 years of age	0 (0)	1 (0.2)	NA	NA	NR

Appendix D Table 12. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=643)	Number and percentage of families with substantiated child protective service reports of abuse or neglect (excludes threats) in the index child's second year of life; verified by matching study sample with HDHS records. Excluded substantiated CPS reports that were based on toxicology screens at the time of the child's birth.	2 years of age	3 (1.1)	3 (0.8)	NA	NA	NR
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=643)	Number and percentage of families with substantiated child protective service reports of abuse or neglect (excludes threats) in the index child's first year of life; verified by matching study sample with HDHS records. Excluded substantiated CPS reports that were based on toxicology screens at the time of the child's birth.	1 years of age	1 (0.4)	0 (0)	NA	NA	NR
Gray et al, 1979 ¹⁵⁵ Poor Total N=100 mothers randomized (N analyzed=50)	Central Child Abuse Registry reports and indications of "abnormal parental practices" involving medical concern	17–35 months follow ing delivery [#]	1 (4)	2 (8)	NA	NA	Calculated RR, 2.0 (95% CI, 0.19 to 20.67) Chi-squared result p<0.46

Appendix D Table 12. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Child Protective Services Reports and Actions, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Reports, G1 No. (%)	Number of Incident Reports, G2 No. (%)	Number of Incident Reports, G3 No. (%)	Number of Incident Reports, G4 No. (%)	Effect Estimate or Other Outcome Measure
Gray et al, 1979 ¹³⁵ Poor Total N=100 mothers randomized (N analyzed=50)	Central Child Abuse Registry reports and indications of “abnormal parental practices” involving medical concern	17 months post delivery	1 (4)	1 (4)	NA	NA	Calculated RR, 1.0 (95% CI, 0.07 to 15.12) Chi-squared result p<0.99
Mejdoubi et al, 2015 ¹⁷⁶ Poor Total N=460 mothers randomized (N analyzed=332)	Child maltreatment during pregnancy and within first 3 years of life; based on reports made by professionals and citizens, such as family members, to CPS on suspected cases of child maltreatment including physical abuse, physical neglect, emotional/psychological abuse, emotional/psychological neglect, or sexual abuse.	3 years and 6 months after randomization; 3 years of age	31 (19)	18 (11)	NA	NA	RR 0.58 (95% CI, 0.28 to 0.96)**
Paradis et al, 2013 ¹⁷⁸ Poor Total N=497 families randomized (N analyzed=216)	Avoidance of CPS reports; based on independent review of CPS reports among participants completing the program “to date”	24 months from baseline ^{††}	NR (95)	NR (98)	NA	NA	p=NS ^{‡‡}
Wagner and Clayton, 1999 ¹⁷⁹ (PAT: Teen) Poor Total N=704 families randomized (N analyzed=363)	Child had opened case of child abuse or neglect; based on child abuse data from the CA Office of Child Abuse Prevention	NR ^{§§}	4 (2.4)	3 (1.3)	4 (2.7)	0 (0)	One-tailed T-values compared with G1: G2: -0.08, p=NS G3: 0.02, p=NS G4: -0.31, p<0.05

* 473 children

Appendix D Table 12. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)—Child Protective Services Reports and Actions, Categorical Outcomes

[†] Reports were coded prior to intervention, during intervention, or during 6 months following termination of intervention

[‡] Intervention lasted for 3 or 9 months. Average age of children was 8.3 years (range: newborn to 20 years).

[§] Infants 6–8 months age on average at baseline, age range 0–5 years.

[‡] From study start toward the end of the study (age of children not specified, but followup for up to 12 months after baseline for other measures, children 25–27 months at baseline).

[¶] Assessment of the difference between CPS reporting during SEEK was adjusted for pre-SEEK differences.

[#] Average age was 26.8 months post-delivery, during home evaluation.

^{**} Authors also reported on results from subgroup analyses stratified by gender or ethnicity of the child revealed no significant differences in CPS reports. No confounders were found significant.

^{††} Average age of children: 6 months (range 1–26 months).

[#] “On recent followup of initial program graduates, 97% of G2 graduates continued to avoid CPS indications after services ended.” No comparison data are given for G1, nor sample size for either group.

^{§§} Unclear, however, program lasted for 3 years and teens were pregnant or had an infant <6 months of age at recruitment.

Abbreviations: CA=California; CPS=child protective services; DCF=(Massachusetts) Department of Children and Families G=group; HDHS=Department of Human Services; KQ=key question; NA=not applicable; NR=not reported; NS=not statistically significant; NYS=New York state; OR=odds ratio; PAT=Parents as Teachers; RR=relative risk; SEEK=Safe Environment for Every Kid.

Appendix D Table 13. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in Main Analysis (KQ 1)– Child Protective Services Reports and Actions, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Frequency of Reports, G1 Mean (SD)	Frequency of Reports, G2 Mean (SD)	Frequency of Reports, G3 Mean (SD)	Frequency of Reports, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=1,060)	Frequency of substantiated CPS reports at Year 1 of age, defined as percentage of women with a substantiated report; obtained from review of CPS records of child abuse and neglect reports	1 year of age	0.07 (NR)	0.09 (NR)	NA	NA	p=NS*
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Frequency of substantiated CPS reports at Year 1 of age, defined as percentage of women with a substantiated report; obtained from review of CPS records of child abuse and neglect reports	2 years of age	0.06 (NR)	0.06 (NR)	NA	NA	p=NS*
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=1,173)	Frequency of CPS reports where the biological mother was confirmed to be the subject or the target child was confirmed to be the victim	Target child's 7 th birthday	0.55 [†] (NR)	0.54 [†] (NR)	NA	NA	Effect size: -0.01, p=NS

* No significant differences were found for prevalence or frequency of substantiated CPS reports. Outcomes reported for prevention subgroup (first-time mothers <19 years old randomly assigned at gestational age of ≤30 weeks), psychologically vulnerable subgroup (per index of CES-D and Mastery of Psychological Coping Resources Scale scores). Neither moderates differences between the HFNY and control groups in substantiated CPS reports.

[†] Outcome reported as least square mean.

Abbreviations: CES-D=Center for Epidemiologic Studies Depression Scale; CPS=child protective services; G=group; HFNY=Healthy Families New York; KQ=key question; NA=not applicable; NS=not statistically significant; NR=not reported; SD=standard deviation.

Appendix D Table 14. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Removal of Child From Home, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Separation Events, G1 No. (%)	Number of Separation Events, G2 No. (%)	Number of Separation Events, G3 No. (%)	Number of Separation Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Barlow et al, 2007 ¹⁰¹ Fair Total N=131 caregivers randomized (N analyzed=131)	Removal of child from home; ascertained by health visitors providing intervention; data source not reported	12 months*	NR (0)	NR (6)	NA	NA	p=NS
Brayden et al, 1993 ¹⁰⁹ Good Total N=314 mothers randomized (N analyzed=263)	Mother-child separation 36 months after live birth of study infants, including separation involving the child from the study pregnancy or the child's siblings if it occurred after the interview; based on review of public agency documents	36 months	1 (0.8)	5 (3.5)	NA	NA	RR, 4.77 (95% CI, 0.51, 38.61)
Brooten et al, 1986 ¹¹⁰ Fair Total N=79 infants randomized (N analyzed=79)	Number of infants placed in foster care; data source not reported	18 months [†]	2 (5)	0 (0)	NA	NA	Calculated RR, 0.21 (95% CI, 0.01 to 4.14)
Marcenko and Spence, 1994 ¹¹⁵ Fair Total N=225 mothers randomized (N analyzed=187)	Number of children formally placed out of the home through child protective services; based on mothers' self-reporting [‡]	Approximately 10.5 months	3 (4)	10 (9)	NA	NA	Calculated RR, 2.33 (95% CI, 0.66 to 8.20)
Marcenko and Spence, 1994 ¹¹⁵ Fair Total N=225 mothers randomized (N analyzed=187)	Number of children informally placed out of the home through family arrangements; based on mothers' self-reporting [‡]	6 months	4 (3.1) [§]	9 (9.9) [§]	NA	NA	Calculated RR, 1.63 (95% CI, 0.96 to 2.78, p=NS)

Appendix D Table 14. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Removal of Child From Home, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Separation Events, G1 No. (%)	Number of Separation Events, G2 No. (%)	Number of Separation Events, G3 No. (%)	Number of Separation Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
McIntosh et al, 2009 ¹⁰² Fair Total N=131 caregivers randomized (N analyzed=131)	Removal of the child from the home Removal status based on substantiation of child abuse and neglect per child protection register documentation	12 months	0 (0)	4 (6)	NA	NA	p=NS
Quinlivan and Streett, 2003 ¹¹⁶ Fair Total N=136 mothers randomized (N analyzed=135)	Placement of an infant (plus or minus mother) into the care of the state as a result of a court order placed by Family and Children's Services staff or as a result of the mother's imprisonment ^{¶¶}	6 months	6 (8.5)	1 (1.5)	NA	NA	RR, 0.30 (95% CI, 0.09 to 1.02, p=0.038) ^{¶¶}
Quinlivan and Streett, 2003 ¹¹⁶ Fair Total N=136 mothers randomized (N analyzed=135)	Placement of an infant (plus or minus mother) into the care of the state as a result of a court order placed by Family and Children's Services staff or as a result of the mother's imprisonment ^{¶¶}	12 months	8 (11.3)	2 (3.1)	NA	NA	RR, 0.28 (95% CI, 0.07 to 0.97, p=0.038) ^{¶¶}

* Assessed for time period between 6 months and 12 months of age.

† Subjects randomized were newborns, so age at followup is likely 18 months.

‡ At followup, the mothers were asked whether they had been involved with CPS and, if so, to describe the circumstances.

§ Number of events calculated based on N analyzed and percentage reported in Marcenko and Spence, 1994.¹¹⁵

‡ Before a child can be placed in foster care by the state, a substantiated risk of child abuse and neglect must be established.

¶ It is not clear from the original study publication whether the reported relative risk is for nonvoluntary foster care of the neonate or for the incidence of all adverse outcomes including neonatal death and nonaccidental injury.

Abbreviations: CI=confidence interval; CPS=child protective services; G=group; KQ=key question; N=number; NA=not applicable; No.=number; NR=not reported; NS=not sufficient; RR=relative risk.

Appendix D Table 15. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Removal of Child From Home, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Separation Events, G1 No. (%)	Number of Separation Events, G2 No. (%)	Number of Separation Events, G3 No. (%)	Number of Separation Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=643)	Placement in foster care. Type of separation (e.g., due to imprisonment, abandonment of the child, CPS intervention, rather than necessary separation to meet professional responsibilities or family obligations) determined by office-based evaluation staff who were unaware of the family intervention group assignment	3 years	NR (0.8)	NR (1.8)	NA	NA	NR
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=643)	Primary caregiver relinquished role at some time in the child's life. In most cases, mother relinquished care to family members.	3 years	NR (8.4)	NR (8.3)	NA	NA	NR
Gray et al, 1979 ¹³⁵ Poor Total N=100 mothers randomized (N analyzed=50)	Removal of the child from the home; measured during at-home follow up visits by the child not being in the biologic home and in foster care placement	On average 26.8 months*	3 (12)	5 (20)	NA	NA	Calculated RR, 1.67 (95% CI, 0.45 to 6.24), Chi-squared result<0.36
Norr et al, 2003 ¹⁷⁷ Poor Total N=588 families [†] (N analyzed=477)	Reported abuse or neglect, including all cases where the infant was placed in foster care arrangements or under protective service supervision by the Department of Children and Family Services by 12 months of age. Outcome determined by family reported foster care or involvement of the Department of Children and Family Services.	12 months	2 (0.91)	6 (2.33)	NA	NA	p=0.23

* Post-delivery. Range 17 to 35 months.

[†] N randomized was not reported. 588 women were recruited into the study. 447 participants remained in the study by the 12-month followup.

Abbreviations: CI=confidence interval; CPS=child protective services; G=group; KQ=key question; N=number; NA=not applicable; No.=number; NR=not reported; RR=relative risk.

Appendix D Table 16. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Other Measures of Abuse or Neglect, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Child Abuse or Neglect Events, G1 No. (%)	Number of Child Abuse or Neglect Events, G2 No. (%)	Number of Child Abuse or Neglect Events, G3 No. (%)	Number of Child Abuse or Neglect Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Brayden et al, 1993 ¹⁰⁹ Good Total N=314 mothers randomized (N analyzed=263)	Neglect reports including abandonment, leaving a child with an inappropriate caretaker, gross failure to seek medical care, failure to provide shelter or nutrition, or gross failure to provide for normal intellectual development; identified from review of public agency documents from the Tennessee Department of Human Services	36 months	5 (4.1) [*]	15 (10.6) [*]	NA	NA	Calculated RR, 2.79 (95% CI, 0.98 to 7.91) [†]
Brayden et al, 1993 ¹⁰⁹ Good Total N=314 mothers randomized (N analyzed=263)	Physically abusive actions including hitting with the hand or objects, biting, burning with objects or by immersion, twisting, shaking, throwing or pushing so as to cause a fall or hair pulling; identified from review of public agency documents from the Tennessee Department of Human Services for reports of physical and sexual abuse	36 months	8 (6.6) [*]	13 (9.2) [*]	NA	NA	Calculated RR, 1.4 (95% CI, 0.58 to 3.62)

* Number of child abuse or neglect events calculated based on percentages reported in Brayden et al, 1993.¹⁰⁹

† Closer hospital monitoring of HR intervention subjects (G2) was found to be a potential confounding variable. By removing three subjects from the analyses who had neglect reports made from the hospital, the percentage of neglect reports changed to 4.1% in G1 and 8.5% in G2; RR, 2.18, (95 % CI, 0.74 to 6.36, p=NS).

Abbreviations: CI=confidence interval; G=group; HR=high risk; KQ=key question; N=number; NA=not applicable; No.=number; NS=not significant; RR=relative risk.

Appendix D Table 17. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in Main Analysis (KQ 1)– Other Measures of Abuse or Neglect, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Safety Score, G1 Mean (SD)	Mean Safety Score, G2 Mean (SD)	Mean Safety Score, G3 Mean (SD)	Mean Safety Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Bugental and Schw artz, 2009 ¹⁰³ Fair Total N=147 caretakers randomized (N analyzed=94)	Neglect of child safety (infants); based on Framingham Safety Survey about household hazards (e.g., exposed electrical outlets, crib sides left down, presence of window s lacking screens)	1 year	1.68 (NR)	1.72 (NR)	NA	NA	F(1,96)=4.94; p=0.03*

* Multivariate test of significance with mean injury score and neglect of child safety yielded significant effect: F(2,95)=3.94; p=0.01; $\eta^2=0.04$.

Abbreviations: G=group; KQ=key question; N=number; NA=not applicable; NR=not reported; SD=standard deviation.

Appendix D Table 18. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Injuries With a High Specificity for Abuse, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Injuries, G1 No. (%)	Number of Incident Injuries, G2 No. (%)	Number of Incident Injuries, G3 No. (%)	Number of Incident Injuries, G4 No. (%)	Effect Estimate or Other Outcome Measure
Quinlivan and Streett, 2003 ¹¹⁶ Fair Total N=136 mothers randomized (N analyzed=132)	Severe nonaccidental injury: hospital admission as a result of an injury that was referred for independent investigation by the Family and Children's Services staff and concluded to have arisen as a result of a nonaccidental injury to the neonate	6 months	1 (1.5)	0 (0)	NA	NA	Calculated RR, 0.37 (95% CI, 0.015 to 8.91)

Abbreviations: CI=confidence interval; G=group; KQ=key question; N=number; NA=not applicable; RR=relative risk.

Appendix D Table 19. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in Sensitivity Analysis (KQ 1)–Injuries With a High Specificity for Abuse, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Injuries, G1 No. (%)	Number of Incident Injuries, G2 No. (%)	Number of Incident Injuries, G3 No. (%)	Number of Incident Injuries, G4 No. (%)	Effect Estimate or Other Outcome Measure
Hardy et al, 1989 ¹⁷³ Poor Total N=290 infants randomized (N analyzed=263)	Sustained trauma, defined as a fall or other injury to the head of sufficient severity to lead to a C&Y clinic visit or emergency department visit. In general, outcome is determined by 1) computerized record system with summaries of visits to the C&Y clinic, the pediatric ED, and other JHU clinics, and brief descriptions of inpatient hospital care, 2) review of medical records, 3) data collected by home visitor on final visit, and 4) telephone interview.	G1: 22.9 months G2: 23.4 months	15 (11.4)	8 (6.1)	NA	NA	Calculated RR, 0.54 (95% CI, 0.24 to 1.22)

Abbreviations: C&Y=children and youth; CI=confidence interval; ED=emergency department; G=group; JHU=Johns Hopkins University; KQ=key question; N=number; NA=not applicable; No.=number; RR=relative risk.

**Appendix D Table 20. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–
Emergency Department Visits, Categorical Outcomes**

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	ED Visits, G1 No. (%)	ED Visits, G2 No. (%)	ED Visits, G3 No. (%)	ED Visits, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 2007 ⁸⁷ Caldera et al, 2007 ⁸⁸ Good Total N=364 families randomized (N analyzed=268)	Child seen in emergency department; measure derived from medical records*	2 years	NR (78)	NR (81)	NA	NA	AOR, 1.23 (95% CI, 0.74 to 2.05, p=0.42)
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ Fair Total N=443 families randomized (N analyzed=391)	Proportion of children seen in hospital for accident/injury or accidental poisoning (0–36 months); based on hospital record data on enrolled child attendances supplemented interview data	36 months	NR (26.3)	NR (17.5)	NA	NA	OR, 0.59 (95% CI, 0.36 to 0.98) for G2 vs. G1 Cohen's d 0.22 (95% CI, 0.02 to 0.41) G2 vs. G1 P<0.05
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=75)	ER use; based on hospital and project charts as well as parent report	6 months	3 (17)	3 (18)	3 (15)	1 (5)	Calculated RR, for G2 vs. G1: 1.06 (95% CI, 0.25 to 4.54) Calculated RR, for G3 vs. G1: 0.90 (95% CI, 0.21 to 3.91) Calculated RR, for G4 vs. G1: 0.30 (95% CI, 0.03 to 2.63) Reported p=0.637
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=68)	ER use; based on hospital and project charts as well as parent report	12 months	2 (11)	4 (27)	5 (31)	0 (0)	Calculated RR, for G2 vs. G1: 2.40 (95% CI, 0.51 to 11.34) Calculated RR, for G3 vs. G1: 2.81 (95% CI, 0.63 to 12.54) Calculated RR, for G4 vs. G1: 0.19 (95% CI, 0.10 to 3.71) Reported p=0.048 [†]
Guyer et al, 2003 ¹¹² Fair Total N=2,235 families [‡] (N analyzed=1,593)	Used emergency department in past year for injury	30 to 33 months	NR (9.1)	NR (9.3)	NA	NA	AOR: 0.94 (95% CI, 0.65 to 1.34, p=NS)

**Appendix D Table 20. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–
Emergency Department Visits, Categorical Outcomes**

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	ED Visits, G1 No. (%)	ED Visits, G2 No. (%)	ED Visits, G3 No. (%)	ED Visits, G4 No. (%)	Effect Estimate or Other Outcome Measure
Guyer et al, 2003 ¹¹² Fair Total N=2,235 families [†] (N analyzed=1,593)	Used emergency department in past year	30 to 33 months	NR (NR)	NR (NR)	NA	NA	AOR: 1.21 (95% CI, 0.96 to 1.52, p=NS)
Minkovitz et al, 2007 ¹¹³ Fair Total N=2,235 families [†] (N analyzed=1,308)	Used emergency department in past year for injury	5 to 5.5 years	61 (10.0)	60 (9.2)	NA	NA	AOR: 0.96 (95% CI, 0.73 to 1.27, p=0.61)
Olds et al, 1994 ⁹⁶ Fair Total N=400 families randomized (N analyzed=209)	Total ED visits from 25 to 50 months of life; determined by review of pediatric and hospital records for the period spanning 25 to 50 months of age	4 years	NR (NR)	NR (NR)	NR (NR)	NA	p=0.0008 ^s Treatment differences detected in subgroup mothers (p<0.05 G3 vs. G1).
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=1,486 at 6 months)	Visits to the ED through 6 months of age for injuries and ingestions	6 months	21 (2.8)	30 (4.1)	NA	NA	Adjusted OR: 1.52 (95% CI, 0.86 to 2.70), p=0.15
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=1,465 at 24 months)	Visits to the ED through 24 months of age for injuries and ingestions	24 months	207 (27.8)	222 (30.8)	NA	NA	Adjusted OR: 1.16 (95% CI, 0.92 to 1.46), p= 0.20

Appendix D Table 20. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Emergency Department Visits, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	ED Visits, G1 No. (%)	ED Visits, G2 No. (%)	ED Visits, G3 No. (%)	ED Visits, G4 No. (%)	Effect Estimate or Other Outcome Measure
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=1,478 at 24 months)	Visits to the ED or hospital admissions through 24 months of age	24 months	577 (76.6)	587 (81.0)	NA	NA	Unadjusted risk difference= 4.3% (97.5% CI, 0.2% to 8.5%); adjusted OR=1.32 (97.5% CI, 0.99 to 1.76); p=0.03
Wiggins et al, 2004 ¹¹⁷ , Wiggins et al, 2005 ¹¹⁸ Fair Total N=731 mother-infant dyads (N=621 analyzed)	Child had visits to accident and emergency department; based on parent self-report	12 months	83 (27)	46 (29)	40 (27)	NA	RR 1.09 (95% CI, 0.80 to 1.48) G2 vs. G1 RR 1.00 (95% CI, 0.73 to 1.38) G3 vs. G1
Wiggins et al, 2004 ¹¹⁷ , Wiggins et al, 2005 ¹¹⁸ Fair Total N=731 mother-infant dyads (N=597 analyzed)	Child had visits to accident and ED; based on parent self-report	18 months	56 (19)	28 (19)	35 (22)	NA	RR, 1.03 (95% CI, 0.68 to 1.54) G2 vs. G1 RR, 1.18 (95% CI, 0.81 to 1.72) G3 vs. G1

* Excludes three families with a fetal or infant death and families known to be out of town for >6 months in Year 2.

† Although the reported p value suggests statistical significance, the calculated RRs have confidence intervals spanning the null.

‡ The RCT-only portion of the study originally randomized 2,584 children at birth before enrollment or check for eligibility. Among them, 2,235 children were enrolled into the study.

§ Nurse-visited children in G3 made 35% fewer visits to the ED than control (G1).

Abbreviations: AOR=adjusted odds ratio; CI=confidence interval; ED=emergency department; ER=emergency room; G=group; KQ=key question; N=number; NA=not applicable; No.=number; NR=not reported; NS=not sufficient; OR=odds ratio; RCT=randomized, controlled trial; RR=relative risk.

Appendix D Table 21. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Emergency Department Visits, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	ED Visits, G1 No. (%)	ED Visits, G2 No. (%)	ED Visits, G3 No. (%)	ED Visits, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 1999 ¹⁴⁵ Poor Total N=730 mothers randomized (N analyzed=564)	Ever used ED in first year of life based on maternal report	1 year	NR (44)	NR (40)	NA	NA	Calculated RR: 0.91, 95% CI, 0.75 to 1.11 Reported p=0.27
Duggan et al, 1999 ¹⁴⁵ Poor Total N=730 mothers randomized (N analyzed=534)	Ever used ED for any reason in first 2 years of life; based on maternal reports because review of pediatric medical records and claims files was still in progress when study was published	2 years	NR (60)	NR (58)	NA	NA	Calculated RR: 0.97, 95% CI, 0.84 to 1.12 Reported p=0.69
Koniak-Griffin et al, 2002 ¹⁷¹ Poor Total N=144 caregivers randomized (N analyzed=101)	Number of children with ED visits; based on maternal reports, verified with medical records when possible; medical record used in cases of discrepancy	24 months	40 (88.9)	36 (64.3)	NA	NA	Calculated RR: 0.72, 95% CI, 0.58 to 0.90 p=0.004
Paradis et al, 2013 ¹⁷⁸ Poor Total N=497 families randomized (N analyzed=216)	Absence of ED visits for injury; assessed via EMR among participants completing the program “to date”	24 months	69 (71)	75 (64)	NA	NA	Calculated RR: 1.28, 95% CI, 0.88 to 1.89 Reported p=NS

Appendix D Table 21. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Emergency Department Visits, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	ED Visits, G1 No. (%)	ED Visits, G2 No. (%)	ED Visits, G3 No. (%)	ED Visits, G4 No. (%)	Effect Estimate or Other Outcome Measure
Wagner and Clayton, 1999 ¹⁷⁹ (Salinas Valley PAT)* Poor Total N=497 families randomized (N analyzed=363)	Child had emergency room treatment in past year; based on annual interview with parents	3 years	NR (24.5)	NR (20.3)	NA	NA	Calculated RR: 0.83, 95% CI, 0.56 to 1.22 Reported T=-0.12, p=NS

* ED visits not reported for PAT: Teen.

Abbreviations: CI=confidence interval; ED=emergency department; EMR=electronic medical record; G=group; KQ=key question; N=number; NA=not applicable; No.=number; NR=not reported; NS=not sufficient; PAT=Parents as Teachers; RR=relative risk.

Appendix D Table 22. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Emergency Department Visits, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Number of Episodes in G1 Mean (SD)	Mean Number of Episodes in G2 Mean (SD)	Mean Number of Episodes in G3 Mean (SD)	Mean Number of Episodes in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=268)	Child seen in ED; measure derived from medical records and limited to families with complete medical record data*	2 years	4.09 (NR)	3.13 (NR)	NA	NA	Effect size=0.24, p=0.31
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=75)	Number of ED visits per infant between 0 and 6 months corrected chronological age; based on hospital charts and parent report	6 months	NR (NR) [†]	NR (NR) [†]	NR (NR) [†]	NR (NR) [†]	Authors reported nonstatistically significant between group differences
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=68)	Number of ED visits per infant between 6 and 12 months corrected chronological age; based on hospital charts and parent report	12 months	NR (NR) [‡]	NR (NR) [‡]	NR (NR) [‡]	NR (NR) [‡]	X ² (3, n=68)=7.91, p=0.05
Kitzman et al, 1997 ⁹³ Fair Total N=743 mothers [§] (N analyzed=697)	Adjusted incidence of ED visits for injuries/ ingestions; summary variable created using medical records to count the total number of encounters	24 months	NR	NR (34)	NR	NR (33)	Log-incidence difference for G4 vs. G2, 0.02 (95% CI, -0.27 to 0.31, p=NS)
Larson et al, 1980 ¹⁰⁷ Fair Total N=115 mother-infant dyads randomized (N analyzed=NR)	Cumulative ED visit rate per child; determined by number of ED visits in each group divided by the mean number of children in the study over the four assessment periods	18 months	1.05 (NR)	1.14 (NR)	NA	NA	p=NS for comparisons that include nonrandomized arm

**Appendix D Table 22. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–
Emergency Department Visits, Continuous Outcomes**

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Number of Episodes in G1 Mean (SD)	Mean Number of Episodes in G2 Mean (SD)	Mean Number of Episodes in G3 Mean (SD)	Mean Number of Episodes in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
McIntosh et al, 2009 ¹⁰² Fair Total N=131 caregivers randomized (N analyzed=NR)	Mean number of A&E visits	12 months	0.83 (NR)	0.43 (NR)	NA	NA	Unclear [†]
Olds et al, 1986 ⁹⁵ Fair Total N=400 families randomized (N analyzed=292)	Mean number of ED visits; determined by review of records for the presence of verified cases of abuse or neglect from the department of social services, ED visits, and other medical visits	1 year	1.02 (NR)	1.12 (NR)	0.74 (NR)	NA	p=0.04 for both G2 vs. G1, and G3 vs. G1 [#]
Olds et al, 1986 ⁹⁵ Fair Total N=400 families randomized (N analyzed=292)	Mean number of ED visits for accidents and poisonings; determined by review of records for the presence of verified cases of abuse or neglect from the department of social services, ED visits, and other medical visits	1 year	0.06 (NR)	0.12 (NR)	0.12 (NR)	NA	p≥0.05 for G3 vs. G1 ^{**}
Olds et al, 1986 ⁹⁵ Fair Total N=400 families randomized (N analyzed=260)	Mean number of ED visits; determined by review of records for the presence of verified cases of abuse or neglect from the department of social services, ED visits, and other medical visits.	2 years	1.09 (NR)	1.04 (NR)	0.74 (NR)	NA	p=0.01 for G3 vs. G1 ^{**}

Appendix D Table 22. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Emergency Department Visits, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Number of Episodes in G1 Mean (SD)	Mean Number of Episodes in G2 Mean (SD)	Mean Number of Episodes in G3 Mean (SD)	Mean Number of Episodes in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Olds et al, 1986 ⁹⁵ Fair Total N=400 families randomized (N analyzed=260)	Mean number of ED visits for accidents and poisonings; determined by review of records for the presence of verified cases of abuse or neglect from the department of social services, ED visits, and other medical visits	2 years	0.34 (NR)	0.32 (NR)	0.15 (NR)	NA	p=0.03 for G3 vs. G1**
Olds et al, 1994 ⁹⁶ Fair Total N=400 families randomized (N analyzed=209)	ED visits for injuries/ingestions from 25 to 50 months of life; determined by review of pediatric and hospital records for the period spanning 25 to 50 months of age	4 years	NR (NR)	NR (NR)	NR (NR)	NA	No program effect (p>0.05). No difference (p>0.05) seen in high-risk subgroup.
Siegel et al, 1980 ⁸⁶ Fair Total N=321 mother-child dyads randomized (N analyzed=161)	Health care utilization, including ED visits; based on medical records and maternal report. Children were considered to have received services if so indicated by either source. ^{††}	12 months	30	11	13	34	p=NS
Wiggins et al, 2004 ¹¹⁷ Fair Total N=731 mother-infant dyads (N=623 analyzed)	Mean number of A&E visits in previous 6 months; based on parent self-report	12 months	0.36 (0.70)	0.38 (0.71)	0.35 (0.67)	NA	Mean difference 0.03 (95% CI, -0.10 to 0.16) for G2 vs. G1 Mean difference 0.01 (95% CI, -0.14 to 0.12) for G3 vs. G1

Appendix D Table 22. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Emergency Department Visits, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Number of Episodes in G1 Mean (SD)	Mean Number of Episodes in G2 Mean (SD)	Mean Number of Episodes in G3 Mean (SD)	Mean Number of Episodes in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Wiggins et al, 2004 ¹¹⁷ Fair Total N=731 mother-infant dyads (N=598 analyzed)	Mean number of A&E visits in previous 6 months; based on parent self-report	18 months	0.23 (0.53)	0.22 (0.48)	0.29 (0.61)	NA	Mean difference -0.01 (95% CI, -0.11 to 0.10) for G2 vs. G1 Mean difference 0.06 (95% CI, -0.05 to 0.18) for G3 vs. G1

* Excludes three families with a fetal or infant death and families known to be out of town for >6 months in Year 2.

