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Evaluation of the Family Nurse Partnership in Scotland:

A natural experiment using routine data

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Executive Summary

Background

This report presents the results of the natural experiment of the Family Nurse Partnership (FNP) programme commissioned by the Scottish Government. The Nurse Family Partnership (NFP) is a licensed intensive home visiting programme for first time young mothers developed in the United States and introduced into Scotland in 2010 following initial adaptation, at which point it became known as the FNP in Scotland. The programme is provided from early pregnancy until the child's second birthday. It follows a schedule of home visits to promote better pregnancy and birth outcomes, improve child health and development, and improve maternal life course. The natural experiment forms part of a programme of work establishing the evidence base for FNP in Scotland. It is intended to complement previous formative work in NHS Lothian and nationally addressing feasibility, acceptability, the plausibility of generating benefits and perceived programme value. Following an evaluability assessment (EA) which explored options for an impact evaluation, a natural experiment using linked routine data was commissioned.

Methods

A report describing in full the methods of the natural experiment and the process and success with linking data has been published previously[1]. The natural experiment involved linked anonymised routine health, education and social care data comparing outcomes between FNP Clients and Controls[2]. The cohort included 8,118 young mothers: 3,203 FNP Clients and 4,915 Controls. FNP Clients were women enrolled onto the FNP programme between January 2010 and March 2016 in one of ten Scottish Health Boards offering FNP at that time and their first-born child(ren). Controls were mothers and their first-born child(ren) eligible for FNP but with an antenatal booking date outside of FNP recruitment periods, between January 2009 and March 2016. The proportion of the cohort included in the analysis for each outcome varied according to records available through each data source. The selection of study outcomes was based on programme aims in the Scottish FNP logic model and the underlying programme theory. All comparative analyses were pre-specified and conducted on an intention to treat basis, i.e. the analysis included all young mothers who were enrolled in FNP programme regardless of the number of visits they received.

Key findings

Tested outcomes

Maternal outcomes: There were no statistically significant differences found for maternal use of alcohol or drugs during pregnancy. There were no statistically significant differences in time between first and subsequent pregnancy or birth. There were no differences between groups in the rates of mothers with a subsequent birth within 2 years of having her first child.

Child outcomes: Rates of breast feeding were statistically significantly higher in the FNP group at 10-14 days and persisted at 6-8 weeks post-partum, whilst no significant differences were found for breastfeeding initiation (first feed). There was no statistically significant difference in duration of breastfeeding among a small cohort of women with dates recorded for ceasing breastfeeding. There was a statistically significant reduction in the child's exposure to second hand smoke over time in the FNP group compared to the Control group, with a greater reduction seen in the FNP group earlier (between 10-14 days and 6-8 weeks) compared to Controls (between 6-8 weeks and 27-30 months). There were no statistically significant differences in rates of pre-term delivery before 37 weeks gestation between groups. A significantly higher proportion of children in the Controls had any newly suspected child development concerns recorded at 27-30 months, with no other differences in any other child development outcomes.

Rates of children achieving their age relevant attainment level (P1, 5-6 year olds and P4, 8-9 year olds) for Reading, Writing, Listening and Talking, Literacy, and for Numeracy were not statistically different between study groups. Sensitivity analyses on achieving age related P1 Level supported the findings of the primary analysis but found a significant differential FNP programme effect in Reading for sex, and by HB. Statistically significantly more children in the FNP group were registered with a dentist by aged 2 years, while attendance rates by 27-30 months were the same in both groups. There was no evidence of a statistically significant difference between groups in time to first dental admission. There were no statistically significant differences between groups for other measures of child health including being of a healthy weight at 27-30 months or at the Primary 1 review, being admitted to hospital with an unintentional injury in the home by age 2 and 5 years, time to first accident and emergency (A&E) attendance with an accidental injury or time to first hospital admission for a serious injury. There were no statistically significant differences between groups in the age of a child's first child protection investigation, or the

number of child protection investigations per child up to the age of five, or in the average number of days a child spent on the child protection register.

Descriptive outcomes

Maternal outcomes: A higher proportion of children born to FNP Clients attended any childcare by the 27–30-month review compared to children born to women in the Control group. FNP Clients that were recorded as leaving school after their antenatal booking date remained in school for a longer duration than Controls. In a reduced cohort of women that returned or remained in education following antenatal booking, more FNP Clients had gained their highest educational achievement at Scottish Credit and Qualifications Framework (SCQF) at Level 5 or above compared to Controls. Subsequent pregnancies by 24 months postpartum were comparable by study group.

Child outcomes: There were comparable proportions of children born extremely pre-term, very pre-term and moderately pre-term in both groups. Birthweights were comparable between babies of FNP Clients and Controls. Rates of admission for serious injuries were similar across study groups at six months, one, two and five years. Unadjusted rates of attendances to A&E (for any reason) were slightly higher in the FNP group compared to Control group. The same pattern was seen for rates of attendances to A&E specifically for accidental injuries. The proportion of children that were subject to a child protection investigation before the age of two and five were rare. Children in the FNP group were subject to a child protection investigation at greater numbers in pregnancy and up to age 2 years, whereas children in the Control group were much more frequently subject to an investigation after age 2 years. A higher proportion of children in the FNP group required a pre-birth or initial review case conference with a similar proportion of children registered. The type of concern identified at case conferences differed between groups with higher proportions of domestic abuse recorded in the FNP group and emotional or physical abuse in Controls. Similar rates of registered children had been deregistered by the end of the five years follow up and spent a similar number of days on the protection registered. The rate of children with at least one care placement was low. Children were placed in care earlier in the FNP group compared to the Control group. Placement type differed slightly

between groups; more Controls had a destination type of at home with biological parents compared to FNP.

Concluding comments

There were few statistically significant differences in outcomes between FNP Clients and Controls. Differences in favour of FNP were generally small but were consistent with other FNP evaluations. Descriptive comparisons offer insight to service providers and stakeholders about prevalence rates but the uncorrected effects of both observed and unobserved confounders merits these being treated with caution. Little variation was found in programme impact by year of booking, by health board or pre-selected subgroups. Variability in data availability, quality and method of collection should be considered when interpreting findings, as should the number of tested comparisons. As the study used only routine data, other outcomes of relevance to FNP could not be assessed but remain of importance.

Abbreviations

Acronym	Definition
A&E	Accident and Emergency
ACEL	Achievement of Curriculum for Excellence (CfE) Levels
aHR	Adjusted hazard ratio
aOR	Adjusted odds ratio
BMI	Body Mass Index
CC	Case Conference
CfE	Curriculum for Excellence
CHSP	Child Health Surveillance Programme
CI	Confidence Interval
CLAC	Looked After Children Longitudinal (CLAC) dataset
CME	Core model elements
EA	Evaluability Assessment
EAS	Education Analytical Services
eDRIS	electronic Data Research and Innovation Service
FG	Fidelity Goals
FNP	Family Nurse Partnership
FNP SIS	FNP Scottish Information System
HBs	Health Boards
HR	Hazard Ratio
ICD10	International Statistical Classification of Diseases and Related Health Problems -10th Revision
IQR	Interquartile Range
IRR	Incidence Rate Ratio
ITT	Intention To Treat

Acronym	Definition
LAC	Looked after child
LMP	Last Menstrual Period
MICE	Multiple Imputation Chained Equation
NFP	Nurse Family Partnership
NNU	Neonatal unit
NRS	National Records of Scotland
OPCS	Classification of Interventions and Procedures
OR	Odds Ratio
P1	Primary 1 (5-6 year olds)
P4	Primary 4 (8-9 year olds).
PBPP	Public Benefit and Privacy Panel
PS	Pre-School
SAP	Statistical Analysis Plan
SCQF	Scottish Credit and Qualifications Framework
SD	Standard Deviation
SIMD	Scottish Index of Multiple Deprivation
SMR	Scottish Morbidity Record

Key Definitions

FNP – Family Nurse Partnership: A licensed US programme known as the Nurse Family Partnership (NFP), which has been adapted in the UK and is known as the Family Nurse Partnership in the UK context. FNP offers intensive, structured home visiting support to first-time young mothers delivered by a specially trained nurse, from early pregnancy until the child's second birthday.

FNP Clients – Young mothers in Scotland expecting their first child who were offered and enrolled to receive FNP.

Controls – Young mothers in Scotland expecting their first child who were not offered FNP but would have been eligible if available.

Data linkage – Data linkage is the process of joining together records that pertain to the same entity, such as a person or business[a].

[a] https://www.ons.gov.uk/methodology/methodologicalpublications/generalmethodology/onsworkingpaperseries/developingstandardtoolsfordatalinkagefebruary2021

Section 1: Introduction

The Family Nurse Partnership

The individual, social and economic circumstances faced by many young mothers present a challenge to a successful start in life for their children and may interrupt the mother's long term economic stability[3]. As such, children of young mothers are more likely to have lower birth weight, not be breastfed, be at greater risk of accidents and early death, do worse educationally, have more emotional and behavioural problems, and become young parents themselves[4–7].

Promoting the healthy development and safety of children is a policy priority in Scotland[8]. Intervention early in the lives of families with young mothers might enhance life chances for both mother and child. The Family Nurse Partnership (FNP) was developed in the USA as the Nurse Family Partnership (NFP) – an intensive preventative home visiting intervention delivered by specially recruited and trained nurses[9]. NFP is available across more than 40 states and provides a service to over 60,000 families annually in the USA[10]. The programme was formally adapted for use under license in the UK. FNP offers home-visiting support to women aged 19 and under and expecting their first child, from early pregnancy until their child's second birthday. Potential programme clients are identified at booking via local maternity systems and referrals are made to local FNP teams. The FNP team make contact to offer participation in the programme and enrol the mother as a client if they meet the programme enrolment criteria and want to participate in the programme.

Evaluating the programme

Three trials in the US demonstrated programme improvements in prenatal health behaviours, birth outcomes, maternal life-course and child development[11–13]. Key positive outcomes observed in two or more of the NFP trials included a reduction in smoking in pregnancy[11,12]; reduced neonatal risk factors (e.g. birth weight); increased initiation and engagement with breastfeeding; reduced visits and hospitalisations for injuries and ingestions[13,14]; greater interval between pregnancies and second births[13,15,16] and greater workforce participation[11,16].

Following the adaptation of NFP to the UK setting, the Building Blocks trial evaluated FNP in England between 2009 and 2014 and found no difference on four primary short-term outcomes: birth weight of the baby, maternal tobacco use in late pregnancy, emergency

attendances and hospital admissions for the child within 24 months post-partum, and proportion of women with a second pregnancy within 24 months post-partum[17]. Some differences were found in favour of FNP for secondary outcomes related to maternally reported child development outcomes. Medium-term programme impacts (up to age 7 years) measured using routine data linked to the Building Blocks trial cohort, found no overall difference between groups for maltreatment outcomes aside from a longer duration in care for children in the usual care group (of two months)[18].

However, there was evidence of programme benefit for school readiness (e.g., achieving a good level of development by the end of the reception year) and attainment (reading) by seven years of age. Furthermore, there were subgroup differences showing improvements in writing by age seven years for children of mothers with greater disadvantage at baseline (being younger, not being in employment, education, or training) and for boys. This was consistent with previously reported patterns of benefit from US trials[19].

The adapted programme in the Netherlands, VoorZorg, reported a reduction in smoking during pregnancy and two-months post-partum and more women in the intervention group were breastfeeding their baby at six months post-partum. Birth weight and gestational age were similar in both groups[20]. However, it should be noted that women recruited into VoorZorg by non-independent programme nurses who screened for up to nine additional risk factors (e.g., history or presence of domestic violence, financial problems)[21]. This contrasts with the broader eligibility applied in the Building Blocks trial in England and to enrolment to FNP in Scotland.

FNP in Scotland and its evaluation

Following preparatory work in 2009, FNP was introduced into Scotland in 2010 for initial feasibility and acceptability testing in NHS Lothian Health Board and then extended to a further nine health boards (HBs) across Scotland[22]. The evaluation in NHS Lothian aimed to determine whether the programme was being implemented as intended, how the programme operates in Scotland (Lothian) and the plausibility of FNP to impact upon short, medium and long-term outcomes and, in particular, those of relevance to Scotland[23]. The evaluation identified implementation issues that if addressed could improve chances of success in broader programme rollout, concluded that implementing FNP with fidelity in Scotland was possible and supported the expectation that positive programme outcomes was plausible.

A subsequent qualitative evaluation of the perceived value of FNP to a range of key stakeholders across Scotland was commissioned to complement the natural experiment described in the current report[24]. Stakeholders included: clients, Family Nurses, regional leads, social workers, and other health care professionals. Findings emphasised the value added through FNP by the central supportive relationship between Family Nurse and client, the programme's holistic approach to addressing intergenerational cycles of poor caregiving, supporting maternal and child outcomes through theoretically articulated processes consistent with the programme logic model and improved inter-agency working. An evaluability assessment (EA) was commissioned by the Scottish Government to inform the optimal approach to evaluate impacts attributable to the programme and considered the likely value and cost to undertake with different evaluation options. The EA recommended a natural experiment design using routine data to compare mothers enrolled onto the programme with mothers giving birth shortly before or after recruitment to FNP began or ended in their health board[25]. Therefore, the commissioned impact evaluation followed a natural experiment design, and its findings are described in this report.

