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SUMMARY WITH CRITICAL APPRAISAL

Prenatal and Postnatal Home Visiting Programs for Parents, Newborns, and Babies: A Review of Clinical Effectiveness, Cost-Effectiveness, and Guidelines

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Authors: Ke Xin Li, Charlene Argáez

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Abbreviations

AMSTAR 2	A Measurement Tool to Assess Systematic Review 2
FNP or NFP	Family Nurse Partnership or Nurse Family Partnership
HANDS	Kentucky Health Access Nurturing Development Services
PRISMA	Reporting Items for Systematic Reviews and Meta-Analyses
QALY	quality-adjusted life year
RCT	randomized controlled trials
SR	systematic review

Context and Policy Issues

In 2019, there were 372,329 babies born in Canada.[1] Public health early child home visiting programs have been delivered for many years in all provinces and territories in Canada.[2] Home visiting is a method for delivering a broad range of child development enhancement services to parents, newborns and their families.[3] It has the advantage of the individually tailoring support to clients in the context of their own homes.[3] However, these services have disadvantages in terms of not being able to provide care to as many mothers/newborns in comparison to centre-based care, and have potential resource implications.[3] In contrast, health centre-based programs may sacrifice specificity of care based on families' different living conditions, and require transportation costs which may be burdensome for families.[3]

The purpose of this report is to examine the clinical effectiveness and cost-effectiveness of prenatal and postnatal home visiting programs for parents, newborns, and babies up to two years of age. Additionally, evidence-based guidelines regarding the provision of prenatal and postnatal home visiting programs for these populations will be reviewed.

Research Questions

1. What is the clinical effectiveness of prenatal and postnatal home visiting programs for parents, newborns, and babies?
2. What is the cost-effectiveness of prenatal and postnatal home visiting programs for parents, newborns, and babies?
3. What are the evidence-based guidelines regarding the provision of prenatal and postnatal home visiting programs for parents, newborns, and babies?

Key Findings

Six relevant publications (four randomized controlled trials and two non-randomized studies) were identified regarding the clinical effectiveness of prenatal and postnatal home visiting programs for mothers, newborns, and babies. One systematic review was identified regarding the cost-effectiveness of prenatal and postnatal home visiting programs for mothers, newborns, and babies up to two years of age. No relevant evidence-based guidelines were identified regarding the provision of home visiting programs for parents, newborns, or babies.

Overall, there was evidence that care delivered in the prenatal and postnatal periods had both short- and long-term health outcomes.

Regarding postnatal maternal health outcomes, one randomized controlled trial of limited quality demonstrated no statistically significant difference in incidence of completed postpartum visits by eight weeks postpartum or postpartum depression between postnatal home visit and standard office visit groups. There was evidence regarding postnatal child health outcomes from four randomized controlled trials and two quasi-experimental studies. Compared to those who received usual care, newborns and babies who received the Family Connects postnatal nurse home visiting program group were found to have statistically significantly reduced incidence of emergency medical care utilization or inpatient hospital overnight stay. Compared to standard care, infants who received a home-based early preventative care postnatal home visit program within their first year of life had a statistically significantly reduced likelihood of having a mathematics impairment and no statistically significant difference in serious adverse events, most developmental outcomes measured at age eight. Compared to no home visit, first-time mothers who received the Kentucky Health Access Nurturing Development Services prenatal and postnatal home visit program had a significantly reduced incidence of preterm birth, delivering low birth weight infants, and child maltreatment. Compared to no home visit, high-risk pregnancy women who received the public health nurse prenatal home visit program in Japan statistically significantly reduced the incidence of preterm birth. No statistically significant difference was found in the proportion of infants born small for gestational age between the group of high-risk pregnant women that received home visits from public health nurses and the group that did not receive home visits. No statistically significant difference was found between first-time teenage mothers who received the Family Nurse Partnership prenatal and postnatal home-visit program and those who received usual care in rates of emergency department attendances or hospital admissions. No statistically significant difference was found between pregnant women who received a postnatal newborn well-child home visits program and those who received standard office visits in the number of health checks, sick visits, or usage of urgent care.

There was low-to-moderate quality evidence from seven studies in the systematic review of economic evaluations that home visiting programs were cost-effective in comparison to no home visits, depending on the willingness-to-pay threshold and the perspective of the payers.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including PubMed, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were prenatal/postnatal care and home visitation programs. No filters were applied to limit the retrieval by study type. The search was also limited to English language documents published between January 1, 2015 and January 21, 2020.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed

for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Parents, newborns (birth to 2 months), and babies up to two years of age in developed countries
Intervention	Prenatal and postnatal home visiting programs (provided by professionals or paraprofessionals)
Comparator	Q1-Q2: No home visiting programs; usual care Q3: No comparator
Outcomes	Q1: Clinical effectiveness (e.g., gestational parent health [e.g., rates of adverse events, postpartum health, satisfaction with care], newborn health [e.g., rates of adverse events, outcomes relating to developmental delay, birth weight, indicators of child development up to eight years of age – physical, language, psychomotor, cognitive, and behavior]) Q2: Cost-effectiveness Q3: Recommendations regarding prenatal and postnatal home visiting programs
Study Designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, economic evaluations, and guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2015. Guidelines with unclear methodology were also excluded.

Critical Appraisal of Individual Studies

The included systematic review (SR) was critically appraised by one reviewer using A Measurement Tool to Assess Systematic Reviews 2 (AMSTAR 2). Randomized controlled trials (RCT) and non-randomized studies were critically appraised using Downs and Black Checklist. Summary scores were not calculated for the included studies; rather, the strengths and limitations of each included study were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 453 citations were identified in the literature search. Following screening of titles and abstracts, 429 citations were excluded and 24 potentially relevant reports from the electronic search were retrieved for full-text review. Three potentially relevant publications were retrieved from the grey literature search for full-text review. Of these potentially relevant articles, 19 publications were excluded for various reasons, and seven publications met the inclusion criteria and were included in this report. These comprised one SR,[4] four RCTs,[5-9] and two non-randomized studies.[10-12] Appendix 1 presents the PRISMA[13] flowchart of the study selection. Additional references of potential interest are provided in Appendix 5.

Summary of Study Characteristics

Additional details regarding the characteristics of included publications are provided in Appendix 2. Recognizing that gender is a spectrum, when the terms “mother” or “women” were used in the included studies we retained these terms in our reporting on these studies.

Study Design

Of the six included publications regarding the clinical effectiveness of prenatal and postnatal home visiting programs, two RCTs (by Goodman et al.[6] and Spittle et al.[9]) and one non-randomized quasi-experimental cohort study by Ichikawa et al.[11] reported health outcomes for the newborns and babies, while two RCTs by Lakin et al.[7] and Robling et al.[8] and one quasi-experimental study[12] reported maternal health outcomes. In the RCT by Spittle et al.,[9] the home care intervention was provided to preterm newborns and babies up to the age of 11 months, and outcomes were measured at eight years of age.

One SR by Stamuli et al.[4] was identified regarding the cost-effectiveness of prenatal and postnatal home visiting programs for mothers and newborns. The SR[4] published in 2015, searched for relevant economic evaluations regarding the cost-effectiveness of home visiting programs. The searches were conducted up to 2015 and identified 12 primary economic studies, of which seven cost-effectiveness studies were relevant to the cost-effectiveness research question of this report.[4]

Country of Origin

The RCT by Robling et al.[8] was by authors in the United Kingdom. The RCTs by Goodman et al.[6] and Lakin et al.,[7] and the quasi-experimental study by Williams et al.[12] were conducted in the United States. The RCT by Spittle et al.[9] was conducted in Australia. The quasi-experimental study by Ichikawa et al.[11] was conducted in Japan. The SR of economic evaluations by Stamuli et al.[4] was by authors in the United Kingdom.

Patient Population

Throughout the remainder of this report, characteristics and findings from included studies are grouped based on the population in which the outcomes were measured (i.e., mothers, newborns, and/or babies up to age two).

