Foundations
What Works Centre for Children & Families

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Intervention website: https://www.gov.uk/government/publications/commissioning-the-family-nurse-partnership-programme

GUIDEBOOK INTERVENTION INFORMATION SHEET

Family Nurse Partnership (FNP)

Please note that in the 'Intervention summary' table below, 'child age', 'level of need', and 'race and ethnicities' information is **as evaluated in studies**. Information in other fields describes the intervention as **offered/supported by the intervention provider**.

Intervention summary	
Description	Family Nurse Partnership (FNP) is a home-visiting intervention for disadvantaged, single mothers, 24 years old or younger, expecting their first child. Mothers enrol early in their pregnancy and are scheduled to receive 64 90-minute home visits until their child's second birthday. Visits take place on a weekly basis during the pregnancy and six weeks after the baby's birth. Visits then continue fortnightly until three months before the child's second birthday when they occur monthly until the intervention's end. During each visit, mothers are provided with advice about their young child's health and development, and support for their own wellbeing.
Evidence rating	4+
Cost rating	5

Intervention summary	
Child outcomes	• Preventing obesity and promoting healthy physical development - Reduced preventable-cause child mortality. • Supporting children's mental health and wellbeing - Improved emotional wellbeing. • Preventing child maltreatment - Reduced accident and emergency visits - Reduced hospitalisations - Reduced child maltreatment. • Enhancing school achievement and employment - Improved early learning - Improved school readiness - Improved speech, language and communication. - Improved literacy. • Preventing crime, violence and antisocial behaviour - Improved behaviour - Reduced antisocial behaviour - Reduced involvement in crime. • Preventing substance abuse - Reduced substance misuse - Reduced smoking.
Child age (population characteristic)	Single adolescent mothers (aged 19 and younger) expecting their first child
Level of need (population characteristic)	Targeted Selected
Race and ethnicities (population characteristic)	• African American • Asian • Hispanic • White.
Type (model characteristic)	Home-visiting
Setting (model characteristic)	Home
Workforce (model characteristic)	Health visitors or nurses.

Intervention summary	
UK available?	Yes
UK tested?	Yes

Model description

Family Nurse Partnership (FNP) is a preventive home-visiting intervention for single mothers expecting their first child. It was originally developed for teenage mothers, but in the UK the age group has been expanded to include first-time mothers up to 24 years old with additional risk factors.

Mothers enrol early in their pregnancy and are scheduled to receive 64 90-minute home visits until their child's second birthday. Visits take place on a weekly basis during the pregnancy and six weeks after the baby's birth. Visits then continue fortnightly until three months before the child's second birthday when they occur monthly until the intervention's end.

During each visit, the Family Nurse provides the mother with advice and support within the following six domains:

- Personal health – The Family Nurse supports the mother's personal health, including her nutrition and exercise, her use of drugs and alcohol, and maintaining mental wellbeing.
- Environmental health – The Family Nurse makes sure that the mother and child have adequate housing and support from their community.
- Life course development – The mother and Family Nurse work in partnership to identify relevant goals for the mother. These goals typically involve plans for the mother to complete her education, find a job and postpone the birth of a second child.
- Maternal role – The Family Nurse works with the mother to help her develop the knowledge and skills to confidently support the health and development of her child.
- Friends and family – The Family Nurse works with the mother to understand and manage her relationships with others (including her own parents and the baby's father) so that they are supportive of the mother and child's needs.
- Health and social services – The mother is signposted or referred to community services to further support her own and her child's needs.
- Pregnancy advice – The Family Nurse makes sure that the mother is attending her pregnancy appointments and that she is prepared for the birth of her child.

The baby's father is invited to attend the sessions when possible and appropriate.

The family nurses are trained and supervised to build a therapeutic alliance with the parents, which provides the context for parents to learn and make positive choices for themselves and the baby.

When working with families, FNP nurses adopt a strengths-based approach which builds upon the parents' intrinsic motivation to do the best for their child.

Learning is supported through tip sheets and demonstrations involving a doll that is brought to the earlier sessions. FNP nurses also provide feedback while the parents interact with their child.

Target population

Age of child	Antenatal to 2 years old
Target population	Vulnerable, first-time mothers aged 24 years old and younger.

Please note that the information in this section on target population is as **offered/supported by the intervention provider**.

Theory of change

Why		Who	How	What		
Science-based assumption	**Science-based assumption**	**Science-based assumption**	**Intervention**	**Short-term outcomes**	**Medium-term outcomes**	**Long-term outcomes**
• Teen pregnancy and social disadvantage are associated with poor outcomes in infancy and later child development • Low birthweight is associated with increased risk of physical impairment, poor cognitive and linguistic development, and reduced quality of the parent–child relationship.	• Maternal smoking, substance misuse poor diet and poor access to antenatal care increase the risk of low birthweight, preterm birth and neurodevelopmental impairment. • Increased mother-child attachment means mothers are more able to care for their baby and meet their baby's needs • Increased maternal self-efficacy and connection to family and community support can lead to increased positive future goals and financial security.	• Young, first-time single mothers are at greater risk of having a low birthweight infant, associated with a greater likelihood of smoking, poor antenatal care, and social isolation • Young, first-time mothers are also more likely to be living in disadvantaged circumstances and have a history of childhood trauma further increasing the likelihood of poor child outcomes.	• Mothers receive personalised support throughout their pregnancy and the child's first two years • Mothers are supported to stop smoking and misuse substances during their pregnancy • Mothers receive advice and support for caring for their child • Mothers are supported to gain economic self-sufficiency.	• Reduced maternal health-risk behaviours during the pregnancy • Reduced risk of birth complications, including low birthweight • Mothers are better able to care for their baby and meet their baby's needs.	• Improved mother–child interaction • Improved mother–child relationship • The mother has better relationships with other family members • The mother is at less risk of abusive relationships • Mothers are better able to access support aimed at increasing financial security.	• Mothers are less likely to remain on benefits • Children are at less risk of future mental health problems • Children are at less risk of child maltreatment • Children are better able to regulate their behaviour • Children have improved school readiness skills leading to improved academic achievement.

Implementation requirements

Who is eligible?	First-time, single mothers aged 24 years or younger.
How is it delivered?	• Family Nurses Partnership is delivered by a specially trained family nurse through up to 64 home-based weekly fortnightly or monthly sessions, to first-time mothers. Each session lasts 60 to 90 minutes. • Teams of up to eight family nurses are led by a supervisor.
What happens during the intervention?	• A series of structured home visits are delivered using a wide range of materials and activities that build self-efficacy, change health behaviour, improve care giving, and increase economic self-sufficiency. • At the heart of the FNP model is the relationship between the client and the nurse. FNP builds on expectant mothers' (and fathers') intrinsic motivation to do the best for their child. • A therapeutic alliance is built by specially trained nurses, which supports families to make changes to their health behaviour and emotional development and form a positive relationship with their baby. • Clients learn parenting skills (e.g. holding baby, bathing baby), sometimes using a doll with the family nurse demonstrating how to interact with the child and providing feedback as the mother interacts with the baby.
Who can deliver it?	Practitioners should be registered nurses with experience of community nursing and working with babies and children. This includes school nurses, health visitors, midwives, and specialist mental health nurses.
What are the training requirements?	Family nurses and supervisors are provided with a bespoke mixed-method learning programme, including both training events and individual and team-based learning materials. Once completed, this learning provides nurses and supervisors with the range of intervention-specific knowledge and skills they require for their role.
How are practitioners supervised?	Supervision is core to the FNP model. Practitioners receive one hour per week of individual supervision and two hours per week of team-based supervision with a supervisor, who must have considerable clinical experience in a relevant nursing profession.
What are the systems for maintaining fidelity?	Regular review of intervention fidelity data at multiple levels – nurse, site, national – generated from a real-time information system. National Unit regularly reviews site-level fidelity data in line with licence and offers quality improvement support to sites.
Is there a licensing requirement?	Yes

Implementation requirements (Cont.)

***Contact details**	Organisation: Nurse Family Partnership Email address: 0-19clinicalprogrammesunit@dhsc.gov.uk Websites: https://www.nursefamilypartnership.org/ https://www.gov.uk/government/publications/commissioning-the-family-nurse-partnership-programme https://nfpinternational.org/ *Please note that this information may not be up to date. In this case, please visit the listed intervention website for up to date contact details.

Evidence summary

FNP has evidence from five large-scale RCTs all consistent with Foundations' Level 3 evidence strength criteria. All five of these studies also had evidence of long-term child benefits. This means that FNP receives a Level 4+ rating, as two of these studies were conducted by an evaluator independent of the intervention developer.

The first RCT involved a primarily White sample of teenage mothers in the United States (Elmira, New York). This study observed that children exposed to FNP during the first two years of their life were less likely to have to go to the hospital for an emergency during their first five years, had fewer behavioural problems, had fewer arrests in adolescence, and were less likely to have a substantiated report of child abuse and neglect compared to children not receiving the intervention. FNP mothers were additionally more likely to reduce their smoking during pregnancy and maintain a healthier diet than mothers not receiving the intervention.

The second RCT primarily involved a sample of young Black mothers living in the United States (Memphis, Tennessee). This study observed that children exposed to FNP during the first two years of their life were less likely to be injured during the first two years of their life, demonstrated improved behaviour and language and cognitive skills by age 6 years old, and were less likely to smoke or use drugs and alcohol in adolescence compared to children not exposed to the intervention. Additionally, a 20-year follow-up observed that FNP children were less likely to die from preventable reasons compared to children not exposed to the intervention.

The second RCT also observed that FNP mothers were more likely to delay the birth of their second child, be in a long-term relationship with their partner, and collect public benefits in comparison to mothers not receiving FNP.

The third RCT involved a predominantly Hispanic population living in the United States (Denver, Colorado). This study observed that FNP was more likely to improve children's internalising behaviour and early language outcomes when delivered by nurses rather than by trained paraprofessional home visitors.

The fourth RCT took place in the Netherlands, observing increased emotional wellbeing and reduced risk of child maltreatment in FNP children compared to those not receiving the

intervention. FNP mothers additionally reported reduced rates of intimate partner violence (victimisation and perpetration) during their pregnancies compared to mothers not receiving the intervention.

The fifth RCT was conducted in the UK, observing improved early language development during the FNP children's first two years compared to children not receiving the intervention. Additionally, FNP children were more likely to be assessed as having a good level of development on the Early Years Foundation Stage Profile and demonstrate improved reading ability at Key Stage 1 compared to children not exposed to the intervention.

FNP can be described as evidence based as it has evidence of a long-term positive impact on child outcomes through multiple rigorous evaluations.

Child outcomes			
Outcome	**Improvement index**	**Interpretation**	**Study**
Reduced preventable-cause mortality	+40	Interpretation 1.6-percentage point reduction in preventable-cause child mortality rate (measured using administrative data) Long-term: 18 months after intervention	2
Reduced internalising behaviours	+11	8.8-percentage point reduction in proportion of participants with internalising problems (measured using the Youth Self-Report) Long-term: 10 years later	2
Reduced internalising behaviours	+7	14-percentage point decrease in proportion of participants with internalising behaviour (measured using the Child Behaviour Checklist – mother report) Immediately after intervention	4
Reduced abuse and neglect	+16	8-percentage point decrease in proportion of participants with a child protective services report (measured using administrative data) (immediately after intervention)	4

Improved intellectual functioning	+7	2.1-point improvement on the Kaufman Assessment Battery for Children (mental processing composite) Long term: 4 years later	2
Improved child receptive language	+7	2.19-point improvement on the Peabody Picture Vocabulary Test Long-term: 4 years later	2
Reduced developmental concerns	+12	4.5-percentage point reduction in proportion of children with a reported developmental concern (measured using the Schedule of Growing Skills – mother report) Immediately after the intervention	5
Improved school readiness	+6	5.8-percentage point difference in proportion of participants achieving a good level of development (Early Years Foundation Stage Profile scores) Long-term: 3 years later	5
Improved reading ability	+6	Reduction in proportion of participants not reaching at least the expected standard of reading (measured using Key Stage 1 scores – reading ability) Long-term: 5 years later	5
Improved child behaviour	+25	3.6-percentage point reduction in proportion of participants with behaviour problems (measured using the Child Behaviour Checklist) Long-term: 4 years later	2
Reduced use of substances	+26	3.4-percentage point reduction in proportion of participants who have used cigarettes, alcohol, or marijuana in the past 30 days (measured using self-report interview) Long-term: 10 years later	2

Search and review

	Number of studies
Identified in search	N/A
Studies reviewed	5
Meeting the L2 threshold	0
Meeting the L3 threshold	5
Contributing to the L4 threshold	5
Ineligible	N/A

Individual study summary: Study 1

Study 1	
Study design	RCT
Country	United States
Sample characteristics	400 highly disadvantaged first-time adolescent mothers (≤ 19 years old) living in the vicinity of Elmira, New York
Race, ethnicities, and nationalities	89% White
Population risk factors	• 47% of the participating women were younger than 19 years of age • 62% were unmarried • 61% came from families in Hollingshead's social classes IV and V (semi-skilled and unskilled labourers).
Timing	• Pregnancy and birth (Study 1a) • The child's second birthday (Study 1b) • The child's third and fourth year (Study 1c) • 15-year follow-up (Studies 1d and 1e) • 19-year follow-up (Study 1f).

Study 1	
Child outcomes	*Pregnancy and childbirth* • Improved birthweight among children whose mothers smoked at the start of pregnancy. *The child's first two years* • Fewer emergency visits to the hospital • Fewer emergency visits for accidents and poisonings. *25- to 50-month follow-up* • Fewer emergency visits to the hospital • Fewer emergency visits for accidents and poisonings • Fewer injuries and ingestions • Fewer recorded behavioural problems. *15-year follow-up* • Less likely to have been stopped by the police • Fewer arrests • Less likely to have been adjudicated a person in need of supervision, as corroborated by state records • Mothers less likely to have a substantiated report of abuse or neglect. *19-year follow-up* • Fewer arrests or convictions (girls only).
Other outcomes	*Pregnancy and childbirth* • Improved maternal diet during pregnancy • More support during labour from family and friends • Fewer kidney infections during pregnancy • Fewer cigarettes smoked per day during pregnancy. *25- to 50-month follow-up* • Fewer hazards in the home • Increased involvement with their child • Increased use of punishment with child.
Study Rating	3
Citations	**Study 1a:** Olds, D. L., Henderson, C. R., Tatelbaum, R. & Chamberlin, R. (1986) Improving the delivery of prenatal care and outcomes of pregnancy: A randomized trial of nurse home visitation. *Pediatrics*. 77, 16–28.

Study 1	
	Study 1b: Olds, D. L., Henderson, C. R., Chamberlin, R. & Tatelbaum, R. (1986) Preventing child abuse and neglect: A randomized trial of nurse home visitation. *Pediatrics*. 78, 65–78. **Study 1c:** Olds, D. L., Henderson Jr, C. R. & Kitzman, H. (1994) 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*. 93(1), 89–98. **Study 1d:** Olds, D., Henderson Jr, C. R., Cole, R., Eckenrode, J., Kitzman, H., Luckey, D., Pettitt, L., Sidora, K., Morris, P. & Powers, J. (1998) Long-term effects of nurse home visitation on children's criminal and antisocial behaviour: 15-year follow-up of a randomized controlled trial. *Journal of the American Medical Association*. 280, 1238–1244. **Study 1e:** Olds, D. L., Eckenrode, J., Henderson, C. R., Kitzman, H., Powers, J., Cole, R., Sidora, K., Morris, P., Pettitt, L.M. & Luckey, D. (1997) 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*. 278, 637–643. **Study 1f:** Eckenrode, J., Campa, M., Luckey, D. W., Henderson, C. R., Cole, R., Kitzman, H., Anson, E., Sidora-Arcoleo, Powe, J. & Olds, D. (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. *Archives of Pediatrics & Adolescent Medicine*. 164, 9–15.