Section 2: Methods

The study methods have previously been published; key parts of this section are reproduced from that report by Cannings-John et al. for ease of reference[1].

Aims of the evaluation

The aim of this study was to examine the association between the provision of FNP when added to existing services[b] and a range of outcomes covering maternal health, child health and development, and parental life course, compared to existing services alone for first time mothers.

The objectives of the study were to:

- Obtain approval and link Client and Control identifiers to health, education, and social care data available in public sector records.
- Identify families from routine data that were in receipt of FNP support (for any length of time) at all relevant Scottish sites (FNP Clients) and a control sample of families who would meet criteria for FNP but did not receive FNP support (Controls).
- Compare FNP Clients and Controls across a range of maternal and child outcomes within programme defined domains of pregnancy outcomes, child health and development and parental economic self-sufficiency.
- Examine the association between enrolment into FNP on a range of pre-specified outcomes and for key sample subgroups.
- Explore variation in effectiveness by geographical area and over time.
- Explore variation in effectiveness by level of exposure to the intervention (number of FNP visits).

Study design and population

This study uses a natural experiment design using linked anonymised routine health, educational and social care data, comparing outcomes between FNP Clients and Controls.

[b] FNP is delivered alongside existing midwifery and maternity services but replaces the universal health visiting service provided to all families in Scotland from pre-birth to age two. When clients graduate from FNP they are transferred to the health visiting service until the child enters school.

The study population includes all women aged 19 years or younger, eligible for the FNP Programme from 1st January 2009 to 31st March 2016 and their first-born child(ren).

Assignment to Control and Exposure Groups

FNP Clients are women enrolled into FNP in one of the ten participating Scottish HBs (FNP sites) since its initiation from 1st January 2010 to 31st March 2016, and identified from the FNP Scottish Information System (SIS). Controls were women eligible for enrolment in the FNP during a period of time, between January 2009 to March 2016, when FNP recruitment was not offered in FNP programme areas and identified through the Scottish Maternity Records (SMR02). Children were identified using the mother-child link within the SMR02.

Follow up

Mothers were followed up from their index date (antenatal booking date) through routine data linkage until 31st March 2020 (dependent on the dataset), whereas children were followed up from birth.

Data sources and outcome measures

The commissioned evaluation required there to be no pre-specified primary outcome(s). The outcomes of this study closely follow the key activities and outcomes in the FNP programme's logic model and were determined in consultation with the Scottish Government (Appendix 1). Table 2.1 lists these outcomes (originally published in Cannings-John et al[1]) and supplies the detail for each outcome including the time period assessed, the data sources used, references to coding lists, populations, and the main analysis approach in the statistical modelling. Table 2.2 lists the datasets accessed and the time interval covered by the extracts.

Table 2.1: Maternal and child outcomes, follow-up time points, data sources, study populations and approach to analysis

	Outcome Type[a]	FOLLOW-UP TIME POINTS								Subgroup	Data source	Population	Analysis[b]
				Post-partum									
		Pregnancy	Birth	10-14 days	6-8 weeks	2 years	27-30 months	Primary 1	5-6 years				
MATERNAL OUTCOMES													
Positive health behaviour													
Alcohol/substance misuse during pregnancy	ST	✓								Deprivation quintiles	SMR01/02/04/ A&E – Code list (Appendix 2)	Mothers	LO
Improved parental life-course													
Childcare use	D						✓				CHSP-PS	Children with a 27-30m review	D
Return to education	ST					✓				Deprivation quintiles	School Leavers/ Scottish Credit and Qualifications Framework	Mothers	D
Highest educational attainment for all school leavers	D								✓		Scottish Credit and Qualifications Framework	Mothers	D
Subsequent birth (live/still)	ST					✓				Deprivation quintiles/ Maternal age at booking	SMR02 – Code list (Appendix 3)	Mothers	LO
Inter-pregnancy interval	MT								✓		SMR02- Code list: Appendix 3/ Deaths	Mothers	COX
Inter-birth interval	MT								✓				
CHILD OUTCOMES													
Competent parenting in terms of child-health													
Breastfeeding initiation	ST		✓							Maternal age at booking	SMR02/CHSP-PS	Child	LO
Breastfeeding	ST*			✓							CHSP-PS	Child	LO
Breastfeeding	ST				✓						CHSP-PS	Child	LO
Duration of breastfeeding	ST			✓	✓						CHSP-PS	Child	NBM

[a] ST - Short term; MT - Medium term; D - Descriptive.

[b] D - Descriptive; LIN – Linear regression; LO – Logistic regression; LO-long – Longitudinal logistic regression; NBM - Negative binominal model; PO – Poisson; COX -Time to event analysis using Cox proportional hazards model.

	Outcome Type[a]	FOLLOW-UP TIME POINTS								Subgroup	Data source	Population	Analysis[b]
				Post-partum									
		Pregnancy	Birth	10-14 days	6-8 weeks	2 years	27-30 months	Primary 1	5-6 years				
Passive smoking	ST			✓	✓		✓			Smoking history	CHSP-PS	Child	LO-long
Improved birth outcomes													
Pre-term delivery (<37 vs 37+ wks)	ST		✓							Maternal age at booking	SMR02	Child	LO
Pre-term delivery (<28, 28 to <32, 32 to <37,37+ wks)	D		✓								SMR02	Child	D
Babies with appropriate birth weight[c]	D		✓							Maternal age at booking (D)	SMR02	Child	D
Improved child health													
Physical development: Healthy Body Mass Index (BMI)	ST						✓			Pre-term delivery	CHSP-PS	Child	LO
Physical development: Healthy BMI	MT							✓			CHSP-P1	Child	LO
Registered with dentist at 24 months	ST						✓				CHSP-PS	Child	LO
Attended a dentist	ST						✓				CHSP-PS	Child	LO
Hospital admissions for dental procedure	MT					✓			✓		SMR01 – Code list: Appendix 4	Child	COX
Hospital admissions for serious injuries	MT					✓			✓		SMR01 – Code list: Appendix 5	Child	COX
Any attendance to A&E	D					✓			✓		A&E	Child	D
Accidental injuries	MT					✓			✓		A&E – Code list: Appendix 6	Child	COX
Competent parenting: child protection													
Safe home environment	ST					✓					SMR01 – Code list: Appendix 7	Child	LO
Safe home environment	MT								✓		SMR01	Child	LO

[c] Birth weight appropriate for gestational age and adjusted for gestational age, maternal height, maternal weight at booking, parity and ethnic group - Gestation Related Optimal Weight (GROW)

	Outcome Type[a]	FOLLOW-UP TIME POINTS								Subgroup	Data source	Population	Analysis[b]
				Post-partum									
		Pregnancy	Birth	10-14 days	6-8 weeks	2 years	27-30 months	Primary 1	5-6 years				
Improved child development													
Any child development concern[d]	ST				✓		✓			Sex	CHSP-PS	Child	LO
Any new child development concern	ST						✓				CHSP-PS	Child	LO
Any student need concern	MT							✓			CHSP-P1	Child	LO
Gross motor skills concern	ST				✓		✓				CHSP-PS	Child	LO
Fine motor skills concern	ST						✓				CHSP-PS	Child	LO
Personal/social & Emotional/ behavioural concern	ST				✓		✓				CHSP-PS	Child	LO
Social, emotional, and behavioural difficulty	MT							✓			CHSP-P1	Child	LO
Speech, language, and communication concern	ST				✓		✓				CHSP-PS	Child	LO
Language or speech disorder/Communication Support Needs	MT							✓			CHSP-P1	Child	LO
Physical or motor impairment	MT							✓			CHSP-P1	Child	LO
Vision concern	ST				✓		✓				CHSP-PS	Child	LO
Vision impairment	MT							✓			CHSP-P1	Child	LO
Hearing concern	ST				✓		✓				CHSP-PS	Child	LO
Hearing impairment	MT							✓			CHSP-P1	Child	LO
Other student need[e]	MT							✓			CHSP-P1	Child	LO
More able pupil	D							✓			CHSP-P1	Child	D

[d] Concern in any of the following areas: Gross and Fine Motor, Speech, Language and Communication, Social, emotional, behavioural, and attention, hearing and vision

[e] Learning disability, Dyslexia, Other specific learning difficulty, Other moderate learning difficulty, Deafblind, Autistic spectrum disorder, Physical health problem, and Mental health problem.

	Outcome Type[a]	FOLLOW-UP TIME POINTS								Subgroup	Data source	Population	Analysis[b]
				Post-partum									
		Pregnancy	Birth	10-14 days	6-8 weeks	2 years	27-30 months	Primary 1	5-6 years				
Child attainment[f]	MT*								✓	Sex	ACEL collections	Child	LO x 5
Improved child protection													
Child protection (CP) investigation	D					✓			✓		Children and Young People: Child protection register	Child	D
Age at first CP investigation	MT*								✓			Child	LIN
Number of CP investigations	MT*								✓		Children and Young People: Child protection register	Child	PO
Investigation requiring a CP Case Conference (CPCC)	D					✓			✓			Child	D
Type of concern identified at CPCC	D					✓			✓			Child	D
Length of time on CP register	MT*					✓			✓			Child	LIN
Child registered as a result of conference	D					✓			✓			Child	D
Child deregistered	D					✓			✓			Child	D
Care experience status	D			✓	✓		✓				CHSP-PS	Child	D
Children with a care experience status	MT*					✓			✓		Children and Young People: Looked after children	Child	D
Time spent in first placement	MT*								✓			Child	D
Placement type	D								✓			Child	D
Placed for adoption	D								✓			Child	D

* Additionally tested outcomes, in response to emerging external evidence regarding programme impacts.

.

[f] Five outcomes: Reading, Writing, Listening and Talking, Literacy, and Numeracy

Table 2.2: Datasets accessed, and period of data covered

Dataset	Data period covered by extract
Mother (M) outcomes only	
FNP Scottish Information System	FNP recruiting period: 1 Jan 2010 to 31 March 2016
Scottish Morbidity Record (SMR) 04 – Mental Health Inpatient and Day Case	Date of antenatal booking to 31 March 2020
Community prescribing and dispensing	Anytime before antenatal booking date
Community Health Index: Demographics	
Children and Young People: Looked after children	
Children and Young People: Child protection register	
Attendance, Absence and Exclusions	
School Leavers (Summer and Christmas)	Anytime before/after antenatal booking date to 31 March 2020
Skills Development Scotland: Destinations	Date of antenatal booking to 31 March 2020
Scottish Credit and Qualifications Framework	
Child (C) outcomes only	
Child Health Surveillance Programme (CHSP) - Pre-School • 10-14 day / 6–8-week assessment, 27–30-month review, 2-year assessment, Unscheduled contacts	Date of birth to 28 February 2019
CHSP-Primary 1 Screening review	
Achievement of Curriculum for Excellence Levels collections	Date of birth to 2018/2019
Both Mother and Child outcomes	
SMR00 – Outpatient Attendance	Date of antenatal booking (M) / Date of birth (C) to 31 March 2020
SMR01 – General/Acute Inpatient and Day Case	
SMR02 – Maternity Inpatient and Day Case	
National Records for Scotland (NRS): Deaths	Date of antenatal booking (M) / Date of birth (C) to 28 Feb 2019
School/Pupil Census	Before antenatal booking date (M) / Date of birth (C) to 31 March 2020
Children and Young People: Looked After Children Longitudinal dataset	Date of antenatal booking (M) / Date of birth (C) to 31 March 2020
Children and Young People: Child protection register	
Unscheduled Care: Accident and Emergency (A&E)	Date of antenatal booking* (M) / Date of birth* (C) to 31 March 2020 **2011 onwards*

Post-hoc outcome additions and changes

Table 2.1 also lists additionally tested outcomes, responding to emerging external evidence regarding programme impacts[18]. These included breastfeeding at 10-14 days post-partum, child attainment (five subjects: Reading, Writing, Listening and Talking, Literacy, and Numeracy), outcomes in child protection (age at first investigation, number of investigations and length of time of the register), and care experienced children and time spent in their first placement. In addition, child attainment by child sex was examined as an additional subgroup analysis.

The maternal outcome “Return to Education”, intended to measure the proportion of mothers still in school at booking that returned to education within two years of first baby using both the School Leaver and Scottish Credit and Qualifications Framework (SCQF) datasets. However, the SCQF data received only contained data of qualifications gained in a school setting and did not include data for further or higher education (university or college), substantially limiting the analysis for this outcome. The “Return to Education” outcome was therefore changed to the duration of days mothers remained in school after antenatal booking. Given that the outcome was not fit for original purpose, based on imprecise measures, and only related to a very small proportion of the original cohort, it was changed to be descriptive in nature as opposed to a tested outcome (by logistic regression as stated in the protocol). The outcome ‘Any new child development concern at 27-30 months’ was analysed as a binary outcome (using logistic regression) as opposed to the intended multinomial (again as stated in protocol).

Statistical analysis

Analysis approach

As mothers enrolled in FNP and their Controls were not matched (although Controls were restricted to the FNP eligibility criteria), this study used multivariable regression, to adjust for maternal characteristics mainly measured at antenatal booking appointment that had a hypothesised influence on effect estimates. These included sociodemographic (maternal age at antenatal booking, ethnic group), area level characteristics (Scottish Index of Multiple Deprivation (SIMD) quintile, Health Board based on postcode at antenatal booking date), pregnancy related health/ characteristics (year of antenatal booking, gestational age at booking and delivery, previous pregnancy), maternal health and behaviours (maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking), social

care and education characteristics (ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced). For child's educational attainment, we additionally adjusted for infant sex and month of birth.

