

NOTAT

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Beskrivelse av studier av Nurse-Family Partnership

Tittel Beskrivelse av studier av Nurse-Family Partnership
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Institusjon Folkehelseinstituttet
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Forord

Folkehelseinstituttet fikk i slutten av september 2021 i oppdrag av Barne-, ungdoms- og familiedirektoratet å beskrive seks studier av programmet Nurse-Family Partnership, i tillegg til å gjøre et enkelt litteratursøk etter ytterligere studier av dette programmet. Nurse-Family Partnership er et program rettet mot mødre/foreldre og barn og består av hyppige hjemmebesøk og støtte av spesialopplært sykepleier (familiesykepleier) fra tidlig i svangerskapet og gjennom de to første årene i barnets liv. FHI's levering skal benyttes inn i direktoratets arbeid med å bestille en randomisert kontrollert studie om effekten av Nurse-Family Partnership i Norge (på norsk kalt 'Familie for første gang'). I tråd med prinsipper for kunnskapsbasert forskning ønsker direktoratet å utforme ny forskning i lys av den forskningen som allerede finnes (<https://tidsskriftet.no/2014/01/kommentar-og-debatt/kunnskapsbasert-forskning>).

Rapporten er oversendt oppdragsgiver 15. oktober 2021.

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Folkehelseinstituttet tar det fulle ansvaret for resultatene som er beskrevet i rapporten.

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Problemstilling

Vi skulle besvare følgende problemstillinger:

- 1) For seks identifiserte randomiserte kontrollerte studier (RCTer) utført på Nurse-Family Partnership-programmet:
 - a. Hva er populasjon (inkludert setting og spesifikke inklusjonskriterier), tiltak (kort), sammenligning og utfall?
 - b. Hvordan beskriver forfatterne at de har gjort de statistiske styrkeberegningene og nås RCTenes mål om utvalgsstørrelser?
 - c. Hva er alle utfallsmål for barn 0-2 år og hvordan og når er de målt?

Dersom det var tid skulle vi også hente ut data om det faktiske utvalget i hver studie og om utfallsmål for barn etter fylte to år, samt se populasjon/inklusionskriterier i de seks studiene i sammenheng.

- 2) I tillegg skulle vi identifisere eventuelle nye studier av Nurse-Family Partnership i databasen Cochrane Central Register of Controlled Trials (CENTRAL).

Metode

Bekrivelse av seks RCTer

Oppdragsgiver, Bufdir, gav oss en oversikt («scientific overview», ikke systematisk) fra McMaster som beskriver de første fem RCTene som er blitt gjort av Nurse-Family Partnership. I dette dokumentet var det referert til 20 publikasjoner fra de fem RCTene; disse 20 publikasjonene er sortert og listet i vedlegg 1. Mot slutten av arbeidet fikk vi også en forespørsel om å inkludere den sist igangsatte RCTen – i Canada – og protokollen som var publisert om denne. Referansen finnes også i vedlegg 1. Totalt var det altså seks RCTer.

Vi tok utgangspunkt i de seks første publikasjonene, eventuelt publiserte protokoller, for å hente ut data om populasjon/setting/inkludjonskriterier, tiltak, sammenligning, utfallsmål for barn 0-2 år og statistiske styrkeberegninger. Teksten er hentet direkte fra publikasjonene og er dermed på engelsk. I tillegg har vi listet utfallsmål for barn i senere studier/publikasjoner.

Vi hentet ut relevant informasjon relatert til styrkeberegninger for hver enkelt studie og inkluderte det i tabellformat. Følgende informasjon ble hentet ut: I hvilken publikasjon relevante styrkeberegninger ble oppgitt, hvorvidt en protokoll for studien var tilgjengelig, beskrivelse av styrkeberegningene (signifikans- og styrkenivå, effektestimert, utfall), estimert nødvendig størrelse på total studiepopulasjon, om estimert nødvendig størrelse ble oppnådd, samt informasjon om frafall.

Litteratursøk i CENTRAL

Vi gjorde et søk i CENTRAL (Cochrane Central Register of Controlled Trials) 5. oktober 2021. Søketermer er listet i vedlegg 2. Bibliotekar Elisabet Hafstad utarbeidet søket og Ingrid Harboe fagfellevurderte.

En av forfatterne (HN) leste referanser og fulltekst for å inkludere studier som angikk Nurse-Family Partnership. Vi laget en liste over studier som så ut til å være aktuelle.

Resultat

Nedenfor presenteres først datauttrekkene fra de seks RCTene, med PICO (populasjon, intervensjon, sammenligning, utfall), utfall på barn 0-2 år, utfall på barn etter to år samt studienes styrkeberegninger. Deretter vises to enkle sammenstillinger av henholdsvis inklusjonskriterier og styrkeberegninger i RCTene. Til slutt beskrives resultatet fra litteratursøket i CENTRAL.

Beskrivelser av seks RCTer

RCT 1 – The Elmira Trial

Olds DL, Henderson CR, Jr., Chamberlin R, Tatelbaum R. Preventing child abuse and neglect: A randomized trial of nurse home visitation. *Pediatrics* 1986; 78: 65-78.

PICO

Tabell 1: Beskrivelse av PICO i The Elmira Trial (Olds 1986)

PICO	
P inclusion criteria	Recruiting: Between April 1978 and September 1980 - 500 women were recruited through the health department antepartum clinic, the offices of private obstetricians, Planned Parenthood, the public schools, and a variety of other health and human service agencies and interviewed for participation in the study. - Women were actively recruited if, at intake: <ul style="list-style-type: none">• they had no previous live births• they had any one of the following characteristics that predispose to infant health and developmental problems:<ul style="list-style-type: none">• young age (<19 years)• single-parent status• low socio-economic status
setting	Small, semirural county of approximately 100,000 residents in the Appalachian region of New York State. At the time the study was initiated, the community was well served from the standpoint of both health and human services. In spite of abundance of these services, the community has consistently exhibited the highest rates of reported and confirmed cases of child abuse and neglect in the state. Moreover, in 1980 the community was rated the worst Standard Metropolitan Statistical Area in the United States in terms of its economic conditions.

actual sample Although there was a clear inclusion criteria, the study design allowed any women who asked to participate and who was bearing a first child to be enrolled. All women were enrolled prior to the 30th week of pregnancy.

Approximately, 10% of the target population was missed due to late registration for prenatal care. An additional 10% was missed because some eligible women from the offices of private obstetricians were not referred.

There were no differences in age, marital status, or education between those women who participated and those who declined. Of the non-white women (mostly blacks), 94% enrolled as opposed to 80% of the whites (p=0.02)

At the registration, 47% of the participating women were younger than 19 years of age, 62% were unmarried, and 61% came from families in Hollingshead's social class IV and V (semiskilled and unskilled laborers; Hollingshead's index¹ was adapted slightly). Eighty-five percent of the women met at least one of the age, marital status, or socioeconomic status criteria, and 23% possessed all three risk characteristics.

Forty-six non-white women were removed from the analyses reported in this article because the sample of nonwhite women was too small to cross-classify race with other variables of importance.

Prior to their assignment to one of the treatment conditions, the women were interviewed to determine their family characteristics, psychologic resources, health conditions, health habits, the availability of informal support, and childhood histories.

At the registration, to determine preintervention equivalence, treatment conditions were examined on sociodemographic characteristics (social class, marital status, age, maternal education) and psychologic and social support variables (maternal sense of control, helping network (number of people, intimates and kin), expected accompaniment to labor and delivery, husband/boyfriend support (availability, contact and anticipated help), grandmother support (availability, contact and anticipated help), predicted positive parenting (scale derived from discriminant analysis to predict quality of care giving, based on weighted sum of mother's reports of being yelled at, spanked and treated restrictively in her own childhood,; the level of psychosocial stress in her family of origin; her level of ego development; her prepregnant level of smoking; the economic status of her current household; and a housing-crowdedness index)).

1: Hollingshead AB: Four-factor index of social status. Working paper. New Haven, CT, Yale University, 1976

I The study had 4 treatment conditions and treatment number 4 (Nurse Family Partnership) was used as intervention. Families assigned to the fourth condition received the same services as those in treatment 3 (see below), but, in addition, the nurse continued to visit until the child was 2 years of age. For 6 weeks following delivery, the nurses visited families every week; from 6 weeks to 4 months, every 2 weeks; from 4 to 14 months, every 3 weeks; from 14 to 20 months, every 4 weeks; and from 20 to 24 months every 6 weeks. When predetermined crisis conditions existed, they visited weekly. The visits lasted approximately one hour and 15 minutes. The visits were consisted of three major activities: parent education regarding fetal and infant development, the involvement of family members and friends in child care and support of the mother, and the linkage of family members with other health and human services. Treatment 4 (n=116) was shown in the tables labeled as "nurse-visited: infancy".

C Remaining 3 treatments conditions were:

- Treatment 1(n=90): During pregnancy, no services were provided through the research project. When the babies were 1 and 2 years of age, an infant specialist hired by the research project screened them for sensory and developmental problems. Suspected problems were referred to other specialists for further evaluation and treatment.
- Treatment 2 (n=94): Families were provided free transportation for regular prenatal and well-child care at local clinics and physicians' offices through a contract with a local taxicab company. Sensory and developmental screenings as in treatment 1, was provided when the babies were 1 and 2 years of age.
- Treatment 3 (n=100): Families were provided a nurse home-visitor during pregnancy in addition to screening and transportation services. The nurses visited families approximately once

every 2 weeks and made an average of nine visits during pregnancy, each of which lasted approximately one hour and 15 minutes.

Treatments 1 and 2 were combined for purposes of analysis after it was determined that there were no differences between these two groups in their use of routine prenatal and well-child care, hence, the combination of treatments 1 and 2 served as the comparison group. Although treatment 3 was shown in the tables labeled as "nurse-visited: pregnancy", comparisons focused on the contrast of the treatment 4 and the comparison group (combination of treatment 1 and 2) for the whole sample and for those subsamples defined as being at risk: the teenagers (<19 years of age), the unmarried, the poor, and the group with all three risk characteristics.

O Interviews and infant assessments were carried out at registration (prior to the 30th week of pregnancy), and at 6, 10, 12, 22, and 24 months of the infant's life. During infancy, the babies were brought to the project office at 6, 12, and 24 months for weighing and measuring. Medical records were abstracted for the infant's first 2 years of life. Reliability of the medical record review procedure was checked on a systematic and regular basis and was found to be acceptable.

The outcomes included attrition, child abuse and neglect, reports of infant temperament and behavioural problems, and maternal concern, conflict, scolding, and spanking, provision of appropriate play materials and avoidance of restriction and punishment and developmental quotient, emergency room visits, and maternal sense of control as a conditioner of treatment effects.