Brief summary

Population characteristics

This study involved 400 highly disadvantaged first-time mothers living in the vicinity of Elmira, New York.

The Elmira community was chosen because it had the highest number of cases of child abuse and neglect in New York State and the highest level of economic disadvantage in the entire US at the time the study was conducted.

While efforts were made to only recruit first-time single mothers aged 19 or younger, any first-time mother who asked to participate was ultimately enrolled. This avoided creating an intervention that was stigmatised as being exclusively for the poor and permitted meaningful subgroup comparisons between highly vulnerable and less vulnerable mothers.

47% of the participating women were younger than 19 years of age, 62% were unmarried, and 61% came from families in Hollingshead's social classes IV and V (semi-skilled and unskilled labourers).

Information about child characteristics (including the number of births) was not reported for the original sample.

The study reports that 46 of the participants were non-White, suggesting that the recruited sample was 89% White. However, the non-White participants were removed from the analysis in Studies 1a, 1b, and 1c, meaning that the sample was 100% White.

Study design

Mothers were randomly assigned to one of four conditions involving two control and two treatment variations:

1. Health and developmental screening at 12 and 24 months (control; n=90)
2. Health and developmental screening at 12 and 24 months combined with free transportation (control; n=94)
3. Health and developmental screening at 12 and 24 months combined with free transportation and FNP during the prenatal period only (treatment; n=100)
4. Health and developmental screening at 12 and 24 months combined with free transportation and FNP, starting during the prenatal period and lasting until the child's second birthday (treatment; n=116).

Mothers were stratified by marital status, race, and geographic region and then randomly assigned to one of the four treatment conditions. The stratification was executed by using separate decks for the groups defined by the women's race, marital status at intake, and, for White women, the geographic region in which they resided. To further ensure balance across the four groups, the decks were reconstituted periodically to overrepresent those treatments with smaller numbers of subjects. At the end of the intake interview, the women drew their treatment assignments from a deck of cards.

The resulting groups were balanced on all demographic characteristics and baseline measures, with the exception that nurse-visited non-smokers in the older than 16-year age group were less securely embedded in a helpful kin network, had less confidence that someone would accompany them to labour and delivery, and were older than their counterparts in the comparison group.

Measurement

Families participated in assessments at registration (during enrolment when the mother was pregnant) and at 32 weeks' gestation. Additional assessments were carried out when the child was 6 months, 10 months, 12 months, 22 months, 24 months, 34 months, 36 months, 46 months, 48 months, 50 months, 15 years, and 19 years.

Pregnancy and childbirth (Study 1a)

- **Parent report** measures included 24-hour diet records completed by mothers at intake and at the 32 weeks' gestation assessment, and interviews at 32 weeks' gestation including questions about health, diet, alcohol consumption, and smoking.
- **Researcher-led** assessments included length of gestation estimations from the mother's last reported period or ultrasounds of their baby at 28 weeks, when available. All information was gathered from practitioners or researchers blind to group assignment.

- **Administrative records** included health information gathered during the mothers' antenatal appointments and childbirth.

The child's first two years (Study 1b)

- **Parent report** measures included interviews concerning common infant behavioural problems in the project office at six, 12 and 24 months and an infant temperament Q-sort at six months.
- **Researcher-led** assessments included the Home Observation for Measurement of the Environment (HOME) Inventory conducted at 10 and 22 months, the Mental Development Index (MDI) of the Bayley Scale (conducted at 12 months) and the Cattell Infant Intelligence Scales (conducted at 24 months).
- **Administrative records** included the child's medical records and state records for substantiated cases of abuse and neglect.

34- to 50-month follow-up (Study 1c)

- **Parent report** measures included an interview regarding the child's exposure to hazards in the home conducted at 34 and 46 months
- **Researcher-led** assessments included the Home Observation for Measurement of the Environment (HOME) Inventory, an observation checklist indicating the degree of the child's exposure to set categories of hazards, a coded observation of mother–child interaction occurring in the family home at 34 and 46 months, and the Standard-Binet Form L-M intelligence test conducted at 36 months and 48 months.
- **Administrative records** included substantiated cases of child maltreatment in Child Protective Services records accessed at 48 months and paediatric and hospital records accessed at 50 months.

15-year follow-up (Studies 1d and 1e)

- **Youth report** measures in included the Youth Self-Report of Problem Behaviors (YSR) and interviews with youths about the incidence of antisocial behaviours (including their history of being adjudicated a person in need of supervision on account of truancy or family theft), arrests and convictions, the number of cigarettes smoked per day, drug and alcohol use, and number of sexual partners within the last six months.
- **Parent report** measures included the parent version of the Child Behavior Checklist (CBCL), a life-history calendar aimed at helping mothers remember key events and questions adapted from the National Comorbidity Survey with questions about substance use, and researcher conducted interviews with the mothers about their children's behaviour, subsequent pregnancies, arrests and convictions, employment history, and use of public benefits.
- **School records** included information about young people's suspensions.
- **Administrative records** included New York state records of youth's history of being adjudicated a person in need of supervision, incidence of youth arrests, incidence of mother arrests, and child protection records.

19-year follow-up (Study 1f)

- **Youth report** measures included telephone interviews concerning history of arrests and convictions, educational achievement, pregnancies, births and use of welfare, and the National Youth Survey.

Study retention

Pregnancy and childbirth (Study 1a)

66 women were excluded from the analysis, including 46 non-White women (because the sample was too small to cross-classify race with other variables of importance in the statistical analyses) and 20 cases with serious foetal or maternal conditions, including one case involving multiple births. The baseline characteristics of these two groups were comparable to the mothers retained in the study, except for the characteristics contributing to their exclusion.

This resulted in 334 mothers remaining in the study. The four groups were collapsed into a treatment and comparison group for the purposes of analyses:

1. 179 mothers receiving FNP antenatally or until the child's second year
2. 155 mothers receiving no treatment.

At the end of the study, 308 mothers (92%) were retained, including 165 (92%) from the nurse visiting group and 143 (93%) from the comparison group. The women who dropped out of the study were more advantaged on several baseline characteristics in comparison to those who remained, but no differential attrition was reported between the two samples.

Further attrition was observed for each of the measures, fluctuating between 24% for the 24-hour diet diaries, and 0% for the childbirth outcomes.

The child's first two years (Study 1b)

This study continued to exclude the 46 non-White women originally excluded in the pregnancy and childbirth study (Study 1a) but included the 20 mothers and infants who were originally omitted due to serious foetal or maternal conditions. This resulted in 356 families being eligible for analysis within the following three groups:

1. 90 mothers receiving FNP antenatally
2. 99 mothers receiving FNP antenatally until the child's second birthday (infancy FNP)
3. 165 mothers receiving no nurse visits.

The study reports that attrition varied between 15 to 21% but does not report how this differentially affected the three samples used in the analyses.

The outcomes table below provides the sample sizes for comparisons involving infancy FNP and no FNP only, suggesting that attrition in fact fluctuated between 3 and 44%, depending on the individual measure.

34- to 50-month follow-up (Study 1c)

The reporting for attrition is identical to what was reported in Study 1b, stating that attrition fluctuated from 15 to 21% and that the 46 non-White mothers were excluded from the analyses.

Differential attrition across the three study samples (no FNP, antenatal FNP and infancy FNP) is not reported. The outcomes table below provides the sample size for the comparisons involving no FNP and infancy FNP only.

15-year follow-up study (Studies 1d and 1e)

This follow-up involved the entire study sample of 400 participants, including the 46 non-White participants who had been excluded in the original study and the 34- to 50-month follow-up. The study reports that the retained sample and three treatment groups were comparable in terms of their demographic and baseline characteristics.

- 83% (330) of the mothers participated in the 15-year follow-up study 1d. This included 81% (81) who received FNP during their pregnancies only, 84% (97) who received FNP during their pregnancies and the child's first two years and 83% (152) who did not receive any nurse visiting.
- 81% (324) of the mothers participated in the 15-year follow-up study 1e. This included 79% (79) who received FNP during their pregnancies only, 84% (97) who received FNP during their pregnancies and the child's first two years and 80% (148) who did not receive any nurse visiting.
- 83% (315) of the study children participated in the 15-year follow-up study. This included 77% (77) whose mothers received FNP during their pregnancies, 81% (94) whose mothers received FNP during their pregnancies and their first two years and 78% (144) who did not receive any nurse visiting.
- School records were available for 73% (291) of the study children, including 68% (68) whose mothers received FNP during their pregnancies, 72% (84) whose mothers received FNP during their pregnancies and their first two years and 76% (139) who did not receive any nurse visiting.
- Family court records were available for 29% (116) of the children, including 27% (27) whose mothers received FNP during their pregnancies, 25% (29) whose mothers received FNP during their pregnancies and their first two years and 33% (60) who did not receive any nurse visiting.

Child protection data was available for 79% (314) of the families, including 77% (77) of those who received FNP only during the mothers' pregnancy, 82% (95) of families who received FNP until the child's second birthday and 77% (142) of families who did not receive any home visiting. 19-year follow-up (Study 1f)

The 19-year follow-up involved the entire study sample of 400 participants, including those who had been excluded from the original study and previous follow-ups. The study reports that the retained sample and three treatment groups were comparable in terms of their demographic and baseline characteristics.

- 78% (310) of the children from original sample participated in the 19-year follow-up telephone interview. This included 79% (79) of those whose mothers received FNP during their pregnancy, 78% (91) of those whose mothers received FNP during pregnancy and until their child's second birthday and 76% (140) of those who received no nurse visits.

Results

Pregnancy and childbirth (Study 1a)

Data-analytic strategy

A 2 x 2 x 2 x 2 factorial structure involving treatment condition (nurse-visiting versus no nurse-visiting), maternal smoking status (zero to four vs five or more cigarettes per day), maternal age (1<17 vs ≥ 17 years), and sex of child was used to analyse the findings. The model was extended to include a repeated-measures structure for dependent variables measured both early and late in pregnancy. Three covariates measured at registration (maternal prepregnant weight, prepregnant height, and number of cigarettes smoked per day at intake) were included in the model when birth weight and length of gestation were analysed as dependent variables. Intention-to-treat was used, but imputation was not used to replace missing values.

Findings

The study observed statistically significant improvements in FNP mothers' diet, awareness of support services available, participation in childbirth classes, use of nutritional support vouchers and fewer kidney infections during pregnancy compared to non-FNP mothers. FNP mothers also reported talking through problems with a support person more frequently, and that their babies' fathers became more interested in their pregnancy; they were also accompanied to hospital by a support person during labour more frequently. Additionally, there were statistically significant reductions in the numbers of cigarettes smoked per day among the mothers who smoked at the start of the intervention. Specifically, FNP mothers reported smoking an average of four fewer cigarettes per day than non-FNP mothers, who increased the number of cigarettes they smoked per day during their pregnancies. Additional subgroup analyses verified that reductions in smoking were associated with a reduced percentage of preterm births in FNP families where the mothers smoked five or more cigarettes per day, compared to their counterparts in non-FNP families.

The child's first two years (Study 1b)

Data-analytic strategy

A 3 x 2 x 2 x 2 factorial structure involving treatment (no FNP, antenatal FNP, and infancy FNP), maternal age (<19 v ≥ 19 years), marital status and social class (Hollingshead classes IV and V vs I, II, and III) was used in the analyses. Two covariates measured at registration (maternal sense of control and reported husband/boyfriend support) were also included in the model for most analyses to adjust for chance differences between treatment groups for certain at-risk subsamples and to reduce error variance. Intention-to-treat was used, but imputation was not used to replace missing values.

Findings

The study observed that FNP children were significantly less likely to have visited the hospital for an emergency during their first two years compared to children whose mothers did not receive the intervention. Specifically, the babies of nurse-visited women, especially the babies of poor, unmarried teenagers, were seen in the emergency department fewer times than their counterparts

in the comparison group – and this was true for both the antenatal and infancy FNP groups. A detailed review of the medical records revealed that these differences were explained by a reduction in visits for upper respiratory tract infections. During the second year, the children of mothers in either FNP group were seen in the emergency department significantly fewer times and presented with fewer accidents and poisonings compared to children whose mothers did not receive FNP.

The study also observed that only 4% of the children in the two FNP groups had a report of abuse and neglect compared to 19% of the non FNP children. While this finding was not significant ($p = .07$), the incidence of abuse and neglect in the comparison group was directly correlated with the number of risk factors present in the family. By contrast, the incidence of abuse and neglect remained low in both FNP groups, regardless of the number of risk factors present in the family.

FNP mothers reported that their babies had more positive moods, but also more frequent occurrences of resisting eating, compared to mothers who did not receive FNP. FNP mothers also reported greater levels of maternal concern about infant behaviour.

All other comparisons were non-significant, including those involving mothers' use of discipline and their children's cognitive development.

34- to 50-month follow-up (Study 1c)

Data-analytic strategy

The analyses utilised a 3 x 2 x 2 x 2 factorial structure involving treatment (no FNP, antenatal FNP and infancy FNP), maternal age (<19 v ≥ 19 years), marital status and social class (Hollingshead classes IV and V vs I, II, and III). Two covariates measured at registration (maternal sense of control and reported husband/boyfriend support) were also included in the model for most analyses to adjust for chance differences between treatment groups for certain at-risk subsamples and to reduce error variance. Intention-to-treat was used, but imputation was not used to replace missing values.

Findings

The study observed no statistically significant differences between FNP and non-FNP children involving rates of child abuse and neglect or children's intellectual functioning from 25 to 48 months of age. Nevertheless, nurse-visited children lived in homes with fewer hazards, had 40% fewer injuries and ingestions; 45% fewer behavioural and parental coping problems noted in the physician record and 35% fewer visits to the emergency department than did children in the comparison group. Nurse-visited mothers were also observed to be more involved with their child and to punish them more frequently than mothers not receiving the intervention.

15-year follow-up (Studies 1d and 1e)

Data-analytic strategy

The analyses utilised a 3 x 2 x 2 x 2 factorial structure, involving treatment groups (no FNP, FNP pregnancy, FNP infancy), maternal marital status (married vs not married at the time of registration) and social class (Hollingshead I and II vs III and IV at registration), and sex of child.

All interactions among the first three factors were included. Intention-to-treat was used with no reported imputation for missing values.

Findings

The study observed that children whose mothers received FNP in pregnancy or until the child's second birthday were significantly more likely to report having been stopped by the police, but less likely to have been arrested, convicted or have violated probation compared to children whose mothers did not receive FNP. Additionally, analysis of state records of a subsample of children indicated that children whose mothers received FNP until their second birthday were less likely to have been adjudicated a person in need of supervision. Mothers who received FNP were also significantly less likely to have a substantiated case of abuse and neglect (based on CPS reports of mothers and/or their children involved directly in the study, not just children).

Additional subgroup analyses observed that mothers who were unmarried and receiving social benefits at the start of the study were more likely to postpone the birth of their second child, state benefits, have substance misuse problems or have been arrested in comparison to their counterparts in the no FNP group.

19-year follow-up (Study 1f)

Data-analytic strategy

Analyses were conducted regardless of intervention participation (intention-to-treat), retaining all available values. The analyses utilised a 3 x 2 x 2 factorial structure in a manner similar to previous studies, involving treatment group, the mothers' marital status, socio-economic risk and the child's gender. Quantitative variables were examined in the general linear model. The Cox proportional hazards method for survival analysis was used to estimate the hazard of first arrest for those in the comparison and nurse-visited groups with the mothers' educational level at intake, the youth's race and gender as covariates. Growth curves for arrests across time were estimated for treatment groups by the youth's sex in a generalised mixed model with cubic age regressions, with log link and negative binomial error.

Findings

The study observed that youths whose mothers were visited by nurses during pregnancy and infancy were significantly less likely to have ever been arrested or convicted than were those in the comparison group. However, subgroup analyses observed that this finding was driven by differences in rates of arrest and convictions for girls and not boys.