Additional bias

Some outcomes could have variable follow-up times (such as 27–30-month health visitor review), and for some of these outcomes, variable length of follow-up might have an impact. One example of this is for developmental outcomes, where if on average the review was carried out at a slightly older age in one group, this might result in better developmental outcomes reported for that group. We therefore examined the average age of children at each of the main study time points (10-14 days, 6-8 weeks, 27-30 months) between FNP Clients and Controls. Bias could also be present for differential follow-up time between FNP Clients and Controls that may affect any longer-term outcomes (see table 3.5). For this reason, we describe the number of mothers and children available for analysis at each follow-up time point, and longer-term outcomes were censored.

Multiple imputation

Multiple imputation was used to account for missing data where data were expected to be missing at random for covariates in all models. We used multiple imputation by chained equations (MICE) to account for missing data which runs a series of univariable regression models of existing data to replace missing data by prediction[26]. The imputation models included all covariates, and the outcome of interest. We imputed missing covariate data using multiple imputation to generate 20 datasets in line with guidance suggesting that the number of imputations should at least be equal to the proportion of missing data[26]. The covariates used to predict the missing values were socio-demographics, area level characteristics, pregnancy related health/characteristics, maternal health and behaviours, and social care and education characteristics (as mentioned under the 'Analysis approach' section). We assessed the robustness/consistency of the final parameter estimates by imputation methods, by examining unadjusted and adjusted models with varying confounders to assess the impact of the missingness.

Descriptive analysis

Using summary statistics (frequencies, proportions, means and standard deviation (SD), medians and interquartile range (IQR)), we describe the study population of mothers and children using maternal socio-demographics at time of pregnancy, pregnancy related health/characteristics, maternal health and behaviours, and social care and education

characteristics (Section 3). Fidelity to the FNP programme model was also described by the Core Model Elements and FNP Fidelity Goals which collectively represent the mechanisms used to ensure fidelity (Section 4).

Main analysis

With no primary outcome, equal importance was given to each short- and medium-term outcome. All comparative analyses were pre-specified and conducted on an intention to treat (ITT) basis, indicating that the analysis included all young mothers according to their original 'allocation', i.e., the intervention group were women enrolled in FNP programme regardless of the number of visits they actually received.

All tested outcomes compared outcomes (intervention effect) between the two groups (FNP Clients and Controls) using multilevel regression models, to allow for clustering of outcome within NHS HB. All parameter estimates representing the FNP effect were accompanied by a 95% confidence interval (CI) and p-value. The method of analysis was dependant on the outcome type e.g., binary (yes/no, presence or absence of events), continuous, time to event, and counts as follows:

Binary outcomes (e.g., registered with a dentist by 24 months or not) were modelled using logistic regression and parameter estimates are presented as odds ratios (OR) which compares the odds of an event in the FNP Client group compared with that in the Controls.

Continuous outcomes (e.g., birthweight) were modelled using a multilevel linear regression model and parameter estimates are presented as difference in means (FNP Clients minus Controls).

Time to event outcomes (e.g., time to subsequent birth) were analysed using a proportional hazards regression model and results presented as hazard ratios. Individuals were followed up until the earliest of an event (e.g., subsequent birth), death, or study end date. We ascertained if the proportional hazards assumption had not been violated by inspecting the log (−log(survival)) plot and Schoenfeld residuals. With a differential length of follow-up between FNP Clients and Controls, the duration of follow-up was truncated to 5 years.

Count based outcomes (e.g., number of child protection investigations) were analysed using a Poisson multilevel model. If the distribution of events displayed signs of over dispersion (greater variance than might be expected in a Poisson distribution), then a

Negative Binomial model was used. Results are presented as the incidence rate ratio (IRR) of the FNP Clients compared to the Controls.
Forest plots were used to graphically show the intervention effects alongside the confidence intervals for outcomes and subgroup analyses within each of the domains.
We summarised descriptive, non-tested outcomes using frequencies and proportions, means and standard deviation (SD), medians and IQR. Differences between FNP Clients and Controls were described (absolute percentage difference, difference in means) alongside 95% CIs.

Subgroup analyses

We modelled the impact of key subgroups (maternal age: <17 years/17+ years; full- or pre-term delivery, and area-level deprivation quintiles) by extending the primary models and testing for interaction effects. FNP programme effects were also examined over time (year of antenatal booking) and between health boards.

Adherence to the FNP programme

Adherence is only relevant for the FNP Clients and cannot be compared to Controls and so the relationship between the number of FNP visits received by the mother and outcomes was described. Adherence is defined as the number of FNP visits that a FNP Client received during their programme enrolment overall or by phase (pregnancy, infancy, toddler), dependent on the timing of the outcome. We used pregnancy phase visits for short-term outcomes such as birth weight, and visits across all phases for longer-term outcomes, to examine the impact of the fidelity of intervention delivery on effectiveness.

Multiple comparisons

In total, 34 main hypotheses were statistically tested, giving a probability of 0.82 (=1-0.95^{34}) of getting at least one significant result by chance when the conclusion is not true in the population. The threshold for significance was therefore adjusted using Bonferroni's correction, so that a p-value <0.0015 (0.05 alpha divided by 34) was deemed as significant. To address the conservative nature of the Bonferroni correction, more powerful approaches that preserve type I error such as the Holm, Hochberg, Dunn-Sidak, and Benjamini-Hochberg adjustments were also explored[27–30]. For transparency, the actual p-values without correction will be presented in this report, and a summary of the conclusions based on difference correction methods will be given, allowing the reader to assess the evidence themselves.

Ethics

An application was made to the Public Benefit and Privacy Panel (PBPP) to access individual level data from national datasets held by NHS National Services Scotland (NSS), FNP data from individual NHS Scotland HBs and to obtain permission to link these to education and social care datasets provided by the Scottish Government Education Analytical Services (EAS).

Guidelines

Before sight of any outcome data, a detailed statistical analysis plan was agreed by the study management group and signed by the co-lead for the project (24th September 2019). The reporting and presentation of results are in accordance with the STROBE and RECORD guidelines to ensure the comprehensive reporting of this evaluation (Appendix 8)[31,32]. The statistical packages IBM SPSS and Stata were used for all analyses[33,34]. We have adhered to the NSS Statistical Disclosure Control protocol throughout[35,36].

Section 3: Data Quality and Cohort Characteristics

Key Findings

- The cohort consisted of 8,118 women (3,203 FNP Clients; 4,915 Controls), with good representation across the 10 health boards.
- Some significant differences were found between FNP Clients and Controls, justifying the need for adjustment of confounders in the analyses.
- FNP Clients were younger, more likely to be recorded as white, ever dispensed medication for asthma or depression, to have ever smoked, ever been in receipt of free school meals, having additional student need, been excluded from school, on the child protection register, and being looked after, when compared to Controls.
- FNP Clients and their Controls had at least three years follow-up with an average length of time in the study of 6.3 and 7.1 years respectively.
- Children of the FNP Clients and Controls had at least two years follow-up with an average length of time in the study of 5.7 and 6.6 years respectively.

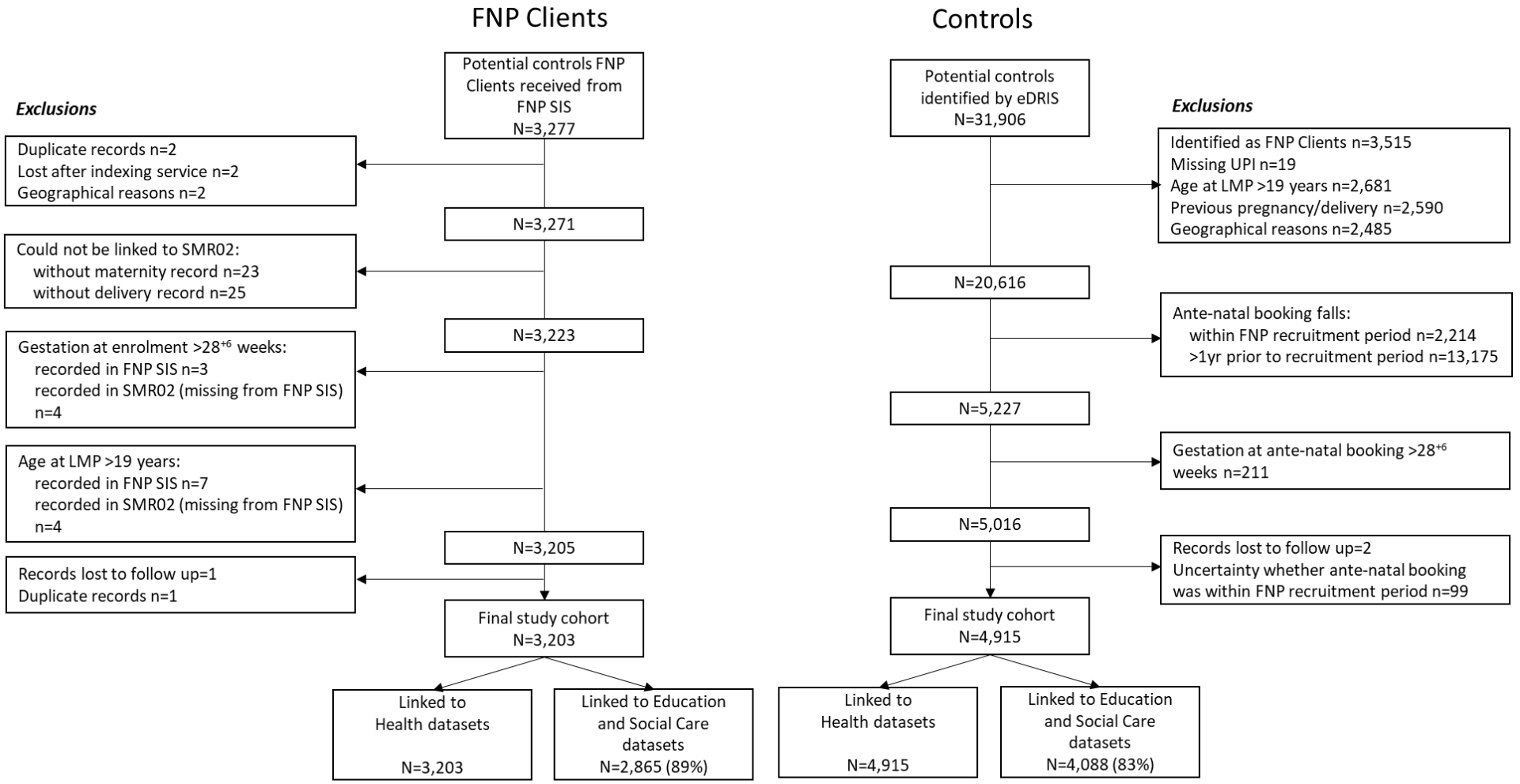
Identifying the study population

The identification of the study cohort has previously been described[1]. In brief, identifiers for FNP Clients enrolled between 2010 and 2016 were sent from ten HBs (FNP SIS and NHS Lothian systems), to the electronic Data Research and Innovation Service (eDRIS). A total of 3,277 FNP Clients were received; 72 (2%) were excluded for reasons of data quality or eligibility, leaving 3,205 FNP Clients (98% of the initial cohort) (Figure 3.1). Potential Controls (N=31,906) were identified by the eDRIS team based on SMR02 fields of which 5,227 (16%) were identified as mothers eligible for FNP (living in an FNP-recruiting NHS HB area, a first time mother, aged 19 years or younger, gestation at booking <28 weeks), with an antenatal booking date outside of FNP recruitment periods (1st Jan 2009 to 31st Mar 2016), of which 26,679 (35%) were excluded for data quality or eligibility reasons. A further 211 women were excluded by the study team with a gestation at booking greater than 28^{+6} week, leaving 5,016 Controls for further linkage with datasets for analysis.

The outcome data was linked to the study cohort and extracted for analysis at two separate time points, February and September 2020. Three records (1 FNP, 2 Controls) could not subsequently be linked and were excluded. One FNP Client linked to two records from different areas; since the correct area at that point could not be ascertained the individual was excluded. Some (n=99, 2%) FNP Clients had enrolment dates recorded earlier than the FNP recruitment period. As we could not ascertain whether these dates were correct and whether the Controls had booking dates within FNP recruitment periods, the latter were excluded.

The final cohort consisted of 8,118 women (3,203 FNP Clients; 4,915 Controls) for analysis. A mother-child link was available within the SMR02 enabling a flag for any children born after antenatal booking date to be derived, typically between 15 to 35 weeks after the antenatal booking date. Once the study cohort and their first-born children were identified, the eDRIS team sent the Community Health Index (CHI) number and a “FNP Client / Control” and a “mother/child” flag to National Records of Scotland (NRS) Indexing team for further linkage to the datasets listed in table 2.2, to be used in the study.

Figure 3.1: Flow diagram of eligible FNP Clients and Controls



SMR02=Scottish Morbidity Record -Maternity Inpatient and Day Case; FNP SIS=Family Nurse Partnership Scottish Information System; UPI=Unique personal identifier; LMP=Last menstrual period

Data quality

Match rates, indicating the quality of the linkage of the study cohort to health, education and social care data (via NRS linkage process) held by eDRIS and Education Analytical Services (EAS) were not provided. However, since SMR02 data was used to identify the study cohort and their children, we assume that all individuals also matched to all received health datasets (i.e., SMR00, SMR01, SMR04, A&E, dispensing).