Utfall på barn 0-2 år

Tabell 2: Beskrivelse av utfall på barn 0-2 år i The Elmira Trial (Olds 1986)

OUTCOMES	MEASUREMENTS	POINT OF TIME
CHILD DEVELOPMENT		
Child abuse and neglect	A list containing the names of all participating women and their children, their children's ages, and their addresses was given to state department of social service workers who thoroughly reviewed the department records for the presence of "indicated" (verified) cases of abuse or neglect. Verified cases consisted of those that were reported for abuse or neglect and investigated by a department caseworker who determined that an episode of abuse or neglect, as defined by state law, had indeed occurred. Those cases were then reviewed by department workers to abstract standard information such as age of the child at the time of the first confirmed report, the specific type of abuse and neglect, the alleged perpetrator, and source of the maltreatment report (mandated sources like professionals required by law to report suspected maltreatment or nonmandated sources like neighbors and family members). The names of children and parents who moved to 15 other states during the investigation were sent for review.	0-24 mo
<i>Reports of infant temperament, behavioural problems, and maternal reaction to behavioural problems</i>	At each of the assessments, the mothers were interviewed concerning common infant behavioral problems, such as feeding difficulties and crying, and how the mothers responded to these problems. When the babies were 6 months of age, the mothers were administered an infant temperament Q-sort procedure *. * Pedersen FA, Anderson BJ, Cain RL: A methodology for assessing parent perception of infant temperament. Presented at the Fourth Biennial Southeastern Conference on Human Development, Nashville, April 1976	
Positive mood (one of five dimensions of infant temperament was measured, the others include adaptability, approach, activity level, and rhythmicity)		6 mo
Crying (number of episodes for the last 2 weeks)		6 mo

Resist eating (number of episodes for the last 2 weeks)		6 mo
Night awake (number of episodes for the last 2 weeks)		6 mo
Worry or concern (sum of positive responses for behavioural problems)		6 mo
Conflict (sum of positive responses for behavioural problems)		6 mo
Yell or scold (number of times for the last 2 weeks)		6 mo
Spank or hit (number of times for the last 2 weeks)		6 mo
Provision of appropriate play materials and avoidance of restriction and punishment	The mothers were interviewed in their homes, and the Caldwell Home Observation checklist and interview procedure was completed. The Caldwell and Bradley procedure evaluates qualities of the home environment and parental care giving according to six dimensions, including the mother's avoidance of restriction and punishment and the provision of appropriate play materials. Rates of inter-observer agreement for the Caldwell procedure on individual items ranged from 82% to 100%. <i>Caldwell B, Bradley R: Home observation for measurement of the environment. Little Rock, AR, University of Arkansas, 1979</i>	10 mo 22mo
Developmental quotient	The infants were administered developmental tests in the project offices, using the Bayley mental development index and the Cattell scale.	12 mo (Bayley) 24 mo (Cattell)
Maternal Sense of Control as a Conditioner of Treatment Effects	Scale measuring extent to which women felt control over their life circumstances using a short-form variant of Rotter's locus of control instrument. <i>Rotter JB: Generalized expectancies for internal versus external control of reinforcement. Psychol Monog Gen Appl 1966;80:1</i>	0-24 mo
USE OF HEALTH SERVICES		
Number of emergency room visits	Medical records were abstracted.	12 mo 24 mo
Number of emergency room visits for accidents and poisonings	Medical records were abstracted.	12 mo 24 mo

Utfall på barn i oppfølgingsstudier (>2 år)

Tabell 3: Beskrivelse av utfall på barn > 2 år i oppfølgingsstudier i The Elmira Trial

STUDY ID	FOLLOW-UP PERIOD	OUTCOMES FOR CHILDREN
1. Olds 1994	25-50 mo	<p>-child abuse and neglect</p> <p>-intellectual functioning by Stanford Binet IQ scores</p> <p>-home and car safety (following categories of hazards in the home: (1) chipped or flaking paint; (2) sharp objects (broken glass, boards with protruding nails, knives, razor blades, etc.); (3) danger of burns (pots or pans with handles turned out, iron left out, exposed heaters and wood stoves, etc.); and (3) dangerously placed objects that pose a risk for falls, such as those on stairways, and also, the presence and accessibility of poisonous substances in the home and the child's use of car seats and safety belts when riding in the car)</p> <p>-health care encounters (the number of health supervision visits, the number of visits to the physician at which separate illnesses were detected (ie, initial sick visits for an illness plus well-child visits at which health problems were identified), the</p>

		<p>number of injuries or ingestions noted in the physician's record, the number of child behavioral and parental coping problems noted in the physician's record, the total number of emergency department encounters, the number of emergency department encounters for injuries and ingestions, the number of hospitalizations, and the number of days hospitalized)</p> <p>-warmth, control and involvement</p> <p>-home inventory (stimulation of language skills, provision of toys, games, reading materials, avoidance of punishment)</p>
2. Olds 1997	15 y	-child abuse and neglect (involving the mother as perpetrator)
3. Olds 1998	15 y	<p>-encounters with the criminal justice system (whether they had been adjudicated a person in need of supervision resulting from incorrigible behaviour such as recurrent truancy or destroying parent's property, number of run aways, number of times that they had been stopped by the police, arrested, convicted of a crime or probation violations and sent to youth correctional facilities)</p> <p>-disruptive behaviour in school (number of suspensions)</p> <p>-behavioural problems (delinquent and aggressive behaviour outside school)</p> <p>-sexual activity (experience of sexual intercourse, rates of pregnancy, number of sexual partners)</p> <p>-use of substances (cigarettes, alcohol and illegal drugs)</p>
4. Eckenrode 2000	15 y	<p>-number of substantiated maltreatment reports (abuse and neglect) involving the study child regardless of the identity of the perpetrator or involving the mother as perpetrator regardless of the identity of the child</p> <p>-number of runaway episodes</p> <p>-number of arrests</p> <p>-number of convictions</p> <p>-number of sex partners</p> <p>-number of days drank alcohol</p>
5. Zielinski 2009	15 y	-developmental timing of maltreatment generally and neglect specifically (such as failure to provide, lack of supervision, inadequate guardianship, educational neglect, medical neglect)
6. Eckenrode 2010	19 y	<p>-history of arrests and convictions</p> <p>-delinquent and criminal behavior (felony assault (aggravated assault, sexual assault, or gang fights), fraud, minor assault (hit parents, teachers, or students), minor theft (stole something worth \$50 or joyriding), illegal services (prostitution or sold marijuana or other drugs), vandalism or damaged property, and public disorder (panhandling or been loud, rowdy, or drunk in public))</p> <p>-use of illegal drugs</p> <p>-engagement in binge drinking (>4 drinks in a row)</p> <p>-educational achievement (whether the youth had graduated from high school, was currently economically productive (ie. in school, the military, or job training or working full time at the time of the interview))</p> <p>-sexual activity (pregnancies, births (had become or made a girl pregnant or become a parent), number of sexual partners, frequency of birth control and condom use (on scales ranging from 1[never] to 7[always]))</p> <p>-use of welfare, food stamps or Medicaid.</p>

Referanser til oppfølgingsstudier

1. Olds DL, Henderson CR, Jr., Kitzman H. Does prenatal and infancy nurse home visitation have enduring effects on qualities of parental caregiving and child health at 25 to 50 months of life? *Pediatrics* 1994; 93: 89-98.
2. Olds DL, Eckenrode J, Henderson CR, et al. Long-term effects of home visitation on maternal life course and child abuse and neglect. Fifteen-year follow-up of a randomized trial. *Journal of the American Medical Association* 1997; 278: 637-643.
3. Olds D, Henderson CR, Jr., Cole R, et al. Long-term effects of nurse home visitation on children's criminal and antisocial behavior: 15-year follow-up of a randomized controlled trial. *Journal of the American Medical Association* 1998; 280: 1238-1244.

4. Eckenrode J, Ganzel B, Henderson CR, Jr., et al. Preventing child abuse and neglect with a program of nurse home visitation: The limiting effects of domestic violence. *Journal of the American Medical Association* 2000; 284: 1385-1391.
5. Zielinski DS, Eckenrode J, Olds DL. Nurse home visitation and the prevention of child maltreatment: Impact on the timing of official reports. *Development and Psychopathology* 2009; 21: 441-453.
6. Eckenrode J, Campa M, Luckey DW, et al. Long-term effects of prenatal and infancy nurse home visitation on the life course of youths: 19-year follow-up of a randomized trial. *Archives of Pediatric and Adolescent Medicine* 2010; 164: 9-15. +ERRATUM

Styrkeberegninger

Tabell 4. Styrkeberegninger for The Elmira Trial ifølge forfatterne (Olds 1986)

Study	RCT 1 – The Elmira Trial (New York) Recruitment: April 1978 - Sept. 1980 N=400
Protocol available?	No
Original publication	Olds 1986
Description of power calculations	No information
Needed sample size according to power calculations	No information
What outcome(s) the calculations are based on	No information
Was estimated needed sample size reached?	No information
Attrition	During the first 2 years of the children's lives, the rates of attrition varied from 15% to 21%, and there were no differences across groups in relation to rate of attrition. In the intervention group, the women who discontinued tended to have a greater sense of control than those who discontinued the comparison group.

RCT 2 – The Memphis Trial

Kitzman H, Olds DL, Henderson CR, et al. Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing. A randomized controlled trial. *Journal of the American Medical Association* 1997; 278: 644-652

PICO

Tabell 5: Beskrivelse av PICO i The Memphis Trial (Kitzman 1997)

PICO	
P	Recruiting: Between June 1990 and August 1991
inclusion criteria	<p>1290 consecutive women from the obstetrical clinic at the Regional Medical Center in Memphis were invited to participate in the study.</p> <ul style="list-style-type: none"> - Women less than 29 weeks pregnant were recruited if they had no previous live births, no specific chronic illnesses thought to contribute to fetal growth retardation or preterm delivery (eg, chronic hypertensive disorders requiring medical treatment, severe cardiac disease, large uterine fibroids) - and at least 2 of the following sociodemographic risk conditions: unmarried, less than 12 years of education, and unemployed.
setting	<p>Public system of obstetric care in Memphis, Tenn. Urban area.</p> <p>[We hypothesized in the current trial that effects of the program on maternal caregiving and childhood injuries would be greater for women with few psychological resources, where psychological resources were defined in terms of women's intellectual functioning and mental health, in addition to their sense of control.]</p>
actual sample	<p>Eighty-eight percent (1139/1290) of the women completed informed consent and were randomized to 1 of 4 treatment conditions described below. Ninety two percent of the women enrolled were African American, 98% were unmarried, 64% were aged 18 years or younger at registration, and 85% came from households with incomes at or below the federal poverty guidelines.</p> <p>Compared with women who refused, those who agreed to participate were more likely to be African American than non-African American (89% vs 74%; $P < .001$); younger (average age, 18 vs 19 years; $P = .001$); and non-high school graduates (89% vs 84%; $P = .01$).</p> <p>A total of 1139 primarily African-American women at less than 29 weeks' gestation, with no previous live births, and with at least 2 sociodemographic risk characteristics (unmarried, <12 years of education, unemployed).</p> <p>[At registration, women were interviewed to determine standard socioeconomic conditions, their mental health, "personality characteristics," obstetrical histories, health-related behaviors (cigarette smoking, alcohol and illegal drug use), and social support. Women also completed brief tests to estimate their levels of intellectual functioning. "Women's pre-pregnancy weights and heights were also determined by self-report. The last weights recorded in the prenatal record before delivery were used to calculate pregnancy weight gains.]</p> <p>[A variable was created to index women's psychological resources measured at registration. It was based on the summed z scores of their intelligence," mental health," and sense of mastery/self-efficacy.]</p>
I	<p>The experimental home-visitation program was carried out by the Memphis/Shelby County Health Department. The nurses completed an average of 7 home visits (range, 0-18) during pregnancy and 26 home visits (range, 0-71) during the first 2 years post-partum. They followed a detailed visit-by-visit protocol to guide their efforts to help women improve their health-related behaviors; care of their</p>

children; and life-course development (pregnancy planning, educational achievement, and participation in the workforce).

Women in treatment 4 (n=228) were provided the same services as those in treatment 3; in addition, they continued to be visited by nurses through the child's second birthday

C Women in treatment 1 (n=166) were provided free round-trip taxicab transportation for scheduled prenatal care appointments; they did not receive any postpartum services or assessments.

Women in treatment 2 (n=515) were provided the free transportation for scheduled prenatal care plus developmental screening and referral services for the child at 6, 12, and 24 months of age.

Those in treatment 3 (n=230) were provided the free transportation and screening offered in treatment 2 plus intensive nurse home-visitation services during pregnancy, 1 postpartum visit in the hospital before discharge, and 1 postpartum visit in the home.

NB: For the evaluation of the prenatal phase of the program, treatments 1 and 2 were combined to form a single comparison group and then contrasted with treatments 3 and 4, a group that was visited by nurses during pregnancy. For the postnatal phase of the study, treatment 2 was contrasted with treatment 4.

An exception: Table 4: Comparison groups were treatment groups 1 and 2; nurse-visited groups, treatment groups 3 and 4.

O Participating women were interviewed by research staff members at the time of registration (before their assignment to treatments), at the 28th and 36th weeks of pregnancy, and at the sixth, 12th, and 24th months of the child's life. Medical and social service records were abstracted. At registration, women were interviewed to determine standard socioeconomic

The outcomes included pregnancy outcomes, birth outcomes, child injuries and hospitalisation outcomes, child mental and behavioural outcomes, and mothers' medical and social outcomes.