Study 1: Outcomes table

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Child outcomes					
Birthweight	Hospital records (administrative records)	Not reported	No	308	Child's birth
Percentage of low birthweight	Hospital records (administrative records)	Not reported	No	308	Child's birth
Gestation period	Hospital records (administrative records)	Not reported	No	308	Child's birth
Percentage preterm delivery	Hospital records (administrative records)	Not reported	No	308	Child's birth
Positive mood	Temperament Q-sort (mother report)	Not reported	Yes	209**	Six-month assessment
Crying episodes	Practitioner-led interview (mother report)	Not reported	No	163**	Six-month assessment

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Resisting eating	Practitioner-led interview (mother report)	Not reported	Yes***	163**	Six-month assessment
Awaking during the night	Practitioner-led interview (mother report)	Not reported	No	163**	Six-month assessment
Cognitive development	MDI (researcher assessment)	Not reported	No	204**	12 months
Cognitive development	Cattell Infant Intelligence Scale (researcher assessment)	Not reported	No	193**	22 months
Cognitive development	Stanford-Binet Form L-M (researcher assessment)	Not reported	No	236**	36 months
Cognitive development	Stanford-Binet Form L-M (researcher assessment)	Not reported	No	236**	48 months
Number of emergency hospital visits	Paediatric and hospital records (administrative records)	Not reported	Yes	223**	12 months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Number of emergency hospital visits	Paediatric and hospital records (administrative records)	Not reported	Yes	196**	24 months
Number of emergency hospital visits, 25 to 50 months	Paediatric and hospital records (administrative records)	Not reported	Yes	221*	50 months
Number of emergency visits for accidents and poisoning	Paediatric and hospital records (administrative records)	Not reported	No	223**	12 months
Number of emergency visits for accidents and poisoning	Paediatric and hospital records (administrative records)	Not reported	Yes	196**	24 months
Number of emergency visits for accidents and poisoning, 25 to 50 months	Paediatric and hospital records (administrative records)	Not reported	No	221**	50 months
Substantiated cases of abuse and neglect, 0 to 24 months	New York State child protection records (administrative records)	Not reported	No	256**	24 months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Substantiated cases of abuse and neglect, 25 to 48 months	New York State child protection records (administrative records)	OR=0.56	No	253**	48 months
Number of scheduled health supervision visits, 25 to 50 months	Paediatric and hospital records (administrative records)	Not reported	No	221**	50 months
Number of scheduled health supervision visits with problems, 25 to 50 months	Paediatric and hospital records (administrative records)	Not reported	No	221**	50 months
Number of injuries/ingestions in physician record, 25 to 50 months	Paediatric and hospital records (administrative records)	Not reported	Yes	221**	50 months
Number of behavioural problems in physician's record, 25 to 50 months	Paediatric and hospital records (administrative records)	Not reported	Yes	221**	50 months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Number of hospital admissions, 25 to 50 months	Paediatric and hospital records (administrative records)	Not reported	No	221**	50 months
Number of days hospitalised, 25 to 50 months	Paediatric and hospital records (administrative records)	Not reported	Yes	221**	50 months
Ever been adjudicated a person in need of supervision	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up
Ever been adjudicated a person in need of supervision	State records (administrative records)	Not reported	Yes	89**	15-year follow-up
Number of times ran away from home	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up
Incidence of times stopped by the police	Researcher-led interview with youth (youth report)	Not reported	Yes***	238**	15-year follow-up
Incidence of arrests	Researcher-led interview with youth (youth report)	Not reported	Yes	238**	15-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Incidence of arrests	Researcher-led interview with mother (mother report)	Not reported	No	249**	15-year follow-up
Incidence of arrests	State records (administrative data)	Not reported	No	89**	15-year follow-up
Incidence of convictions and probation violations	Researcher-led interview with youth (youth report)	Not reported	Yes	238**	15-year follow-up
Incidence of times sent to youth corrections	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up
Number of minor antisocial acts	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up
Number of major antisocial acts	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Number of externalising problems	Composite score of mother and youth completion of the YSR (mother and youth report)	Not reported	No	238**	15-year follow-up
Number of internalising problems	Composite score of mother and youth completion of the YSR (mother and youth report)	Not reported	No	238**	15-year follow-up
Ever had sexual intercourse	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up
Ever pregnant or made someone pregnant	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up
Incidence of sex partners	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up
Incidence of long-term school suspension	School records (administrative records)	Not reported	No	223**	15-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Incidence of short-term school suspension	School records (administrative records)	Not reported	No	223**	15-year follow-up
Incidence of cigarettes smoked per day	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up
Incidence of days drinking alcohol	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up
Incidence of days used drugs	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up
Alcohol impairment	Researcher-led interview with youth (youth report)	Not reported	No	238**	15-year follow-up
Alcohol and drug impairment	Research-led interview with parent (parent report)	Not reported	No	249**	15-year follow-up
Substantiated maternal cases of child abuse and neglect	State records	Not reported	Yes	237**	15-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Arrest over lifetime	Researcher-led interview with young person (young person report)	RR=0.33	Yes	117§	19-year follow-up
Convictions over lifetime	Researcher-led interview with young person (young person report)	RR=0.20	Yes	117§	19-year follow-up
Number of arrests over lifetime	Researcher-led interview with young person (young person report)	IRR=0.18	Yes	117§	19-year follow-up
Number of convictions over lifetime	Researcher-led interview with young person (young person report)	IRR=0.11	Yes	117§	19-year follow-up
Arrests in the last year	Researcher-led interview with young person (young person report)	Not reported	No	231	19-year follow-up
Convictions in the last year	Researcher-led interview with young person (young person report)	Not reported	No	231	19-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Felony assault	Researcher-led interview with young person (young person report)	Not reported	No	231	19-year follow-up
Illicit drug use	Researcher-led interview with young person (young person report)	Not reported	No	231	19-year follow-up
Binge drinking	Researcher-led interview with young person (young person report)	Not reported	No	231	19-year follow-up
Minor assault	Researcher-led interview with young person (young person report)	Not reported	No	231	19-year follow-up
Minor theft	Researcher-led interview with young person (young person report)	Not reported	No	231	19-year follow-up
Fraud	Researcher-led interview with young person (young person report)	Not reported	No	231	19-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Illegal services	Researcher-led interview with young person (young person report)	Not reported	No	231	19-year follow-up
Vandalism	Researcher-led interview with young person (young person report)	Not reported	No	231	19-year follow-up
Public disorder	Researcher-led interview with young person (young person report)	Not reported	No	231	19-year follow-up
Graduated from high school	Researcher-led interview with young person (young person report)	RR=0.95	No	231	19-year follow-up
Economically productive	Researcher-led interview with young person (young person report)	RR=1.05	No	231	19-year follow-up
Ever been pregnant or made someone pregnant	Researcher-led interview with young person (young person report)	RR=1.02	No	231	19-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Ever fathered a child or given birth	Researcher-led interview with young person (young person report)	RR=1.02	No	231	19-year follow-up
Ever used Aid to Families with Dependent Children	Researcher-led interview with young person (young person report)	RR=1.46	No	231	19-year follow-up
Ever used food stamps	Researcher-led interview with young person (young person report)	RR=1.04	No	231	19-year follow-up
Ever used Medicaid	Researcher-led interview with young person (young person report)	RR=0.92	No	231	19-year follow-up
Parent outcomes					
Bleeding during pregnancy	Change between 1st & 3rd trimester (administrative records)	Not reported	No	295	3rd Trimester

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Spotting during pregnancy	Change between 1st & 3rd trimester (administrative records)	Not reported	No	308	3rd Trimester
Blood pressure during pregnancy	Change between first and last visit (administrative records)	Not reported	No	295	Last antenatal visit before birth
Number of alcoholic drinks per week during pregnancy	Practitioner interview during intake and 32 weeks' gestation (mother report)	Not reported	No	293	32 weeks' gestation
Mother's weight gain during pregnancy	Change between self-report pre pregnancy & last visit (administrative records)	Not reported	No	289	Last antenatal visit before birth
Adequacy of the diet during pregnancy	24-hour diet assessment (mother report)	Not reported	Yes	253	32 weeks' gestation

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Number of cigarettes per day during pregnancy	Practitioner interview during intake and 32 weeks' gestation (mother report)	Not reported	Yes	141*	32 weeks' gestation
Number of kidney infections during pregnancy	Health records (administrative records)	Not reported	Yes	306	Anytime during the pregnancy
Number of bladder infections during pregnancy	Health records (administrative records)	Not reported	No	306	Anytime during the pregnancy
Hematocrit (percentage of red blood cells)	Health records (administrative records)	Not reported	No	308	Anytime during the pregnancy
Protein in urine during pregnancy	Health records (administrative records)	Not reported	No	308	Anytime during the pregnancy
Edema during pregnancy	Health records (administrative records)	Not reported	No	308	Anytime during the pregnancy
Hypertensive disorder of pregnancy	Health records (administrative records)	Not reported	No	308	Anytime during the pregnancy

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Number of services known	Practitioner-led interview (mother report)	Not reported	Yes	294	The child's birth
Participated in childbirth education	Practitioner-led interview (mother report)	Not reported	Yes	249	The child's birth
Use of nutritional supplement vouchers	Practitioner-led interview (mother report)	Not reported	Yes	288	The child's birth
Number of antenatal visits	Practitioner-led interview (mother report)	Not reported	No	292	The child's birth
Number of calls to the physician or clinic	Practitioner-led interview (mother report)	Not reported	No	292	The child's birth
Had a support person to discuss problems	Practitioner-led interview (mother report)	Not reported	Yes	296	The child's birth
Father was interested in the mother's pregnancy	Practitioner-led interview (mother report)	Not reported	Yes	278	The child's birth

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
A support person accompanied the mother to labour	Practitioner observation (practitioner report)	Not reported	Yes	269	The child's birth
A support person accompanied the mother to delivery	Practitioner observation (practitioner report)	Not reported	No	264	The child's birth
Help was available to the mother in the household	Practitioner-led interview (mother report)	Not reported	No	296	The child's birth
Worries and concerns about behaviour	Practitioner-led interview (mother report)	Not reported	Yes***	163**	Six-month assessment
Conflict surrounding behavioural problems	Practitioner-led interview (mother report)	Not reported	No	163**	Six-month assessment
Yells or scolds child	Practitioner-led interview (mother report)	Not reported	No	159**	Six-month assessment
Spanks or hits	Practitioner-led interview (mother report)	Not reported	No	159**	Six-month assessment

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Reduced avoidance of restriction and punishment	HOME (researcher observation)	Not reported	No	191**	10 months
Reduced avoidance of restriction and punishment	HOME (researcher observation)	Not reported	No	180**	22 months
Reduced avoidance of restriction and punishment	HOME (researcher observation)	Not reported	No	211**	34 months
Reduced avoidance of restriction and punishment	HOME (researcher observation)	Not reported	Yes	211**	46 months
Provision of appropriate toys	HOME (researcher observation)	Not reported	No	201**	10 months
Provision of appropriate toys	HOME (researcher observation)	Not reported	No	198**	22 months
Provision of appropriate toys	HOME (researcher observation)	Not reported	No	224**	34 months
Provision of appropriate toys	HOME (researcher observation)	Not reported	No	224**	46 months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Stimulation of language skills	HOME (researcher observation)	Not reported	No	225**	34 months
Stimulation of language skills	HOME (researcher observation)	Not reported	No	225**	46 months
Quality of home total score	HOME (researcher observation)	Not reported	No	238**	34 months
Quality of home total score	HOME (researcher observation)	Not reported	No	238**	46 months
Improved mother involvement	Quality of mother–child interaction (researcher observation)	Not reported	Yes	Not reported	34 months
Improved mother involvement	Quality of mother–child interaction (researcher observation)	Not reported	No	Not reported	46 months
Children's exposure to hazards in the home	Home observation checklist and researcher-led interview (researcher assessment and mother report)	Not reported	Yes	209**	34 months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Children's exposure to hazards in the home	home observation checklist and researcher-led interview (researcher assessment and mother report)	Not reported	Yes	209**	46 months
Subsequent pregnancies	Life course diary (mother report)	Not reported	No	245**	15-year follow-up
Subsequent births	Life course diary (mother report)	Not reported	No	245**	15-year follow-up
Months between the birth of the first and second child	Life course diary (mother report)	Not reported	No	245**	15-year follow-up
Months receiving Aid to Families with Dependent Children	Researcher-led interview with mother (mother report)	Not reported	No	245**	15-year follow-up
Months receiving food stamps	Researcher-led interview with mother (mother report)	Not reported	No	245**	15-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Months receiving Medicaid	Researcher-led interview with mother (mother report)	Not reported	No	245**	15-year follow-up
Substance use impairments	National comorbidity survey (mother report)	Not reported	No	245**	15-year follow-up
Arrests	Researcher-led interview with mother (mother report)	Not reported	No	245**	15-year follow-up
Arrests	New York State records (administrative records)	Not reported	No	245**	15-year follow-up
Convictions	Researcher-led interview with mother (mother report)	Not reported	No	245**	15-year follow-up
Convictions	New York State records (administrative records)	Not reported	No	245**	15-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Days in jail	Researcher-led interview with mother (mother report)	Not reported	No	245**	15-year follow-up

*Only mothers who smoked were included in the analysis.

**Comparison involves the control and FNP infancy groups.

***Significance in favour of control group; higher levels of resisting eating, police stops and worries and concerns about behaviour in the FNP group

§ Nurse-visited vs non-nurse-visited girls only.

Individual study summary: Study 2

Study 2	
Study design	RCT
Country	United States
Sample characteristics	1,139 highly disadvantaged first-time adolescent mothers (≤ 19 years old) living in the vicinity of Memphis, Tennessee.
Race, ethnicities, and nationalities	92% African American
Population risk factors	• 98% were unmarried • 64% were an average age of 18 years or younger at the start of the study • 85% came from households with incomes below the US federal poverty line.
Timing	• 28 and 36 weeks' gestation • Six, 12, 24 months • When the child was 6 years, 9 years, 12 years, and 20 years old.
Child outcomes	*Pregnancy until the child's 2nd birthday* • Fewer injuries and ingestions. *Six-year follow-up* • Improved intellectual functioning • Improved receptive vocabulary • Improved behaviour. *12-year follow-up* • Reduced tobacco, alcohol, or marijuana use • Reduced internalising problems. *20-year follow-up* • Fewer preventable deaths.
Other outcomes	*Pregnancy until the child's 2nd birthday* • Fewer incidences of pregnancy induced hypertension • Fewer second pregnancies. *Six-year follow-up* • Fewer pregnancies

Study 2	
	• Longer intervals between pregnancies • Longer relationship with their current partner • Less likely to receive public assistance • Less likely to receive food stamps. *Nine-year follow-up* • More likely to delay the birth of their second child • Less time receiving public benefits • Increased mastery over their own lives • More likely to be in a long-term relationship with an employed partner. *12-year follow-up* • More likely to report being in a long-term relationship with their partner • Less role impairment due to alcohol or drug use • Less likely to receive food stamps • Less likely to receive welfare support. Reduced government spending on food stamps, welfare, and Medicaid for nurse-visited mothers. *20-year follow-up* • Fewer deaths from all causes and external causes.
Study Rating	3
Citations	**Study 2a**: Kitzman, H., Olds, D. L., Henderson, C. R., Hanks, C., Cole, R. Tatelbaum, R., McConnochie, K. M., Sidora, K., Luckey, D. W., Shaver, D., Englehardt, K., James, D. & Barnard, K. (1997) Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing. *Journal of the American Medical Association*. 278 (8), 644–652. **Study 2b:** Olds, D. L., Kitzman, H., Cole, R., Robinson, J., Sidora, K., Luckey, D. W, Henderson, C. R., Hanks, C., Bondy, J. & Holmberg, J. (2004) Effects of nurse home-visiting on maternal life course and child development: Age-6 follow-up results of a randomized trial. *Pediatrics*. 114 (6), 1550–1559. **Study 2c:** Olds, D. L., Kitzman, H., Hanks, C., Cole, R., Anson, E., Sidora-Arcoleo, K. Luckey, D. W., Henderson, C. R., Holmberg, J., Tutt, R.A., Stevenson, A. J. & Bondy, J. (2007) Effects of nurse home visiting on maternal and child functioning: Age-9 follow-up of a randomized trial. *Pediatrics*. 120, 832–845. **Study 2d:** Kitzman, H., Olds, D. L., Cole, R. E., Hanks, C. A., Anson, E. A., Arcoleo, K. J., Luckey, D. W., Knudtson, M. D., Henderson, C. R. & Holmberg, J. R. (2010) Enduring effects of prenatal and infancy home

Study 2	
	visiting by nurses on children: Follow-up of a randomized trial among children at age 12 years. *Archives of Pediatrics & Adolescent Medicine*. 164 (5), 412–418. **Study 2e:** Olds, D. L., Kitzman, H. J., Cole, R. E., Hanks, C. A., Arcoleo, K. J., Anson, E. A., Luckey, D. W., Knudston, M. D., Henderson, C. R., Bondy, J. & Stevenson, A. J. (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. *Archives of Pediatrics & Adolescent Medicine*. 164 (5), 419–424. **Study 2f:** Olds, D. L., Kitzman, H., Knudtson, M. D., Anson, E., Smith, J. A. & Cole, R. (2014) Effect of home visiting by nurses on maternal and child mortality: Results of a 2-decade follow-up of a randomized clinical trial. *JAMA Paediatrics*. 168 (9), 800–806.