Study Populations that Included Mothers, Newborns and Babies up to Age Two

The RCT by Robling et al.[8] included first-time mothers aged 19 years or younger, living within the catchment area of a local home visiting team, of less than 25 weeks' gestation, and able to provide consent and speak English. The RCT by Lakin et al.[7] included prenatal patients recruited from an urban underserved residency clinic.

The quasi-experimental study by Williams et al.[12] included mothers with a live singleton birth that were referred to the home visiting program.

The SR by Stamuli et al.[4] included economic evaluations regarding the cost-effectiveness of home visitation programs for pregnant women who are vulnerable (defined as being of low socio-economic status) or young (i.e., defined as adolescents).

Study Populations that Included Newborns and Babies up to Age Two

The RCT by Goodman et al.[6] included families living in Durham County in which a child was born at one of the two county hospitals from July 2009 to December 2010. The RCT by Spittle et al.[9] included infants born at less than 30 weeks of gestation, living within 100 km of the hospital and parents who could speak English.

The quasi-experimental cohort study by Ichikawa et al.[11] included high-risk pregnant women, defined as having mental illness, first pregnancy under the age of 20 or over the age of 35, pregnant with twins, late to register their pregnancy or unhappy about being pregnant, single marital status, non-Japanese women who were not fluent in Japanese, or assessed by public health nurses at registration as requiring any additional support including medical, psycho-social, nutrition counseling.[11]

Interventions and Comparators

Interventions and Comparators in Studies that Included Mothers, Newborns, and Babies up to Age Two

The RCT by Robling et al.[8] compared the Family Nurse Partnership (FNP) home visiting program delivered by nurses plus usual care from early pregnancy until the child was two years old to usual care (primary care public health and social care services). The RCT by Lakin et al.[7] compared Newborn Well-Child Home Visits program postnatal home visits by resident physicians (at one week and one month) to standard office visits by primary resident physician.

The quasi-experimental study by Williams et al.[12] compared Kentucky Health Access Nurturing Development Services (HANDS) program (a minimum of one home visit by both professionals and paraprofessionals, starting prenatally and could continue postnatally) versus no home visit program.

The SR by Stamuli et al.[4] included economic evaluations that compared the cost-effectiveness of prenantal and postnatal home visiting programs (Nurse-Family Partnership program, or a home visiting program with 18 months of weekly visits, delivered by trained home visitors, paraprofessionals, or nurses) to standard of care.

Interventions and Comparators in Newborns and Babies up to Age Two

The RCT by Goodman et al.[6] compared Family Connects (one to three postnatal home visits by registered nurses) to a controll group (services as usual). The RCT by Spittle et al.[9] compared a postnatal home visiting program (nine home visits by a physiotherapist and psychologist at two weeks, four weeks and at three, four, six, eight, nine, and 11 months) against standard care.

The quasi-experimental cohort study by Ichikawa et al.[11] compared a prenatal home visit program (at least one nurse home visit lasting more than one hour during mid- or late-term pregnancy) versus no home visiting program.

Outcomes

Outcomes in Studies that Included Mothers, Newborns, and Babies up to Age Two

The RCT by Robling et al.[8] reported on smoking cessation outcomes of mothers (proportion of mothers who smoked at late pregnancy, reported number of cigarettes smoked per day at late pregnancy) and health outcomes of newborns (mean birthweights, emergency attendances or hospital admissions, and serious adverse events associated with pregnancy and infancy period). The RCT by Lakin et al.[7] reported health outcomes of mothers (completed post-partum visits, post-partum depression) and health outcomes of newborns (usage of acute care services measured by number of well-child health checks, visits to health services when the newborn was sick, and phone calls to answering service).

The quasi-experimental study by Williams et al.[12] reported health outcomes of mothers (pregnancy-induced hypertension, maternal morbidity, maternal weight gain during pregnancy, and prenatal care measured by whether first prenatal care visit was during the first trimester and number of prenatal care visits attended) and health outcomes of the newborn and baby (preterm birth, and child maltreatment).

The relevant outcomes in the SR of economic evaluations by Stamuli et al.[4] were benefit-to-cost ratio, quality-adjusted life years (QALY), extra cost per an extra unit of maternal sensitivity and infant cooperativeness, and the willingness-to-pay threshold at which there was 95% probability that home visiting interventions would be cost-effective.

Outcomes in Newborns and Babies up to Age Two

The included RCT by Goodman et al.[6] reported on child emergency medical care use up to 24 months of child age. The RCT by Spittle et al.[9] reported on child neurodevelopmental outcomes that included general cognition, attention, working memory, executive function, academic achievement, and motor development outcomes.

The cohort study by Ichikawa et al.[11] reported newborn health outcomes including preterm birth, gestational age, and birth weight.

Summary of Critical Appraisal

Systematic Review

The included SR[4] had clearly defined research questions, objectives, and eligibility criteria. Key search terms and the dates of the searches were provided, increasing the reproducibility of the literature search, and literature searches were performed in multiple databases.[4] In addition, a grey literature search was conducted, decreasing the risk for missing relevant literature not indexed in databases.[4] The review included a flow chart illustrating study selection and provided reasons for article exclusion.[4] The review included a list of the included and excluded studies.[4] Finally, the review authors stated that they had no related conflicts of interest.[4]

As for the limitations of the SR,[4] it was not reported that review methods were prospectively registered in a published protocol, which may increase the risk for selective reporting.[4] It was unclear if study selection, data extraction, and quality assessment were conducted in duplicate, increasing the risk for inconsistencies in these processes.[4] Lastly, the included economic evaluations were published in the United Kingdom and United States; their relevance to the Canadian health care setting was unclear.[4]

Randomized Controlled Trials and Non-Randomized Studies

The strengths of the included RCTs[5-9] and quasi-experimental studies[10-12] included clearly described objectives, main outcomes, population characteristics, interventions and main findings. Patients from the home visit group and the control group were recruited from the same population over the same time period.[5-12] The statistical tests used to assess the main outcomes were appropriate.[5-12] Patient adherence to the interventions was likely reliable due to the documented observed nature of the home visit program.[5-12] The main outcome measures used were reliable for all[5-7,9-12] except one study[8] in which one of the main outcome measures used was patient-reported number of cigarettes smoked, which increased risk of detection bias due to the self-reported nature of the outcome Probability

values (i.e., *P*-values) were reported for the main outcomes.[5-12] Potential conflicts of interest were reported by authors of all[4-6,8-11] but two studies.[7,12]

There were also several limitations identified in the included RCTs[5-9] and non-randomized studies.[10-12] The RCTs[5-9] were not double-blinded, which may lead to response bias in patient reported outcomes. The patients who were asked to participate and prepared to participate in the studies were recruited via convenience sample (perinatal patients presenting to the hospital),[5-12] and it was unclear whether they were representative of the entire population of mothers and newborns.[5-12]

Summary of Findings

Appendix 4 presents a table of the main study findings and authors' conclusions.

Clinical Effectiveness of Home Visiting Programs

Maternal Health Outcomes

Prenatal Outcomes

In the included RCT by Robling et al.,[8] there was no statistically significant difference between the home visit group and the usual care alone group in the proportion of mothers who smoked during late pregnancy (defined as 34–36 weeks gestation), or the number of cigarettes smoked per day during late pregnancy.

In the quasi-experimental study by Williams et al.,[12] compared to the no home visit group the prenatal (and could continue to postnatal) home visit group had statistically significantly lower pregnancy-induced hypertension, maternal complications during delivery, and maternal weight gain during pregnancy. There was no significant difference between home visit and no home visit groups in incidence of entering prenatal care during first trimester.[12]

Postnatal Outcomes

In the included RCT by Lakin et al.,[7] there was no statistically significant difference between home visit and standard office visit groups in the incidence of completed postpartum visits by eight weeks postpartum, or postpartum depression, when comparing a postnatal home visit program and standard office visits.

