THE LANCET

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

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Appendix: Supplementary materials to Building Blocks trial report

Contents

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3. Description of intervention, adaptation, nurse recruitment and training, and site selection

Intervention description

Overview: The Nurse Family Partnership (NFP) program was developed in the US to address the problems of poor birth outcomes, social exclusion, child abuse and neglect, and diminished economic self-sufficiency of socially disadvantaged younger first time mothers. The NFP is a structured, intensive program of home visits delivered by specially trained nurses, provided from early pregnancy until the child is two years old.

Theoretical Model: The NFP draws upon theories of human ecology, self-efficacy and human attachment. Visits cover core content areas of personal and environmental health, life course development, maternal role, family and friends and access to health and social services. Time allocated to each content domain is prescribed by the program but also varies over the duration of the program. Maternal behaviour change is supported through the promotion of self-efficacy. Education and modelling activities are included in the program to promote sensitive and competent care giving via a strengths-based approach with the aim of reducing maltreatment.

Delivery structure: A scheduled maximum of 64 visits commence, ideally, early in the second trimester, and decrease in frequency over the first two years of the child's life. Whilst actual number of visits received may vary by individual need, engagement, and gestational age at enrolment, minimum targets are specified to support desired program outcomes.

Goals: Program goals are to improve pregnancy outcomes, child health and development, including a reduction in child maltreatment, and an increase in maternal self-sufficiency.

Fidelity: Fidelity requirements on program recruitment and delivery are specified by the developers of the US program.

Staffing: Family Nurses are recruited from existing registrants on the Nursing Midwifery Council of the UK, mainly from Health Visiting but also from Nursing and Midwifery. Training in delivery of the program will be provided to the Family Nurses by the FNP central team

Programme adaptation

Adapting the programme for delivery in England as the Family Nurse Partnership involved adoption of young maternal age as a criterion for programme eligibility. This was selected as a proxy for low income and associated with long-term child outcomes that would be easily measurable in clinical practice. Programme materials were adapted to reflect a UK English speaking clientele. Three additional requirements for FNP as introduced in England were the provision of regular psychological support via specialist supervision to Family nurses, the provision of safeguarding supervision and systems and the incorporation of FNP into local clinical governance arrangements. Following a programme of model improvement particularly on client retention led by the Prevention Research Centre at the University of Colorado, Denver Motivational Interviewing was introduced as a core model element and a central part of the Family Nurse training when introduced in England. This aims for nurses to use a mainly guiding communication style with clients.

Nurse recruitment and training

Programme person specifications require Family nurses (Band 7) to have a nursing or midwifery qualification and be registered with the NMC and educated to degree level (or equivalent professional qualification). A master's level education was desirable while the nurse was required to undertake specialist post graduate training and be assessed on competence following training. Supervisors (Band 8a) were similarly required to be nursing or midwifery qualified, NMC registered, be educated to degree level and also to be educated at master's level. Licensing requires nurses to attend all elements of a core FNP learning programme, mostly in the first year of employment as a Family Nurse. Training modes included residential blocks (baseline, infancy and toddlerhood – a total of 12 days), team-based learning packs (e.g. for pregnancy, infancy, and specialist parenting and dyadic observational tools) and specialist master classes.

Site selection

The first wave of Family Nurse Partnership sites in England were asked to demonstrate strong partnership working and a high degree of NHS / Local Authority service integration, community engagement, commitment to progressive universalism, workforce capacity and capability, effective local leadership, a relevant demographic profile and capacity to identify families, IT capacity, a record of successful innovation, and a plan that demonstrated the capacity to deliver according to the proposed timetable. Successful sites were offered funding to deliver the FNP programme for one year provided the Primary Care Trusts (PCTs) / Local Authorities were committed to supporting the service until the clients' children were 24 months old.

Potential sites formally applied to the Department of Health with a case summarising local clinical need, and the commitment to sustain FNP delivery by local consortia made up of local stakeholders, including Primary Care Trust (PCT), Acute Trust (AT) and Local Authority staff. Following 63 applications, ten were selected; two sites were established in London and one in each of the remaining Government Office regions. The first ten sites to offer FNP also undertook the implementation evaluation. During the second commissioning process to expand the number of FNP sites, sites were encouraged to express willingness to participate in the trial. Eight implementation evaluation sites took part in the trial and a further ten new sites were selected. At most cases FNP was delivered across the whole area covered by each PCT, but for some sites availability of the programme was restricted to particular areas within the PCT. NHS Trusts providing maternity services at each trial site were identified. Fourteen sites had one corresponding NHS Trust, three sites had two NHS Trusts, and one site had three NHS Trusts.

4. Construction of primary outcome variables and selected secondary outcomes

(i) Prenatal tobacco use

A calibrated measure of number of cigarettes smoked per day at baseline and late pregnancy was calculated using a combination of urinary cotinine results and self-reported number of cigarettes smoked per day. The calibration method was developed by Dukic and colleagues[1] and used self-reported smoking data (number of cigarettes smoked on the three days prior to interview, time of last cigarette, hours since last cigarette) and urine cotinine levels collected at baseline and the late pregnancy interview, and also variables such as time of interview. A modified version of the Dukic method was developed in discussion with the author and is presented below:

Main procedure of calibrating the self-reported numbers of cigarettes with the participant's cotinine level

1. The first step is to calculate the self reported weighted number of cigarettes (N_{self}) based on the participant's last 3-day self-reports. In general, we adopt the scenario 2 of Dukic's approach. We assume the urine samples were taken at the interview facility during the interview. We also assume that each woman voids in the morning at 7 am and 12 noon on the day of interview. Furthermore, we assume no voiding between 7 A.M. and the time of interview if the interview was before noon, and one voiding at noon if the interview was in the afternoon. In this scenario, we calculate the weight of each cigarette as the difference between the fraction of the cotinine from the cigarette that would be in the urine sample had the woman not voided at all prior to the interview, and the fraction that was actually in her urine whenever she last voided prior to the interview (at 7 A.M. or at noon). Formulae (A.7) to (A.9) in Dukic appendix are used. Moreover, if the participant has provided the smoking time of the last cigarette on the interview day, we will implement this information to adjust smoking time interval on the day of interview.

2. The second step is to calculate the weighted numbers of cigarettes (N_{cot}) based on the participant's cotinine level. Here we use 150 ng/ml per weighted cigarette as the standard which was recommended in Dukic's paper [1].

3. The third step is to classify the participants into 4 reporting groups: over-reporter, accurate reporter, under-reporter and extreme under-reporter, by comparing their N_{cot} and N_{self} values.

Classify the woman as an over-reporter if

$$\sqrt{\frac{N_{\text{cot}}}{N_{self}}} - 1 < -0.15, \text{ i.e., } \sqrt{\frac{N_{\text{cot}}}{N_{self}}} < 0.85,\ \frac{N_{\text{cot}}}{N_{self}} < 0.7225;$$

Classify the woman as an accurate reporter if

$$\left| \sqrt{\frac{N_{\text{cot}}}{N_{self}}} - 1 \right| < 0.15, \text{ i.e., } 0.85 < \sqrt{\frac{N_{\text{cot}}}{N_{self}}} < 1.15,\ 0.7225 < \frac{N_{\text{cot}}}{N_{self}} < 1.3225;$$

Classify the woman as an under-reporter if

$$0.15 < \sqrt{\frac{N_{\text{cot}}}{N_{self}}} - 1 < 0.35, \text{ i.e., } 1.15 < \sqrt{\frac{N_{\text{cot}}}{N_{self}}} < 1.35,\ 1.3225 < \frac{N_{\text{cot}}}{N_{self}} < 1.8225;$$

Classify the woman as an extreme under-reporter if

$$\sqrt{\frac{N_{\text{cot}}}{N_{self}}} - 1 > 0.35, \text{ i.e., } \sqrt{\frac{N_{\text{cot}}}{N_{self}}} > 1.35,\ \frac{N_{\text{cot}}}{N_{self}} > 1.8225.$$

4. If the participant reports zero cigarettes, i.e., N_{self} is zero, we use an alternative rule to make the classification. We propose to classify these participants according to their cotinine level: if their cotinine level N_{cot} is <=100ng/ml, they are classified as accurate reporters; if their cotinine level N_{cot} is >100ng/ml and <1000ng/ml, they are under reporter; and if their cotinine level N_{cot} is >=1000ng/ml, they are extreme under reporter.

For participants in each reporting group, we then calculate the averaged differences between their weighted self-report number of cigarettes and weighted cotinine number of cigarettes. Then, for each participant, we use the averaged weighted difference of her reporting group to calibrate her mean number of cigarettes, where the averaged weighted difference will be transformed back to the actual number of the cigarette in line with the participant's last-3-day self -report pattern.

The primary analysis of pre-natal tobacco use comprised two parts:

Part 1
The first part of the analysis used a binary variable (smoker or not) and compared the odds of being a smoker at late pregnancy follow-up in the FNP arm versus the usual care arm. The definition of a non-smoker was as follows:

- For those with self-report and cotinine data at both baseline and follow-up: a participant with self-reported zero cigarettes in the 3 days prior to interview and a follow-up cotinine level of <100 ng/ml.
- For those with self-report at baseline and follow-up but cotinine only at baseline: a participant with self-reported zero cigarettes in the 3 days prior to interview and baseline reporting behaviour classified as either accurate or over-reporter.

All other participants in the primary analysis dataset were classified as smokers.

The calibration method used baseline cotinine-self-report relationship to calibrate end of pregnancy self-report for those women who only had cotinine at baseline. Therefore, the number of cases included in the main analysis for this outcome exceeds the number for whom we obtained cotinine at follow-up. We undertook a sensitivity analysis that verified consistency of this relationship for the proportion of our sample who provided cotinine samples at both baseline and follow-up and also found that there was little variation between study group.

Part 2
The second part of the analysis assessed smoking as a continuous variable among those who were classified as a smoker in part 1. It compared the mean number of calibrated cigarettes smoked at late pregnancy follow-up between the trial arms. This analysis was based on a subset of randomised participants. Baseline characteristics of smokers were examined at follow up by trial arm, and in a secondary analysis further adjusted for variables that exhibited marked differences between arms.

A note about cessation and uptake of smoking: For the 590 women assessed as smokers at baseline, cessation rates were 16.7% (49/293, FNP) and 16.5% (49/297, usual care). However, of the 502 women categorised as non-smokers as baseline 118 were subsequently recorded as smokers at follow-up (60/254, 23.6% in FNP, 58/248, 23.4% in usual care). The latter group reflects the natural volatility of smoking behaviour in this population and cautions against focusing exclusively upon cessation rates as a marker of potential intervention effects.

(ii) Subsequent pregnancy
The subsequent pregnancies primary outcome was constructed from four data sources: self-report (6, 12, 18, and 24 months), abortions, Health and Social Care Information Centre (HSCIC) (inpatients and outpatients), and GP data.

Self-report: From each post-birth interview participants were asked if they were pregnant or had been pregnant in the last six months (current pregnant, termination, miscarriage or had a baby) with response option: Yes, No or Not sure, Missing (did not answer the question) or non-response (interview had not been conducted). A variable was created to flag if they had ever been pregnant over any of the four time points where 1=Reported a subsequent pregnancy at any time point, 0=No report of a subsequent pregnancy across ALL time points, -8=Partial data (missing data at some or all time points / responses were 0).