Brief summary

Population characteristics

This study involved 1,139 highly disadvantaged first-time adolescent mothers (≤ 19 years old) living in the vicinity of Memphis, Tennessee.

92% were African American, 98% were unmarried, 64% were an average age of 18 years or younger at the start of the study and 85 came from households with incomes below the US federal poverty line.

Study design

Mothers were randomly assigned to one of four conditions involving two control and two treatment variations:

1. Free round trip taxicab transportation to antenatal appointments (control; n=166)
2. Free transportation for antenatal care the child's developmental screening until the second birthday (control; n=515)
3. Free transportation for antenatal care the child's developmental screening until the second birthday plus intensive FNP home visiting during the mother's pregnancy (treatment; n=230)
4. Free transportation for antenatal care the child's developmental screening until the second birthday plus intensive FNP home visiting until the child's second birthday (treatment; n=228).

Randomisation was conducted by a computer-generated sequence, stratifying for the following characteristics: maternal race, maternal age (<17, 17 – 18, ≥ 18 years), gestational age at enrolment (< 20 weeks, ≥ 20 weeks), employment status (employed, unemployed), geographical region.

The resulting groups were balanced on all demographic and baseline characteristics, with the exception that women in condition 4 were more likely to be unemployed and have less discretionary income.

Measurement

Families participated in assessments at registration (during enrolment when the mother was pregnant) and at 28 and 36 weeks' gestation. Information about the child's birth was also gathered from the hospital records. Additional assessments were conducted with the two post childbirth conditions (free transportation with health screening vs infancy FNP) when the child was 6, 12, 24 months, and follow-up assessments when the child was 6, 9, 12, and 20 years.

Pregnancy until the child's second birthday (Study 2a)

- **Parent report** measures included the completion of the Child Behavioural Checklist (CBCL) when the child was 24 months.
- **Researcher-led** assessments included interviews with the mothers conducted at 28 and 36 weeks' gestation including questions the mothers' health, their mental health symptoms and their sense of mastery. At six months, researcher conducted further interviews with the mothers about their breastfeeding, their attitudes about punishment and child abuse and neglect (using Bavolek's Adult-Adolescent Parenting Inventory) (AAPI-2), their employment, and education. These interviews were then repeated either in the home, office, or telephone at 12 and 24 months. Researchers also coded videotaped observation of the mothers teaching their child a developmentally challenging task with the Nursing Child Assessment Satellite Training (NCAST) when the child was 6 and 12 months. At 12 and 24 months, researchers conducted assessments of the home with the Home Observation for the Measurement of the Environment (HOME) scales. An assessment of children's intelligence was carried out at 24 months with the Bayley Scales of Infant Development. Researchers were blind to group assignment for all assessments.
- **Administrative records** included the mothers' health and childbirth records which were obtained and coded throughout the mothers' pregnancy until the child's birth. These included maternal urine samples to verify substance use and children's visits to the hospital. The mother and child's health records, including the child's vaccines, were accessed until the child's second birthday.

Six-year follow-up (Study 2b)

- **Parent report** measures included the completion of the Child Behavioural Checklist (CBCL).
- **Researcher-led** assessments included interviews with the mothers about significant life events, a coded observation of children completing the McArthur Story Stem battery, the Kaufman Assessment Battery for Children (KABC) and the Peabody Picture Vocabulary Test (PPVT-III).
- **Teacher report** measures included the completion of the Hightower Teacher–child rating scale for each child.

Nine-year follow-up (Study 2c)

- **Researcher-led** assessments included interviews with the mothers about significant life events.
- **Teacher report** measures included the Social Competence Scale,the Social Health Profile and the Teacher Observation of Child Adjustment Revised
- **Administrative records** included children's school grades, their scores on the Tennessee Comprehensive Assessment Program Achievement Test and Tennessee state death records.

12-year follow-up (Studies 2d and 2e)

- **Child report** measures included the youth self-report version of the Child Behavioural Checklist (Study 2d).
- **Parent report** measures included the Child Behaviour Checklist (Study 2d).
- **Researcher-led** assessments included interviews with the child about their substance misuse and the administration of the Peabody Individual Achievement Test (PIAT) and the Leiter-R Sustained Attention Test (Study 2d). Researchers also conducted interviews with their mothers about significant life events (Study 2e).
- **Teacher report** measures included the teacher version of the Child Behavioural Checklist (Study 2e).
- **Administrative records** included children's school grades and their scores on the Tennessee Comprehensive Assessment Program Achievement Test (Study 2d). State records pertaining to the mothers' access to public assistance were also obtained (Study 2e).

20-year follow-up (Study 2f)

- **Administrative records** involving the National Death Index were extracted to determine the rates of natural and preventable deaths in the mothers and children enrolled in the study.

Study retention

Pregnancy until the child's second birthday (Study 2a)

The comparison used in the analyses varied depending on the outcomes and the measurement timepoint. Analyses involving pregnancy and childbirth outcomes collapsed the comparison groups and the treatment groups with all 1,139 participants.

- 93% (1063) of the mothers completed the 28-week interviews. This included 95% (157) from the transportation only non-treatment group, 94% (485) of the transportation plus health screening group, 91% (210) from the antenatal FNP group, and 93% (211) from the infancy FNP group.
- 80% (916) of the mothers completed the 36-week interviews. This included 83% (137) from the transportation only non-treatment group, 80% (411) of the transportation plus health screening group, 78% (179) from the antenatal FNP group and 83% (189) from the infancy FNP group.
- The obstetrical records were available for 99% (1,130) of the mothers. This included 98% (163) from the transportation only non-treatment group, 99% (511) of the transportation

plus health screening group, 99% (228) from the antenatal FNP group, and 100% (228) from the infancy FNP group.
- The perinatal records were available for 83% (949) of the mothers. This included 84% (140) from the transportation only non-treatment group, 83% (427) of the transportation plus health screening group, 83% (191) from the antenatal FNP group, and 84% (191) from the infancy FNP group.
- The labour and deliver records were available for 99% (1,126) of the mothers. This included 98% (162) from the transportation only non-treatment group, 99% (509) of the transportation plus health screening group, 99% (228) from the antenatal FNP group and 100% (227) from the infancy FNP group.
- The newborn records were available for 95% (1,082) of the mothers. This included 95% (157) from the transportation only non-treatment group, 94% (486) of the transportation plus health screening group, 96% (220) from the antenatal FNP group and 96% (219) from the infancy FNP group.

Analyses involving post-childbirth outcomes compared the transportation/health check group to FNP infancy involving a total of 743 participants.

- 90% (672) of the participants completed the 6-month assessment. This included 91% (469) from the free transportation/health screening group and 89% (203) from the infancy FNP group.
- 92% (682) of the participants completed the 12-month home visit. This included 92% (472) from the free transportation/health screening group and 93% (211) from the infancy FNP group.
- 92% (681) of the participants completed the 12-month office visit. This included 91% (467) from the free transportation/health screening group and 93% (211) from the infancy FNP group.
- 91% (674) of the participants completed the 24-month home visit. This included 91% (472) from the free transportation/health screening group and 91% (208) from the infancy FNP group.
- 90% (671) of the participants completed the 24-month office visit. This included 90% (464) from the free transportation/health screening group and 90% (206) from the infancy FNP group.
- The well child and illness records were available for 90% (671) of the children. This included 91% (467) from the free transportation/health screening group and 89% (204) from the infancy FNP group.
- The immunisations records were available for 92% (680) of the children. This included 91% (470) from the free transportation/health screening group and 92% (210) from the infancy FNP group.
- The A&E and hospitalisation records were available for 94% (697) of the children. This included 93% (481) from the free transportation/health screening group and 95% (216) from the infancy FNP group.
- The public assistance records were available for 88% (656) of the families. This included 88% (455) from the free transportation/health screening group and 88% (201) from the infancy FNP group.

Six-year follow-up (Study 2b)

- 93% (693) of the post-childbirth study participants participated in at least one of the follow-up assessments. This included 86% (641) mothers completing interviews (86% (444) who did not receive FNP and 86% (197) who did) and 83% (615) children undergoing assessments (83% (425) who did not receive FNP and 83% (190) who did).

The study reports that baseline equivalence was maintained at the six-year follow-up, with the exception that FNP women at an elevated risk compared to those in the comparison group. Specifically, they had higher baseline scores for childrearing attitudes associated with child maltreatment, they reported less discretionary income and lived in higher housing densities compared to the woman allocated to the control.

Nine-year follow-up (Study 2c)

- 93% (690) of the post-childbirth study participants participated in at least one of the follow-up assessments. This included 84% (627) of the study mothers completing interviews, representing 85% (436) assigned to no FNP and 84% (191) infancy FNP recipients).
- Teacher reports were available for 75% (558) of the children, including 75% (387) whose mothers did not receive FNP and 75% (171) of the children who did.
- The school records were abstracted for 81% (604) of the children, including 68% (416) whose mothers did not receive FNP and 83% (188) of those allocated to infancy FNP.
- The achievement test scores were available for 77% (570) of the children, including 75% (388) of the non FNP children and 80% (182) of the infancy FNP children.

The study reported potential imbalances in study attrition on intake measures of household poverty and maternal attitudes about child maltreatment at intake.

12-year follow-up (Studies 2d and 2e)

Information was available for approximately 80% of the participants from the original study.

- 80% (594) of the mothers participated in the life course interviews, including 79% (407) assigned to the comparison group receiving free transportation to health checks and 82% (187) assigned to infancy FNP.
- Parental perspectives (the child's mother or other adult with custody of the child) were gathered via interviews and validated measures for 83% (613) of the children, including 82% (422) from the non-FNP group and 84% (191) from the infancy FNP group.
- 78% (578) of the children participated in the 12-year follow-up interviews and completed validated measures, including 77% (398) of the non-FNP children and 79% (180) of the infancy FNP children.
- Teacher reports were available for 75% (558) of the children, including 73% (378) of the non-FNP children and 75% (170) of the children exposed to FNP during their first two years.
- School records were available for 85% (635) of the children, including 85% (439) of non-FNP children and 86% (196) of the infancy FNP children.

- Social service records involving state expenditure were available for 83% (613) of the families, including 82% (422) of the non-FNP families and 84% (191) of infancy FNP families.

Differential attrition was minimal. Baseline equivalence was comparable to previous follow-ups with the following exceptions: FNP mothers lived in households with less discretionary income, higher person-per-room density, and higher scores on the household poverty index in comparison to non-FNP mothers. FNP mothers also had higher scores on childrearing attitudes associated with child maltreatment.

20-year follow-up (Study 2f)

- The records of 1,138 (out of 1,139) mothers originally recruited to the study were successfully matched with National Death Index records.
- The study also attempted to match all the children with the original National Death Index but insufficient information was available for the children in conditions 1 and 3. Sufficient information was, however, available for 95% (706) of the children in conditions 2 and 4. This included 95% (489) in condition 2 (free transportation to health checks during the child's first two years and 92% (208) of the children exposed to infancy FNP.

Results

Pregnancy until the child's second birthday (Study 2a)

Data-analytic strategy

The analyses involving pregnancy and childbirth outcomes compared the families assigned to both control conditions (no nurse visiting) to the families assigned to both FNP conditions. The analyses involving post-childbirth outcomes compared the families receiving free transportation with health screening to those receiving infancy FNP. Linear modelling, controlling for key variables, was used to analyse the data using an intention-to-treat approach.

Findings

The study observed a variety of statistically significant health benefits for mothers and children receiving FNP in comparison to those who did not. During the antenatal period, these benefits included fewer incidences of pregnancy-induced hypertension, fewer injuries and ingestions during the child's first year of life, and fewer second pregnancies. FNP was not, however, associated with improved childbirth outcomes, immunisation rates, maternal mental health, children's cognitive or behaviour development, or the mother's education and employment.

Six-year follow-up (Study 2b)

Data-analytic strategy

An intention-to-treat approach was used involving all available data, regardless of intervention participation, with no imputation for missing values. The primary statistical model consisted of a two-level treatment factor (no nurse visiting condition 2 vs infancy FNP) and three covariates –

household income, housing density and maternal child-rearing attitudes regarding child maltreatment.

Findings

The study observed that FNP mothers had significantly fewer pregnancies in the years following the intervention, they also had longer intervals between their pregnancies, had longer relationships with their current partners and were less likely to be receiving welfare benefits and food stamps compared to the mothers who were not visited by the nurses. Additionally, FNP children were assessed as having significantly better intellectual functioning, receptive vocabulary, and behaviour compared to non-FNP children.

Nine-year follow-up (Study 2c)

Data-analytic strategy

An intention-to-treat approach was used involving all available data, regardless of intervention participation, with no imputation for missing values. The primary statistical model consisted of a two-level treatment factor (no nurse visiting condition 2 vs infancy FNP), a two-level factor reflecting mothers' psychological resources (above versus below the sample median), the interaction between these classification factors, and two covariates (household poverty and maternal childrearing attitudes associated with child maltreatment) measured at intake to adjust for potential non-equivalence in the nine-year follow-up sample. Child gender was also introduced as a covariate for analyses involving child outcomes.

Findings

The study observed no statistically significant differences between FNP and non-FNP children, although the findings were trending towards significantly fewer preventable deaths among children whose mothers received FNP throughout their infancies ($p = .08$). Among the study's mothers, those who received infancy FNP were significantly more likely to delay the birth of their second child, spend less time on public benefits, report greater mastery over their own lives, and were in a longer-term relationship with an employed partner compared to their counterparts who did not receive FNP.

12-year follow-up (Studies 2d and 2e)

Data-analytic strategy

An intention-to-treat approach was used involving all available data, regardless of intervention participation, with no imputation for missing values. The primary statistical model consisted of a two-level treatment factor, a two-level factor reflecting mothers' psychological resources (above versus below the sample median), a two-level factor for child gender; adjusting for potential imbalances in the baseline characteristics related to attrition over time.

Findings

The study observed that FNP children were significant less likely to report tobacco, alcohol, or marijuana use in the past 30 days, as well as report an internalising behaviour compared to

children whose mothers did not receive FNP during their infancies. Additionally, FNP mothers were more likely to report being in a long-term relationship with their partners and less likely to receive government assistance in the form of food stamps and other welfare benefits. There was also less government spending on food stamps and Medicaid for FNP families compared to mothers who did not receive any nurse home visiting.