Newborn and Baby up to Age Two Health Outcomes

The RCT by Goodman et al.[6] reported that there was a statistically significantly reduced incidence of total child emergency medical care utilization, and significantly lower rates of inpatient hospital overnight stay, from birth through age 24 months, in the group that received a nurse home visiting program in the postpartum period compared to the group that received services as usual. In the RCT by Robling et al.,[8] there was no statistically significant difference between the home visit group and usual care group in rates of emergency department attendances and hospital admissions within 24 months of birth, or serious adverse events. In the RCT by Spittle et al.,[9] there were no statistically significant differences between home visit within the first year of life and standard care groups with respect to developmental outcomes (general cognition, attention, working memory, executive function, academic achievement in word reading and spelling, and motor outcomes) measured at eight years old, except children in the home visit group were statistically significantly less likely to have a mathematics impairment compared with the standard care group. In the included RCT by Lakin et al.,[7] the authors reported no

statistically significant difference in home visit and standard office visit groups in number of health checks, sick visits, or usage of urgent care measured by utilization of phone calls to answering services before 6 months of age. In the quasi-experimental study by Williams et al.,[12] compared to the no home visit group the prenatal (and could continue to postnatal) home visit group had statistically significantly lower incidence of preterm birth, delivering low birth weight infants, substantiated child maltreatment. Additionally, in the quasi-experimental cohort study by Ichikawa et al.,[11] preterm birth was significantly lower in a group that received nurse home visits in comparison to no home visits. There were no significant differences in the proportion of infants born small for gestational age between the group that received home visits and the group that did not receive home visits.[11]

Cost-Effectiveness of Home Visiting Programs

The included SR by Stamuli et al.[4] reported a benefit-to-cost ratio of 2.37 to 2.88 for the home visiting programs (method of measurement and units not provided), and a higher QALYs gained for each mother-child dyad with the home visits by nurses and paraprofessionals compared to standard of care. The cost per one extra unit of maternal sensitivity was £2,723 in resources, while the cost per one extra unit of infant cooperativeness was £2,033. The willingness-to-pay thresholds at which there was 95% probability that home visiting interventions would be cost-effective for maternal sensitivity and infant cooperativeness were £16,100 and £4,000 per unit of improvement, respectively.[4] The probability of a positive net present benefit value was 71%.[4]

Guidelines

No relevant evidence-based guidelines regarding the provision of prenatal and postnatal home visiting programs for mothers and newborns were identified; therefore, no summary can be provided.

Limitations

The economic evaluation studies in the included SR[4] were assessed to be of low to moderate quality by the SR authors. Therefore, although the economic evaluations suggested that home visit interventions may be cost-effective, additional studies with more robust clinical inputs and more clearly reported timeframes are needed to improve certainty in the evidence.[4] As all included studies[4-12] were conducted in countries outside of Canada, the applicability of the evidence to Canadian settings was unclear. There were no evidence-based guidelines regarding prenatal and postnatal home visiting programs for mothers and newborns. Although the terms “mothers” and “women” were used throughout the included studies, results may be generalizable to others who do not identify with these labels.

Conclusions and Implications for Decision or Policy Making

This report provides a summary of recent evidence regarding the clinical effectiveness and cost-effectiveness of prenatal and postnatal home visiting programs for parents, newborns, and babies up to two years of age. This review was comprised of one SR of economic evaluations,[4] four RCTs,[5-9] and two quasi-experimental studies[10-12,14] regarding prenatal and postnatal home visiting programs for mothers, newborns, and babies.

Evidence of limited quality (one RCT by Robling et al.[8] and one quasi-experimental study by Williams et al.[12]) was found regarding the clinical effectiveness of a nurse-led prenatal and postnatal home-visitation program for first-time teenage mothers[8] and the HANDS

Program[12] with respect to prenatal maternal health outcomes. Compared to pregnant women who received usual care usual care, there was no statistically significant difference in the proportion of mothers who smoked or the number of cigarettes smoked per day during late pregnancy in pregnant women who received home visits.[8] Between home visit and no home visit groups, there was no significant difference in the incidence of entering prenatal care during first trimester; however, the home visit group had statistically significantly lower incidence of pregnancy-induced hypertension, maternal complications during delivery, or maternal weight gain during pregnancy.[12]

Regarding postnatal maternal health outcomes, one RCT of limited quality by Lakin et al.[7] demonstrated no statistically significant difference in home visit and standard office visit groups in incidence of completed postpartum visits by eight weeks postpartum or postpartum depression.

There was evidence on postnatal child health outcomes from four RCTs[6-9] and two quasi-experimental studies.[11,12] No statistically significant difference was found in the proportion of infants born small for gestational age between the group that received public health nurses home visits for high-risk pregnant women and the group that did not receive home visits.[11] No statistically significant difference was found between the FNP prenatal and postnatal home-visit program for first-time teenage mothers and usual care group in rates of emergency department attendances and hospital admissions.[8] No statistically significant difference was found between postnatal newborn well-child home visits program and standard office visits in the number of health checks, sick visits, or usage of urgent care measured by utilization of phone calls to answering services.[7] No statistically significant difference was found between home-based early preventative care program for preterm infants and their parents in serious adverse events, most developmental outcomes measured at eight years follow-up.[9]

The cost-effectiveness analyses in the included SR of economic evaluations were based on clinical effectiveness data from RCTs or meta-analysis of RCTs and cost inputs from a variety of sources not specified in the SR.[4] Findings from six primary studies[15-20] within the SR of economic evaluations found the NFP home visiting program in the United States was cost-effective compared to no home visiting program.[4] Findings from one additional economic evaluation[21] within the SR suggested that whether a different 18-month intensive prenatal and postnatal home visiting program was deemed cost-effective was context-specific, depending on the willingness-to-pay threshold and the perspective of the payers.

Regarding evidence-based guideline recommendations on the topic, no relevant evidence-based guidelines that provided recommendations on the provision of home visiting programs were identified.

The limitations of the included studies and of this report should be considered when interpreting the results. Additional studies of high methodological quality may further aid in making definitive conclusions about prenatal and postnatal home visiting programs for parents and newborns.

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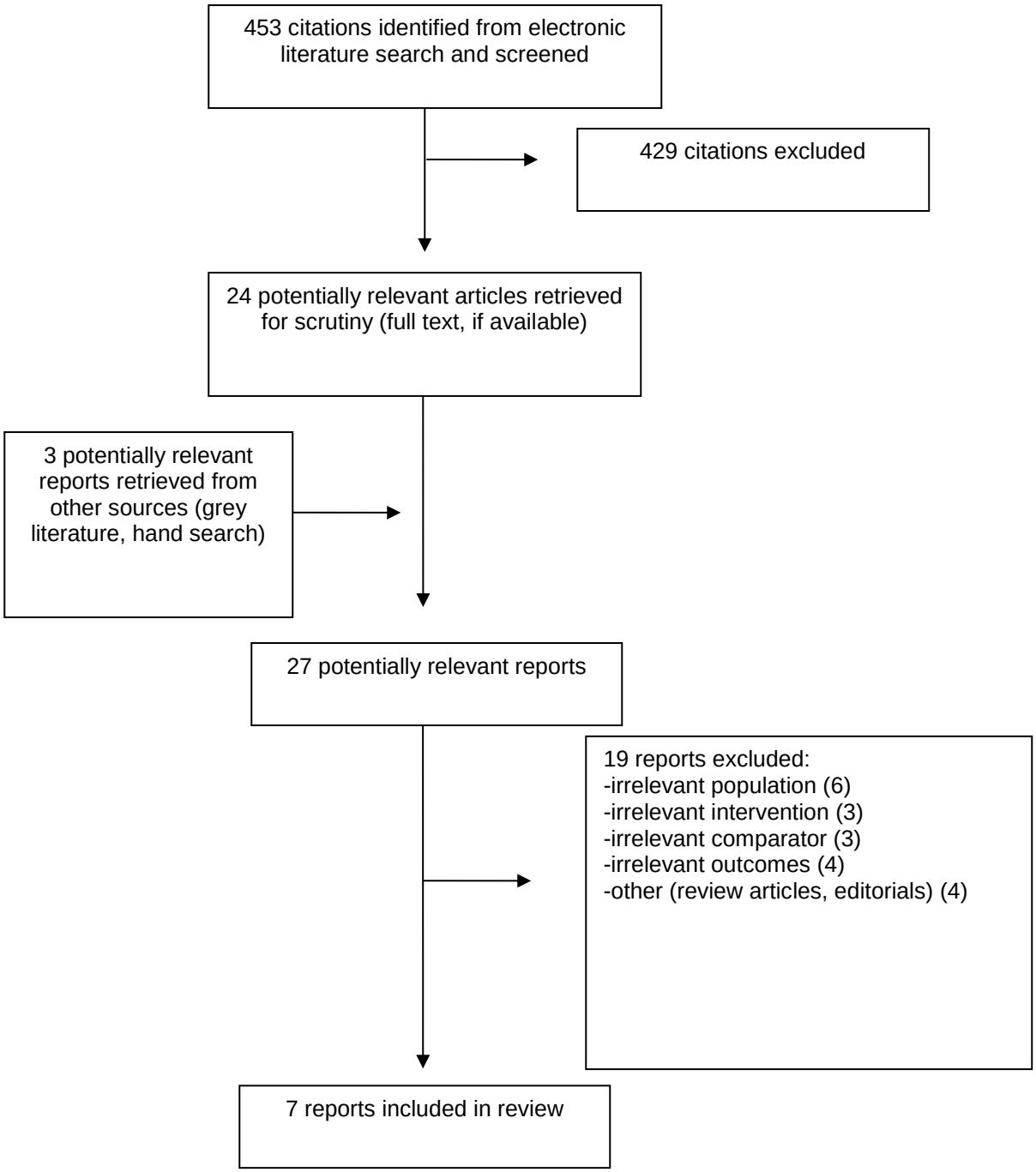
Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Systematic Review