Utfall på barn 0-2 år

Tabell 6: Beskrivelse av utfall på barn 0-2 år i The Memphis Trial (Kitzman 1997)

OUTCOMES	MEASUREMENTS	POINT OF TIME
BIRTH OUTCOMES		
Obstetrical and newborn records were abstracted directly and verified against an on-line perinatal database from the University of Tennessee. Discrepancies between the perinatal database and our independent abstraction were resolved on a case-by-case basis.		
Birth weight, g	Birth weight (in grams) was recorded from the hospital record.	0 mo
Gestational age, wk	Gestational age (in days) was estimated from reported last menstrual period (LMP) and ultrasound scans obtained before 26 weeks' gestation. (Ultrasound was performed on all subjects at registration for prenatal care.) If LMP and ultrasound converged within 14 days, then LMP was used for estimating gestational age. When LMP and ultrasound differed by more than 14 days, ultrasound was used as the estimate. When ultrasound was not done before 26 weeks' gestation, or LMP was unknown, the record was reviewed by 2 clinicians, independently and unaware of treatment condition, to determine the most reliable estimate of gestational age.	0 mo
5-min Apgar score		0 mo
Low birth weight (<2500 g)		0 mo

IUGR,§ %	Intrauterine growth restriction (IUGR): cases with birth weights less than 10th percentile for gestational age.	0 mo
Preterm (<37 wk)		0 mo
Indicated preterm delivery	Preterm birth was divided into 2 categories: (1) spontaneous preterm birth after preterm labor, with or without premature rupture of the membranes, Or (2) indicated preterm birth performed for maternal or fetal complications.	0 mo
Spontaneous preterm delivery		0 mo
Breastfeeding	Attempted, duration	6 mo
CHILD DEVELOPMENT		
Beliefs associated with child abuse, Bavolek total score	Mothers completed interviews that assessed (...) and their beliefs about children associated with child abuse and neglect (belief in physical punishment, unrealistic expectations, lack of empathy, and role reversal)." Mothers and children were observed while the mothers <i>Bavolek SJ. Handbook for the AAPI: Adult-Adolescent Parenting Inventory. Eau Claire, Wis: Family Development Resources Inc; 1984.</i>	6 mo 12 mo 24 mo
Emotional / cognitive stimulation, HOME total score	During the home visits, the educational and socioemotional properties of the home environment were assessed, by means of the Home Observation for Measurement of the Environment. <i>Caldwell B, Bradley R. Home Observation for Measurement of the Environment. Little Rock: University of Arkansas; 1979.</i>	12 mo 24 mo
Child responsiveness, NCAST child total score	Mothers and children were observed while the mothers taught their children a developmentally challenging task by means of the Nursing Child Assessment Satellite Training procedure." The mothers' behaviors were coded and summarized to characterize their sensitivity, responsiveness, and quality of teaching. The infants' behaviors were coded and aggregated to characterize their responsiveness and clarity of communication toward their mothers. <i>NCAST Caregiver/Parent-Child Interaction Teaching Manual. Seattle: NCAST Publications, University of Washington, School of Nursing; 1994.</i>	6 mo 12 mo 24 mo
Bayley mental development score	At the 24-month office visit, the children were tested with the Bayley scales of infant development...	24 mo
Behavior problems total score	...and their mothers completed the Achenbach Child Behavior Checklist <i>Achenbach TM. Child Behavior Checklist for Ages 2-3. Burlington: University of Vermont; 1988.</i>	24 mo
USE OF HEALTH SERVICES		
Immunizations up to date at 2 y	The dates and types of children's immunizations were recorded. Whether children were completely immunized by their 24th month of life was determined. Children needed to have 4 or more diphtheria, pertussis, and tetanus vaccines, 3 or more oral poliovirus vaccines, and 1 or more <i>Haemophilus influenzae</i> type band measles, mumps, and rubella vaccines to be considered completely immunized.	24 mo

No. of well-child visits	0-24 mo
USE OF HEALTH SERVICES	
Incidence of Child Health Care Encounters in Which Injuries and Ingestions Were Detected During Children's First 2 Years of Life	
The children's medical records were reviewed with a focus on hospitalizations, emergency department visits, and outpatient encounters in which injuries and ingestions were detected. A summary variable was created to count the total number of health care encounters of all types (outpatient, emergency, and hospital admissions) in which injuries or ingestions were detected. We calculated the number of days that children were hospitalized and in which injuries or ingestions were noted.	
Total No. of health care encounters - injuries/ingestions	0-24 mo
No. of outpatient visits - injuries/ingestions	0-24 mo
No. of emergency department visits - injuries/ingestions	0-24 mo
No. of hospitalizations - injuries/ingestions	0-24 mo
No. of days hospitalized - injuries/ingestions	0-24 mo

Utfall på barn i oppfølgingsstudier (>2 år)

Tabell 7: Beskrivelse av utfall på barn > 2 år i oppfølgingsstudier i The Memphis Trial

STUDY ID	FOLLOW-UP PERIOD	OUTCOMES FOR CHILDREN
1. Kitzman 2000	0-3 y	(only outcomes for mothers)
2. Olds 2004B	6 y	<ul style="list-style-type: none"> - behavior problems, Achenbach Child Behavior Checklist (CBCL) (reported by mother) - classroom behavior, Hightower Teacher-Child Rating Scale (reported by teacher) - responses to 8 story beginnings, from the McArthur Story Stem Battery (MSSB) (videotaped and coded for a series of content themes, observable affective expressions, and coherence in completing the stories): <ul style="list-style-type: none"> * the dysregulated aggression index (created through aggregation of the following observational codes: aggression, personal injury, dishonesty, danger, destruction, inappropriate child power, and negative parenting representations in the narrative responses) * the warmth/empathy variable (derived through aggregation of codes for representations of parents as warm or supportive, as well as empathy, affiliation, affection, and expressions of reparation and guilt among story characters) * degree of emotional expression (story coherence in the context of emotional expression, ie, the degree to which children lose coherence and become dysregulated as emotional expressions increase) - cognitive and language skills, assessed with the Kaufman Assessment Battery for Children (KABC) and the Peabody Picture Vocabulary Test (PPVT-III)
3. Olds 2007	9 y	<ul style="list-style-type: none"> - reading (school records) - math (school records) - school conduct (school records) - antisocial behavior (teacher's report) - child disruptive behavior disorders (eg, conduct disorder, oppositional defiant disorder, attention-deficit/hyperactivity disorder) and depressive and anxiety disorders

		(major depression, dysthymia, generalized anxiety disorder, separation anxiety disorder, and social phobia) for the past year using the Computerized Diagnostic Interview Schedule for Children (mother's report) - times retained in grades 1-3 (counted the numbers) - placed in special education - behavior in the classroom (teacher's report) - death (age in days, cause of death)
4. Kitzman 2010	12 y	- use of substances (cigarettes, alcohol, and marijuana) - reading and math achievement (tests, grade points) - externalizing and total behavioral problems (parents', teachers', and youths' reports) - internalizing problems (youths' reports) - arrests (mothers', and youths' reports) - special education placement (school records) - grade retention (school records) - conduct grades (school records) - sustained attention (Sustained Attention test)
5. Olds 2009	12 y	(only outcomes for mothers)
6. Olds 2014	18 y	- death * <i>natural: disease related</i> * <i>preventable: sudden infant death syndrome, unintentional injury, homicide, suicide</i>

Referansanser til oppfølgingsstudier

1. Kitzman H, Olds DL, Sidora K, et al. Enduring effects of nurse home visitation on maternal life course: A 3-year follow-up of a randomized trial. *Journal of the American Medical Association* 2000; 283: 1983-1989.
2. Olds DL, Kitzman H, Cole R, et al. Effects of nurse home-visiting on maternal life course and child development: Age 6 followup results of a randomized trial. *Pediatrics* 2004 B; 114: 1550-1559.
3. Olds DL, Kitzman H, Hanks C, et al. Effects of nurse home visiting on maternal and child functioning: Age 9 follow-up of a randomized trial. *Pediatrics* 2007; 120: 832-845
4. Kitzman HJ, Olds DL, Cole RE, et al. Enduring effects of prenatal and infancy home visiting by nurses on children: Follow-up of a randomized trial among children at age 12 years. *Archives of Pediatric and Adolescent Medicine* 2010; 164: 412-418.
5. Olds DL, Kitzman HJ, Cole RE, et al. Enduring effects of prenatal and infancy home visiting by nurses on maternal life course and government spending: Follow-up of a randomized trial among children at age 12 years. *Archives of Pediatric and Adolescent Medicine* 2010; 164: 419-24.
6. Olds DL, Kitzman H, Knudtson MD, et al. Effect of Home Visiting by Nurses on Maternal and Child Mortality: Results of a 2- Decade Follow-up of a Randomized Clinical Trial. *Journal of the American Medical Association Pediatrics* 2014; 168: 800-806.

Styrkeberegninger

Tabell 8: Styrkeberegninger for The Memphis Trial ifølge forfatterne (Kitzman 1997)

Study	RCT 2 – The Memphis Trial Recruitment: June 1990 - August 1991 N=1139
Protocol available?	No
Original publication	Kitzman 1997

Description of power calculations	For all calculations, $\alpha = 0.05$ (2-tailed) and $\beta = 0.20$ were used. Sample size was estimated so that it would be sufficiently large (after attrition) to detect program effects that were limited to one half of the total sample defined as being at higher risk according to characteristics such as mothers' having few psychological resources.
Needed sample size according to power calculations	1468 for the prenatal phase and 734 for the postnatal phase of the study. Smaller sample was estimated for the postnatal phase based on larger treatment effects for postnatal outcomes than for prenatal outcomes in the Elmira study.
What outcome(s) the calculations are based on	Birth weight, children's health care encounters in which injuries were detected, proportion of second pregnancies
Was estimated needed sample size reached?	Prenatal: No (1139 (72%)), Postnatal: newborn: Yes (data extracted from newborn medical records – 1082); 6 weeks postnatal: No (672 (91%))
Attrition	During first 2 years of childrens lives attrition varied between 9 to 11 %. No clarification on how much attrition that would be acceptable without being underpowered

RCT 3 – The Denver Study

Olds DL, Robinson J, O'Brien R, et al. Home visiting by paraprofessionals and by nurses: A randomized, controlled tri-al. *Pediatrics* 2002; 110: 486-496.

PICO

Tabell 9: Beskrivelse av PICO i The Denver Study (Olds 2002)

PICO	
P	Recruiting: From March 29, 1994, through June 15, 1995
inclusion criteria	<p>-1178 consecutive women from 21 antepartum clinics serving low-income women were invited to participate in the study.</p> <p>- Women were actively recruited if, at intake:</p> <ul style="list-style-type: none"> • they had no previous live births • they were either qualified for Medicaid or had no private health insurance. <p>Women were allowed to enroll at any time before delivery.</p>
setting	Denver Metropolitan area
actual sample	<p>A total of 735 women were randomized into the control and treatment groups.</p> <p>Women could refuse participation actively or passively (not respond before they delivered). Compared with active refusals (n=244) and passive refusals (n=199), those who accepted were more likely to be Hispanic (45% accepted vs 37% active refusals and 39% passive refusals), and less likely to smoke cigarettes (27% accepted vs 44% active refusals and 32% passive refusals). These groups were similar on the other major sociodemographic characteristics, such as maternal age, language preference (English vs Spanish), and marital status.</p> <p>At registration, interviews were conducted with participating women to determine their socioeconomic conditions (eg. maternal education, household annual income, housing density), mental health, personality characteristics, obstetric histories, psychoactive drug use, conflict with partners, conflict with their own mothers, and experience of domestic violence.</p> <p>Women completed brief tests to measure their intellectual functioning¹ and supplied urine samples that were assayed with gas chromatography/mass spectrometry for cotinine (the major nicotine metabolite) and creatinine, tetrahydrocannabinol, and cocaine metabolites. Cocaine, marijuana, and alcohol use were too infrequently occurring to serve as valid outcomes to assess changes in women's substance use. Individuals with creatinine-adjusted cotinine values ≥ 80 ng/mL at intake were designated as smokers.</p> <p>A variable was created to index women's psychological resources measured at registration and based on the averaged z scores of their: 1) mental health, 2) sense of mastery, and 3) intelligence. It was dichotomized at raw score values that corresponded to the 50th percentile of these 3 variables used to construct a corresponding variable which splitted the Denver sample into low (40% of the sample) and higher (60%) functioning groups.</p> <p>1. Shiple W. A self-administered scale for measuring intellectual impairment and deterioration. <i>J Psychol.</i> 1940;9:371–377</p>
I	<p>There were 2 intervention groups:</p> <ul style="list-style-type: none"> • Women in the nurse group (n=235) were provided screening and referral plus nurse home visitation during pregnancy and infancy (the first 2 years of the child's life). • Women assigned to the paraprofessional group (n=245) were provided the screening and referral services plus paraprofessional home visitation during pregnancy and infancy. <p>The home-visitation program delivered by both nurses and paraprofessionals had 3 broad goals: 1) to improve maternal and fetal health during pregnancy by helping women improve their health-</p>

related behaviors; 2) to improve the health and development of the child by helping parents provide more competent caregiving; and 3) to enhance parents' personal development by helping them plan future pregnancies, continue their education, and find work. Visit-by-visit guidelines and detailed objectives provided direction to the visits. Visitors adapted the program to the needs and interests of families.