20-year follow-up (Study 2f)

Data-analytic strategy

The Kaplan–Meier method was used to estimate survival functions for all-cause mortality outcomes.

Findings

The study observed that children exposed to FNP during their first two years were significantly less likely to die for preventable reasons 20 years later in comparison to children not exposed to FNP. Similarly, there was a reduction in all-cause mortality, as well as a decrease in deaths due to external causes (not natural causes) for FNP mothers in comparison to mothers who did not receive FNP.

Study 2: Outcomes table

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Child outcomes					
Birth weight	Hospital/health records (administrative records)	Not reported	No	1,126*	The child's birth
Gestational Age	Hospital/health records (administrative records)	Not reported	No	1,126*	The child's birth
Apgar	Hospital/health records (administrative records)	Not reported	No	1,126*	The child's birth

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
% Low birthweight	Hospital/health records (administrative records)	Not reported	No	1,126*	The child's birth
Intrauterine growth restriction	Hospital/health records (administrative records)	Not reported	No	1,126*	The child's birth
Preterm (< 37 weeks) (%)	Hospital/health records (administrative records)	Not reported	No	1,126*	The child's birth
(%) Indicated preterm delivery	Hospital/health records (administrative records)	Not reported	No	1,126*	The child's birth
(%) Spontaneous preterm delivery	Hospital/health records (administrative records)	Not reported	No	1,126*	The child's birth
Child responsiveness	NCAST (coded observations)	Not reported	No	681**	12 months
Total Developmental Score	Bayley Scales (researcher assessment)	Not reported	No	671**	24 months
Behavioural problems	CBCL (parent report)	Not reported	No	671**	24 months
Immunisations up to date	Hospital/health records	Not reported	No	680**	24 months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Number of well child visits	Hospital/health records	Not reported	No	671**	24 months
Number of health care encounters for injuries and ingestions	Hospital/health records	Not reported	No	671**	24 months
Number of outpatient visits for injuries and ingestions	Hospital/health records	0.57 log-incidence difference	Yes	671**	24 months
Number of emergency department visits for injuries and ingestions	Hospital/health records	Not reported	No	697**	24 months
Number of hospitalisations for injuries and ingestions	Hospital/health records	Not reported	No	697**	24 months
Number of days hospitalised for injuries and ingestions	Hospital/health records	1.64 log-incidence difference	Yes	697**	24 months
Child attended preschool	Researcher-led interview with mother	Not reported	Yes	615**	Six-year follow-up
Academically engaged	Hightower Teacher-child rating scale (teacher report)	Not reported	No	615**	Six-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Improved social skills in the classroom	Hightower Teacher-child rating scale (teacher report)	Not reported	No	615**	Six-year follow-up
Dysregulated aggression	McArthur Story Stem (researcher assessment)	Not reported	No	615**	Six-year follow-up
Warmth/empathy	McArthur Story Stem (researcher assessment)	Not reported	No	615**	Six-year follow-up
% incoherent stories	McArthur Story Stem (researcher assessment)	Not reported	No	615**	Six-year follow-up
Intellectual skills	KABC (researcher assessment)	SMD = 0.18	Yes	615**	Six-year follow-up
Arithmetic achievement	KABC (researcher assessment)	Not reported	No	615**	Six-year follow-up
Reading achievement	KABC (researcher assessment)	Not reported	No	615**	Six-year follow-up
Receptive vocabulary	PPVT-III (researcher assessment	SMD = 0.17	Yes	615**	Six-year follow-up
Internalising behaviour	CBCL (parent report)	Not reported	No	615**	Six-year follow-up
Externalising behaviour	CBCL (parent report)	Not reported	No	615**	Six-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Total problems	CBCL (parent report)	0.32 Odds Ratio	Yes	615**	Six-year follow-up
Reading and maths grades	School records	Not reported	No	604**	Nine-year follow-up
State achievement test	State-wide achievement test	Not reported	No	570**	Nine-year follow-up
Conduct grades	School records	Not reported	No	604**	Nine-year follow-up
Antisocial behaviour	Composite scores from teacher assessments	Not reported	No	558**	Nine-year follow-up
Academically focussed behaviour	Composite scores from teacher assessments	Not reported	No	558**	Nine-year follow-up
Peer affiliation	Composite scores from teacher assessments	Not reported	No	558**	Nine-year follow-up
Count of conduct failures	Teacher assessment	Not reported	No	558**	Nine-year follow-up
Count of depression and anxiety disorders	Teacher assessment	Not reported	No	558**	Nine-year follow-up
Count of disruptive behaviours	Teacher assessment	Not reported	No	558**	Nine-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Any academic failures	School records	Not reported	No	604**	Nine-year follow-up
Ever retained in a grade	School records	Not reported	No	604**	Nine-year follow-up
Ever placed in special education	School records	Not reported	No	604**	Nine-year follow-up
Child deaths	State death records	Not reported	No	743**	Nine-year follow-up
Use of cigarettes, alcohol, or marijuana during the last 30 days	Researcher-led interview	0.31 Odds Ratio	Yes	578**	12-year follow-up
Number of substances used in the last 30 days	Researcher-led interview	0.22 Incidence Ratio	Yes	578**	12-year follow-up
Number of days using substances in the last 30 days	Researcher-led interview	0.15 Incidence Ratio	Yes	578**	12-year follow-up
Ever arrested	Researcher-led interview	Not reported	No	578**	12-year follow-up
Internalising symptoms	CBCL (child report)	0.63 Odds Ratio	Yes	578**	12-year follow-up
Externalising symptoms	CBCL (child, parent & teacher composite)	Not reported	No	578**	12-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Total problems CBCL	CBCL (child, parent & teacher composite)	Not reported	No	578**	12-year follow-up
School Conduct Grades; Grades 1 through 6	School records	Not reported	No	635**	12-year follow-up
School Conduct Grades; Grades 4 through 6	School records	Not reported	No	635**	12-year follow-up
Ever placed in Special Education Grades 1–6	School records	Not reported	No	635**	12-year follow-up
Ever retained in a grade	School records	Not reported	No	635**	12-year follow-up
Reading and math achievement	PIAT (researcher administered)	Not reported	No	578**	12-year follow-up
School Grade-point average; reading and math Grades 1–6	School records	Not reported	No	635**	12-year follow-up
School Grade-point average; reading and math grades 4 – 6	School records	Not reported	No	635**	12-year follow-up
Sustained attention	Leiter Sustained Attention Scaled (researcher assessment)	Not reported	No	578**	12-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Child Deaths – all causes	National Death Index	Not reported	No	706**	20-year follow-up
Child deaths – preventable deaths	National Death Index	Not reported	Yes	706**	20-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Parent outcomes					
Gestational weight gain	Obstetrical records	Not reported	No	1,130*	Pregnancy
Systolic blood pressure (at labour)	Obstetrical records	Not reported	No	1,126*	Pregnancy
Diastolic blood pressure (at labour)	Obstetrical records	Not reported	No	1,126*	Pregnancy
Number of prenatal visits	Obstetrical records	Not reported	No	1,130*	Pregnancy
Number of obstetric observations	Obstetrical records	Not reported	No	1,130*	Pregnancy
Number of hospital visits during pregnancy	Obstetrical records	Not reported	No	1,130*	Pregnancy
Number of Gardnerella infections	Obstetrical records	Not reported	No	1,130*	Pregnancy
Number of yeast infections	Obstetrical records	0.29 Log-Incidence Difference	Yes	1,130*	Pregnancy
Number of sexually transmitted diseases	Obstetrical records	Not reported	No	1,130*	Pregnancy

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Used other community services	Interview with researcher	1.8 Odds Ratio	Yes	916*	Pregnancy
Employed	Interview with researcher during pregnancy	Not reported	No	916*	36 weeks' gestation
Pregnancy-induced hypertension	Obstetrical records	0.6 Odds Ratio	Yes	1,130*	Pregnancy
Attempted breastfeeding	Interview with researcher	1.9 Odds Ratio	Yes	672**	Six months
Beliefs associated with child abuse	AAPI-2 during researcher interview	SMD = 1.9	Yes	672**	Six months
Total HOME score (including emotional and cognitive stimulation)	HOME inventory (researcher assessment)	SMD = -1.3	Yes	675**	24 months
Maternal teaching	NCAST (coded observation)	Not reported	No	681**	24 months
Fewer subsequent pregnancies	Researcher interview	0.6 Odds Ratio	Yes	675*	24 months
Fewer subsequent live births	Researcher interview	0.6 Odds Ratio	Yes	675*	24 months
Spontaneous abortions	Researcher interview	Not reported	No	675*	24 months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Therapeutic abortion	Researcher interview	Not reported	No	675*	24 months
Number of months worked	Researcher interview	Not reported	No	675*	0–12 months
Number of months worked	Researcher interview	Not reported	No	675*	13–24 months
Number of months on public assistance	Researcher interview	Not reported	No	675*	0–12 months
Number of months on public assistance	Researcher interview	Not reported	No	675*	13–24 months
Anxiety	Researcher interview	Not reported	No	675*	24 months
Depression	Researcher interview	Not reported	No	675*	24 months
Sense of mastery	Researcher interview	SMD = -2.2	Yes	675*	24 months
Number of subsequent pregnancies	Researcher interview	SMD = -0.22	Yes	641**	Six-year follow-up
Number of subsequent births	Researcher interview	SMD = -0.22	Yes	641**	Six-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Number of months between the births of the first and second child	Researcher interview	SMD = 0.26	Yes	641**	Six-year follow-up
Sense of mastery	Researcher interview	Not reported	No	641**	Six-year follow-up
Mental health	Researcher interview	Not reported	No	641**	Six-year follow-up
Months mother employed	Researcher interview	Not reported	No	641**	Six-year follow-up
SES of current job	Researcher interview	Not reported	No	641**	Six-year follow-up
Receiving public assistance	Researcher interview	SMD = -0.22	Yes	641**	Six-year follow-up
Months receiving food stamps	Researcher interview	SMD = -0.24	Yes	641**	Six-year follow-up
Months of Medicaid	Researcher interview	Not reported	No	641**	Six-year follow-up
Months with current partner	Researcher interview	SMD = 0.24	Yes	641**	Six-year follow-up
Highest grade completed by current partner	Researcher interview	Not reported	No	641**	Six-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
SES of partners job	Researcher interview	Not reported	No	641**	Six-year follow-up
Mother graduated from high school or equivalent	Researcher interview	Not reported	No	641**	Six-year follow-up
Married	Researcher interview	Not reported	No	641**	Six-year follow-up
Has current partner	Researcher interview	Not reported	No	641**	Six-year follow-up
Lives with father of study child	Researcher interview	Not reported	No	641**	Six-year follow-up
Subsequent miscarriage	Researcher interview	Not reported	No	641**	Six-year follow-up
Subsequent abortion	Researcher interview	Not reported	No	641**	Six-year follow-up
Subsequent low birthweight baby	Researcher interview	Not reported	No	641**	Six-year follow-up
Subsequent special care admissions	Researcher interview	Not reported	No	641**	Six-year follow-up
Currently using marijuana	Researcher interview	Not reported	No	641**	Six-year follow-up
Moderate/heavy drinker	Researcher interview	Not reported	No	641**	Six-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Behavioural problems attributed to substance abuse	Researcher interview	Not reported	No	641**	Six-year follow-up
Incidence of domestic abuse	Researcher interview	Not reported	No	641**	Six-year follow-up
Number of months between birth of first and second child	Researcher interview	SMD = 0.29	Yes	627**	Nine-year follow-up
Cumulative subsequent live births per year (0 to 9 years)	Researcher interview	SMD = −0.14	Yes	627**	Nine-year follow-up
Cumulative subsequent live births per year (6 to 9 years)	Researcher interview	Not reported	No	627**	Nine-year follow-up
Number of months with current partner (6 to 9 years)	Researcher interview	SMD = 0.23	Yes	627**	Nine-year follow-up
Number of months with current partner (at 9 years)	Researcher interview	SMD = 0.28	Yes	627**	Nine-year follow-up
Number of months on public benefits (0 to 9 years)	Researcher interview	SMD = −0.14	Yes	627**	Nine -year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Number of months on public benefits (6 to 9 years)	Researcher interview	Not reported	No	627**	Nine -year follow-up
Number of months on food stamps per year (0 to 9 years)	Researcher interview	SMD = −0.17	Yes	627**	Nine-year follow-up
Number of months on food stamps per year (6 to 9 years)	Researcher interview	SMD = −0.21	Yes	627**	Nine-year follow-up
Maternal mastery (6 months to 9 years)	Researcher interview	SMD = 0.15	Yes	627**	Nine-year follow-up
Maternal mastery (at 9 years)	Researcher interview	Not reported	No	627**	Nine-year follow-up
Number of months on Medicaid per year (0 to 9 years)	Researcher interview	Not reported	No	627**	Nine-year follow-up
Number of months on Medicaid per year (6 to 9 years)	Researcher interview	Not reported	No	627**	Nine-year follow-up
Number of months employed per year (2 to 9 years)	Researcher interview	Not reported	No	627**	Nine-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Number of months employed per year (6 to 9 years)	Researcher interview	Not reported	No	627**	Nine-year follow-up
Number of months with employed partner (6 to 9 years)	Researcher interview	SMD = 0.25	Yes	627**	Nine-year follow-up
Number of months with employed partner (at 9 years)	Researcher interview	0.30	Yes	627**	Nine-year follow-up
Maternal depression	Researcher interview	Not reported	No	627**	Nine-year follow-up
Number of maternal arrests	Researcher interview	Not reported	No	627**	Nine-year follow-up
Number of substances used since last interview	Researcher interview	Not reported	No	627**	Nine-year follow-up
Number of subsequent miscarriages (0 to 9 years)	Researcher interview	Not reported	No	627**	Nine-year follow-up
Number of subsequent abortions (0 to 9 years	Researcher interview	Not reported	No	627**	Nine-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Number of low birthweight newborns (0 to 9 years)	Researcher interview	Not reported	No	627**	Nine-year follow-up
Relationship with the father scale	Researcher interview	Not reported	No	627**	Nine-year follow-up
Married	Researcher interview	Not reported	No	627**	Nine-year follow-up
Mother jailed	Researcher interview	Not reported	No	627**	Nine-year follow-up
Partnered	Researcher interview	Not reported	No	627**	Nine-year follow-up
Subsequent still birth	Researcher interview	Not reported	No	627**	Nine-year follow-up
Any domestic violence	Researcher interview	Not reported	No	627**	Nine-year follow-up
Partnered, cohabitating, or married to the child's biological father	Researcher interview	Not reported	No	594**	12-year follow-up
Intimate partner violence	Researcher interview	Not reported	No	594**	12-year follow-up
Alcohol or other drug use	Researcher interview	Not reported	No	594**	12-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Role impairment due to alcohol or drug use	Researcher interview	Not reported	Yes	594**	12-year follow-up
Mother jailed	Researcher interview	Not reported	No	594**	12-year follow-up
Psychological impairment	Researcher interview	Not reported	No	594**	12-year follow-up
Duration of current partner relationship	Researcher interview	SMD = 6.91	Yes	594**	12-year follow-up
Time employed in months	Researcher interview	Not reported	No	594**	12-year follow-up
Cumulative subsequent births	Researcher interview	Not reported	No	594**	12-year follow-up
Sense of mastery	Researcher interview	Not reported	No	594**	12-year follow-up
Maternal arrests	Researcher interview	Not reported	No	594**	12-year follow-up
Child in foster care placement	Researcher interview	Not reported	No	613**	12-year follow-up
Use of food stamps 0 to 12 years	State records	SMD = −0.59	Yes	613**	12-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Use of food stamps 10 to 12 years	State records	Not reported	No	613**	12-year follow-up
Use of public assistance 0 to 12	State records	SMD = −0.50	Yes	613**	12-year follow-up
Use of public assistance 10 to 12	State records	Not reported	No	613**	12-year follow-up
Use of Medicaid 0 to 12	State records	Not reported	No	613**	12-year follow-up
Use of Medicaid 10 to 12	State records	Not reported	No	613**	12-year follow-up
Government spending on food stamps 0 to 12	State records	Not reported	Yes	613**	12-year follow-up
Government spending on food stamps 10 to 12	State records	Not reported	No	613**	12-year follow-up
Government spending on public assistance 0 to 12	State records	Not reported	No	613**	12-year follow-up
Government spending on public assistance 10 to 12	State records	Not reported	No	613**	12-year follow-up

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Government spending on Medicaid 0 to 12	State records	Not reported	Yes	613**	12-year follow-up
Government spending on Medicaid 10 to 12	State records	Not reported	No	613**	12-year follow-up
Total government expenditure 0 to 12	State records	Not reported	Yes	613**	12-year follow-up
Total government expenditure 10 to 12	State records	Not reported	No	613**	12-year follow-up
All causes of mortality	National Death Index	Not reported	Yes	1,138	20-year follow-up
Externally caused mortality	National Death Index	Not reported	Yes	1,138	20-year follow-up

*Comparisons involved the entire sample, divided into no nurse visiting (variations 1 & 2) and nurse visiting (variations 3 & 4).