Abortions*:* The dataset of 1618 women were linked to the Abortions dataset by Department of Health, Abortion Statistics Team. Registered medical practitioners are legally required under the Abortion Act 1967 to notify the Chief Medical Officer (CMO) of every therapeutic abortion performed. The Department of Health (DH) receives these notifications on form HSA4 and undertakes statistical processing and analysis. Approval was sought and granted by the CMO to access abortions data under the Abortions Act 1967. Due to the sensitive nature of the abortions data, records were obtained in a pseudonymised manner to lessen the risk of identifying individuals. This involved providing the Department of Health's Abortions Statistics Manager with the women's identifiable personal data (NHS number, date of birth and postcode) – this was provided to be used alongside other Building Blocks datasets to (self-report, HSCIC and GP data) in the ascertainment and analysis of second pregnancies. The abortions data was attached to this dataset, de-identified and returned for analysis.

Outpatients: The data was restricted to participants with outpatient appointments after their first (Building Blocks) baby's date of birth, with a main speciality of obstetrics or midwifery, and attendance type of a first appointment (either attended, did not attend, patient or hospital cancelled). The distribution of days after first baby indicated a natural cut off of 100 days where appointments were related to the first baby and more than 100 days related to a new subsequent pregnancy. Appointments before 100 days were excluded.

Inpatients: The data was restricted to participants with inpatient episodes (defined by their admission date) after their first (Building Blocks) baby's date of birth and flagged for any pregnancy related codes (ICD10[2] chapter O and ICD10 codes Z321, Z33-Z39) or if an episode type was a delivery (with an associated maternity tail) with no associated pregnancy ICD10 codes. The distributions of days after 1st baby was examined and codes up to 100 days examined. Episodes less than 29 days after birth were not part of a new pregnancy, episodes between 29 and 100 days were related to post pregnancy diagnoses (such as post-partum haemorrhage) and were excluded. Episodes between 100 and 150 days all related to early pregnancy symptoms. Thus a cut off of 100 days after first birth was used and any episode occurring after this date was defined as a new subsequent pregnancy.

GP: The GP dataset was based on 951 records collected from the participants and pregnancy fields indicated if a pregnancy had occurred by the following categories: live births, terminations, miscarriage, stillbirth or currently pregnant. If any of the pregnancy fields were coded as missing then no subsequent pregnancy was assumed.

A final variable was constructed from all data sources where 1 = ANY of the data sources indicated an event, 0 = ALL of the data sources indicate no event. For the remainder of the participants where they had not yet been allocated a 1 or 0 (due to missing data), if the GP or self-report data sources indicated that no pregnancy was found then we assumed no subsequent pregnancy. If GP or self-report data was missing and no event was found in outpatients and inpatients data we could not assume that a pregnancy had not occurred. Based on these assumptions, a sample of 1,289 participants had an outcome with 329 missing due to incomplete follow-up (withdrawal or leaving the GP practice before 2 years and had no event from another source or missing self-report or GP data, and no event found in HSCIC sources or abortions).

(iii) Emergency attendances and admissions for children
The primary data source for this outcome was data arising from HSCIC (Inpatients and A&E data).

Inpatients*:* Emergency admissions to hospital were identified from Inpatient records where the basic counting unit for calculation is the Finished Consultant Episode (FCE), which is the total time a patient spends under the care of an individual consultant. Any one hospital admission might have associated with it a number of different episodes as a patient might pass between different hospital consultants. Hospital admissions occurring in the two years since the child's birth were included. All elective admissions and any FCEs relating to the child's birth were excluded to ensure that only episodes subject to external factors were included. Transfers between providers (e.g. birth transfers between hospitals, transfers between hospitals for any non-birth associated events) were also excluded to avoid double counting.

Accidents and emergency: Attendances to A&E for the children were examined and linked to the inpatients data using a common identifier (HESID) and arrival date in A&E attendance data and episode start date in inpatient data. To enable linkage to the inpatients data (to identify attendances that subsequently result in an admission), ID and arrival date/episode start date needed to be unique in both datasets. True duplicates (same ID, arrival date and arrival time) were deleted but a number of attendances occurred on the same day but with different times of arrival and departure. In the majority of cases these attendances are related and are thus restricted to 'first attendances' to avoid duplicates. After linkage, the resulting dataset had 1,164 children with either an attendance at A&E and/or a hospital admission with 314 experiencing no event (22 could not be ascertained as they withdrew before an event).

(iv) Cognitive Development

Table S4.1 Items used at each time point to measure cognitive development

Item	12 month interview	18 month interview	24 month interview
Is your baby sitting independently, that is without help, on their own?	✓ (delay grossmotor)	✓ (delay grossmotor)	
Is your baby crawling or bottom shuffling?	✓	✓ (delay grossmotor)	
Is your baby walking around furniture?	✓	✓ (delay grossmotor)	✓ (delay grossmotor)
Is your baby walking with one hand held?	✓	✓ (delay grossmotor)	✓ (delay grossmotor)
Is your baby walking independently, that is without help, on their own?	✓	✓ (delay grossmotor)	✓ (delay grossmotor)
Can your baby clap their hands?	✓ (delay finemotor)		
Can your baby throw toys?	✓		
Can your baby pick up small objects like raisins or small sweets?	✓ (delay finemotor)	✓ (delay finemotor)	
Does your baby drink from a beaker?	✓		
Does your baby wave bye-bye?	✓ (delay social)		
Does your baby show an interest in books?	✓		
Can your baby use a spoon to feed him/herself?		✓	✓ (delay finemotor)
Does your baby throw toys deliberately?		✓ (delay finemotor)	
Can your child run confidently stopping and starting without bumping into objects?			✓ (delay grossmotor)
Can your child pick up an object from floor when standing without falling over?			✓ (delay grossmotor)
Can child walk and turn corners and stop suddenly?			✓ (delay grossmotor)
Can your child turn pages of a book 1 at a time?			✓ (delay finemotor)
Can your child turn pages of a book several at a time?			✓ (delay finemotor)
How many bricks can your child build in a tower?			✓
Can your child do to and fro scribbling?			✓
Can your child do circular scribbling?			✓
Can your child copy straight lines?			✓

Note: If a child did not score positively on some items they were scored as being developmentally delayed.

(v) Language Development

Table S4.2 Items used at each time point to measure language development

Item	12 month interview	18 month interview
Is your baby chewing food yet?	✓	✓
Is your baby making recognised sounds like ma ma, ba ba, dada?	✓	✓
Does your baby have two or three recognised words with meaning?	✓	✓
Does your baby put two words together?		✓
Does your baby name objects?		✓
Does your baby repeat words?		✓

(vi) Safeguarding

Safeguarding was counted as any record in GP notes indicating the initiation, progression or closure of a safeguarding process (e.g. initial assessment, being identified as a Child in need, child protection conference).

(vii) Use of routine data in this trial

Using routine data such as available from the Health and Social Care Information Centre (HSCIC) offers the potential to more comprehensively measure outcome without the subsequent need for direct participant contact. Successfully accessing data required (i) additional governance approval, including requiring using approved HSCIC wording for participant consent forms, (ii) availability, accuracy and verification of identifiers for linkage (such as NHS number and date of birth) and (iii) developing algorithms for utilising data arising from multiple sources (e.g. subsequent pregnancies).

The table below describes the availability of data accrued from different sources in the trial

Table S4.3 Routine data available for analysis: potential records and reasons for loss to follow-up

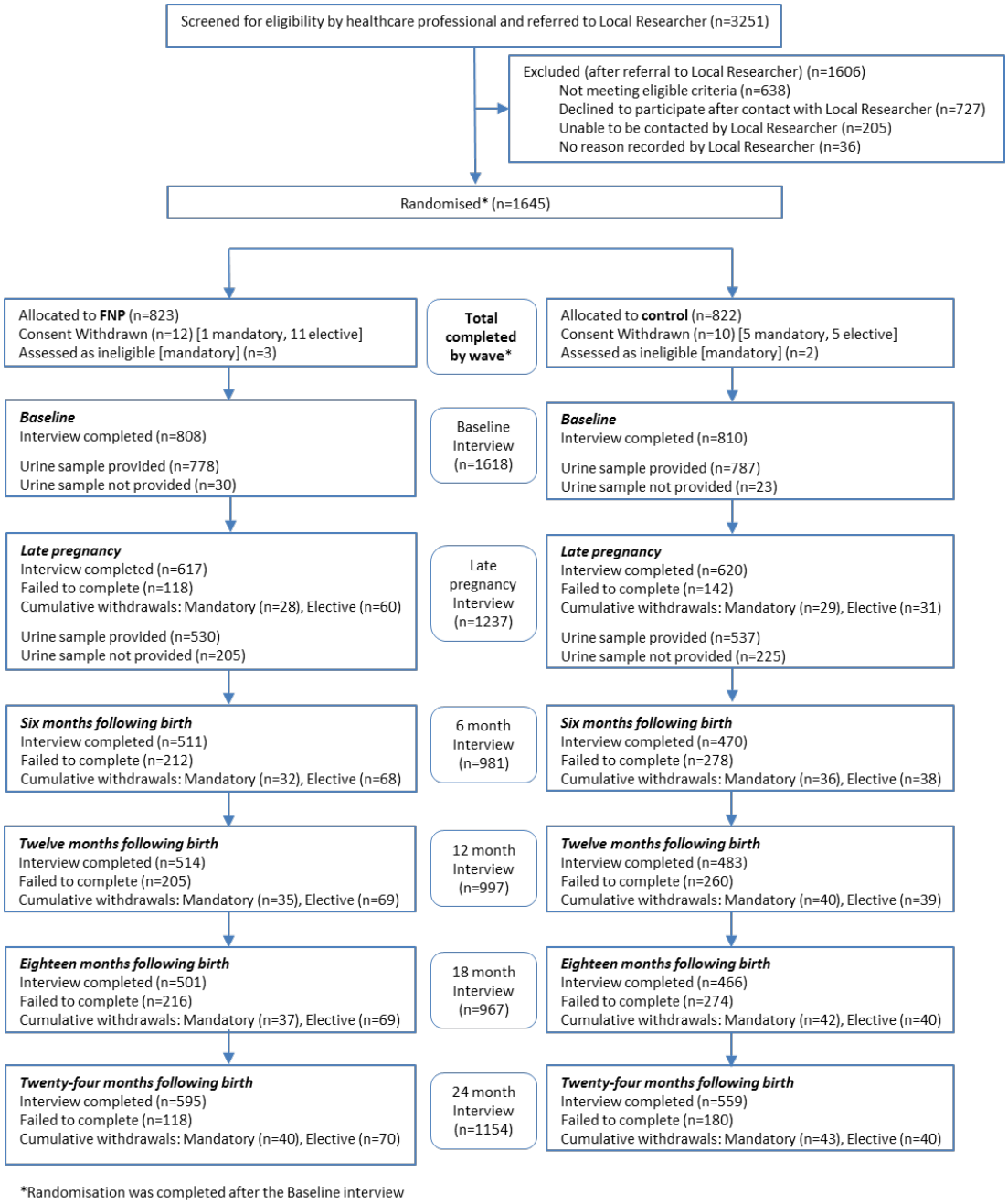
	Maternity *Mother and baby*		**Primary care** *Mother and baby*		**Secondary care** *Mother only*		**Secondary care** *Baby only*		**Immunisation** *Baby only*		**Abortion** *Mother only*	
	FNP	Usual care	FNP	Usual care	FNP	Usual care	FNP	Usual care	FNP	Usual care	FNP	Usual care
Potentially available	**823**	**822**	**823**	**822**	**823**	**822**	**732***	**761***	**732***	**761***	**823**	**822**
Ineligible	3	2	3	2	3	2	-	-	-	-	3	2
Consent withdrawn	12	10	12	10	12	10	2	1	2	1	12	10
Ethics restriction	26	14	-	-	-	-	-	-	-	-	-	-
Matching failure	-	-	-	-	3	4	4	1	10	10	-	-
Not provided on request	-	-	332	324	-	-	-	-	181	191	-	-
Available for analysis	**782**	**796**	**476**	**486**	**805**	**806**	**726†**	**759†**	**539‡**	**559‡**	**808**	**810**

* Numbers exclude 5 stillborn babies, 3 in the FNP arm, 2 in the usual care arm. † Secondary care (HES) data were also collected on 11second twins, 6 in the FNP arm and 5 in the usual care arm. There was one failure to match on a second twin in the FNP arm. ‡ Immunisation data were also collected on 6 second twins, 4 in the FNP arm and 2 in the usual care arm. Data were not provided on 6 second twins, 3 in the FNP arm and 3 in the usual care arm

(viii) Maternal reported data in this trial

The figure below describes follow-up by trial arm via interview across each wave of data collection in the study following allocation.