Of the 8,118 first time young mothers in the final study population, 1,165 (14.4%) were not linked to any EAS dataset in which we would expect them to appear (e.g., School census dataset). These individuals were therefore assumed to be unmatched (as opposed to not experiencing the event). Where a dataset only recorded the event (e.g., where a child protection investigation occurred or an exclusion), then those matched but with no event were assumed not to have the event.

Table 3.1 shows the associations between study and maternal characteristics and the odds of not linking to any EAS datasets. There was evidence to show that a lack of linkage to EAS datasets was associated with being in the control group (with an antenatal booking from earlier in the study period), older at booking, of ethnic background other than white, experiencing a previous pregnancy, later gestation at booking, a current smoker at booking, and drug use during pregnancy. As a result, sensitivity analyses were carried out that involved truncating the follow-up to exclude data from 2009-2012. For each outcome, this made no difference to the results.

Missing data

Table 3.2 details the proportion of missing data in maternal and child characteristics. Variables such as exposure groups (FNP Clients/Controls), year of booking, NHS health board, age at last menstrual period, and the dispensing data were all complete.

Table 3.1: Associations between study and maternal characteristics and missing education and social care datasets

Maternal characteristics	Unadjusted OR[a] (95% CI)	p-value
FNP Client (Ref=Control)	0.58 (0.51 to 0.67)	<0.001
Year of antenatal booking (2009-2016)	-	Overall <0.001
NHS Health Board	-	Overall <0.001
Age at antenatal booking (years)	1.59 (1.49 to 1.68)	<0.001
Medication for asthma	0.47 (0.39 to 0.57)	<0.001
Medication for depression	0.79 (0.61 to 1.03)	0.083
Diabetes	0.66 (0.33 to 1.31)	0.235
Ethnic background other than white	1.36 (1.16 to 1.60)	<0.001
SIMD quintile	-	Overall <0.001
Previous pregnancy	1.74 (1.53 to 1.99)	<0.001
Gestation at booking (weeks)	1.08 (1.07 to 1.10)	<0.001
Current smoker at booking (Ref: Non/Ex-smoker)	1.21 (1.06 to 1.38)	0.004
BMI at antenatal booking	1.00 (0.99 to 1.01)	0.943
Alcohol consumed in the course of a typical week at antenatal booking	1.22 (0.92 to 1.63)	0.170
Drug Misuse at any time during the current pregnancy	1.84 (1.38 to 2.45)	<0.001
Injected illegal drugs prior to current pregnancy	2.04 (0.74 to 5.62)	0.169

BMI=Body mass index, OR=Odds ratio, SIMD=Scottish Index of Multiple Deprivation

a OR compares participants missing Education Analytical Services (EAS) data to not missing; OR>1 indicates a greater odds of not linking to EAS data (a lower odds of linking); OR<1 indicates a lower odds of not linking to EAS data (a greater odds of linking).

Table 3.2: Completeness of maternal and child characteristics

	N	Not known[a] (%)	Missing (%)
Maternal characteristics			
Exposure (FNP/Control)	8,118	0	0
Year of booking	8,118	0	0
NHS Health Board	8,118	0	0
Age at LMP	8,118	0	0
Medication for asthma	8,118	0	0
Medication for antidepressant	8,118	0	0
SIMD quintiles	8,111	0	7 (0.09)
Previous pregnancy	8,108	0	10 (0.12)
Gestation at antenatal booking	8,106	0	12 (0.2)
Diabetes	7,950	168 (2.1)	0
History of smoking at antenatal booking	7,814	304 (3.7)	0
Smoking during pregnancy	7,706	412 (5.1)	0
BMI at booking	7,615	0	503 (6.2)
Ethnicity	7,552	0	566 (7.0)
Alcohol consumed in typical week at antenatal booking	7,360	0	758 (9.3)
Drug Misuse	6,764	1,304 (16.1)	50 (0.6)
Injected illegal drugs prior to current pregnancy	6,733	1,334 (16.4)	51 (0.6)
Free school meals	6,953	0	1,165 (14.4)
Additional student needs	6,953	0	1,165 (14.4)
Left school by antenatal booking	6,953	0	1,165 (14.4)
Exclusion in school	6,953	0	1,165 (14.4)
Care experienced child before antenatal booking	6,953	0	1,165 (14.4)
Child protection episode	6,953	0	1,165 (14.4)
Child characteristics			
Sex	8,166	0	0
Gestation at delivery	8,150	0	16 (0.2)
Birth weight	8,163	0	4 (0.05)

BMI=Body mass index, LMP=Last menstrual period, SIMD=Scottish Index of Multiple Deprivation. a Certain fields such as drug use or smoking at antenatal booking had a distinct field ‘Not known’ as well as missing data.

Maternal characteristics

FNP clients compared to Controls

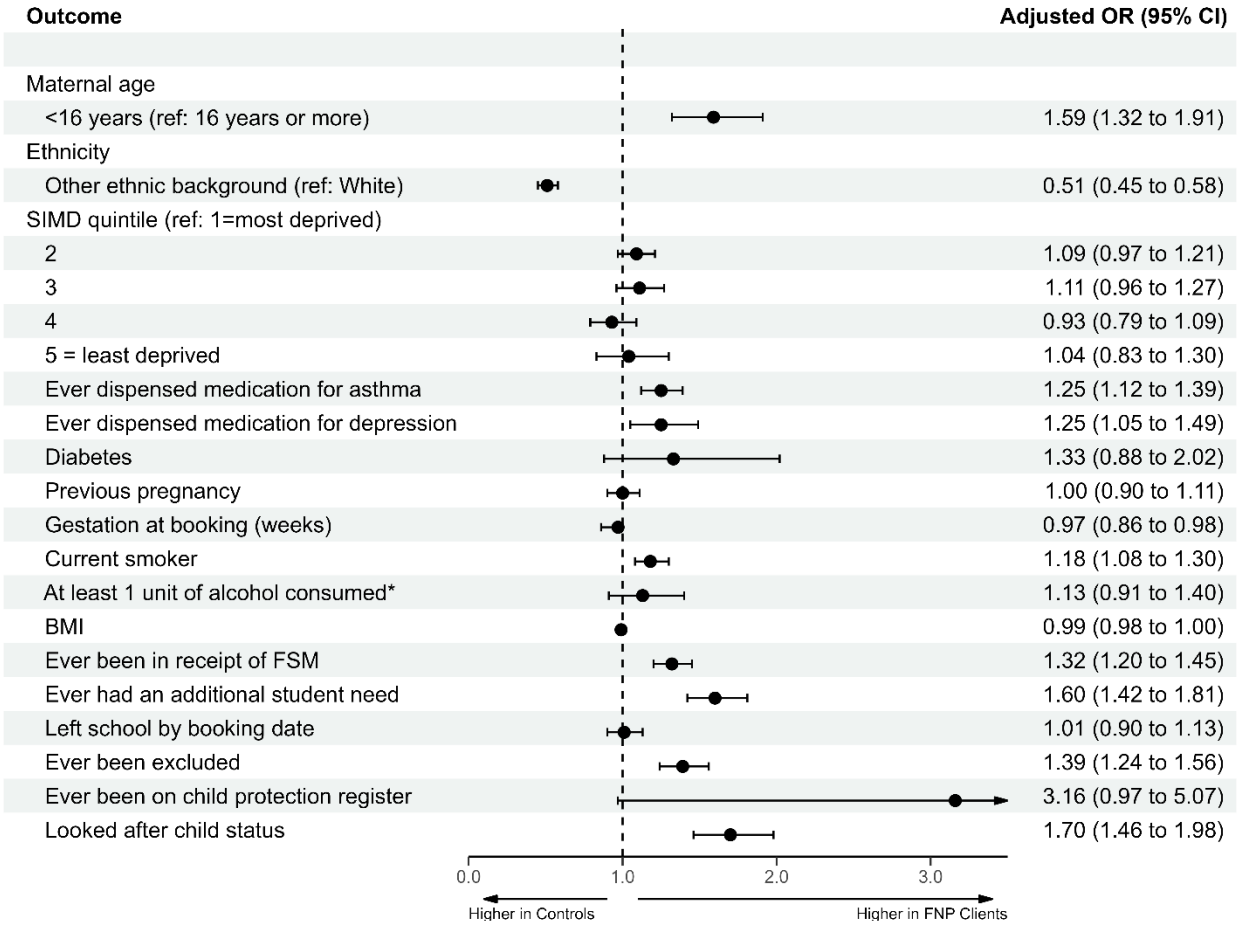
Table 3.3 describes the maternal characteristics of the FNP Clients and Controls identified from the 1-year pre and post recruitment periods (n=2,737 and 452 respectively) and within intervals when recruiting stopped (n=1,726). Each HB had a good representation of FNP Clients and Controls. The two groups were comparable on FNP eligibility criteria (mean age at LMP and gestational age at booking) and for deprivation, BMI, drug use, alcohol use and diabetes, previous pregnancies, multiples and live births. Differences between the FNP Clients and Control group are observed in some maternal characteristics such as age <16 years (vs 16+ years), ethnicity, dispensing of medication for asthma and depression, smoking at antenatal booking, student need, care experienced, and receipt of free school meals, justifying the reason for adjustment of the characteristics in the regression models. Figure 3.2 shows the characteristics associated with mothers enrolled to FNP compared to Controls.

FNP enrolled compared to eligible non-enrolled mothers

For a better understanding of which mothers were more likely to be enrolled into the FNP programme by nurses, the characteristics of eligible mothers during periods of recruitment but not enrolled, were sought. These mothers were either (a) approached for FNP but not enrolled or (b) not approached e.g. due to insufficient capacity in team, nearing the end of the enrolment period, near full caseloads. Following advice from the Public Benefit and Privacy Panel (PBPP), it was not possible to access these potential Controls.

Whilst we were not able to hold individual information for these mothers, aggregate statistics on selected characteristics were provided from Family Nurse Partnership Scottish Information System (FNP SIS) via eDRIS. When this cohort of 2,214 eligible non-enrolled mothers were compared to enrolled FNP Clients, it suggested that those enrolled into FNP were more likely to be of a white ethnicity (FNP Clients 87.7% vs non-enrolled mothers 82.8%), marginally younger at time of last menstrual period (mean=17.9 years vs 18.4 years), and more likely to be a current smoker (40.9% vs 30.7%) (Table 3.3). All other characteristics such as BMI and the rate of previous pregnancy were comparable.

Figure 3.2: Associations between enrolment into FNP and maternal characteristics (compared to Controls)



* typical week at antenatal booking

BMI=Body mass index, CI=Confidence interval, FSM=Fee school meals, OR=Odds ratio, SIMD=Scottish Index of Multiple Deprivation

Table 3.3: Maternal characteristics at / prior to antenatal booking for mothers (N=8,118) and non-enrolled mothers (n=2,214) by group*

** Some discrepancies occur between results previously reported[1] and this report due to the data refreshed and provided again; previously missing data are now complete.*

Maternal characteristics	FNP Clients N=3,203	Controls N=4,915	FNP eligible non-enrolled mothers N=2,214
Source: SMR02			
NHS Health Board of residence, n (%)			
Ayrshire and Arran	227 (7.1)	469 (9.5)	-
Borders	24 (0.7)	42 (0.9)	-
Fife	380 (11.9)	435 (8.9)	-
Forth Valley	100 (3.1)	263 (5.4)	-
Grampian	93 (2.9)	172 (3.5)	-
Greater Glasgow and Clyde	404 (12.6)	1,319 (26.8)	-
Highland	100 (3.1)	197 (4.0)	-
Lanarkshire	250 (7.8)	722 (14.7)	-
Lothian	895 (27.9)	862 (17.5)	-
Tayside	730 (22.8)	434 (8.8)	-
Ethnicity n (%)			
White	2,723 (87.7)	3,494 (78.6)	1,733 (82.8)
Other ethnic minorities	383 (12.3)	952 (21.4)	360 (17.2)
Missing	*97 (3.0)*	*469 (9.5)*	*121 (5.5)*
Scottish Index of Multiple Deprivation quintile n (%)			
1 (most deprived)	1,530 (47.9)	2,423 (49.3)	992 (44.9)
2	821 (25.7)	1,197 (24.4)	588 (26.6)
3	441 (13.8)	631 (12.8)	316 (14.3)
4	264 (8.3)	451 (9.2)	214 (9.7)
5 (least deprived)	140 (4.4)	213 (4.3)	101 (4.6)
Missing	*7 (0.2)*	*0 (0.0)*	3 (0.1)
Age at last menstrual period (years); Mean (SD)	17.9 (1.28)	18.2 (1.23)	18.4 (2.20)
Age <16 years, n (%)	242 (7.6)	241 (4.9)	-
Age 16-17 years, n (%)	1,252 (39.1)	1,571 (32.0)	-