** Comparisons involved conditions 1 and 4 only.

Individual study summary: Study 3

Study 3	
Study design	RCT
Country	United States
Sample characteristics	735 single, first-time teenage mothers living in disadvantaged communities in the Denver, Colorado metropolitan area
Race, ethnicities, and nationalities	• 45% Hispanic • 36% White • 16% African American.
Population risk factors	• Mothers were on average 19 years old. • 14% were married • 20% were living below the poverty line • All mothers were eligible for Medicaid and receiving other public health benefits • 16% of the mothers had reported an incidence of domestic violence in the last six months.
Timing	• 36 weeks' gestation • 6, 12, 21, and 24 months • 4, 6, and 9 years.
Child outcomes	*Pregnancy until the child's second birthday* • Less likely to show vulnerability in fearful situations at six months (nurse-visited children) • Less likely to have a language delay at 21 months (nurse-visited children). *Four-year follow-up* • More likely to have attended early education (nurse-visited children).

Study 3	
Other outcomes	*Pregnancy until the child's second birthday* • Less cotinine in the urine at 36 weeks' gestation (mothers who smoked only). • More responsive to infant • Less cotinine in the urine at 36 weeks' gestation (mothers who smoked only). • Less likely to be pregnant within two years of first baby's birth • More likely to be in employment. *Four-year follow-up* • Increased employment (paraprofessionally visited mothers) • Greater sense of mastery (paraprofessionally visited mothers) • Improved mental health (paraprofessionally visited mothers) • Fewer miscarriages (paraprofessionally visited mothers) • Less risk of a subsequent low birthweight baby (paraprofessionally visited mothers) • Increased maternal sensitivity (paraprofessionally visited mothers) • Increased likelihood of a delayed second birth (nurse-visited mothers) • Reduced reports of domestic violence (nurse-visited mothers).
Study Rating	3
Citations	**Study 3a:** Olds, D. L., Robinson, J., O'Brien, R., Luckey, D. W., Pettitt, L. M., Henderson, C. R., Ng, R. K., Sheff, K. L., Korfmacher, J., Hiatt, S. & Talmi, A. (2002) Home visiting by paraprofessionals and by nurses: A randomized, controlled trial. *Pediatrics*. 110, 486–496. **Study 3b:** Olds, D. L., Robinson, J., Pettitt, L., Luckey, D. W., Holmberg, J., Ng, R. K., Isacks, K., Sheff, K. & Henderson, C. R. (2004) Effects of home visits by paraprofessionals and by nurses: Age-4 follow-up results of a randomized trial. *Pediatrics*. 114, 1560–1568. **Study 3c:** Olds, D. L., Holmberg, J. R., Donelan-McCall, N., Luckey, D. W., Knudtson, M. D. & Robinson, J. (2014) Effects of home visits by paraprofessionals and by nurses on children: Follow-up of a randomized trial at ages 6 and 9 years. *JAMA Pediatrics*. 168, 114–121.

Brief summary

Population characteristics

This study involved 735 single, first-time teenage mothers living in disadvantaged communities in the Denver, Colorado metropolitan area. The mothers were on average 19 years old and 14% were married.

The average household income was $13,023 and one-fifth were living below the poverty line. All mothers were eligible for Medicaid and receiving other public health benefits.

16% of the mothers had reported an incidence of domestic violence in the last six months.

45% of the mothers were Hispanic, 36% were White, and 16% were African American.

Study design

Mothers were randomly assigned to one of three conditions involving one control group and two treatment variations:

1. Developmental screening for the child at 6, 12, 15, 21, and 24 months old (control; n=255).
2. Developmental screening for the child at 6, 12, 15, 21, and 24 months old along with FNP delivered by a paraprofessional, starting during the mother's pregnancy and continuing until the child's second birthday (treatment; n=245).
3. Developmental screening for the child at 6, 12, 15, 21, and 24 months old along with FNP delivered by nurses, starting during the mother's pregnancy and continuing until the child's second birthday (treatment; n=235).

Randomisation was conducted via a computer programme to the three study groups, stratifying for race, gestational age, and geographic region. Women assigned to one of the two home-visitation groups were subsequently re-randomised to the home visitors responsible for their geographic region.

The three groups were equivalent at baseline except for five variables trending towards statistical significance: maternal age, housing density, registration post-28 weeks of gestation, maternal conflict with her partner, and maternal conflict with her mother.

Measurement

Families participated in assessments at registration (during enrolment when the mother was pregnant) and at 36 weeks' gestation. Further assessments were conducted when the child was 6, 12, 21, and 24 months, and follow-ups occurring when the child was four, six and nine years.

Pregnancy until the child's second birthday (Study 3a)

- **Parent report** measures included reports of the child's reactivity at 6 months and completion of the Child Behaviour Checklist at 24 months.
- **Researcher-led** assessments included interviews with the mothers conducted at 36 weeks' gestation including questions the mothers' health, their mental health symptoms, and their sense of mastery. Additional interviews considering the mother's employment, subsequent pregnancies and other life course events took place at 12, 15, 21, and 24 months.

- Infant reactivity was coded via videotaped sessions of the mother and child interacting at 6 months. Further videotaped recordings of mother–child interaction were made at 12 and 21 months. Assessments of the home environment were conducted with the Home Observation for the Measurement of the Environment (HOME) inventory at 12 and 21 months. Children's language development was assessed at 21 months with the Preschool Language Scales. Children's mental development was assessed with the Mental Development Index (MDI) from the Bayley Scale at 21 months.
- **Biological assessments** involving the mothers' urine were made to identify the presence of nicotine, marijuana, and cocaine at the mothers' 36 weeks' gestation assessment.

Researchers were blind to group assignment for all assessments.

Four-year follow-up (Study 3b)

- **Parent report** measures included the Child Behaviour Checklist..
- **Researcher-led** assessments included interviews with the mothers regarding their sense of mastery, their employment history, their relationships with romantic partners, their mental health symptoms, their use of tobacco, drugs and alcohol, and their use of public benefits. Researchers also conducted assessments of the quality of the home environment with the HOME inventory. Child language was assessed with the Preschool Language Scales. The children completed a series of cognitive tasks (including the Walk-a-Line test, the day/night test) that contributed to composite score of executive function. Coded observations further considered the children's emotional reactivity and behaviour regulation during the cognitive tasks.

Researchers were blind to group assignment for all assessments.

Six- and nine-year follow-up (Study 3c)

- **Parent report** measures included the Child Behavioral Checklist (CBCL) and the Connor's Continuous Performance and Continuous Confidence Index that were completed when the child was 6 and 9 years old. Mother's also reported on whether their child had been retained in school, or was receiving specialist support for learning or emotional needs.
- **Teacher report** measures included the Child Behavioral Checklist (CBCL) and the Connor's Continuous Performance test that were completed when the child was 6 and 9 years old.
- **Researcher-led** assessments included the MacArthur Story Stem Battery (MSSB), the Peabody Picture Vocabulary Test and the Kaufman Assessment Battery (KABC) at age 6, and the Leiter Sustained Attention Scale at age 6 and 9 years old. Researchers additionally administered the Trail Marking Test, the Digit Span task and the Peabody Individual Achievement Test (PIAT) at age 9 years old.

Researchers were blind to group assignment for all assessments.

Study retention

Pregnancy until the child's second birthday (Study 3a)

The retained sample fluctuated at each assessment point as follows:

- 70% (515) of the mothers completed assessments at 36 weeks' gestation, including 71% (182) from the control group, 70% (171) of the mothers visited by paraprofessionals, and 69% (162) of the nurse-visited mothers.
- 82% (605) of the mothers participated in interviews when the child was aged 6 months old, including 86% (220) from the control group, 82% (201) of the mothers visited by paraprofessionals, and 78% (184) of the nurse-visited mothers.
- 74% (543) of the mothers and infants participated in the six-month coded observation, including 77% (197) from the control group, 73% (180) of the mothers visited by paraprofessionals, and 71% (166) of the nurse-visited mothers.
- 83% (612) of the mothers participated in interviews when the child was aged 12 months old, including 86% (219) from the control group, 84% (206) of the mothers visited by paraprofessionals, and 80% (187) of the nurse-visited mothers.
- 79% (581) of the mothers and infants participated in the 12-month child assessments, including 82% (210) from the control group, 79% (193) of the mothers visited by paraprofessionals, and 76% (178) of the nurse-visited mothers.
- 76% (560) of the mothers participated in interviews when the child was aged 15 months old, including 82% (209) from the control group, 71% (175) of the mothers visited by paraprofessionals, and 75% (176) of the nurse-visited mothers.
- 67% (493) of the mothers and infants participated in the 15-month child assessments, including 74% (188) from the control group, 64% (156) of the mothers visited by paraprofessionals, and 63% (149) of the nurse-visited mothers.
- 87% (642) of the mothers participated in interviews when the child was aged 21 months old, including 88% (225) of the mothers in the control group, 88% (215) of the mothers visited by paraprofessionals, and 86% (202) of the nurse-visited mothers.
- 83% (610) of the mothers and infants participated in the 21-month child assessments, including 85% (216) from the control group, 83% (204) of the mothers visited by paraprofessionals, and 81% (190) of the nurse-visited mothers.
- 86% (630) of the mothers participated in interviews when the child was aged 24 months old, including 87% (223) of the mothers in the control group, 87% (213) of the mothers visited by paraprofessionals, and 83% (194) of the nurse-visited mothers.
- 76% (560) of the mothers and infants participated in the 24-month child assessments, including 80% (204) from the control group, 77% (188) of the mothers visited by paraprofessionals, and 71% (168) of the nurse-visited mothers.

Attrition at this timepoint was notably higher than in previous FNP trials. Additionally, the authors note that the retained nurse-visited sample was higher functioning in comparison to their counterparts in the control and paraprofessional groups. Specifically, the nurse-visited women were an average of two years older and reported less conflict with their mothers in comparison to the women in the control and paraprofessional groups.

Four-year follow-up (Study 3b)

- 86% (635) of the mothers completed interviews when their child was aged 4 years old, including 86% (220) allocated to the control group, 86% (211) of those visited by paraprofessionals, and 87% (204) of those receiving nurse visits.

- 82% (605) of the children participated in the four-year assessments, including 83% (211) whose mothers were allocated to the control group, 81% (198) whose mothers were visited by paraprofessionals, and 83% (196) of those whose mothers were visited by nurses.

Baseline equivalence was comparable to what was observed at randomisation and accounted for in the Data-analytic strategy.

Six-year follow-up (Study 3c)

- 82% (604) of the mothers completed interviews and validated child measures, including 82% (210) allocated to the control group, 84% (206) of those visited by paraprofessionals, and 80% (188) of those visited by nurses.
- 82% (599) of the children participated in assessments, including 82% (208) whose mothers were allocated to the control group, 83% (203) whose mothers were visited by paraprofessionals, and 80% (188) whose mothers were visited by nurses.
- 71% (523) of the children had assessments completed by their teachers, including 73% (172) whose mothers were allocated to the control group, 71% (174) whose mothers visited by paraprofessionals, and 80% (188) mothers were visited by nurses.

Nine-year follow-up (Study 3c)

- 75% (553) of the mothers completed interviews and validated child measures, including 75% (192) allocated to the control group, 76% (187) of those visited by paraprofessionals, and 74% (174) of those visited by nurses.
- 78% (571) of the children participated in assessments, including 79% (201) whose mothers were allocated to the control group, 79% (193) whose mothers were visited by paraprofessionals, and 75% (177) whose mothers were visited by nurses.
- 64% (471) of the children had assessments completed by their teachers, including 66% (169) whose mothers were allocated to the control group, 65% (160) whose mothers visited by paraprofessionals, and 60% (142) mothers were visited by nurses.

Results

Pregnancy until the child's second birthday (Study 3a)

Data-analytic strategy

An intention-to-treat approach was used involving all available data, regardless of intervention participation, with no imputation for missing values. The primary statistical model included treatment (control, paraprofessional, nurse-visited), maternal psychological resources (high vs low) and the interaction between these factors. In addition, five covariates were included to control for non-equivalence at intake: maternal age, housing density, registration post-28 weeks of gestation, maternal conflict with her partner, and maternal conflict with her mother.

Findings

The study observed that children of nurse-visited mothers were significantly less likely to exhibit less vulnerability to fear stimulation at age 6 months old compared to the infants whose mothers received no visits. Children of nurse-visited mothers were also less likely to have a language delay

at age 21 months old in comparison to children whose mothers did not receive any home visiting, although this main effect was largely driven by improvements in the children born to low resource mothers.

The study also observed that nurse-visited mothers were significantly more responsive to their infant in comparison to mothers who received no home visiting. Nurse-visited mothers were also significantly less likely to be pregnant within two years of their first baby's birth and more likely to have worked in comparison to the mothers not receiving home visiting. Additionally, nurse-visited mothers who smoked had greater reductions in their cotinine levels compared to the mothers in the control group.

Subgroup analyses observed that intervention benefits were frequently stronger for mothers identified as more vulnerable (i.e. younger and with fewer psychological resources).

By comparison, the intervention delivered by paraprofessionals did not provide any statistically significant benefits in contrasts involving the entire sample.

Four-year follow-up (Study 3b)

Data-analytic strategy
An intention-to-treat approach was used involving all available data, regardless of intervention participation, with no imputation for missing values. The primary statistical model considered treatment (three levels) and six covariates included to control for potential non-equivalence at intake, including maternal psychologic resources, registration date, maternal age, housing density, mother's conflict with her partner, and mother's conflict with her mother.

Findings
Statistically significant benefits were observed for both the paraprofessional and nurse-visited mothers in comparison to the control group

- Paraprofessionally-visited mothers compared to the control group were significantly more likely to have worked more, report a greater sense of mastery and better mental health, have fewer subsequent miscarriages, have a subsequent low birthweight baby and display greater sensitivity when interacting with her child.
- Nurse-visited mothers compared to the control group were significantly more likely to have delayed the birth of their second child, report less domestic violence within a six-month period, and enrol their child in early education.

Six- and nine-year follow-up (Study 3c)

Data-analytic strategy

An intention-to-treat approach was used involving all available data, regardless of intervention participation, with no imputation for missing values. The primary statistical model considered treatment (three levels) and six covariates included to control for potential non-equivalence at intake, including maternal psychologic resources, registration date, smoking status, housing density, mother's conflict with her mother and neighbourhood disadvantage. Continuous dependent variables were analysed using analysis of covariance with mean differences converted to

effect sizes. Dichotomous outcomes were analysed in a modified poisson regression with differences converted to relative risks.

Findings

This study considered child outcomes only, observing no statistically significant differences between the three treatment groups in analyses involving the entire sample. However, subgroup analyses involving children born to low-resource mothers observed statistically significant improvements in their receptive language and sustained attention (not reported in the outcomes table below).