First Author, Publication Year, Country	Study Designs and Numbers of Primary Studies Included	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
Stamuli et al. 2015[4] **UK**	**Study design:** SR without MA **Literature search strategy:** The authors searched NHS EED, HEED, MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, CINAHL, BNI, PsycINFO, CDSR, CENTRAL, DARE, HTA Database, ASSIA, Social Services Abstracts, Sociological Abstracts. **Included study characteristics:** 12 included economic evaluation studies Included studies published 2004-2015 Studies conducted in the United States (10 studies), UK (1 study), Chile (1 study), **Relevant studies:** 7 Relevant studies published 2004-2015 Studies conducted in the United States (6 studies), UK (1 study) **Quality assessment tool:** Drummond and colleagues checklist **Objective:** To Identify relevant economic evaluations of home visitation programs for young or vulnerable pregnant women; to examine the methods employed for the economic analysis of these interventions and critically appraise their quality of conduct; to present the results and the conclusions of these studies, and examine the factors influencing the results (including the perspective chosen, the type of economic evaluation and included costs); to discuss the generalizability/applicability of the results to the present day UK context of decision making.	N = 2,300 young or vulnerable pregnant women **Included:** full economic evaluations of home visitation programs for pregnant women who were vulnerable (i.e., of low socio-economic status) or young (i.e., adolescent). **Excluded:** Studies that could not be translated into English, reported only the effectiveness results or were based on subjects that would not be considered young/vulnerable as defined in earlier Nurse Family Partnership studies, where the intervention was not based on home visits or home visits did not start during pregnancy.	**Included relevant interventions:** home visits from health visitor, paraprofessionals, and nurses that started during pregnancy **Relevant Interventions:** standard of care	**Outcomes:** benefit-to-cost ratio, QALY, extra cost per an extra unit of maternal sensitivity and infant cooperativeness, probability of a positive net present benefit value, willingness-to-pay threshold at which 95% probability that home visiting intervention will be cost-effective **Length of follow-up**: 1-15 years

BNI = British Nursing Index; CENTRAL = Cochrane Central Register of Controlled Trials; CDSR = Cochrane Database of Systematic Reviews; CINAHL = Cumulative Index to Nursing and Allied Health Literature; DARE = Database of Abstracts of Reviews of Effects; HEED = Health Economic Evaluation Database; HTA = Health Technology Assessment; MA = meta-analysis; NHS EED = National Health Service Economic Evaluation Database; QALY = quality-adjusted life-year; UK = United Kingdom.

Table 3: Characteristics of Included Primary Clinical Studies

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
Randomized Controlled Trials				
Goodman et al. 2019[6] **United States**	**Study design:** non-blinded RCT **Setting:** home settings in Durham County, North Carolina **Objective:** to examine Family Connects effects on child emergency medical care utilization and associated billing costs through age 24 months; to understand whether the program conveys benefits for all groups of families; to examine Family Connects effects on costs of emergency medical care	**Inclusion criteria:** families living in Durham County giving birth at one of the two county hospitals from July 1, 2009 to December 31, 2010 **Excluded:** NR **Number of patients:** 4,777 patients n = 2,327 in home visit group n = 2,450 in control group n = 549 analyzed **Mother mean age:** 28.5 years	**Intervention of interest**: Family Connects with 1-3 postnatal registered nurses home visits Family Connect consists of 4–7 manualized contacts, including: • an initial contact shortly after birth (ideally in the birthing hospital) • 1–3 home visits with a registered nurse (typically at 3-12 weeks infant age, to provide physical assessments for infant and mother, intervention and education, assessment of family-specific needs, and connections to matched community resources for longer term support, for families with significant needs) • 1–2 nurse follow-up contacts with community service providers • a telephone follow-up 1 month after the nurse closes the case **Comparator**: Control (services as usual)	**Relevant Outcome: Newborn and baby health outcomes:** child emergency medical care use measured by hospital emergency department records **Length of follow-up**: 24 months

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
Robling et al. 2016[8] **United Kingdom**	**Study design:** pragmatic, open-labelled RCT **Setting:** home settings in England **Objective:** to assess the effectiveness of giving the program to teenage first-time mothers on infant and maternal outcomes up to 24 months after birth	**Inclusion criteria:** nulliparous women (first-time mother) aged 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 **Excluded:** None **Number of patients:** 1,645 women n = 823 in home visit group n = 822 in control group **Mean age:** 17.9 years in home visit group 17.9 in usual care group	**Intervention of interest**: home visiting program plus usual care – FNP program from early pregnancy until children were 2 years old **Comparator**: Usual care alone (primary care public health and social care services)	**Relevant Outcome: Maternal health outcomes:** proportion of mothers who smoked at late pregnancy (34–36 weeks gestation) measured by self-report and urine sample; self-reported number of cigarettes smoked per day at late pregnancy **Newborn and baby health outcomes:** mean birthweights measured by health records; emergency attendances or hospital admissions measured by health records; serious adverse event measured by standard recording templates **Length of follow-up**: 24 months
Spittle et al. 2016[9] **Australia**	**Study design:** single-blinded RCT **Setting:** home settings in Australia **Objective:** to determine the long-term neurodevelopmental outcomes for very preterm children after a preventative care program conducted within the home during the first year of life	**Inclusion criteria:** Infants born at <30 weeks of gestation, living within 100 km of the hospital, and parents who could speak English, recruited between January 2005 and December 2007 from the Royal Women's Hospital and/or Royal Children's Hospital **Excluded:** infants with congenital anomalies likely to affect neurodevelopment **Number of patients:** 120 children n = 61 in home visit group n = 59 in control group At 8-year follow-up: n = 53 in home visit group	**Intervention of interest**: Home-based early preventative care program (9 postnatal home visits by physiotherapist and psychologist at 2 weeks, 4 weeks and at 3, 4, 6, 8, 9, and 11 months) **Comparator**: Standard care	**Relevant Outcome: Child health outcomes:** general cognition measured by General Conceptual Ability score, attention measured by Test of Everyday Attention for Children, working memory measured by Working Memory Test Battery for Children, executive function measured by Tower of London test, academic achievement measured by Wide Range Achievement Test, social-emotional functioning measured by parent-reported Social Skills Improvement System Rating Scales and the Total Problem Score from the Strengths and Difficulties Questionnaire,