† Between discharge and the time infants were 6 months CCA (age corrected for gestation), 15 infants in the control group had no ED visits and 3 infants made one visit to the ED. Data were missing for two infants in the control group. In the HH group, 14 infants had no ED visits, 1 had one visit, 1 had two visits, and 1 had six visits. Data were missing for four infants in the HH group. In the HV group, 17 infants had no ED visits, 2 had one visit, and 1 had two visits. In the HH/HV group, 19 infants had no ED visits and 1 child made one visit to the ED.

‡ Between 6 and 12 months CCA (age corrected for gestation), two infants in the control group visited the ED for acute illness. Four infants in the HH group visited the ED (3 with 1 visit and 1 with 4 visits; all visits were for acute illness), five infants in the HV group visited the ED (2 for illness, 1 for injury, 1 for unspecified reason, and 1 with 3 visits for acute illness). Nineteen infants in the HH/HV group had no ED visits. Overall mean number of ED visits was 0.25, range 0 to 4, SD=0.68.

§ Of the 1,139 mothers randomized, 743 were enrolled for followup.

‡ This is for G2 in the original study design.

¶ Authors reported nonsignificant p values. However, it is not clear whether the reported p values were for continuous A&E visit outcomes or for cost.

p <0.05 for high-risk subgroup. Significant differences were found due to reduction in visits for upper respiratory tract infections. ED visits for accidents and poisoning in first year of life also reported; no difference found in all participants included in the analysis or in the high-risk subgroup.

** No difference (p>0.05) seen in high-risk subgroup.

†† Siegel et al⁸⁶ randomized neonates with no health problems to four arms (control, early and extended contact, home visits, early and extended contact plus home visits).

Neonates with delivery complications were in an observation nursery for 24 hours so did not receive early contact. They were subsequently randomized to extended contact and no visit. The analysis above combines the Ns for the control group and for the combination interventions as did the previous reports. These numbers are total events (means and SDs are not reported). The study reports no differences for six arms but does not provide standard deviations or other measures of dispersion to calculate individual effect sizes by arms.

Abbreviations: A&E=accident & emergency department; CCA=gestation-corrected chronological age ; CI=confidence interval; ED=emergency department; G=group; HH=health home; HV=home visit; KQ=key question; N=number; NA=not applicable; NR=not reported; NS=not sufficient; SD=standard deviation.

Appendix D Table 23. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Emergency Department Visits, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Number of Episodes in G1 Mean (SD)	Mean Number of Episodes in G2 Mean (SD)	Mean Number of Episodes in G3 Mean (SD)	Mean Number of Episodes in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Barth, 1991 ¹³⁴ Poor Total N=191 caregiver randomized (N analyzed=NR)	Number of times new born was taken to emergency medical service; based on mother self-report	3 years (Range 2–5 years)	1.44 (0.50)	1.44 (0.50)	NA	NA	Calculated mean difference 0.0 (95% CI, -0.142 to 0.142)
Hardy et al, 1989 ¹⁷³ Poor Total N=290 infants randomized (N analyzed=263)	Mean number of ED visits at follow up; determined by (1) computerized record system with summaries of visits to the C&Y clinic, the pediatric ED, and other JHU clinics, and brief descriptions of inpatient hospital care, (2) review of medical records, (3) data collected by home visitor on final visit, and (4) telephone interview	10–30 months after birth	4.3 (NR)	3.0 (NR)	NA	NA	NR
Koniak-Griffin et al, 2002 ¹⁷⁵ Poor Total N=144 caregivers randomized (N analyzed=102)	Total number of ED visits; based on maternal reports, verified with medical records when possible; medical records used in cases of discrepancy	12 months	80 (NA)	90 (NA)	NA	NA	p=NS

Appendix D Table 23. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Emergency Department Visits, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Number of Episodes in G1 Mean (SD)	Mean Number of Episodes in G2 Mean (SD)	Mean Number of Episodes in G3 Mean (SD)	Mean Number of Episodes in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Koniak-Griffin et al, 2003 ¹⁷¹ Poor Total N=144 caregivers randomized (N analyzed=101)	Total number of episodes of ED visits; based on maternal reports, verified with medical records when possible; medical records used in cases of discrepancy	24 months	118 (NR)	149 (NR)	NA	NA	NR
Paradis et al, 2013 ¹⁷⁸ Poor Total N=497 families randomized (N analyzed=216)	Absence of ED visits for injury; assessed via EMR among participants completing the program “to date.”	24 months	2.7 (3.6)	2.6 (2.4)	NA	NA	Mean difference -0.01 (95% CI, -0.90 to 0.70) Reported p=NS

Abbreviations: CI=confidence interval; C&Y=children and youth; ED=emergency department; EMR=electronic medical record; ER=emergency room; G=group; JHU=Johns Hopkins University; KQ=key question; N=number; NA=not applicable; NR=not reported; NS=not sufficient; SD=standard deviation.

Appendix D Table 24. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Hospitalization, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Hospitalization Events, G1 No. (%)	Hospitalization Events, G2 No. (%)	Hospitalization Events, G3 No. (%)	Hospitalization Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰² Fair Total N=131 caregivers randomized (N analyzed=131)	Admissions to hospital (maternal report): Proportion of admissions of baby to hospital since birth; ascertained by health visitors	6 months*	NR (14.3)	NR (8.1)	NA	NA	RR, 1.38 (95% CI, 0.68 to 2.8)
Brooten et al, 1986 ¹¹⁰ Fair Total N=79 infants randomized (N analyzed=79)	Hospitalizations were measured as the number of infants rehospitalized (cause of rehospitalization was not specified) after discharge from the hospital	14 days	5 (12.5)	4 (10.3)	NA	NA	Calculated RR, 0.82 (95% CI, 0.24 to 2.83)
Brooten et al, 1986 ¹¹⁰ Fair Total N=79 infants randomized (N analyzed=79)	Hospitalizations were measured as the number of infants rehospitalized (cause of rehospitalization was not specified) after discharge from the hospital	18 months [†]	10 (25)	10 (25.6)	NA	NA	Calculated RR, 1.03 (95% CI, 0.48 to 2.19)
Caldera et al, 2007 ⁸⁸ Good Total N=364 families randomized (N analyzed=268)	Proportion of children with no hospitalizations during the study period	2 years	NR (58) [‡]	N (63) [‡]	NA	NA	AOR, 1.20 (95% CI, 0.58 to 2.48, p=0.63)

Appendix D Table 24. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Hospitalization, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Hospitalization Events, G1 No. (%)	Hospitalization Events, G2 No. (%)	Hospitalization Events, G3 No. (%)	Hospitalization Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Fergusson et al, 2005 ¹⁰⁵ , Fergusson et al, 2013 ¹⁰⁶ Fair Total N=443 families randomized (N analyzed=391)	Admitted to hospital for child abuse or neglect	36 months	5 (2.4) [§]	2 (1.1) [§]	NA	NA	p=0.31 for intervention group vs. control group
Fergusson et al, 2013 ¹⁰⁶ Fair Total N=443 families randomized (N analyzed=370)	Admitted to hospital for unintentional injury	9 years	NR (42.1)	NR (28.3)	NA	NA	d=0.29 (95% CI, 0.09 to 0.49), p<0.05
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=76)	Number of hospitalizations that are less than 24 hours in duration; based on hospital and project charts as well as parent report	6 months	2 (11)	3 (18)	1 (5)	0 (0)	p=0.226
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=70)	Number of hospitalizations that are less than 24 hours in duration; based on hospital and project charts as well as parent report	12 months	1 (6)	3 (15)	2 (14)	0 (0)	p=0.197
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=77)	Number of hospitalizations that are more than 24 hours in duration; based on hospital and project charts as well as parent report	6 months	5 (26)	9 (50)	5 (25)	1 (5)	p=0.017

Appendix D Table 24. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Hospitalization, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Hospitalization Events, G1 No. (%)	Hospitalization Events, G2 No. (%)	Hospitalization Events, G3 No. (%)	Hospitalization Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=68)	Number of hospitalizations that are more than 24 hours in duration; based on hospital and project charts as well as parent report	12 months	0 (0)	4 (27)	4 (25)	2 (11)	p=0.085
Minkovitz et al, 2007 ¹¹³ Fair Total N=2,235 families ^{II} (N analyzed=1,308)	Hospital visits in the past year	5 to 5.5 years	21 (4)	21 (3)	NA	NA	AOR, 0.96 (95% CI, 0.51 to 1.79, p=0.81)
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=1,487 at 6 months)	Hospital admissions through 6 months of age for injuries and ingestions	6 months	18 (2.4)	14 (1.9)	NA	NA	Adjusted OR: 0.79 (95% CI, 0.39 to 1.60), p=0.51
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=1,467 at 24 months)	Hospital admissions through 24 months of age for injuries and ingestions	24 months	49 (6.6)	35 (4.8)	NA	NA	Adjusted OR: 0.72 (95% CI, 0.46 to 1.12), p=0.15
Wiggins et al, 2004 ¹¹⁷ Fair Total N=731 mother-infant dyads (N=652 analyzed)	Overnight hospital stays in the previous 6 months	12 months	19 (6)	13 (8)	13 (8)	NA	RR, 1.36 (95% CI, 0.69 to 2.68) G2 vs. G1 RR, 1.38 (95% CI, 0.70 to 2.72) G3 vs. G1

Appendix D Table 24. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Hospitalization, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Hospitalization Events, G1 No. (%)	Hospitalization Events, G2 No. (%)	Hospitalization Events, G3 No. (%)	Hospitalization Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Wiggins et al, 2004 ¹¹⁷ Fair Total N=731 mother-infant dyads (N=597 analyzed)	Overnight hospital stays in the previous 6 months	18 months	13 (4)	7 (5)	6 (4)	NA	RR, 1.11 (95% CI, 0.45 to 2.70) for G2 vs. G1 RR, 0.87 (95% CI, 0.34 to 2.25) for G3 vs. G1

* Assessed for time period between birth and 6 months of child's age.

† Subjects randomized were newborns, so age at followup is likely 18 months.

‡ Number of events differs from those reported in Duggan et al, 2007⁸⁷ because the latter was focused on hospitalizations for ambulatory-care sensitive conditions.

§ Percentage calculated based on number of events reported and N analyzed.

¶ The RCT-only portion of the study originally randomized 2,584 children at birth before enrollment or check for eligibility. Among them, 2,235 children were enrolled into the study.

Abbreviations: AOR=adjusted odds ratio; CI=confidence interval; G=group; KQ=key question; N=number; NA=not applicable; No.=number; NR=not reported; RCT=randomized, controlled trial; RR=relative risk.

Appendix D Table 25. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Hospitalization, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Hospitalization Events, G1 No. (%)	Hospitalization Events, G2 No. (%)	Hospitalization Events, G3 No. (%)	Hospitalization Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 1999 ¹⁴⁵ Poor Total N=730 mothers randomized (N analyzed=564)	Ever hospitalized for any reason in first year of life; based on maternal reports because review of pediatric medical records and claims files was still in progress when study was published	1 year	NR (18)	NR (17)	NA	NA	p=0.69
Duggan et al, 1999 ¹⁴⁵ Poor Total N=730 mothers randomized (N analyzed=534)	Ever hospitalized for any reason in first 2 years of life; based on maternal reports because review of pediatric medical records and claims files was still in progress when study was published	2 years	NR (22)	NR (19)	NA	NA	p=0.44
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=573)	Trauma admissions among patients with complete hospitalization data; measured by maternal interview and review of the child's primary care records. Hospitalizations for trauma might indicate inadequate safety precautions or physical abuse and/or hospitalizations that might have been avoided with adequate primary care that might indicate medical neglect.	3 years	NR (1.7)	NR (1.5)	NA	NA	p=NS
Hardy et al, 1989 ¹⁷³ Poor Total N=290 infants randomized (N analyzed=263)	Children with hospital admission; determined by (1) computerized record system with summaries of visits to the C&Y clinic, the pediatric ED, and other JHU clinics, and brief descriptions of inpatient hospital care, (2) review of medical records, (3) data collected by home visitor on final visit, and 4) telephone interview	G1: 22.9 months G2: 23.4 months	20 (15.2)	8 (6.1)	NA	NA	p<0.01

Appendix D Table 25. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Hospitalization, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Hospitalization Events, G1 No. (%)	Hospitalization Events, G2 No. (%)	Hospitalization Events, G3 No. (%)	Hospitalization Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Infante-Rivard et al, 1989 ¹⁷⁴ Poor Total N=47 mother-child dyads randomized (N analyzed=47)	Percentage of children hospitalized during the previous year; obtained from questions asked during follow up visit	15 months	NR (19.2)	NR (14.3)	NA	NA	p=NS
Kitzman et al, 1997 ⁹³ Fair Total N=743 mothers* (N analyzed=743)	Number of children hospitalized for injuries or ingestions; based on medical records review	2 years of age	NA	3 (1.3) [†]	NA	13 (2.5) [†]	NR
Koniak-Griffin et al, 2002 ¹⁷⁵ Poor Total N=144 caregivers randomized (N analyzed=102)	Number of children hospitalized; based on maternal reports and verified with medical records when possible; medical record used in cases of discrepancy	12 months	13 (28)	12 (22)	NA	NA	p=NS
Koniak-Griffin et al, 2003 ¹⁷¹ Poor Total N=144 randomized (N analyzed=101)	Number of children hospitalized; based on maternal reports and verified with medical records when possible; medical record used in cases of discrepancy	24 months	16 (35.6)	12 (21.4)	NA	NA	p=NS

* Of the 1,139 mothers randomized, 743 were enrolled for followup.

[†] Calculated based on author-reported diagnoses for hospitalizations in which injuries and ingestions were detected.

Abbreviations: C&Y=children and youth; ED=emergency department; G=group; JHU=Johns Hopkins University; KQ=key question; N=number; NA=not applicable; NR=not reported; NS=not sufficient.

Appendix D Table 26. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Hospitalization Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Number of Episodes in G1 Mean (SD)	Mean Number of Episodes in G2 Mean (SD)	Mean Number of Episodes in G3 Mean (SD)	Mean Number of Episodes in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰² Fair Total N=131 caregivers randomized (N analyzed=131)	Median days stayed in hospital; ascertained by health visitors	6 months*	4 (1.1)	3 (8.7)	NA	NA	p=NS
Finello et al, 1998 ¹¹¹ Fair Total N=81 infants randomized (N analyzed=77)	Mean number of hospitalizations; based on hospital and project charts as well as parent report	0–6 months	NR (NR) [†]	NR (NR) [†]	NA	NA	NR
Kitzman et al, 1997 ⁹³ Fair Total N=743 mothers randomized (N analyzed=NR)	Incidence of hospital admissions for injuries or ingestions (log-incidence), adjusted for maternal psychological resources, discretionary household income, and poverty level of census tract	24 months	NR	0.03 (-3.63)	NR	0.01 (-4.31)	Log incidence difference for G4 vs. G2=0.68 (95% CI, -0.66 to 2.02)
Olds et al, 1994 ⁹⁶ Fair Total N=400 families randomized (N analyzed=209)	Adjusted [‡] means (log incidence) of number of hospital admissions; determined by review of pediatric and hospital records for the period spanning 25 to 50 months of age	4 years	0.11(-5.40)	0.11 (-2.27)	0.14 (-5.30)	NA	Log incidence difference=0.10 (95%CI, -0.17 to 0.17), p>0.05 for G3 vs. G1 [§]

Appendix D Table 26. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Hospitalization Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Number of Episodes in G1 Mean (SD)	Mean Number of Episodes in G2 Mean (SD)	Mean Number of Episodes in G3 Mean (SD)	Mean Number of Episodes in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Olds et al, 1994 ⁹⁶ Fair Total N=400 families randomized (N analyzed=209)	Adjusted [‡] means (log incidence) of number of days hospitalized; determined by review of pediatric and hospital records for the period spanning 25 to 50 months of age	4 years	0.31 (-1.46)	0.43 (-1.22)	0.49 (-0.80)	NA	Log incidence difference=-0.66 (95%CI, -1.21 to -0.13), p<0.05 for G3 vs. G1 [§]
Siegel et al, 1980 ⁸⁶ Fair Total N=321 mother-child dyads randomized (N analyzed=NR)	Total number of hospitalizations; children were considered to have received services if so indicated by either medical records or maternal report	12 months	10	4	1	8	p=NS
Wiggins et al, 2004 ¹¹⁷ Fair Total N=731 mother-infant dyads (N=652 analyzed)	Mean number of inpatient episodes in previous 6 months; based on parent self-report	12 months	0.07 (0.31)	0.08 (0.35)	0.06 (0.24)	NA	Mean difference -0.01 (95% CI, -0.05 to 0.08) for G2 vs. G1 Mean difference 0.01 (95% CI, -0.06 to 0.04) for G3 vs. G1
Wiggins et al, 2004 ¹¹⁷ Fair Total N=731 mother-infant dyads (N=652 analyzed)	Mean number of inpatient days; based on parent self-report	12 months	0.73 (10.1)	0.18 (1.02)	0.25 (1.35)	NA	Mean difference -0.55 (95% CI, -2.18 to 0.13) for G2 vs. G1 Mean difference -0.48 (95% CI, -1.95 to 0.25) for G3 vs. G1
Wiggins et al, 2004 ¹¹⁷ Fair Total N=731 mother-infant dyads (N=596 analyzed)	Mean number of inpatient episodes in previous 6 months; based on parent self-report	18 months	0.04 (0.21)	0.06 (0.31)	0.05 (0.24)	NA	Mean difference 0.01 (95% CI, -0.04 to 0.06) for G2 vs. G1 Mean difference 0.001 (95% CI, -0.04 to 0.04) for G3 vs. G1

Appendix D Table 26. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Hospitalization Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Number of Episodes in G1 Mean (SD)	Mean Number of Episodes in G2 Mean (SD)	Mean Number of Episodes in G3 Mean (SD)	Mean Number of Episodes in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Wiggins et al, 2004 ¹¹⁷ Fair Total N=731 mother-infant dyads (N=596 analyzed)	Mean number of inpatient days; based on parent self-report	18 months	0.07 (0.42)	0.21 (1.35)	0.17 (1.04)	NA	Mean difference 0.14 (95% CI, -0.01 to 0.44) for G2 vs. G1 Mean difference 0.10 (95% CI, -0.03 to 0.32) for G3 vs. G1

* Assessed for time period between birth and 6 months of child's age.

† Mean number of hospitalizations was 0.43 (SD=0.92; range, 0 to 4) with an average number of days hospitalized at 2.75 (SD=8.64; range 0 to 54).

‡ For marital status, social class, and all interactions, plus maternal sense of control, husband/boyfriend support, and age.

§ No difference ($p>0.05$) between nurse-visited children and comparison-group children for total sample and high-risk subgroup as well.

† These numbers are total events (means and SDs are not reported).

Abbreviations: CI=confidence interval; G=group; KQ=key question; N=number; NA=not applicable; NR=not reported; NS=not sufficient; SD=standard deviation.

Appendix D Table 27. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Hospitalization, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Number of Episodes in G1 Mean (SD)	Mean Number of Episodes in G2 Mean (SD)	Mean Number of Episodes in G3 Mean (SD)	Mean Number of Episodes in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Hardy et al, 1989 ¹⁷³ Poor Total N=290 infants randomized (N analyzed=263)	Total number of admissions, including multiple admissions for a single child; determined by (1) computerized record system with summaries of visits to the C&Y clinic, the pediatric ED, and other JHU clinics, and brief descriptions of inpatient hospital care, (2) review of medical records, (3) data collected by home visitor on final visit, and (4) telephone interview	NR	23 (NR)	0.03 (-3.63)	NA	NA	NR
Koniak-Griffin et al, 2002 ¹⁷⁵ Poor Total N=144 caregivers randomized (N analyzed=102)	Number of episodes of hospitalizations for all indications; based on maternal reports, verified with medical records when possible; medical records used in cases of discrepancy	12 months	24 (NR)	14 (NR)	NA	NA	X ² =4.43; p=0.03
Koniak-Griffin et al, 2003 ¹⁷¹ Poor Total N=144 caregivers randomized (N analyzed=101)	Number of episodes of hospitalizations for all indications; based on maternal reports, verified with medical records when possible; medical records used in cases of discrepancy	24 months	36 (NR)	19 (NR)	NA	NA	X ² =9.73; p=0.002

Appendix D Table 27. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Hospitalization, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Mean Number of Episodes in G1 Mean (SD)	Mean Number of Episodes in G2 Mean (SD)	Mean Number of Episodes in G3 Mean (SD)	Mean Number of Episodes in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Koniak-Griffin et al, 2002 ¹⁷⁵ Poor Total N=144 caregivers randomized (N analyzed=102)	Days of infant hospitalization excluding birth related; based on maternal reports, verified with medical records when possible; medical records used in cases of discrepancy	12 months	154 (NR)	74 (NR)	NA	NA	$\chi^2=42.28$; $p<0.001$
Koniak-Griffin et al, 2003 ¹⁷¹ Poor Total N=144 caregivers randomized (N analyzed=101)	Days of infant hospitalization excluding birth related; based on maternal reports, verified with medical records when possible; medical records used in cases of discrepancy	24 months	211 (NR)	143 (NR)	NA	NA	$\chi^2=32.48$; $p<0.001$
Koniak-Griffin et al, 2003 ¹⁷¹ Poor Total N=144 caregivers randomized (N analyzed=55)	Mean number of episodes of hospitalizations per hospitalized child excluding birth related; based on maternal reports, verified with medical records when possible; medical records used in cases of discrepancy	24 months	2.19 (2.46)	1.58 (1.44)	NA	NA	Calculated mean difference -0.61 (95% CI, -1.84 to 0.62)

Abbreviations: C&Y=children and youth; CI=confidence interval; ED=emergency department; G=group; JHU=Johns Hopkins University; KQ=key question; N=number; NA=not applicable; NR=not reported; SD=standard deviation.

Appendix D Table 28. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Failure to Thrive, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Events, G1 No. (%)	Number of Incident Events, G2 No. (%)	Number of Incident Events, G3 No. (%)	Number of Incident Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Brooten et al, 1986 ¹¹⁰ Fair Total N=79 infants randomized (N analyzed=79)	Neglect measured by incidence of failure to thrive; method of ascertainment not reported	18 months*	1 (2.5)	0 (0)	NA	NA	Calculated RR, 0.34 (95% CI, 0.01 to 8.14)

*Subjects randomized were newborns, so age at followup is likely 18 months.

Abbreviations: CI=confidence interval; G=group; KQ=key question; N=number; NA=not applicable; No.=number; RR=relative risk.

Appendix D Table 29. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in Sensitivity Analysis (KQ 1)–Failure to Thrive, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Events, G1 No. (%)	Number of Incident Events, G2 No. (%)	Number of Incident Events, G3 No. (%)	Number of Incident Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Gray et al, 1979 ¹³⁵ Poor Total N=100 mothers randomized (N analyzed=50)	Neglect measured by incidence of failure to thrive; method of ascertainment not reported	17 months	2 (8)	3 (12)	NA	NA	Calculated RR, for G2 vs. G1 1.50 (95% CI, 0.27 to 8.22)

Abbreviations: CI=confidence interval; G=group; KQ=key question; N=number; NA=not applicable; No.=number; RR=relative risk.

Appendix D Table 30. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Delayed or No Immunization, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Events, G1 No. (%)	Number of Incident Events, G2 No. (%)	Number of Incident Events, G3 No. (%)	Number of Incident Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Quinlivan and Streett, 2003 ¹¹⁶ Fair Total N=136 mothers randomized (N analyzed=124)	No vaccination; based on parent self-report	6 months	9 (14.5)	4 (6.5)	NA	NA	Calculated RR, 0.49 (95% CI, 0.16 to 1.52)

Abbreviations: CI=confidence interval; G=group; KQ=key question; N=number; NA=not applicable; No.=number; RR=relative risk.

Appendix D Table 31. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in Sensitivity Analysis (KQ 1)–Delayed or No Immunization, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Events, G1 No. (%)	Number of Incident Events, G2 No. (%)	Number of Incident Events, G3 No. (%)	Number of Incident Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Dubowitz et al, 2009 ¹⁴⁸ Poor Total N=729 parents randomized (N analyzed=558)	Delayed immunization; obtained from children's medical charts	3 years	24 (9.6)*	10 (3.3)*	NA	NA	Calculated RR, 0.34 (95% CI, 0.16 to 0.69)
Infante-Rivard et al, 1989 ¹⁷⁴ Poor Total N=47 mother-child dyads randomized (N analyzed=47)	Percentage of children with incomplete diphtheria-pertussis-tetanus immunization; obtained from questions asked during follow up visit	15 months	12 (46.2) [†]	3 (14.3) [†]	NA	NA	Calculated RR, 0.31 (95% CI, 0.10 to 0.96)
Infante-Rivard et al, 1989 ¹⁷⁴ Poor Total N=47 mother-child dyads randomized (N analyzed=47)	Percentage of children with no measles-mumps-rubella immunization; obtained from questions asked during follow up visit	15 months	16 (61.5) [†]	12 (57.1) [†]	NA	NA	Calculated RR, 0.93 (95% CI, 0.58 to 1.50)
Norr et al, 2003 ¹⁷⁷ Poor Total N=588 families* (N analyzed=323)	Immunization at 12 months in African American families; based on other self-report number of immunizations the baby received (immunizations completed at age 12 months). Verified by review of official immunization card or, if the mother did not have the card, medical record. All reported immunizations were verified.	12 months	105 (74.6) [§]	139 (76.4) [§]	NA	NA	Calculated RR, of incomplete immunizations 0.93 (95% CI, 0.63 to 1.36)

Appendix D Table 31. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in Sensitivity Analysis (KQ 1)–Delayed or No Immunization, Categorical Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Events, G1 No. (%)	Number of Incident Events, G2 No. (%)	Number of Incident Events, G3 No. (%)	Number of Incident Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Norr et al, 2003 ¹⁷⁷ Poor Total N=588 families [†] (N analyzed=154)	Immunization at 12 months among Mexican American families; based on other self-report number of immunizations the baby received (immunizations completed at 12 months of age). Verified by review of official immunization card or, if the mother did not have the card, medical record. All reported immunizations were verified.	12 months	72 (92.3) [§]	61 (80.3) [§]	NA	NA	Calculated RR, of incomplete immunizations 2.57 (95% CI, 1.05 to 6.26) [¶]

* Number of events calculated based on N analyzed and percentage reported in Dubowitz et al, 2009.¹⁴⁸

† Number of events calculated based on N analyzed and percentage reported in Infante-Rivard et al, 1989.¹⁷⁴

‡ N randomized was not reported. 588 women were recruited into the study. 447 participants remained in the study by the 12-month followup.

§ Number of events calculated based on N analyzed and percentage reported in Norr et al, 2003.¹⁷⁷

|| Data reflect maternal report or documented in medical record. By 12 months of age, 79% of the infants in this study were up to date on all four required immunization series.

There were no differences in the proportion of infants fully immunized at 1 year for the REACH-Futures compared with the control groups for African Americans. Overall, study found no increase in the immunization rates for infants in REACH-Futures. An earlier evaluation of the program had found higher immunization rates in REACH-Futures participants compared with women served in a prior program or the general city population.¹⁸⁰

¶ Data reported are for completed immunizations as documented by the mother OR medical record. Using this metric, Mexican American infants had a significantly lower immunization rate than the African American group. However, the Mexican American infants were more likely to be fully immunized than the African American infants (p<0.01).

Abbreviations: CI=confidence interval; G=group; KQ=key question; N=number; NA=not applicable; No.=number; OR=odds ratio; REACH=Resources, Education and Care in the Home; RR=relative risk.

Appendix D Table 32. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Decreased Internalizing, Externalizing, or Internalizing and Externalizing Behaviors, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G1 No. (%)	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G2 No. (%)	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G3 No. (%)	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G4 No. (%)	Effect Estimate or Other Outcome Measure
Caldera et al, 2007 ⁸⁸ Good Total N=364 families randomized (N analyzed=249)	Percentage of participants with a normal CBCL internalizing score	2 years	NR (79)	NR (87)	NA	NA	AOR, 0.36 (95% CI, 1.31 to 3.25, p<0.01)
Caldera et al, 2007 ⁸⁸ Good Total N=364 families randomized (N analyzed=249)	Percentage of participants with a normal CBCL externalizing score	2 years	NR (77)	NR (82)	NA	NA	AOR, 1.48 (95% CI, 1.14 to 1.94, p<0.01)
Guyer et al, 2003 ¹¹² Fair Total N=2,235 families* (N analyzed=1,593)	Percentage of children more aggressive; based on CBCL score ≥14, completed during parent interview	30–33 months	NR (14.6)	NR (17.0)	NA	NA	AOR, 1.20 (95% CI, 0.89 to 1.61, p>0.05)
Guyer et al, 2003 ¹¹² Fair Total N=2,235 families* (N analyzed=1,593)	Percentage of children more anxious or depressed; based on CBCL score ≥9, completed during parent interview	30–33 months	NR (9.0)	NR (10.5)	NA	NA	AOR, 1.35 (95% CI, 0.93 to 1.95, p>0.05)
Lowell et al, 2011 ¹¹⁴ Good Total N=157 families randomized (N analyzed=117)	ITSEA externalizing	6 months	(36.5)	(22.8)	NA	NA	p=NS

Appendix D Table 32. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Decreased Internalizing, Externalizing, or Internalizing and Externalizing Behaviors, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G1 No. (%)	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G2 No. (%)	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G3 No. (%)	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G4 No. (%)	Effect Estimate or Other Outcome Measure
Low ell et al, 2011 ¹⁴ Good Total N=157 families randomized (N analyzed=117)	ITSEA externalizing	12 months	(29.1)	(17.0)	NA	NA	P<.05
Low ell et al, 2011 ¹⁴ Good Total N=157 families randomized (N analyzed=117)	ITSEA internalizing	6 months	(1.6)	(3.5)	NA	NA	P=NS
Low ell et al, 2011 ¹⁴ Good Total N=157 families randomized (N analyzed=117)	ITSEA internalizing	12 months	(1.8)	(1.9)	NA	NA	P=NS
Minkovitz et al, 2007 ¹³ Fair Total N=2,235 families* (N analyzed=1,308)	Clinical/borderline concern regarding child's behavior; based on CBCL	5.5 years	100 (16.5)	132 (20.2)	NA	NA	AOR, 1.26 (95% CI, 0.94 to 1.69, p=0.09)

* The RCT-only portion of the study originally randomized 2,584 children at birth before enrollment or before they were checked for eligibility. Among them, 2,235 children were enrolled into the study.

Abbreviations: AOR=adjusted odds ratio; CBCL=Child Behavior Checklist; CI=confidence interval; G=group; ITSEA=Infant Toddler Social Emotional Adjustment Scale; KQ=key question; N=number; NA=not applicable; No.=number; NR=not reported; NS=not sufficient; RCT=randomized, controlled trial.