Nurses were required to have BSN degrees and experience in community or maternal and child health nursing. Paraprofessionals were required to have a high school education but were excluded if they had college preparation in the helping professions or a bachelor's degree in any discipline. Both groups were required to have strong "people skills."

C Women in the control group (n=255) were provided developmental screening and referral services for their children at 6, 12, 15, 21, and 24 months old.

They also were interested in detecting effects that were limited to half of the total sample that would be at higher risk (such as mothers with low psychological resources). For mother-child interaction, home environment, and child outcomes, treatment group contrasts are reported for the low psychological resources group as well as the whole sample. Because of constraints of sample size and cost, the study was not designed to make direct comparisons between paraprofessionals and nurses. Planned contrasts focused on the test of nurse versus control and paraprofessional versus control. They nevertheless conducted secondary analyses that compared their effect sizes.

O The multiplicity of settings in which participants obtained health care in Denver and low rates of state-verified cases of child abuse and neglect in the target population made it impossible to use medical and child-protective-service records to assess obstetric, newborn, childhood-injury, and child maltreatment outcomes in the current trial. They therefore focused greater attention on measurement of infants' early emotional development, as infants' emotional communications are connected to their being abused, neglected, and reared by depressed mothers.

The outcomes included in the study are; end-of-pregnancy assessments (prenatal use of tobacco, preventive services (mental health + legal aid + drug/alcohol treatment + child birth classes + rent and utility assistance + education and employment) and emergency services (emergency housing + emergency food banks)), maternal life course outcomes (educational achievement, participation in the work force, use of welfare), mother-infant interaction and quality of the home environment, child emotional, mental, and behavioural development.

Utfall på barn 0-2 år

Tabell 10: Beskrivelse av utfall på barn 0-2 år i The Denver Study (Olds 2002)

OUTCOMES FOR CHILDREN	MEASUREMENTS	POINT OF TIME
CHILD DEVELOPMENT		
Mother-Infant Responsive Interaction	Mother-infant interaction was videotaped either in the laboratory or at home at all postpartum assessments using 2 validated procedures ^{2,3} . 2. Sumner GA, Spietz A. NCAST Caregiver/Parent-Child Interaction Teaching Manual. Seattle, WA: NCAST Publications, University of Washington, School of Nursing; 1995 3. Biringen Z, Robinson JL. Emotional availability in mother-child dyads. <i>Am J Orthopsychiatry</i> . 1991;61:258-271	At all postpartum assessments (6, 12, 15, 21, 24 mo)
Home environment	Caldwell B, Bradley R. Home Observation for Measurement of the Environment. Little Rock, AR: University of Arkansas; 1979	12 mo 21 mo

Child emotional, mental, and behavioural development		
Vulnerable: fear stimuli	In the laboratory, infants' emotional reactivity (latency to react and intensity of facial, body, and vocal cues) and looking at mother were videotaped and coded separately for their responses to stimuli designed to elicit fear, joy, and anger. Emotional vulnerability was defined as high distress reactions to fear stimuli coinciding with limited efforts by the infants to look at or seek assistance or comfort from their mothers. Emotional vitality was defined as the lively expression of joyful and angry affect that was shared with others.	6 mo
Low vitality: joy stimuli		6 mo
Low vitality: anger stimuli		6 mo
Language development	Tested in home. Zimmerman IL, Steiner VG, Pond RE. <i>Preschool Language Scale—3</i> . New York, NY: Psychological Corporation; 1992	21 mo
Mental development index	Tested in laboratory. Bayley N. <i>Bayley Scales of Infant Development</i> . 2nd ed. New York, NY: Psychological Corporation; 1993	24 mo
Language delay	Children with language scores <85 were classified as delayed.	21 mo
Mental development delay	Children with MDI scores <77 (>1.5 SD below the population mean of 100) were classified as developmentally delayed as this is a typical threshold for referring children for developmental services.	24 mo
Irritable temperament	Reported by mothers.	6 mo
Behaviour problems score	Reported by mothers.	24 mo

Utfall på barn i oppfølgingsstudier (>2 år)

Tabell 11: Beskrivelse av utfall på barn > 2 år i oppfølgingsstudier i The Denver Study

STUDY ID	FOLLOW-UP PERIOD	OUTCOMES FOR CHILDREN
1. Olds 2004	25-48 mo	<p>-child attended Head Start, preschool, center-based day care, or government-supported family care</p> <p>-home total score</p> <p>-sensitive/responsive interaction</p> <p>-total language score</p> <p>-executive function composite</p> <p>-behavioural adaptation in testing (attention, activity level, organization of behavior/impulse control, and sociability)</p> <p>-emotional regulation in testing (anxiety, energy and feelings, regulation of mood, and sensory reactivity)</p> <p>-externalizing behavior problems (rule-breaking and aggressive behaviour)</p>
Referanser til oppfølgingsstudier		
1. Olds DL, Robinson J, Pettitt L, et al. Effects of home visits by paraprofessionals and by nurses: Age 4 follow-up results of a randomized trial. <i>Pediatrics</i> 2004; 114: 1560-1568.		

Styrkeberegninger

Tabell 12: Styrkeberegninger for The Denver Study ifølge forfatterne (Olds 2002)

Study	RCT 3 – The Denver Study Recruitment: March 29, 1994, through June 15, 1995 N=735
Protocol available?	No
Original publication	Olds 2002
Description of power calculations	For all calculations, $\alpha = 0.05$ (2-tailed) and $\beta = 0.20$ were used, assuming effects in the range of 0.30 SD's between each treatment and control. To detect effects that were limited to half of the total sample that would be at higher risk (such as mothers with low psychological resources), they had estimated power to detect differences in the 0.42 SD range
Needed sample size according to power calculations	750 (allows for 20% attrition rate)
What outcome(s) the calculations are based on	Unclear, but paper states the following main outcomes: Prenatal: changes in women's urine cotinine; women's use of ancillary services. Postnatal: subsequent pregnancies and births, educational achievement, workforce participation, and use of welfare; mother-infant responsive interaction; families' home environments; infants' emotional outcomes, and children's language and mental development, temperament, and behavioral problems.
Was estimated needed sample size reached?	Recruitment: yes, Analysis: Prenatal: No: (Completed 36-wk interviews = 70,1% (for prenatal smoking)), Postnatal: Yes (Completed 24-mo interviews: 85,7% (subsequent pregnancies))
Attrition	Prenatal: 29,9 % (for prenatal smoking), Completed 24-mo interviews: 14,3% (subsequent pregnancies). There was higher study attrition among nurse-visited women.

RCT 4 – Nederland

Mejdoubi J, van den Heijkant S, van Leerdam FJM, et al. Effects of nurse home visitation on cigarette smoking, pregnancy outcomes and breastfeeding: A randomized controlled trial. *Midwifery*, 2013; 30: 688-695.

1. Study Protocol - Mejdoubi, Jamila & Heijkant, Silvia & Struijf, Elle & Leerdam, F.J.M. & Hirasing, Remy & Crijnen, Alfons. (2011). Addressing risk factors for child abuse among high risk pregnant women: design of a randomised controlled trial of the Nurse Family Partnership in Dutch preventive health care. *BMC public health*. 11. 823. 10.1186/1471-2458-11-823.
2. Mejdoubi J, van den Heijkant S, van Leerdam FJM, et al. Effect of nurse home visits versus usual care on reducing intimate partner violence in young high-risk pregnant women: A randomized controlled trial. *PLOS ONE*, published online October 21, 2013.
3. Mejdoubi J, van den Heijkant S, van Leerdam FJM, et al. The effect of VoorZorg, the Dutch Nurse-Family Partnership, on child maltreatment and development: A randomized controlled trial. *PLOS ONE*, published online April 1, 2015.

*The three references above were also used for the additional details of PICO when extracting the data from the study.

PICO

Tabell 13: Beskrivelse av PICO i studien fra Nederland (Mejdoubi 2013)

PICO	
P	Recruiting: a 2½ year period from 2007 to 2009
inclusion criteria	<p>-Women were actively recruited with a two-stage selection procedure.</p> <p>-<u>During the first stage</u>, women were selected by general practitioners, midwives and other professionals on the following criteria:</p> <ul style="list-style-type: none">• maximum age of 25 years,• low educational level (primary school or prevocational secondary school),• maximum 28 weeks of gestation,• no previous live births,• understanding of the Dutch language. <p><u>During the second stage</u> women were interviewed by VoorZorg nurses, and an inclusion criterion was that women reported at least one of the following additional risk factors:</p> <ul style="list-style-type: none">• no social support,• previously or currently experiencing domestic violence,• psychosocial symptoms,• unwanted and/or unplanned pregnancy,• financial problems,• housing difficulties,• no education and/or employment• alcohol and/or drug use. <p>When a potential participant did not meet all of the inclusion criteria for the first stage, but had multiple risk factors, the VoorZorg nurse presented the case to an independent expert committee, which decided on inclusion or exclusion.</p>

setting	20 municipalities in the Netherlands
actual sample	Out of prior evaluation, it is known that about 50% of the women that were recruited in the first stage were excluded after the interview by the VoorZorg nurses in the second stage because they did not meet the second stage criteria.
	<p>A total of 460 participants were eligible and randomly assigned into the control or the intervention group. The number (%) of participants recruited by the expert committee was 77 (16,7%).</p> <p>At baseline, interviewers collected demographic information including age, ethnicity and education level at 16 to 28 weeks of pregnancy.</p> <p>All eligible women were randomized after stratification by region and ethnicity (Dutch, Surinamese/Antillean, Turkish, Moroccan, Cape Verdean or other). Ethnicity classification was performed by the VoorZorg nurse based on participants' self-reports.</p> <p>At inclusion, participants were on average 19.4 years old and were included on average at 19.8 weeks pregnancy. The difference between control and intervention group was not significant for any of the variables.</p> <p>Data were collected at between 16 and 28 weeks and at 32 weeks of pregnancy, at 2, 6, 12 and 24 months post birth. Trained female interviewers were available in each region and women were interviewed at home. All questionnaires were validated or were applied in other studies and published in the literature. The interviewers were independent from the VoorZorg nurses. Women were usually interviewed by the same interviewers at each data collecting moment. The interviews were conducted in private if possible.</p>
I	<p>Prior to this study, the NFP was translated into Dutch and culturally adapted to accommodate the needs of pregnant women in the Netherlands and to be integrated into the Dutch child health care system.</p> <p>Women in the intervention group (n=237) received the VoorZorg programme and were offered, in addition to usual care, approximately 10 home visits during pregnancy, 20 during the first year and 20 during the second life year of the child by trained, specialised VoorZorg nurses. The duration of each visit is between one hour and one and a half hour.</p> <p>The VoorZorg nurses were certified nurses working in Youth Health Care organizations and received specialised training (according to the NFP). The VoorZorg trainings also included training on how to reduce smoking with the V-MIS a nationwide smoking cessation programme¹, and how to promote breastfeeding. According to the protocol, six domains were discussed during the home visits: (1) the health status of the mother, (2) the child's health and safety, (3) the personal development of the mother, (4) the role of the mother, (5) the mother's relation with her partner, family and friends and (6) the use of (health) care organizations.</p> <p>1. deVries, H., Mudde, A., Leijts, I., et al., 2003. The European Smoking prevention Framework Approach (EFSA): an example of integral prevention. <i>Health Education Research</i> 18, 611–626.</p>
C	All women received usual care provided by the Dutch Youth Health Care Organizations (n=223). Every pregnant woman in the Netherlands receives maternal health care by a midwife. The caregiver (midwife or obstetrician) offers health education, performs physical examinations and monitors the development of the fetus. In the Netherlands, every newborn will automatically be registered in a Youth Health Care organization (ambulatory well-baby clinic) to monitor the health and development of the child, and parents are supported in their parenthood. From 2002 onwards the V-MIS was disseminated among all midwives in the Netherlands. The V-MIS aimed at smoking cessation and is adjusted for pregnant women.
O	<p>The trial outcomes included; maternal cigarette smoking at 16-28 weeks and 32 weeks of pregnancy and two months after birth as well as maternal smoking near the child, adverse pregnancy outcomes, birth weight and gestational age, breastfeeding, child development at 6, 18, and 24 months of age and intimate partner violence.</p> <p>Number of risk factors for child abuse such as demographic factors (age, ethnicity, whether the pregnancy was wanted, whether women received financial help or housing assistance from the</p>

government), depression, domestic violence, and substance use were also measured by self-reporting.