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
		n = 47 in control group **Mean age at 8-year assessment:** 8.2 years in home visit group 7.8 years in usual care group		and motor outcomes measured by Movement Assessment Battery for Children **Length of follow-up**: 8 years
Lakin et al. 2015[7] **United States**	**Study design:** non-blinded RCT **Setting:** home settings in United States **Objective:** to pilot a home visit program targeting new families conducted by family medicine residents. This study examined the effects of resident-led newborn home visits (as compared with office visits) on certain maternal and child outcomes in the first 6 months of life.	**Inclusion criteria:** prenatal patients recruited from an urban underserved residency clinic from June 2012 to May 2013 **Excluded:** NR **Number of patients:** 18 women recruited n = 17 completed study n = 9 in home visit group n = 8 in control group **Mean age of women:** 25.7 years in home visit group 24.3 years in usual care group	**Intervention of interest**: Newborn Well-Child Home Visits program - postnatal home visits at 1 week and 1 month, replacing the corresponding office visits by residents **Comparator**: Control (standard well-child office visits by primary resident physician)	**Relevant Outcome:** **Maternal health outcomes:** completed post-partum visit, post-partum depression, breastfeeding – all outcomes from the electronic medical record **Newborn and baby health outcome**: number of well-child checks, sick visits, phone calls to answering service – all outcomes from the electronic medical record **Length of follow-up**: 6 months
Non-randomized Studies				
Williams et al. 2017[12] **United States**	**Study design:** quasi-experimental study **Setting:** home settings in Kentucky **Objective:** to understand the impact of HANDS on maternal and child health outcomes in Kentucky.	**Inclusion criteria: first-time high-risk** mother with completed sociodemographic information on a live singleton birth referred to HANDS between July 2011 and June 2012 **Excluded:** families that were missing the sociodemographic variables, families whose pregnancy resulted in a fetal death, families who reported a multiple birth pregnancy **Number of patients:** 5,870 women	**Intervention of interest**: HANDS program – a voluntary home visiting program by both professionals and paraprofessionals (minimum of one home visit), starting prenatally and can continue postnatally **Comparator**: Control (families that were referred to the HANDS program and completed the referral screen and assessment but did not have a home visit)	**Relevant Outcome:** **Maternal outcomes:** prenatal care measured by whether first prenatal care visit during the first trimester and number of prenatal care visits attended, pregnancy-induced hypertension from live birth certificate data, maternal morbidity from live birth certificate data, maternal weight gain during pregnancy calculated from birth certificate data **Newborn and baby outcome:**

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
		n = 2,831 in home visit group n = 3,039 in control group **Mean age:** NR		preterm birth (< 37 weeks) measured by gestational age, birth weight from the birth certificate, child maltreatment from the Department for Community Based Services data **Length of follow-up**: NR
Ichikawa et al. 2015[11] **Japan**	**Study design:** quasi-experimental cohort study **Setting:** home settings in Kyoto, Japan **Objective:** to evaluate the effectiveness of the home-visit program conducted by public health nurses to high-risk pregnant women to prevent adverse birth outcomes by using the propensity score-matching model	**Inclusion criteria:** High-risk pregnant women (mental illness; primiparas under the age of 20; primiparas over the age of 35 with some unfavorable conditions such as poverty; pregnant with twins; late to register their pregnancy or unhappy about being pregnant; single marital status, non-Japanese women who were not fluent in Japanese, women who were assessed by public health nurses at registration as requiring any additional support including both medical, psycho-social, nutrition counseling) **Excluded:** NR **Number of patients:** 1,023 women n = 429 in home visit group n = 594 in control group **Mean age:** 30.5 in home visit group 30.0 in control group	**Intervention of interest**: public health nurses for high-risk pregnant women prenatal home visit program (at least 1 home visit to high-risk pregnant women lasting for more than 1 hour during mid- or late-term pregnancy (mean gestational age: 27.2 weeks, range: 7–40 weeks) **Comparator**: Control (no home visit)	**Relevant Outcome:** **Newborn outcomes:** Preterm birth, gestational age, birth weight – from birth records **Length of follow-up**: NR

CBCL = Child Behavior Checklist for Ages 1½ -5; Family nurse partnership; HANDS = Kentucky Health Access Nurturing Development Services; HVP = home visiting program; NR = not reported; RCT = randomized controlled trial; ToP+ = additive responsive parenting program.

Appendix 3: Critical Appraisal of Included Publications

Table 5: Strengths and Limitations of Systematic Review using AMSTAR II[22]

Strengths	Limitations
Stamuli et al. 2015[4]	
• The research questions and inclusion criteria for the review included the components of population, intervention, comparison, and outcomes. • The review authors used a comprehensive literature search strategy. • The potential sources of conflict of interest and funding were disclosed.	• A protocol was not reported to have been established prior to the conduct of the review. • The literature search, study selection and data extraction were not performed in duplicate by two reviewers. • A list of excluded studies was not published. • The authors did not explain the reason for the lack of meta-analysis. • The included studies were not described in adequate detail. Interventions and comparators were not described in some of the included studies. • The authors did not assess the risk of bias of included individual studies. • The sources of funding for the included studies were not reported.

Table 6: Strengths and Limitations of Clinical Studies using Downs and Black Checklist[23]

Strengths	Limitations
Randomized Controlled Trials	
Goodman et al. 2019[6]	
• The objective, main outcomes, characteristics, interventions, confounders and main findings of the study were clearly described. • Patient adherence to the interventions was likely reliable due to the documented observed nature of the home visit program. • The patients were randomized to the treatment groups using even and odd birth dates. • The patients in different intervention groups were recruited from the same population and over the same time period. • The statistical tests used to assess the main outcomes were appropriate. • An a priori power calculation was conducted to determine the required sample size. • The main outcome measure used was reliable as it was emergency care utilization measured by hospital emergency department records. • Probability values were reported as ***P***-values for the main outcomes. • Potential conflicts of interest were reported in the article.	• The study was not blinded, which can increase risk of detection bias • It was unclear whether the patients who participated, staff, places, and facilities in the study in United States were representative of the Canadian population. • The patients who were asked to participate and prepared to participate in the study were recruited via convenience sample (patients giving birth within a certain time period). It was unclear whether they were representative of the entire population of mothers and newborns
Robling et al. 2016[8]	
• The objective, main outcomes, characteristics, interventions, confounders and main findings of the study were clearly described.	• The study was not blinded, which can increase risk of detection bias

Strengths	Limitations
• Patient adherence to the interventions was likely reliable due to the documented observed nature of the home visit program. • The patients were randomized to the treatment groups and the allocation was concealed. • The patients in different intervention groups were recruited from the same population and over the same time period. • The statistical tests used to assess the main outcomes were appropriate. • An a priori power calculation was conducted to determine the required sample size. • The authors reported source of funding and declared no conflict of interest.	• One of the main outcome measures used was patient-reported number of cigarettes smoked. There was risk of detection bias due to the self-reported nature of the outcome. • It was unclear whether the patients who participated, staff, places, and facilities in the study in England were representative of the Canadian population. • The patients who were asked to participate and prepared to participate in the study were recruited via convenience sample (patients giving birth within a certain time period in a region). It was unclear whether they were representative of the entire population of mothers and newborns
Spittle et al. 2016[9]	
• The objective, main outcomes, characteristics, interventions, confounders and main findings of the study were clearly described. • Patient adherence to the interventions was likely reliable due to the documented observed nature of the home visit program. • The patients were randomized to the treatment groups using computer-generated random sequences and the allocation was concealed using opaque envelopes. • The patients in different intervention groups were recruited from the same population and over the same time period. • The statistical tests used to assess the main outcomes were appropriate. • The main outcome measures used were reliable. • An a priori power calculation was conducted to determine the required sample size. • The authors reported source of funding and declared no conflict of interest.	• The study was single blinded, which can increase risk of detection bias • It was unclear whether the patients who participated, staff, places, and facilities in the study in Australia were representative of the Canadian population. • The patients who were asked to participate and prepared to participate in the study were recruited via convenience sample (patients giving birth within a certain time period in a region). It was unclear whether they were representative of the entire population of mothers and newborns
Lakin et al. 2015[7]	
• The objective, main outcomes, characteristics, interventions, confounders and main findings of the study were clearly described. • Patient adherence to the interventions was likely reliable due to the documented observed nature of the home visit program. • The patients were randomized to the treatment groups using computer-generated random sequences and the allocation was concealed using opaque envelopes. • The patients in different intervention groups were recruited from the same population and over the same time period. • The statistical tests used to assess the main outcomes were appropriate. • The main outcome measures used were reliable.	• The study was not blinded, which can increase risk of detection bias • The sample size contained 18 mothers. • It was unclear whether the patients who participated, staff, places, and facilities in the study in Australia were representative of the Canadian population. • The patients who were asked to participate and prepared to participate in the study were recruited via convenience sample (patients giving birth within a certain time period in a region). It was unclear whether they were representative of the entire population of mothers and newborns • The authors did not report source of funding or conflict of interest.