Appendix D Table 33. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Decreased Internalizing, Externalizing, or Internalizing and Externalizing Behaviors, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G1 No. (%)	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G2 No. (%)	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G3 No. (%)	Number of Participants Exhibiting Internalizing, Externalizing, or Both Behavioral Problems, G4 No. (%)	Effect Estimate or Other Outcome Measure
Mejdoubi et al, 2015 ¹⁷⁶ Poor Total N=460 mothers randomized (N analyzed=223)	Number of children exhibiting internalizing behavior; based on score within 90 th percentile on the CBCL 1.5–5 years Internalizing Behavior Subscale administered to mothers during follow up visit	24 months	69 (30.9)*	40 (16.9) [†]	NA	NA	RR, 0.56 (95% CI, 0.24 to 0.94, p=0.04)
Mejdoubi et al, 2015 ¹⁷⁶ Poor Total N=460 mothers randomized (N analyzed=223)	Number of children exhibiting externalizing behavior; based on score within 90 th percentile on the CBCL 1.5–5 years Externalizing Behavior Subscale administered to mothers during follow up visit	24 months	78 (35.0)*	59 (24.9) [†]	NA	NA	RR, 0.71 (95% CI, 0.34 to 1.09, p=0.12)

* Based on the 223 participants randomized to the control group (G1).

[†] Based on the 237 participants randomized to the intervention group (G2).

Abbreviations: CBCL=Child Behavior Checklist; CI=confidence interval; G=group; KQ=key question; NA=not applicable; No.=number; RR=relative risk.

Appendix D Table 34. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Decreased Internalizing, Externalizing, or Internalizing and Externalizing Behaviors, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Kitzman et al, 1997 ⁹³ Fair Total N=743 mothers* (N analyzed=NR)	Behavior problems total scores as measured by the Achenbach CBCL completed by mothers	24 months	NA	49.2 (NR)	NA	46.0 (NR)	Mean difference 3.2 (95%CI, -0.6 to 7.0, p=NS) for G2 vs. G4
Caldera et al, 2007 ⁸⁸ Good Total N=364 families randomized (N analyzed=249)	CBCL internalizing score	2 years	51 (NR)	48.2 (NR)	NA	NA	Effect size 0.36 (95% CI, -4.2 to -1.5, p<0.01)
Caldera et al, 2007 ⁸⁸ Good Total N=364 families randomized (N analyzed=249)	CBCL externalizing score	2 years	53 (NR)	50.8 (NR)	NA	NA	Effect size 0.28 (95% CI, -5.0 to 0.5, p=0.09)
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=897)	Rule-breaking behaviors; measured by CBCL, completed by mothers	7 years	2.66 (NR)	2.74 (NR)	NA	NA	Effect size 0.03, p=NS
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=897)	Aggressive behaviors; measured by CBCL, completed by mothers	7 years	6.72 (NR)	6.99 (NR)	NA	NA	Effect size 0.04, p=NS

Appendix D Table 34. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Decreased Internalizing, Externalizing, or Internalizing and Externalizing Behaviors, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=897)	Anxious depressed behaviors; measured by CBCL, completed by mothers	7 years	2.97 (NR)	2.89 (NR)	NA	NA	Effect size -0.03, p=NS
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=897)	Withdrawn depressed behaviors; measured by CBCL, completed by mothers	7 years	1.54 (NR)	1.47 (NR)	NA	NA	Effect size -0.04, p=NS
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=132) [†]	Rule-breaking behaviors among children in the HPO subgroup; measured by CBCL, completed by mothers	7 years	2.90 (NR)	2.38 (NR)	NA	NA	Effect size=-0.23, p=NS
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers (N analyzed=132) [†]	Aggressive behaviors among children in the HPO subgroup; measured by CBCL, completed by mothers	7 years	6.76 (NR)	6.06 (NR)	NA	NA	Effect size=-0.12, p=NS
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=132) [†]	Anxious depressed behaviors among children in the HPO subgroup; measured by CBCL, completed by mothers	7 years	2.80 (NR)	2.64 (NR)	NA	NA	Effect size=-0.12, p=NS

Appendix D Table 34. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Decreased Internalizing, Externalizing, or Internalizing and Externalizing Behaviors, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=132) [†]	Withdrawn depressed behaviors among children in the HPO subgroup; measured by CBCL completed by mothers	7 years	1.35 (NR)	1.16 (NR)	NA	NA	Effect size=-0.13, p=NS
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ Fair Total N=443 families randomized (N analyzed=391)	Mean externalizing score; externalizing behaviors assessed using the Infant Toddler Social and Emotional scale; scaled to a mean of 10 and SD of 1	36 months	10.09 (NR)	9.9 (NR)	NA	NA	OR, 0.09 (95% CI, -0.01 to 0.19) Cohen's D 0.19 (95% CI, -0.01 to 0.39, p<0.07)
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ Fair Total N=443 families randomized (N analyzed=391)	Mean internalizing score; internalizing behaviors assessed using the Infant Toddler Social and Emotional scale; scaled to a mean of 10 and SD of 1	36 months	10.12 (NR)	9.86 (NR)	NA	NA	OR, 0.13 (95% CI, 0.03 to 0.23) Cohen's D 0.26 (95% CI, 0.06 to 0.47, p<0.01)
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ Fair Total N=443 families randomized (N analyzed=391)	Mean total behavior score; calculated by summing the externalizing and internalizing scores	36 months	10.11 (NR)	9.87 (NR)	NA	NA	OR 0.12 (95% CI, 0.02 to 0.22) Cohen's D 0.24 (95% CI, 0.04 to 0.44, p<0.05)

Appendix D Table 34. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Decreased Internalizing, Externalizing, or Internalizing and Externalizing Behaviors, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ Fair Total N=443 families randomized (N analyzed=391)	Mean total parent-reported SDQ score, assesses child behavior domains including externalizing behaviors (conduct problems and hyperactivity/inattention) and internalizing behaviors (emotionality and peer difficulties) during the 6 months before assessment.	5, 6, 9 years	10.08 (NR)	9.91 (NR)	NA	NA	Cohen's D 0.17 (95% CI, 0.06-0.29, p<0.05)
Guyer et al, 2003 ¹¹² Fair Total N=2,235 families [‡] (N analyzed=1,593)	Aggressive behavior measured on the CBCL	30–33 months	8.4 (5.0)	8.7 (5.1)	NA	NA	Adjusted OR, 0.23 (95% CI, -0.29 to 0.75, p=NS) [§]
Guyer et al, 2003 ¹¹² Fair Total N=2,235 families [‡] (N analyzed=1,593)	Anxious depressed behaviors measured on the CBCL	30–33 months	4.7 (2.8)	4.8 (2.9)	NA	NA	Adjusted OR, 0.13 (95% CI, -0.16 to 0.41, p=NS) [§]
Lowell et al, 2011 ¹¹⁴ Good Total N=157 families randomized (N analyzed=117)	ITSEA externalizing	6 months	18.4 (9.4)	15.4 (7.6)	NA	NA	F-value=2.61 Effect size=0.037 p=NS

Appendix D Table 34. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Decreased Internalizing, Externalizing, or Internalizing and Externalizing Behaviors, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Low ell et al, 2011 ¹⁴ Good Total N=157 families randomized (N analyzed=117)	ITSEA externalizing	12 months	18.4 (9.6)	13.8 (7.6)	NA	NA	F-value=7.08 Effect size=0.094 p<0.05
Low ell et al, 2011 ¹⁴ Good Total N=157 families randomized (N analyzed=117)	ITSEA internalizing	6 months	15.8 (6.3)	15.4 (7.9)	NA	NA	F-value=0.47 Effect size=0.007 p=NS
Low ell et al, 2011 ¹⁴ Good Total N=157 families randomized (N analyzed=117)	ITSEA internalizing	12 months	14.6 (7.0)	13.1 (5.9)	NA	NA	F-value=1.07 Effect size=0.015 p=NS

* Of the 1,139 mothers randomized, 743 were enrolled for followup.

† This is the high prevention opportunity (HPO) subgroup: first-time mothers <19 years enrolled at 30 weeks pregnant or less.

‡ The RCT-only portion of the study originally randomized 2,584 children at birth before enrollment or before they were checked for eligibility. Among them, 2,235 children were enrolled into the study.

§ Authors reported that the intervention group was more likely to report some types of problem behaviors.

Abbreviations: CBCL=Child Behavior Checklist; CI=confidence interval; G=group; HPO=high prevention opportunity; ITSEA=Infant Toddler Social Emotional Adjustment Scale; KQ=key question; N=number; NA=not applicable; NR=not reported; NS=not sufficient; OR=odds ratio; RCT=randomized, controlled trial. SD=standard deviation; SDQ=Strengths and Difficulties Questionnaire.

Appendix D Table 35. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Decreased Internalizing, Externalizing, or Internalizing and Externalizing Behaviors, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
DePanfilis et al, 2005 ¹⁷² Poor Total N=154 families* randomized (N analyzed=111)	CBCL internalizing behavior domain	6 months	8.4 (8.3)	NR	5.4 (5.9)	NA	Study reported significant main effect of time for the entire sample (F=5.744, p=0.004); also a significant interaction between group and time (F=3.105, p=0.049) with G3 having greater improvements; no significant main effect of group (p=0.147)
DePanfilis et al, 2005 ¹⁷² Poor Total N=154 families* randomized (N analyzed=111)	CBCL externalizing behavior domain	6 months	15.0 (10.8)	NR	12.8 (10.2)	NA	Study reported significant main effect of time for the entire sample (F=17.433, p<0.001); no statistically significant main effect of group (p=0.580) or interaction between group and time (p=0.117)

*473 children

Abbreviations: CBCL=Child Behavior Checklist; G=group; KQ=key question; N=number; NA=not applicable; NR=not reported; SD=standard deviation.

Appendix D Table 36. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Other Social, Emotional, and Developmental Problems Not Otherwise Categorized, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Participants Exhibiting Other Social, Emotional, or Developmental Problems, G1 No. (%)	Number of Participants Exhibiting Other Social, Emotional, or Developmental Problems, G2 No. (%)	Number of Participants Exhibiting Other Social, Emotional, or Developmental Problems, G3 No. (%)	Number of Participants Exhibiting Other Social, Emotional, or Developmental Problems, G4 No. (%)	Effect Estimate or Other Outcome Measure
Guyer et al, 2003 ¹¹² Fair Total N=2,235 families* (N analyzed=1,593)	Percentage of children with more problems sleeping; based on score ≥6 on CBCL item on sleep problems	30-33 months	NR (12.2)	NR (15.3)	NA	NA	AOR, 1.37 (95% CI, 1.01 to 1.86, p<0.05)

* The RCT-only portion of the study originally randomized 2,584 children at birth before enrollment or before they were checked for eligibility. Among them, 2,235 children were enrolled into the study.

Abbreviations: AOR=adjusted odds ratio; CBCL=Child Behavior Checklist; CI=confidence interval; G=group; KQ=key question; No.=number; NA=not applicable; NR=not reported.

Appendix D Table 37. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Other Social, Emotional, and Developmental Problems Not Otherwise Categorized, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Barlow et al, 2007 ^{101, 102} Fair Total N=131 caregivers randomized (N analyzed=131)	Infant-toddler social and emotional adjustment; based on BITSEA competence and problems subscales	12 months	NR (NR)	NR (NR)	NR (NR)	NR (NR)	p=ns
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers (N analyzed=897)	Attention problems as measured by the CBCL completed by mothers	7 years	4.75 (NR)	4.77 (NR)	NA	NA	Effect size=0.01, p=ns/NR.
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers (N analyzed=897)	Social problems as measured by the CBCL completed by mothers	7 years	1.15 (NR)	1.31 (NR)	NA	NA	Effect size=-0.04, p=ns/NR
Guyer et al, 2003 ¹¹² Fair Total N=2,235 families* (N analyzed=1,593)	Sleep problems as measured by the CBCL completed by mothers	30–33 months	2.7 (2.3)	2.9 (2.5)	NA	NA	AOR, 0.12 (95% CI, -0.13 to 0.36, p=ns/NR)
Guyer et al, 2003 ¹¹² Fair Total N=2,235 families* (N analyzed=1,593)	Sleep problems: percentage of children who meet the cutoff based on CBCL scores (completed by mothers)	30–33 months	12.2%	NA	15.3%	NA	AOR: 1.37, 95% CI, 1.01 – 1.86, p <.05

Appendix D Table 37. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Other Social, Emotional, and Developmental Problems Not Otherwise Categorized, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Lowell et al, 2011 ¹¹⁴ Good Total N=157 families randomized (N analyzed=131)	Child social-emotional/behavioral problems assessed with ITSEA dysregulation domain. Dysregulation items included sleep, eating, sensory sensitivities, and negative emotionality	6 months	21.4 (8.1)	18.4 (9.2)	NA	NA	F-value=1.45 Effect size (Partial η^2)=0.021, p=ns/NR
Lowell et al, 2011 ¹¹⁴ Good Total N=157 families randomized (N analyzed=117)	Child social-emotional/behavioral problems assessed with ITSEA dysregulation domain. Dysregulation items included sleep, eating, sensory sensitivities, and negative emotionality	12 months	20.7 (8.9)	16.4 (7.8)	NA	NA	F-value=3.82 Effect size (Partial η^2)=0.053, p=ns/NR
Minkovitz et al, 2007 ¹¹³ Fair Total N=2,235 families* (N analyzed=1,308)	Child's social skills measured by the Social Skills Rating System based on parental report	5 to 5.5 years	55.2 (10.0)	55.9 (9.8)	NA	NA	p=0.40
Olds et al, 2007 ⁹⁴ Fair Total N=743 mothers† (N analyzed=594)	Conduct grades for grades 1 to 3, based on school records; reported as mean (SE)	9 years	NR	2.68 (0.04)	NR	2.71 (0.07)	Effect size=0.03 (95% CI, -0.11 to 0.17, p=0.673)

Appendix D Table 37. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Other Social, Emotional, and Developmental Problems Not Otherwise Categorized, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Olds et al, 2007 ⁹⁴ Fair Total N=743 mothers [†] (N analyzed=558)	Antisocial behavior in grade 3; based on teacher reports of classroom behavior using items from the Social Competence Scale and Social Health Profile from the Fast Track trial and the Teacher Observation of Child Adjustment Revised; reported as mean (SE)	9 years	NR	100.08 (0.51)	NR	99.77 (0.77)	Effect size=-0.03 (95% CI, -0.21 to 0.15, p=0.742)
Olds et al, 2007 ⁹⁴ Fair Total N=743 mothers [†] (N analyzed=558)	Academically focused behavior in grade 3; based on teacher reports of classroom behavior using items from the Social Competence Scale and Social Health Profile from the Fast Track trial and the Teacher Observation of Child Adjustment Revised; reported as mean (SE)	9 years	NR	100.08 (0.51)	NR	100.10 (0.77)	Effect size=0.00 (95% CI, -0.18 to 0.18, p=0.981)
Olds et al, 2007 ⁹⁴ Fair Total N=743 mothers [†] (N analyzed=558)	Peer affiliation in grade 3; based on teacher reports of classroom behavior using items from the Social Competence Scale and Social Health Profile from the Fast Track trial and the Teacher Observation of Child Adjustment Revised; reported as mean (SE)	9 years	NR	99.92 (0.51)	NR	100.35 (0.77)	Effect size=0.04 (95% CI, -0.14 to 0.23, p=0.643)

* The RCT-only portion of the study originally randomized 2,584 children at birth before enrollment or before they were checked for eligibility. Among them, 2,235 children were enrolled into the study.

[†] Of the 1,139 mothers randomized, 743 were enrolled for followup.

Abbreviations: AOR=adjusted odds ratio; BIT SEA=Brief Infant-Toddler Social and Emotional Assessment; CBCL=Child Behavior Checklist; CI=confidence interval; G=group; IT SEA=Infant Toddler Social Emotional Adjustment Scale; KQ=key question; N=number; NA=not applicable; NR=not reported; ns=not sufficient; RCT=randomized, controlled trial; SD=standard deviation; SE=standard error.

Appendix D Table 38. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Healthy Social-Emotional Development Based on Bayley Scales of Infant Development, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Participants Exhibiting Normal Social-Emotional Development, G1 No. (%)	Number of Participants Exhibiting Normal Social-Emotional Development, G2 No. (%)	Number of Participants Exhibiting Normal Social-Emotional Development, G3 No. (%)	Number of Participants Exhibiting Normal Social-Emotional Development, G4 No. (%)	Effect Estimate or Other Outcome Measure
Caldera et al, 2007 ⁸⁸ Good Total N=364 families randomized (N analyzed=249)	Healthy development, reported as percentage of participants scoring ≥85 on the BSID MDI	2 years	NR (48)	NR (58)	NA	NA	AOR,* 1.55 (95% CI, 1.01 to 2.37, p<0.05)
Caldera et al, 2007 ⁸⁸ Good Total N=364 families randomized (N with baseline data obtained=325, and N analyzed=249)	Healthy development, reported as percentage of participants scoring ≥85 on the BSID PDI	2 years	NR (80)	NR (85)	NA	NA	AOR,* 1.36 (95% CI, 0.72 to 2.58, p=0.35)

* Adjusted for variables on which the two groups differed: poor psychological resources and prenatal enrollment.

Abbreviations: AOR=adjusted odds ratio; BSID=Bayley Scales of Infant Development; CI=confidence interval; G=group; KQ=key question; MDI=Mental Development Index; NA=not applicable; No.=number; NR=not reported; PDI=Psychomotor Development Index.

Appendix D Table 39. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Healthy Social-Emotional Development Based on Bayley Scales of Infant Development, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Barlow et al, 2007 ¹⁰¹ Fair Total N=131 caregivers randomized (N analyzed=122)	Infant development, based on BSID	12 months	NR (NR)	NR (NR)	NA	NA	p=NS
Caldera et al, 2007 ⁸⁸ Good Total N=364 families randomized (N analyzed=249)	Mean score on Bayley Scales MDI	2 years	84.8 (NR)	88.0 (NR)	NA	NA	Effect size=0.29, p<0.05 Mean difference 3.2 (95% CI, 1.2 to 5.2)
Caldera et al, 2007 ⁸⁸ Good Total N=364 families randomized (N analyzed=249)	Mean score on Bayley Scales PDI	2 years	96.0 (NR)	98.1 (NR)	NA	NA	Effect size=0.19, p=0.16 Mean difference 2.1 (95% CI, -1.2 to 5.4)
Kitzman et al, 1997 ⁹³ Fair Total N=743 mothers* (N analyzed=671)	Bayley mental development score, based on Bayley Scales MDI	24 months	NR	94.3 (NR)	NR	94.5 (NR)	Mean difference for G4 vs. G2=-0.2 (95% CI, -2.4 to 2.0, p=NS)
Olds et al, 1986 ⁹⁵ Fair Total N=400 families randomized (N analyzed=272)	Development quotient at 12 months of life; based on Bayley Scales MDI	12 months	109.94 (NR)	105.44 (NR)	111.23 (NR)	NA	No difference was observed between control and treatment groups.†

* Of the 1,139 mothers randomized, 743 were enrolled for followup.

† Authors reported higher development quotients for babies assigned to nurse-visited groups among poor, unmarried teen subgroup (p=0.06 for G2 vs. G1 and p=0.08 for G3 vs. G1).

Abbreviations: BSID=Bayley Scales of Infant Development; CI=confidence interval; G=group; KQ=key question; MDI=Mental Development Index; N=number; NA=not applicable; NR=not reported; NS=not sufficient; PDI=Psychomotor Development Index; SD=standard deviation.

Appendix D Table 40. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Healthy Social-Emotional Development Based on Bayley Scales of Infant Development, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=564)	Bayley Scales PDI score	1 year	106.8 (NR)	106.5 (NR)	NA	NA	p=0.81
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=534)	Bayley Scales PDI score	2 years	90.4 (NR)	92.1 (NR)	NA	NA	p=0.12
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=564)	Bayley Scales MDI score	1 year	102.6 (NR)	102.3 (NR)	NA	NA	p=0.92
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=534)	Bayley Scales MDI score	2 years	89.2 (NR)	90.0 (NR)	NA	NA	p=0.60
Infante-Rivard et al, 1989 ¹⁷⁴ Poor Total N=47 mother-child dyads randomized (N analyzed=47)	Mean Bayley mental development scale; based on Bayley Scales MDI	15 months	114.9 (3.3)	115.5 (7.0)	NA	NA	NR
Infante-Rivard et al, 1989 ¹⁷⁴ Poor Total N=47 mother-child dyads randomized (N analyzed=47)	Mean Bayley motor development score; based on Bayley Scales PDI	15 Months	114.2 (13.2)	118.4 (8.8)	NA	NA	NR

Appendix D Table 40. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)–Healthy Social-Emotional Development Based on Bayley Scales of Infant Development, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Norr et al, 2003 ¹⁷⁷ Poor Total N=588 families* (N analyzed=323)	Infant (mental) development status at 12 months for African American infants participating in the study; based on Bayley Scales MDI	12 months	97.7 (16.9)	99.4 (15.7)	NA	NA	t-value=0.93 (p=NS)
Norr et al, 2003 ¹⁷⁷ Poor Total N=588 families* (N analyzed=154)	Infant (mental) development status at 12 months for Mexican American infants participating in the study; based on Bayley Scales MDI	12 months	97.4 (16.7)	97.9 (16.3)	NA	NA	t-value=0.19 (p=NS)
Norr et al, 2003 ¹⁷⁷ Poor Total N=588 families* (N analyzed=323)	Infant (motor) development status at 12 months for African American infants participating in the study; based on Bayley Scales PDI	12 months	94.8 (14.9)	97.8 (12.7)	NA	NA	t-value=1.98 (p<0.05)
Norr et al, 2003 ¹⁷⁷ Poor Total N=588 families* (N analyzed=154)	Infant (motor) development status at 12 months for Mexican American infants participating in the study; based on Bayley Scales PDI	12 months	99.4 (14.5)	98.5 (11.4)	NA	NA	t-value=-0.41 (p=NS)

* N randomized was not reported. 588 women were recruited into the study. 447 participants remained in the study by the 12-month followup.

Abbreviations: G=group; KQ=key question; MDI=Mental Development Index; N=number; NA=not applicable; NR=not reported; NS=not sufficient; PDI=Psychomotor Development Index; SD=standard deviation.

Appendix D Table 41. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Other Measures of Healthy Social-Emotional Development and Delayed Developmental Delays, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Participants Exhibiting Development Problems, G1 No. (%)	Number of Participants Exhibiting Development Problems, G2 No. (%)	Number of Participants Exhibiting Development Problems, G3 No. (%)	Number of Participants Exhibiting Development Problems, G4 No. (%)	Effect Estimate or Other Outcome Measure
Minkovitz et al, 2007 ¹¹³ Fair Total N=2,235 families* (N analyzed=1,308)	Proportion with a significant concern regarding child's development; based on Parents' Evaluation of Development Status (PEDS)	5 to 5.5 years	137 (21.7)	138 (20.4%)	NA	NA	Calculated RR, 0.94 (95% CI, 0.76 to 1.16)
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=976 at 12 months)	Maternal concern on cognitive development item from checklist	12 months	45 (9.5)	44 (8.7)	NA	NA	Adjusted OR: 0.91 (95% CI, 0.59 to 1.40), p-value: 0.66
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=946 at 18 months)	Maternal concern on cognitive development item from checklist	18 months	26 (5.7)	17 (3.5)	NA	NA	Adjusted OR: 0.59 (95% CI, 0.32 to 1.11), p-value: 0.10
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=1,091 at 24 months)	Maternal concern on cognitive development item from checklist	24 months	66 (12.6)	46 (8.1)	NA	NA	Adjusted OR: 0.61 (95% CI, 0.40 to 0.90), p-value: 0.013

Appendix D Table 41. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– Other Measures of Healthy Social-Emotional Development and Delayed Developmental Delays, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Participants Exhibiting Development Problems, G1 No. (%)	Number of Participants Exhibiting Development Problems, G2 No. (%)	Number of Participants Exhibiting Development Problems, G3 No. (%)	Number of Participants Exhibiting Development Problems, G4 No. (%)	Effect Estimate or Other Outcome Measure
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=974 at 12 months)	Maternal concern on language development item from checklist	12 months	94 (19.9)	55 (11.0)	NA	NA	Adjusted OR: 0.50 (95% CI, 0.35 to 0.72), p<0.001
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=945 at 18 months)	Maternal concern on language development item from checklist	18 months	110 (24.2)	84 (17.1)	NA	NA	Adjusted OR: 0.66 (95% CI, 0.48 to 0.90), p=0.009

* The RCT-only portion of the study originally randomized 2,584 children at birth before enrollment or check for eligibility. Among them, 2,235 children were enrolled into the study.

Abbreviations: CI=confidence interval; G=group; KQ=key question; N=number; NA=not applicable; PEDS=Parents' Evaluation of Development Status; RR=relative risk.

Appendix D Table 42. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1)—Other Measures of Healthy Social-Emotional Development and Delayed Developmental Delays, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Participants Exhibiting Development Problems, G1 No. (%)	Number of Participants Exhibiting Development Problems, G2 No. (%)	Number of Participants Exhibiting Development Problems, G3 No. (%)	Number of Incident Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Gray et al, 1979 ¹³⁵ Poor Total N=100 mothers randomized (N analyzed=50)	Not normal development, based on test manual for Denver Development Screening Test	17 to 35 months	3 (12)	3 (12)	NA	NA	Calculated RR, 1.00 (95% CI, 0.22 to 4.49)
Gray et al, 1979 ¹³⁵ Poor Total N=100 mothers randomized (N analyzed=50)	Not normal development, based on failed items for Denver Developmental Screening Test	17 to 35 months	3 (12)	7 (27)	NA	NA	Calculated RR, 2.33 (95% CI, 0.68 to 8.01)

Abbreviations: CI=confidence interval; G=group; KQ=key question; N=number; NA=not applicable; No.=number; RR=relative risk.

Appendix D Table 43. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)–Other Measures of Healthy Social-Emotional Development and Delayed Developmental Delays, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average Score in G1 Mean (SD)	Average Score in G2 Mean (SD)	Average Score in G3 Mean (SD)	Average Score in G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Olds et al, 1986 ⁹⁵ Fair Total N=400 families randomized (N analyzed=257)	Development quotient at 24 months of life; based on the Cattell Scale	2 years	106.49 (NR)	105.73 (NR)	109.34 (NR)	NA	Authors reported no difference among intervention groups.*
Robling et al, 2016 ⁹² Fair Total N=1,645 randomized (N analyzed=895 at 24 months)	Early Language Milestone Scale score	2 years	55.7 (31.4)	60.8 (31.4)	NA	NA	Reported adjusted difference in means: 4.49 (95% CI, 0.52 to 8.45); calculated absolute difference in means: 5.1 (95% CI, 1.47 to 8.75), p=0.006

* Authors reported higher development quotients for babies assigned to nurse-visited groups among poor, unmarried teen subgroup (p=0.06 for G2 vs. G1 and p=0.08 for G3 vs. G1).

Abbreviations: G=group; KQ=key question; N=number; NA=not applicable; NR=not reported; SD=standard deviation.

Appendix D Table 44. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– School Attendance and Performance, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Events, G1 No. (%)	Number of Events, G2 No. (%)	Number of Events, G3 No. (%)	Number of Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers (N analyzed=793)	Children who reported skipping school “often”	7 years	NR (6.47)	NR (2.35)	NA	NA	Adjusted OR, 0.35, p<0.01*
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers (N analyzed=122)	Children in the high prevention opportunity subgroup who reported skipping school “often”	7 years	NR (4.53)	NR (1.85)	NA	NA	Adjusted OR, 0.35, p=NS
Olds et al, 2007 ⁹⁴ Fair Total N=743 mothers [†] (N analyzed=NR); at 9 years N=627	Any academic failures during grades 1 through 3; measured by whether child failed both reading and math (GPA <1.0) in any grade, based on school records	9 years	NR	NR (5.1)	NR	NR (7.0)	OR, 1.40 (95% CI, 0.67 to 2.92, p=0.372) for G2 vs. G4
Olds et al, 2007 ⁹⁴ Fair Total N=743 mothers [†] (N analyzed=NR); at 9 years N=627	Ever retained during grades 1 through 3; based on school records	9 years	NR	NR (12.4)	NR	NR (16.0)	OR, 1.35 (95% CI, 0.82 to 2.21, p=0.247) for G2 vs. G4
Olds et al, 2007 ⁹⁴ Fair Total N=743 mothers [†] (N analyzed=NR); at 9 years N=627	Ever placed in special education during grades 1 through 3; based on school records	9 years	NR	NR (2.3)	NR	NR (2.2)	OR, 0.98 (95% CI, 0.36 to 2.65, p=0.972) for G2 vs. G4

* Authors also reported on mothers who reported on whether their children skipped school. No difference was found between study groups.

† Of the 1,139 mothers randomized, 743 were enrolled for followup.

Abbreviations: CI=confidence interval; G=group; GPA=grade point average; KQ=key question; N=number; NA=not applicable; No.=number; NR=not reported; NS=not sufficient; OR=odds ratio.

Appendix D Table 45. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1)– School Attendance and Performance, Continuous Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Average, G1 Mean (SD)	Average, G2 Mean (SD)	Average, G3 Mean (SD)	Average, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Fergusson et al, 2005 ¹⁰⁵ , Fergusson et al, 2013 ¹⁰⁶ Fair Total N=443 families randomized (N analyzed=391)	Mean duration of early childhood education, used to assess the extent to which families used nonmedical community services; based on parent report	36 months*	13.6 (NR)	16.4 (NR)	NA	NA	OR, 0.11 (95% CI, 0.01 to 0.21) Cohen's D 0.22 (95% CI, 0.02 to 0.42, p<0.05)
Olds et al, 2007 ⁹⁴ Fair Total N=743 mothers† (N analyzed=627)	GPA (reading and math) for grades 1 through 3, based on school records, reported as mean (SE)	9 years	NR	2.59 (0.04)	NR	2.69 (0.06)	Effect size 0.09 (95% CI, -0.05 to 0.22); p=0.200 G2 vs. G4
Olds et al, 2007 ⁹⁴ Fair Total N=743 mothers† (N analyzed=627)	Achievement test score (reading and math) for grades 1 through 3, based on school records, reported as mean (SE)	9 years	NR	41.63 (1.34)	NR	44.61 (1.86)	Effect size 0.11 (95% CI, -0.05 to 0.26); p=0.174 G2 vs. G4

* Outcome reported was the cumulative mean at 36 months.

† Of the 1,139 mothers randomized, 743 were enrolled for followup.

Abbreviations: CI=confidence interval; G=group; GPA=grade point average; KQ=key question; N=number; NA=not applicable; NR=not reported; OR=odds ratio; SD=standard deviation; SE=standard error.