Not all the outcomes are included in the analyses of this study. This study just used four data collection moments (16-28 wk, 32 wk, 2 mo, 6 mo) for the analyses.

Utfall på barn 0-2 år

Tabell 14: Beskrivelse av utfall på barn 0-2 år i studien fra Nederland (Mejdoubi 2013)

OUTCOMES FOR CHILDREN	MEASUREMENTS	POINT OF TIME
BIRTH OUTCOMES		
Data concerning birth outcomes were extracted from databases of Youth Health Care Organizations.		
Average birth weight (g)	Both nominal and ordinal birth weight were studied, for which four categories were made: very low <1000 g., low 1000-2500 g., normal 2500-4000 g. and high >4000 g.	0 mo
Low birth weight (<2500 g)		0 mo
Average gestational age (wk)	Gestational age was categorized in the following categories: extreme premature < 32 weeks, premature <37 weeks, normal gestation 37 to 41 weeks and serotine > 42 weeks.	0 mo
Preterm gestation (<37 wk)		0 mo
Small for gestational age	Small for gestational age (dysmaturity) was defined as a neonate with birth weight below the tenth percentile of the growth curve.	0 mo
CHILD DEVELOPMENT		
Breastfeeding: Breastfeeding initiation and duration were assessed at six months post birth by asking participants whether they had initiated breastfeeding. When participants answered this question positively, they were asked whether they were still breastfeeding their child. Participants who answered this question negatively were asked more detailed questions about when they quit breastfeeding.		
	Initiated breastfeeding	6 mo
	Ended breastfeeding <1 wk	6 mo
	Ended breastfeeding >1 wk	6 mo
	Breastfeeding at 6 mo	6 mo
Home observation measurement for environment	Bradley RH, Caldwell BM: Home Observation for Measurement of the Environment - Revision of the Preschool Scale. American Journal of Mental Deficiency 1979, 84:235-244.	6 mo 18 mo 24 mo
Language of the child		18 mo
Parental stress	Brock dAJ, Vermulst AA, Gerris JRM: De Nijmeegse Ouderlijke Stress Index. Tijdschrift voor primaire leefvormen 1990, 2:57-75.	18 mo
Child behaviour	Child behaviour checklist was used. The internalizing and externalizing behaviour subscales were used and children were considered to exhibit internalizing or externalizing behaviours if they scored \geq the 90th percentile. Harsh parenting and questions about raising the child were also addressed.	24 mo
	Achenbach TM, Dumenci L: Advances in empirically based assessment: Revised cross-informant syndromes and new DSM-oriented scales for the CBCL, YSR, and TRF: Comment on Lengua, Sadowksi, Friedrich, and Fisher (2001). Journal of Consulting and Clinical Psychology 2001, 69:699-702	

Child abuse	Child abuse reports about the perpetrator, the frequency, type and severity of the abuse were obtained from a maltreatment reporting agency where both professionals and the general public can report cases (Advies & Meldpunt Kindermishandeling).	0-2 y
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Utfall på barn i oppfølgingsstudier (>2 år)

Tabell 15: Beskrivelse av utfall på barn > 2 år i oppfølgingsstudier i studien fra Nederland (Mejdoubi 2013)

STUDY ID	FOLLOW-UP PERIOD	OUTCOMES FOR CHILDREN
1. Mejdoubi 2013*	-	(this study specifically addressed self-reported intimate partner violence and did not include outcomes for children)
2. Mejdoubi 2015	3 y	- child protective services agency reports - home environment (just measured at 6, 18 and 24 mo) - child internalizing and externalizing behaviour (just measured at 24 mo)

* This study did not conduct any follow-up for the RCT (used the main intervention period (till the child is two years old)), hence is not considered as a follow-up study.

References for the follow-up studies

1. Mejdoubi J, van den Heijkant S, van Leerdam FJM, et al. Effect of nurse home visits versus usual care on reducing intimate partner violence in young high-risk pregnant women: A randomized controlled trial. PLOS ONE, published online October 21, 2013.
2. Mejdoubi J, van den Heijkant S, van Leerdam FJM, et al. The effect of VoorZorg, the Dutch Nurse-Family Partnership, on child maltreatment and development: A randomized controlled trial. PLOS ONE, published online April 1, 2015.

Styrkeberegninger

Tabell 16: Styrkeberegninger for studien fra Nederland ifølge forfatterne (Mejdoubi 2013)

Study	RCT 4 – Nederland Recruitment: a 2½year period from 2007 to 2009 N=460
Protocol available?	Yes
Original publication	Mejdoubi 2013
Description of power calculations	For all calculations, $\alpha = 0.05$ (2-tailed) and $\beta = 0.20$ were used.
Needed sample size according to power calculations	A sample size of 57 smokers per group were estimated in order to detect an average decrease in smoking by 4 cigarettes a day (8 SD) during pregnancy. They estimate that 25% of all women smoke at the start of the pregnancy, hence a total estimated needed sample size was 456 with a 1:1 group ratio
What outcome(s) the calculations are based on	Sample size calculation was based on finding effect in smoking cessation (number of cigarettes /day) from start of pregnancy to the time of birth, and 12 and 24 months post partum. The numbers used in calculations were based on findings from the effect study of the NFP (Olds 1986)."

Was estimated needed sample size reached?	Recruitment: yes; Analysis: No (analyzed: 188 control arm, 217 intervention arm = total: 405)
Attrition	15,7 % control arm, 8,5 % intervention arm (analyzed/randomized)

RCT 5 – England

Robling M, Bekkers MJ, Bell K, et al. Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Building Blocks): A pragmatic randomised controlled trial. *Lancet*, 2015; 387: 146-155.

Suppl. Mat. [https://www.thelancet.com/cms/10.1016/S0140-6736\(15\)00392-X/attachment/d4c9859f-2224-4f17-8ca4-79e1e6e6eac8/mmc1.pdf](https://www.thelancet.com/cms/10.1016/S0140-6736(15)00392-X/attachment/d4c9859f-2224-4f17-8ca4-79e1e6e6eac8/mmc1.pdf)

Owen-Jones E, Bekkers M-J, Butler CC, et al. The effectiveness and cost-effectiveness of the Family Nurse Partnership home-visiting programme for first time teenage mothers in England: a protocol for the Building Blocks randomised controlled trial. *BMC Pediatrics* 2013; 13: 114.

PICO

Tabell 17: Beskrivelse av PICO i studien fra England (Robling 2015)

PICO	
P	Recruiting: Between June 16, 2009, and July 28, 2010
inclusion criteria	To be eligible, women had to be nulliparous, 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. Women expecting multiple births and those with a previous pregnancy ending in miscarriage, stillbirth, or termination were eligible. Women planning to have their child adopted or to move outside of the FNP catchment area for longer than 3 months were not eligible.
setting	The 18 study sites were partnerships of primary and secondary local National Health Service (NHS) organisations and local authorities. Sites applied to the Department for Health to deliver FNP and additionally to participate in the trial with selection against set eligibility criteria (appendix). Women were identified and approached via local maternity services and recruited usually at their home by locally based researchers.
actual sample	(only in table)
I	Adapting the programme for delivery in England as the Family Nurse Partnership involved adoption of young maternal age as a criterion for programme eligibility. This was selected as a proxy for low income and associated with long-term child outcomes that would be easily measurable in clinical practice. Programme materials were adapted to reflect a UK English speaking clientele. Three additional requirements for FNP as introduced in England were the provision of regular psychological support via specialist supervision to Family nurses, the provision of safeguarding supervision and systems and the incorporation of FNP into local clinical governance arrangements. Following a programme of model improvement particularly on client retention led by the Prevention Research Centre at the University of Colorado, Denver Motivational Interviewing was introduced as a core model element and a central part of the Family Nurse training when introduced in England. This aims for nurses to use a mainly guiding communication style with clients. + usual care (see below)
C	Usual care: All participants (both groups) were eligible to receive usually provided publicly funded health and social care. This included the HCP (universally offered screening, education, immunisation, and support from birth to the child's second birthday) delivered by either family nurses (FNP group) or specialist community public health nurses (usual care group), and maternity care appropriate to clinical need.

O	Primary endpoints were biomarker-calibrated self-reported tobacco use by the mother at late pregnancy, birthweight of the baby, the proportion of women with a second pregnancy within 24 months post-partum, and emergency attendances and hospital admissions for the child within 24 months post-partum.
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Utfall på barn 0-2 år

Tabell 18: Beskrivelse av utfall på barn 0-2 år i studien fra England (Robling 2015)

OUTCOMES	MEASUREMENTS	POINT OF TIME
BIRTH OUTCOMES		
Gestation at delivery	Medical record	0 mo
Birth weight (gram)	Medical record	0 mo
Apgar score (1, 5 mins)	Medical record	0 mo
Head circumference	Medical record	0 mo
Neonatal unit admission	Medical record	0 mo
CHILD DEVELOPMENT		
Breastfeeding initiation, duration	Interview (0-18 mo telephone; 24 mo face-to-face)	6, 12, 18, 24 mo
Baby diet	Interview	18, 24 mo
Cognitive development	<ul style="list-style-type: none"> - Is your baby sitting independently, that is without help, on their own? - Is your baby crawling or bottom shuffling? - Is your baby walking around furniture? - Is your baby walking with one hand held? - Is your baby walking independently, that is without help, on their own? - Can your baby clap their hands? - Can your baby throw toys? - Can your baby pick up small objects like raisins or small sweets? - Does your baby drink from a beaker? - Does your baby wave bye-bye? - Does your baby show an interest in books? - Can your baby use a spoon to feed him/herself? - Does your baby throw toys deliberately? - Can your child run confidently stopping and starting without bumping into objects? - Can your child pick up an object from floor when standing without falling over? - Can child walk and turn corners and stop suddenly? - Can your child turn pages of a book 1 at a time? - Can your child turn pages of a book several at a time? - How many bricks can your child build in a tower? - Can your child do to and fro scribbling? - Can your child do circular scribbling? - Can your child copy straight lines? 	12, 18, 24 mo
Language development	<ul style="list-style-type: none"> - Is your baby chewing food yet? - Is your baby making recognised sounds like ma ma, ba ba, dada? 	12, 18, 24 mo

	<ul style="list-style-type: none"> - Does your baby have two or three recognised words with meaning? - Does your baby put two words together? - Does your baby name objects? - Does your baby repeat words? (Early Language Milestone Scale)	
	<i>Coplan J, Gleason JR, Ryan R, Burke MG, Williams ML: Validation of an early language milestone scale in a high-risk population. Pediatrics 1982, 70(5):677–683</i>	
Child safety	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).	12, 18, 24 mo
USE OF HEALTH SERVICES		
Childcare	Interview	6, 12, 18, 24 mo
Immunisations	Medical record	6, 12, 18 mo + 0-24 mo
EMERGENCY ATTENDANCES & ADMISSIONS		
Primary care consultation (injuries & ingestions)	Medical record	0-24 mo
Medically attended injuries & ingestions	Medical record	0-24 mo
Referral from primary care (social care, other, safeguarding)	Medical record	0-24 mo
OTHER		
Adverse events	Adverse event, serious adverse event, or expected serious adverse event	0-24 mo

Utfall på barn i oppfølgingsstudier (>2 år)

Blant de 20 identifiserte studiene var det ingen oppfølgingsstudier fra England.

Styrkeberegninger

Tabell 19: Styrkeberegninger for studien fra England ifølge forfatterne (Mejdoubi 2013)

Study	RCT 5 – England Recruitment: June 16, 2009, and July 28, 2010 N=1645
Protocol available?	Yes
Original publication	Robling 2015
Description of power calculations	For all calculations, $\alpha = 0.05$ (2-tailed) and $\beta = 0.10$ were used. For each outcome measure, the expected improvement for the NFP arm relates to a small standardised difference (approx. 0.2 or odds ratio 0.6). Allow for a pregnancy loss of 1.5%.

Needed sample size according to power calculations	1418, aimed to recruit 1600 pregnant women to detect differences between the two arms of 10% (40% to 30%) in the proportion having any emergency attendance or emergency admission to hospital within two years, and of 7.5% (20% to 12.5%) in the proportion with a second pregnancy within two years. This takes into account anticipated pregnancy loss and loss to follow up.
What outcome(s) the calculations are based on	Two primary outcomes for the mother (smoking and second pregnancy) and two for the baby (birth weight and emergency attendances/admissions).
Was estimated needed sample size reached?	Recruitment: yes, (1645). Analysis: Yes for (1510 for birthweight, 1478 child ED episodes), no (1289 for second pregnancy, 1192 for smoking)
Attrition	No clarification on how much attrition that would be acceptable without being underpowered

RCT 6 – Canada

Catherine N, Gonzalez A, Boyle M, Sheehan D, Jack SM, Hougham KA, et al. Improving children's health and development in British Columbia through nurse home visiting: a randomized controlled trial protocol. *BMC HealthServ Res.* 2016;16:349.29.