Maternal characteristics	FNP Clients N=3,203	Controls N=4,915	FNP eligible non-enrolled mothers N=2,214
18-19 years	1,709 (53.4)	3,103 (63.1)	-
Gestation (weeks) at antenatal booking	n=3,191	n=4,915	
Mean (SD)	10.76 (4.93)	11.49 (4.68)	-
n (%) booking within 12 wks[a]	2,221 (69.6)	2,919 (59.4)	-
Missing	*12 (0.4)*	*0 (0.0)*	-
Body mass index (BMI) (kg/m2) at antenatal booking			
Mean (SD)	23.94 (4.95)	24.29 (5.07)	24.4 (5.10)
Missing	*51 (1.6)*	*452 (9.2)*	*87 (3.9)*
BMI category at antenatal booking, n (%)			
Underweight (<18.5)	259 (8.2)	321 (7.2)	-
Healthy weight (18.5 to 24.9)	1,839 (58.3)	2,545 (57.0)	-
Overweight (25 to 29.9)	680 (21.6)	989 (22.2)	-
Obese (30+)	374 (11.9)	608 (13.6)	-
Missing	*51 (1.6)*	*452 (9.2)*	-
Maternal smoking at first antenatal booking, n (%)			
Current smoker	1,284 (40.9)	1,731 (37.0)	739 (34.7)
Never smoked/former smoker	1,855 (59.1)	2,944 (63.0)	1,389 (65.3)
Never smoked	*1,253 (39.9)*	*2,171 (46.4)*	*1,048 (49.2)*
Former smoker	*602 (19.2)*	*773 (16.5)*	*341 (16.0)*
Not known/Missing	*64 (2.0)*	*240 (4.9)*	*86 (3.9)*
Ever injected illegal drugs prior to current pregnancy, n (%)			
Not prior to current pregnancy	6,713 (99.7)		-
Yes – prior to current pregnancy	20 (0.3)[b]		-
Not known/Missing	271 (8.5)	1,114 (22.7)	-
Drug Misuse at any time during the current pregnancy[c], n (%)			

Maternal characteristics	FNP Clients N=3,203	Controls N=4,915	FNP eligible non-enrolled mothers N=2,214
None	2,786 (94.7)	3,700 (96.8)	-
Yes	156 (5.3)	122 (3.2)	-
Not known/Missing	261 (8.1)	1,093 (22.2)	-
Alcohol consumed in the course of a typical week at antenatal booking[c], n (%)			
None	2,895 (94.9)	4,108 (95.3)	-
At least one unit	156 (5.1)	201 (4.7)	-
Missing	*152 (4.7)*	*606 (12.3)*	-
Diabetes, n (%)			
No	3,117 (98.6)	4,742 (99.0)	-
Yes[d]	43 (1.4)	48 (1.0)	-
Unknown/Missing	*43 (1.3)*	*125 (2.5)*	-
Previous pregnancy, n (%)			
No	2,374 (74.2)	3,641 (74.2)	1,656 (74.9)
Yes	826 (25.8)	1,267 (25.8)	555 (25.1)
Missing	*3 (0.1)*	*7 (0.1)*	*3 (0.1)*
Births, n (%)			
Singleton	3,182 (99.3)	4,888 (99.5)	-
Multiple (2+ births)	21 (0.7)	27 (0.5)	-
Source: Dispensing data			
Ever been dispensed medication for asthma, n (%)			
No	2,491 (77.8)	3,998 (81.3)	-
Yes	712 (22.2)	917 (18.7)	-
Ever been dispensed medication for depression, n (%)			
No	2,952 (92.2)	4,602 (93.6)	-
Yes	251 (7.8)	313 (6.4)	-
EAS datasets linked, n (%)	**2,865 (89.4)**	**4,088 (83.2)**	**-**
Source: Looked after children database			

Maternal characteristics	FNP Clients N=3,203	Controls N=4,915	FNP eligible non-enrolled mothers N=2,214
Care experienced child before/at booking, n (%)			
No	2,470 (86.2)	3,733 (91.3)	-
Yes	395 (13.8)	355 (8.7)	-
Source: Child protection register database			
Ever been on child protection register, n (%)			
No	2,811 (98.1)	4,062 (99.4)	-
Yes	54 (1.9)	26 (0.6)	-
Source: School/pupil census data			
Ever had an additional student need, n (%)			
No	2,230 (77.8)	3,443 (84.2)	-
Yes	635 (22.2)	645 (15.8)	-
Ever been in receipt of Free School Meals, n (%)			
No	1,371 (47.9)	2,187 (53.5)	-
Yes	1,494 (52.1)	1,901 (46.5)	-
Source: Attendance, Absence and Exclusions			
Ever been excluded, n (%)			
No	2,110 (73.6)	3,243 (79.3)	-
Yes	755 (26.4)	845 (20.7)	-
Source: School leavers			
Left school by booking date, n (%)			
Left school after booking date (still in school)	614 (21.4)	881 (21.6)	-
Left school before/by antenatal booking date	2,251 (78.6)	3,207 (78.4)	-

a The 'early access to antenatal services' standard states that at least 80% of pregnant women will have booked for antenatal care by the 12th week of gestation, defined as being up to and including 12 weeks and 6 days[37]; b cell numbers suppressed as <10; c The practice of recording the drug and alcohol misuse questions in the SMR02 varies across the country in terms of information gleaned and the point in the pregnancy at which it is obtained. The data items are intended to provide indicators of risk to mothers and baby as a result of the mother's behaviour during pregnancy rather than answers to specific questions asked at specific times e.g. at booking. In addition, the reliability of self-reported alcohol consumption is known to be problematic e.g. underestimating actual alcohol intake, particularly during pregnancy [38]**;** d Diabetes includes gestational diabetes and pre-existing diabetes/time of diagnosis unknown.

Birth and child characteristics

Table 3.4 describes the characteristics of the 8,167 children born to FNP Clients (n=3,225) and Controls (n=4,942). Over 63% of births were delivered spontaneously (FNP Clients: 63.2%; Controls:64.0%) with 16% via caesarian section (16.0%; 15.6%). The overall rate of still birth was 0.6% in both groups, with a rate of admission to NNU under 10% (8.4%; 9.1%). The average head circumference and crown to heel measurements were comparable in both groups, as was the Apgar score at five minutes (98% normal). Stillbirths (n=48) were excluded from all further analyses (apart from birthweight and pre-term delivery), as was one child not linked and missing follow-up data. This left 8,118 children (FNP Clients: 3,209; Controls: 4,909) for analyses.

Table 3.4: Birth and child characteristics for children (n=8,167) by group

All births	**FNP Clients N=3,225**	**Controls N=4,942**
Mode of birth, n (%)		
Spontaneous	2,037 (63.2)	3,163 (64.0)
Caesarean – Emergency and unspecified	517 (16.0)	771 (15.6)
Forceps	384 (11.9)	569 (11.5)
Cephalic vaginal delivery, with abnormal presentation of the head at delivery, without instruments, with/without manipulation	63 (2.0)	88 (1.8)
Vacuum (Ventouse with/without rotation)	136 (4.2)	220 (4.5)
Caesarean – Elective	72 (2.2)	114 (2.3)
Vaginal breech	14 (0.4)	15 (0.3)
Other and unspecified, missing	2 (0.1)	2 (0.0)
Outcome, n (%)		
Live birth	3,209 (99.5)	4,910 (99.4)
Still birth	16 (0.5)	32 (0.6)
Birth weight (grams) Mean (SD)	3,266.1 grams (609.2)	3,284.2 grams (595.9)
Missing	*2 (0.1)*	*2 (0.0)*
Sex, n (%)		
Boys	1,688 (52.3)	2,481 (50.2)
Girls	1,537 (47.7)	2,461 (49.8)

All births	FNP Clients N=3,225	Controls N=4,942
Apgar Score at 5 minutes, n (%)		
Low/abnormal score (score 0-7)	127 (4.0)	160 (3.3)
Normal (score 8-10)	3,049 (96.0)	4,704 (96.7)
Missing	*49 (1.5)*	*77 (1.6)*
Head circumference (cm), Mean (SD)	342.8 (17.9)	343.7 (16.4)
Missing	*986 (30.6)*	*2097 (42.4)*
Crown to heel (cm), Mean (SD)	50.9 (3.2)	51.3 (3.1)
Missing	*1,201 (37.2)*	*2,574 (52.1)*
Neonatal Unit (NNU) admission, n (%)		
Not admitted	2,917 (91.6)	4,431 (90.9)
Admitted	266 (8.4)	443 (9.1)
Missing/ Not known	*26 (0.8)*	*36 (0.7)*

Follow-up

For all FNP Clients and Controls, the antenatal booking date from the SMR02 was taken as individuals' index (start) date in the study. Outcome data were extracted either up to 28th February 2019 or 31st March 2020 (Table 2.2), giving all mothers at least three years follow-up (mean (SD) length of time in study FNP Clients: 6.3 (1.4) years vs Controls: 7.1 (1.7) years) (Table 3.5). The index date for children was their date of birth, giving all children at least two years follow-up (mean (SD) length of time in study FNP Clients: 5.7 (1.4) years vs Controls: 6.6 (1.7) years). Table 3.6 shows the average child age at which the child health reviews / assessments were conducted for children of FNP Clients and Controls. Average age at which children received child health reviews / assessments were comparable between FNP Clients and Controls.

Table 3.5: Number and % of mothers and children still in the study at each follow-up period (years)

	1-2 years	3 years	4 years	5 years	6 years	7 years	8 years	9 years	Mean (SD) age at end of study (years)
Mothers									
FNP N=3,203	3,203 (100%)	3,203 (100%)	3,192 (99%)	2,527 (79%)	1,731 (54%)	832 (26%)	342 (11%)	143 (5%)	6.3 (1.4)
Controls N=4,915	4,915 (100%)	4,915 (100%)	4,915 (100%)	4,372 (89%)	3,376 (69%)	2,626 (53%)	1478 (30%)	673 (14%)	7.1 (1.7)
Children									
FNP N=3,225	3,209 (99%)	99%[a]	2,880 (89%)	2,119 (66%)	1,296 (40%)	465 (14%)	223 (7%)	141 (4%)	5.7 (1.4)
Controls N=4,941	4,910 (99%)	99%[a]	4,806 (97%)	3,750 (76%)	2,864 (58%)	2,255 (46%)	874 (18%)	396 (8%)	6.6 (1.7)

SD=standard deviation

a Numbers suppressed as <10 had left study between age 2 and 3 years old

Table 3.6: Child age (days) at which child health reviews/assessments

Child age (days) – Mean (SD)	FNP Clients	Controls
10-14 days assessment	13.0 (5.7)	13.6 (6.3)
6-8 week assessment	56.8 (22.5)	54.7 (17.2)
27-30 month review	874.3 (60.8)	883.6 (62.1)
Primary 1 Health Review	63.0 (6.2)	64.7 (5.1)

SD=standard deviation

Section 4: Intervention Fidelity

Key Findings

- 52% of eligible young mothers were enrolled to FNP by the end of their 16th week of pregnancy, with substantial variation across HBs (FNP sites). Nearly all enrolled clients met programme eligibility criteria.
- 84% of FNP Clients graduated or their child reached their second birthday whilst on the FNP programme.
- Over 99% of women had at least one visit in the pregnancy phase, 96% in the infancy phase and 98% in the toddlerhood phase.
- The median number of visits varied by phase and HBs.
- 74% of clients received 80%+ of their scheduled visits during the pregnancy phase; 57% received 65% or more of their scheduled visits during the infancy phase; 53% received 65% or more of their scheduled visits in the toddlerhood phase.

Introduction

Specified within the Scotland FNP management manual are Core Model Elements and FNP Fidelity Goals which collectively represent the mechanisms used to ensure fidelity to the programme model alongside the Education and Learning Programme. Core Model Elements are licensing requirements intended to ensure replication of the original US programme criteria and relate to both programme delivery and infrastructure requirements[39]. Core model elements are prescribed for five aspects of the programme:-

- Client enrolment and engagement
- Family nurse recruitment, education and working practices
- Supervisor recruitment, education and working practices
- Administrative support
- Interpreter support

Additional Scotland specific requirements included, relate to regular psychological support provided to each Family Nurse, the provision of child protection systems and the incorporation of FNP into local clinical governance arrangements.

Fidelity goals are intended to provide evidence that the programme is being delivered to a high standard. They address matters relating to client recruitment, retention, visit dosage, and content coverage. As some of these goals are viewed as potentially challenging for nurses, particularly in newly established sites where recruitment pathways take time to develop, they have been regarded as ”stretch goals”.

The quality of intervention delivery specifically assessed against programme Core Model Elements and Fidelity Goals are summarised below, where data allows.

Client enrolment, recruitment and engagement

Core Model Element: *Enrolment and participation in the FNP is voluntary.*

Voluntariness of enrolment and participation is not directly reported within the FNP SIS but is affirmed in FNP guidance, training and policy documents.

Core Model Element: *Eligible clients include first-time and high-risk mothers only.*

Fidelity Goal: *100% clients enrolled are first-time mothers, within the specified site age bracket.*

Being a first time mother is assessed locally by FNP supervisors, maternity records and other referrers such as midwives. Relevant maternity data (from SMR02) was checked by eDRIS for all FNP Clients, and none were found to have had a previous live birth. As part of the FNP inclusion criteria, FNP Clients had to be 19 years and under at last menstrual period (LMP) (the criterion for high risk being applied in Scotland). Age at enrolment was collected on the FNP SIS (or if missing, the age at LMP as recorded on the SMR02 was used); 11/3,277 (0.34%) clients were found to be aged over 19 years of age at the date of their LMP and were consequently excluded from the study (see Figure 3.1).