Appendix D Table 46. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1) – Mortality, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Incident Mortality, G1 No. (%)	Incident Mortality, G2 No. (%)	Incident Mortality, G3 No. (%)	Incident Mortality, G4 No. (%)	Effect Estimate or Other Outcome Measure
Barlow et al, 2007 ¹⁰¹ Fair Total N=131 caregivers randomized (N analyzed=NR)	Death for which there were child protection concerns and for which an open verdict was reached	12 months	1 (NR)	0 (NR)	NA	NA	NR
Brooten et al, 1986 ¹¹⁰ Fair Total N=79 infants randomized (N analyzed=79)	Death from sudden infant death syndrome	18 months*	0 (0)	1 (2.5)	NA	NA	RR, 3.08 (95% CI, 0.13 to 73.27)
Olds et al, 2007 ⁹⁴ Fair Total N=743 mothers [†] (N analyzed=720)	Child mortality; reported at maternal assessment or from CDC National Death Index	9 years	NR	10 (2.0)	NR	1 (0.5)	OR, 0.22 (95% CI, 0.03 to 1.74, p=0.08) for G4 vs. G2
Quinlivan and Streett, 2003 ¹¹⁶ Fair Total N=136 mothers randomized (N analyzed=135)	Neonatal death confirmed by reference to a death certificate	6 months	2 (3)	1 (1.6)	NA	NA	NR

* Subjects randomized were newborns, so age at followup is likely 18 months.

[†] Of the 1,139 mothers randomized, 743 were enrolled for followup.

Abbreviations: CDC=Centers for Disease Control and Prevention; CI=confidence interval; G=group; KQ=key question; N=number; NA=not applicable; No.=number; NR=not reported; OR=odds ratio; RR=relative risk.

Appendix D Table 47. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Sensitivity Analysis (KQ 1) – Mortality, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Incident Mortality, G1 No. (%)	Incident Mortality, G2 No. (%)	Incident Mortality, G3 No. (%)	Incident Mortality, G4 No. (%)	Effect Estimate or Other Outcome Measure
Norr et al, 2003 ¹⁷⁷ Poor Total N=588 families* (N analyzed=477)	Infant death	12 months	0 (0)	0 (0)	NA	NA	NR

* N randomized was not reported. 588 women were recruited into the study. 447 participants remained in the study by the 12-month followup.

Abbreviations: G=group; KQ=key question; N=number; NA=not applicable; No.=number; NR=not reported.

Appendix D Table 48. Benefits of Primary Care Interventions for Child Maltreatment Prevention From RCTs in the Main Analysis (KQ 1) – Combination Adverse Neonatal Outcomes

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Number of Incident Events, G1 No. (%)	Number of Incident Events, G2 No. (%)	Number of Incident Events, G3 No. (%)	Number of Incident Events, G4 No. (%)	Effect Estimate or Other Outcome Measure
Quinlivan and Streett, 2003 ¹¹⁶ Fair Total N=136 mothers randomized (N analyzed=135)	Incidence of predefined adverse neonatal outcomes: infant death,* severe nonaccidental injury, [†] and nonvoluntary foster care [‡]	6 months	9 (13)	2 (3)	NA	NA	RR, 0.24 (95% CI, 0.05 to 1.08, p=0.04) Adjusted RR, 0.22 (95% CI, 0.02 to 0.98, p=0.04)

* Confirmed through documentation via death certificate.

[†] Defined as having a documented hospitalization for injury and confirmation of the nonaccidental nature of the injury via an independent investigation by Family and Children's Services.

[‡] Defined as placement in foster care as the result of a court order or as the result of mother's imprisonment.

Abbreviations: CI=confidence interval; G=group; KQ=key question; N=number; NA=not applicable; RR=relative risk.

Appendix E Table 1. Quality Ratings for RCTs, Part 1

Author, Year, Program/Trial Name	Overall Quality Rating	Overall Rationale for Quality Rating	Was method of randomization adequate?	Was allocation concealment adequate?	Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰² (Family Partnership Model)	Fair [*]	For abuse outcomes, the methods only state that "participating health visitors provided data relating to case conferences, children on the protection register, children removed from the home and child deaths." Because health visitors had far more contact with the intervention group, it is unclear how this method is equally valid for each group. It is unclear where health visitors got the information about these outcomes (e.g., via health records or purely self-report).	Probably yes	Yes	Yes	Low	None
Barth, 1991 ¹³⁴ (Child Parent Enrichment Program)	Poor	Randomization not maintained. No information given on missing data or attrition.	Probably yes	No information	Yes	High	Method of random assignment not described well: "random assignment occurred at the central office," When families assigned to G2 refused services or accepted fewer than 5 visits (there were only 6 such families, and their mean number of visits was 2.1), they were reassigned to the control group.
Brayden et al, 1993 ¹⁰⁹	Good	Low potential bias arising from each domain.	Yes	Probably yes	Probably yes	Low	HR control and HR intervention groups were similar except HR intervention had mean age of 21.2 years; HR control was 22.4 years.
Brooten et al, 1986 ¹¹⁰	Fair	Limited information about missing data	Probably yes	Probably yes	Yes	Low	None
Bugental and Schwartz, 2009 ¹⁰³ (Healthy Start+)	Fair	Study groups were different at baseline and ITT analysis was not possible.	Probably yes	No information	No	Some concerns	The education level of mothers at intake was lower in G1 than in G2. In addition, there were significantly more immigrant families in G1 than in G2. To control for these differences, immigration status was included as a between-subjects variable and maternal education as a covariate.

Appendix E Table 1. Quality Ratings for RCTs, Part 1

Author, Year, Program/Trial Name	Overall Quality Rating	Overall Rationale for Quality Rating	Was method of randomization adequate?	Was allocation concealment adequate?	Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
Caldera et al, 2007 ⁸⁸ Duggan et al, 2007 ⁸⁷ (Healthy Families Alaska)	Good	Low potential bias arising from each domain.	Yes	Probably yes	Yes	Low	At baseline, HFAK mothers were less likely than controls to have poor psychological resources and to have enrolled prenatally. However, this difference does not appear to be the result of poor or failed randomization and would bias the effect measure toward the null.
DePanfilis and Dubowitz, 2005 ¹⁷² (Family Connections)	Poor	Poorly specified intervention arm and high and uneven attrition.	Yes	Probably yes	Yes	Low	None
Dubowitz et al, 2009 ¹⁴⁸ (SEEK)	Poor	Randomization problems and potential for contamination yield high risk of bias for between-group comparisons.	No	No	No	High	2 clinic days were randomly assigned to intervention and 2 other days were randomly assigned to be control clinics. There are many ways that group differences could be confounded by differences in clinic on those days of the week. G2 children were younger and their families had fewer children than G1.

Appendix E Table 1. Quality Ratings for RCTs, Part 1

Author, Year, Program/Trial Name	Overall Quality Rating	Overall Rationale for Quality Rating	Was method of randomization adequate?	Was allocation concealment adequate?	Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
Dubowitz et al, 2012 ¹⁴⁷ (SEEK)	Poor	Potential bias caused by lack of randomization of two control practices, lack of blinding, possible effects of unblinding on outcome measures, as well as some concerns raised by missing information and attrition.	No	NA	No	High	Practices were randomized to SEEK or control groups, stratified by size, by drawing paper lots. 1 SEEK practice withdrew before recruitment. 1 SEEK practice had a large number of health professionals, which created an imbalance between groups. As a result, 2 additional practices were assigned to the control group without randomization. Despite efforts to adjust for baseline variations using statistical analyses, large socioeconomic and child medical assistance differences are evident between groups, potentially caused by adding the 2 control practices. Allocation was not concealed to participants or health professionals due to nature of intervention.
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶	Poor	Low study attrition across 3 years of follow up assessments. Sample size and the multiple follow up points yielded substantial study power to detect group differences for nearly all outcomes. However, deviation from intended intervention (fidelity) significantly threatens validity. Because of the low intervention retention and lack of specificity regarding implemented components and the fidelity with which they were implemented, it is impossible to draw clear conclusions about the relationship between the intervention and the study outcomes.	Yes	Probably yes	Probably yes	Low	G1: higher maternal employment prior to enrollment (52% vs. 44%, p=0.05); poor maternal general mental health and partner violence less common in the HSP group than control group (43% vs. 50%, p=0.05; 43% vs. 52%, p=0.02).

Appendix E Table 1. Quality Ratings for RCTs, Part 1

Author, Year, Program/Trial Name	Overall Quality Rating	Overall Rationale for Quality Rating	Was method of randomization adequate?	Was allocation concealment adequate?	Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
DuMont et al, 2008 ⁸⁹ DuMont et al, 2010 ⁹⁰ (Healthy Families New York)	Good	Low potential bias arising from each domain.	Yes	No information	Yes	Low	None
Easterbrooks et al, 2013 ¹⁰⁴ (Healthy Families Massachusetts)	Fair	Limited information about bias due to randomization, missing data departures from intended intervention	No information	No information	Probably yes	Uncertain because no information	None
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ (Early Start Program)	Fair	Some concerns regarding lack of blinding, potential bias in CAN self-report only data, and lack of information about intervention delivery and fidelity.	Yes	Probably yes	Yes	Low	None
Finello et al, 1998 ¹¹¹	Fair	Randomization not described, nonblinded, not powered adequately, significant differential attrition, skeletal information about the implementation of the HH, HV, and HH/HV interventions.	No information	No	Probably no	Some concerns	The authors report that at the first weekly discharge meeting following the infant's birth, those infants meeting birth weight criteria for enrollment were discussed and assigned at random to one of the four groups. There was no attempt to assign infants by "risk" status to any particular group. However, the randomization process does not provide specific information about the randomization method.
Gray et al, 1977 ¹³⁶ Gray et al, 1979 ¹³⁵	poor	Half the sample is missing from the outcomes.	No information	No information	No information	Uncertain because no information	Baseline characteristics not reported so no ability to determine bias.

Appendix E Table 1. Quality Ratings for RCTs, Part 1

Author, Year, Program/Trial Name	Overall Quality Rating	Overall Rationale for Quality Rating	Was method of randomization adequate?	Was allocation concealment adequate?	Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
Guyer et al, 2003 ¹¹² Minkovitz et al, 2007 ¹¹³ (Healthy Steps for Young Children)	fair	This was a complex multisite study. The intervention entailed a defined core of interventions based on written protocols and guidelines. The program design provided for adapting elements of the package to the needs of the individual families. Some program components could have been implemented at control sites due to the spreading of best/new practices in the HS model. High attrition for longer-term outcomes	Yes	Yes	Yes	Low	None
Hardy and Streett, 1989 ¹⁷³	Poor	Issues with randomization, blinding, characterization of the intervention inputs.	Probably no	No	Yes	High	Assignment to intervention and control groups was based on odd/even digits of infant medical record numbers. Authors ascertained that the children in the two groups were comparable.
Infante-Rivard et al, 1989 ¹⁷⁴	Poor	High risk of bias for randomization and attrition. Several domains with little or no information.	No information	No information	No	High	Inadequate randomization scheme used. Authors state that a randomized block design was used, but there is no information on the methods for randomization itself. Also no allocation concealment. Baseline results suggest that randomization did not “work.” Mothers in G2 were slightly older than mothers in G1 and were more likely to live alone and to have no other children and were less likely to have a low educational level, to live below the poverty line, as well as less likely to be single or separated.

Appendix E Table 1. Quality Ratings for RCTs, Part 1

Author, Year, Program/Trial Name	Overall Quality Rating	Overall Rationale for Quality Rating	Was method of randomization adequate?	Was allocation concealment adequate?	Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
Kitzman et al, 1997 ⁹³ Olds et al, 2007 ⁹⁴ (The Memphis Trial)	Fair	Long-term attrition, lack of ITT analysis	Yes	Yes	Probably yes	Low	None
Koniak-Griffin et al, 2002 ¹⁷⁵ Koniak-Griffin et al, 2003 ¹⁷¹ (Early Intervention Program)	Poor	High and differential attrition	Yes	Probably yes	Probably yes	Some concerns	Baseline characteristics only described for analysis sample after attrition
Lam et al, 2009 ¹⁰⁰	Fair	Several domains with little or no information	No information	No information	Yes	Low	No information on some items, but no signal of inadequate randomization
Larson, 1980 ¹⁰⁷	fair	Differential attrition rates	no	No information	Yes	Some concerns	Assignment not fully random. Assignment to groups B (G3) and C (G1) was random, ended when 80 subjects entered. Then group A (G2) mothers were entered until predetermined date; analysis in this review limited to randomized groups.
Lowell et al, 2011 ¹¹⁴ (Child FIRST)	Good	Low potential bias arising from each domain. In areas of some concern, the researchers made attempts to correct for potential bias.	Yes	No	Probably yes	Some concerns	The PI assigned families by coin toss, suggesting no concealment of allocation. Although there were some differences in maternal education and family CPW involvement history, differences do not appear to be the result of poor randomization.

Appendix E Table 1. Quality Ratings for RCTs, Part 1

Author, Year, Program/Trial Name	Overall Quality Rating	Overall Rationale for Quality Rating	Was method of randomization adequate?	Was allocation concealment adequate?	Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
Marcenko and Spence, 1994 ¹¹⁵	Fair	Some concerns in the departures from intended intervention domain due to no information provided regarding outcome assessors, cross-overs, or contamination; also no mention of masking or blinding. Some concerns in the missing outcome data domain because ITT analysis was not used; differences in reasons for attrition and rates of attrition between arms.	No information	No information	Yes	Uncertain because no information	None
Mejdoubi et al, 2015 ¹⁷⁶ (VoorZorg)	Poor	Bias due to missing outcome data because attrition was high and intent-to-treat analysis was not used. CPS reports were not available from some agencies, creating a potential for systematic differences in attrition.	Yes	NA	Yes	Low	None
Norr et al, 2003 ¹⁷⁷ (REACH-Futures)	Poor	Randomization process was unlikely adequate given deviations, deviation from intended intervention is not reported but is probable given downsizing during the intervention, primary benefit outcome is not ascertained, and potential reporting bias.	Probably no	No information	Yes	Some concerns	Subjects assigned to treatment/control groups based on their medical record number. African American and Mexican American subjects were supposedly randomized into treatment and control groups. but no further information was reported. Group characteristics were balanced within each ethnic group but not overall. Authors reported substantial background characteristics differences between African American and Mexican American subjects at intake (mostly $p < 0.01$). More African American women in treatment arm proportionately (56%) than Mexican American women (49%), unclear why.

Appendix E Table 1. Quality Ratings for RCTs, Part 1

Author, Year, Program/Trial Name	Overall Quality Rating	Overall Rationale for Quality Rating	Was method of randomization adequate?	Was allocation concealment adequate?	Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
Olds et al, 1986 ⁹⁵ Olds et al, 1994 ⁹⁶ Olds et al, 1997 ⁹⁷ Eckenrode et al, 2000 ⁹⁸ Zielinski et al, 2009 ⁹⁹ (The Elmira Trial)	Fair	Some concern about potential deviation from the intervention during the study duration.	Probably yes	Probably no	Probably yes	Some concerns	Some randomization overridden to avoid having women in the same house have different treatment assignments.
Paradis et al, 2013 ¹⁷⁸ (Building Healthy Children)	Poor	Critical information on study methods is missing or unclear for this preliminary analysis. Evaluation is ongoing for the trial. There is concern that this paper only reports on early completers who may be significantly different from the rest of the study population. It is also unclear who the analytic sample includes and how it is different from the enrolled sample.	Probably yes	Probably yes	Yes	Low	None
Quinlivan et al, 2003 ¹¹⁶	Fair	Some baseline imbalance, details not reported	Yes	Yes	No	Some concerns	Authors note that the following factors seemed imbalanced between the two groups at baseline: ethnic origin, social isolation, involvement of the father of the baby, and homelessness. Analyses controlled for these factors.
Robling et al, 2016 ⁹²	Fair	No blinding to allocation, some attrition and no sensitivity analyses, usual care received co-interventions that diluted the effect of the active intervention, poor fidelity	Yes	No	Yes	Low	No blinding to allocation concealment, but given the negative results, it does not seem likely that even if they were unblinded, it had an effect on study results.
Sadler et al, 2013 ⁹¹ (Minding the Baby)	Fair	Attrition >20%, no imputation for missing data, unclear whether CPS outcome measurement was record-based or self-report	Probably yes	yes	Yes	Low	None

Appendix E Table 1. Quality Ratings for RCTs, Part 1

Author, Year, Program/Trial Name	Overall Quality Rating	Overall Rationale for Quality Rating	Was method of randomization adequate?	Was allocation concealment adequate?	Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
Siegel et al, 1980 ⁸⁶	Fair	High attrition	No information	No information	Probably yes	Some concerns	Method of randomization is not described. Baseline data are only shown for those who had 4- and 12-month assessments completed. However a larger group of participants was used for determining health outcomes, and their baseline data are not shown. Authors report that there were not significant differences. Also, the mothers in the intervention group had higher scores on the vocabulary test that was given. In addition, there was some concern about the 41 participants who did not receive the intervention. If they were randomized, they should have been included, but it is not clear whether they were randomized or not.
Silovsky et al, 2011 ¹⁰⁸ (SafeCare+)	Far	High attrition	Yes	Probably yes	Yes	Low	None
Wagner and Clayton, 1999 ¹⁷⁹ (PAT: Salinas Valley)	Poor for	High level of attrition from study intervention, medium level of attrition.	No information	No information	Yes	Uncertain because no information	No information
Wagner and Clayton, 1999 ¹⁷⁹ (PAT: Teen)	Poor	High level of attrition from study evaluation and intervention.	No information	No information	Yes	Uncertain because no information	No information

Appendix E Table 1. Quality Ratings for RCTs, Part 1

Author, Year, Program/Trial Name	Overall Quality Rating	Overall Rationale for Quality Rating	Was method of randomization adequate?	Was allocation concealment adequate?	Were group characteristics balanced at baseline?	Bias arising from randomization or selection?	Comments
Wiggins et al, 2005 ¹¹⁸ , Wiggins et al, 2004 ¹¹⁷ (The Social Support and Family Health Study)	Fair	Some concerns about lack of blinding and poor uptake of second active intervention (CGS). Also CAN outcomes are based solely on parent self-report and not verified against medical records. Otherwise fair quality study.	Yes	Yes	Probably yes	Low	None

* Fair for abuse outcomes. Good for behavioral outcomes.

Abbreviations: CAN=Child abuse and neglect; CPS=Child Protective Services; CGS=Community group support; CPS= Child Protective Services; G=group; HFAK=Healthy Families Alaska ; HH=health home; HR=hazard ratio; HSP= Healthy Start Home visitation program plus ; HV=Home visits; IIT=intent to treat; PAT=Parents as Teachers; SEEK= Safe Environment for Every Kid ; vs.=versus.

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰² (Family Partnership Model)	Attrition at 12-month follow up: Overall: 8.4% G1: 7.9% G2: 8.8%	Yes	No information	Probably no	Probably no	Low	Although methods state that intent-to-treat analysis was used, data tables report analytic samples with attrition and no description of handling missing data is given; however, attrition is low.
Barth, 1991 ¹³⁴ (Child Parent Enrichment Program)	NR	No information	No information	No information	No information	Some concerns	No information about attrition
Brayden et al, 1993 ¹⁰⁹	Overall: 13.5% G1: 20.8% G2: 11.9%	Yes	Probably yes	Probably no	No information	Low	Subjects were lost due to women not having a live infant at birth and women who delivered at another hospital. Sufficient information was available for 88% of HR intervention subjects, 79% of HR control subjects, and 90% of LR control subjects. Scoring or randomization errors resulted in exclusion of data from 7 additional subjects in the LR control group. Overall, attrition was low and no information was provided as to whether intent-to-treat analysis was used.
Brooten et al, 1986 ¹¹⁰	No information	No information	No information	yes	No information	Uncertain because no information	No information provided regarding attrition

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Bugental and Schwartz, 2009 ¹⁰³ (Healthy Start+)	Overall: 7.2% G1: 3.4% G2: 11.8%	Yes	No information	No	No information	Some concerns	Completers of the program were significantly more likely to be immigrants compared with noncompleters. ITT analysis was not used.
Caldera et al, 2007 ⁸⁸ Duggan et al, 2007 ⁸⁷ (Healthy Families Alaska)	Overall: 15% G1: 14% G2: 15%	Yes	Probably no	Yes	Yes	Low	Families with versus those without a baseline interview were comparable on the Family Stress Checklist (FSC). However, in families followed up vs. those who withdrew, mothers were more likely to have worked before study enrollment (76% vs. 57%, $p=0.01$), more likely to be married or living with the child's partner (56% vs. 34%, $p<0.01$), and less likely to have enrolled prenatally (44% vs. 66%, $p=0.01$).
DePanfilis and Dubowitz, 2005 ¹⁷² (Family Connections)	Overall: NR G1: 5% G2: 25%	No	No	Yes	Yes	High	Differential attribution

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Dubowitz et al, 2009 ¹⁴⁸ (SEEK)	Overall: 24% G1: 23% G2: 24%	No	Probably yes	yes	No	Some concerns	There was >20% attrition from the study sample. No information is given on how missing data were dealt with, but only those who completed the study protocol were used in the analysis. The article reported using ITT analysis because participants were retained in their randomized arms regardless of how much intervention they received.
Dubowitz et al, 2012 ¹⁴⁷ (SEEK)	Practices: 1 INT practice/17 total practices (5.9%) withdrew before recruitment and after randomization Attrition at 6-month follow up: Overall: 19% G1: 22% G2: 17% Attrition at 12-month follow up: Overall: 20% G1: 22% G2: 18%	Yes	No information	No	No information	Uncertain because no information	The overall attrition and attrition by group were low. Attrition did not vary much between outcomes. The proportion of participants with missing data is similar across interventions, but slightly higher among SEEK participants. Reasons for missing data or attrition are unknown. Intent-to-treat analysis was not used, and no information was provided on the use of statistical methods to account for missing data.

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶	Intervention attrition: 51% Follow up attrition: 12%	No	Yes	Yes	Yes	High	About half of the enrolled families left the program within a year. ¹⁴⁶ But authors noted that all baseline participants were kept in the evaluation unless data were not available for specific outcomes. Reasons for attrition within the HSP group within the first year of the program included refusing service: 31%; moved: 11%; unable to contact: 4%; returned to work or school: 3%; became ineligible: 2%. Authors also noted that because families were identified through universal screening, attrition rate was expected to be higher. In addition, Hawaii suffered from a serious economic downturn. Budget cuts and funding leveling contributed to staff anxiety and turnover, which might have compromised service quality.

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
DuMont et al, 2008 ⁸⁹ DuMont et al, 2010 ⁹⁰ (Healthy Families New York)	Overall: 15.4% G1: 15% G2: 16%	Yes	No	Yes	Yes	Low	No information reported regarding whether attrition varied for different outcomes.
Easterbrooks et al, 2013 ¹⁰⁴ (Healthy Families Massachusetts)	No Information	No information	No information	Yes	No information	Uncertain because no information	No information regarding attrition or missing data was reported.
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ (Early Start Program)	Attrition at 3-year follow up: Overall: 11.7% G1: 7.2% G2: 16.4% Attrition at 6-year follow up: Overall: 13.1% G1: 8.1% G2: 18.2% Attrition at 9-year follow up: Overall: 16.5% G1: 10.7% G2: 22.3%	Yes	No information	Yes	Probably yes	Low	None

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Finello et al, 1998 ¹¹¹	<p>Overall attrition by outcomes:</p> <p>CPS abuse 6 m: 1/81, 1% CPS abuse 12 m: 12/81, 15%</p> <p>CPS neglect 6 m: 1/81, 1% 12 m: 12/81, 15%</p> <p>ER 6 m: 6/81, 7% 12 m: 13/81, 16%</p> <p>Hosp <24h 6 m: 5/81, 6% 12 m: 11/81, 14%</p> <p>Hosp >24h 6 m: 4/81, 5% 12 m: 13/81, 16%</p> <p>Group attrition by outcomes:</p> <p>CPS abuse 6 m: G1 0/20, 0% G2 1/21, 5% G3 0/20, 0% G4 0/20, 0%; 12 m: G1 1/20, 5% G2 5/21, 24% G3 5/20, 25% G4 1/20, 5%;</p> <p>CPS neglect 6 m: G1 0/20, 0% G2 1/21, 5% G3 0/20, 0% G4 0/20, 0%; 12 m: G1 1/20, 5% G2 5/21, 24% G3 5/20, 25% G4 1/20, 5%;</p> <p>ER</p>	Probably no	Probably no	Probably yes	Probably no	Some concerns	G2 and G3 are missing >20% data for most 12-month outcomes

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Finello et al, 1998 ¹¹¹ (continued)	6 m: G1 2/20, 10% G2 4/21, 19% G3 0/20, 0% G4 0/20, 0%; 12 m: G1 2/20, 10% G2 6/21, 29% G3 4/20, 20% G4 1/20, 5%; Hosp<24 6 m: G1 1/20, 5% G2 4/21, 19% G3 0/20, 0% G4 0/20, 0%; 12 m: G1 3/20, 15% G2 1/21, 5% G3 6/20, 30% G4 1/20, 5%; Hosp>24 6 m: G1 1/20, 5% G2 3/21, 14% G3 0/20, 0% G4 0/20, 0%; 12 m: G1 2/20, 10% G2 6/21, 29% G3 4/20, 20% G4 1/20, 5%						
Gray et al, 1977 ¹³⁶ Gray et al, 1979 ¹³⁵	No information	No information	No information	Yes	No information	High	Study did not report on attrition. Instead of analyzing all 150 participants, researchers took a random sample of 75 (25 in the high-risk intervention group, 25 in the high-risk nonintervention, and 25 in the low-risk control group) to conduct at-home visits and collect follow up information). The 75 randomly selected participants were all included in the analyses.

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Guyer et al, 2003 ¹¹² Minkovitz et al, 2007 ¹¹³ (Healthy Steps for Young Children)	Overall attrition at 2- to 4-month follow up: 12% Overall attrition at 30- to 33-month follow up: 34% Overall attrition at 5- to 5.5-year follow up: 43%	No	Probably yes	Yes	Yes	Some concerns	Missing data were purposefully not statistically adjusted for in the interest of an ITT analytic approach. High attrition. No information provided were missing data in control group vs. intervention group.
Hardy and Streett, 1989 ¹⁷³ (Child and Youth Program)	Overall: <1% G1: 0% G2: 1%	Yes	Yes	NA	NA	Low	None

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Infante-Rivard et al, 1989 ¹⁷⁴	Overall: 12-33%	Probably no	No information	Probably no	No information	High	21% (n=17) mothers admitted to the study (n=73) did not actually participate. An additional 12% of subjects (n=9) lost to follow up after the child was born. 26 dyads that were enrolled and had consented to participate (i.e., were randomized) were then dropped due to refusing after signing consent, experiencing post-natal exclusion criteria, moving, or not being able to be reached. This loss after randomization may account for some of differences in the experimental and control groups.) Authors noted that the choice of socially deprived mothers as a target group may have led to high dropout rate. Attrition in this study was highest among what has been referred to as attenuated nuclear families (only the mother and the children are present in the home). Unclear if ITT used.

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Kitzman et al, 1997 ⁹³ Olds et al, 2007 ⁹⁴ (The Memphis Trial)	No information	Probably yes	Yes	Probably no	No information	Some concerns	Low attrition at 6-month follow up. Attrition increased over time (9 years) but similar across groups. Lack of information on how missing data were handled.
Koniak-Griffin et al, 2002 ¹⁷⁵ Koniak-Griffin et al, 2003 ¹⁷¹ (Early Intervention Program)	Overall: 29.9% G1: 37.5% G2: 22.2%	No	No	No	No information	High	High attrition and differential attrition, no ITT analysis.
Lam et al, 2009 ¹⁰⁰	Overall: 17% G1: NR G2: NR	Yes	No information	Probably yes	Yes	Some concerns	Small sample size, some missing data, use of multiple imputation stated in methods, but N for analysis not clearly specified.
Larson, 1980 ¹⁰⁷	Overall: 22% G1: 16% G2: 26% G3: 25%	No	Probably no	Probably yes	Probably no	Some concerns	Control group with lower attrition than either intervention group.
Lowell et al, 2011 ¹¹⁴ (Child FIRST)	Attrition at 6-month follow up: Overall: NR G1: 15.5% G2: 17.9% Attrition at 12-month follow up: Overall 25.5% G1: 25.3% G2: 25.6%	Probably yes	Yes	Yes	Probably yes	Low	Analyses of CPS involvement were conducted on the total number of participants randomized at enrollment (n=157). Participants who withdrew from the two groups were similar on all baseline characteristics.

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Marcenko and Spence, 1994 ¹¹⁵	Overall: 17% G1: 23% G2: 12%	Yes	No	No	No information	Some concerns	Intent-to-treat analysis was not used. Greater attrition in control group because participants not followed by the intervention team.
Mejdoubi et al, 2015 ¹⁷⁶ (VoorZorg)	Attrition at 24 months after birth for female caregivers Overall: 52% G1: 58% G2: 45%	No	Yes	No	Yes	High	Missing outcome data raises some concerns due to relatively high attrition (52% overall) and high differential attrition, although researchers found no significant differences in baseline characteristics among completers and noncompleters assigned to the control and intervention groups.

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Norr et al, 2003 ¹⁷⁷ (REACH-Futures)	Children not retained sufficiently in the intervention (i.e., ≥ 10 months): G1: 10% G2: 8%	No information	No information	No	Probably yes	Uncertain because no information	Inclusion criteria are problematic because they comprise study retention (i.e., only families with a high level of program/study retention were included in the analysis). Even taking into account those lost to follow up because they did not reach the 10-month minimum for inclusion, the study had remarkably low attrition for a home visiting effort, which is likely attributable to the home visiting program being an extension of a comprehensive primary care program. It seems that their analysis was not ITT, as the 27 subjects that were excluded should have been included in the analysis.