Merk at vi kun har sett protokollen for denne RCTen fra Canada og ikke eventuelle publiserte resultater fra studien.

PICO

Tabell 20: Beskrivelse av PICO i studien fra Canada (Catherine 2016)

PICO	
P	Recruiting: October 2013 and approximately three years
inclusion criteria	<p>Women are eligible to participate if they meet all inclusion criteria at time of baseline interviews:</p> <ol style="list-style-type: none">1. Age 24 years or younger2. First birth. Women are eligible if a previous pregnancy ended in termination, miscarriage or still-birth, or if previous parenting involved step-parenting only3. Less than 28 weeks gestation. Women are recruited prior to 28 weeks gestation to ensure that participants randomized to NFP receive their first home visit by the end of the 28th week of gestation, according to NFP fidelity requirements.4. Competent to provide informed consent, including conversational competence in English5. Experiencing socioeconomic disadvantage:<ul style="list-style-type: none">• Age 19 or younger• Age 20–24: Meets 2 of 3 indicators: Lone parent; less than grade 12; or low income which requires one or more of:<ol style="list-style-type: none">i. Receiving Medical Services Plan Premium Assistance, disability assistance or other income assistance;ii. Finding it very difficult to live on total household income with respect to food or rent; oriii. Homeless, defined as living on the streets, living in a place not meant as a long-term dwelling (e.g., car or tent), staying in a shelter, or staying somewhere temporarily with no permanent address (e.g., "couch surfing") <p>Women are ineligible to participate if they meet any exclusion criteria at time of baseline interviews</p> <ol style="list-style-type: none">1. Planning to have the child adopted2. Planning to leave the BCHCP catchment area (designated Local Health Areas) for three months or longer during the trial. <p>(First Nations and Aboriginal or Indigenous women who are living "on reserve" at the time of enrollment are not eligible for the RCT.)</p>
setting	Local Health Areas that include a range of urban, suburban and smaller communities.
actual sample	(this is just a protocol)
I	PHNs [public health nurses] deliver NFP to eligible and consenting women through regular home visits throughout the pregnancy and continuing until the child's second birthday – up to 64 visits in total over 2.5 years (if the program starts by the 16th week of pregnancy). Each visit typically lasts 60–90 min. PHNs use visit-to-visit guidelines that were adapted for Canadian settings. Beyond their intensive NFP education, PHNs also receive regular individual and team reflective supervision and support to ensure fidelity to essential elements of the NFP program model.

C	Within BC's universal healthcare system, all trial participants, including those receiving NFP, are eligible to receive existing services (usual care) provided in their Health Authority. Existing health services for pregnant women and young children vary across BC but may include: primary healthcare services, provided by physicians and also by midwives in some circumstances; specialist physician services; public health programs including pregnancy screening and outreach, prenatal classes and brief forms of home visiting by (non-NFP) nurses or paraprofessionals; and a variety of targeted and universal parenting and early child development programs. Health Authorities also provide adult mental healthcare including substance misuse and harm reduction services. In BC, all basic public health services are typically provided at no cost.
O	<p>One primary outcome indicator has been identified: the average number of physician encounters per child for (intentional and unintentional) injuries, measured in community/outpatient, emergency and hospital settings from birth through to age two years.</p> <p>Four secondary outcome indicators have also been identified: prenatal nicotine and alcohol use; child cognitive development (language and cognitive ability) at age two years; child behaviour (internalizing and externalizing problems) at age two years; and the incidence of subsequent pregnancies by 24 months postpartum.</p>

Utfall på barn 0-2 år

Tabell 21: Beskrivelse av utfall på barn 0-2 år i studien fra Canada (Catherine 2016)

OUTCOMES	MEASUREMENTS	POINT OF TIME
BIRTH		
Pre-term birth		0 mo
Birth weight		0 mo
Apgar score (1 + 5 min)		0 mo
Intensive care admission(s)		0 mo
DEVELOPMENT		
Language	Ages and Stages <i>Squires J, Potter L, Bricker D. The ASQ user's guide for the Ages and Stages Questionnaires: a parent completed monitoring system. Baltimore: Brookes; 1999.</i>	10, 18 mo
Language + cognition	Bayley SID-III; MacArthur-Bates Communication Development Inventories <i>Bayley N. Bayley Scales of Infant and Toddler Development. San Antonio: Psychological Corporation; 2006.</i> <i>Fenson L, Dale PS, Reznick JS, Thal D, Bates E, Hartung JP, et al. Communicative Development Inventory: users guide and technical manual. San Diego: Singular Publishing Company; 1993.</i>	24 mo
Behaviour	Child Behavior Checklist <i>Achenbach T, Edelbrock C. Manual for the Child Behavior Checklist and Revised Behavior Profile. Burlington: University of Vermont; 1983.</i>	24 mo

Achenbach TM, Ruffle TM. *The Child Behavior Checklist and related forms for assessing behavioral/emotional problems and competencies. Pediatr Rev. 2000;21:265–71*

HEALTH & USE OF HEALTH SERVICES		
General health + long-term illness		24 mo
Immunizations		24 mo
Healthcare encounters for injuries	Independent data on healthcare encounters for child injuries will be obtained from personal records made available through secure data-sharing agreements with the BC Ministry of Health, which accesses and holds data on healthcare encounters across the province.	2, 10, 18, 24 mo
Substantiated abuse or neglect		2, 10, 18, 24 mo
Early child development programs		2, 10, 18, 24 mo

Utfall på barn i oppfølgingsstudier (>2 år)

Vi har ikke sett på eventuelle oppfølgingsstudier fra Canada.

Styrkeberegninger

Tabell 22: Styrkeberegninger for studien fra Canada ifølge forfatterne (Catherine 2016)

Study	RCT 6 – Canada Recruiting: October 2013 and approximately three years N= (not available in the protocol)
Protocol available?	Yes
Original publication	Protocol: Catherine 2016
Description of power calculations	For all calculations, $\alpha = 0.05$ (2-tailed) and $\beta = 0.20$ were used. Numbers used in calculations were based on minimal clinically meaningful reduction in risk as a relative risk of 0.70, i.e. a reduction from 0.30 (30 %) in the comparison group to 0.21 (21 %) in the intervention (NFP) group.
Needed sample size according to power calculations	n = 1040 (Allowing for 5 % attrition)
What outcome(s) the calculations are based on	Reduction of the number of physician encounters for injuries per child in community/ outpatient, emergency and hospital settings.
Was estimated needed sample size reached?	N/A
Attrition	N/A

Sammenligninger av seks RCTer

Inklusjonskriterier

Under følger er en enkel sammenstilling av inklusjonskriteriene i de seks RCTene.

Tabell 23: Oversikt over inklusjonskriterier i seks RCTer om Nurse-Family Partnership

Study	Inclusion criteria
RCT 1 – The Elmira Trial	<p>Length of pregnancy: –</p> <p>Previous births: no previous live births</p> <p>Mothers health: –</p> <p>Sociodemographic risk conditions: <u>one of the following</u> characteristics:</p> <ul style="list-style-type: none"> * young age (<19 years) * single-parent status * low socio-economic status
RCT 2 – The Memphis Trial	<p>Length of pregnancy: less than 29 weeks pregnant</p> <p>Previous births: no previous live births</p> <p>Mothers health: no specific chronic illnesses thought to contribute to fetal growth retardation or preterm delivery (eg, chronic hypertensive disorders requiring medical treatment, severe cardiac disease, large uterine fibroids)</p> <p>Sociodemographic risk conditions: <u>at least 2 of the following</u> sociodemographic risk conditions:</p> <ul style="list-style-type: none"> * unmarried * less than 12 years of education * unemployed
RCT 3 – The Denver Study	<p>Length of pregnancy: –</p> <p>Previous births: no previous live births</p> <p>Mothers health: –</p> <p>Sociodemographic risk conditions: either qualified for Medicaid or had no private health insurance</p>
RCT 4 – Nederland	<p>Length of pregnancy: maximum 28 week of gestation</p> <p>Previous births: no previous live births</p> <p>Mothers health: –</p> <p>Sociodemographic risk conditions: maximum age of 25 years, low educational level (primary school or prevocational secondary school), and reported <u>at least one of the following</u> conditions:</p> <ul style="list-style-type: none"> • no social support • previously or currently experiencing domestic violence • psychosocial symptoms • unwanted and/or unplanned pregnancy • financial problems • housing difficulties • no education and/or employment • alcohol and/or drug use
RCT 5 – England	<p>Length of pregnancy: of less than 25 weeks' gestation</p> <p>Previous births: no previous live births</p> <p>Mothers health: –</p> <p>Sociodemographic risk conditions: 19 years or younger</p>
RCT 6 - Canada	<p>Length of pregnancy: less than 28 weeks gestation</p> <p>Previous births: no previous live births</p> <p>Mothers health: –</p> <p>Sociodemographic risk conditions: Experiencing socioeconomic disadvantage:</p>

-
- Age 19 or younger
 - Age 20–24: Meets 2 of 3 indicators: Lone parent; less than grade 12; or low income which requires one or more of:
 - i. Receiving Medical Services Plan Premium Assistance, disability assistance or other income assistance;
 - ii. Finding it very difficult to live on total household income with respect to food or rent; or
 - iii. Homeless, defined as living on the streets, living in a place not meant as a long-term dwelling (e.g., car or tent), staying in a shelter, or staying somewhere temporarily with no permanent address (e.g., “couch surfing”)
-

I fire av RCTene var det inklusjonskriterium at mor ikke skal ha kommet lenger i svangerskapet enn 25-28-29 uker (England, Nederland, Canada, Memphis). I de øvrige oppgis det ingen slik grense, men i RCT 1 oppgis det at alle kvinnene ble tatt opp i programmet før uke 30, og i RCT 3 ble alle kvinnene intervjuet i uke 36.

Alle RCTene hadde som kriterium at kvinnene skal være førstegangsfødende (første fødsel av levende barn). Kun én RCT stilte krav om at mor ikke skulle ha noen kroniske sykdommer som kunne føre til begrensninger på fosterets vekt eller til for tidlig fødsel (Memphis).

Når det gjelder sosiodemografiske variabler hadde fire av RCTene en øvre aldersgrense (19-25 år) enten som absolutt krav eller som ett av flere mulige kriterier som skulle tilfredsstilles (Elmira, England, Nederland, Canada). Øvrige sosiodemografiske kriterier er knyttet til det å være alenemor, ha lav utdanning, være arbeidsløs og/eller ha dårlig økonomi. Kun den engelske RCTen hadde ingen slike krav (bare alder).

Styrkeberegninger

Nedenfor er en enkel sammenstilling av noen punkter fra de tidligere presenterte styrkeberegningene i de seks RCTene.