Core Model Element/Fidelity Goal: *Sites enrol at least 60% of clients by the 16th week of pregnancy and 100% no later than the 28th week*

Fifty two percent (1,664/3,185) of FNP Clients were enrolled by the 16th week of pregnancy (Table 4.1). Across sites the proportion of women recruited into the study under 16+6 weeks ranged from 42% (Greater Glasgow and Clyde) to 75% (Borders) suggesting substantial variation in the enrolment rate of eligible young mothers by the end of their 16th week of pregnancy across HBs. A hundred percent of FNP Clients were enrolled no later than the 28th week of pregnancy.

Core Model Element: *Each client enrolled is visited by the same family nurse throughout her pregnancy and the first 2 years of her child's life*

Fidelity Goal: *75% of eligible clients who are offered the programme are enrolled*

Fidelity Goal: *Each family nurse enrols 25 families (or pro rata adjusted) within 9 months of recruitment commencing*

These Core Model Elements/Fidelity Goals cannot be assessed for this study as we do not hold the required information.

Table 4.1: Number (%) of FNP Clients enrolling into the programme before 16^{+6} weeks gestation and completing the programme by Health Board

NHS Health Board	Gestation at enrolment $<16^{+6}$ weeks	Women completing FNP[a]
Ayrshire and Arran	131 (58)	187 (82)
Borders	18 (75)	20 (83)
Fife	176 (46)	313 (82)
Forth Valley	42 (45)	85 (85)
Grampian	45 (49)	70 (75)
Greater Glasgow and Clyde	167 (42)	342 (85)
Highland	57 (58)	83 (83)
Lanarkshire	121 (49)	224 (90)
Lothian	532 (60)	742 (83)
Tayside	375 (51)	613 (84)
Total	**1,664 (52)**	**2,679 (84)**

a Recorded on FNP SIS as 'Graduated' or 'Child reached second birthday'.

Client attrition

Fidelity Goals: *Clients leave the programme at no more than these rates:-*

- Cumulative programme attrition is 40% or less to the child's second birthday:

- 10% or less during the pregnancy phase (enrolment to birth)

- 20% or less during the infancy phase (0-12 months)

- 10% or less during the toddlerhood phase (12-24 months)

Table 4.1 describes the overall retention rates by HB. A total of 84% of FNP Clients were recorded by FNP SIS as either graduating from the programme or the child reaching their second birthday whilst still on the programme. The remaining 16% did not reach the end of the programme. The reasons for attrition were due to the client moving out of FNP service area, moving into long-term care or parental rights being terminated, the client no longer wishing to receive the programme as they feel that it is too much commitment or they have strong family/friend support, or no contact made with the programme for 6 months. A miscarriage, termination or a maternal or infant death would also be a reason for not completing the programme.

Dosage

The frequency of visits received by FNP Clients by phase is described in Table 4.2. More than 99% of women enrolled into FNP received at least one visit in the pregnancy phase with marginally less in the infancy and toddlerhood phases (3,012 (96.0%) and 2,718 (97.5%)) respectively.

Table 4.2: Client retention and attrition per phase

	Pregnancy phase (enrolment to birth)	Infancy phase (birth to 1 years old)	Toddlerhood phase (1 to 2 years old)
N (%) withdrawing before phase[a]	NA	67 (1.9%)	347 (10.8%)
N starting phase	3,203	3,136[b]	2,789[b]
N (%) women receiving at least one visit	>99%	3,012 (96.0%)	2,718 (97.5%)
Median (IQR) visits received	10 (8 to 12)	19 (16 to 22)	14 (10 to 17)
N (%) women not receiving a single visit	<10	124 (4.0%)	71 (2.5%)

IQR=Interquartile range, NA=not applicable
a Withdrawal reasons included the FNP client moving out of the service area, or a maternal, intrapartum or infant death;
b Number FNP Clients enrolled minus withdrawals in previous phase (Infancy phase: N=3,203-67=3,136; Toddler phase: N=3,136-347=2,789).

Table 4.3 shows the median number of visits by HB. The median number of visits in the pregnancy phase was 10, 19 visits in the infancy phase, and 14 visits in the toddlerhood phase. In pregnancy, the expected number of scheduled visits to be received depends on the length of time between enrolment and giving birth (e.g., a maximum of 14 visits would be scheduled for a FNP Client enrolled by 16 weeks and a giving birth at full term). In infancy the maximum expected number of scheduled visits to be received is 28 visits and 22 visits in toddlerhood.

Table 4.3: Visits received by phase and health board – median number of visit, percentage receiving no visits

	Pregnancy (enrolment to birth)	**Infancy (birth to 1 years old)**		**Toddlerhood (1 to 2 years old)**	
	Median visits[a,b]	Median visits[a]	N (%) women with no visits	Median visits[a]	N (%) women with no visits
Ayrshire and Arran	10	19	<10	14	<10
Borders	13	23	0 (0)	13.5	0 (0)
Fife	11	20	26 (6.8)	15	10 (2.6)
Forth Valley	8	16	<10	12	<10
Grampian	10	19	<10	11.5	<10
Greater Glasgow and Clyde	9	17	12 (3.0)	12	15 (3.7)
Highland	12	23	<10	16.5	<10
Lanarkshire	10	19	<10	14	<10
Lothian	10	19	36 (4.0)	14	15 (1.7)
Tayside	10	20	31 (4.2)	14	15 (2.1)
Total	**10**	**19**	**124 (3.9)**	**14**	**71 (2.2)**

a For those who had a visit; b In the pregnancy phase, the majority of mothers received at least one visit in each of the HBs.

Support delivered (scheduled visits received)

The benchmark states that FNP Clients should receive at least 80%, 65% and 60% or more of scheduled visits during pregnancy, infancy, and toddlerhood respectively. The scheduled numbers of visits were provided by FNP SIS, for all FNP Clients who, at the start of each phase, (a) had enrolled on to (for the pregnancy phase), and (b) were still in the programme by the end of the phase. This is to give an optimal picture based on clients that completed the phase. For example, Table 4.4 examines the distribution of the percentage of scheduled visits actually received for (a) all enrolled clients who started the pregnancy phase and (b) and all enrolled clients completing the pregnancy phase. Table 4.5 and 4.6 examine the distribution of the percentage of scheduled visits received for the infancy and toddlerhood phase respectively.

Pregnancy phase: Of the 3,203 FNP Clients enrolled into the programme, we calculated the percentage of visits received for 3,184 FNP Clients; 19 did not have valid data for the number of scheduled visits (either missing or zero scheduled visits). Of these 3,184 FP Clients, 2,351 (73.8%) received at least 80% of their scheduled visits (Table 4.4). For 3,120 Clients who completed the pregnancy phase, 2,346 (75.1%) received 80% or more of their scheduled visits.

Of the 3,143 FNP Clients who started the infancy phase, 3,129 FNP Clients had a valid number of scheduled visits. Of these, 1,793 (57.3%) received 65% or more of their scheduled visits (Table 4.5). For those who completed the infancy phase (n=2,864), 1,780 (62.2%) received 65% or more of their scheduled visits.

Of the 2,862 FNP Clients who started the toddlerhood phase, 1,508 (52.7%) received more than 60% or more of their scheduled visits (Table 4.6). For those who completed the toddlerhood phase (n=2,677), 1,504 (56.2%) received 60% or more of their scheduled visits.

Table 4.4: Distribution of the percentage of scheduled visits[a] received for the pregnancy phase

	All enrolled clients who started the pregnancy phase		All enrolled clients completing the pregnancy phase	
Percentage of scheduled visits received	**N (%)**	**Cumulative %**	**N (%)**	**Cumulative %**
<10%	29 (0.9)	0.9	16 (0.5)	0.5
10-19%	46 (1.4)	2.4	39 (1.2)	1.8
20-29%	56 (1.8)	4.1	52 (1.7)	3.5
30-39%	55 (1.8)	5.8	44 (1.4)	4.9
40-49%	72 (2.3)	8.1	65 (2.1)	7.0
50-59%	144 (4.5)	12.6	137 (4.4)	11.4
60-69%	164 (5.2)	17.8	162 (5.2)	16.6
70-79%	267 (8.4)	26.2	263 (8.4)	25.0
80-89%	363 (11.4)	37.6	360 (11.5)	36.5
90-100%	873 (27.4)	65.0	871 (27.8)	64.4
101-120%	661 (20.8)	85.7	660 (21.0)	85.5
121%+	454 (14.3)	100.0	452 (14.4)	100.0
Total	**3,184[b]**		**3,120[c]**	
N (%) reaching fidelity goal of 80%+	**2,351 (73.8)**		**2,346 (75.1)**	

a Scheduled visits take into account gestation at intake and leaving the programme; b Excludes women who did not have valid data (either missing or zero expected visits) (n=19; 3,203-19=3184); c Excludes women who stopped receiving the programme in the pregnancy phase (n=67; 3,187-67=3,120).

Table 4.5: Distribution of the percentage of scheduled visits (28 visits) received for the infancy phase

	All enrolled clients who started the infancy phase		All enrolled clients completing the infancy phase	
Percentage of all expected visits	**N (%)**	**Cumulative %**	**N (%)**	**Cumulative %**
<10%	140 (4.5)	4.5		
10-19%	34 (1.1)	5.6	31 (1.1)[a]	1.1
20-29%	59 (1.9)	7.4		
30-39%	121 (3.9)	11.3	97 (3.4)	4.5
40-49%	155 (4.9)	16.3	145 (5.1)	9.5
50-59%	409 (13.0)	29.3	401 (14.0)	23.5
60-69%	780 (24.9)	54.3	769 (26.8)	50.4
70-79%	784 (25.0)	79.3	778 (27.1)	77.5
80-89%	432 (13.8)	93.1	430 (15.0)	92.6
90-100%	137 (4.4)	97.5	136 (4.7)	97.3
101-120%	63 (2.0)	99.5	63 (2.2)	99.5
121%+	15 (0.5)	100.0	14 (0.5)	100.0
Total	**3,129[b]**		**2,864[c]**	
N (%) reaching fidelity goal of 65%+	**1,793 (57.3)**		**1,780 (62.2)**	

a cells under 5 suppressed; percentage of all expected visits <10%, 10-19%, 20-29% combined; b Table 4.4 states that 3,120 women completed the pregnancy phase, however, 3,129 contributed data to the infancy phase; c Excludes women who stopped receiving the programme during the infancy phase (n=265; 3,129-265=2,864).

Table 4.6: Distribution of the percentage of scheduled visits (22 visits) received for the toddler phase

	All enrolled clients who started the toddler phase		All enrolled clients completing the toddler phase	
Percentage of all expected visits	**N (%)**	**Cumulative %**	**N (%)**	**Cumulative %**
<10%	123 (1.5)	4.3	20 (0.7)	0.7
10-19%	74 (0.9)	6.9	46 (1.7)	2.5
20-29%	128 (1.6)	11.4	104 (3.9)	6.4
30-39%	185 (2.3)	17.8	176 (6.6)	12.9
40-49%	288 (3.5)	27.8	280 (10.5)	23.4
50-59%	556 (6.8)	47.3	547 (20.4)	43.8
60-69%	576 (7.1)	67.4	574 (21.4)	65.3
70-79%	400 (4.9)	81.4	400 (14.9)	80.2
80-89%	276 (3.4)	91.0	276 (10.3)	90.5
90-100%	177 (2.2)	97.2	176 (6.6)	97.1
101-120%	59 (0.7)	99.3	58 (2.2)	99.3
121%+	20 (0.2)	100.0	20 (0.7)	100.0
Total	**2,862[a]**		**2,677[b]**	
N (%) reaching fidelity goal of 60%+	**1,508 (52.7)**		**1,504 (56.2)**	

a Table 4.5 states that 2,864 women completed the infancy phase, however, 2,862 contributed data to the toddler phase;
b Excludes women who stopped receiving the programme during the toddler phase (n=185).