Figure S4.1 Participant follow-up by trial arm for each wave of direct assessment



5. Full listing of secondary trial outcomes and when assessed

Table S5.1 Secondary Outcomes: data source and assessment points (self-report apart from routine data for maternity and HES/GP)

Outcome*	Baseline	Late pregnancy	Maternity	6 months	12 months	18 months	24 months†	HES/GP‡	Analysis
Pregnancy and birth outcomes									
Maternal outcomes									
Place of birth: planned, actual§			*x*						NA
Antenatal pre-eclampsia / hypertension‖			*x*						LO-1
Parenting / child outcomes									
Live birth			*x*						LO-1
Gestation at delivery			*x*						LIN-1
Apgar score: 1 min, 5 mins			*x*						LO-1
Head circumference			*x*						LIN-1
Neonatal unit admission			*x*						LO-1
Child health and development outcomes									
Parenting / child outcomes									
Infant feeding intentions and duration		*x*							LO-1
Anticipatory parenting[3, 4]		*x*							LIN-1
Prenatal attachment*[, 5]		*x*							LIN-1
Parental role strain[3,4]				*x*	*x*	*x*	*x*		LIN-3
Maternal-child interaction*[, 6]							*x*		LIN-1
Mother and child living apart				*x*	*x*	*x*	*x*		LO-1
Initiation of breast or mixed feeding			*x*						LO-1
Breastfeeding cessation				*x*					SURV
Introduction of solids				*x*					LO-1
Time to introduction to solids				*x*					SURV
Baby diet: unhealthy food score						*x*	*x*		LIN-3
Baby diet: healthy food every day						*x*	*x*		LO-3
Cognitive development: 12 months, 18 months, 24 months*[, 7]					*x*	*x*	*x*		LO-1
Language development: 12 months, 18 months (SOGS[7])					*x*	*x*			LO-1
Language development: ELM[8]							*x*		LIN-1
Child safety*[, 9]					*x*	*x*	*x*		LO-3
Use of childcare				*x*	*x*	*x*	*x*		LO-3
Immunisations				*x*	*x*	*x*		*x*	LO-1
Primary care consultation for injuries & ingestions		*x*		*x*	*x*	*x*		*x*	LO-1
A&E attendance for injuries & ingestions		*x*		*x*	*x*	*x*	*x*	*x*	LO-1
Hospital admissions for injuries & ingestions		*x*		*x*	*x*	*x*	*x*	*x*	LO-1
Referral to a non-NHS service							*x*		LO-1
Referral to social services							*x*	*x*	LO-1
Safeguarding procedures							*x*	*x*	LO-1
Parental life course outcomes									
Maternal outcomes									
Not in education, employment or training (NEET)¶[, 3,4]	*x*			*x*	*x*	*x*	*x*		LO-4
Hours in formal education*[, 3,4]				*x*	*x*	*x*	*x*		LIN-3
In paid employment*[, 3,4]	*x*			*x*	*x*	*x*	*x*		LO-2
Type of employment*[,§, 3,4]	*x*			*x*	*x*	*x*	*x*		NA
In receipt of benefits*[, **, 3,4]	*x*						*x*		LO-2
Other financial support*[, ††, 3,4]	*x*						*x*		LO-2
Ever been homeless[3,4]	*x*			*x*	*x*	*x*	*x*		LO-2
General health status[10]	*x*	*x*		*x*	*x*	*x*	*x*		LO-4
Maternal weight[3,4]	*x*						*x*		LIN-2
Psychological distress[11]	*x*						*x*		LIN-2
Depressive symptoms[12]				*x*	*x*	*x*	*x*		LO-3
Postnatally depressed[13]				*x*					LO-1
General self-efficacy[14]	*x*			*x*	*x*	*x*	*x*		LIN-4
Adaptive functioning*[,15, 16]	*x*						*x*		LO-2
Intimate partner violence[17]							*x*		LO-1
Smoking reduction method[18, 19]		*x*		*x*					LO-1
Anyone smoking in home				*x*	*x*	*x*	*x*		LO-1
Problem alcohol and drug use[20]	*x*						*x*		LIN-2
Contraceptive use and method[§,3,4]				*x*	*x*	*x*	*x*		LO-3
Social support and networks[21,22]	*x*			*x*	*x*	*x*	*x*		LO-4
Family resources*[, 23]	*x*			*x*	*x*	*x*	*x*		LIN-4
Partner-relationship quality[24]	*x*	*x*		*x*	*x*	*x*	*x*		LIN-4
Dental care							*x*		LO-1

Outcome*	Baseline	Late pregnancy	Maternity	6 months	12 months	18 months	24 months†	HES/GP‡	Analysis
Antenatal check-ups			*x*					*x*	NBIN-1
Planned attendances at day assessment units			*x*					*x*	NBIN-1
Unplanned hospital admissions			*x*					*x*	NBIN-1
Antenatal hospital admissions			*x*					*x*	NBIN-1
Primary care consultations		*x*		*x*	*x*	*x*		*x*	NBIN-1
A&E attendances / hospital admissions		*x*		*x*	*x*	*x*		*x*	NBIN-1
Use of Connexions personal advisor				*x*	*x*	*x*			LO-3
Use of additional services: Children's Centre Toddler group, Social worker, Crèche				*x*	*x*	*x*	*x*		LO-3
Foster care for mother				*x*	*x*	*x*			NA

* Items amended or partially sourced from existing measures, citations below and full detail provided in the published report (bit.ly/buildingblocks). † A minimum dataset was collected by telephone or post at 24 months if face-to-face interview was not possible. ‡ For period from recruitment or birth until 24 months post birth (mother and child). § No formal analysis - descriptive summary provided in the published report (bit.ly/buildingblocks). ‖ Not assessed as secondary outcome - exploratory analysis only. ¶NEET status is only considered for participants aged 16 or older at interview. ** Income support, jobseekers allowance, housing benefit, council tax benefit, DLA and incapacity benefit, other care grant from Social Fund. †† Education grants, maintenance support, or regular cash from parents or relatives.

Analysis Key

LIN=Linear regression	1=Single outcome (either one time point or constructed over several time points)
LO=Logistic regression	2=Baseline adjusted single outcome
NBIN=Negative binomial	3=Repeated measures (over more than one time point)
SURV=Survival	4= Baseline adjusted repeated measures
NA=Not analysed – numbers too small for formal analysis or descriptive only	

6. Sensitivity analyses for tobacco use and second pregnancy

(i) Tobacco use

Analyses were repeated for those participants who had complete self-report data and urinary cotinine data at both baseline and late pregnancy (n=870) (Table S6.1). The effect and confidence intervals are unchanged by this analysis.

Table S6.1 Percentage of smokers by trial arm, main analysis and complete case

		n	%	Adjusted OR* (97.5% CI)
Main analysis N=1092	FNP (N=547)	304	55.6	0.90 (0.64 to 1.28)
	Usual care (N=545)	306	56.1	
Complete case analysis N=870	FNP (N=439)	248	56.5	0.90 (0.62 to 1.31)
	Usual care (N=431)	249	57.8	

* FNP compared to usual care. Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

(ii) Second pregnancy - Impact of data source

Since several data sources could be used to detect a more accurate rate of second pregnancies, the impact of using these data sources was examined (Table S6.2). A much lower rate of pregnancies is detected by using just Health and Social Care Information Centre (HSCIC) data. Using only maternally self-reported second pregnancies or those detected through GP records a greater proportion is detected, although in the maternal report a greater proportion is reported from those randomised to the usual care arm and vice versa for the GP records.

Table S6.2 Percentage of participants with a second pregnancy within twenty four months of first birth, by trial arm

		n	%	Adjusted OR* (97.5% CI)
HSCIC (Inpatients and Outpatients) N=1611	FNP (N=450)	194	24.1	0.85 (0.63 to 1.15)
	Usual care (N=418)	211	26.1	
Maternal Self report only N=868	FNP (N=450)	223	49.6	0.78 (0.58 to 1.07)
	Usual care (N=418)	230	55.0	
GP records only N=951	FNP (N=471)	257	54.6	1.17 (0.87 to 1.57)
	Usual care (N=480)	244	50.8	

* FNP compared to usual care. Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

7. Narrative description of secondary outcomes results

Tables S7.1 to S7.3 below present all the secondary outcomes for the Pregnancy and birth, Child health and development, and the Parental life course domains. Within each domain we present by *maternal* or *parenting and /child* outcomes. We highlight here all associations with a p value of less than 0.05 and selected others.

Table S7.1 Secondary pregnancy and birth outcomes

Outcome*	**Arm**[†]	**Maternal birth record N=1578** *(FNP=782, UC=796)*	**Adjusted**[‡] **intervention effect (95% CI)**	***P***
Maternal outcomes				
Antenatal pre-eclampsia/hypertension	FNP	80/766 (10·4)	1·26[§]	0·18
	UC	67/776 (8·6)	(0·90 to 1·79)	
Child outcomes				
		Child birth record N=1510 *(FNP=742, UC=768)*		
Live birth	FNP	739 (99·6)	0·65[§]	0·63
	UC	766 (99·7)	(0·11 to 3·88)	
Gestation at delivery	FNP	N=735 39·16 (2·33)	-0·005[**] (-0·24 to 0·23)	0·97
	UC	N=763 39·16 (2·31)		
Normal Apgar score (≥7) at 1 minute	FNP	614/682 (90·0)	1·14[§]	0·46
	UC	621/699 (88·8)	(0·81 to 1·61)	
Normal Apgar score (≥7) at 5 minutes	FNP	666/681 (97·8)	0·91[§]	0·80
	UC	686/700 (98·0)	(0·44 to 1·88)	
Head circumference (cm) (at birth)	FNP	N=456 33·9 (2·1)	-0·14[**] (-0·41 to 0·14)	0·34
	UC	N=495 34·1 (1·8)		
No neonatal unit admission (direct or subsequent)	FNP	653/733 (89·1)	0·81[§]	0·23
	UC	695/764 (91·0)	(0·58 to 1·14)	

Data are n (%), mean (SD), median (25th to 75th centile) or n/N(%)

* Missing data varies by outcome. Full details are documented in the published report (bit.ly/buildingblocks). † FNP=Family Nurse Partnership Programme + Usual care, UC= Usual care. ‡ Adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). §Adjusted odds ratio: FNP compared to usual care. ** Adjusted difference in means: FNP minus usual care.