Study 3: Outcomes table

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Child outcomes					
Vulnerability to fear	Coded observation of mother–child interaction (researcher assessment)	Not reported	Yes	363*	Six months
Low vitality in response to joy stimulation	Coded observation of mother–child interaction (researcher assessment)	Not reported	No	363*	Six months
Low vitality in response to anger stimulation	Coded observation of mother–child interaction (researcher assessment)	Not reported	No	363*	Six months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Irritable temperament	Coded observation of mother–child interaction (researcher assessment)	Not reported	No	363*	Six months
Language delay	Preschool language scales (researcher assessment)	Not reported	Yes	406*	21 months
Language development	Preschool language scales (researcher assessment)	Not reported	No	406*	21 months
Mental delay	MDI (researcher assessment)	Not reported	No	372*	24 months
Mental development	MDI (researcher assessment)	Not reported	No	372*	24 months
Behavioural problems	CBCL (parent report)	Not reported	No	372*	24 months
Attended early education	Researcher-led interview	0.62 Odds Ratio	Yes	407*	Four years
Child language	Preschool Language Scales (researcher assessment)	Not significant	No	407*	Four years
Executive functions	Coded observation composite score	Not significant	No	407*	Four years

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Behavioural adaptation	Coded observation composite score	Not significant	No	407*	Four years
Emotional regulation	Coded observation composite score	Not significant	No	407*	Four years
Externalising behavioural problems	CBCL (parent report)	Not significant	No	407*	Four years
Total behavioural problems	Composite score derived from the CBCL (parent and teacher report)	Not significant	No	398*	Six years
Total behavioural problems	Composite score derived from the CBCL (parent and teacher report)	Not significant	No	366*	Nine years
Internalising problems	Composite score derived from the CBCL (parent and teacher report)	Not significant	No	398*	Six years
Internalising problems	Composite score derived from the CBCL (parent and teacher report)	Not significant	No	366*	Nine years

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Externalising problems	Composite score derived from the CBCL (parent and teacher report)	Not significant	No	398*	Six years
Externalising problems	Composite score derived from the CBCL (parent and teacher report)	Not significant	No	366*	Nine years
Attention regulation	Composite score derived from the Connor's Continuous performance test (parent and teacher report)	Not significant	No	366*	Nine years
Receptive language	Peabody Picture Vocabulary Test (researcher assessment)	Not significant	No	396*	Six years
Intellectual functioning	KABC (researcher assessment)	Not significant	No	396*	Six years
Sustained attention	Leiter Sustained Attention Scale (researcher assessment)	Not significant	No	396*	Six years
Sustained attention	Leiter Sustained Attention Scale (researcher assessment)	Not significant	No	378*	Nine years

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Visual attention	Trail Making Test part B (researcher assessment)	Not significant	No	378*	Nine years
Arithmetic achievement	PIAT (researcher-led)	Not significant	No	396*	Six years
Arithmetic achievement	PIAT (researcher-led)	Not significant	No	378*	Nine years
Reading achievement	PIAT (researcher-led)	Not significant	No	396*	Six years
Reading achievement	PIAT (researcher-led)	Not significant	No	378*	Nine years
Ever held back a grade	Researcher-led interview with mother	Not significant	No	398*	Six years
Ever held back a grade	Researcher-led interview with mother	Not significant	No	366*	Nine years
Receiving special services	Researcher-led interview with mother	Not significant	No	398*	Six years
Ever held back a grade	Researcher-led interview with mother	Not significant	No	366*	Nine years
Parent outcomes					

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Cotinine reduction in urine	Biological sample	Not reported	Yes	49§	36-week gestation assessment
Use of preventive services	Researcher-led interview	Not significant	No	417*	24 months
Use of emergency services	Researcher-led interview	Not significant	No	417*	24 months
Subsequent pregnancy	Researcher-led interview	Not reported	Yes	417*	24 months
Subsequent birth	Researcher-led interview	Not reported	Yes	417*	24 months
Educational achievement	Researcher-led interview	Not significant	No	417*	24 months
Number of months employed 0 to 12 months	Researcher-led interview	Not reported	Yes	406*	12 months
Number of months employed 13 to 24 months	Researcher-led interview	Not significant	No	417*	24 months
Receiving public assistance 0 to 12 months	Researcher-led interview	Not significant	No	406*	12 months
Receiving public assistance 13 to 24 months	Researcher-led interview	Not significant	No	417*	24 months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Quality of mother–child interaction	Coded observation (averaged score)	Not reported	Yes	363*	24 months
Quality of the home environment	HOME Inventory (researcher assessment; average score)	Not significant	No	406*	24 months
Number of subsequent pregnancies	Researcher-led interview	Not significant	No	461*	Four years
Number of subsequent live births	Researcher-led interview	Not significant	No	461*	Four years
Months between the birth of the 1st and 2nd child	Researcher-led interview	d = .32	Yes	461*	Four years
Sense of mastery	Researcher-led interview	d = .20	Yes	472**	Four years
Mental health	Researcher-led interview	d = -.03	Yes	472**	Four years
Months employed	Researcher-led interview	d = .11	Yes	472**	Four years
Months with current partner	Researcher-led interview	Not significant	No	461*	Four years
Months receiving public assistance	Researcher-led interview	Not significant	No	472*	Four years

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Months receiving food stamps	Researcher-led interview	Not significant	No	461*	Four years
Months of Medicaid	Researcher-led interview	Not significant	No	461*	Four years
Graduated from high school	Researcher-led interview	Not significant	No	461*	Four years
Married	Researcher-led interview	0.61 Odds Ratio	Yes	472**	Four years
Lives with partner	Researcher-led interview	Not significant	No	461*	Four years
Lives with father of child	Researcher-led interview	0.64 Odds Ratio	Yes	472**	Four years
Subsequent miscarriage	Researcher-led interview	0.50 Odds Ratio	Yes	472**	Four years
Subsequent abortion	Researcher-led interview	Not significant	No	461*	Four years
Subsequent low birthweight infant	Researcher-led interview	0.34 Odds Ratio	Yes	472**	Four years
Subsequent neonatal unit/special care admission	Researcher-led interview	Not significant	No	461*	Four years
Currently using marijuana	Researcher-led interview	Not significant	No	461*	Four years

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Moderate/heavy drinker	Researcher-led interview	Not significant	No	461*	Four years
Behavioural problems attributed to substance misuse	Researcher-led interview	Not significant	No	461*	Four years
Domestic violence past 6 months	Researcher-led interview	0.47 Odds Ratio	Yes	461*	Four years
Domestic violence past 2 years	Researcher-led interview	Not significant	No	461*	Four years
Quality of the home environment	HOME inventory (researcher assessment)	Not significant	No	461*	Four years
Maternal sensitivity	Coded observation	d = .23	Yes	472**	Four years

§ Comparison involved mothers who smoked in the control condition and nurse visiting condition only.

*Sample is for comparisons involving the control and nurse-visited families, as this contrast was more likely to be statistically significant.

** Sample is for comparison involving the control and paraprofessionally visited families. This contrast is only reported when significant.

Individual study summary: Study 4

Study 4	
Study design	RCT

Study 4	
Country	The Netherlands
Sample characteristics	460 young, first-time mothers (25 years or younger) living in 20 separate municipalities in the Netherlands
Race, ethnicities, and nationalities	• 48% Dutch • 27% Surinamese/Antillean • 5% Cape Verdean • 3% Turkish • 2% Moroccan.
Population risk factors	The average age was 19 years: • 95% had a pre-vocational education or less • 29% were employed • 23% were married • 45% smoked.
Timing	Assessments were carried out at baseline (16 weeks' gestation), 28 and 32 weeks of pregnancy, the child's birth, and 2, 6, 18, and 24 months post-birth and child protection records were accessed when the child was 3 years old.
Child outcomes	*24-month follow-up* • Reduced internalising behaviours • Reduced rates of child maltreatment.
Other outcomes	*32 weeks' gestation* • Reduced number of mothers who smoked • Reduced intimate partner violence victimisation • Reduced intimate partner violence perpetration. *Six months post-birth* • A reduced number of cigarettes smoked per day • Reduced smoking next to the baby • Increased rates of breast feeding. *24-month follow-up* • Reduced intimate partner violence victimisation • Reduced intimate partner violence perpetration • Improved quality of the home environment.
Study Rating	3

Study 4	
Citations	**Study 4a:** Mejdoubi, J., van den Heijkant, S., van Leerdam, F. J. M., Crone, M., Crijnen, A. & HiraSing, R. A. (2014) Effects of nurse home visitation on cigarette smoking, pregnancy outcomes and breastfeeding: A randomized controlled trial. *Midwifery*. 30, 688–695. **Study 4b:** Mejdoubi, J., van den Heijkant, S. C. C. M., van Leerdam, F. K. M., Heymans, M. W., Hirasing, R. A. & Crijnen, A. A. M. (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), e78185 **Study 4c:** Mejdoubi, J., van den Heijkant, S. C. C. M., van Leerdam, F. J.M.,Heymans, M. W., Crijnen, A. & Hirasing, R.A. (2015) The effect of VoorZorg, the Dutch Nurse-family Partnership, on child maltreatment and development: A randomized controlled trial. *PLOS One*. 10 (4), e0120182.

Brief summary

Population characteristics

This study involved 460 young, first-time mothers living in 20 separate municipalities in the Netherlands involving a mixture of urban and rural communities.

Women were eligible for the study if they were (1) < 26 years, (2) had a secondary education level or less, (3) were no more than 28 weeks' gestation, (4) had no previous live birth and (5) had some understanding of the Dutch language. The women also had to have at least one of the following risk factors present: (1) were single, (2) experienced domestic abuse, (3) had symptoms of a mental health problem, (4) the pregnancy was unwanted or unplanned, (5) experiencing financial difficulties, (6) were unemployed, and (7) alcohol and/or drug use.

In the resulting sample, 95% had a pre-vocational education or less and 29% were employed. 23% were married and 45% smoked.

100% reported experiencing psychological violence, 58% reported experiencing physical violence, 26% reported experiencing injuries after a fight and 16% experienced sexual violence during pregnancy.

48% were Dutch, 2% Moroccan, 3% Turkish, 27% Surinamese/Antillean, and 5% Cape Verdean. A participant was classified as a certain ethnicity if at least one of her biological parents was born in a particular country.

Study design

237 mothers were randomly assigned to the VoorZorg intervention (combining FNP with intensive smoking cessation advice) and 223 to a control group receiving no treatment except services as usual.

Randomisation was conducted via a computer-generated random numbers list, stratifying for ethnicity and location.

Measurement

Families participated in assessments at registration (16 weeks' gestation), 28 and 32 weeks of pregnancy, the child's birth and 2, 6, 18, and 24 months post-birth, and child protection records were accessed when the child was 3 years old.

Pregnancy, childbirth, and breastfeeding (Study 4a)

- **Researcher-led** assessments included interviews with the mothers at 28 and 32 weeks' gestation, and at two and six months post-birth. Researchers were blind to group assignment at all assessments.
- **Administrative** records included information about the mothers' pregnancy and childbirth extracted from the mothers' health care organisations.

Intimate partner violence during pregnancy and the child's first two years (Study 4b)

- **Parent report** measures included the Conflict Tactics Scale (CTS2) completed at 32 weeks' gestation and when the child was 24 months old.

Child development and child maltreatment during the first 36 months (Study 4c)

- **Parent report** measures included the Child Behaviour Checklist completed when the child was 24 months.
- **Researcher-led** assessments included home visits involving the Home Observation for Measurement of the Environment at age 6, 18 and 24 months. Researchers were blind to group assignment at both assessments.
- **Administrative records** included substantiated cases of child abuse and neglect in 8 of the 10 Child Protection Services regions covering the mothers participating in the study.

Study retention

Pregnancy, childbirth, and breastfeeding (Study 4a)

- 88% (405) of the mothers were retained in the sample until the six-month assessment, including 92% (217) of the VoorZoorg mothers and 84% (188) receiving business-as-usual.

The study reports that the attritors were similar to those retained in the sample and that baseline equivalence was maintained for all of the demographic and intake variables.

Intimate partner violence during pregnancy and the child's first two years (Study 4b)

- 79% (349) of the mothers completed the CTS2 at the 32 weeks' gestation assessment, including 85% (202) of the VoorZoorg mothers and 66% (147) of the mothers receiving business-as-usual.
- 58% (266) of the mothers completed the CTS2 at the 24-month assessment, including 62% (146) of the VoorZoorg mothers and 54% (120) of the mothers receiving business-as-usual.

The study reports that the attritors were similar to those retained in the sample and that baseline equivalence was maintained for all of the demographic and intake variables. It appears that all missing values were imputed for the analyses.

Child development and child maltreatment during the first 36 months (Study 4c)

- 60% (277) of the children were assessed at 6 months old, including 68% (162) of the VoorZoorg families and 52% (115) of the families receiving business-as-usual.
- 52% (238) of the children were assessed at 18 months old, including 58% (138) of the VoorZoorg families and 45% (100) of the families receiving business-as-usual.
- 48% (223) of the children were assessed at 24 months old, including 55% (130) of the VoorZoorg families and 42% (93) of the families receiving business-as-usual.
- 72% (332) of the CPS records were available for the children at 36 months old, including 71% (168) of the VoorZoorg families and 74% (164) of the families receiving business-as-usual.

The study reports that the attritors were similar to those retained in the sample. Additionally, there were no differences between the participants represented by the eight agencies that submitted child protection records compared to the two that did not.

Results

Pregnancy, childbirth, and breastfeeding (Study 4a)

Data-analytic strategy

Multi-level modelling controlling for key variables within an intention-to-treat design was used to analyse the findings. All analyses used the retained sample, except for the dichotomous variables involving smoking, where analyses were conducted with the retained sample and the full sample, using the last observation carried forward method for imputing values.

Findings

The study observed that VoorZoorg mothers were significantly less likely to smoke than the mothers who received business-as-usual when the analyses involved the imputed sample at 32 weeks' gestation. The VoorZoorg mothers who did smoke also reported smoking fewer cigarettes after the baby's birth and were less likely to smoke in front of the baby.

VoorZoorg mothers were also more likely to be breastfeeding when the baby was aged 6 months old in comparison to the mothers who did not receive the intervention. The study did not, however, observe any differences in the birth outcomes between the groups.

Intimate partner violence during pregnancy and the child's first two years (Study 4b)

Data-analytic strategy

Multi-level modelling controlling for key variables within an intention-to-treat design was used to analyse the findings. The retained sample was used in all analyses involving findings at 32 weeks' gestation. The missing values for the analyses involving the 24-month findings were obtained using last observation carried forward analysis with multiple imputation.

Findings

The study observed that at 32 weeks' gestation, VoorZoorg mothers reported significantly less intimate partner violence than their counterparts not receiving the intervention. Specifically, VoorZoorg mothers were significantly less likely to report being the victim of severe (Level 2) psychological aggression, moderate (Level 1) and severe physical assault (Level 2), and moderate (Level 1) sexual coercion compared to women not receiving the intervention.

At 32 weeks' gestation, VoorZoorg mothers also reported significantly less perpetration of IPV compared to those not receiving the intervention. This included significantly fewer reports of severe (Level 2) psychological aggression, moderate (Level 1) physical assault, and moderate (Level 1) injury.

At 24 months after the child's birth, VoorZoorg mothers were significantly less likely to report being a victim of moderate physical assault and a perpetrator of moderate sexual coercion.

Child development and child maltreatment during the first 36 months (Study 4c)

Data-analytic strategy

For administrative records and the CBCL, poisson regression models were used to assess the differences between the control and intervention groups, with intention-to-treat. All analyses were adjusted for potential confounders, including region, age, ethnicity, gender of the child, age mother, weeks of gestation, and birth weight. Multiple imputation analyses were used to estimate the CBCL findings (children's internalising and externalising behaviours) at 24 months. For the IT-HOME measure, linear regression models were used.