Tabell 24: Oversikt over styrkeberegninger i seks RCTer om Nurse-Family Partnership

	Description of power calculations	Needed sample size according to power calculations	Was estimated needed sample size reached?
RCT 1 – The Elmira Trial (New York) Recruitment: April 1978 - Sept. 1980 N=400	No information	No information	No information

RCT 2 – The Memphis Trial Recruitment: June 1990 - August 1991 N=1139	For all calculations, $\alpha = 0.05$ (2-tailed) and $\beta = 0.20$ were used. Sample size was estimated so that it would be sufficiently large (after attrition) to detect program effects that were limited to one half of the total sample defined as being at higher risk according to characteristics such as mothers' having few psychological resources.	1468 for the prenatal phase and 734 for the postnatal phase of the study. Smaller sample was estimated for the postnatal phase based on larger treatment effects for postnatal outcomes than for prenatal outcomes in the Elmira study.	No (prenatal: 72% of estimated needed sample size, postnatal: 91% of estimated needed sample size)
RCT 3 – The Denver Study Recruitment: March 29, 1994, through June 15, 1995 N=735	For all calculations, $\alpha = 0.05$ (2-tailed) and $\beta = 0.20$ were used, assuming effects in the range of 0.30 SD's between each treatment and control. To detect effects that were limited to half of the total sample that would be at higher risk (such as mothers with low psychological resources), they had estimated power to detect differences in the 0.42 SD range	750 (allows for 20% attrition rate)	Recruitment: yes, Analysis: Prenatal: No: (Completed 36-wk interviews = 70,1% (for prenatal smoking)), Postnatal: Yes (Completed 24-mo interviews: 85,7%
RCT 4 – Nederland Recruitment: a 2½ year period from 2007 to 2009 N=460	For all calculations, $\alpha = 0.05$ (2-tailed) and $\beta = 0.20$ were used.	A sample size of 57 smokers per group were estimated in order to detect an average decrease in smoking by 4 cigarettes a day (8 SD) during pregnancy. They estimate that 25% of all women smoke at the start of the pregnancy, hence a total estimated needed sample size was 456 with a 1:1 group ratio	Recruitment: yes; Analysis: No (analyzed: 188 control arm, 217 intervention arm = total: 405)
RCT 5 – England Recruitment: June 16, 2009, and July 28, 2010 N=1645	For all calculations, $\alpha = 0.05$ (2-tailed) and $\beta = 0.10$ were used. For each outcome measure, the expected improvement for the NFP arm relates to a small standardised difference (approx. 0.2 or odds ratio 0.6). Allow for a pregnancy loss of 1.5%.	1418, aimed to recruit 1600 pregnant women to detect differences between the two arms of 10% (40% to 30%) in the proportion having any emergency attendance or emergency admission to hospital within two years, and of 7.5% (20% to 12.5%) in the proportion with a second pregnancy within two years. This takes into account anticipated pregnancy loss and loss to follow up.	Recruitment: yes, (1645). Analysis: Yes for (1510 for birthweight, 1478 child ED episodes), no (1289 for second pregnancy, 1192 for smoking)
RCT 6 – Canada	For all calculations, $\alpha = 0.05$ (2-tailed) and $\beta = 0.20$ were used. Numbers used in calculations were based on minimal clinically meaningful reduction in risk as a relative risk of 0.70, i.e., a reduction from 0.30 (30 %) in the comparison group to 0.21 (21 %) in the intervention (NFP) group.	n = 1040 (Allowing for 5% attrition)	N/A

Alle studiene som rapporterte styrkeberegninger benyttet 5 % signifikansnivå ($\alpha = 0,05$) og styrkenivå på 0.8 ($\beta = 0,20$), med unntak av RCT 5, som benyttet et styrkenivå på 0,9 ($\beta = 0,10$). I studien av den først utførte RCTen (The Elmira Trial) gis det ingen opplysninger om hvorvidt styrkeberegninger er blitt utført. I den andre utførte

RCTen (The Memphis Trial) ble det ikke oppnådd ønsket utvalgsstørrelse ved rekruttering for den prenatale fasen og den postnatale fasen (≥ 6 ukers alder), men tilstrekkelig utvalgsstørrelse ble oppnådd for utfall basert på data hentet ut fra den nyfødtes medisinske journaler. De tre RCTene som er utført deretter (The Denver Study, Nederland og England) tilfredsstilte den estimerte utvalgsstørrelsen når det gjaldt det rekrutterte utvalget, men utvalgsstørrelsen ble kun i noen tilfeller nådd i analyser av primære utfallsmål. For den siste RCTen (fra Canada) er kun protokollen tilgjengelig, hvor styrkeberegninger beskrives, men ingen resultater fra studien er publisert.

Litteratursøk i CENTRAL

Litteratursøket i CENTRAL ga 357 treff (272 publiserte studier, 69 registrerte studier og 16 konferanseabstrakter). Etter gjennomlesning fant vi 69 publiserte studier, 15 registrerte studier og ett konferanseabstrakt som var relevante. Disse 85 referansene er listet nedenfor.

Studier som allerede var identifisert (de 20 studiene beskrevet tidligere) er satt i fet font og understreket. Publiserte studier merket med X ser ut til å være ordinære effektstudier av programmet (n=50) mens de øvrige studiene (n=19) er kvalitative studier, prosessevalueringer, effektstudier av programmet forsterket med en komponent (f.eks. rettet mot partnervold) eller andre typer studier. Vi har av tidshensyn ikke kontrollert om de registrerte studiene er publisert.

Tabell 22: Aktuelle publiserte studier fra CENTRAL (N=69)

Studier	
1. Catherine, N. L., et al. (2016). "Improving children's health and development in British Columbia through nurse home visiting: a randomized controlled trial protocol." <i>BMC Health Services Research</i> 16(a): 349.	X
2. Catherine, N. L. A., et al. (2020). "Nurse home visiting and prenatal substance use in a socioeconomically disadvantaged population in British Columbia: analysis of prenatal secondary outcomes in an ongoing randomized controlled trial." <i>CMAJ open</i> 8(4): E667-E675.	X
3. Corbacho, B., et al. (2017). "Cost-effectiveness of the Family Nurse Partnership (FNP) programme in England: evidence from the building blocks trial." <i>Journal of Evaluation in Clinical Practice</i> 23(6): 1367-1374.	X
4. Eckenrode, J., et al. (2010). "Long-term effects of prenatal and infancy nurse home visitation on the life course of youths: 19-year follow-up of a randomized trial." <i>Archives of Pediatrics and Adolescent Medicine</i> 164(1): 9-15	X
5. Eckenrode, J., et al. (2000). "Preventing child abuse and neglect with a program of nurse home visitation: the limiting effects of domestic violence." <i>JAMA</i> 284(11): 1385-1391.	X
6. Eckenrode, J., et al. (2001). "Child maltreatment and the early onset of problem behaviors: can a program of nurse home visitation break the link?" <i>Development and Psychopathology</i> 13(4): 873-890.	X
7. Enoch, M. A., et al. (2016). "A Prospective Cohort Study of Influences on Externalizing Behaviors Across Childhood: results From a Nurse Home Visiting Randomized Controlled Trial." <i>Journal of the American Academy of Child and Adolescent Psychiatry</i> 55(5): 376-382.	X
8. Feder, L., et al. (2011). "The Need for Experimental Methodology in Intimate Partner Violence: finding Programs That Effectively Prevent IPV." <i>Violence against women</i> 17(3): 340-358.	
9. Feder, L., et al. (2018). "An Intimate Partner Violence Prevention Intervention in a Nurse Home Visitation Program: a Randomized Clinical Trial." <i>Journal of women's health</i> (2002) 27(12): 1482-1490.	
10. Fiscella, K., et al. (1998). "Does child abuse predict adolescent pregnancy?" <i>Pediatrics</i> 101(4 I): 620-624.	
11. Gray, S., et al. (2006). "Having the best intentions is necessary but not sufficient: what would increase the efficacy of home visiting for preventing second teen pregnancies?" <i>Prevention science</i> 7(4): 389-395.	

12. Hayward, S. (1998). "Nurse home visits reduced child abuse and neglect over a 15 year period." Evidence based nursing 1(3): 77.	X
13. Hayward, S. (1998). "Nurse home visits to low income, first time mothers reduced pregnancy induced hypertension and childhood injuries." Evidence based nursing 1(3): 76-77.	X
14. Hayward, S. (2000). "Nurse home visits during pregnancy and early childhood had positive effects on aspects of maternal life course 3 years later...commentary on Kitzman H, Olds DL, Sidora K et al. Enduring effects of nurse home visitation on maternal life course: a 3-year follow-up of a randomized trial. JAMA 2000 Apr;283: 1983-9." Evidence based nursing: 115-115.	
15. Holland, M. L., et al. (2018). "Low birthweight in second children after nurse home visiting." Journal of Perinatology 38(12): 1610-1619.	X
16. Holland, M. L., et al. (2012). "Mother-child interactions and the associations with child healthcare utilization in low-income urban families." Maternal and child health journal 16(1): 83-91.	X
17. Izzo, C. V., et al. (2005). "Reducing the impact of uncontrollable stressful life events through a program of nurse home visitation for new parents." Prevention science 6(4): 269-274.	X
18. Jack, S. M., et al. (2019). "Effect of Addition of an Intimate Partner Violence Intervention to a Nurse Home Visitation Program on Maternal Quality of Life: a Randomized Clinical Trial." JAMA 321(16): 1576-1585.	
19. Jack, S. M., et al. (2021). "Nurse-Family Partnership nurses' attitudes and confidence in identifying and responding to intimate partner violence: an explanatory sequential mixed methods evaluation." Journal of Advanced Nursing 77(9): 3894-3910.	
20. Jacob-Files, E., et al. (2015). "Should Home-Based Contraceptive Dispensing become a Routine part of Public Health Nurse Practice? Review of Nurse Perceptions." Public health nursing (Boston, Mass.) 32(6): 702-710.	
21. Kitzman, H., et al. (1997). "Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing. A randomized controlled trial." JAMA 278(8): 644-652.	X
22. Kitzman, H., et al. (2019). "Prenatal and Infancy Nurse Home Visiting and 18-Year Outcomes of a Randomized Trial." Pediatrics 144(6).	X
23. Kitzman, H., et al. (2000). "Enduring effects of nurse home visitation on maternal life course: a 3-year follow-up of a randomized trial." JAMA 283(15): 1983-1989.	X
24. Kitzman, H. J., et al. (2010). "Enduring effects of prenatal and infancy home visiting by nurses on children: follow-up of a randomized trial among children at age 12 years." Archives of Pediatrics and Adolescent Medicine 164(5): 412-418.	X
25. Klerman, L. V., et al. (2003). "Second births among teenage mothers: program results and statistical methods." Journal of Adolescent Health 32(6): 452-455.	X
26. Korfmacher, J., et al. (1999). "Differences in program implementation between nurses and paraprofessionals providing home visits during pregnancy and infancy: a randomized trial." American Journal of Public Health 89(12): 1847-1851.	X
27. Levenstein, P. and S. Levenstein (1999). ""Long-term effects of nurse home visitation on children's criminal and antisocial behavior 15-year follow-up of a randomized controlled trial" Comment." Journal of the American Medical Association 281(15): 1376.	
28. Lorber, M. F., et al. (2019). "The Impact of a Preventive Intervention on Persistent, Cross-Situational Early Onset Externalizing Problems." Prevention science 20(5): 684-694.	X
29. Mejdoubi, J., et al. (2011). "Addressing risk factors for child abuse among high risk pregnant women: design of a randomised controlled trial of the nurse family partnership in Dutch preventive health care." BMC Public Health 11: 823.	
30. Mejdoubi, J., et al. (2013). "Effect of Nurse Home Visits vs. Usual Care on Reducing Intimate Partner Violence in Young High-Risk Pregnant Women: a Randomized Controlled Trial." PloS One 8(10).	X

31. Mejdoubi, J., et al. (2014). "Effects of nurse home visitation on cigarette smoking, pregnancy outcomes and breastfeeding: a randomized controlled trial." <i>Midwifery</i> 30(6): 688-695.	X
32. Mejdoubi, J., et al. (2015). "The effect of VoorZorg, the Dutch nurse-family partnership, on child maltreatment and development: a randomized controlled trial." <i>PloS One</i> 10(4): e0120182.	X
33. Nguyen, J. D., et al. (2003). "A comparison pilot study of public health field nursing home visitation program interventions for pregnant Hispanic adolescents." <i>Public health nursing (Boston, Mass.)</i> 20(5): 412-418.	
34. O'Donnell, K. J., et al. (2018). "DNA methylome variation in a perinatal nurse-visitation program that reduces child maltreatment: a 27-year follow-up." <i>Translational psychiatry</i> 8(1): 15.	
35. Olds, D. (1999). "Long-term effects of nurse home visitation on children's criminal and antisocial behavior 15-year follow-up of a randomized controlled trial" Reply." <i>Journal of the American Medical Association</i> 281(15): 1377.	X
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48. Olds, D. L., et al. (1986). "Improving the delivery of prenatal care and outcomes of pregnancy: a randomized trial of nurse home visitation." <i>Pediatrics</i> 77(1): 16-28.	X
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54. Olds, D. L., et al. (2007). "Effects of nurse home visiting on maternal and child functioning: age-9 follow-up of a randomized trial." <i>Pediatrics</i> 120(4): e832-845.	X
55. Olds, D. L., et al. (2014). "Effect of home visiting by nurses on maternal and child mortality: results of a 2-decade follow-up of a randomized clinical trial." <i>JAMA pediatrics</i> 168(9): 800-806.	X
56. Olds, D. L., et al. (1995). "Effect of home visitation by nurses on caregiving and maternal life-course." <i>Archives of Pediatrics and Adolescent Medicine</i> 149: P76.	X
57. Olds, D. L., et al. (2010). "Enduring effects of prenatal and infancy home visiting by nurses on maternal life course and government spending: follow-up of a randomized trial among children at age 12 years." <i>Archives of Pediatrics and Adolescent Medicine</i> 164(5): 419-424.	X
58. Olds, D. L., et al. (2002). "Home visiting by paraprofessionals and by nurses: a randomized, controlled trial." <i>Pediatrics</i> 110(3): 486-496.	X
59. Olds, D. L., et al. (2004). "Effects of home visits by paraprofessionals and by nurses: age 4 follow-up results of a randomized trial." <i>Pediatrics</i> 114(6): 1560-1568.	X
60. Olds, D. L., et al. (2007). "Programs for parents of infants and toddlers: recent evidence from randomized trials." <i>Journal of Child Psychology and Psychiatry and Allied Disciplines</i> 48(3-4): 355-391.	
61. O'Reilly (2010). "Variation in Smoking Cessation and Birthweight Outcomes among Nurse-Family Partnership Programs throughout the Commonwealth of Pennsylvania." <i>Pediatric academic society</i> http://www.abstracts2view.com/pas/(2842.162) .	X
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66. Sierau, S., et al. (2016). "Effects of Home Visitation on Maternal Competencies, Family Environment, and Child Development: a Randomized Controlled Trial." <i>Prevention science</i> 17(1): 40-51.	X
67. Tiedje, L. B. (2003). "Toward evidence-based practice. Home visiting by paraprofessionals and by nurses: a randomized, controlled trial." <i>MCN, american journal of maternal child nursing</i> 28(3): 214.	X
68. Wu, J., et al. (2017). "The Cost-effectiveness Analysis of Nurse-Family Partnership in the United States." <i>Journal of Health Care for the Poor and Underserved</i> 28(4): 1578-1597.	X
69. Zielinski, D. S., et al. (2009). "Nurse home visitation and the prevention of child maltreatment: impact on the timing of official reports." <i>Development and Psychopathology</i> 21(2): 441-453.	X