Table S7.2 Secondary child health and development outcomes

Outcome[*]	**Arm**[†]	**Late pregnancy N=1237** *(FNP=617, UC=620)*	**Maternal birth record N=1578** *(FNP=782, UC=796)*	**6 months N=981** *(FNP=511, UC=470)*	**12 months N=997** *(FNP=514, UC=483)*	**18 months N=967** *FNP=501, UC=466)*	**24 months**[‡] **N=1154** *(FNP=595, UC=559)*	**Adjusted**[§] **intervention effect (95% CI)**	***P***
Parenting/child outcomes									
Breastfeeding or mixed Infant feeding intentions	FNP UC	344/589 (58·4) 298/591 (50·4)	- -	- -	- -	- -	- -	1·32[**] (1·02 to 1·70)	0·036
Intended breastfeeding duration 6 weeks or more	FNP UC	300/334 (89·8) 253/287 (88·2)	- -	- -	- -	- -	- -	1·22[**] (0·73 to 2·03)	0·45
Anticipatory parenting score[††]	FNP UC	N=593 8·60 (2·03) N=591 8·80 (1·97)	- -	- -	- -	- -	- -	-0·20[‡‡] (-0·43 to 0·02)	0·08
Prenatal attachment score[§§]	FNP UC	N=587 11·58 (3·17) N=589 11·73 (3·15)	- -	- -	- -	- -	- -	-0·09[‡‡] (-2·10 to 1·92)	0·93
Parental role strain score[***]	FNP UC	-	-	N=477 9·10 (2·14) N=471 9·27 (2·40)	N=496 9·43 (2·27) N=471 9·58 (2·37)	N=481 9·62 (2·25) N=451 9·74 (2·52)	N=535 10·52 (2·58) N=536 10·56 (2·48)	-0·16[‡‡] (-0·35 to 0·03)	0·11
Maternal-child interaction outcomes[†††]:									
Maternal sensitivity score	FNP UC	-	-	-	-	-	N=256 11·05 (1·66) N=252 11·06 (1·62)	-0·07[‡‡] (-0·41 to 0·27)	0·67
Maternal intrusiveness score	FNP UC	-	-	-	-	-	N=256 1·67 (1·85) N=252 1·53 (1·60)	0·12[‡‡] (-0·19 to 0·43)	0·44
Child responsiveness score	FNP UC	-	-	-	-	-	N=256 18·43 (2·25) N=252 18·60 (2·82)	-0·26[‡‡] (-0·77 to 0·25)	0·31
Child positive affect score	FNP UC	-	-	-	-	-	N=256 3·13 (1·92) N=251 3·35 (2·24)	-0·23[‡‡] (-0·59 to 0·13)	0·21

Child negative affect score	FNP	-	-	-	-	-	N=256 0·89 (1·27)	0·09‡‡ (-0·12 to 0·30)	0·40
	UC	-	-	-	-	-	N=252 0·79 (1·11)		
Mother and child ever lived apart	FNP	-	-	-	-	-	24/359 (6·7)	0·73** (0·41 to 1·32)	0·30
	UC	-	-	-	-	-	27/312 (8·7)		
Child Outcomes	**Arm**		**Child birth record N=1510** *(FNP=742, UC=768)*	**6 months N=987** *(FNP=514, C=473)*	**12 months N=1004** *(FNP=519, C=485)*	**18 months N=975** *(FNP=506, C=469)*	**24 months N=1164** *(FNP=602, C=562)*	**Adjusted§ odds ratio/ difference in means (95% CI)**	***P***
Initiation of breast or mixed feeding	FNP	-	317/723 (43·8)	-	-	-	-	1·10**	0·37
	UC	-	312/753 (41·4)	-	-	-	-	(0·89 to 1·37)	
Breastfeeding cessation time (days)	FNP	-	-	N=254 7 (2 to 31)	-	-	-	1.03‡‡‡ (0·86 to 1·24)	0·76
	UC	-	-	N=223 14 (2 to 42)	-	-	-		
Introduction of solids by 6 months	FNP	-	-	471/488 (96·5)	-	-	-	1·24** (0·63 to 2·45)	0·54
	UC	-	-	435/455 (95·6)	-	-	-		
Time (weeks) to introduction of solids	FNP	-	-	N=471 16 (16 to 20)	-	-	-	0·92‡‡ (0·81 to 1·05)	0·22
	UC	-	-	N=435 16 (16 to 20)	-	-	-		
Unhealthy food score§§§	FNP	-	-	-	-	N=491 7·94 (1·85)	N=572 8·69 (1·69)	-0·005‡‡ (-0·20 to 0·19)	0·96
	UC	-	-	-	-	N=455 8·13 (1·91)	N=518 8·63 (1·74)		
Child received healthy food every day****	FNP	-	-	-	-	356/490 (72·7)	374/573 (65·3)	0·95** (0·7 to 1·28)	0·72
	UC	-	-	-	-	330/456 (72·4)	348/523 (66·5)		
Cognitive development concern	FNP	-	-	-	44/504 (8·7)	17/491 (3·5)	46/569 (8·1)	**12m:** 0·91** (0·59 to 1·40)	0·66
	UC	-	-	-	45/472 (9·5)	26/455 (5·7)	66/522 (12·6)	**18m:** 0·59** (0·32 to 1·11)	0·10
								24m: 0·61** (0·40 to 0·90)	0·013
Language development concern	FNP	-	-	-	55/502 (11·0)	84/490 (17·1)	-	**12m:** 0·50** (0·35 to 0·72)	<0·001
	UC	-	-	-	94/472 (19·9)	110/455 (24·2)	-	**18m:** 0·66**	0·009

								(0·48 to 0·90)	
Early Language Milestone Scale score[††††]	FNP	-	-	-	-	-	N=480 60·8 (31·4)	4·49[‡‡] (0·52 to 8·45)	0.027
	UC	-	-	-	-	-	N=415 55·7 (31·4)		
Child safety[‡‡‡‡]	FNP	-	-	-	100/466 (21·5)	142/460 (30·9)	96/510 (18·8)	1·26[**]	0·08
	UC	-	-	-	77/452 (17·0)	120/431 (27·8)	79/490 (16·1)	(0·97 to 1·62)	
Use of childcare	FNP	-	-	36/110 (32·7)	83/500 (16·6)	128/488 (26·2)	160/569 (28·1)	1·28[**]	0·18
	UC	-	-	33/105 (31·4)	64/472 (13·6)	100/453 (22·1)	136/522 (26·1)	(0·90 to 1·83)	
Receipt of all 10 immunisations required by 24m	FNP	-	-	-	-	-	421/529 (79·6)	0·94[**]	0·77
	UC	-	-	-	-	-	432/534 (80·9)	(0·60 to 1·46)	
Consultations for injuries and ingestions									
Primary care consultation at 6m	FNP	-	-	-	-	-	#		
	UC	-	-	-	-	-	#		
Primary care consultation at 24m	FNP	-	-	-	-	-	48/461 (10·4)	0·87[**]	0·53
	UC	-	-	-	-	-	55/471 (11·7)	(0·58 to 1·33)	
A&E attendance at 6m	FNP	-	-	-	-	-	30/731 (4·1)	1·52[**]	0·15
	UC	-	-	-	-	-	21/755 (2·8)	(0·86 to 2·70)	
A&E attendance at 24m	FNP	-	-	-	-	-	222/721 (30·8)	1·16[**]	0·20
	UC	-	-	-	-	-	207/744 (27·8)	(0·92 to 1·46)	
Hospital admission at 6m	FNP	-	-	-	-	-	14/731 (1·9)	0·79[**]	0·51
	UC	-	-	-	-	-	18/756 (2·4)	(0·39 to 1·60)	
Hospital admission at 24m	FNP	-	-	-	-	-	35/722 (4·8)	0·72[**]	0·15
	UC	-	-	-	-	-	49/745 (6·6)	(0·46 to 1·12)	
Referral to non-NHS service	FNP	-	-	-	-	-	122/583 (20·9)	1·23[**]	0·19
	UC	-	-	-	-	-	96/542 (17·7)	(0·91 to 1·66)	
Referral to social services	FNP	-	-	-	-	-	119/580 (20·5)	1·27[**]	0·13
	UC	-	-	-	-	-	91/541 (16·8)	(0·93 to 1·73)	
Safeguarding procedure[§§§§]	FNP	-	-	-	-	-	64/469 (13·6)	1·85[**]	0·005
	UC	-	-	-	-	-	38/476 (8·0)	(1·02 to 2·85)	

Data are n (%), mean (SD), median (25th to 75th centile) or n/N(%), '#' suppression of low cell count indicates a value between 1 and 5

* Missing data varies by outcome. Full details are documented in the published report (bit.ly/buildingblocks).

† FNP=Family Nurse Partnership Programme + Usual care, UC=Usual care

‡ A minimum dataset was collected by telephone or post at 24 months if face-to-face interview was not possible (n=32)

§ Adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

** Adjusted odds ratio: FNP compared to usual care

†† A 5 item scale with scores ranging from 5 to 25 where a low score indicates more structured parenting

‡‡ Adjusted difference in means: FNP minus usual care

§§ An 8 item scale with scores ranging from 8 to 32 where a low score indicates lower attachment

*** A 6 item scale with scores ranging from 6 to 24 where a low score indicates lower parental strain
††† A low score indicates low level of each reported measure
‡‡‡ Adjusted hazard ratio (HR) with a HR>1 indicating that the FNP arm presented sooner than the usual care arm
§§§ A 3 item scale with scores ranging from 3 to 12 where a low score indicates that unhealthy food was less frequently consumed
**** A 2 item scale with scores ranging from 2 to 8 and a binary outcome was used where a score of 2 indicates that the participants gave their babies healthy food every day
†††† Percentile scores where a low score indicates that language is less developed
‡‡‡‡ Positive response to all safety feature questions
§§§§ Recorded in primary care notes