Section 5: Maternal Outcomes

Key Findings

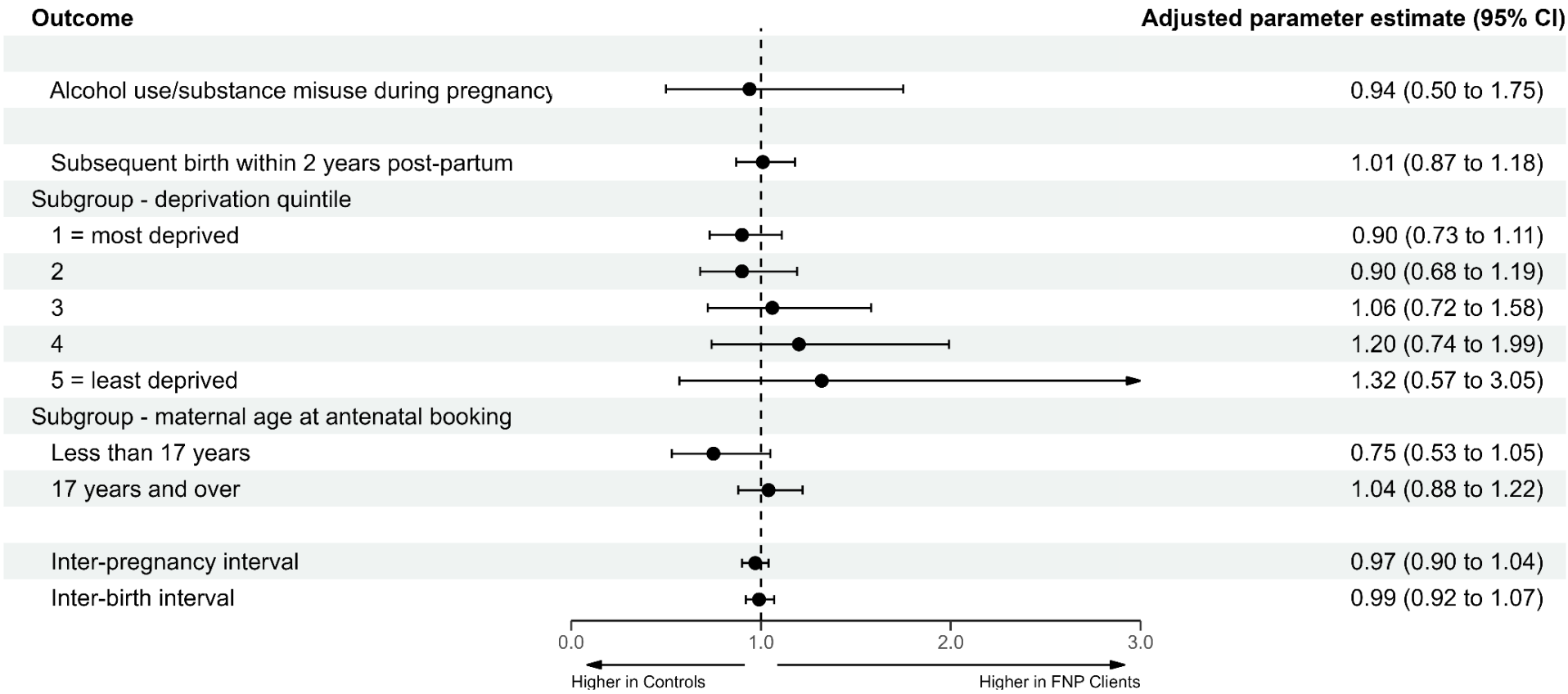
Tested outcomes:

- Less than 1% of mothers experienced a hospital admission or A&E attendance indicating alcohol or substance misuse during pregnancy, with no evidence of a statistically significant difference between FNP Clients and Controls after adjusting for background characteristics.
- A subsequent birth within 24 months of the first baby was recorded in 14% of mothers in both groups. When tested, there was no evidence of a difference in rates between FNP Clients and Controls.
- The inter-pregnancy and inter-birth intervals between FNP Clients and Controls were similar and were not significantly different.

Descriptive outcomes:

- Three fifths (60%) of children born to FNP Clients attended any childcare by the 27–30-month review compared to 56% of children born to women in the Control group. A higher proportion of children of FNP Clients attended nursery compared to Controls (42.1% vs 36.0% respectively); a higher proportion of children from the Controls attended a playgroup (11.1% vs 8.3%).
- 91% percent of FNP Clients left school before or on the same day as their antenatal booking date and did not return, compared to 93% in Controls.
- In mothers that left school after their antenatal booking date, the median (interquartile range) duration between antenatal booking date and subsequent school leaving date was 193 days (86 to 410) in FNP Clients compared to 151 days (70 to 330.5) in Controls.
- Limited data was available on mothers' highest educational achievements. For FNP Clients, 55% of FNP Clients had gained their highest SCQF at level 5 or above compared to 51.6% of Controls. In mothers whose highest SCQF was Level 4 or under, FNP Clients had a higher proportion with 2 qualifications or more (68.8% vs 58.1% respectively).
- A subsequent pregnancy within 24 months of the first baby was recorded in 25% of mothers in both groups and was comparable between FNP Clients and Controls.

Figure 5.1: Forest plot of estimates from tested outcomes in the Maternal domain including subgroups



Data sources: SMR00/01/02

CI=Confidence interval
Note: Parameter estimate for all outcomes are odds ratios (ORs), apart from the inter pregnancy/birth interval, where the estimate is presented as a hazard ratio (HR). ORs and HRs compare outcomes for FNP Clients to Controls; e.g., an OR>1 indicates that an outcome is higher for FNP Clients; an OR<1 indicates that an outcome is lower for FNP Clients. Vertical dashed line represents no effect (ratio = 1). Descriptive outcomes are not shown.

5.1 Positive health behaviour

Alcohol use or substance misuse during pregnancy

Data source: *SMR01 – General/Acute Inpatient and Day Case, SMR02 – Maternity Inpatient and Day Case, SMR04 – Mental Health Inpatient and Day Case, Accident & Emergency (A&E)*

Hypothesised direction of FNP programme effect: *Reduced alcohol use/substance misuse during pregnancy*

Of the 8,118 mothers in the study cohort, 7,467 (92%) (3,061 (FNP) and 4,406 (Controls)) had data linked to the data sources used to measure alcohol use or substance misuse during pregnancy. 651 mothers with an antenatal booking in 2009/2010 were excluded from this analysis due to the availability of A&E data (commencing in 2011). Sixty one mothers (0.8%) were recorded as experiencing alcohol use or substance misuse during pregnancy; 1% of young mothers enrolled in FNP compared to 0.7% of the Controls (Table 5.1). There was no evidence to suggest a statistical difference between the two groups (adjusted odds ratio (aOR): 0.94, 95% confidence interval (CI): 0.50 to 1.75, p=0.835). Pre-planned subgroup analyses were conducted to ascertain any differential FNP programme effects across the deprivation quintiles, over time and by HB; no differential programme effects were observed (interaction p-value=0.263, 0.145, 0.238 respectively). FNP Clients experiencing alcohol use or substance misuse were too rare to examine by the number of FNP visits received.

Table 5.1: Alcohol use or substance misuse during pregnancy by FNP Clients and Controls

	FNP Clients N=3,061	Controls N=4,406	Adjusted[a] OR (95% CI)	p-value
Evidence of alcohol use or substance misuse, n (%)				
No	3,032 (99.0)	4,374 (99.3)	Reference	
Yes	29 (1.0)	32 (0.7)	0.94 (0.50 to 1.75)	0.835

CI=Confidence interval, OR=Odds ratio.
a Adjusted for year of antenatal booking (index year), maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced.

5.2 Improved parental life-course

Childcare use at 27-30 months review

Data source: *Child Health Surveillance Programme (CHSP) Pre-School*
Hypothesised direction of FNP programme effect: *Uncertainty in direction of effect – descriptive*

This outcome is only applicable to children who had data recorded at a 27–30-month child heath review (n=6,542) or an unscheduled review (n=119). Still-births/deaths were excluded as were children who did not have data recorded at the 27–30-month review. Due to the uncertainty in the direction of the FNP programme effect, childcare use was a descriptive outcome only. This means that the absolute difference observed between FNP Clients and Controls are not adjusted for confounders. A total of 6,661 children with 27–30-month review data were examined; 60% of children born to FNP Clients attended any childcare by the 27–30-month review compared to 56% of children born to Controls, a difference of 3.7% (95% CI: 1.2 to 6.1%). The proportion of children attending nursery was higher for children of FNP Clients (42% vs 36% respectively) whilst children attending a playgroup was higher for children of Controls (8.3% vs 11% respectively).

Table 5.2 Childcare at 27-30 months post-partum by FNP Clients and Controls

	FNP Clients	Controls	Absolute difference[a] (95% CI)
Children with 27–30-month review data, n (%)	2,676 (83.0)	3,985 (80.7)	
Attends childcare, n (%)			
Yes[b]	1,531 (59.8)	2,111 (56.1)	3.7% (1.2 to 6.1%)
Nursery	1,127 (42.1)	1,433 (36.0)	6.1% (3.7 to 8.5%)
Playgroup	222 (8.3)	442 (11.1)	-2.8% (-4.2 to -1.4%)
Registered childminder	109 (4.1)	139 (3.5)	0.6% (-0.3 to 1.6%)
Other childcare	117 (4.4)	165 (4.1)	0.3% (-0.7 to 1.3%)
Incomplete/Missing	115	223	

CI=Confidence interval
a FNP Clients minus Controls; b Children can attend more than one setting.

Return to education

Data source: *School Leavers /Scottish Credit and Qualifications Framework/Pupil-School Census*
Hypothesised direction of FNP programme effect: *Outcome limited – descriptive*

This outcome used the school leaving dates (dd/mm/yyyy) from the School Leavers dataset (SLD) to determine the last date the mother was recorded as being in school. Mothers were categorised as either leaving school before/on the same day as their antenatal booking date and not returning, or as leaving school after their antenatal booking date. A total of 89% (n=2,865) of FNP Clients and 86% (n=6,953) of Controls, were linked to the SLD; the majority had their most recent leaving date recorded in the SLD (FNP Clients: 86% vs Controls: 84%) (Table 5.3). Ninety-one percent of FNP Clients left school before or on the same day as their antenatal booking date and did not return (i.e., last leaving date was recorded before or on their antenatal booking date), compared to 93% of Controls. Mothers leaving school before booking were on average 18 years of age in both FNP Clients and Controls. A total of 477 (8.0%) mothers had a date/year of leaving school recorded *after* their antenatal booking date indicating that they were still in school at the time of their antenatal booking (FNP Clients: 9.2% vs Controls: 7.2%). These mothers were on average 16 years of age, younger than mothers who had already left and not returned. The median (IQR) duration between antenatal booking and subsequent school leaving date was 193 days (86 to 410) in FNP Clients vs 151 days (70 to 331) in Controls.

Table 5.3: Mothers returning to education post-partum by FNP Clients and Controls

	FNP Clients N=3,203	**Controls N=4,915**
Mothers' records linked to School Leavers Dataset[a], n (%)	2,865 (89.4)	4,088 (83.2)
with a date of leaving recorded:	2,476 (86.4)	3,451 (84.4)
Left school before or on same day as antenatal booking date and did not return, n (%)	2,249 (90.8)	3,201 (92.8)
Maternal age at booking (years): Mean (SD)	*18.1 (1.1)*	*18.3 (1.1)*
Left school after antenatal booking date, n (%)	227 (9.2)	250 (7.2)
Maternal age at booking (years): Mean (SD)	*15.8 (1.0)*	*15.9 (0.9)*
Duration[a] remained in school: Median (IQR)	N=227	N=250
Days	193 (86 to 410)	151 (70 to 331)
Months	6.4 (2.9 to 13.7)	5 (2.3 to 11.0)

IQR=Interquartile range, SD=Standard deviation.
a Time (days/months) from antenatal booking to school leaving date

Highest educational attainment for all school leavers

Data source: *Scottish Credit and Qualifications Framework (SCQF)*
Hypothesised direction of FNP programme effect: *Improved education/skills – descriptive*

Of the 477 (FNP Clients: N=227, Controls: N=250) mothers previously identified as leaving school after their antenatal booking using the school leavers date (Table 5.3), 368 (77%) were matched to SCQF attainment data. Fifty nine percent of FNP Clients and 67% of Controls had their latest/last school-based qualification recorded before or in the same year as their year antenatal booking. To note, mothers that gained their last school-based qualification in the year of their antenatal booking year, had their school leaving date recorded as after their antenatal booking. As we cannot be certain that mothers with their highest attainment in the same year as their antenatal booking date had been exposed to the FNP programme, we only describe the highest SCQF level, and the number of qualifications gained from mothers where attainment was recorded in the years after booking (Table 5.4); n= 71 FNP Clients and n=64 Controls (total n=135).

Fifty five percent of FNP Clients had gained their highest SCQF at Level 5 or above compared to 52% of Controls, whereas 45% of FNP Clients had gained their highest Level at 4 or under compared to 48% of Controls. Within those whose highest SCQF was Level 5 or above, comparable proportions of mothers had gained 4 or more qualifications (28% vs 27% respectively), whereas of those whose highest SCQF was Level 4 or under, FNP Clients had a higher proportion of mothers with 2 qualifications or more (69% vs 58% respectively). Of those that attained a Level 4 qualification or under there was a difference between groups in the stage at which this was achieved with 75% of FNP Clients achieving this Level in S4 compared to 52% of Controls. Due caution should be taken in interpretation of these figures due to the small denominator because of imprecise recording in the timings of qualifications.

Table 5.4: School leavers' highest school attainment level by FNP Clients and Controls

	FNP Clients	Controls
Mothers left school after antenatal booking date (based on SLD)	N=227	N=250
Mothers not matched to SCQF attainment data, n	55	54
Mothers matched to SCQF attainment data, n (%)	N=172 (75.8)	N=196 (78.4)
Maternal age at booking (years): Mean (SD)	*15.9 (1.0)*	*15.9 (0.9)*
Mothers that had their latest/last recorded qualification gained:		
Before/same year as antenatal booking year, n (%)	101 (58.7)	132 (67.3)
Post antenatal booking year, n (%)	71 (41.3)	64 (32.7)
Number of qualifications gained post antenatal booking year[a] by highest SCQF level gained, n (%)	n=71	n=64
Level 4 or under	32 (45.1)	31 (48.4)
1 qualification gained	10 (31.2)	13 (41.9)
2 or more[b]	22 (68.8)	18 (58.1)
Level 5 or above	39 (54.9)	33 (51.6)
1-3[b] qualifications gained	28 (71.8)	24 (72.7)
4 or more qualifications gained	11 (28.2)	9 (27.3)
Stage attained by highest SCQF post antenatal booking year[a], n (%)		
Level 4 or under	32 (45.1)	31 (48.4)
S4 and under[b]	24 (75.0)	16 (51.6)
S5/6[b]	8 (25.0)	15 (48.4)
Level 5 or above (max Level 7)	39 (54.9)	33 (51.6)
S4/5[b]	20 (51.3)	14 (42.4)
S6	19 (48.7)	19 (57.6)

a Does not include any qualifications attained in the same year as or before booking year due to imprecision of dates (years) i.e. we cannot ascertain whether the attainment or the booking came first and what could be interpreted as an effect of the intervention; b Categories combined due to small numbers.