Strengths	Limitations
Non-Randomized Studies	
Williams et al. 2017[12]	
• The objective, main outcomes, characteristics, interventions, confounders and main findings of the study were clearly described. • The patients in different intervention groups were recruited from the same population and over the same time period. • The statistical tests used to assess the main outcomes were appropriate. • The main outcome measures used were reliable as it was objective measures of preterm birth, prenatal care measured by whether first prenatal care visit during the first trimester and number of prenatal care visits attended, pregnancy-induced hypertension, child maltreatment, maternal morbidity, maternal weight gain during pregnancy, and breastfeeding. • Patient adherence to the interventions was reliable with documented home visit frequency. • Probability values were reported as *P*-value for the main outcomes.	• It was unclear whether the patients who participated, staff, places, and facilities in the study in United States were representative of the Canadian population. • The patients who were asked to participate and prepared to participate in the study were recruited via convenience sample (patients giving birth within a certain time period). It was unclear whether they were representative of the entire population of mothers. • The authors did not declare potential conflict of interest or disclose study funding.
Ichikawa et al. 2015[11]	
• The objective, main outcomes, characteristics, interventions, confounders and main findings of the study were clearly described. • The patients in different intervention groups were recruited from the same population and over the same time period. • The statistical tests used to assess the main outcomes were appropriate. • The main outcome measures used were reliable as it was objective measures of preterm birth, prenatal care measured by whether first prenatal care visit during the first trimester and number of prenatal care visits attended, pregnancy-induced hypertension, child maltreatment, maternal morbidity, maternal weight gain during pregnancy, and breastfeeding. • Patient adherence to the interventions was reliable with documented home visit frequency. • Probability values were reported as *P*-value for the main outcomes. • The authors declared no conflict of interest.	• It was unclear whether the patients who participated, staff, places, and facilities in the study in Japan were representative of the Canadian population. • The patients who were asked to participate and prepared to participate in the study were recruited via convenience sample (patients giving birth within a certain time period). It was unclear whether they were representative of the entire population of mothers.

CBCL = Child Behavior Checklist for Ages 1½ -5.

Appendix 4: Main Study Findings and Authors' Conclusions

Table 8: Summary of Findings Included Systematic Review

Main Study Findings	Authors' Conclusion
Stamuli et al. 2015[4]	

Relevant primary studies:
Lee et al. 2015[16] – update of Lee et al. 2012[17]
• **Intervention and comparators:** NFP programs vs. control
• Year of costing: 2013
• Discount rate: 3%
• **Benefit-to-cost ratio**: 2.77
• **Probability of a positive net present benefit value:** 71%
 	
Lee et al. 2012[17] – update to Lee, 2008[18]
• **Intervention and comparators:** NFP programs vs. control
• Year of costing: 2011, timeframe not stated
• Discount rate: 3%
• Benefit-to-cost ratio: 2.37
 	
Lee, 2008[18] – update of Aos, 2004[20]
• **Intervention and comparators:** NFP programs vs. control
• Year of costing: 2007, timeframe not stated
• Net benefits: $18,054
• Benefit-to-cost ratio: 3.02
• "The majority of savings was produced by the reduction in crime for both mother and child, and the improvement in test scores for children followed by reduction in child abuse and neglect." (p. 33)[4]
 	
Karoly, 2005[19] – report the results based on analysis by Karoly, 1998[24] and Aos, 2004[20]
• Year of costing: 2003
• Discount rate: 3%
• **Benefit-cost ratio:**
  ○ High-risk group: 5.70
  ○ Low-risk group: 1.26
  ○ Full sample: 2.88
 	
Aos, 2004[20]
• **Objective:** To determine whether early prevention programmes, amongst which there is home visitation programme for vulnerable first-time mothers, are a good investment from Washington state governmental perspective
• **Intervention and comparators:** NFP programs vs. control
• Based on meta-analysis of data from the three NFP trials (Elmira, Memphis, Denver)
• "Human capital" approach to monetize some of the outcomes
• Benefits and costs calculated over the number of years over which the outcomes are evaluated (i.e., up to the last follow-up point). However, it was not clear what longest follow-up point was used in the analysis.
• Cost data came from a variety of sources
• Washington state governmental perspective
• Year of costing: 2003
• Discount rate: 3%
• Return of $2.88 for each dollar spent
	"In general, the conclusion was that the NFP programme provides a good return to the initial investment in the USA. The UK and Chilean studies provide the cost per unit of outcome leaving the judgement on the value for money of the intervention to the decision makers." (*p34*)[4]

Main Study Findings	Authors' Conclusion
• "The savings were due to improvement of outcomes for both mother and child: reduction in rate of crime for both, better high school graduation rates and test scores for the child, reduction in grades repetition for the child, reduction in child abuse and neglect and reduction in alcohol and illicit drug usage by the child." (p. 33)[4] **Olds et al. 2011[15]** • Based on the results of Denver NFP trial through year 9 • Screening and referral (n = 225) vs. screening and referral plus home visit by paraprofessionals (n = 245) vs. screening and referral plus home visit by nurses (n = 235) • Length: pregnancy to study child age 2; Economic analysis conducted at year 9 • Year of costing: 2005 • Discount rate: 3% • Societal and governmental perspective • **Nurse-visited mothers: QALYs gained for each mother–child dyad, 0.15; estimated benefit ratio,** 3.05 • **Paraprofessional-visited mothers: QALYs gained for each mother–child dyad, 0.07; estimated benefit ratio 2.33** **McIntosh, 2009[21]** • RCT, N = 131 • Standard of care (n = 64) vs. 18 months of weekly home visits by health visitor (n = 67) • Year of costing: 2004 • Discount rate: 3.5% • Societal perspective • **Extra cost per one extra unit of maternal sensitivity cost:** £2,723 in resources • **95% probability that home visiting intervention will be cost-effective for maternal sensitivity outcome if the willingness-to-pay threshold is £16,100 per unit of improvement** • **Extra cost per one extra unit of improvement in infant cooperativeness:** £2,033 • **95% probability that home visiting intervention will be cost-effective for infant cooperativeness outcome if the willingness-to-pay threshold is £4,000 per unit of improvement** • "The authors conclude that home visiting is likely to be more costly but also more effective for certain outcomes. There is no established willingness-to-pay value for these outcomes and therefore it is difficult to judge whether these benefits are worth the additional cost." (p. 34)[4]	

NFP = Nurse Family Partnership; QALY = quality-adjusted life year; RCT = randomized controlled trial; UK = United Kingdom; USA = United States of America.