Table S7.3 Secondary parental life course outcomes

Outcome[*]	**Arm**[†]	**Baseline N=1618** *(FNP=808, UC=810)*	**Late pregnancy N=1237** *(FNP=617, UC=620)*	**Birth record N=1578** *(FNP=782, UC =796)*	**6 months N=981** *(FNP=511, UC =470)*	**12 months N=997** *(FNP=514, UC =483)*	**18 months N=967** *FNP=501, UC =466)*	**24 months**[‡] **N=1154** *(FNP=595, UC=559)*	**Adjusted**[§] **intervention effect (95% CI)**	***P***
Maternal outcomes										
Not in education, employment or training (NEET)[**]	FNP	333/695 (47·9)	-	-	369/468 (78·9)	336/496 (67·7)	306/493 (62·1)	368/593 (62·1)	0·86[††] (0·60 to 1·23)	0·41
	UC	330/685 (48·2)	-	-	344/435 (79·1)	333/466 (71·5)	300/456 (65·8)	388/557 (69·7)		
In formal education	FNP	-	-	-	62/476 (13·0)	84/495 (17·0)	99/485 (20·4)	101/572 (17·7)	1·09[††] (0·75 to 1·60)	0·65
	UC	-	-	-	66/448 (14·7)	78/470 (16·6)	90/461 (19·5)	74/527 (14·0)		
Hours per week in formal education	FNP	-	-	-	N=62 17·8 (8·9)	N=84 17·5 (9·0)	N=99 16·6 (7·4)	N=101 18·4 (9·4)	-0·98[‡‡] (-3·01 to 1·06)	0·35
	UC	-	-	-	N=66 19·0 (8·6)	N=78 18·9 (8·1)	N=90 18·5 (9·0)	N=74 18·7 (10·0)		
In paid employment	FNP	174/808 (21·5)	-	-	31/483 (6·4)	65/504 (12·9)	75/496 (15·1)	111/594 (18·7)	1·15[††] (0·76 to 1·74)	0·51
	UC	164/810 (20·2)	-	-	25/452 (5·5)	57/478 (11·9)	64/462 (13·9)	88/559 (15·7)		
In receipt of state benefits	FNP	212/593 (35·8)	-	-	-	-	-	517/593 (87·2)	1·17[††] (0·81 to 1·68)	0·40
	UC	196/557 (35·2)	-	-	-	-	-	494/557 (88·7)		
Other financial support received	FNP	290/584 (49·7)	-	-	-	-	-	279/584 (47·8)	1·19[††] (0·91 to 1·55)	0·21
	UC	234/538 (43·5)	-	-	-	-	-	273/538 (50·7)		
Ever been homeless *(from baseline until 24m)*	FNP	144/808 (17·8)	-	-	-	-	-	123/405 (30·4)	0·76[††] (0·55 to 1·05)	0·09
	UC	170/810 (21·0)	-	-	-	-	-	136/375 (36·3)		
In full health[§§]	FNP	518/808 (64·1)	268/614 (43·6)		378/507 (74·6)	393/510 (77·1)	397/499 (79·6)	428/594 (72·1)	1·07[††] (0·86 to 1·32)	0·55
	UC	512/807 (63·4)	252/616 (40·9)		346/469 (73·8)	364/480 (75·8)	358/465 (77·0)	414/558 (74·2)		
Maternal weight (kg)	FNP	N=334 59·9 (11·3)	-	-	-	-	-	N=334 63·6 (13·4)	0·47[‡‡] (-0·88 to 1·83)	0·49
	UC	N=337 60·6 (13·6)	-	-	-	-	-	N=337 63·9 (14·3)		

Psychological distress score[***]	FNP	N=580 21·37 (6·53)	-	-	-	-	-	N=580 16·86 (7·65)	-0·39[‡‡] (-1·19 to 0·40)	0·33
	UC	N=536 21·28 (6·44)	-	-	-	-	-	N=536 17·19 (7·19)		
Displaying depressive symptoms[†††]	FNP	-	-	-	167/496 (33·7)	162/505 (32·1)	149/496 (30·0)	197/583 (33·8)	0·80[††] (0·60 to 1·05)	0·11
	UC	-	-	-	163/456 (35·7)	164/479 (34·2)	166/464 (35·8)	190/538 (35·3)		
Postnatally depressed (score>13)[‡‡‡]	FNP	-	-	-	60/493 (12·2)	-	-	-	1·03[††] (0·69 to 1·52)	0·90
	UC	-	-	-	54/456 (11·8)	-	-	-		
Self-efficacy score[§§§]	FNP	N=798 30 (28 to 33)	-	-	N=487 33 (30 to 37)	N=503 34 (31 to 38)	N=491 34 (30 to 38)	N=578 32 (30 to 36)	0·44[‡‡] (0·10 to 0·78)	0·011
	UC	N=794 30 (27 to 32)	-	-	N=456 32 (30 to 36)	N=477 33 (30 to 37)	N=458 33 (30 to 37)	N=531 32 (30 to 35)		
Adaptive functioning: Difficulty in at least one basic skills	FNP	152/581 (26·2)	-	-	-	-	-	127/581 (21·9)	0·91[††] (0·66 to 1·24)	0·54
	UC	120/536 (22·4)	-	-	-	-	-	116/536 (21·6)		
Adaptive functioning: At least one life burden	FNP	164/573 (28·6)	-	-	-	-	-	99/573 (17·3)	0·95[††] (0·70 to 1·31)	0·76
	UC	167/531 (31·5)	-	-	-	-	-	97/531 (18·3)		
Adaptive functioning: Three or less life skills	FNP	131/578 (22·7)	-	-	-	-	-	76/578 (13·1)	0·93[††] (0·65 to 1·32)	0·69
	UC	142/534 (26·6)	-	-	-	-	-	76/534 (14·2)		
Intimate partner violence – no reported abuse[****]	FNP	-	-	-	-	-	-	202/324 (62·3)	1·17[††] (0·84 to 1·63)	0·37
	UC	-	-	-	-	-	-	160/273 (58·6)		
Smoking reduction method (on own vs· other methods)	FNP	-	117/139 (84·2)	-	120/123 (97·6)	-	-	-	Late Preg: 1·07[††] (0·55 to 2·07)	0·84
	UC	-	114/136 (83·8)	-	105/112 (93·8)	-	-	-	6m: 3·14[††] (0·75 to 13·2)	0·12
Anyone ever smoked in home *(from 6m to 24m)*	FNP	-	-	-	-	-	-	298/486 (61·3)	0·82[††] (0·62 to 1·09)	0·18
	UC	-	-	-	-	-	-	290/445 (65·2)		
Problem alcohol and drug use score[††††]	FNP	N=554 1·31 (1·55)	-	-	-	-	-	N=554 0·37 (0·84)	-0·03[‡‡] (-0·12 to 0·07)	0·58

	UC	N=514 1·27 (1·47)	-	-	-	-	-	N=514 0·37 (0·83)		
Contraceptive use[‡‡‡‡]	FNP	-	-	-	424/503 (84·3)	392/509 (77·0)	387/499 (77·6)	432/595 (72·6)	1·25[††]	0·08
	UC	-	-	-	373/465 (80·2)	370/479 (77·2)	349/465 (75·1)	379/558 (67·9)	(0·98 to 1·60)	
Maximum social support[§§§§]	FNP	160/799 (20·0)	-	-	118/479 (24·6)	124/505 (24·6)	127/495 (25·7)	162/581 (27·9)	1·50[††]	0·023
	UC	167/804 (20·8)	-	-	111/447 (24·8)	111/473 (23·5)	93/459 (20·3)	123/533 (23·1)	(1·06 to 2·12)	
Family resources score[*****]	FNP	N=775 13·4 (4·2)	-	-	N=452 14·4 (3·7)	N=492 13·8 (3·9)	N=490 14·1 (3·8)	N=567 13·6 (3·9)	-0·03[‡‡]	0·89
	UC	N=776 13.4 (4.2)	-	-	N=425 14.3 (3.9)	N=467 13.8 (4.0)	N=453 13.7 (3.7)	N=529 13.4 (3.6)	(-0·51 to 0·45)	
Partner-relationship quality score[†††††]	FNP	N=637 28·0 (4·8)	N=45 29·6 (4·1)	-	N=330 29·0 (4·5)	N=312 29·0 (4·3)	N=288 29·3 (3·8)	N=374 29·1 (4·4)	0·74[‡‡]	0·002
	UC	N=640 28·2 (4·8)	N=34 29·4 (4·0)	-	N=310 28·3 (4·7)	N=267 28·4 (4·5)	N=241 28·5 (4·6)	N=340 28·4 (4·4)	(0·28 to 1·20)	
Routine dental check-up since child was born	FNP	-	-	-	-	-	-	393/595 (66·1)	0·96[††]	0·72
	UC	-	-	-	-	-	-	373/557 (67·0)	(0·75 to 1·22)	
Antenatal check-ups	FNP	-	-	N=782 10·38 (3·69)	-	-	-	-	1·02[‡‡‡‡‡]	0·32
	UC	-	-	N=796 10·22 (3·47)	-	-	-	-	(0·98 to 1·05)	
Planned antenatal attendances at day assessment units	FNP	-	-	N=757 1·45 (2·42)	-	-	-	-	0·95[‡‡‡‡‡]	0·55
	UC	-	-	N=768 1·59 (2·80)	-	-	-	-	(0·82 to 1·11)	
Unplanned antenatal hospital admissions	FNP	-	-	N=757 1·68 (1·99)	-	-	-	-	1·04[‡‡‡‡‡]	0·49
	UC	-	-	N=768 1·63 (2·00)	-	-	-	-	(0·93 to 1·17)	
Antenatal hospital admissions	FNP	-	-	N=757 0·71 (0·05)	-	-	-	-	0·96[‡‡‡‡‡]	0·61
									(0·81 to 1·13)	

	UC	-	-	N=768 0·76 (0·05)	-	-	-	-		
Primary care consultations[§§§§§]	FNP	-	-	-	-	-	-	N=461 12·00 (10·2)	1·09[‡‡‡‡‡] (0·98 to 1·21)	0·13
	UC	-	-	-	-	-	-	N=468 10·91 (9·13)		
Maternal emergency attendances and admissions[******]	FNP	-	-	-	-	-	-	N=808 3·35 (4·17)	1·26[‡‡‡‡‡] (0·98 to 1·62)	0·07
	UC	-	-	-	-	-	-	N=810 3·21 (3·96)		
Contact with a Connexions personal advisor	FNP	-	-	-	159/483 (32·9)	121/504 (24·0)	84/496 (16·9)	-	1·15[††] (0·85 to 1·53)	0·36
	UC	-	-	-	126/452 (27·9)	112/476 (23·5)	79/462 (17·1)	-		
Use of Children's Centre	FNP	-	-	-	187/483 (38·7)	184/460 (40·0)	142/432 (32·9)	206/584 (35·3)	1·18[††] (0·94 to 1·48)	0·15
	UC	-	-	-	172/452 (38·1)	172/443 (38·8)	140/421 (33·3)	149/538 (27·7)		
Use of Toddler group	FNP	-	-	-	40/483 (8·3)	64/498 (12·9)	81/472 (17·2)	114/584 (19·5)	1·01[††] (0·78 to 1·30)	0·96
	UC	-	-	-	37/452 (8·2)	53/466 (11·4)	71/436 (16·3)	120/538 (22·3)		
Use of Social worker	FNP	-	-	-	54/483 (11·2)	38/489 (7·8)	41/474 (8·6)	78/584 (13·4)	1·44[††] (0·87 to 2·38)	0·16
	UC	-	-	-	47/452 (10·4)	36/464 (7·8)	29/449 (6·5)	54/537 (10·1)		
Use of Crèche/day nursery	FNP	-	-	-	55/483 (11·4)	79/495 (16·0)	-	-	1·19[††] (0·73 to 1·95)	0·49
	UC	-	-	-	47/452 (10·4)	71/469 (15·1)	-	-		
Ever needing to be in foster care	FNP	-	-	-	-	-	-	#		
	UC	-	-	-	-	-	-	#		

Data are n (%), mean (SD), median (25th to 75th centile) or n/N(%), '#' suppression of low cell counts indicates a value between 1 and 5
* Missing data varies by outcome. Full details are documented in the published report (bit.ly/buildingblocks)
† FNP=Family Nurse Partnership Programme + usual care, UC=Usual care
‡ A minimum dataset was collected by telephone or post at 24 months if face-to-face interview was not possible (n=32)
§ Adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)
** NEET status applicable only to those whose age at end of previous academic year was >16 years
†† Adjusted odds ratio: FNP compared to usual care
‡‡ Adjusted difference in means: FNP minus usual care
§§ EQ5D score was dichotomised so that full health represents a score of 1
*** A 10 item scale with scores ranging from 10 to 50 where a low score indicates a low level of psychological distress