Findings

The study observed significantly fewer substantiated cases of child maltreatment in the VoorZoorg families compared to those who did not receive the intervention. Additionally, VoorZoorg children were observed to have fewer internalising problems and improved home environment at 24 months.

Study 4: Outcomes table

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Child outcomes					
Average birthweight	Health records	β = -2.4	No	405	Child's birth
Average gestational age	Health records	β = -0.2	No	405	Child's birth
% low birth weight babies	Health records	OR = 1.1	No	405	Child's birth
% preterm gestation (<37 weeks)	Health records	OR = 1.2	No	405	Child's birth
Small for gestational age	Health records	OR = 0.8	No	405	Child's birth
Internalising behaviour	CBCL (parent report)	Relative Risk: 0.56	Yes	460*	24 months
Externalising behaviour	CBCL (parent report)	Relative Risk: 0.71	No	460*	24 months
Substantiated cases of child maltreatment	CPS records	Relative Risk: 0.58	Yes	332	36 months
Parent outcomes					

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Current smoker	Researcher-led interview	OR = 0.9	No	405	32 weeks' gestation
Current smoker*	Researcher-led interview	OR = 0.5	Yes	460	32 weeks' gestation
Average number of cigarettes smoked per day	Researcher-led interview	β = 0.5	No	405	32 weeks' gestation
Current smoker	Researcher-led interview	OR = 0.5	No	405	2 months post-birth
Current smoker*	Researcher-led interview	OR = 0.5	Yes	460	2 months post-birth
Average number of cigarettes smoked per day	Researcher-led interview	β = 4.4	Yes	405	2 months post-birth
Number of cigarettes smoked in front of the baby	Researcher-led interview	β = = 1.6	Yes	405	2 months post-birth
Initiated breastfeeding	Researcher-led interview	OR = 1.3	No	405	6 months post-birth
Ended breastfeeding before the first week	Researcher-led interview	OR = 0.6	No	405	6 months post-birth

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Ended breastfeeding after the first week	Researcher-led interview	OR = 1.7	No	405	6 months post-birth
Still breastfeeding at six months	Researcher-led interview	OR = 2.6	Yes	405	6 months post-birth
Psychological aggression (Level 1 victimisation)	Conflict Tactics Scale (parent report)	Not reported	No	349	32 weeks pregnancy
Psychological aggression (Level 2 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.55	Yes	349	32 weeks pregnancy
Psychological aggression (Level 1 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.99	No	460*	24 months
Psychological aggression (Level 2 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.63	No	460*	24 months
Physical assault (Level 1 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.38	Yes	349	32 weeks pregnancy

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Physical assault (Level 2 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.57	Yes	349	32 weeks pregnancy
Physical assault (Level 1 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.46	Yes	460*	24 months
Physical assault (Level 2 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.63	No	460*	24 months
Sexual coercion (Level 1 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.47	Yes	349	32 weeks pregnancy
Sexual coercion (Level 2 victimisation)	Conflict Tactics Scale (parent report)	OR = 1.09	No	349	32 weeks pregnancy
Sexual coercion (Level 1 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.49	No	460*	24 months
Sexual coercion (Level 2 victimisation)	Conflict Tactics Scale (parent report)	OR = 1.61	No	460*	24 months pregnancy

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Injury (Level 1 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.57	No	349	32 weeks pregnancy
Injury (Level 2 victimisation)	Conflict Tactics Scale (parent report)	OR = 1.13	No	349	32 weeks pregnancy
Injury (Level 1 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.63	No	460*	24 months
Injury (Level 2 victimisation)	Conflict Tactics Scale (parent report)	OR = 0.22	No	460*	24 months pregnancy
Mean number of IPV victimisation types	Conflict Tactics Scale (parent report)	Not reported	No	349	32 weeks pregnancy
Mean number of IPV victimisation types	Conflict Tactics Scale (parent report)	OR = 0.32	No	460*	24 months
> 2 forms of IPV victimisation	Conflict Tactics Scale (parent report)	OR = 0.49	Yes	349	32 weeks pregnancy
> 2 forms of IPV victimisation	Conflict Tactics Scale (parent report)	OR = 0.51	No	460*	24 months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Psychological aggression (Level 1 perpetration)	Conflict Tactics Scale (parent report)	OR = 1.59	No	349	32 weeks pregnancy
Psychological aggression (Level 2 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.57	Yes	349	32 weeks pregnancy
Psychological aggression (Level 1 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.89	No	460*	24 months
Psychological aggression (Level 2 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.97	No	460*	24 months
Physical assault (Level 1 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.57	Yes	349	32 weeks pregnancy
Physical assault (Level 2 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.78	No	349	32 weeks pregnancy
Physical assault (Level 1 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.54	No	460*	24 months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Physical assault (Level 2 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.48	No	460*	24 months
Sexual coercion (Level 1 perpetration)	Conflict Tactics Scale (parent report)	OR = 1.10	No	349	32 weeks pregnancy
Sexual coercion (Level 2 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.47	No	349	32 weeks pregnancy
Sexual coercion (Level 1 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.1	Yes	460*	24 months
Sexual coercion (Level 2 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.6	No	460*	24 months
Injury (Level 1 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.53	Yes	349	32 weeks pregnancy
Injury (Level 2 perpetration)	Conflict Tactics Scale (parent report)	OR = 1.19	No	349	32 weeks pregnancy
Injury (Level 1 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.63	No	460*	24 months

Outcome	Measure	Effect size	Statistical significance	Number of participants	Measurement time point
Injury (Level 2 perpetration)	Conflict Tactics Scale (parent report)	OR = 0.81	No	460*	24 months
Mean number of IPV perpetrator types	Conflict Tactics Scale (parent report)	Not reported	Yes	349	32 weeks pregnancy
Mean number of IPV perpetrator types	Conflict Tactics Scale (parent report)	OR = 0.4	Yes	460*	24 months
> 2 forms of IPV perpetration	Conflict Tactics Scale (parent report)	OR = 0.53	Yes	349	32 weeks pregnancy
> 2 forms of IPV perpetration	Conflict Tactics Scale (parent report)	OR = 0.58	No	460*	24 months
Quality of the home environment	HOME Inventory (researcher assessment)	Not reported	No	247	6 months
Quality of the home environment	HOME Inventory (researcher assessment)	Not reported	No	238	18 months
Quality of the home environment	HOME Inventory (researcher assessment)	Not reported	Yes	223	24 months
*Full sample imputed.					

Individual study summary: Study 5

Study 5	
Study design	RCT
Country	The United Kingdom
Sample characteristics	1,645 mothers ≤ 19 years old living in community midwifery settings at 18 partnerships between local authorities and primary and secondary care organisations in England
Race, ethnicities, and nationalities	• 88% White • 5% Mixed • 4% Black • 2% Asian • <1% Other.
Population risk factors	• 48% were not in education, employment or training (NEET) • 1% were married and 56% smoked.
Timing	Assessments were conducted at: • Baseline (enrolment) • 34 to 36 weeks' gestation • the child's birth • 6, 12, 18, and 24 months post-birth Administrative outcomes, involving routine data linkage continued until the child's seventh birthday.
Child outcomes	*Pregnancy until the child's second birthday* • Reduced developmental concern • Improved language, speech, and communication. *Routine data linkage until age 7 (Study 5b)* • More likely to achieve a good level of development through the Early Years Foundation Stage Profile (EYFSP) at age 4 • More likely to achieve the expected standard of reading at the Key Stage 1 assessment at age 6.
Other outcomes	*Pregnancy until the child's second birthday* • Increased intention to breastfeed • Increased maternal self-efficacy • Increased social support • Improved relationship with partner.

Study 5	
Study Rating	3
Citations	**Study 5a**: Robling, M., Bekkers, M. J., Bell, K., Butler, C. C., Cannings-John, R., Channon, S., ... & Torgerson, D. (2016) Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Building Blocks): A pragmatic randomised controlled trial. *The Lancet*. 387 (10014), 146–155. **Study 5b**: Robling, M., Lugg-Widger, F., Cannings-John, R., Sanders, J., Angel, L., Channon, S., ... & Jones, E. (2021) The Family Nurse Partnership to reduce maltreatment and improve child health and development in young children: The BB: 2–6 routine data-linkage follow-up to earlier RCT. *Public Health Research*. 9 (2).

Brief summary

Population characteristics

This study involved 1,645 first-time adolescent mothers (≤ 19 years) living in community midwifery settings at 18 partnerships between local authorities and primary and secondary care organisations in England.

Women were eligible for the study if they were 19 years or younger, expecting their first child and were less than 25 weeks' gestation.

In the resulting sample, 35% had an A-level qualification or higher, 20% were employed, 48% were not in education, employment or training (NEET), 1% were married and 56% smoked. 45% were living with their own parents, and 76% reported having a close relationship with the baby's father.

88% were White; 4% were Black; 5% were mixed, 2% were Asian, and fewer than 1% were other. 96% spoke English exclusively.

The study reports 83 mandatory withdrawals over the course of the study, due to ineligibility (5), miscarriage (51), stillbirths or infant death (12), death of mother infant pair (1) and adoptions (14).

This resulted in 1,510children included in the analysis, including 24sets of twins. Gender is not reported.

Study design

823 women were randomly assigned to FNP and 822 to business-as-usual. Randomisation was stratified by site, gestation, smoking, and whether English was the preferred language. The allocation programme was created by a programmer at the Bristol Randomised Trials

Collaboration and allocation was concealed using a remote computer-based system, accessible via telephone and internet by the recruiting researcher.

The study reports that baseline characteristics were well balanced between trial groups.

Measurement

Families participated in assessments at baseline (enrolment), 34 to 36 weeks' gestation, the child's birth, and 6, 12, 18, and 24 months post-birth. Administrative outcomes, involving routine data linkage, continued until the child's seventh birthday.

Pregnancy until the child's second birthday (Study 5a)

- **Researcher-led** assessments included a home visit at baseline, and computer assisted telephone interviews at the 6, 12, and 18 months assessments. Interviews included short-answer questions, as well as validated measures which included:
    - EuroQol 5-Dimension (EQ-5D) general health questionnaire at all timepoints
    - The Maternal Attachment Inventory (MAI) at 34 to 36 months
    - The Kessler Scale (psychological distress), the CRAFFT scale (substance use) and the Composite Scale (intimate partner violence) at baseline and 24 months
    - The Whooley Scale (maternal depression), the Edinburgh Postnatal Depression Scale (EPDS; maternal depression) the Generalised Self-Efficacy Scale, the MOS Survey (social networks), the Golombok Rust Inventory of Marital State scale at 6, 12, 18, and 24 months.
    - The Growing Skills Scale (early cognitive development), and the Early Language Milestone Scale at 12, 18, and 24 months.

A final 24-month assessment was conducted in the home. This included a face-to-face interview and a videotaped recording of the mother and child interaction, which was coded with Crittenden's CARE Index. Interviewers were not blind to treatment group allocation.

- **Biological samples** included a urine sample collected for cotinine assessment at baseline and 34 to 36 weeks' gestation.
- **Administrative records** include hospital, obstetric, and medical records accessed during the study, as well as data linkages to the Health and Social Care Information Centre (HSCIC).

Routine data linkage until age 7 (Study 5b)

- **Administrative records:** A unique child and parent identifier was used to access Hospital Episode Statistics data (NHS Digital), social care and educational data (National Pupil Database), and maternal abortions data (Department of Health and Social Care).

Study retention

Pregnancy until the child's second birthday (Study 5a)

- 75% (1,237) of the mothers participated in interviews at 34 to 36 weeks' gestation. This included 75% (617) of the FNP mothers and 75% (620) of those receiving business-as-usual.

- Urine samples were provided by 66% (1,092) of the mothers at the 34-to-36-week assessment, including 64% (547) of the FNP mothers and 65% (545) of the mothers receiving business-as-usual.
- Maternal birth records were available for 96% (1,578) of the families. This included 95% (782) of those receiving FNP and 97% (796) of those receiving business-as-usual.
- Childbirth outcomes were available for 92% (1,510) of the children, including 90% (742) born into FNP households and 93% (768) born into homes allocated to business-as-usual.
- 60% (981) of the mothers participated in the 6-month interview, including 62% (511) of those receiving FNP and 57% (470) receiving business-as-usual.
- 61% (997) of the mothers participated in the 12-month interview, including 62% (514) of those receiving FNP and 59% (483) of those allocated to business-as-usual.
- 59% (967) of the mothers participated in the 18-month interview, including 61% (501) of those receiving FNP and 57% (466) of those allocated to business-as-usual.
- 70% (1,154) of the families participated in the 24-month assessment, including 72% (595) of those receiving FNP and 68% (559) of those allocated to business-as-usual.

Routine data linkage until age 7 (Study 5b)

- Data for 1,537 mothers and 1,547 children (1,517 singletons, 15 sets of twins; representing 98% of the children born into the study) were sent to NHS Digital and the National Pupil Database for matching, forming the BB:2–6 study population. Match rates for children were 98.3% (NHS Digital) and 97.4% (National Pupil Database).

Results

Pregnancy until the child's second birthday (Study 5a)

Data-analytic strategy

Analyses used mixed-effects three-level regression models to compare outcomes between groups, adjusting for site as a stratification variable and allowing for clustering by a family nurse in the intervention group. A simpler two-level model was used when clustering was negligible in the FNP group at level of family nurse, as assessed by the Family Nurse level variance component from the three-level model. Minimisation variables were also controlled for in analyses. An intent-to-treat approach was used, with no imputation for missing data.

Findings

The study observed no statistically significant differences with respect to the evaluation's four primary outcomes: reductions in smoking, improved breastfeeding rates, birth weight, and subsequent pregnancies. Specifically, rates of smoking in late pregnancy were 56% in both groups, with mothers in both groups reporting that they smoked an average of eight cigarettes a day. Both groups were also similar in terms of infant birth weight (3.2kg for both groups), visits to A&E (81% for FNP children and 76% for control group children), and subsequent pregnancies within 24 months (66% in both groups).

The study did, however, observe that FNP mothers reported fewer concerns about their child's development at 24 months (8.1% of FNP children had a concern, compared to 12.6% in the control group), less developmental delay in language at 12 and 18 months (at 18 months 17% of FNP mothers reported language delay in their child compared to 24% in the control group), and improved language milestones at 24 months.

The FNP mothers also reported higher self-efficacy, increased social support, an improved relationship with their partner, and increased intention to breastfeed, in comparison to mothers who were not receiving the intervention.

FNP children were also more likely to have a safeguarding referral compared to children not exposed to the intervention, although none of these were linked to substantiated cases of abuse or neglect. This increased rate was subsequently linked to increased access to support, rather than an increase in safeguarding concerns.

Routine data linkage until age 7 (Study 5b)

Data-analytic strategy

Three-level multilevel modelling was used (accounting for site, family nurse and family), with intention-to-treat. Where the effect of clustering at the nurse level was small, a two-level model (with site and participant) was used instead.

Findings

FNP and non-FNP families were comparable on the study's primary outcomes, including referrals to children's social care, subsequent maternal pregnancies, emergency visits to the hospital, or requiring specialist support.

Statistically significant benefits were, however, observed with respect to children's school readiness. Specifically, FNP children were more likely to be assessed by their teachers as achieving a good level of development through the Early Years Foundation Stage Profile (EYFSP) at age4 and achieving their expected standard of reading through the Key Stage 1 assessment at age 6 (after adjusting for birth month).

Additional subgroup analyses observed that these benefits were greater for FNP boys (Key Stage 1: writing); children of younger mothers (Key Stage 1: writing, Key Stage 1: mathematics); and children of mothers not in employment, education or training at study baseline (Key Stage 1: writing).

Study 5: Outcomes table

The UK evaluation of FNP (study 5a) included over 70 secondary child and parental outcomes at multiple timepoints. A complete table of outcomes with all measures can be found at https://doi.org/10.1016/S0140-6736(15)00392-X.

Other studies

No other studies were assessed for this intervention.