Table 9: Summary of Findings of Included Primary Clinical Studies

Main Study Findings	Authors' Conclusion
Randomized Controlled Trials	
Goodman et al. 2019[6]	

Child emergency medical care use:
 	
Birth to 24-month:
• Total emergency medical care use: Family Connects home visit group 37% less than service as usual group, *P* < 0.001
  ○ Mean total emergency medical care visit in service as usual group: 2.41
  ○ Mean total emergency medical care visit in Family Connects group: 1.52
• Total presentations to emergency medical care for accidents and injuries: Family Connects children had 13% fewer than service as usual group *P* = 0.45
  ○ Mean total presentations for accidents and injuries in service as usual group: 0.30
  ○ Mean total presentations for accidents and injuries in Family Connects group: 0.27
• Present to emergency medical care multiple times for accidents and injuries: Family Connects children 52% less likely compared to service as usual group, *P* = 0.10,
  ○ Likelihood of presentations multiple times for accidents and injuries in service as usual group: 0.06
  ○ Likelihood of presentations multiple times for accidents and injuries in Family Connects group: 0.03
• Percentage of children coded for maltreatment-related injuries: no between-group differences, *P* < 0.30
  ○ Percentage of children coded for maltreatment-related injuries in service as usual group: 0.02
  ○ Percentage of children coded for maltreatment-related injuries in Family Connects group: 0.02
• Inpatient hospital overnights: Family Connects children 85% less than service as usual group, *P* < 0.001
  ○ Mean inpatient hospital overnights in service as usual group: 0.86
  ○ Mean inpatient hospital overnights in Family Connects group: 0.13
• Outpatient ER visits, Family Connects children 10% less than service as usual group, *P* = 0.47
  ○ Mean outpatient ER visits in service as usual group:1.55
  ○ Mean outpatient ER visits in Family Connects group: 1.39
 	
12-month to 24-month:
• Total emergency medical care use: Family Connects 13% less than service as usual group, *P* = 0.73
  ○ Mean total emergency medical care visit in service as usual group: 0.84
  ○ Mean total emergency medical care visit in Family Connects group: 0.73
	"A brief, postpartum nurse home visiting program delivered with high-quality and community-wide reach can significantly reduce population rates of child emergency medical care utilization through age 24 months, with the potential for meaningful cost savings to communities. These findings further indicate that such a public health prevention approach has benefits to families and communities that are sustained beyond infancy, improving early child health and reducing emergency medical care costs, making such programs a worthy community investment." (*p1871*)[6]

Main Study Findings	Authors' Conclusion

• Inpatient hospital overnights: Family Connects children 82% less than service as usual group, *P* = 0.06
  ○ Mean inpatient hospital overnights in service as usual group: 0.11
• Mean inpatient hospital overnights in Family Connects group: 0.02Outpatient ER visits, no statistically significant difference in rates between groups, *P* = 0.88
  ○ Mean outpatient ER visits in service as usual group:0.72
  ○ Mean outpatient ER visits in Family Connects group: 0.71	

Robling et al. 2016[8]	

Proportion of mothers who smoked at late pregnancy:
• n = 870, women with complete self-report data and recorded cotinine concentrations at both baseline and follow-up
• Home visit group: 56%
• Usual care: 56%
• Comparing the odds of an event in FNP compared with usual care group: Adjusted OR 0.90, 97.5% CI 0.64 to1.28
  ○ Rationale for using 97.5% CI not reported
  ○ Adjusted for site stratification and minimization variables (gestational age and smoking status at recruitment, and first or preferred language)
• No significant difference between home visit group and control group
 	
Reported number of cigarettes smoked per day at late pregnancy:
• n = 610, women classified at baseline as smokers
• Comparing the mean adjusted number of cigarettes smoked in FNP compared with usual care group: 0.12 cigarettes, 97.5% CI 0.73 to 0.97
  ○ Adjusted for site stratification and minimization variables (gestational age and smoking status at recruitment, and first or preferred language)
  ○ Significant difference between home visit group and control group
 	
Mean birthweights of babies:
• Home visit group: 3,217.4 g (SD 618.0 g)
• Usual care: 3,197.5 g (581.5 g)
• Comparing the mean adjusted birthweight in FNP compared with usual care group: 20.75 g, 97.5% CI 47.73 to 89.23
Adjusted for site stratification and minimization variables (gestational age and smoking status at recruitment, and first or preferred language)
 	
Rates of emergency attendances or hospital admissions within 24 months of birth:
• Home visit group: 81%
• Usual care: 77%
• OR 1.32, 97.5% CI 0.99 to 1.76
 	
Proportion of participants with at least one serious adverse event:
• mainly clinical events associated with pregnancy and infancy period
• Home visit group, n/N, %: 357/810, 44%
• Usual care, n/N, %: 310 of 808, 38%
• Numerically similar, no statistical difference reported by study authors
	"In conclusion, we show substantial additional cost, no benefit for policy relevant main outcomes, and some advantage for a few secondary outcomes for mother and child when adding FNP to existing health service provision in England. Evidence for benefit for child development outcomes would mainly arise in children after the age of 2 years, requiring longer-term follow-up for this outcome." (*p154*)[8]

Main Study Findings	Authors' Conclusion
Spittle et al. 2016[9]	
School-Age Child Outcomes at 8 years follow-up (home visits during first year of life): Outcomes adjusted for stratification factors of multiple birth and white matter abnormality grade 3 or 4. **General cognition**, adjusted mean difference between preterm intervention and preterm control (95% CI) • General conceptual ability: ○ Score: 0.9 (–4.5 to 6.4), *P* = 0.74 ○ Impairment: 1.21 (0.47 to 3.09), *P* = 0.69 • Verbal composite: ○ Score: 1.2 (–4.7 to 7.1), *P* = 0.70 ○ Impairment: 0.92 (0.36 to 2.33), *P* = 0.86 • Nonverbal reasoning composite: ○ Score: 2.0 (–3.4 to 7.3), *P* = 0.47 ○ Impairment: 1.07 (–0.41 to 2.87), *P* = 0.88 • Spatial reasoning composite: ○ Score: 2.7 (–3.5 to 8.8), *P* = 0.40 ○ Impairment: 0.97 (0.34 to 2.79), *P* = 0.96 **Attention**, adjusted mean difference between preterm intervention and preterm control (95% CI) • Selective attention: ○ Score: 0.6 (–1.0 to 2.2), *P* = 0.47 ○ Impairment: 0.45 (0.18 to 1.09), *P* = 0.08 • Shifting attention: ○ Score: −0.3 (–2.0 to 1.3), *P* = 0.69 ○ Impairment: 0.99 (0.41 to 2.37), *P* = 0.98 • Sustained attention: ○ Score: −1.1 (–2.5 to 0.4), *P* = 0.16 ○ Impairment: 1.23 (0.59 to 2.77), *P* = 0.53 • Divided attention: ○ Score: 0.0 (1.8 to 1.8), *P* = 0.99 ○ Impairment: 1.21 (0.51 to 2.88), *P* = 0.66 **Working memory**, adjusted mean difference between preterm intervention and preterm control (95% CI) • Digit recall: ○ Score: 4.8 (–3.0 to 12.6), *P* = 0.23 ○ Impairment: 0.97 (0.38 to 2.49), *P* = 0.88 • Block recall: ○ Score: −1.7 (9.8 to 6.4), *P* = 0.68 ○ Impairment: 0.96 (0.35 to 2.64), *P* = 0.94 • Backward digit recall: ○ Score: 5.4 (–2.3 to 13.2), *P* = 0.17 ○ Impairment: 0.75 (0.29 to 1.95), *P* = 0.56 **Executive function**, adjusted mean difference between preterm intervention and preterm control (95% CI) • TOL (N correct in 60 s): ○ Score: −0.5 (–1.6 to 0.6), *P* = 0.36 ○ Impairment: 0.93 (0.35 to 2.47), *P* = 0.89	"There were no significant differences between intervention and standard care groups for the child outcomes for the continuous scores, with both preterm groups performing below their term-born peers (Table 2). With respect to impairment rates, there were no differences between the intervention and standard care groups (Table 3), except children in the intervention group (38%) were less likely to have a mathematics impairment compared with the standard care group (53%) (OR, 0.42; 95% CI, 0.18 to 0.98; P = .045)."(*p4*)[9] "Our preventative care program for preterm infants and their caregivers in the first year of life mostly had no long-term benefits on child outcomes, with the exception of reduced mathematical computation difficulties. However, parents did report sustained benefits on their mental health, with primary caregivers in the intervention group reporting lower rates of depression at the 8-year follow-up of age, which is a clinically important result that has the potential to support child and parent quality of life and functioning over time." (*p6-7*)[9]

Main Study Findings	Authors' Conclusion

• TOL (N correct on first attempt):
  ○ Score: −0.8 (–1.7 to 0.7), *P* = 0.07
  ○ Impairment: 1.37 (0.52 to 3.62), *P* = 0.52
 	