††† A positive response to both items on the Depression Screening tool indicates that the participant was displaying depressive symptoms
‡‡‡ A 10 item scale with scores ranging from 0 to 30 where a higher score indicates more depressive symptoms. A binary outcome was used with scores of greater than 13 categorising mothers likely to be suffering from a depressive illness of varying severity
§§§ A 10 item scale with scores ranging from 10 to 40 where a higher score indicates higher self-efficacy
**** CAS was only administered in face-to-face interviews and where the participant was alone. Scores ranged from 0 to 145 and dichotomised so that a score of 0 indicated no reported abuse
†††† A 6 item scale with scores ranging from 0 to 6 where a higher score indicates a greater risk of problems
‡‡‡‡ Data at baseline not used in analysis as not equivalent for interpretation purposes
§§§§ Scores ranged from 0 to 100 where higher scores indicate more support, and was dichotomised so that a score of 100 indicated maximum support
***** A 4 item scale with scores ranging from 4 to 20 where a higher score indicates more family resources
††††† A 7 item scale with scores ranging from 7 to 35 where a higher score indicates higher relationship quality
‡‡‡‡‡ Adjusted incidence rate ratio (IRR) where a IRR>1 indicating a higher rate in the FNP compared to the usual care
§§§§§ Data extracted from primary care notes and cover the period since recruitment to the trial. Consultations are for GP and nurse visits and exclude antenatal visits
****** Data extracted from the HSCIC A&E and hospital inpatients records and cover the period since recruitment to the trial and excluded any events relating to the birth of the child

Pregnancy and birth
See table S7.1

There was no evidence for differences between trial arms for either maternal or parenting and child outcomes.

Child health and development
See table S7.2

Breastfeeding More pregnant participants in the FNP arm expressed an intention to breast feed (n=344/589, (58.4%)) than in the usual care arm (n=298/591, (50.4%)), an adjusted odds ratio of 1.32 (95% CI: 1.02 to 1.70). However, there was no difference in the proportion of participants in the FNP arm initiating breast or mixed feeding (n=317/723, (43.8%)) compared to the usual care arm (n=312/753, (41.4%)), or in the median duration of breast feeding reported at six months by participants in the FNP arm (7 days) and usual care arm (14 days) where initiated and subsequently ceased.

Developmental concern There was no difference between arms at 12 and at 18 months in terms of maternally reported developmental concerns (based on items drawn from the Schedule of Growing Skills). However, at 24 months the proportions of children with a concern were 8.1% (n=46/569) and 12.6% (n=66/522) in the FNP and usual care arms respectively (adjusted odds ratio: 0.61, 95% CI 0.40 to 0.90).

Language Maternally reported rate of developmental delay in language was lower for children in the FNP arm (n=55/512, (11.0%)) compared to the usual care arm (n=94/472, (19.9%)) at 12 months with an adjusted odds ratio of 0.50 (95% CI 0.35 to 0.72). At 18 months the pattern was similar with 17.1% (n=84/490) in the FNP arm compared to 24.2% (n=110/455) in the usual care arm an adjusted odds ratio of 0.66 (95% CI 0.48 to 0.90). At the end of the trial period, maternally reported language development was better in the FNP arm compared to the usual care arm with mean (SD) Early Language Milestone percentiles of 60.8 (31.4) and 55.7 (31.4) respectively (adjusted difference in means of 4.49, 95% CI: 0.52 to 8.45).

Injuries / ingestions A greater proportion of children in the FNP arm than the usual care arm attended an Emergency Department (ED) for an injury or ingestion by six months (4.1% (n=30/731) and 2.8% (n=21/755) respectively; adjusted OR: 1.52, 95% CI: 0.86 to 2.70), and by 24 months of age (30.8% (n=222/721) and 27.8% (n=207/744) respectively; adjusted OR: 1.16, 95% CI: 0.92 to 1.46). However, a smaller proportion of children in the FNP arm were admitted to hospital with an injury or ingestion compared to the usual care arm by six months of age (1.9% (n=14/731) and 2.4% (n=18/756) respectively; adjusted odds ratio 0.79, 95% CI 0.39 to 1.60), and by 24 months (4.8% (n=35/722) and 6.6% (n=49/745) respectively; adjusted odds ratio: 0.72, 95% CI: 0.46 to 1.12). However, there was no statistical evidence of differences between trial arms for children with injuries and ingestions presenting to an ED or being admitted.

Social services referral At two years postpartum a greater proportion of participants in the FNP arm reported that their child had ever been referred to social services (n=119/580, 20.5%) compared to the usual care arm (n=91/541, 16.8%), an adjusted odds ratio of 1.27 (95% CI of 0.93 to 1.73).

Safeguarding Over the same time period, for the 945 children for whom data were available, a greater proportion of children in the FNP arm had a safeguarding event recorded in their GP record (n=64/469, 13.6%) compared to the usual care arm (n=38/476, 8.0%) an adjusted odds ratio of 1.85 (95% CI of 1.02 to 2.85).

Other outcomes There was no statistical evidence for differences between trial arms for any other maternal or parenting and child outcomes.

Parental life-course
See Table S7.3

NEET / employment / education For the period from birth to two years postpartum, there was no overall difference between trial arms in reported rates of either employment or education. However, at two years postpartum participants in the FNP arm reported lower rates of not being in employment, education or training (n=368/593, 62.1%) than in the usual care arm (n=388/557, 69.7%). At the same point in time, participants in the FNP arm reported higher rates of being in paid employment (n= 111/594, 18.7%) than in the usual care arm (n=88/559, 15.7%) but there was no statistical evidence for a difference. However, for both outcomes there was no overall difference between arms across the full follow-up period.

Connexions At six months postpartum participants in the FNP arm reported higher rates of access to the Connexions (employment) advisory service (n=159/483, 32.9%) than in the usual care arm (n=126/452, 27.9%) but there was no statistical evidence for a difference across the reporting period.

Visiting Children's Centre Although a larger proportion of participants in the FNP arm (n=206/584, 35.3%) reported at 24 months visiting a Children's Centre than in the usual care arm (n=149/538, 27.7%), there was no overall difference across the full follow-up period.

Contraception Reported contraceptive use at 24 months postpartum was 72.6% (n=432/595) in the FNP arm and 67.9% (n=379/558) in the usual care arm. However, across the whole period up two years the odds of contraceptive use by participants in the FNP arm compared to the usual care arm was 1.25 (95% CI: 0.98 to 1.60).

Social support A larger proportion of participants in the FNP arm reported a maximum level of social support at 18 months postpartum (n=127/495, 25.7%) compared to those in the usual care arm (n=93/459, 20.3%) with a similar difference at 24 months (27.9% (n=162/581) v 23.1% (n=123/533)). Across the whole follow-up period there was a small difference between arms with an odds ratio of 1.50 (95% CI: 1.06 to 2.12). Similarly with relationship quality, a small difference was observed between arms in relationship quality score with an adjusted difference in means of 0.17 (95% CI: 0.28 to 1.20).

Homelessness 30.4% (n=123/405) of participants in the FNP arm reported ever being homeless in the period from study entry to 24 months postpartum compared to 36.3% (n=136/375) in the usual care arm (adjusted odds ratio of 0.76, 95% CI: 0.55 to 1.05).

Self-efficacy Across the full follow-up period there was a small difference between arms for self-efficacy score of 0.44 (95% CI: 0.10 to 0.78) with higher reported levels in the FNP arm.

Other outcomes There was no statistical evidence for differences between trial arms for any other maternal outcome.

8. Representativeness of study sample

Scope and purpose: We assessed whether women allocated to the intervention were similar to women currently being enrolled into FNP across sites in England. We compared baseline demographic characteristics using summary data sourced from the FNP's own clinical information system. Aggregate data for non-trial FNP clients enrolled to the program from the 1st January 2010 to the 31st of December 2013 were obtained for both non-trial sites (n=8755) and trial sites outside of the trial recruitment phase (n=3311). Note that the data reported are FNP management data, which is why we only compare Intervention arm trial participants to non-trial participants. These data are also therefore not directly comparable to data presented elsewhere (for example, smoking data at baseline).

Comparisons: The three groups are similar in terms of mean maternal age at enrolment (Table S8.1). Mean weeks gestation at enrolment was slightly higher for trial clients than for women enrolled at non-trial sites, but slightly lower than the mean gestation for non-trial clients enrolled at trial sites. The proportion of women enrolled by 16 weeks gestation was similar in both trial (39.7%) and non-trial (41.6%) clients at trial sites and in both cases lower than that achieved at non-trial sites (48.9%). Whilst the proportion of ethnically white women was slightly higher amongst trial clients than in non-trial site clients (85.5% and 82.9% respectively), it was lower amongst non-trial clients enrolled at trial sites (77.5%). The proportion of women not in education, employment or training (NEET) was higher amongst trial clients (68.1%) than non-trial clients at the same sites (60.5%), and also higher than that found for non-trial site clients (63.3%). Rates of recent smoking recorded at intake were also highest for trial clients (40.8%) compared to non-trial clients at the same sites (32.9%) and at non-trial sites (34.0%).

Conclusion: While there are some differences between women recruited to the trial (and enrolled in FNP) and women enrolled in FNP but not participating in the trial (either enrolled subsequent to the end of the trial period or at a non-trial site), the sample is broadly representative of women expected to receive the intervention.

Table S8.1 FNP client characteristics at enrolment: Building Blocks clients, non-trial clients (from trial sites) and non-trial clients (from non-trial sites)

	FNP Clients RCT N=718*	**FNP Programme non-RCT (RCT sites only) N=3311**	**FNP Programme non-RCT (non RCT sites only) N=8755**
Mean age (years)	17.4	17.2	17.3
Mean gestation at enrolment (weeks)	17.9	18.2	17.4
Mean gestation at birth (weeks)	39.4	39.2	39.1
Premature infants (%)	7.5	7.8	7.4
Enrolled by 16 weeks gestation (%)	39.7	41.6	48.9
Ethnicity (%)			
White background	85.5	77.5	82.9
Mixed background	5.7	5.0	5.0
Asian background	2.1	3.4	1.4
Black background	3.6	7.1	4.9
Other background	0.4	1.7	1.2
Missing	2.7	5.3	4.6
NEET (16+ only) (%)	68.1	60.5	63.3
Relationship status (%)			
With a current partner	79.5	76.6	76.4
With biological father of child	100	95.0	95.9
Relationship status recorded	*97.4*	*94.8*	*95.5*
Living (%)			
Living with own mother not including husband/ partner	45.0	43.8	45.1
Living with own mother including husband/ partner	10.2	8.5	8.7
Living with other adults	9.5	9.3	9.6
Living with foster parents	1.4	1.5	1.2
Living with husband/partner only	11.0	10.4	10.5
Living with husband/partner and others (not own mother)	7.8	6.7	7.4
Living alone	6.8	7.3	6.5
Living in a group home/shelter	4.3	5.1	4.7
Homeless	1.8	2.1	1.7
Living arrangements recorded	*97.8*	*94.8*	*95.4*
Smoking at intake			
Smoked (in last 48 hours) (%)	40.8	32.9	34.0
Smoked (in last 48 hours) recorded (%)	*96.1*	*93.3*	*92.8*
Mean number of cigarettes/smoked in last 48 hrs	4.5	4.2	4.2

* 718 clients included, 3 could not be included in the dataset from the FNP IS as they did not have any recoded data

9. Assessment of loss to follow-up – self-report at 24 months

Table S9.1 provides an overview of how the trial sample was affected by loss to follow-up by self-report interview at 24 months and how that differed by trial arm. Amongst those who were lost to follow up, there were no differences between trial arms by age or by ethnicity. However, the proportion of women closely involved / with a boyfriend was greater in the FNP arm compared to the usual care arm (75.6% vs 68.1%). Similarly, the proportion of women living with the father of their baby was greater in the FNP arm than the usual care arm (26.8% vs 20.7%). There was a small difference in the proportion of women either not employed, in education or training between FNP and usual care arms (56.8% vs 52.5%) and a similarly small difference for deprivation score (mean IMD scores of 41.4 vs 39.2). There was no difference between trials arms for baseline self-efficacy scores. There was a small difference between FNP and usual care arms for those reporting difficulty with basic skills (35.7% vs 29.5%) but no differences on life skills or having a life burden. Finally, the proportion reporting smoking was similar between FNP and usual care arms. Overall this may suggest that women who are in a significant relationship and who are more vulnerable are more likely to disengage from the trial if they are allocated to FNP.