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Olds et al, 1986 ⁹⁵ Olds et al, 1994 ⁹⁶ Olds et al, 1997 ⁹⁷ Eckenrode et al, 2000 ⁹⁸ Zielinski et al, 2009 ⁹⁹ (The Elmira Trial)	Overall 15-21% in the first 2 years of the children's lives; nondifferential across treatments. ⁹⁵ Attrition at 15 years after birth: ⁹⁷ G1: 19.6% G2: 21.0% G3: 16.4%	Probably yes	Probably yes	Yes	No information	Uncertain because no information	Unclear how total N reduced from 314 to 237.
Paradis et al, 2013 ¹⁷⁸ (Building Healthy Children)	No information [†]	No information	No information	No information	No information	High	Evaluation is ongoing for the trial. There is concern that this paper only reports on early completers who may be significantly different from the rest of the study population. It is also unclear who the analytic sample includes and how it is different from the enrolled sample.
Robling et al, 2016 ⁹²	Overall: 78.3% G1 (usual care): 78.6% G2 (NFP): 78.1% For ED visits/hospitalizations: G1=753/822, G2=725/823; lower for other outcomes (<80%)	Probably no	Yes	No	No	Some concerns	ED/admission data did not use ITT, nor did they provide sensitivity analyses, but given negative results and similarity of dropout, not clear if failure to do ITT had an impact

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Sadler et al, 2013 ⁹¹ (Minding the Baby)	Attrition at 12-month follow up: Overall: 26% G1: 24% G2: 27% Attrition at 24-month follow up: Overall: 29% G1: 31% G2: 27%	No	Yes	Probably no	Probably yes	Some concerns	High attrition; analyses do not appear to account for missing data.
Siegel et al, 1980 ⁸⁶	Data from 321 women were included in the analysis but unclear if the N randomized was the N eligible (525) or a smaller number. If the N randomized was 525, attrition could have been 38.9%	Probably no	Yes	No	Probably no	Some concerns	For the health outcomes, all 321 participants were used, so there is less bias for those than the attachment measures. Unclear whether N analyzed is N randomized
Silovsky et al, 2011 ¹⁰⁸ (SafeCare+)	Attrition at 10-month follow up: Overall: 16.2% G1: 21.1% G2: 10.4% Attrition at 17-month follow up: Overall: 24.8% G1: 21.1% G2: 29.1%	no	Probably yes	Yes	Yes	Some concerns	High differential attrition at 17 months
Wagner and Clayton, 1999 ¹⁷⁹ (PAT: Salinas Valley)	Overall: 27% (for emergency room visits) G1: 23% G2: 30%	No	Yes	Probably yes	Probably no	Some concerns	Somewhat high attrition; no description of handling missing data. Attrition from intervention was much higher than from evaluation.

Appendix E Table 2. Quality Ratings for RCTs, Part 2

Author, Year, Program/Trial Name	What was the overall attrition and attrition by group? Did attrition vary for different outcomes?	Did the study have low attrition?	Are the proportion of participants and reasons for missing data similar across interventions?	For benefits outcomes, was intent-to-treat analysis used?	Were appropriate statistical methods used to account for missing data?	Bias arising from missing outcome data?	Comments
Wagner and Clayton, 1999 ¹⁷⁹ (PAT: Teen)	Overall: 48% (for emergency department visits, 15% for CPS) G1: 46% G2: 49% G3: 49% G4: 49%	No	Yes	Probably yes	Probably no	High	Very high attrition, no description of handling missing data. Attrition from intervention was much higher than from evaluation.
Wiggins et al, 2005 ¹¹⁸ Wiggins et al, 2004 ¹¹⁷ (The Social Support and Family Health Study)	Attrition at 12-month follow up: Overall: NR G1: 10% G2: 11% G3: 10% Attrition at 18-month follow up: Overall: NR G1: 18% G2: 15% G3: 20%	Yes	Probably yes	Yes	Probably yes	Low	Overall attrition for both follow up time points was at or lower than 20% and there was no differential attribution between groups.

* Authors reported in Fergusson et al, 2013¹⁰⁶ 11% attrition in the intervention group compared to 16% of attrition in the control at the 9-year followup. Author's calculation omits the 2 cases in the control group and the 14 cases in the intervention group that declined participation within the first month after assignment.

† Evaluation is ongoing for the trial. Analyses were conducted on those who completed the study "to date," which is only 43% of the 497 enrolled families. Abstract states that 85% of families remained enrolled by age 3 but paper only presents data on 43%, which appears to be those who completed the program.

Abbreviations: CPS=Child Protective Services; ER=emergency room; FSC=Family Stress Checklist; G=group; HR=hazard ratio; HSP= Healthy Start Home visitation program; ITT=intent to treat; LR=Lowrisk ; N=number; NA=not applicable; NR=not reported; PAT=Parents as Teachers; SEEK= Safe Environment for Every Kid.

Appendix E Table 3. Quality Ratings for RCTs, Part 3

Author, Year, Program/Trial Name	Were the patients unaware of the intervention status of participants?	Were the trial personnel and clinicians unaware of the intervention status of participants?	Were outcome assessors unaware of the intervention status of participants?	Was intervention fidelity adequate?	Were crossovers or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰² (Family Partnership Model)	Probably no	Probably no	Yes	Probably yes	Probably yes	Low	None
Barth, 1991 ¹³⁴ (Child Parent Enrichment Program)	No	No	No	Probably yes	No	Some concerns	Post-test measures were completed by interviewers who knew the client's status, not blinded.
Brayden et al, 1993 ¹⁰⁹	No	No	Yes	Probably yes	Probably yes	Low	As a result of closer monitoring, an increased number of reports were made to DHS for physical abuse and neglect in the HR intervention group; analyses were run excluding these participants with no significant differences found.
Brooten et al, 1986 ¹¹⁰	No	No	Probably yes	No information	Probably yes	Low	None
Bugental and Schwartz, 2009 ¹⁰³ (Healthy Start+)	Probably no	No	No information	Probably yes	No information	Low	None

Appendix E Table 3. Quality Ratings for RCTs, Part 3

Author, Year, Program/Trial Name	Were the patients unaware of the intervention status of participants?	Were the trial personnel and clinicians unaware of the intervention status of participants?	Were outcome assessors unaware of the intervention status of participants?	Was intervention fidelity adequate?	Were crossovers or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Caldera et al, 2007 ⁸⁸ Duggan et al, 2007 ⁸⁷ (Healthy Families Alaska)	Probably no	Probably no	Yes	Probably yes	Yes	Low	Because the foundation of the intervention was home visits, it is likely participants in the control and home visitation groups were aware of their intervention status. Similarly, personnel conducting the intervention were aware of the type of visitation to be conducted with each participating family. However, other study staff and outcome assessors were blinded. The nature of the intervention also limited the ability of participants to cross over.
DePanfilis and Dubowitz, 2005 ¹⁷² (Family Connections)	Probably no	No	Probably no	Probably no	Probably no	high	No blinding of intervention providers. Patients self-reported outcomes. "High-dose" group (FC9) was actually a combination of the FC9 and FC9+g groups of the original protocol design.
Dubowitz et al, 2009 ¹⁴⁸ (SEEK)	Probably yes	Probably yes	No	Probably yes	No information	Some concerns	The study assessed the extent to which targeted problems were identified and addressed during intervention sessions via the medical chart review; however, they do not present results of this analysis. It is unclear how much contamination occurred and risk for contamination seems high.

Appendix E Table 3. Quality Ratings for RCTs, Part 3

Author, Year, Program/Trial Name	Were the patients unaware of the intervention status of participants?	Were the trial personnel and clinicians unaware of the intervention status of participants?	Were outcome assessors unaware of the intervention status of participants?	Was intervention fidelity adequate?	Were crossovers or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Dubowitz et al, 2012 ¹⁴⁷ (SEEK)	No	No	No	Probably yes	Probably yes	Some concerns	The researchers adjusted for unknown differences and random effects from practices, which helps account for unintended exposure. Contamination and cross over were probably minimal due to private practice setting, trained health professionals, and on-site social worker, which were all out of access to the control group. However, caregivers, trial personnel and clinicians, and outcome assessors were aware of the intervention status of participants due to the nature of the SEEK program and use of PSQs. Although children <5 years were likely unaware of their intervention status, mothers' unblinding may raise concern for bias and minimally affect the CTS, PC outcome measure.

Appendix E Table 3. Quality Ratings for RCTs, Part 3

Author, Year, Program/Trial Name	Were the patients unaware of the intervention status of participants?	Were the trial personnel and clinicians unaware of the intervention status of participants?	Were outcome assessors unaware of the intervention status of participants?	Was intervention fidelity adequate?	Were crossovers or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶	Probably no	No	Yes	No	No information	High	Authors reported several issues regarding fidelity: 1) agencies taking part in the evaluation varied greatly in family retention rates, home visit frequency, and home visitor ratings likely reflecting differences in philosophy (i.e., whether the entire family is the primary client or just the index child); 2) intervention model seemed to be applied differently in different settings by different agencies; 3) home visitors likely lacked sufficient expertise and supervision to address family risks for abuse, motivate families to change, and link families with professional services; 4) program's management information system had incomplete data for monitoring service delivery.
DuMont et al, 2008 ⁸⁹ DuMont et al, 2010 ⁹⁰ (Healthy Families New York)	Probably no	No	Yes	No information	Probably yes	Some concerns	Likely patients were not blinded and clinicians were not blinded. No information on fidelity.

Appendix E Table 3. Quality Ratings for RCTs, Part 3

Author, Year, Program/Trial Name	Were the patients unaware of the intervention status of participants?	Were the trial personnel and clinicians unaware of the intervention status of participants?	Were outcome assessors unaware of the intervention status of participants?	Was intervention fidelity adequate?	Were crossovers or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Easterbrooks et al, 2013 ¹⁰⁴ (Healthy Families Massachusetts)	Probably no	Probably no	No information	No information	No information	Uncertain because no information	No information
Fergusson et al, 2005, ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ (Early Start Program)	Probably no	Probably no	Probably no	No information	No information	Some concerns	No blinding to group assignment was undertaken. Although fidelity data not provided, authors report level of participation in the intervention, with fairly high rates (59.5% of participants active in the program at the 3-year follow up).
Finello et al, 1998 ¹¹¹	No	No information	No information	No information	No information	Some concerns	The different interventions were “systems” interventions already in place at the hospital. There is very limited information provided about the intended intervention and no information about implementation.
Gray et al, 1977 ¹³⁶ Gray et al, 1979 ¹³⁵	No	No	No information	No information	Probably yes	Uncertain because no information	Patients and investigators not blinded to group assignment due to the nature of the study. No information about whether assessors were blinded to participants’ assigned group.

Appendix E Table 3. Quality Ratings for RCTs, Part 3

Author, Year, Program/Trial Name	Were the patients unaware of the intervention status of participants?	Were the trial personnel and clinicians unaware of the intervention status of participants?	Were outcome assessors unaware of the intervention status of participants?	Was intervention fidelity adequate?	Were crossovers or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Guyer et al, 2003 ¹¹² Minkovitz et al, 2007 ¹¹³ (Healthy Steps for Young Children)	Probably yes	Probably no	Yes	Yes	No information	Some concerns	Authors noted that the sites participating in this clinical trial might not be comparable to all pediatric practices and cautioned that the randomizataion design might introduce possible spillover effects. HS incorporated into its package of services a number of strategies that were already in use in pediatric practices or other agencies in the community. The evaluation gathered information on the number of duplicate services as well as changing practice patterns that might have influenced the findings.
Hardy and Streett, 1989 ¹⁷³ (Child and Youth Program)	Probably no	No	No information	No information	No information	Some concerns	The intervention was developed for the purpose of this small, single study and delivered by exactly one home visitor, which is an unusual model and one that raises concerns about any bias that one provider may have brought to the intervention. No information reported on intervention fidelity. Analyses present the findings from the home visiting effort, without taking into account intervention considerations associated with the comprehensive care services.

Appendix E Table 3. Quality Ratings for RCTs, Part 3

Author, Year, Program/Trial Name	Were the patients unaware of the intervention status of participants?	Were the trial personnel and clinicians unaware of the intervention status of participants?	Were outcome assessors unaware of the intervention status of participants?	Was intervention fidelity adequate?	Were crossovers or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Infante-Rivard et al, 1989 ¹⁷⁴	No information	No information	No information	No information	Probably yes	Uncertain because no information	No information
Kitzman et al, 1997 ⁹³ Olds et al, 2007 ⁹⁴ (The Memphis Trial)	No	Probably no	Probably yes	Probably yes	Probably yes	Some concerns	Clinicians who treated the participants were aware of assignments and did some of the outcome assessments. It was not possible to blind participants in this kind of intervention. Outcome assessors extracting data from medical records were blinded. Interviewers were mostly unaware of treatment assignment in both studies. Those coding interview data were blinded. Teachers, who completed evaluations when children were age 9, were probably blinded.
Koniak-Griffin et al, 2002 ¹⁷⁵ Koniak-Griffin et al, 2003 ¹⁷¹ (Early Intervention Program)	No	No	Yes	Probably yes	Yes	Low	None
Lam et al, 2009 ¹⁰⁰	No information	Probably no	No information	Yes	No information	Uncertain because no information	Unclear whether outcome assessors were masked.
Larson, 1980 ¹⁰⁷	Probably no	Probably no	Yes	No information	Probably yes	Low	None

Appendix E Table 3. Quality Ratings for RCTs, Part 3

Author, Year, Program/Trial Name	Were the patients unaware of the intervention status of participants?	Were the trial personnel and clinicians unaware of the intervention status of participants?	Were outcome assessors unaware of the intervention status of participants?	Was intervention fidelity adequate?	Were crossovers or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Lowell et al, 2011 ¹¹⁴ (Child FIRST)	No	Probably No	Probably no	Probably yes	Probably yes	Low	Some concerns were raised in this domain due to the lack of blinding among participants. Efforts were made to keep the research assistants unaware of group status, although they frequently learned about participants' status during follow up interviews. Researchers attempted to mask the effect of unblinding by ensuring research assistants are trained to administer and assess items in a standard fashion. This section was given a low bias rating because the impact of unblinding on participant outcomes is likely minimal.
Marcenko and Spence, 1994 ¹¹⁵	Probably no	Probably no	No information	Probably yes	No information	Some concerns	No information provided regarding outcome assessors, cross-overs, or contamination; also no mention of masking or blinding.
Mejdoubi et al, 2015 ¹⁷⁶ (VoorZorg)	No	No	Yes	No information	Yes	Some concerns	No information

Appendix E Table 3. Quality Ratings for RCTs, Part 3

Author, Year, Program/Trial Name	Were the patients unaware of the intervention status of participants?	Were the trial personnel and clinicians unaware of the intervention status of participants?	Were outcome assessors unaware of the intervention status of participants?	Was intervention fidelity adequate?	Were crossovers or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Norr et al, 2003 ¹⁷⁷ (REACH-Futures)	No information	No information	Yes	Probably no	No information	Some concerns	No information on whether the participants and trained interviewers knew of the intervention status of the mothers. Analysis took into account all baseline differences between the African American and Mexican American mothers and presumably between intervention and control group participants within each racial group. Authors noted that downsizing during the program likely affected program delivery to Mexican Americans more than African Americans, because as a group they were recruited into the study later.
Olds et al, 1986 ⁹⁵ Olds et al, 1994 ⁹⁶ Olds et al, 1997 ⁹⁷ Eckenrode et al, 2000 ⁹⁸ Zielinski et al, 2009 ⁹⁹ (The Elmira Trial)	Yes	Probably yes	No	No information	Probably yes	Some concerns	A few cases of mothers inadvertently revealing that they were visited by a nurse, but the staff gathering the data were told that the 15-year follow up study was designed to assess the long-range effect of prenatal and early childhood services, including home visitations by nurses. ⁹⁷ The principal investigators and statisticians had access to the families' treatment assignments.

Appendix E Table 3. Quality Ratings for RCTs, Part 3

Author, Year, Program/Trial Name	Were the patients unaware of the intervention status of participants?	Were the trial personnel and clinicians unaware of the intervention status of participants?	Were outcome assessors unaware of the intervention status of participants?	Was intervention fidelity adequate?	Were crossovers or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Paradis et al, 2013 ¹⁷⁸ (Building Healthy Children)	Probably no	Probably no	No information	No information	No information	Some concerns	No discussion of blinding or intervention fidelity.
Robling et al, 2016 ⁹²	No	No	Probably yes	Probably yes	Probably no	Some concerns	Usual care received more frequent home visiting services than intervention arm, likely washing out the intervention effect. Only CATI outcomes were collected by blinded assessors. Field assessors were not blinded. This is less of an issue for ED visits/hospitalizations than it would be for some of the behavioral outcomes
Sadler et al, 2013 ⁹¹ (Minding the Baby)	Probably no	Probably no	Probably yes	Yes	No information	Low	None
Siegel et al, 1980 ⁸⁶	No	No	Yes	Probably yes	Yes	Low	None
Silovsky et al, 2011 ¹⁰⁸ (SafeCare+)	Probably no	Probably no	Probably no	Yes	No information	Low	None
Wagner and Clayton, 1999 ¹⁷⁹ (PAT: Salinas Valley)	Probably no	Probably no	Yes	No	Probably yes	Some concerns	Does not specify how training accomplished for the parent educators providing the intervention; large variation of education with some with bachelor's degrees and others without.

Appendix E Table 3. Quality Ratings for RCTs, Part 3

Author, Year, Program/Trial Name	Were the patients unaware of the intervention status of participants?	Were the trial personnel and clinicians unaware of the intervention status of participants?	Were outcome assessors unaware of the intervention status of participants?	Was intervention fidelity adequate?	Were crossovers or contamination minimal such that it would not raise concern for bias?	Bias arising from departures from intended interventions?	Comments
Wagner and Clayton, 1999 ¹⁷⁹ (PAT: Teen)	Probably no	Probably no	Yes	No	Probably yes	Some concerns	Does not specify how training accomplished for the parent educators providing the intervention; large variation of education with some with bachelor's degrees and others without.
Wiggins et al, 2005 ¹¹⁸ Wiggins et al, 2004 ¹¹⁷ (The Social Support and Family Health Study)	No	No	No*	Probably yes	Probably yes	Some concerns	Because of the nature of the interventions, it was not possible for either the trial participants or the researchers to be blinded to group allocation. Authors noted that potential confounders were balanced in randomization. However, authors did note poor uptake of CGS intervention.

* Data entry staff were blind to allocation at the second followup but not the first followup when the questionnaires contained additional sections for the two intervention arms of the trial.

Abbreviations: CGS=Community group support; CTSPC=Conflict Tactics Scale (Parent-Child) ; DHS=Department of Health Services; FC9=Family connections for 9 months; HR=hazard ratio; PAT=Parents as Teachers; PSQ=Parent Screening Questionnaire ; SEEK= Safe Environment for Every Kid .

Appendix E Table 4. Quality Ratings for RCTs, Part 4

Author, Year, Program/Trial Name	Were benefit outcomes adequately described, prespecified, valid, and reliable?	Were similar techniques used among groups to ascertain benefit outcomes?	Was the duration of follow up adequate to assess benefit outcomes?	Bias arising from measurement of benefit outcomes?	Comments
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰² (Family Partnership Model)	No information	Probably no	Yes	Some concerns	For abuse outcomes, the methods only state that “participating health visitors provided data relating to case conferences, children on the protection register, children removed from the home and child deaths.” Because health visitors had far more contact with the intervention group, it is unclear how this method is equally valid for each group. It is unclear where health visitors got the information about these outcomes (e.g., via health records or purely self-report). Behavioral outcomes appear to have low concern for bias.
Barth, 1991 ¹³⁴ (Child Parent Enrichment Program)	Probably yes	Yes	Yes	Low	Outcomes were not well described, but most are objective and based on reports and so likely valid and reliable.
Brayden et al, 1993 ¹⁰⁹	Yes	Yes	No information	Low	It is possible that one unintended effect of the intervention was increased surveillance leading to closer contact with the health care system, which may have led to increased identification of maltreatment, leading to detection of maltreatment that would have otherwise been unrecognized. To control for this, the 6 physical abuse reports made by the hospital were removed and the differences between the groups were nonsignificant
Brooten et al, 1986 ¹¹⁰	No information	Probably yes	Yes	Uncertain because no information	No information about how the 2 reports of child abuse were described or assessed.
Bugental and Schwartz, 2009 ¹⁰³ (Healthy Start+)	Yes	Yes	Yes	Low	None

Appendix E Table 4. Quality Ratings for RCTs, Part 4

Author, Year, Program/Trial Name	Were benefit outcomes adequately described, prespecified, valid, and reliable?	Were similar techniques used among groups to ascertain benefit outcomes?	Was the duration of follow up adequate to assess benefit outcomes?	Bias arising from measurement of benefit outcomes?	Comments
Caldera et al, 2007 ⁸⁸ Duggan et al, 2007 ⁸⁷ (Healthy Families Alaska)	Probably yes	Yes	Yes	Low	This study assessed a number of outcome measures to ascertain child maltreatment. While some measures were adequately described, others were limited in their description, especially those derived from scales and subscales; cutoff measures were not specified for continuous measures.
DePanfilis and Dubowitz, 2005 ¹⁷² (Family Connections)	Yes	Yes	Yes	Low	None
Dubowitz et al, 2009 ¹⁴⁸ (SEEK)	Yes	Yes	Probably yes	Low	None
Dubowitz et al, 2012 ¹⁴⁷ (SEEK)	Probably yes	Yes	Yes	Low	None
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ ,	Yes	Yes	Yes	Low	None
DuMont et al, 2008 ⁸⁹ DuMont et al, 2010 ⁹⁰ (Healthy Families New York)	Yes	Yes	Yes	Low	None
Easterbrooks et al, 2013 ¹⁰⁴ (Healthy Families Massachusetts)	Yes	Yes	Yes	Low	None

Appendix E Table 4. Quality Ratings for RCTs, Part 4

Author, Year, Program/Trial Name	Were benefit outcomes adequately described, prespecified, valid, and reliable?	Were similar techniques used among groups to ascertain benefit outcomes?	Was the duration of follow up adequate to assess benefit outcomes?	Bias arising from measurement of benefit outcomes?	Comments
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ (Early Start Program)	Probably yes	Yes	Yes	Low	Authors reported that “no blinding to assignment was undertaken,” which suggests that study personnel, assessors, and participants were not blinded. Child abuse and neglect outcomes only assessed via parent report using severe/very severe assault subscale of the Parent-Child Tactics Scale and parent report of involvement with CPS. The latter is subject to bias without confirmatory data from child welfare records. Authors do provide additional CAN data: 7 children were admitted to the hospital for child abuse and neglect (5 from control group and 2 from Early Start group).
Finello et al, 1998 ¹¹¹	Yes	Yes	Yes	Low	None
Gray et al, 1977 ¹³⁶ Gray et al, 1979 ¹³⁵	No information	Probably yes	Yes	Uncertain because no information	Children were assessed for the presence of incidents of “abnormal parenting practices” including verified reports of abuse and neglect to the Central Child Abuse registry, injury secondary to lack of adequate care/surgery or suspicious for inflicted trauma, failure to thrive thought secondary to deprivation, relinquishments, foster care placements, parental kidnappings. More specific information about outcomes not specified.
Guyer et al, 2003 ¹¹² Minkovitz et al, 2007 ¹¹³ (Healthy Steps for Young Children)	Yes	Yes	Yes	Low	None
Hardy and Streett, 1989 ¹⁷³ (Child and Youth Program)	Yes	Yes	Probably yes	Low	None

Appendix E Table 4. Quality Ratings for RCTs, Part 4

Author, Year, Program/Trial Name	Were benefit outcomes adequately described, prespecified, valid, and reliable?	Were similar techniques used among groups to ascertain benefit outcomes?	Was the duration of follow up adequate to assess benefit outcomes?	Bias arising from measurement of benefit outcomes?	Comments
Infante-Rivard et al, 1989 ¹⁷⁴	Probably no	Yes	Probably yes	Some concerns	Outcome information obtained during follow up visit. Authors did not mention whether outcomes are ascertained by review of medical records and it sounds like they asked mothers about health outcomes “at the 15-month visit, information on the child’s disease status and immunization during the preceding year was obtained.”
Kitzman et al, 1997 ⁹³ Olds et al, 2007 ⁹⁴ (The Memphis Trial)	Yes	Yes	Yes	Low	None
Koniak-Griffin et al, 2002 ¹⁷⁵ Koniak-Griffin et al, 2003 ¹⁷¹ (Early Intervention Program)	Yes	Yes	Yes	Low	None
Lam et al, 2009 ¹⁰⁰	Yes	Yes	Probably yes	Low	None
Larson, 1980 ¹⁰⁷	Yes	Yes	Yes	Low	None
Lowell et al, 2011 ¹¹⁴ (Child FIRST)	Yes	Yes	Yes	Low	None
Marcenko and Spence, 1994 ¹¹⁵	Probably yes	Yes	Yes	Low	None
Mejdoubi et al, 2015 ¹⁷⁶ (VoorZorg)	Yes	Yes	Yes	Low	None
Norr et al, 2003 ¹⁷⁷ (REACH-Futures)	Yes	No	Probably yes	Some concerns	Primary benefit outcome is reported abuse or neglect, which were not verified against official CPS records. Authors noted potential underestimate because only more serious cases tend to be reported and families may want to conceal these incidents during self-report.

Appendix E Table 4. Quality Ratings for RCTs, Part 4

Author, Year, Program/Trial Name	Were benefit outcomes adequately described, prespecified, valid, and reliable?	Were similar techniques used among groups to ascertain benefit outcomes?	Was the duration of follow up adequate to assess benefit outcomes?	Bias arising from measurement of benefit outcomes?	Comments
Olds et al, 1986 ⁹⁵ Olds et al, 1994 ⁹⁶ Olds et al, 1997 ⁹⁷ Eckenrode et al, 2000 ⁹⁸ Zielinski et al, 2009 ⁹⁹ (The Elmira Trial)	Yes	Yes	Yes	Low	None
Paradis et al, 2013 ¹⁷⁸ (Building Healthy Children)	Yes	Probably yes	Probably yes	Low	None
Robling et al, 2016 ⁹²	Yes	Yes	Yes	Low	None
Sadler et al, 2013 ⁹¹ (Minding the Baby)	Probably yes	Probably yes	Yes	Some concerns	No information on how CPS outcomes were measured: unclear whether record-based or self-report.
Siegel et al, 1980 ⁸⁶	Probably yes	Yes	Yes	Low	None
Silovsky et al, 2011 ¹⁰⁸ (SafeCare+)	Yes	Yes	Yes	Low	None
Wagner and Clayton, 1999 ¹⁷⁹ (PAT: Salinas Valley)	Yes	Yes	Yes	Low	None
Wagner and Clayton, 1999 ¹⁷⁹ (PAT: Teen)	Yes	Yes	Yes	Low	None

Appendix E Table 4. Quality Ratings for RCTs, Part 4

Author, Year, Program/Trial Name	Were benefit outcomes adequately described, prespecified, valid, and reliable?	Were similar techniques used among groups to ascertain benefit outcomes?	Was the duration of follow up adequate to assess benefit outcomes?	Bias arising from measurement of benefit outcomes?	Comments
Wiggins et al, 2005 ¹¹⁸ Wiggins et al, 2004 ¹¹⁷ (The Social Support and Family Health Study)	Probably no	NA	Probably yes	Some concerns	All outcomes are based on parent self-report and not verified against medical records.

Abbreviations: CAN=Child abuse and neglect; CPS=child protective services; NA=not applicable; PAT=Parents as Teachers.

Appendix E Table 5. Quality Ratings for RCTs, Part 5

Author, Year, Program/Trial Name	Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias arising from selection of reported results?	Comments
Barlow et al, 2007 ¹⁰¹ McIntosh et al, 2009 ¹⁰² (Family Partnership Model)	Probably yes	Low	None
Barth, 1991 ¹³⁴ (Child Parent Enrichment Program)	Yes	Low	None
Brayden et al, 1993 ¹⁰⁹	Yes	Low	None
Brooten et al, 1986 ¹¹⁰	Yes	Low	None
Bugental and Schwartz, 2009 ¹⁰³ (Healthy Start+)	Probably yes	Low	None
Caldera et al, 2007 ⁸⁸ Duggan et al, 2007 ⁸⁷ (Healthy Families Alaska)	Yes	Low	None
DePanfilis and Dubowitz, 2005 ¹⁷² (Family Connections)	Probably yes	Low	None
Dubowitz et al, 2009 ¹⁴⁸ (SEEK)	Probably yes	Low	None
Dubowitz et al, 2012 ¹⁴⁷ (SEEK)	Yes	Low	None
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶	Yes	Low	None
DuMont et al, 2008 ⁸⁹ DuMont et al, 2010 ⁹⁰ (Healthy Families New York)	Yes	Low	None
Easterbrooks et al, 2013 ¹⁰⁴ (Healthy Families Massachusetts)	Yes	Low	None
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ (Early Start Program)	Probably yes	Low	None
Finello et al, 1998 ¹¹¹	Probably yes	Low	None

Appendix E Table 5. Quality Ratings for RCTs, Part 5

Author, Year, Program/Trial Name	Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias arising from selection of reported results?	Comments
Gray et al, 1977 ¹³⁶ Gray et al, 1979 ¹³⁵	Yes	Low	None
Guyer et al, 2003 ¹¹² Minkovitz et al, 2007 ¹¹³ (Healthy Steps for Young Children)	Yes	Low	None
Hardy and Streett, 1989 ¹⁷³ (Child and Youth Program)	Yes	Low	None
Infante-Rivard et al, 1989 ¹⁷⁴	Probably yes	Low	None
Kitzman et al, 1997 ⁹³ Olds et al, 2007 ⁹⁴ (The Memphis Trial)	Yes	Low	None
Koniak-Griffin et al, 2002 ¹⁷⁵ Koniak-Griffin et al, 2003 ¹⁷¹ (Early Intervention Program)	Probably yes	Low	None
Lam et al, 2009 ¹⁰⁰	Yes	Low	None
Larson, 1980 ¹⁰⁷	Yes	Low	None
Lowell et al, 2011 ¹¹⁴ (Child FIRST)	Yes	Low	None
Marcenko and Spence, 1994 ¹¹⁵	Probably yes	Low	None
Mejdoubi et al, 2015 ¹⁷⁶ (VoorZorg)	Yes	Low	None
Norr et al, 2003 ¹⁷⁷ (REACH-Futures)	Probably no	Some concerns	This publication appears to be a subgroup analysis of the larger REACH-Futures study, which is a program run by the University of Illinois at Chicago through its community clinics. A separate publication reported program results on 666 study participants (including African American, Latina, and other ethnic groups). The relationship between the two studies is unclear. Cannot identify the mother study protocol to determine if there is indeed a reporting bias.

Appendix E Table 5. Quality Ratings for RCTs, Part 5

Author, Year, Program/Trial Name	Is the reported effect estimate unlikely to be selected, on the basis of the results, from multiple outcomes measurements within the domain, multiple analyses, or different subgroups?*	Bias arising from selection of reported results?	Comments
Olds et al, 1986 ⁹⁵ Olds et al, 1994 ⁹⁶ Olds et al, 1997 ⁹⁷ Eckenrode et al, 2000 ⁹⁸ Zielinski et al, 2009 ⁹⁹ (The Elmira Trial)	Yes	Low	None
Paradis et al, 2013 ¹⁷⁸ (Building Healthy Children)	Probably no	Some concerns	Unclear whether they are reporting on all of their prespecified outcomes of interest
Robling et al, 2016 ⁹²	Probably yes	Low	None
Sadler et al, 2013 ⁹¹ (Minding the Baby)	Yes	Low	None
Siegel et al, 1980 ⁸⁶	Probably yes	Low	None
Silovsky et al, 2011 ¹⁰⁸ (SafeCare+)	Yes	Low	None
Wagner and Clayton, 1999 ¹⁷⁹ (PAT: Sallinas Valley)	Yes	Low	None
Wagner and Clayton, 1999 ¹⁷⁹ (PAT: Teen)	Yes	Low	None
Wiggins et al, 2005 ¹¹⁸ Wiggins et al, 2004 ¹¹⁷ (The Social Support and Family Health Study)	Yes	Low	None

* Questions 17 through 19 in the EPC's risk of bias assessment form pertain to bias from measurement of harm outcomes, which are not applicable to included studies.