Academic achievement, adjusted mean difference between preterm intervention and preterm control (95% CI)
• Word reading:
  ○ Score: −0.2 (–7.1 to 6.8), *P* = 0.96
  ○ Impairment: 0.84 (0.34 to 2.09), *P* = 0.72
• Spelling:
  ○ Score: −0.8 (–8.2 to 6.6), *P* = 0.83
  ○ Impairment: 1.10 (0.44 to 2.73), *P* = 0.84
• Mathematical computation:
  ○ Score: 1.9 (–4.4 to 8.1), *P* = 0.56
  ○ Impairment: 0.42 (0.18 to 0.98), *P* = 0.045 (statistically significant)
 	
Motor outcome, adjusted mean difference between preterm intervention and preterm control (95% CI)
• Total standard score:
  ○ Score: 0.2 (–1.5 to 1.9), *P* = 0.82
• <15th percentile
  ○ Impairment: 1.42 (0.52 to 3.86), *P* = 0.49
 	
Behavior outcome, adjusted mean difference between preterm Intervention and preterm control (95% CI)
○ **Any social-emotional impairment**
  ○ Impairment: 0.93 (0.35 to 2.45), *P* = 0.88	

Lakin et al. 2015[7]	
Completed postpartum visit by 8 weeks postpartum Control group vs. home visit group, % (n): 62.5% (5) vs. 77.8% (7), *P* = 0.62 **Diagnosis of postpartum depression** Control group vs. home visit group, % (n): 25.0% (2) vs. 22.2% (2), *P* = 1 **Average number of well-child checks prior to 6 months of age** Control group vs. home visit group: 4.63 ± 1.29 5. vs. 29 ± 0.76, *P* = 0.32 **Average number of sick visits prior to 6 months of age** Control group vs. home visit group: 3.38 ± 1.15 vs. 1.63 ± 1.77, *P* = 0.05 **Average number of phone calls to answering service** Control group vs. home visit group:3.71 ± 1.97 vs. 1.78 ± 1.56, *P* = 0.05	"The results from our pilot home visit program suggest that newborn home visits by resident physicians are valuable for both patients and residents. One important outcome of this study was an overall lower usage of acute care services in the home visit group, in the form of decreased phone calls to the answering service and sick visits for the child in their first 6 months of life… Mothers who received home visits for their newborns reported higher overall quality of life scores among all domains, with the environmental and social domains nearing statistical significance…We found similar rates of postpartum depression, adherence to contraception, and adherence to well visits for children in both groups."(*p219-220*)[7]

Main Study Findings	Authors' Conclusion
Non-randomized Studies	
Williams et al. 2017[12]	
Preterm birth Home visit group had significantly lower incidence than control: 10.6 vs. 13.7%, OR 0.74, 95%CI 0.61 to 0.88 **Rates of delivering low birth weight infants:** Home visit group had significantly lower incidence than control: 7.2 vs. 12.4%, OR 0.54, 95%CI 0.44 to 0.67 **Substantiated child maltreatment** Home visit group significantly less likely to have a substantiated report of child maltreatment compared to controls: 6.0 vs. 11.0%, OR 0.53, 95%CI 0.43 to 0.65. **Prenatal care** **Rates of entering prenatal care during the first trimester:** No significant difference between groups **Rates of receiving adequate prenatal care:** Home visit group had significantly higher incidence than control: 73.6 vs. 71.0%, OR 1.14, 95%CI 1.00 to 1.30 **Maternal morbidity** **Pregnancy-induced hypertension:** Home visit group significantly less likely to have pregnancy-induced hypertension vs. control: 9.4 vs. 17.5%, OR 0.51, 95%CI 0.42 to 0.60 **Maternal complications during delivery:** Home visit group had significantly fewer than control: 1.6 vs. 2.7%, OR 0.61, 95%CI 0.40 to 0.91 **Maternal weight gain during pregnancy** Home visit group gained an average of 1.2 pounds less than control group, *P* = 0.0457	"Controlling for the potential effects of race/ethnicity and socioeconomic status, HANDS program participation appears to result in improvements in maternal and infant health outcomes. Getting families linked to services, ideally prenatally, but particularly in the first few months of life, can offer these children a better chance of improved outcomes." (*p1173*)[12]
Ichikawa et al. 2015[11]	
Effects of home-visit program compared to no home visit on birth outcomes Unadjusted odds ratio (95% CI) ○ **LBW (<2500g):** 0.70 (0.49 to 0.98) ○ **Preterm birth (<37 week):** 0.62 (0.41 to 0.94) ○ **SGA (<10th percentile):** 0.62 (0.43 to 0.91) Propensity score-matched + multivariable adjusted for gestational age, sex, and parity, odds ratio (95% CI) ○ **LBW (<2500g):** 0.26 (0.052 to 1.26) ○ **Preterm birth (<37 week):** 0.26 (0.001 to 0.64) ○ **SGA (<10th percentile):** 0.71 (0.22 to 2.34)	"Our findings suggest that home visits by public health nurses for high-risk pregnant women in Japan might be effective in preventing preterm birth, but not SGA. This study adds to the evidence of the effectiveness of population-based home-visit programs as a public healthcare measure." (*p11*)[11]

CBCL = Child Behavior Checklist for Ages 1½ -5; CI = confidence interval; ER = emergency room; FNP = family nurse partnership; HR = hazard ratio; IPW: Inverse Probability Weighted results; OR = odds ratio; SGA = small for gestational age; TOL = Tower of London assessment; UW = Unweighted results.

Appendix 5: Additional References of Potential Interest

Related CADTH Reports

Dulong C, Argáez C. In-home physical post-natal and post-partum assessments: clinical effectiveness and guidelines. (*CADTH rapid response report: summary of abstracts*). Ottawa (ON): 2018 Dec. https://www.cadth.ca/sites/default/files/pdf/htis/2018/RB1284%20In-home%20Postnatal%20Assessments%20Final.pdf Accessed 2020 Feb 19.

Randomized Controlled Trials – Alternative Population

Doyle O, McGlanaghy E, O'Farrelly C, Tremblay RE. Can Targeted Intervention Mitigate Early Emotional and Behavioral Problems?: Generating Robust Evidence within Randomized Controlled Trials. *PLoS One*. 2016;11(6):e0156397. PubMed: PM27253184

Evidence-based Guidelines – Alternative Outcome

NICE. Postnatal care up to 8 weeks after birth. (*NICE clinical guideline no. CG37*). London (UK): National Institute for Health and Care Excellence; 2015 Feb (updated). https://www.nice.org.uk/guidance/cg37/resources/postnatal-care-up-to-8-weeks-after-birth-pdf-975391596997 Accessed 2020 Feb 18.

Guidelines with Unclear Methodology

Smith S. Routine postnatal care of women and their babies: clinical guidelines. Essex, England: NHS Mid Essex Hospital Services; 2018 Dec.

Standards of Postnatal Care for Mothers and Newborns in Ontario: final report. Toronto (ON): Provincial Council for Maternal and Child Health; 2017 Jun. http://www.pcmch.on.ca/wp-content/uploads/2017/10/Standards-of-Postnatal-Care-for-Mothers-and-Newborns-in-Ontario-Final-Report-Part-I-2017Oct10.pdf Accessed 2020 Feb 18.

Provincial public health nursing standards: prenatal, postpartum, and early childhood (*Supplemental document 1*). Winnipeg (MB): Manitoba Provincial Public Health; 2015. https://www.gov.mb.ca/health/publichealth/phnursingstandards/docs/nursing_standards_suppl.pdf Accessed 2020 Feb 18.

Sangha J. Postnatal care guidelines. Reading, England: Royal Berkshire NHS Foundation Trust; 2015 Mar. http://www.royalberkshire.nhs.uk/Downloads/GPs/GP%20protocols%20and%20guidelines/Maternity%20Guidelines%20and%20Policies/Postnatal/Postnatal%20guideline_V4.2_GL890.pdf *See section* 3.3 : Community postnatal care Accessed 2020 Feb 18.