Table S9.1 Assessment of attrition: participant baseline characteristics by follow-up at 24 month completion by trial arm

	All participants (1618)		Participants lost to follow-up (464)		Remaining participants (1154)	
	FNP (n=808)	**Usual Care (n=810)**	**FNP (n=213)**	**Usual Care (n=251)**	**FNP (n=595)**	**Usual Care (n=559)**
Age in years						
Median	17.8	17.8	17.7	17.7	17.9	17.9
(25th to 75th centile)	(17.0 to 18.8)	(16.9 to 18.8)	(17.0 to 18.6)	(16.8 to 18.7)	(17.0 to 18.8)	(16.9 to 18.8)
Ethnicity						
White background	711 (88.0)	714 (88.1)	185 (86.9)	214 (85.3)	526 (88.4)	500 (89.4)
Mixed background	47 (5.8)	42 (5.2)	11 (5.2)	16 (6.4)	36 (6.1)	26 (4.7)
Asian background	16 (2.0)	11 (1.4)	2 (0.9)	4 (1.6)	14 (2.4)	7 (1.3)
Black background	31 (3.8)	40 (4.9)	13 (6.1)	16 (6.4)	18 (3.0)	24 (4.3)
Other background	3 (0.4)	3 (0.4)	2 (0.9)	1 (0.4)	1 (0.2)	2 (0.4)
Relationship status with baby's father						
Married	9 (1.1)	11 (1.4)	4 (1.9)	4 (1.6)	5 (0.8)	7 (1.3)
Separated	79 (9.8)	86 (10.6)	23 (10.8)	39 (15.5)	56 (9.4)	47 (8.4)
Closely involved/boyfriend	613 (75.9)	609 (75.2)	161 (75.6)	171 (68.1)	452 (76.0)	438 (78.4)
Just friends	107 (13.2)	104 (12.8)	25 (11.7)	37 (14.7)	82 (13.8)	67 (12.0)
Live with father of baby						
Yes	184 (22.8)	184 (22.7)	57 (26.8)	52 (20.7)	127 (21.3)	132 (23.6)
No	552 (68.3)	560 (69.1)	134 (62.9)	169 (67.3)	418 (70.3)	391 (69.9)
Missing	72 (8.9)	66 (8.1)	22 (10.3)	30 (12.0)	50 (8.4)	36 (6.4)
NEET status*:	N=697	N=667	N=183	N=200	N=514	N=487
Yes	333 (47.8)	330 (49.5)	104 (56.8)	105 (52.5)	229 (44.6)	225 (46.2)
No	362 (51.9)	335 (50.2)	79 (43.2)	93 (46.5)	283 (55.0)	262 (53.8)
Missing	2 (0.3)	2 (0.3)	0 (0.0)	2 (1.0)	2 (0.4)	0
Index of Multiple Deprivation Score†	N=802	N=804	N=213	N=250	N=589	N=554
Median	39.1	39.2	41.3 (29.3 to 53.4)	39.2	38.3	39.2
(25th to 75th centile)	(24.9 to 52.3)	(25.5 to 51.6)		(25.4 to 50.9)	(23.5 to 52.2)	(29.5 to 51.7)
Generalized self-efficacy scale (score 10 to 40) §	N=798	N=794	N=211	N=245	N=587	N=549
Median	30.1	29.9	29.5	29.7	30.3	29.9
(25th to 75th centile)	(28.0 to 33.0)	(27.0 to 32.0)	(27.0 to 32.0)	(28.0 to 32.0)	(28.0 to 33.0)	(27.0 to 33.0)
Adaptive functioning						
Difficulty in at least one basic skill						
Yes	230 (28.5)	200 (24.7)	76 (35.7)	74 (29.5)	154 (25.9)	126 (22.5)
No	577 (71.4)	608 (75.1)	136 (63.8)	176 (70.1)	441 (74.1)	432 (77.3)
Missing	1 (0.1)	2 (0.2)	1 (0.5)	1 (0.4)	0 (0.0)	1 (0.2)
Had 3 or less life skills (out of 5)						
Yes	205 (25.4)	229 (28.3))	69 (32.4)	79 (31.5)	136 (22.9)	150 (26.8)
No	599 (74.1)	579 (71.5	141 (66.2)	172 (68.5)	458 (76.9)	407 (72.8)
Missing	4 (0.5)	2 (0.2)	3 (1.4)	0 (0.0)	1 (0.2)	2 (0.4)
At least one burden						
Yes	228 (28.2)	248 (30.6)	60 (28.2)	71 (28.3)	168 (28.2)	177 (31.7)
No	573 (70.9)	558 (68.9)	152 (71.4)	179 (71.3)	421 (70.8)	379 (67.8)
Missing	7 (0.9)	4 (0.5)	1 (0.4)	1 (0.4)	6 (1.0)	3 (0.5)
Smoking (Participant self-reported)						
Ever smoked	649 (80.3)	645 (79.6)	174 (81.7)	200 (79.7)	475 (79.8)	445 (79.6)

	All participants (1618)		Participants lost to follow-up (464)		Remaining participants (1154)	
	FNP (n=808)	**Usual Care (n=810)**	**FNP (n=213)**	**Usual Care (n=251)**	**FNP (n=595)**	**Usual Care (n=559)**
Never smoked	159 (19.7)	165 (20.4)	39 (18.3)	51 (20.3)	120 (20.2)	114 (20.4)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Values are N (%) unless otherwise stated

* Definition of NEET status: Not in education employment or training (applicable only to those whose age at end of previous academic year at time of baseline interview was >16)

† Higher IMD score indicated more deprivation

§ Higher score indicates higher level of self-efficacy

10. Attrition to primary smoking analysis

Table S10.1 provides an overview of how the trial sample was affected by loss to follow-up for the main smoking analysis. There was no difference between trials arms in those not included in the analysis by age. There was a small difference in ethnicity, with more women from a white background not included in the FNP arm (90.4%) compared to the usual care arm (86.4%). More women at baseline who were closely involved / with a boyfriend were not included in analysis in the FNP (76.6%) compared to the usual care arm (67.5%). There was also a small difference in the proportion of women who at baseline lived with the father of their baby who were not included in analysis between FNP (26.4%) and usual care arm (22.6%). There was a small difference in the proportion of women either not employed, in education or training between FNP (57.5%) and usual care (53.1%) arms not included in analysis. There was a difference in the proportion of women reporting difficulty in at least one basic skill at baseline not included in the analysis between FNP (36%) and usual care (27.9%) arms. There were no other group differences observed. Similar to the assessment of attrition at 24 months, this may suggest that women who are in a significant relationship and who are more vulnerable are more likely to disengage from the trial if they are allocated to FNP.

Table S10.1 Assessment of attrition: participant baseline characteristics by inclusion in smoking analysis

	All participants (1618)		Not in primary smoking analysis (526)		In Primary Analysis (1092)	
	FNP (n=808)	**Usual Care (n=810)**	**FNP (n=261)**	**Usual Care (n=265)**	**FNP (n=547)**	**Usual Care (n=545)**
Age in years						
Median	17.8	17.8	17.9	17.9	17.9	17.8
(25^{th} to 75^{th} centile)	(17.0 to 18.8)	(16.9 to 18.8)	(17.0 to 18.6)	(17.0 to 18.7)	(17.0 to 18.8)	(16.9 to 18.8)
Ethnicity						
White background	711 (88.0)	714 (88.1)	236 (90.4)	229 (86.4)	475 (86.8)	485 (89.0)
Mixed background	47 (5.8)	42 (5.2)	13 (5.0)	14 (5.3)	34 (6.2)	28 (5.1)
Asian background	16 (2.0)	11 (1.4)	1 (0.4)	8 (3.0)	15 (2.7)	3 (0.6)
Black background	31 (3.8)	40 (4.9)	10 (3.8)	14 (5.3)	21 (3.8)	26 (4.8)
Other background	3 (0.4)	3 (0.4)	1 (0.4)	0 (0.0)	2 (0.4)	3 (0.6)
Relationship status with baby's father						
Married	9 (1.1)	11 (1.4)	2 (0.8)	6 (2.3)	7 (1.3)	5 (0.9)
Separated	79 (9.8)	86 (10.6)	34 (13.0)	31 (11.7)	45 (8.2)	55 (10.1)
Closely involved/boyfriend	613 (75.9)	609 (75.2)	200 (76.6)	179 (67.5)	413 (75.5)	430 (78.9)
Just friends	107 (13.2)	104 (12.8)	25 (9.6)	49 (18.5)	82 (15.0)	55 (10.1)
Live with father of baby						
Yes	184 (22.8)	184 (22.7)	69 (26.4)	60 (22.6)	115 (21.0)	124 (22.8)
No	552 (68.3)	560 (69.1)	168 (64.4)	174 (65.7)	384 (70.2)	386 (70.8)
Missing	72 (8.9)	66 (8.1)	24 (9.2)	31 (11.7)	48 (8.8)	35 (6.4)
NEET status*:	N=697	N=667	N=219	N=224	N=478	N=463
Yes	333 (47.8)	330 (49.5)	126 (57.5)	119 (53.1)	207 (43.3)	211 (45.6)
No	362 (51.9)	335 (50.2)	92 (42.0)	103 (46.0)	270 (56.5)	252 (54.4)
Missing	2 (0.3)	2 (0.3)	1 (0.5)	2 (0.9)	1 (0.2)	0 (0.0)
Socio-economic status:						
Overall Index of Multiple Deprivation Score†	N=802	N=804	N=260	N=263	N=542	N=541
Median	39.1	39.2	39.8	41.3	37.0	37.6
(25^{th} to 75^{th} centile)	(24.9 to 52.3)	(25.5 to 51.6)	(27.6 to 53.7)	(26.4 to 52.6)	(23.5 to 51.8)	(25.3 to 51.3)
Generalized self-efficacy scale§ (score 10 to 40)	N=798	N=794	N=258	N=255	N=540	N=539
Median	30.1	29.9	30	30	30	30
(25^{th} to 75^{th} centile)	(28.0 to 33.0)	(27.0 to 32.0)	(28 to 33)	(28 to 33)	(28 to 33)	(27 to 32)
Difficulty in at least one basic skill						
Yes	230 (28.5)	200 (24.7)	94 (36.0)	74 (27.9)	136 (24.9)	126 (23.1)
No	577 (71.4	608 (75.1)	166 (63.6)	190 (71.7)	411 (75.1)	418 (76.7)
Missing	1 (0.1)	2 (0.2)	1 (0.4)	1 (0.4)	0 (0)	1 (0.2)
Had 3 or less life skills (of 5)						
Yes	205 (25.4)	229 (28.3)	86 (33.0)	87 (32.8)	119 (21.8)	142 (26.1)
No	599 (74.1)	579 (71.5)	171 (65.5)	177 (66.8)	428 (78.2)	402 (73.8)