Abbreviations: REACH=Resources, Education and Care in the Home; PAT=Parents as Teachers.

Appendix F1. Characteristics of Studies by Outcome

Child Protective Services Reports

Fourteen fair- or good-quality studies reported on CPS outcomes.^{86, 87, 89, 91, 92, 95, 100, 101, 104-106, 108, 110, 111, 114} Seven of them were not included in the 2004¹⁸¹ or 2013¹ report for the USPSTF.^{91, 100, 104, 108, 110, 111} All studies identified in the previous review were evaluated for inclusion in this update, but two were excluded because of poor quality.^{134, 145, 146}

Seven of the 14 included trials recruited participants during pregnancy or immediately after birth.^{86, 87, 92, 95, 101, 110, 111} The other seven trials either included a subset of participants recruited in the perinatal period or focused recruitment on families of infants or children. Four trials reported child maltreatment at baseline,^{89, 91, 100, 114} although, in accordance with our inclusion criteria, no study had more than 50 percent of participants with substantiated reports. Other trials either did not specify prior experience of maltreatment or had participants who had not perpetrated or experienced maltreatment. Most trials (10 of 14) identified participants based on the risk of maltreatment, although the specific risk factors varied across studies.^{87, 89, 95, 100, 101, 105, 106, 108, 110, 111, 114} The other studies did not specify risk status or recruited from a low-risk population.^{86, 91, 92, 104} In four studies, the majority of mothers were under the age of 20.^{91, 92, 95, 104}

All but one study¹⁰⁰ included a home visiting component. The exception was a study set in a clinic for parents entering outpatient substance abuse treatment. Many (6 of 13) had clinical teams (nurses, psychologists) delivering the active intervention.^{91, 95, 100, 110, 114} Nearly all studies included a usual-care arm, with one exception, which compared active treatments for alcohol abuse, with or without parent skills training.¹⁰⁰

All but three were based in the United States; the exceptions were set in the United Kingdom^{92, 101} and New Zealand.^{105, 106} Three were primarily clinic-based interventions.^{86, 100, 110}

Removal of Child from Home

Five studies, one good-quality trial¹⁰⁹ and four fair-quality studies,^{101, 102, 110, 115, 116} reported on child removal outcomes. Four trials identified in the 2013¹⁰¹ or 2004^{101, 110, 115} previous review are included in this update. We identified one new fair-quality study not summarized in the previous reviews, published in 2003,¹¹⁶ and a second article¹⁰² that was published in 2009 reporting outcomes of a study included in the 2013 review.¹⁰¹

Four studies recruited women during pregnancy,^{101, 102, 109, 115, 116} and one recruited mothers of very low birthweight infants postpartum.¹¹⁰ One study sample comprised only first-time, adolescent mothers,¹¹⁶ and one study predominantly comprised mothers under age 20 years.¹¹⁵ One trial recruited only low-income participants (<200% Federal poverty limit FPL),¹⁰⁹ whereas the other three trials were with conducted with a predominantly low-income population.^{101, 102, 110, 116} In three studies, the majority of participants were single mothers.^{109, 110, 115} Two of the five studies reported that mothers had previous involvement with CPS,^{109, 115} and neither study had more than 50 percent of participants with substantiated reports. All five studies screened and selected participants based on the presence of demographic risk factors associated with child maltreatment,^{101, 102, 109, 110, 115, 116} with risk factors varying by study.

One study evaluated a comprehensive prenatal and pediatric program,¹⁰⁹ and four studies evaluated home visiting interventions.^{101, 102, 110, 115, 116} Four of the five intervention approaches

Appendix F1. Characteristics of Studies by Outcome

involved a multidisciplinary clinical team.^{109, 110, 115, 116} The prenatal and pediatric program, which was clinic based but included home visits in some cases following missed appointments, was provided through the child's second birthday.¹⁰⁹ The home visiting interventions varied in duration, intensity, and timing: weekly, biweekly, then monthly visits beginning prenatally through 12 months postpartum;¹¹⁵ weekly home visits beginning at 6 months postpartum and provided up to 18 months postpartum^{101, 102}; five home visits from birth through 18 months postpartum, supplemented by nurse consultation while the infant was in the hospital and weekly phone contact during the first 8 weeks postpartum;¹¹⁰ and five home visits during the first 4 months postpartum.¹¹⁶

All five trials compared the active intervention to routine care. The context for the routine care varied: in one study, both arms were conducted in high-risk groups, so the control was also characterized as a "high-risk control."¹⁰⁹ In a second study, early discharge interventions for very low birthweight infants were compared with routine care.¹¹⁰

The studies varied in their definitions of and data sources for evaluating removals. Three of the five trials used child welfare and/or court data documenting removal and placement in out-of-home care.^{101, 102, 109, 116} One trial included both removal of the child's siblings or the target child as the outcome but did not specify sibling or target child in reporting the outcome.¹⁰⁹ Similarly, another trial defined removal as placement in foster care with or without the mother or due to the mother's incarceration but did not specify this data in reporting outcomes.¹¹⁶ Another study assumed removal had occurred if a child's records showed substantiated child abuse or neglect but did not gather documentation on removal per se.^{101, 102} The two trials that did not report child welfare or court records as data sources either relied solely on mothers' self-report¹¹⁵ or provided no information.¹¹⁰ Additionally, although one of these studies¹¹⁵ reported the number of children in foster care at followup, specific data on how many children had been removed prior to the study was not provided.

All trials focused on outcomes during the first 3 years of the child's life, each with assessment at different time points: at birth and at 6 months,¹¹⁵ 6 months with removal data for the period between 6 months and 12 months also reported,¹¹⁶ 12 months (assessing the period between the 6-month and 12-month assessment time points),^{101, 102} 18 months,¹¹⁰ and 36 months¹⁰⁹ after the study child's birth.

Three studies were set in the United States,^{109, 110, 115} one in the United Kingdom,^{101, 102} and one in Australia.¹¹⁶ One intervention was provided primarily in the clinic.¹⁰⁹

Other Measures of Abuse or Neglect

Two RCTs, of good¹⁰⁹ and fair¹⁰³ quality, respectively, reported on study-specific measures of neglect. The good-quality study randomized 314 pregnant women in Metropolitan Nashville General Hospital (1984 to 1986) with income less than 200 percent of the Federal poverty level who were identified to be at high risk of maltreatment based on responses to a structured interview, the Maternal History Interview-2.¹⁰⁹ The interview included questions on knowledge of parenting skills, philosophy about discipline, personality, positive and negative feelings about pregnancy, and the mother's perception of her nurture as a child. The study randomized women to a comprehensive primary care intervention or usual care. The primary care intervention

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included prenatal, postnatal, and pediatric care, provided for 2 years by a multidisciplinary team including nurse midwives, nurse practitioners, social workers, paraprofessional home visitors, a nutritionist, and a psychologist. Abuse and neglect were identified based on review of public agency documents from the Tennessee Department of Human Services through 36 months of age. Specifically, abuse was defined as “hitting with the hand or objects, biting, burning with objects or by immersion, twisting, shaking, throwing or pushing so as to cause a fall, or hair pulling.” Neglect could arise from “abandonment, leaving a child with an inappropriate caretaker, gross failure to seek medical care, failure to provide shelter or nutrition, or gross failure to provide for normal intellectual development.”

The fair-quality study randomized 147 families of children born at medical risk (preterm or with a medical condition) in California; 87 percent of the families were Latino. The study compared a cognitively based extension of the Healthy Start home visitation program with a home visitation condition that did not include a cognitively based component.¹⁰³ In the intervention arm, the parents learned to recognize children’s distress and learned problem-solving techniques. The neglect measure, reported at 1 year following intake, was based on the Framingham Safety Survey, which included questions about exposed electrical outlets, crib sides left down, and the presence of windows lacking screens.

Injuries with a High Specificity for Abuse or Neglect

One fair-quality study reported on the risk of injury with a high specificity for abuse or neglect. Specifically, this study of pregnant Australian adolescents examined the effect of home visits versus usual care (1998 to 2000) on severe nonaccidental injury at 6 months. This outcome was defined as hospital admission as a result of an injury that was “referred for independent investigation by the Family and Children’s Services staff and concluded to have arisen as a result of a nonaccidental injury to the neonate.”¹¹⁶

Emergency Room Visits

Eleven fair- or good-quality studies reported on ER visits.^{86-88, 92-99, 101, 102, 105-107, 110-113, 117, 118} We did not include studies that reported measures that could potentially have included nonemergency care (“acute care visits” that did not specify whether these were ER visits¹¹⁰). Six of the identified 11 studies were included in the earlier reviews.^{86-88, 93-99, 101, 105, 106}

Nine of the 11 fair- or good-quality trials recruited participants during pregnancy or immediately after birth.^{86-88, 92-99, 101, 102, 107, 110-113} Two of the included trials recruited participants in early infancy.^{105, 106, 117, 118} None of the studies reported on child maltreatment at baseline. Nine of the 11 trials identified participants based on the risk of maltreatment with specific risk factors varying across the studies.^{86-88, 93-99, 101, 102, 105-107, 110, 111, 117, 118} The remaining trials randomized all newborns at the study site regardless of baseline risk for maltreatment.^{92, 112, 113} One study specifically targeted very low birth weight infants.^{110, 111} In three studies, the majority of all mothers were under age 20 years.⁹²⁻⁹⁹

All studies included a home visiting component. Home visits ranged from 4 weeks to 5 years postnatally. The study of very low birth weight infants paired early discharge and home visits.^{110, 111} All studies had a usual-care arm, except one that provided transportation to and from prenatal

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clinic visits to the control group.^{93, 94} Six of the 11 studies had multiple active comparisons against the usual-care arm.^{86, 93-99, 107, 111, 117, 118}

Seven of the 11 studies were based in the United States. The exceptions were three studies set in the United Kingdom,^{92, 101, 102, 117, 118} one in New Zealand,^{105, 106} and one in Canada.^{95-99, 107} Two used a combination of parental report and medical record data,^{86, 111} and three fair- or good-quality studies used parental report only.^{101, 102, 107, 117, 118}

Seven of 11 included studies reported ER visit outcomes at 1 to <2 years after enrollment or recruitment.^{86, 92, 95-99, 101, 102, 107, 111, 117, 118} Two of these studies reported only medical record data.^{92, 95-99} Two used a combination of parental report and medical record data,^{86, 111} and three fair- or good-quality studies used parental report only.^{101, 102, 107, 117, 118}

Six of 11 included studies reported ER visit outcomes at 2 to >4 years of followup.^{87, 88, 92-99, 105, 106, 112, 113} With one exception^{112, 113} outcomes were taken from medical records.

Hospitalization

Twelve fair- or good-quality studies reported on hospitalization outcomes.^{86-88, 92, 93, 96, 101, 105, 106, 110, 111, 113, 116, 118} We included five trials not previously summarized in the 2004¹⁸¹ or 2013¹ reports.^{110, 111, 113, 116, 118} and two studies published since 2013,^{92, 106} one of which¹⁰⁶ reports 9-year followup outcomes of a study included in the last review.¹⁰⁵

Ten of the 12 fair- or good-quality trials recruited all participants during pregnancy or immediately after birth.^{86, 92, 93, 96, 101, 110, 111, 113, 116, 118} Other fair- or good-quality trials focused recruitment on families of infants or children, often identified as high risk during the prenatal or perinatal period.^{87, 88, 105, 106} One trial reported child maltreatment at baseline,⁹³ although, in accordance with our inclusion criteria, no study had more than 50 percent of its sample with identified maltreatment, including CPS involvement, at baseline. Other trials either did not specify prior experience of maltreatment or had participants who had not perpetrated or experienced maltreatment. Most trials (7 of 12) identified participants based on the risk of maltreatment, although the specific risk factors varied across studies.^{87, 88, 93, 96, 101, 105, 106, 110, 111} The other studies did not specify risk status or recruited from a low-risk population.^{86, 92, 113, 116, 118} In four studies, the majority of or all mothers were under age 20 years.^{92, 93, 116}

All but two studies^{86, 113} included a home visiting component. Many (8 of 12) had clinical teams delivering the active intervention.^{92, 93, 96, 105, 106, 110, 113, 116, 118} All studies included a usual-care arm. Five studies had multiple active comparisons against the usual-care arm.

All but five studies were based in the United States; the exceptions were three set in the United Kingdom,^{92, 101, 118} one in New Zealand,^{105, 106} and one in Australia.¹¹⁶ Three were primarily clinic-based interventions.^{86, 110, 113}

Failure to Thrive

One fair-quality trial of early discharge with nurse home visits for very low birthweight infants recruited from the Hospital of the University of Pennsylvania (1982 to 1984) reported on failure to thrive (N=72 mothers and 79 infants).¹¹⁰ Mothers of infants weighing $\leq 1,500$ g were

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randomized to early discharge followed by home visits or routine nursery policy. The early-discharge group received nurse home visits in the first week and at 1, 9, 12, and 18 months; regular telephone contact for 8 weeks; and an on-call nurse specialist backed up by a neonatologist. The usual-care group was discharged when the infant was approximately 2,200 g as long as the child was clinically well and feeding well. The study reported failure to thrive at 18 months.

Failure to Immunize

One fair-quality study of pregnant Australian adolescents that examined home visits versus usual care (1998 to 2000) reported on the proportion with no vaccinations at 6 months.¹¹⁶

Internalizing and Externalizing Behaviors

Six fair- or good-quality studies reported on internalizing and externalizing behavioral outcomes in children.^{87-90, 93, 94, 101, 105, 106, 112-114} The primary outcome measures used by most studies to assess behavior symptoms were the CBCL and the ITSEA. In addition to the CBCL and ITSEA, several other measures were used, including the Strengths and Difficulties Questionnaire, the Social Skills Rating System, and the Computerized Diagnostic Interview Schedule for Children.^{93, 94}

We identified one fair or good trial not previously summarized in the 2004 or 2013 report.^{112, 113}

Five of the six fair- or good-quality trials recruited participants during pregnancy or immediately after birth.^{87-90, 93, 94, 101, 105, 106, 112, 113} One good-quality study recruited mothers of children ages 6 to 36 months.¹¹⁴ Three of the six fair- or good-quality trials reported child maltreatment at baseline,^{89, 90, 93, 94, 114} but no study had more than 50 percent of participants with substantiated reports of abuse or neglect. Other trials did not have participants with a history of maltreatment. Five of six fair- or good-quality trials identified participants based on risk of maltreatment.^{87-90, 101, 105, 106, 112, 114} One fair-quality study^{112, 113} offered services to all families in a primary care setting regardless of vulnerability. For five of the six fair- or good-quality studies, most or all of the mothers were under age 20 years.^{87-90, 93, 94, 101, 105, 106, 114}

All of the six fair- or good-quality trials included a home visiting component.^{87-90, 93, 94, 101, 105, 106, 112, 113} Four of the six trials were conducted by clinical teams delivering the actual intervention.^{93, 94, 105, 106, 112-114} All of the studies included a usual-care arm or no treatment group comparator.

All but two of the studies were based in the United States; one study took place in New Zealand.^{105, 106} One fair-quality study took place in a primary care setting with a home visiting component.^{112, 113}

Four fair- or good-quality studies reported on behavior symptoms using the Internalizing and Externalizing Scales of the CBCL^{87-90, 93, 94, 112, 113}; two fair- or good-quality studies reported on internalizing and externalizing behavior problems in children using the ITSEA.^{105, 106, 114} One study also used the Strengths and Difficulties Questionnaire.^{105, 106} One study later used the Computerized Diagnostic Interview Schedule for Children to assess for behavior symptoms.^{93, 94}

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Social, Emotional, and Developmental Outcomes Not Otherwise Categorized

Five studies evaluated discrete social, emotional, or other developmental outcomes separately from overall measures of externalizing or internalizing problems.^{90, 94, 101, 102, 112-114} Two were good-quality trials,^{90, 114} and three were fair-quality studies.^{94, 101, 102, 112, 113} Four studies identified in the previous 2013 review^{89, 94, 101, 114} are included in this update. We identified one new fair-quality trial^{112, 113} and one final evaluation report⁹⁰ of a study previously included in the 2013 review.⁸⁹

Two studies recruited women during pregnancy,^{94, 101} one study recruited women during pregnancy or up to 4 months postpartum,^{89, 90} one study recruited families of newborns up to 4 weeks of age,^{112, 113} and one study recruited mothers of children between the ages of 6 and 36 months.¹¹⁴

Two studies were conducted with a predominantly low-income population;^{94, 101, 102, 114} the other two studies had a socioeconomically mixed population.^{89, 90, 112, 113} One study sample was predominantly African American.⁹⁴ Three trials had study samples comprised predominantly of single mothers.^{89, 90, 94} One study actively recruited first-time pregnant adolescents under the age of 19 years but also admitted other pregnant women into the study.⁹⁴ Two trials included mothers with a previous history of CPS involvement, which met the threshold for inclusion in this review.^{89, 90, 114} Three trials screened and selected participants based on level of risk, either for child maltreatment^{89, 90} or on general sociodemographic and psychosocial risk and/or the presence of child social-emotional/behavioral problems.^{94, 101, 114}

Four studies evaluated home visiting models that focused on intervening for a substantive period starting before and/or during some portion of the child's first 3 years and that varied on frequency, intensity, and duration.^{89, 90, 94, 101, 102, 114} One program initiated visits with children between the ages of 6 and 36 months, providing 12 months of weekly home visits, with the number of visits individualized based on participants' needs (an average of 22 visits during a 1-year period).¹¹⁴ One trial evaluated a 2-year intervention program that began during pregnancy and provided home visits through the child's second birthday (an average of 22 home visits during a 2-year period).^{89, 90} One home visiting study evaluated a program that began during pregnancy and provided biweekly home visits through the child's second birthday.⁹⁴ A fourth home visiting trial evaluated a program of weekly visits beginning 6 months postpartum and provided up to 18 months postpartum.^{101, 102} One trial evaluated an enhanced pediatric well-child care model that provided families with a developmental specialist and multiple services including up to six home visits during the child's first 3 years, including developmental assessments, written materials, parent groups, and linkages to community resources.^{112, 113} Two trials used a clinical team in the intervention approach;¹¹²⁻¹¹⁴ one of these interventions involved a developmental and mental health specialist teaming with a paraprofessional, reflective of the ethnic and cultural diversity of the family, providing care coordination.¹¹⁴ One study intervention was delivered solely by nurses,⁹⁴ another by community midwives,^{101, 102} while another intervention relied on trained paraprofessionals.^{89, 90}

Three of the five trials compared the active intervention to usual care.^{101, 102, 112-114} One study⁹⁴ randomized participants into four arms: free transportation to prenatal care appointments (group 1); development screening and referral services for the child at 6, 12, and 24 months plus free

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transportation for prenatal care (group 2); nurse visitation during pregnancy, one postpartum visit in the hospital before discharge, one postpartum visit in the home plus group 2 services (group 3); and nurse visitation through the child's first 2 years of life plus group 3 services (group 4). The study then combined groups 1 and 2 for the comparator group. Another study provided control group participants with information and referrals to other appropriate services in the community.^{89, 90}

Each of the five studies reported different social, emotional, or other developmental outcomes that fell outside the categories of externalizing or internalizing behavior or that were combined with internalizing and/or externalizing outcomes in their measurement. One trial examined dysregulation (i.e., problems with sleep, eating; sensory sensitivities; negative emotionality) as an outcome.¹¹⁴ Another study reported on children's sleep problems¹¹² and social skills (i.e., positive social behaviors such as cooperation, empathy, assertion, and self-control; externalizing, internalizing, and hyperactivity problem behaviors; and academic competence).¹¹³ A third trial evaluated outcomes using the attention and social problems subscales of a measure used to assess problem behavior;^{89, 90} this study also reported these outcomes for a subgroup of young, first-time mothers who engaged in the program prenatally. A fourth trial examined children's conduct problems (1st to 3rd grade), antisocial behavior, academically focused behavior, and peer affiliation using either school records or teacher reports and teacher structured observation.⁹⁴ One study included a measure of infant/toddler social and emotional adjustment but did not report any specific outcomes associated with that measure;¹⁰¹ however, a subsequent cost evaluation of the trial¹⁰² reported generally on outcomes.

The timing of assessments varied considerably across the studies, with three studies reporting long-term followup results.^{90, 94, 113} One trial reported outcomes at 6 and 12 months post-baseline assessment.¹¹⁴ One trial assessed outcomes at 12 months into an 18-month intervention (reflecting the period between the 6-month and 12-month time points).^{101, 102} One study evaluated outcomes close to the end of the 3-year intervention period (when children were 30 to 33 months old).¹¹² The studies evaluating longer-term effects reported outcomes at different developmental and followup time points: 5 to 5.5 years (approximately 2 years post-intervention completion),¹¹³ 7 years (5 years post-intervention completion),⁹⁰ and 9 years (7 years post-intervention completion).⁹⁴

Four studies were set in the United States.^{89, 90, 94, 112-114} One study was conducted in the United Kingdom.^{101, 102}

Child Development as Measured by the Bayley Scales of Child Development

Four fair- or good-quality studies reported on child development as measured by the Bayley Scales of Child Development.^{87, 88, 93-99, 101} In addition, three poor-quality studies reported on child development as measured by the Bayley Scales of Child Development.^{145, 146, 174, 177} All previous studies were included in this update, although one was changed from a good-quality rating to a fair-quality rating⁹⁵⁻⁹⁹ and another was changed from a fair-quality to poor-quality rating.^{145, 146} In both cases, these changes were due to deviations from the intervention.

We identified two poor-quality trials not previously summarized in the 2004 or 2013 review.^{174, 177} One good-quality trial had been summarized previously, but the outcomes related to the

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Bayley scales had not been included in previous reviews.^{87, 88} Of these, none had been published in 2013 or later.

All four of the fair- to good-quality studies recruited participants during pregnancy or immediately after birth.^{87, 88, 93-99, 101} None of the studies reported child maltreatment at baseline, though two of the fair-quality studies specifically recruited first-time mothers.⁹³⁻⁹⁹ The four fair- to good-quality studies did identify participants based on risk factors, though different risk factors were used.^{87, 88, 93-99, 101} Two studies had a majority of mothers who were under age 20.⁹³⁻⁹⁹ Another study had about 20 percent of mothers who were under age 17.¹⁰¹

All studies included a home visiting component. This was compared to usual care,¹⁰¹ transportation to appointments,⁹³ referral to other services,⁸⁸ and developmental screening for the child at 1 and 2 years of age.⁹⁵ One study compared a group consisting of participants who got developmental screening at 1 and 2 years of age with or without transportation assistance to two active comparison groups.⁹⁵ The two active comparison groups in this study got the developmental screening and transportation assistance as well as prenatal visits for one of the active comparison groups and prenatal and postnatal visits for the other active comparison group.

One of the studies was in the United Kingdom,¹⁰¹ and the others were in the United States.

Other Development Outcomes

Three fair-quality studies reported on other outcome measures.^{92, 95, 113} One study actively recruited pregnant women with characteristics that predisposed their children to poorer health and development problems (younger than 19 years, single-parent, low socioeconomic status) but also admitted other pregnant women into the study. The study randomized participants into four arms: sensory and development screening for children at 12 and 24 months (group 1), free transportation to regular prenatal and well-child visits plus group 1 services (group 2), nurse visitation during pregnancy plus group 2 services (group 3), and nurse visitation through the child's first 2 years of life plus group 3 services (group 4). The study then combined groups 1 and 2 for the comparator group. The study reported mean scores on the Cattell Scale at 6, 12, and 24 months of age.⁹⁵ A second study included both a randomized and quasi-experimental component (Healthy Steps for Young Children; 1996 to 1998); this review focuses on the randomized component comparing usual care with a comprehensive pediatric care model with developmental specialists, enhanced developmental services, and home visits. This study reported the proportion of parents with a significant concern regarding the child's development on the Parents' Evaluation of Development Status at 5 to 5.5 years of age.¹¹³ A third study randomized pregnant teenagers to a nurse home visiting program or usual care. The study reported the number of mothers with concerns on cognitive and language development and also reported results on an early language scale (Early Language Milestone Scale) for the child.

School Performance: Overview of the Evidence

One study of fair quality^{93, 94} reported on developmental outcome scores and school outcomes. One fair-quality trial⁹³ of nurse prenatal and infancy home visits with mothers recruited from an obstetrical clinic at the Regional Medical Center in Memphis (1990 to 1991) reported on mental development (N=1,139 mothers).⁹³ This study was previously included in the 2013¹ report, but

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the results for school performance had not been previously reported. High-risk pregnant mothers less than 29 weeks' gestation were randomized to one of four treatment conditions: Group 1: free transportation by cab to scheduled prenatal care appointments; Group 2: free transportation to prenatal care appointments plus developmental screening and referral services for the child at 6, 12, and 24 months; Group 3: free transportation and screening plus intensive nurse home visitation services during pregnancy, one postpartum visit in the hospital, and one postpartum visit in the home; or Group 4: all of Group 3 interventions plus nurse visits through the child's second birthday. Treatment group 2 was contrasted with group 4 for the postnatal phase of the study. The study reported mental development scores on the Bayley Scales of Infant Development at 24 months. In a followup study,⁹⁴ the children were evaluated again at 9 years of age (N=743). The study reported children's grade point averages in reading and math and achievement test scores in grades 1 to 3.

School Attendance: Overview of the Evidence

One good-quality study^{89, 90} of home visiting, modeled after Healthy Families New York (HFNY), by paraprofessionals pre- and postnatally for high-risk infants recruited from a university hospital (2000 to 2001) reported on school attendance. This study was previously included in the 2013¹ report, but the results for school performance had not been previously reported. Mothers of high-risk infants were randomized to HFNY or usual care. The HFNY group received an average of 22 home visits by trained paraprofessionals biweekly during pregnancy and once weekly after birth with a focus on promoting healthy behaviors and parent-child relationships, improving adherence to scheduled immunizations and well-child visits, and connecting with community resources. The usual-care group was provided with information and referral to other appropriate services in the community. The followup study⁹⁰ reported on improved school attendance assessed by child and maternal reports of skipping school often at age 7 years.

Death

Four studies of fair quality reported on the outcome of child death.^{93, 94, 101, 110, 116} All studies identified in the previous review are included in this review. We identified one fair-quality study not previously summarized in the 2004 or 2013 report.¹¹⁶ We identified one fair-quality study that was included in the 2004 review but not included in the 2013 review.¹¹⁰

All four fair-quality studies recruited all participants during pregnancy or immediately after birth.^{93, 94, 101, 110, 116} Only one fair-quality trial reported child maltreatment at baseline.^{93, 94} Other trials did not specify experience of prior maltreatment. Three of the four studies identified participants based on risk of maltreatment, although the specific risk factors varied across studies.^{93, 94, 101, 110} The other study recruited from a low-risk population.¹¹⁶ In two studies, the majority of or all mothers were under age 20 years.^{93, 94, 116}

All four fair-quality studies included a home visiting component. Three had clinical teams delivering the active intervention.^{93, 94, 110, 116} All four fair-quality studies included a usual-care arm.

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Two of four fair-quality studies were set in the United States.^{93, 94, 110} The others took place in the United Kingdom¹⁰¹ and Australia.¹¹⁶

Composite Outcome

One fair-quality trial of home visits by nurse midwives to teenage mothers recruited from an Australian public-care teenage pregnancy clinic (1998 to 2000) reported on a composite outcome of child abuse and neglect, which the study defined as the pooled incidence of infant death, severe nonaccidental injury, and involuntary foster care placement (N=136 adolescent mostly low-income mothers and infants).¹¹⁶ Participants were not identified to be at risk, and no baseline child maltreatment was reported. Mothers presenting for antenatal visits were recruited and then after delivery randomized to receive a set of postnatal visits from the nurse midwives at 1 week, 2 weeks, 1 month, 2 months, 4 months, and 6 months after delivery or not. Visits with the nurse midwives lasted 1 to 4 hours. The composite outcome was assessed at 6 months.