Tabell 23: Aktuelle registrerte studier fra CENTRAL (N=15)

Studier
1. Nct (2007). "Age 6 Test of Home Visits by Nurses vs Paraprofessionals." https://clinicaltrials.gov/show/NCT00438282
2. Nct (2007). "Age 9 Follow-up of Preventive Intervention (Denver)." https://clinicaltrials.gov/show/NCT00438594
3. Nct (2007). "Age 12 Follow-up of Early Preventive Intervention (Memphis)." https://clinicaltrials.gov/show/NCT00438165
4. Nct (2007). "Follow-up Evaluation of Home Nurse Visitation Program for Socially Disadvantaged Women and Their Children." https://clinicaltrials.gov/show/NCT00443586
5. Nct (2007). "Follow-up of Families in Early Preventive Intervention." https://clinicaltrials.gov/show/NCT00438516
6. Nct (2007). "Longitudinal Follow Up of Subjects Enrolled in Randomized Trial of Prenatal and Infancy Home Visitation." https://clinicaltrials.gov/show/NCT00443638
7. Nct (2008). "Age-17 Follow-up of Home Visiting Intervention." https://clinicaltrials.gov/show/NCT00708695
8. Nct (2009). "Nurse Family Partnership (NFP) Contraceptive Study." https://clinicaltrials.gov/show/nct00928538
9. Nct (2011). "Nurse-family Partnership (NFP) Curriculum Study." https://clinicaltrials.gov/show/NCT01372098
10. Nct (2012). "BC Healthy Connections Project." https://clinicaltrials.gov/show/NCT01672060
11. Nct (2013). "Enhanced Nurse Home Visitation to Prevent Intimate Partner Violence." https://clinicaltrials.gov/show/NCT01811719
12. Nct (2017). "Nurse-Family Partnership Impact Evaluation in South Carolina." https://clinicaltrials.gov/show/NCT03360539
13. Nct (2017). "The Prenatal/Early Infancy Project: an Adolescent Follow-up." https://clinicaltrials.gov/show/NCT03079752
14. McConnell, M. A., et al. (2020). "Protocol for a randomized controlled trial evaluating the impact of the Nurse-Family Partnership's home visiting program in South Carolina on maternal and child health outcomes." <i>Trials</i> 21(1).
15. Owen-Jones, E., et al. (2013). "The effectiveness and cost-effectiveness of the Family Nurse Partnership home visiting programme for first time teenage mothers in England: a protocol for the Building Blocks randomised controlled trial." <i>BMC Pediatrics</i> 13: 114.

Tabell 24: Aktuelle konferanseabstrakter fra CENTRAL (N=1)

Studier
1. (2017). "A validation and calibration process on self-reported tobacco with participants: cotinine levels in building blocks." <i>Trials Conference: 4th International Clinical Trials Methodology Conference , ICTMC and the 38th Annual Meeting of the Society for Clinical Trials. United Kingdom. 18(Supplement 1).</i>

Diskusjon/konklusjon

Vi har gjennomgått publikasjoner fra seks RCTer om Nurse-Family Partnership og hentet ut data om PICO og detaljer om utfallsmål på barn samt styrkeberegninger.

Litteratursøket i CENTRAL identifiserte ytterligere rundt 50 studier dersom vi inkluderer eksperimentelle studier av Nurse-Family Partnership med tilleggskomponenter (om partnervold), studier av implementeringsprosesser, kvalitative studier, flere studier av de seks RCTene og det som ser ut til å kunne være andre RCTer. Vi søkte kun i databasen CENTRAL og det kan derfor finnes flere publiserte studier som dette søket ikke fanget opp.

Så langt har vi ikke identifisert noen systematiske oversikter over Nurse-Family Partnership-programmet. Vårt arbeid viser gode forutsetninger for å utføre en systematisk oversikt over effekter – og kanskje også erfaringer med – Nurse-Family Partnership-programmet internasjonalt.

Vedlegg 1: Studier fra seks RCTer

RCT 1 – The Elmira Trial (New York)

Recruiting: Between April 1978 and September 1980

N=400

Studies

1	Eckenrode J, Ganzel B, Henderson CR, Jr., et al. Preventing child abuse and neglect with a program of nurse home visitation: The limiting effects of domestic violence. <i>Journal of the American Medical Association</i> 2000; 284: 1385-1391.
2	Eckenrode J, Campa M, Luckey DW, et al. Long-term effects of prenatal and infancy nurse home visitation on the life course of youths: 19-year follow-up of a randomized trial. <i>Archives of Pediatric and Adolescent Medicine</i> 2010; 164: 9-15. + ERRATUM
3	Olds DL, Henderson CR, Jr., Chamberlin R, Tatelbaum R. Preventing child abuse and neglect: A randomized trial of nurse home visitation. <i>Pediatrics</i> 1986; 78: 65-78.
4	Olds DL, Henderson CR, Jr., Kitzman H. Does prenatal and infancy nurse home visitation have enduring effects on qualities of parental caregiving and child health at 25 to 50 months of life? <i>Pediatrics</i> 1994; 93: 89-98.
5	Olds DL, Eckenrode J, Henderson CR, et al. Long-term effects of home visitation on maternal life course and child abuse and neglect. Fifteen-year follow-up of a randomized trial. <i>Journal of the American Medical Association</i> 1997; 278: 637-643.
6	Olds D, Henderson CR, Jr., Cole R, et al. Long-term effects of nurse home visitation on children's criminal and antisocial behavior: 15-year follow-up of a randomized controlled trial. <i>Journal of the American Medical Association</i> 1998; 280: 1238-1244.
7	Zielinski DS, Eckenrode J, Olds DL. Nurse home visitation and the prevention of child maltreatment: Impact on the timing of official reports. <i>Development and Psychopathology</i> 2009; 21: 441-453.

RCT 2 – The Memphis Trial

Recruiting: Between June 1990 and August 1991

N=1139

Studies

1	Kitzman H, Olds DL, Henderson CR, et al. Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing. A randomized controlled trial. Journal of the American Medical Association 1997; 278: 644-652.
2	Kitzman H, Olds DL, Sidora K, et al. Enduring effects of nurse home visitation on maternal life course: A 3-year follow-up of a randomized trial. Journal of the American Medical Association 2000; 283: 1983-1989.
3	Kitzman HJ, Olds DL, Cole RE, et al. Enduring effects of prenatal and infancy home visiting by nurses on children: Follow-up of a randomized trial among children at age 12 years. Archives of Pediatric and Adolescent Medicine 2010; 164: 412-418.
4 (B)	Olds DL, Kitman H, Cole R, et al. Effects of nurse home-visiting on maternal life course and child development: Age 6 followup results of a randomized trial. Pediatrics 2004; 114: 1550-1559.
5	Olds DL, Kitman H, Hanks C, et al. Effects of nurse home visiting on maternal and child functioning: Age 9 follow-up of a randomized trial. Pediatrics 2007; 120: 832-845.
6	Olds DL, Kitman HJ, Cole RE, et al. Enduring effects of prenatal and infancy home visiting by nurses on maternal life course and government spending: Follow-up of a randomized trial among children at age 12 years. Archives of Pediatric and Adolescent Medicine 2010; 164: 419-24.
7	Olds DL, Kitman H, Knudtson MD, et al. Effect of Home Visiting by Nurses on Maternal and Child Mortality: Results of a 2- Decade Follow-up of a Randomized Clinical Trial. Journal of the American Medical Association Pediatrics 2014; 168: 800-806.

RCT 3 – The Denver Study

Recruiting: From March 29, 1994, through June 15, 1995

N=735

Studies

1	Olds DL, Robinson J, O'Brien R, et al. Home visiting by paraprofessionals and by nurses: A randomized, controlled trial. Pediatrics 2002; 110: 486-496.
2 (A)	Olds DL, Robinson J, Pettitt L, et al. Effects of home visits by paraprofessionals and by nurses: Age 4 follow-up results of a randomized trial. Pediatrics 2004; 114: 1560-1568.

RCT 4 – Nederland

Recruiting: a 2½year period from 2007 to 2009

N=460

Studies

1 (A)	Mejdoubi J, van den Heijkant S, van Leerdam FJM, et al. Effects of nurse home visitation on cigarette smoking, pregnancy outcomes and breast-feeding: A randomized controlled trial. Midwifery, 2013; 30: 688-695.
2 (B)	Mejdoubi J, van den Heijkant S, van Leerdam FJM, et al. Effect of nurse home visits versus usual care on reducing intimate partner violence in young high-risk pregnant women: A randomized controlled trial. PLOS ONE, published online October 21, 2013.
3	Mejdoubi J, van den Heijkant S, van Leerdam FJM, et al. The effect of VoorZorg, the Dutch Nurse-Family Partnership, on child maltreatment and development: A randomized controlled trial. PLOS ONE, published online April 1, 2015.

RCT 5 – England

Recruiting: Between June 16, 2009, and July 28, 2010

N=1645

Studies

1	Robling M, Bekkers MJ, Bell K, et al. Effectiveness of a nurse-led intensive home-visit programme for first-time teenage mothers (Building Blocks): A pragmatic randomised controlled trial. Lancet, 2015; 387: 146-155.
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RCT 6 – Canada

Recruiting: October 2013 and approximately three years

N= (not available in the protocol)

Studies

1	Catherine N, Gonzalez A, Boyle M, Sheehan D, Jack SM, Hougham KA, et al. Improving children's health and development in British Columbia through nurse home visiting: a randomized controlled trial protocol. BMC Health Serv Res. 2016;16:349.29.
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Vedlegg 2: Litteratursøk

Cochrane Central Register of Controlled Trials

Issue 10 of 12, October 2021

ID	Search	Hits
#1	[mh Family] OR [mh Parents] OR [mh "Maternal Behavior"] OR [mh "Parent-Child Relations"] OR [mh Pregnancy] OR [mh ^"Pregnant Women"] OR [mh ^"Prenatal Care"] OR [mh Infant] OR [mh Child] OR (family OR families OR parent OR parents OR parental OR father* OR matern* OR mother* OR pregnan* OR prenatal* OR pre-natal* OR postnatal* OR post-natal* OR neonate* OR infant* OR infancy OR child OR children* OR childhood)	300252
#2	((([mh Nurses] OR [mh "Maternal-Child Nursing"] OR [mh "Pediatric Nursing"] OR [mh ^"Community Health Nursing"] OR [mh ^"Family Nursing"]) AND [mh ^"House Calls"]) OR [mh ^"Home Health Nursing"]) OR (nurs* NEAR/5 (home NEXT visit* OR house NEXT call*))	699
#3	("nurse-family partnership" OR "nurse family partnership")	56
#4	((#1 AND #2) OR #3) in Trials	381

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