Table S10.1 Assessment of attrition: participant baseline characteristics by inclusion in smoking analysis

	All participants (1618)		Not in primary smoking analysis (526)		In Primary Analysis (1092)	
	FNP (n=808)	**Usual Care (n=810)**	**FNP (n=261)**	**Usual Care (n=265)**	**FNP (n=547)**	**Usual Care (n=545)**
Missing	4 (0.5)	2 (0.2)	4 (1.5)	1 (0.4)	0 (0)	1 (0.2)
At least one burden						
Yes	228 (28.2)	248 (30.6)	77 (29.5)	83 (31.3)	151 (27.6)	165 (30.3)
No	573 (70.9)	558 (68.9)	182 (69.7)	180 (67.9)	391 (71.5)	378 (69.4)
Missing	7 (0.9)	4 (0.5)	2 (0.8)	2 (0.8)	5 (0.9)	2 (0.4)
Smoking						
Ever smoked	649 (80.3)	645 (79.6)	215 (82.4)	220 (82.6)	433 (79.2)	424 (77.8)
Never smoked	159 (19.7)	165 (20.4)	46 (17.6)	46 (17.4)	114 (20.8)	121 (22.2)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Values are N (%) unless otherwise stated

***** Definition of NEET status: Not in education employment or training (applicable only to those whose age at end of previous academic year at time of baseline interview was >16)

† Higher IMD score indicated more deprivation

§ Higher score indicates higher level of self-efficacy

11. Delivery of FNP against program fidelity goals

Note: Family Nurse Partnership Management Manual (2012) clarifies fidelity targets for (i) Recruitment and enrolment (ii) Attrition (iii) Dosage and (iv) Programme Content.

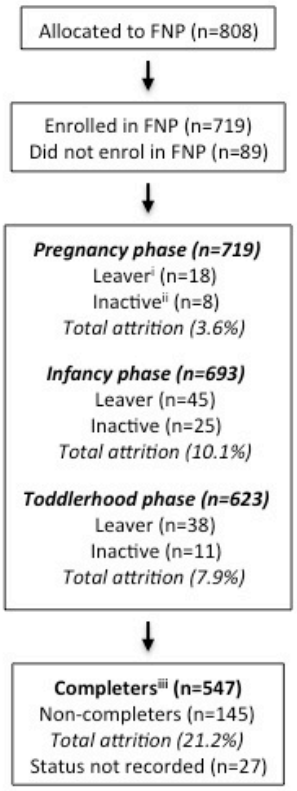
We assessed intervention implementation against FNP Core Model Elements and Fidelity goals using programme monitoring data and trial recruitment records. FNP clients met programme eligibility criteria and a high proportion of women (75%) offered FNP enrolled. The proportion of participants enrolled onto the programme by 16 weeks gestation (39.7%) was lower than targeted (60%) but similar to that observed at the same trial sites in the two and a half year period subsequent to the end of trial recruitment (41.6%). The mean number of valid visits received by phase (9.71, 18.63 and 13.22) was lower than targeted (14, 28 and 22) but greater than observed in the English implementation evaluation, and the first two US NFP trials. The proportion of participants who completed the programme meeting or exceeding target rates of expected visits (Pregnancy: 80%, Infancy: 65% and Toddlerhood: 60%) were 57.7%, 53.0% and 43.6% respectively. Rates of programme attrition by phase were 3.6%, 10.1% and 7.9% respectively with a cumulative attrition rate of 21.2%, well within the maximum acceptable rates (by phase:10%, 20%, 10%, overall: 40%). On average, visits were 79.14 minutes in duration, approximately 30% longer than the target minimum of 60 minutes. Nurse-reported programme content was broadly in line with prescribed targets although with a greater emphasis upon Environmental health in each phase and with less variability in overall domain coverage than indicated by independent rating of consultation recordings.

Table S11.1 Fidelity goal: Enrolment into FNP program

Fidelity goal	Available evidence
At least 60% of clients enrolled into FNP by 16th week pregnancy, 100% no later than 28 weeks	Of the 718 trial participants allocated to FNP who could be linked to enrolment data from the FNP IS, 285 (39.7%) were enrolled by 16 weeks gestation. *We also reviewed aggregate data for all FNP clients enrolled at the same trial sites (n=3311) and FNP clients at non-trial sites in England (n=8755) enrolled outside of the trial recruitment window (1st January 2010 to 31st December 2013). The proportions of women enrolled by the 16th week of pregnancy in these two groups were 41.6% and 48.6% respectively.*
100% clients are first-time mothers, within specified site age bracket	Ensured by trial eligibility criteria
75% of eligible clients offered program enrolled	710 of 808 women randomised to FNP enrolled on the program (89%)
Each nurse enrols 25 families (or pro rata adjusted) within 12 months of recruitment commencing	No evidence available to trial team

Fidelity goal: Cumulative attrition is 40% or less through to child's second birthday (and 10% / 20% / 10% or less during pregnancy, infancy, toddlerhood phases respectively).

Table S11.2 Fidelity goal: Attrition from FNP by phase



(i) Client has moved out of service area as indicated by completing the FNP data collection form UK004B.

(ii) Recorded in UK004B as 'INACTIVE' and INACTIVE COMPLETERS'. INACTIVE means that the client has had no Family Nurse contact for 6 months and INACTIVE COMPLETERS are clients for whom 2 years has passed after infant date of birth and the client is in a programme status of INACTIVE.

(iii) Client has completed the FNP programme, as indicated by completing the UK004B form.

Dosage

Fidelity goal: Average home visit with participants is 60 minutes or longer in duration. ***Evidence:*** The average nurse-reported duration of valid visits was 79 minutes.

Fidelity goal: Clients receive 80% / 65% / 60% or more of expected visits during pregnancy, infancy, toddlerhood phase respectively.

Table S11.3 Fidelity goal: program dosage - valid visits per phase for n=719 women

Phase	Pregnancy	Infancy	Toddlerhood
N (%) women receiving at least one valid visit	713 (99.2%)	669 (93.0%)	606 (84.3%)
Median (25^{th} to 75^{th} centile) valid visits received	10 (8 to12)	19 (14.5 to 22)	13 (8 to 16)
Mean (sd) valid visits received	9.71 (3.45)	18.63 (6.04)	13.22 (1.49)
Range valid visits received	1 to 20	1 to 44	1 to 37
N (%) women not receiving a single valid visit N (%)	6* (0.8%)	28 (3.9%)	81 (11.3%)
N (%) withdrew in previous phase	NA	22 (3.1%)	32 (4.5%)

* Reasons for the total of 9,504 non-valid visits: i) Visit encounter form not completed (n=12, 0.1%), ii) visit not completed (n=8,887, 93.5%), visit <15 minutes duration (n=62, 0.7%), iii) visit without client present (n=284, 3.0%), iv) visit scheduled and subsequent to another scheduled visit (n=259, 2.7%). Visits excluded using hierarchy of reasons ordered above (i-iv), in some cases visit may have been excluded due to more than one reason.

Programme content

Fidelity goal: Home visit content reflects variation in developmental needs by programme phase (within specific ranges).

Table S11.4 Fidelity goal: program content - nurse-reported visit domain coverage during pregnancy, infancy and toddlerhood

Delivery phase		Personal Health	Maternal Role	Friends and Family	Life Course	Environmental Health
Pregnancy	***Target***	***35-40%***	***23-25%***	***10-15%***	***10-15%***	***7-10%***
N=713[i]	Median	34.7	25.8	15.0	12.7	12.3
	(25^{th} to 75^{th} centiles)	(27.6 to 39.5)	(22.9 to 29.1)	(12.9 to 18.5)	(10.0 to 15.2)	(9.5 to 16.0)
	Mean (SD)	33.7 (7.8)	26.0 (5.6)	15.7 (4.4)	13.0 (4.3)	12.9 (4.7)
Infancy	***Target***	***14-20%***	***45-50%***	***10-15%***	***10-15%***	***7-10%***
N=669[ii]	Median	20.9	40.5	14.1	12.3	12.3
	(25^{th} to 75^{th} centiles)	(18.6 to 24.3)	(35.0 to 46.0)	(11.7 to 16.7)	(10.0 to 15.0)	(10.1 to 15.7)
	Mean (SD)	21.8 (5.1)	40.3 (8.2)	14.5 (3.8)	12.4 (3.7)	13.1 (4.1)
T'hood	***Target***	***10-15%***	***40-45%***	***10-15%***	***18-20%***	***7-10%***
N=606[iii]	Median	17.1	40.5	14.7	15.0	13.0
	(25^{th} to 75^{th} centiles)	(14.1 to 20.8)	(35.7 to 44.5)	(12.8 to 17.4)	(12.2 to 18.0)	(10.5 to 16.4)
	Mean (SD)	17.8 (5.8)	40.2 (8.0)	15.2 (3.8)	15.0 (4.7)	13.7 (5.2)

(i) N=3 participants did not receive a valid visit in the pregnancy phase, (ii) N=21 withdrawals in the pregnancy phase, N=26 participants did not receive a valid visit in the infancy phase, (iii) N=30 withdrawals in the pregnancy or infancy phase, N=80 participants did not receive a valid visit in the toddler phase

12. Withdrawals and adverse events

Table S12.1 Summary of withdrawals by treatment allocation and reported Serious Adverse Events (SAEs)

Reason for withdrawal	FNP	Usual Care	Total
Mandatory*			
Ineligible	3	2	5
Miscarriage / Termination of pregnancy	24	27	51†
Stillbirth / neonatal / infant death	5	7	12
Death of mother infant pair	1	0	1
Adoption of child	7	7	14
Elective			
No longer wished to take part in the trial	46	36‡	82
Did not wish to commit to FNP programme	15	0	15
Moved outside FNP area	0	1	1
Adoption planned following birth	0	1	1
No reason given	9	2	11
Total	**110**	**83**	**193**

* Due to the nature of antenatal and infancy care, including frequent hospitalisations, during the trial many trial participants or their child incurred a Good Clinical Practice defined Serious Adverse Event (SAE). A total of 1315 SAEs (primarily clinical events associated with pregnancy and infancy period) were reported with 667 (41.2%) of participants (mother or child) having at least one event, 310 in the usual care arm, and 357 in the FNP arm. Throughout the trial period none of the SAEs were considered by the trial management group to have been FNP related.

† Includes miscarriages, terminations and termination of molar pregnancy

‡Includes one woman who did not wish to continue as not allocated FNP

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