Appendix F Table 1. Contribution of Poor-Quality Studies to the Results

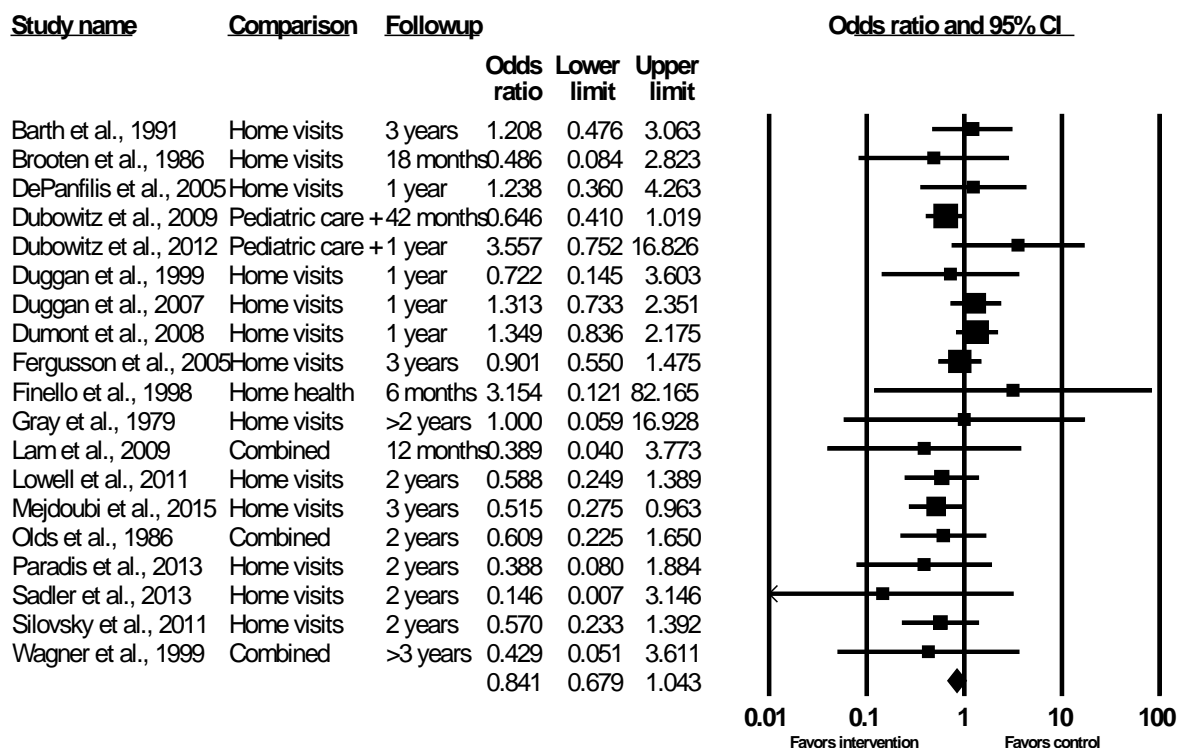
Outcome	Results From All Studies, Including Poor Quality
Reports to CPS	<ul style="list-style-type: none"> Adding nine poor-quality studies^{134, 135, 145-148, 172, 176, 178, 179} to the pooled estimate of effect for first report of results from studies did not alter the direction of effect, although it improved the precision (OR, 0.84; 95% CI, 0.68 to 1.04, I^2: 9.2%; Appendix F, Figure 1). Poor-quality studies reporting outcomes at multiple time points also did not find statistically significant results with repeated measures.^{135, 146}
Removal of the child from the home	<ul style="list-style-type: none"> Adding three poor-quality studies to the pooled estimate altered the direction but not the precision of the results (RR, 1.51; 95% CI, 0.63 to 3.66; I^2: 38.3%; 7 studies; N=1,779%; Appendix F, Figure 2).^{135, 145, 146, 169, 177}
Injuries with a high specificity for abuse or neglect	<ul style="list-style-type: none"> One poor-quality study found no differences.¹⁷³
ER visits	<ul style="list-style-type: none"> One poor-quality study reported no statistically significant differences in the number of children seen in the ER when comparing study arms in the first year.¹⁴⁵ One poor-quality study reported the total number of ER visits at 12 months (without means or standard deviations); the study noted no statistically significant results.^{171, 175} One poor-quality study reported no difference in the number of times a new born was taken to the ER.¹³⁴ Three poor-quality studies reported number of children using the ER after the second year^{145, 146, 171, 175, 179}; of these, one found statistically significant results (calculated RR, 0.72, 95% CI, 0.58 to 0.90).¹⁷¹ One poor-quality study¹⁷⁸ reported the absence of ER visits for injuries at 2 years and found no statistically significant difference between arms. Two studies reported numbers of ER visits; of these, one reported no differences¹⁷⁵ and one did not report estimates of effect.¹⁷³
Hospitalizations	<ul style="list-style-type: none"> Three of five poor-quality studies showed significant between-group differences in hospitalization outcomes among home visitation only¹⁷¹ and comprehensive primary care interventions with home visits.^{135, 173} Two poor-quality home visitation programs reported no difference.^{145, 146, 174}
Failure to thrive	<ul style="list-style-type: none"> One poor-quality study also did not find statistically significant differences between study arms.¹³⁵
Failure to immunize	<ul style="list-style-type: none"> Three poor-quality studies reported delayed immunizations,¹⁴⁸ complete immunizations at 12 months for African American and Mexican infants,¹⁷⁷ or no DPT or MMR immunization at 15 months.¹⁷⁴ <ul style="list-style-type: none"> One study found a significant lower risk of delayed immunizations at 3 years in the intervention arm when compared with the control arm (calculated RR, 0.34; 95% CI, 0.16 to 0.69).¹⁴⁸ A second study found no significant differences.¹⁷⁷ A third study found a statistically significant difference for DPT immunization only, for which the intervention arm had lower risk of incomplete immunizations (calculated RR, 0.31; 95% CI, 0.10 to 0.96).¹⁷⁴
Internalizing and externalizing behaviors	<ul style="list-style-type: none"> Two poor-quality studies found no difference in the number of children¹⁷⁶ with or mean scores¹⁷² for internalizing or externalizing behavior.

Appendix F Table 1. Contribution of Poor-Quality Studies to the Results

Outcome	Results From All Studies, Including Poor Quality
Bayley development scales	<ul style="list-style-type: none"> Three poor-quality studies reported on the Bayley index at 1 year of age.^{145, 174, 177} <ul style="list-style-type: none"> Two of the three poor-quality studies reported the Bayley mental index and psychomotor index at 1 year of age.^{145, 177} One study reported no significant difference in the mean scores in either index.¹⁴⁵ The other found no significant differences between the experimental and control groups for the Mexican American children in this study on either the motor index or mental index. For the African American children, although there was a statistically significant ($p<0.05$) difference between the experimental group and the control group on the Bayley mental index, there was no difference in the motor index. It is not clear that the study was powered to detect these subgroup differences, although it was specifically seeking participants from these two groups.¹⁷⁷ One poor-quality study reported the Bayley mental and motor scores at 15 months of age.¹⁷⁴ The scores for the control and experimental groups were similar for the mental index and motor index in this study. For the mental index, the means were 115.5 (SD 7.0) for the experimental group ($n=21$) vs. 114.9 (SD 3.3) for the control group ($n=26$). For the motor index, the means were 118.4 (SD 8.8) for the experimental group vs. 114.2 (SD 13.2) for the control group. The authors do not comment on whether the Bayley scores themselves were statistically significantly different. One poor-quality study reported the Bayley mental index and psychomotor index at 2 years of age¹⁴⁵ and reported no significant difference between the mean scores in either index in this study.
Other development outcomes (concern regarding child's development)	<ul style="list-style-type: none"> One poor-quality study also found no differences.^{135, 136}
Death	<ul style="list-style-type: none"> One poor-quality study reported no deaths in either arm.¹⁷⁷

Abbreviations: CI=confidence interval; CPS=child protective services; DPT=diphtheria, pertussis (whooping cough), and tetanus; ER=emergency room; I²=proportion of the observed variance that reflects variance in true effect sizes rather than sampling error; MMR=measles, mumps, and rubella; N=number; OR=odds ratio.

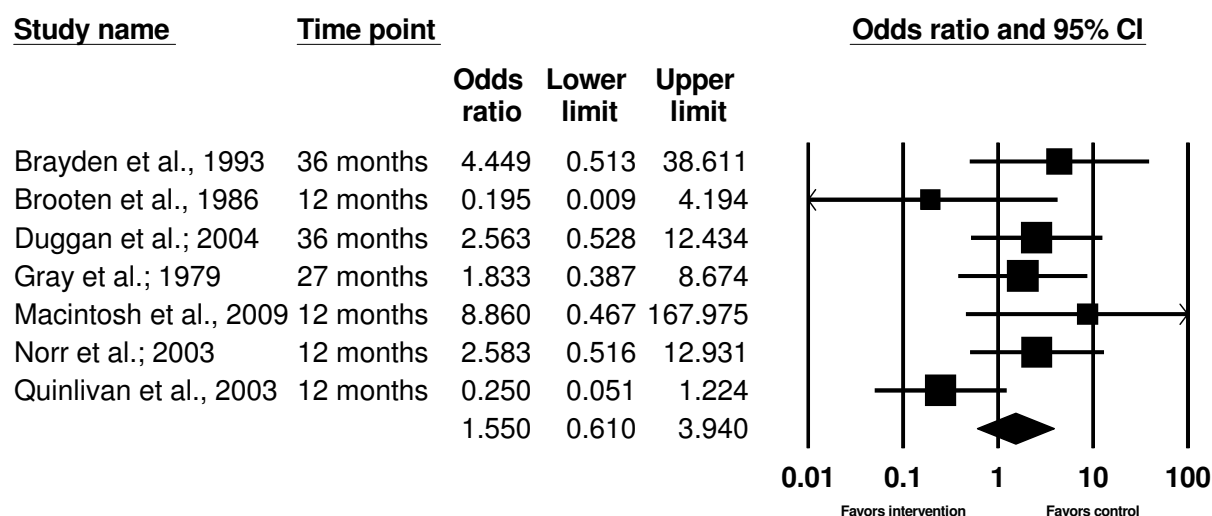
Appendix F Figure 1. Child Protective Services Reports: Sensitivity Analysis With Poor-Quality Studies



I-squared: 9.2%

Abbreviation: CI=confidence interval.

Appendix F Figure 2. Child Removal From the Home: Sensitivity Analysis With Poor-Quality Studies



I-squared: 39.4%

Abbreviation: CI=confidence interval.

Appendix F3. Contextual Question Related to Caregiver Self-Reported Measures of Potential for or Commission of Child Abuse and Neglect

We found 21 trials of interventions to prevent child maltreatment that reported on caregiver self-reported instruments measuring the potential for or commission of abuse or neglect.^{87, 89, 95, 100, 103, 105, 106, 108, 113, 134, 145-148, 157, 158, 161, 182-185} This evidence base includes four trials excluded from the main analysis because of high risk of bias, and five trials excluded from the review because they did not report any eligible outcomes.

These studies reported on several instruments. The most commonly reported outcome was the child conflict tactic scale (CTS), in either the traditional version or the revised version (10 studies).^{87, 89, 103, 105, 106, 147, 148, 158, 182-184} Investigators typically reported one or more subscales, combinations of items, and individual items on the CTS. Five studies reported on the Child Abuse Potential Inventory.^{108, 134, 157, 161, 185} Two studies reported items on the use⁹⁵ or nonuse¹⁸⁴ of use of force. One study reported on each of the following: Parenting Scale,¹⁰⁰ Parent Screening Questionnaire,¹⁴⁷ and Mother–Child Neglect Scale (MCN).¹⁸³ The followup ranged from 6 months to 7 years.

Eight studies reported one or more statistically significant results from the CTS.^{87, 89, 103, 105, 106, 145-148, 158, 184} The studies reported on various subscales or combinations of items from CTS: minor assault, corporal punishment, psychological aggression, harsh parenting, neglect, and severe or very severe physical assault.

Studies reporting on instruments other than CTS did not find any statistically significant results, with two exception. One study reported statistically significant differences in the *never use* of slapping hands for infants age 6 months to 1 year.¹⁸⁴ One study reported a difference in the overreactivity subscale of the Parenting Scale, for fathers.¹⁰⁰

For every outcome with a statistically significant result, the same study or other studies reported no differences, suggesting inconsistent and inconclusive evidence. The one study reporting *never use* of slapping hands also reported nonsignificant results for five other measures of use of force toward the child (all at 1 year).¹⁸⁴ Another study reported no difference on the use of force at 6 months.⁹⁵

One study found a difference at the 2-year followup in the use of corporal punishment in the past year,⁸⁷ but not in the past week.⁸⁷ One study found in the use of corporal punishment for infants at 1 year,¹⁰³ and a second found no differences at 5 to 5.5 years.¹¹³

Three studies reported on harsh parenting and all found one or more statistically significant difference, favoring the intervention arm.^{100, 105, 106, 158} One of the three studies, however, reported measures of overreactivity for mothers and father separately at the 6- and 12-month followup; the statistically significant difference was at 12 months for fathers only.¹⁰⁰

For minor assault, one study reported statistically significant results for minor assault at 12 months, but not at 6 months.¹⁴⁷ Two other studies reported no differences for minor assault at 2 years^{87, 148} or at 3 years.¹⁴⁸

For psychological aggression, two studies found no differences at 6 months¹⁸³ and 3 years,¹⁴⁸ respectively, and one study found a difference at 2 years.⁸⁷ Other studies were not consistent

Appendix F3. Contextual Question Related to Caregiver Self-Reported Measures of Potential for or Commission of Child Abuse and Neglect

over time. One study found results favoring the intervention group for psychological aggression at the 1-year followup,⁸⁹ but not at 2⁸⁹ or 7 years.⁹⁰ A second study found no difference at 6 months, but found differences at 12 months.¹⁴⁷

For neglect, one study found statistically significant differences on the revised CTS but not the traditional CTS scale.¹⁴⁶ Three other studies found no differences.^{87, 89, 90, 183}

Results for subscales for serious or very serious physical abuse were also inconsistent: two studies showed a difference in the prevalence and frequency of very serious physical abuse at 1⁸⁹ and 3 years¹⁴⁸ but one of two studies did not find an effect at 2 years⁸⁹ or at a 7-year followup.⁹⁰ A third study found no differences at 2 years.⁸⁷

In summary, the preponderance of the evidence for parent-self-report of abuse or neglect (or the potential for abuse or neglect) does not demonstrate benefit for interventions to prevent child maltreatment. Of the 10 studies reporting one or more statistically significant outcome, 7 reported other nonsignificant results as well for other subscales, items, or time points. Because studies did not specify whether one or more of these outcomes was specified a priori, the potential for reporting bias cannot be ruled out. Specifically, studies that reported only statistically significant results of subscales from the CTS did not specify whether this outcome had been selected a priori, and why results of the entire scale were not analyzed.^{103, 158} Similarly, studies reporting a minority of statistically significant results alongside a much larger set of statistically nonsignificant results may have obtained those results by chance.

Appendix F Table 2. Parent Self-Reported Outcomes – Multiple CTS Subscales Combined, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 1999 ¹⁴⁵ Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Mother's self-reported severe abuse and frequent psychological abuse or minor assault in Year 1; based on CTS, defined as severe or very severe physical abuse and reported using either acts of psychological aggression or minor physical assault more often than the sample median.*	1 year	NR (3)	NR (4)	NA	NA	NR [†]
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Mother's self-reported severe abuse and frequent psychological abuse or minor assault in Year 2; based on CTS, defined as severe or very severe physical abuse and reported using either acts of psychological aggression or minor physical assault more often than the sample median.*	2 years	NR (6)	NR (7)	NA	NA	NR [†]
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Mother's self-reported severe abuse and frequent psychological abuse or minor assault in Year 3; based on CTS, defined as severe or very severe physical abuse and reported using either acts of psychological aggression or minor physical assault more often than the sample median.*	3 years	NR (8)	NR (8)	NA	NA	AOR, 1.02 (95% CI, 0.61-1.71; p=0.94) [‡]

Appendix F Table 2. Parent Self-Reported Outcomes – Multiple CTS Subscales Combined, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=1,060)	Serious abuse and neglect composite scale per parent-child Conflict Tactics Scale (CTS-PC): prevalence	1 year	NR (7.28)	NR (5.67)	NA	NA	p=ns
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Serious abuse and neglect composite scale per parent-child Conflict Tactics Scale (CTS-PC): prevalence	2 years	NR (7.83)	NR (6.78)	NA	NA	p=ns

* This measure is used as the denominator to calculate recognition rates (rate of which home visitors recognize and respond to child maltreatment).

† Authors only reported adjusted odds ratio for the 3-year followup. Of families receiving a high dose of HSP services, 3%, 8%, and 5% mothers reported both frequent and severe abusive behavior in years 1, 2, and 3, respectively.

‡ Of families receiving a high dose of HSP services, 3%, 8%, and 5% mothers reported both frequent and severe abusive behavior in years 1, 2, and 3, respectively.

Abbreviations: AOR=adjusted odds ratio; CI=confidence interval; CTS=Conflict Tactics Scales; CTSPC=Parent-Child Conflict Tactics Scales; G=group; N=n=number; NA=not applicable; NR=not reported.

Appendix F Table 3. Parent Self-Reported Outcomes – Multiple CTS Subscales Combined, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	CTS Score, G1 Mean (SD)	CTS Score, G2 Mean (SD)	CTS Score, G3 Mean (SD)	CTS Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=1,060)	Serious abuse and neglect composite scale per parent-child CTS-PC: frequency*	1 year	0.53 (NR)	0.27 (NR)	NA	NA	p=ns
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Serious abuse and neglect composite scale per parent-child CTS-PC: frequency*	2 years	0.35 (NR)	0.38 (NR)	NA	NA	p=ns

*All mean CTS scores are adjusted for prior substantiated reports of child abuse or neglect, 2 dummy codes representing race/ethnicity, random assignment at gestational age 30 weeks or less, site of participation, status as first-time mother, born in United States, mothers' age at intake, welfare recipient, mothers' own history of abuse, physical health status, psychologically vulnerable index, current depressive symptoms.

Abbreviations: CTS-PC=Parent-Child Conflict Tactics Scales; G=group; N\ n=number; NA=not applicable; NR=not reported; ns=not sufficient; SD=standard deviation.

Appendix F Table 4. Parent Self-Reported Outcomes – Corporal Punishment (CTS), Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
Bugental and Schw artz, 2009 ¹⁰³ Fair Total N=147 caretakers randomized (N analyzed=94)	Corporal punishment assessed by Conflict Tactics Scale. Measure is dichotomous but analysis was ANOVA.	1 year	NR (35)	NR (21)	NA	NA	F(1,96)=5.08, p=0.03, n ² =0.05*
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Corporal/verbal punishment on child performed ever in the past week; measured using the parent-child Conflict Tactics Scale (CTS-PC) traditional subscale. This measure included a combination of three items: shout, yell, or scream; spank on bottom with bare hand; and slap on hand, arm, or leg.	2 years	NR (68)	NR (66)	NA	NA	AOR, 0.92 (95% CI, 0.52 to 1.65, p=0.79)
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Common corporal punishment performed on child ever in the past year; measured using the parent-child CTS-PC revised subscale	2 years	NR (92)	NR (91)	NA	NA	AOR,.080 (95% CI, 0.37 to 1.72, p=0.56)

*Interaction between immigration status and condition was not significant, F(1,96)=2.05, p=0.26. Larger differences in prevalence rates were found for native-born mothers (G2 28% vs. G1 67%) than immigrant mothers (G1 27% vs. G2 18%).

Abbreviations: ANOVA=analysis of variance; AOR=adjusted odds ratio; CI=confidence interval; CTSPC=Parent-Child Conflict Tactics Scales; G=group; N\|n=number; NA=not applicable; No.=number; NR=not reported.

Appendix F Table 5. Parent Self-Reported Outcomes – Corporal Punishment (CTS), Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	CTS Score, G1 Mean (SD)	CTS Score, G2 Mean (SD)	CTS Score, G3 Mean (SD)	CTS Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Corporal/verbal punishment on child performed ever in the past week; measured using the CTS-PC traditional subscale. This measure included a combination of three items: shout, yell, or scream; spank on bottom with bare hand; and slap on hand, arm, or leg.	2 years	4.57 (NR)	4.02 (NR)	NA	NA	Effect size=0.06, p=0.54
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Common corporal punishment performed on child ever in the past year; measured using the CTS-PC revised subscale	2 years	24.17 (NR)	19.48 (NR)	NA	NA	Effect size=0.20, p < 0.05

Abbreviations: CTS-PC=Parent-Child Conflict Tactics Scales; N=number; NA=not applicable; NR=not reported

Appendix F Table 6. Parent Self-Reported Outcomes – Harsh Parenting (CTS), Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
Bugental et al, 2002 ¹⁵⁸ Unknown study quality* Total N=96 families randomized (N analyzed=NR)	Harsh parenting, assessed on the basis of responses to the CTS assessing the presence or absence of physical abuse (hitting, beating up, kicking, biting, shaking, throwing or tossing child down); administered as a post-program measure	1 year	NR (26)	NR (23)	NR (4)	NA	Comparing G3 with combined G2/G1: Chi-square 5.52, p<0.05 [†]
Bugental et al, 2002 ¹⁵⁸ Unknown study quality* Total N=96 families randomized (N analyzed=NR)	Harsh parenting, assessed on the basis of responses to the CTS to assess the presence or absence of legally nonabusive use of force (spanking/slapping); administered as a post-program measure	1 year	NR [‡]	NR [‡]	NR (7)	NA	Comparing G3 with combined G2/G1: Chi-square 5.04, p<0.05 [†]
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ Fair Total N=443 families randomized (N analyzed=391)	Percentage of parent-reported harsh punishment: A measure was constructed from the CTS-PC, include shaking, hitting with an object, hitting with a fist or kicking, grabbing by the neck/choking, hitting as hard as possible, burning/scalding, throwing/knocking down, and slapping on the head	Annually from 1 to 6 years, and at 9 years [§]	NR (20.1)	NR (9.8)	NA	NA	Cohen's d 0.29 (95% CI, 0.09-0.49) for G2 compared to G1, p<0.01

*This study was excluded from the review for ineligible outcome; quality of the study was not assessed.

[†] Chi-square analyses were used to compared effects in the cognitive-based extension of HSP home visitation program with the effects from the HSP home visitation and control groups combined.

[‡] G1 and G2 combined: 42%

[§] Authors reported that outcome time frame was 0 to 9 years.

^{||} Client families were assessed on a structured interview administered in the clients' homes by a trained survey interviewer. Interviews typically lasted between 45 minutes to an hour.

Abbreviations: CI=confidence interval; CTS=Conflict Tactics Scales; CTS-PC=Parent-Child Conflict Tactics Scales; G=group; N\ n=number; NA=not applicable; NR=not reported; SD=standard deviation.

Appendix F Table 7. Parent Self-Reported Outcomes – Harsh Parenting (CTS and PS), Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	CTS Score, G1 Mean (SD)	CTS Score, G2 Mean (SD)	CTS Score, G3 Mean (SD)	CTS Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Bugental et al, 2002 ¹⁵⁸ Unknown study quality* Total N=96 families randomized (N analyzed=NR)	Harsh parenting, assessed on the basis of responses to the CTS using a frequency scale to assess two categories: physical abuse (hitting, beating up, kicking, biting, shaking, throwing or tossing child down) and legally nonabusive use of force (spanking/slapping); administered as a post-program measure	1 year	0.25 (NR)	0.23 (NR)	0.06 (NR)	NA	p=0.05 [†]
Lam et al, 2009 ¹⁰⁰ Fair Total N=30 male patients with their female partners and custodial children randomized (N analyzed=30)	Over-reactivity subscale of the PS, comprising items describing harsh parenting	12 weeks	Mother: 2.7 (1.4) Father: 3.5 (1.4)	Mother: 2.6 (1.4) Father: 3.0 (1.0)	Mother: 2.2 (1.3) Father: 2.5 (1.0)	NA	Effect size contrasts between PSBCT (G3) and IBT (G1) revealed medium to large effects for fathers' ratings of over-reactivity, and smaller, yet meaningful effects for mothers' (r >.20). PSBCT vs. BCT (G2) comparisons at each follow up assessment also revealed clinically meaningful differences favoring PSBCT (r>.20). Calculated mean differences not statistically significant.
Lam et al, 2009 ¹⁰⁰ Fair Total N=30 male patients with their female partners and custodial children randomized (N analyzed=30)	Over-reactivity subscale of the PS, comprising items describing harsh parenting	6 months	Mother: 2.9 (1.1) Father: 3.5 (1.2)	Mother: 2.6 (1.2) Father: 3.1 (1.2)	Mother: 2.3 (1.2) Father: 2.6 (1.2)	NA	Calculated mean differences not statistically significant

Appendix F Table 7. Parent Self-Reported Outcomes – Harsh Parenting (CTS and PS), Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	CTS Score, G1 Mean (SD)	CTS Score, G2 Mean (SD)	CTS Score, G3 Mean (SD)	CTS Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Lam et al, 2009 ¹⁰⁰ Fair Total N=30 male patients with their female partners and custodial children randomized (N analyzed=30)	Over-reactivity subscale of the Parenting Scale (PS), comprising items describing harsh parenting	1 year	Mother: 3.0 (1.3) Father: 3.5 (1.0)	Mother: 2.7 (1.3) Father: 3.0 (1.0)	Mother: 2.1 (1.2) Father: 2.6. (1.0)	NA	No reported effect sizes, calculated mean difference statistically significant only for fathers at 12 months: -0.9 (95% CI, -1.78 to -0.02)

*This study was excluded from the review for ineligible outcome; quality of the study was not assessed.

†Authors reported significant difference between study groups among high-risk infants within the study: HV plus cognitive group, 0.07 (SD, 0.20) vs. HV standard/control, 0.42 (SD, 0.44); $p < 0.05$.

Abbreviations: BCT=behavioral couples therapy; CI=confidence interval; CTS-PC=Parent-Child Conflict Tactics Scales; G=group; IBT=individual based therapy; N/n=number; NA=not applicable; NR=not reported; PSBCT=parent skills and behavioral couples therapy; PS=parent screening; SD=standard deviation.

Appendix F Table 8. Parent Self-Reported Outcomes – Minor Assault (CTS), Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Mild physical assault on child performed ever in the past year, using the CTS-PC traditional subscale	2 years	NR (85)	NR (80)	NA	NA	AOR, 0.70 (95% CI, 0.40 to 1.23, p=0.22)

Abbreviations: AOR=adjusted odds ratio; CI=confidence interval; CTS-PC=Parent-Child Conflict Tactics Scales; G=group; N=number; NA=not applicable; NR=not reported.

Appendix F Table 9. Parent Self-Reported Outcomes – Minor Assault (CTS), Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	CTS Score, G1 Mean (SD)	CTS Score, G2 Mean (SD)	CTS Score, G3 Mean (SD)	CTS Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Dubowitz et al, 2012 ¹⁴⁷ Poor Total N=1,119 families randomized (N analyzed=1,119)	CTSPC measuring how parents resolve conflict with children using the minor, severe, and very severe physical assault scales. Minor physical assault included 3 items. Respondents reported the frequency of each item/behavior during the past year (for initial assessment) or past 6 months (for 6-month follow up assessment). Weighted scoring was used to give more frequent behavior a higher score.	6 months	1.9 (4.6)	1.8 (4.6)	NA	NA	Effect size=-0.08 (95% CI, -0.22 to 0.05), p-value=0.245*
Dubowitz et al, 2012 ¹⁴⁷ Poor Total N=1,119 families randomized (N analyzed=1,119)	CTSPC measuring how parents resolve conflict with children using the minor, severe, and very severe physical assault scales. Minor physical assault included 3 items. Respondents reported the frequency of each item/behavior during the past year (for initial assessment) or past 6 months (for 12-month follow up assessment). Weighted scoring was used to give more frequent behavior a higher score.	12 months	2.6 (5.6)	2.1 (4.7)	NA	NA	Effect size=-0.14 (95% CI, -0.28 to -0.005, p-value=0.043*
Dubowitz et al, 2012 ¹⁴⁷ Poor Total N=1,119 families randomized (N analyzed=558 [†])	Minor physical assault (weighted score on CTS minor physical assault subscale, Parent-Child version)	3 years	5 (12.4)	3.5 (8.3)	NA	NA	p=0.17
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Mild physical assault on child performed ever in the past year, using the CTS-PC traditional subscale	2 years	11.93 (NR)	9.56 (NR)	NA	NA	effect size=0.18, p<0.05

*Multivariate analyses were used and adjusted for family income, mother's marital status and education, child's ethnicity and age, and the random effects of participant and practice. Findings for severe and very severe physical assault were extremely low (<1% of sample) and were excluded from the analyses. Initial measures represent an early effect of SEEK, not baseline, due to some SEEK exposure before enrollment in the study.

[†] Study authors noted that sample sizes for scales varied slightly because of missing values.

Abbreviations: CI=confidence interval; CTS=Conflict Tactics Scales; CTS-PC=Parent-Child Conflict Tactics Scales; G=group; N=n=number; NA=not applicable; NR=not reported.

Appendix F Table 10. Parent Self-Reported Outcomes – Psychological Aggression (CTS), Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Psychological aggression on child performed ever in the past year, using the CTS-PC traditional subscale	2 years	NR (83)	NR (84)	NA	NA	AOR, 1.10 (95% CI, 0.63 to 1.90, p=0.75)
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Percentage of mothers reporting having committed an act of psychological aggression at least once; based on traditional CTS, include shout, yell or scream; threaten to spank or hit; swear or curse at child; threaten to leave child; call child dumb or lazy	3 years	NR (89)	NR (88)	NA	NA	NR
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Percentage of mothers reporting having committed assault on child's self-esteem at least once; based on revised CTS, include four items: swore or cursed at the child, called him/her dumb or lazy, said you would leave him/her, and slapped on the face, head or ears. The first three items traditionally classified as psychological aggression and the last traditionally as severe physical abuse.	3 years	NR (44)	NR (42)	NA	NA	NR

Appendix F Table 10. Parent Self-Reported Outcomes – Psychological Aggression (CTS), Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=1,060)	Self-reported acts of psychological aggression per CTS-PC: prevalence	1 year	NR (56.13)	NR (51.18)	NA	NA	p=ns [*]
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Self-reported acts of psychological aggression per CTS-PC: prevalence	2 years	NR (77.74)	NR (76.44)	NA	NA	p=ns [*]
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=897)	Parental reporting of psychological aggression based on responses on the CTS-PC as reported by mothers during interview	Year 7 of study	NR (86.49)	NR (87.92)	NA	NA	AOR=1.18, p=ns
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=793)	Child reporting of psychological aggression based on responses on the Conflict Tactics Scale - Pictured Card version as reported by children during child interview	Year 7 of study	NR (85.14)	NR (84.47)	NA	NA	AOR=1.00, p=ns

*Outcomes reported for prevention subgroup (first-time mothers <19 yo randomly assigned at gestational age of ≤30 wks), psychologically vulnerable subgroup (per index of CES-D and Mastery of Psychological Coping Resources Scale scores). Neither moderates differences between the HFNY and control groups in self-reported psychological aggression.

Abbreviations: AOR=adjusted odds ratio; CI=confidence interval; CTS=Conflict Tactics Scales; CTS-PC=Parent-Child Conflict Tactics Scales; G=group; N/n=number; NA=not applicable; No.=number; NR=not reported; ns=not sufficient.

Appendix F Table 11. Parent Self-Reported Outcomes – Psychological Aggression (CTS), Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	CTS Score, G1 Mean (SD)	CTS Score, G2 Mean (SD)	CTS Score, G3 Mean (SD)	CTS Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Dubowitz et al, 2012 ¹⁴⁷ Poor Total N=1,119 families randomized (N analyzed=1,119)	CTS-PC measuring how parents resolve conflict with children using the psychological aggression scale, with two items. Respondents reported the frequency of each item/behavior during the past year (for initial assessment) or past 6 months (for 6-month follow up assessment). Weighted scoring was used to give more frequent behavior a higher score.	6 months	6.1 (8.5)	5.4 (8.6)	NA	NA	Effect size=-0.06 (95% CI, -0.18 to 0.06), p=0.306*
Dubowitz et al, 2012 ¹⁴⁷ Poor Total N=1,119 families randomized (N analyzed=1,119)	CTS-PC measuring how parents resolve conflict with children using the psychological aggression scale, with two items. Respondents reported the frequency of each item/behavior during the past year (for initial assessment) or past 6 months (for 12-month follow up assessment). Weighted scoring was used to give more frequent behavior a higher score.	12 months	7.0 (9.3)	5.7 (8.0)	NA	NA	Effect size=-0.12 (95% CI, -0.24 to -0.002), p=0.047*
Dubowitz et al, 2009 ¹⁴⁸ Poor Total N=729 parents randomized (N analyzed=558)	Psychological aggression (weighted score on Conflict Tactics Scale psychological aggression subscale, Parent-Child version)	3 years	9.1 (16.4)	7.5 (14.9)	NA	NA	p=0.41
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Psychological aggression on child performed ever in the past year, using the CTS-PC traditional subscale	2 years	13.09 (NR)	11.17 (NR)	NA	NA	Effect size=0.14, p<0.05

Appendix F Table 11. Parent Self-Reported Outcomes – Psychological Aggression (CTS), Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	CTS Score, G1 Mean (SD)	CTS Score, G2 Mean (SD)	CTS Score, G3 Mean (SD)	CTS Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Percentage of mothers reporting having committed an act of psychological aggression at least once; based on traditional CTS, include shout, yell, or scream; threaten to spank or hit; swear or curse at child; threaten to leave child; call child dumb or lazy	3 years	NR	NR	NA	NA	AOR, 0.76 (95% CI, 0.54 to 1.07, p=0.11)
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Percentage of mothers reporting having committed assault on child's self-esteem at least once; based on revised CTS, includes four items: swore or cursed at the child, called him/her dumb or lazy, said you would leave him/her, and slapped on the face, head or ears. The first three items traditionally classified as psychological aggression and the last traditionally as severe physical abuse.	3 years	NR	NR	NA	NA	AOR, 0.90 (95% CI, 0.67-1.20, p=0.46)
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=1,060)	Self-reported acts of psychological aggression per CTS-PC: frequency [†]	1 year	4.74 (NR)	3.34 (NR)	NA	NA	p=0.007 [‡]
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Self-reported acts of psychological aggression per CTS-PC: frequency [†]	2 years	9.84 (NR)	9.37 (NR)	NA	NA	p=ns [‡]
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=897)	Parental reporting of psychological aggression based on responses on the CTS-PC as reported by mothers during interview	Year 7 of study	15.21 (NR)	15.33 (NR)	NA	NA	Effect size=0.01, p=ns

Appendix F Table 11. Parent Self-Reported Outcomes – Psychological Aggression (CTS), Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	CTS Score, G1 Mean (SD)	CTS Score, G2 Mean (SD)	CTS Score, G3 Mean (SD)	CTS Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
DuMont et al, 2010 ⁹⁰ Good Total N=1173 mothers randomized (N analyzed=793)	Child reporting of psychological aggression based on responses on the Conflict Tactics Scale - Pictured Card version as reported by children during child interview	Year 7 of study	2.68 (NR)	2.78 (NR)	NA	NA	Effect size=0.05, p=ns
Guterman et al, 2013 ¹⁸³ Unknown study quality [¶] Total N=138 families randomized (N analyzed=NR)	CTS-PC psychological aggression subscale that includes items assessing a range of self-reported mother-to-child behaviors, including how many times in the past 6 months (from “never” to “more than 20 times”) the mother shouted, swore, threatened, or cursed at the child ^{**}	6 months	7.79 (5.91)	7.27 (6.42)	NA	NA	Difference in Cohen's D scores for G1 vs. G2: 0.122 [#] Authors reported no significance difference between G1 and G2.

* Multivariate analyses were used and adjusted for family income, mother's marital status and education, child's ethnicity and age, and the random effects of participant and practice. Initial measures represent an early effect of SEEK, not baseline, due to some SEEK exposure before enrollment in the study.

[†] All means are adjusted for prior substantiated reports of child abuse or neglect, 2 dummy codes representing race/ethnicity, random assignment at gestational age 30 weeks or less, site of participation, status as first-time mother, born in United States, mothers' age at intake, welfare recipient, mothers' own history of abuse, physical health status, psychologically vulnerable index, and current depressive symptoms.

[‡] Outcomes reported for prevention subgroup (first-time mothers <19 yo randomly assigned at gestational age of ≤30 weeks), psychologically vulnerable subgroup (per index of CES-D and Mastery of Psychological Coping Resources Scale scores). Neither moderates differences between the HFNY and control groups in self-reported psychological aggression.

[¶] This study was excluded from the review for ineligible outcome; quality of the study was not assessed.

[#] Cohen's D score=(6-month followup mean–baseline mean) / (pooled $\sigma \sqrt{2(1-p)}$) Marginally significant decline in self-reported psychological aggression among G2 (time=-1.09, p=0.10).

^{**} Additional information about the subscale scoring was not provided, data collectors were blinded to the random assignment of mothers interviewed, and all sensitive questions were answered privately by respondents, using audio-recorded, computer-assisted self-interviewing technology, whereby mothers listened to each question read to them on headphones, and directly entered their own answers onto the laptop computer, without the data collector's knowledge of the nature of their response.

Abbreviations: AOR=adjusted odds ratio; CI=confidence interval; CTS=Conflict Tactics Scales; CTS-PC=Parent-Child Conflict Tactics Scales; G=group; N=number; NA=not applicable; NR=not reported; ns=not sufficient; SD=standard deviation.

Appendix F Table 12. Parent Self-Reported Outcomes – Neglect (CTS), Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Neglectful behavior toward child performed by mother ever in the past year; measured using the CTS-PC traditional subscale	2 years	NR (22)	NR (19)	NA	NA	AOR, 0.81 (95% CI, 0.51 to 1.30, p=0.38)
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Neglectful behavior toward child performed ever in the past year; measured using the CTS-PC revised subscale	2 years	NR (18)	NR (18)	NA	NA	AOR, 0.97 (95% CI, 0.57 to 1.64, p=0.90)
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Neglect; based on traditional CTS, include being too caught up in one's problems to express love to the child, inability to provide necessary food, and inability to provide necessary medical care, leaving child at home alone, being too drunk or high to care for child	3 years	NR (29)	NR (26)	NA	NA	NR
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Neglect; based on revised CTS, includes 3 of the 5 items traditionally categorized as neglect: being too caught up in one's problems to express love to the child, inability to provide necessary food, and inability to provide necessary medical care	3 years	NR (27)	NR (22)	NA	NA	NR

Appendix F Table 12. Parent Self-Reported Outcomes – Neglect (CTS), Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=1,060)	Self-reported acts of neglect per CTS-PC: Prevalence	1 year	NR (8.27)	NR (5.52)	NA	NA	p=0.07
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Self-reported acts of neglect per CTS-PC: Prevalence	2 years	NR (7.18)	NR (8.09)	NA	NA	p=ns
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=897)	Parental reporting of neglect based on responses on the Conflict Tactics Scale-Parent Child Version as reported by mothers during interview	Year 7 of study	NR (16.74)	NR (15.77)	NA	NA	AOR, 0.93, p=ns

Abbreviations: AOR=adjusted odds ratio; CI=confidence interval; CTS=Conflict Tactics Scales; CTS-PC=Parent-Child Conflict Tactics Scales; G=group; NA=not applicable; No.=number; NR=not reported.

Appendix F Table 13. Parent Self-Reported Outcomes – Neglect (CTS and MCNS), Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	CTS Score, G1 Mean (SD)	CTS Score, G2 Mean (SD)	CTS Score, G3 Mean (SD)	CTS Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Neglectful behavior toward child performed by mother ever in the past year; measured using the CTS-PC traditional subscale	2 years	0.75 (NR)	0.92 (NR)	NA	NA	Effect size=0.05, p=0.74
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Neglectful behavior toward child performed ever in the past year; measured using the CTS-PC revised subscale	2 years	0.66 (NR)	0.65 (NR)	NA	NA	Effect size=0.01, p=0.99
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Neglect; based on traditional CTS, includes being too caught up in one's problems to express love to the child, inability to provide necessary food, and inability to provide necessary medical care, leaving child at home alone, being too drunk or high to care for child	3 years	NR	NR	NA	NA	AOR, 0.80 (95% 0.60-1.05, p=0.11)
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Neglect; based on revised CTS, include 3 of the 5 items traditionally categorized as neglect: being too caught up in one's problems to express love to the child, inability to provide necessary food, and inability to provide necessary medical care	3 years	NR	NR	NA	NA	AOR, 0.72 (95% 0.54-0.96, p=0.02)
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=1,060)	Self-reported acts of neglect per CTS-PC: frequency*	1 year	0.21 (NR)	0.22 (NR)	NA	NA	p=ns
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Self-reported acts of neglect per CTS-PC: frequency*	2 years	0.46 (NR)	0.22 (NR)	NA	NA	p=0.08

Appendix F Table 13. Parent Self-Reported Outcomes – Neglect (CTS and MCNS), Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	CTS Score, G1 Mean (SD)	CTS Score, G2 Mean (SD)	CTS Score, G3 Mean (SD)	CTS Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=897)	Parental reporting of neglect based on responses on the CTS-PC as reported by mothers during interview	Year 7 of study	0.64 (NR)	0.53 (NR)	NA	NA	Effect size=0.05, p=ns
Guterman et al, 2013 ¹⁸³ Unknown study quality [†] Total N=138 families randomized (N analyzed=NR)	CTS-PC neglect subscale that includes items assessing a range of self-reported mother-to-child behaviors, including how many times in the past 6 months (from "never" to "2 or more times per day") the mother left the child alone, did not give the child food when needed, or did not take the child to the doctor even when needed [‡]	6 months	1.81 (3.03)	1.29 (3.61)	NA	NA	Cohen's D score for G1 compared to G2: 0.156 No differences were observed comparing families in G2 with G1 observed after 6 months of service [§]
Guterman et al, 2013 ¹⁸³ Unknown study quality [†] Total N=138 families randomized (N analyzed=NR)	MCNS indicates in 11 Likert-type questions the degree to which mothers agree/disagree on a 4-point scale (from 0 "strongly agree" to 4 "strongly disagree") on statements such as, "When I couldn't be with my child, I made sure s/he was with someone," "I made sure my child saw a doctor when s/he needed one," or "I kept unsafe objects away from my child." [‡]	6 months	11.88 (2.08)	11.70 (2.23)	NA	NA	Cohen's D score for G1 compared with G2: 0.083 No significance difference between G1 and G2 [§]

* All means are adjusted for prior substantiated reports of child abuse or neglect, 2 dummy codes representing race/ethnicity, random assignment at gestational age 30 wks or less, site of participation, status as first-time mother, born in United States, mothers' age at intake, welfare recipient, mothers' own history of abuse, physical health status, psychologically vulnerable index, current depressive symptoms

[†] This study was excluded from the review for ineligible outcome; quality of the study was not assessed.

[‡] Additional information about the subscale scoring was not provided, data collectors were blinded to the random assignment of mothers interviewed, and all sensitive questions were answered privately by respondents, using audio-recorded, computer-assisted self-interviewing technology, whereby mothers listened to each question read to them on headphones, and directly entered their own answers onto the laptop computer, without the data collector's knowledge of the nature of their response.

[§] Cohen's D score=(6-month followup mean–baseline mean) / (pooled $\sigma \sqrt{2(1-\rho)}$) Because the CTS-PC Neglect scale was only used at followup, D scores were calculated according to the conventional D score formula comparing means and standard deviations across groups.

Abbreviations: CTS=Conflict Tactics Scales; CTS-PC=Parent-Child Conflict Tactics Scales; G=group; MCNS= Mother–Child Neglect Scale; N=number; NA=not applicable; NR=not reported; ns=not sufficient; SD=standard deviation.

Appendix F Table 14. Parent Self-Reported Outcomes – Physical Abuse (CTS), Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=10,60)	Self-reported acts of very serious physical abuse per CTS-PC: prevalence	1 year	NR (1.33)	NR (0.93)	NA	NA	p=ns
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=1,060)	Self-reported acts of serious physical abuse per CTS-PC: prevalence	1 year	NR (0.81)	NR (0.85)	NA	NA	p=ns
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Self-reported acts of very serious physical abuse per CTS-PC: prevalence	2 years	NR (2.85)	NR (2.62)	NA	NA	p=ns
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Self-reported acts of serious physical abuse per CTS-PC: prevalence	2 years	NR (1.21)	NR (0.60)	NA	NA	p=ns
DuMont et al, 2010 ⁹⁰ Good Total N=1173 mothers randomized (N analyzed=897)	Parental reporting of serious physical abuse based on responses on the Conflict Tactics Scale-Parent Child version as reported by mothers during interview	Year 7 of study	NR (3.18)	NR (1.76)	NA	NA	AOR=0.55, p=ns*

* Analyses control for annual earnings at random assignment and being white.

Abbreviations: AOR=adjusted odds ratio; CTS-PC=Parent-Child Conflict Tactics Scales; N=number; NA=not applicable; NR=not reported; ns=not sufficient.

Appendix F Table 15. Parent Self-Reported Outcomes – Physical Abuse (CTS), Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	CTS Score, G1 Mean (SD)	CTS Score, G2 Mean (SD)	CTS Score, G3 Mean (SD)	CTS Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=1,060)	Self-reported acts of very serious physical abuse per CTS-PC: frequency*	1 year	0.08 (NR)	0.01 (NR)	NA	NA	p=0.04
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=1,060)	Self-reported acts of serious physical abuse per CTS-PC: frequency*	1 year	0.01 (NR)	0.01 (NR)	NA	NA	p=ns
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Self-reported acts of very serious physical abuse per CTS-PC: frequency*	2 years	0.13 (NR)	0.13 (NR)	NA	NA	p=ns
DuMont et al, 2008 ⁸⁹ Good Total N=1,173 mothers randomized (N analyzed=992)	Self-reported acts of serious physical abuse per CTS-PC: frequency*	2 years	0.04 (NR)	0.01 (NR)	NA	NA	p=0.03
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=897)	Parental reporting of serious physical abuse based on responses on the CTS-PC as reported by mothers during interview	Year 7 of study	0.15 (NR)	0.03 (NR)	NA	NA	Effect size=-0.20, p<0.01

* All means are adjusted for prior substantiated reports of child abuse or neglect, 2 dummy codes representing race/ethnicity, random assignment at gestational age 30 wks or less, site of participation, status as first-time mother, born in United States, mothers' age at intake, welfare recipient, mothers' own history of abuse, physical health status, psychologically vulnerable index, and current depressive symptoms.

Abbreviations: CTS=Conflict Tactics Scales; CTS-PC=Parent-Child Conflict Tactics Scales; G=group; N=number; NA=not applicable; NR=not reported; ns=not sufficient; SD=standard deviation.

Appendix F Table 16. Other Parent Self-Reported Child Abuse or Neglect Outcomes, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
Dubowitz et al, 2012 ¹⁴⁷ Poor Total N=1,119 families randomized (N analyzed=1,107)	Proportion of families with one or more problems related to possible abuse or neglect documented in the medical records*	From study start to 12 months after	45 (9)	85 (14)	NA	NA	OR, 1.14, p=0.76
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Severe assault on child performed ever in the past year, using the CTS-PC traditional subscale	2 years	NR (7)	NR (9)	NA	NA	AOR, 1.28 (95% CI, 0.41 to 4.00, p=0.67)
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Parental threat to child esteem performed ever in the past year; measured using the CTS-PC revised subscale	2 years	NR (22)	NR (24)	NA	NA	AOR, 1.17 (95% CI, 0.63 to 2.18, p=0.63)
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Child hit with object by mother ever in the past year; measured using the CTS-PC revised subscale	2 years	NR (5)	NR (10)	NA	NA	AOR, 2.40 (95% CI, 0.47 to 12.14, p=0.71)
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Extreme physical punishment to child, performed ever in the past year; measured using the CTS-PC revised subscale	2 years	NR (3)	NR (2)	NA	NA	AOR, 0.75 (95% CI, 0.17 to 3.31, p=0.71)
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Severe physical abuse; based on traditional CTS, include hit somewhere other than bottom with hard object, slap on face, head, or ears, hit with fist or kick hard, throw or knock child down	3 years	NR (15)	NR (22)	NA	NA	NR

Appendix F Table 16. Other Parent Self-Reported Child Abuse or Neglect Outcomes, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Very severe physical abuse; based on traditional CTS, include shake child, choke child, burn, or scald on purpose	3 years	NR (7)	NR (6)	NA	NA	NR
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Extreme physical abuse; based on revised CTS, includes 4 of the 7 items traditionally classified in the severe and very severe physical abuse subscales: hit with fist or kick hard; threw or knocked child down; choked child; and burned or scalded child on purpose	3 years	NR (2)	NR (4)	NA	NA	NR
Duggan et al, 2004 ¹⁴⁶ Poor Total N=730 mothers randomized (N analyzed=NR)	Shook child; based on revised CTS. Authors reported that mothers interpreted this outcome widely, including taking a standing child by the shoulders and shaking gently while making a point verbally	3 years	NR (7)	NR (6)	NA	NA	NR
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=897)	Parental reporting of minor physical aggression based on responses on the CTS-PC as reported by mothers during interview	Year 7 of study	NR (59.17)	NR (64.12)	NA	NA	AOR, 1.25, p=ns
DuMont et al, 2010 ⁹⁰ Good Total N=1173 mothers randomized (N analyzed=793)	Child reporting of minor physical aggression based on responses on the Conflict Tactics Scale - Pictured Card version as reported by children during child interview	Year 7 of study	NR (77.23)	NR (70.79)	NA	NA	AOR, 0.74, p<0.05

Appendix F Table 16. Other Parent Self-Reported Child Abuse or Neglect Outcomes, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
Fergusson et al, 2005 ¹⁰⁵ Fergusson et al, 2013 ¹⁰⁶ Fair Total N=443 families randomized (N analyzed=391)	Proportion of parents reporting severe physical punishment; on the severe/very severe assault subscales of the CTS-PC	12, 24, and 36 months	NR (11.7)	NR (4.4)	NA	NA	OR, 0.35 (95% CI, 0.15 to 0.80) for G2 vs. G1 Cohen's D: 0.26 (95% CI, 0.07 to 0.48) for G2 vs. G1 p<0.01
Kan and Feinberg, 2014 ¹⁸² Unknown study quality† Total N=169 couples randomized (N analyzed=NR)	Parent-child physical aggression assessed with the 6-item corporal punishment subscale of the CTS-PC (e.g., shook; hit on bottom with a hard object; slapped on hand, arm, or leg); 7-point scale for each item (ranging from 0 times to more than 20 times)	3.4 years (average)	NR*	NR*	NA	NA	No significant main effects of treatment condition on parent-child aggression.
LeCroy et al, 2011 ¹⁸⁴ Unknown study quality† Total N=195 families randomized (N analyzed=168)	Disciplinary practice (smack/threaten hit) reportedly never used with infants age 6 months to 1 year	1 year	NR (63.5)	NR (69.5)	NA	NA	p=0.30
LeCroy et al, 2011 ¹⁸⁴ Unknown study quality† Total N=195 families randomized (N analyzed=168)	Disciplinary practice (slapped hand) reportedly never used with infants age 6 months to 1 year	1 year	NR (38.8)	NR (69.5)	NA	NA	p=0.03
LeCroy et al, 2011 ¹⁸⁴ Unknown study quality† Total N=195 families randomized (N analyzed=168)	Disciplinary practice (spanked) reportedly never used with infants age 6 months to 1 year	1 year	NR (65.9)	NR (71.1)	NA	NA	p=0.19
LeCroy et al, 2011 ¹⁸⁴ Unknown study quality† Total N=195 families randomized (N analyzed=168)	Disciplinary practice (hit elsewhere) reportedly never used with infants age 6 months to 1 year	1 year	NR (96.5)	NR (98.8)	NA	NA	p=0.28

Appendix F Table 16. Other Parent Self-Reported Child Abuse or Neglect Outcomes, Categorical Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Child Abuse or Neglect, G1 No. (%)	Child Abuse or Neglect, G2 No. (%)	Child Abuse or Neglect, G3 No. (%)	Child Abuse or Neglect, G4 No. (%)	Effect Estimate or Other Outcome Measure
LeCroy et al, 2011 ¹⁸⁴ Unknown study quality† Total N=195 families randomized (N analyzed=168)	Disciplinary practice (slapped on face) reportedly never used with infants age 6 months to 1 year	1 year	NR (97.6)	85§ (100)	NA	NA	p=0.99
LeCroy et al, 2011 ¹⁸⁴ Unknown study quality† Total N=195 families randomized (N analyzed=168)	Disciplinary practice (threw object at child) reportedly never used with infants age 6 months to 1 year	1 year	NR (98.8)	85§ (100)	NA	NA	p=0.32
Minkovitz et al, 2007 ¹¹³ Fair Total N=2,235 families (N analyzed=1,308)	Parental response to misbehavior: ever slap in face/spank with object	5 to 5.5 years	79 (13)	74 (11)	NA	NA	AOR, 0.85 (95% CI, 0.60 to 1.22, p=0.40)

* Medical records were reviewed by two medical students. Students were not blinded due to Parent Screening Questionnaires (PSQs) in SEEK children's records. A study pediatrician met regularly with the students to resolve issues and uncertainties. Reviewers ascertained whether problems occurred before or during SEEK. This outcome measure is based on problems occurring during SEEK. No further information is provided as to what is considered a problem related to possible child abuse or neglect. Authors also did not clarify whether the outcome is verified against review of medical records or reported by parents as part of the PSQ.

† This study was excluded from the review for ineligible outcome; quality of the study was not assessed.

‡ Authors reported 73.2% mothers overall and 75.6% fathers overall reporting having committed any physical aggression.

§ Calculated based on percentages reported and N analyzed.

|| The RCT-only portion of the study originally randomized 2,584 children at birth before enrollment or check for eligibility. Among them, 2,235 children were enrolled into the study.

Abbreviations: AOR=adjusted odds ratio; CI=confidence interval; CTS=Conflict Tactics Scales; CTS-PC=Parent-Child Conflict Tactics Scales; G=group; N=number; NA=not applicable; No.=number; NR=not reported; ns=not sufficient; OR=odds ratio.

Appendix F Table 17. Other Parent Self-Reported Child Abuse or Neglect Outcomes, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Followup Timing	Instrument Score, G1 Mean (SD)	Instrument Score, G2 Mean (SD)	Instrument Score, G3 Mean (SD)	Instrument Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Barth, 1991 ¹³⁴ Poor Total N=191 caregiver randomized (N analyzed=191)	CAPI administered to mother, mean score for terms from the three subscales most able to predict abuse (distress, rigidity, unhappiness)	6 months, or when the child was 4 months old	93.4 (46.6)	99.8 (45.8)	NA	NA	p=NS
Barth, 1991 ¹³⁴ Poor Total N=191 caregiver randomized (N analyzed=191)	Mean CAPI score. Items from the three subscales most able to predict abuse (distress, rigidity, and unhappiness) were used, reducing the number of CAPI items from 77 to 35, which reduced the total possible score from 475 to 221	Post-test but timing unspecified	93.37 (46.61)	99.76 (45.82)	NA	NA	p=NS*
Black et al, 1994 ¹⁵⁷ Unknown study quality† Total N=60 caregivers randomized (N analyzed=NR)	CAPI, raw scores converted to Z-scores using the normative sample.	18 months	1.4 (0.2)	1.1 (0.2)	NA	NA	G1: CAPI scores were significantly elevated in reference to norms (t=7.43, p<0.01) G2: CAPI scores did not differ from norms Multivariate analysis: G1 and G2 did not differ in their pattern of scores
Dubowitz et al, 2009 ¹⁴⁸ Poor Total N=729 parents randomized (N analyzed=558)	Reported instances of severe or very severe physical assault; based on average weighted score on CTS-PC	3 years	0.33 (1.96)	0.11 (0.75)	NA	NA	p=0.04

Appendix F Table 17. Other Parent Self-Reported Child Abuse or Neglect Outcomes, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Instrument Score, G1 Mean (SD)	Instrument Score, G2 Mean (SD)	Instrument Score, G3 Mean (SD)	Instrument Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Severe assault on child performed ever in the past year, using the CTS-PC traditional subscale	2 years	0.3 (NR)	0.41 (NR)	NA	NA	Effect size=0.05, p=0.68
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Parental threat to child esteem performed ever in the past year; measured using the CTS-PC revised subscale	2 years	0.64 (NR)	0.95 (NR)	NA	NA	Effect size=0.14, p=0.30
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Child hit with object by mother ever in the past year; measured using the CTS-PC revised subscale	2 years	0.46 (NR)	0.33 (NR)	NA	NA	Effect size=0.06, p=0.66
Duggan et al, 2007 ⁸⁷ Good Total N=364 families randomized (N analyzed=249)	Extreme physical punishment to child, performed ever in the past year; measured using the CTS-PC revised subscale	2 years	0.04 (NR)	0.19 (NR)	NA	NA	Effect size=0.14, p=0.18
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=897)	Parental reporting of minor physical aggression based on responses on the CTS-PC as reported by mothers during interview [‡]	Year 7 of study	4.51 (NR)	4.26 (NR)	NA	NA	Effect size=-0.02, p=ns

Appendix F Table 17. Other Parent Self-Reported Child Abuse or Neglect Outcomes, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Follow up Timing	Instrument Score, G1 Mean (SD)	Instrument Score, G2 Mean (SD)	Instrument Score, G3 Mean (SD)	Instrument Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
DuMont et al, 2010 ⁹⁰ Good Total N=1,173 mothers randomized (N analyzed=793)	Child reporting of minor physical aggression based on responses on the Conflict Tactics Scale - Pictured Card version as reported by children during child interview [‡]	Year 7 of study	2.35 (NR)	2.27 (NR)	NA	NA	Effect size=-0.04, p=ns
Fraser et al, 2000 ¹⁶¹ Unknown study quality† Total N=181 families randomized (N analyzed=NR)	Child abuse risk; beliefs associated with parental maltreatment of children were measured using the CAPI.	18 months	140.89 (113.40)	106.41 (73.67)	NA	NA	Post-hoc paired t-tests indicated a significant reduction between baseline (M=11.40, SD=3.13) and 7 months (M=10.46, SD=3.34) in the intervention group, [t(77)=3.16, p<0.03]; the reduction in score was maintained at 18 months.
Guterman et al, 2013 ¹⁸³ Unknown study quality† Total N=138 families randomized (N analyzed=NR)	CTS-PC physical aggression subscale that includes items assessing a range of self-reported mother-to-child behaviors, including how many times in the past 6 months (from “never” to “more than 20 times”) the mother shook the child; pinched him/her; slapped him/her on the head, face, or ears§	6 months	4.54 (4.03)	4.08 (4.17)	NA	NA	Difference in Cohen's D scores for G1 compared with G2: 0.185 No significant difference between G1 and G2

Appendix F Table 17. Other Parent Self-Reported Child Abuse or Neglect Outcomes, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Followup Timing	Instrument Score, G1 Mean (SD)	Instrument Score, G2 Mean (SD)	Instrument Score, G3 Mean (SD)	Instrument Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Kan and Feinberg, 2014 ¹⁸² Unknown study quality† Total N=169 couples randomized (N analyzed=NR)	Parent-child physical aggression assessed with the 6-item corporal punishment subscale of the CTS-PC (e.g., shook; hit on bottom with a hard object; slapped on hand, arm, or leg); 7-point scale for each item (ranging from 0 times to more than 20 times); frequency scores for each parent were calculated by recoding each item as the midpoint of the response category and summing across items	3.4 years (average)	NR	NR	NA	NA	Authors reported no significant main effects of treatment condition on parent-child aggression
LeCroy et al, 2011 ¹⁸⁴ Unknown study quality† Total N=195 families randomized (N analyzed=168)	Count of aggressive discipline practices based on a modified version of the Revised Parent-Child CTS, a short version using the most serious indicators of abusive and neglectful behavior	1 year	1.83 (0.16)	1.44 (0.16)	NA	NA	F=2.67 (1, 188), p=0.10
Nair et al, 2003 ¹⁸⁵ Unknown study quality† Total N=161 caregivers randomized (N analyzed=NR)	CAP total score#	6 months	176.4 (132.9)	195 (103.9)	NA	NA	NR

Appendix F Table 17. Other Parent Self-Reported Child Abuse or Neglect Outcomes, Continuous Outcome

Author, Year, Quality, Sample Size Analyzed Overall and by Study Group	Outcome Definition	Followup Timing	Instrument Score, G1 Mean (SD)	Instrument Score, G2 Mean (SD)	Instrument Score, G3 Mean (SD)	Instrument Score, G4 Mean (SD)	Effect Estimate or Other Outcome Measure
Nair et al, 2003 ¹⁸⁵ Unknown study quality† Total N=161 caregivers randomized (N analyzed=NR)	CAPI total score#	18 months	166.2 (99.4)	181.7 (99.7)	NA	NA	NR
Olds et al, 1986 ⁹⁵ Fair Total N=400 families randomized (N analyzed=NR)	Average number of times spanked or hit in the last 2 weeks	6 months	1.09 (NR)	1.71 (NR)	0.9 (NR)	NA	Mean difference (SD) for G3 vs. G1: 0.9 (1.71), p=NS**
Silovsky et al, 2011 ¹⁰⁸ Fair Total N=105 caregivers randomized (N analyzed=105)	CAPI score	17 months	128.3 (103.3)	168.6 (107.2)	NA	NA	G1 17-month change: 28.2 (SD: 11.2), p<0.05 G2 17-month change: 39.0 (SD: 12.9), p<0.001 Between group r ² =0.89; 17-month G1-G2 change: -10.8 (SD: 17.1), p=NS
Silovsky et al, 2011 ¹⁰⁸ Fair Total N=105 caregivers randomized (N analyzed=105)	CAPI score	10 months	170.8 (109.3)	166.5 (105.0)	NA	NA	G1 10-month change: 15.0 (SD: 11.9), p=NS G2 10-month change: 42.4 (SD: 11.8), p<0.001 Between group r ² =0.89; 10-month G1-G2 change: -27.5 (SD: 16.7), p<0.10

* Reporting of between-group post-test differences in CAPI is unclear. Table 2 footnote states that “No between group differences in post-tests are significant,” but this may be only referring to a combined “parental wellness” variable, which includes CAPI along with three other scales (CES-D, STAI, Pearlin Mastery Scale).

†This study was excluded from the review for ineligible outcome; quality of the study was not assessed.

‡Analyses control for annual earnings at random assignment and being white.

Appendix F Table 17. Other Parent Self-Reported Child Abuse or Neglect Outcomes, Continuous Outcome

[§]Additional information about the subscale scoring was not provided, data collectors were blinded to the random assignment of mothers interviewed, and all sensitive questions were answered privately by respondents, using audio-recorded, computer assisted self-interviewing technology, whereby mothers listened to each question read to them on headphones, and directly entered their own answers onto the laptop computer, without the data collector's knowledge of the nature of their response.

[†] Cohen's D score = (6-month followup mean - baseline mean) / (pooled $\sigma \sqrt{2(1-\rho)}$)

Significant decline in physical assault in G2 (time = -1.23, $p=0.05$) from baseline to six-month followup point but no significant decline in G1.

[¶] Parent-child physical frequency (based on raw/nonimputed data): Mothers (overall): 10.87 (14.37); Fathers (overall): 10.06 (12.95).

[#] Authors reported outcomes of subgroups categorized by number of environmental risk factors: 0-2 risks, 3 risks, 4 risks, 5 or more risks. Risk were depression, domestic violence, nondomestic violence, family size, homelessness, incarceration, absence of significant other in home, negative life events, psychiatric symptomatology, severity of drug use.

** Analysis adjusted for boyfriend/husband support and maternal sense of control.

Abbreviations: CAPI=Child Abuse Potential Inventory; CTS=Conflict Tactics Scales; G=group; N=number; NA=not applicable; NR=not reported; NS=not sufficient; SD=standard deviation.