Subsequent birth within 24 months post-partum

Data source: *SMR02 – Maternity Inpatient and Day Case*

Hypothesised direction of FNP programme effect: *Less births within 24 months of first child*

Subsequent pregnancy and births in the post-partum period were flagged by eDRIS by evidence of the earliest of the following events: an estimated gestation, booking or admission date (for pregnancies), birth date (for births). Time to pregnancy or birth was measured as the duration between the birth of their first baby and a subsequent pregnancy or birth and then dichotomised as having the event within 24 months post-partum or not. Evidence of a subsequent pregnancy within 24 months of first baby was recorded in 25% and 25% of FNP Clients and Controls respectively, a difference of 0.3 percentage points (95% CI: -2.3 to 1.6%) (descriptive analysis only) (Table 5.5a). Evidence of a subsequent birth within 24 months of the first baby was recorded in 15% of FNP Clients and 14% of Controls, a difference of 0.2 percentage points (95% CI: -1.3 to 1.8%) (Table 5.5a). When tested statistically, there was no difference between the two groups in the prevalence of births within the first 24 months post partum (aOR: 1.01, 95% CI: 0.87 to 1.18, p=0.888).

Table 5.5a: Subsequent pregnancy and birth within 24 months of first baby by FNP Clients and Controls

	FNP Clients N=3,203	Controls N=4,915	Absolute difference[a] (95% CI)	p-value
Subsequent pregnancy within 24 months of first baby, n (%)				
No subsequent pregnancy	2,401 (75.0)	3,665 (74.7)	Descriptive only	
Subsequent pregnancy	800 (25.0)	1,244 (25.3)	-0.3 (-2.3 to 1.6)	na
			Adjusted[b] OR (95% CI)	
Subsequent birth within 24 months of first baby, n (%)				
No subsequent birth	2,732 (85.3)	4,201 (85.6)	Reference	
Subsequent birth	469 (14.7)	708 (14.4)	1.01 (0.87 to 1.18)	0.888

CI=Confidence interval, OR=Odds ratio.
a FNP Clients minus Controls; b Adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced.

Pre-planned subgroup analysis on subsequent births within 24 months were conducted. This was employed by appropriate interaction terms in the regression model to ascertain any differential effects of the FNP Client and Control groups across the following baseline categories: age of the mother at booking (less than 17 years, 17 years and over) and deprivation quintiles. Table 5.5b shows the odds ratio alongside 95% CIs for each strata, and the p-value from the interaction. There is no evidence to suggest that age and deprivation had any influence on the effect of the FNP on the rate of subsequent births (interaction p-value= 0.212 and 0.802 respectively). There was no significant variation across HBs or year of antenatal booking in subsequent births by 24 months (p-value=0.510 and 0.518 respectively).

Table 5.5b: Subgroup analysis – n (%) subsequent births within 24 months of first baby by maternal age group at antenatal booking and deprivation quintiles

	FNP Clients	Controls	Adjusted[a] OR (95% CI)	Interaction p-value[b]
Maternal age (years) at antenatal booking, n (%)				0.212
Maternal age <17 years	90 (12.1)	116 (13.6)	0.75 (0.53 to 1.05)	
Maternal age ≥ 17 years	379 (15.4)	592 (14.6)	1.04 (0.88 to 1.22)	
Scottish Index of Multiple Deprivation quintiles, n (%)				0.802
1 = most deprived	229 (15.0)	370 (15.3)	0.90 (0.73 to 1.11)	
2	119 (14.5)	174 (14.6)	0.90 (0.68 to 1.19)	
3	67 (15.2)	86 (13.6)	1.06 (0.72 to 1.58)	
4	39 (14.8)	59 (13.1)	1.20 (0.74 to 1.99)	
5 = least deprived	14 (10.0)	19 (8.9)	1.32 (0.57 to 3.05)	

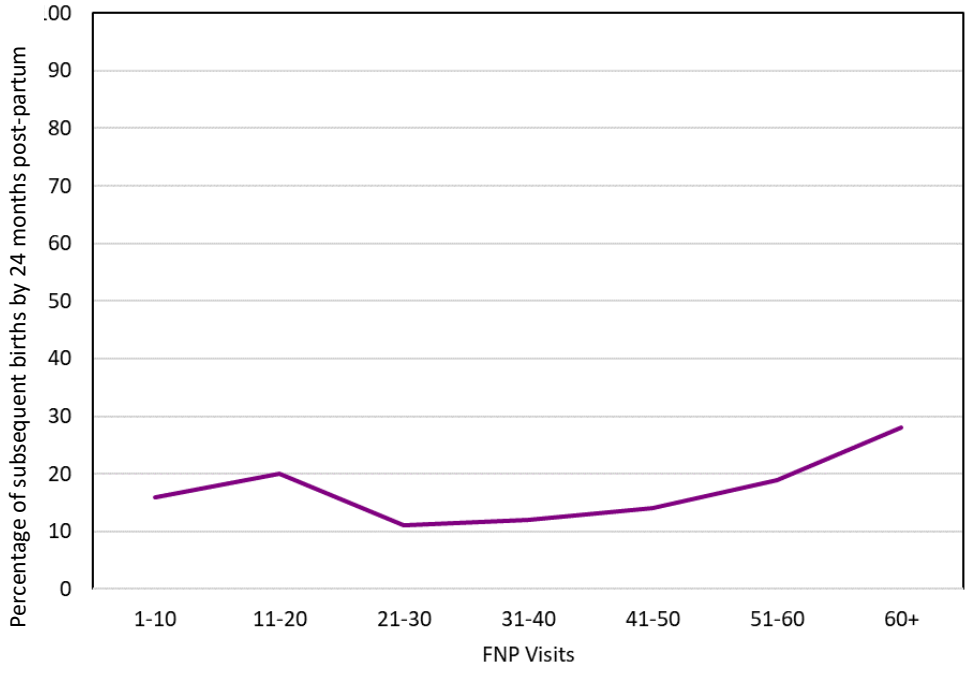
CI=Confidence interval, OR=Odds ratio.
a Adjusted for year of antenatal booking, ethnic group, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced. b Overall p-value from the interaction term (group x maternal age or deprivation quintile) in the main model. Assesses whether the effect of FNP is different in one strata to another strata (e.g. maternal age <17 years vs 17 years+).

The number of FNP visits received during the study period was categorised to obtain sufficient numbers in each group. Based on the observed data, the percentage of mothers experiencing a subsequent birth by 24 months post-partum was around 16-20% in those with 20 visits or less. Subsequent births by 24 months post-partum reduced to 11% at 21-30 visits and then gradually increased to 28% for women who received 60 visits or more, suggestive of a potential dosage effect (Table 5.5c, Figure 5.1).

Table 5.5c: Subsequent births within 24 months of first birth by total number of FNP visits received over the entire programme

Number of visits	Number of mothers	Subsequent birth n (%)
1-10	197	32 (16)
11-20	131	26 (20)
21-30	307	34 (11)
31-40	761	92 (12)
41-50	1,221	168 (14)
51-60	479	90 (19)
60+	85	24 (28)
Total	**3,181**	**466 (15)**

Figure 5.1: Percentage of subsequent births by 24 months post-partum by total number of FNP visits received over the entire programme



Inter-pregnancy interval

Data source: *SMR02 – Maternity Inpatient and Day Case*

Hypothesised direction of FNP programme effect: *Increased spacing to pregnancy*

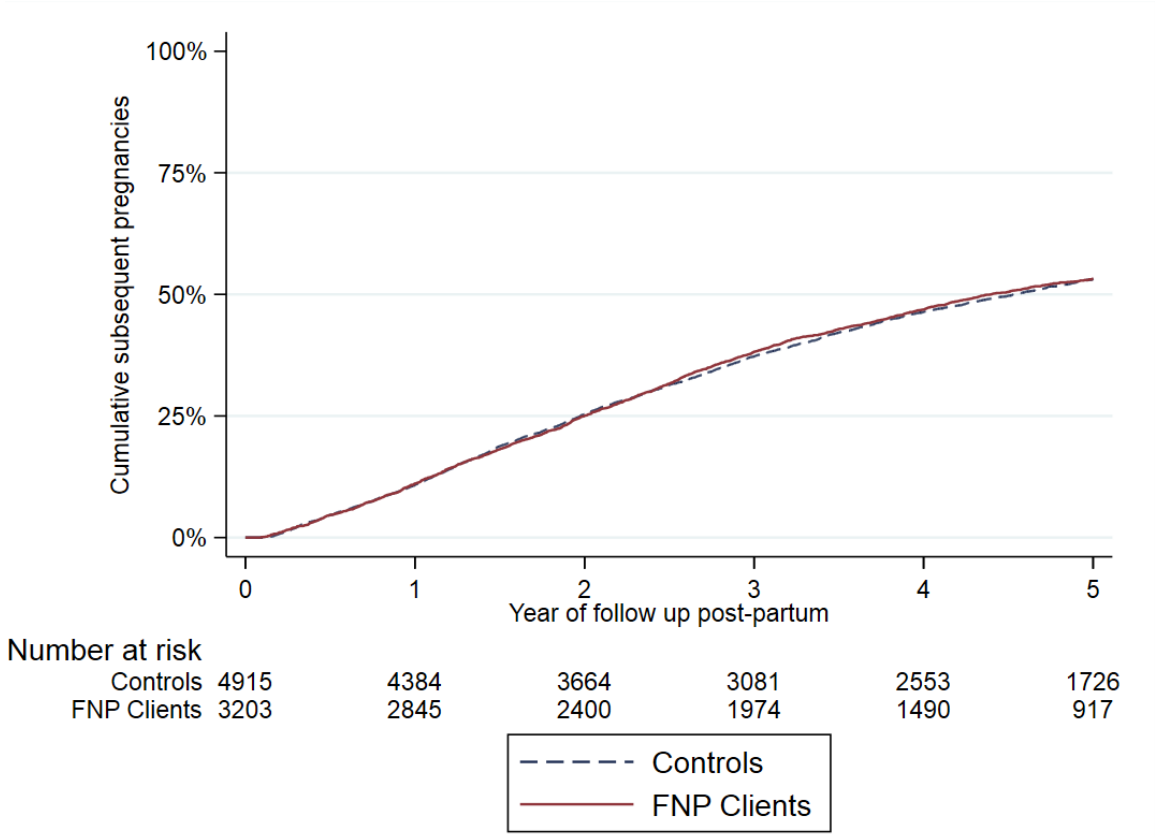
Time to subsequent pregnancy was measured as the duration in years between the birth of the first baby and a subsequent pregnancy. Mothers not experiencing a subsequent pregnancy within the follow-up period, were followed up from the birth of their first baby to either five years postpartum or their date of death (whichever soonest). When the follow-up was truncated to less than 5 years to account for differential follow-up in the FNP Clients and Control groups, the median time to a subsequent pregnancy, was 2.1 years for FNP Clients and 2.1 years for Controls (Table 5.6). The probability of not having a subsequent pregnancy by different follow-up time points were comparable across groups (Table 5.6). There was no evidence of a difference in the time to subsequent pregnancy the adjusted hazard ratio (aHR) was 0.97 (95% CI: 0.90 to 1.04, p-value=0.349) (Figure 5.2).

Table 5.6: Inter-pregnancy interval (years) by FNP Clients and Controls

	FNP Clients N=3,203	Controls N=4,915	Adjusted[a] HR (95% CI)	p-value
Inter-pregnancy interval (years), Median (IQR)	2.05 (1.13 to 3.04)	2.05 (1.14 to 3.21)	0.97 (0.90 to 1.04)	0.349
Probability of not having a subsequent pregnancy[b] by:				
1 year follow-up	88.9	89.2		
2 years follow-up	75.0	74.6		
3 years follow-up	61.8	62.8		
4 years follow-up	53.1	53.6		
5 years follow-up	46.8	46.9		

CI=Confidence interval, HR= Hazard ratio, IQR=Interquartile range
a Adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced; b 'Survivor' functions (or in this case not having a subsequent pregnancy) are presented at certain time points. The probability of 'surviving' the end of the k^{th} time-period is calculated by the probability of surviving to the end of the $(k-1)^{th}$ time-period, multiplied by the probability of surviving the k^{th} time-period.

Figure 5.2: Cumulative subsequent pregnancies during the 5 years post-partum by FNP Clients and Controls



Inter-birth interval

Data source: *SMR02 – Maternity Inpatient and Day Case*

Hypothesised direction of FNP programme effect: *Increased spacing to subsequent birth*

Time to subsequent birth was measured as the duration between the birth of the first baby and a subsequent birth. Mothers not experiencing a subsequent birth within the follow-up period, were followed up from the birth of their first baby to five years postpartum or date of death (whichever was soonest).

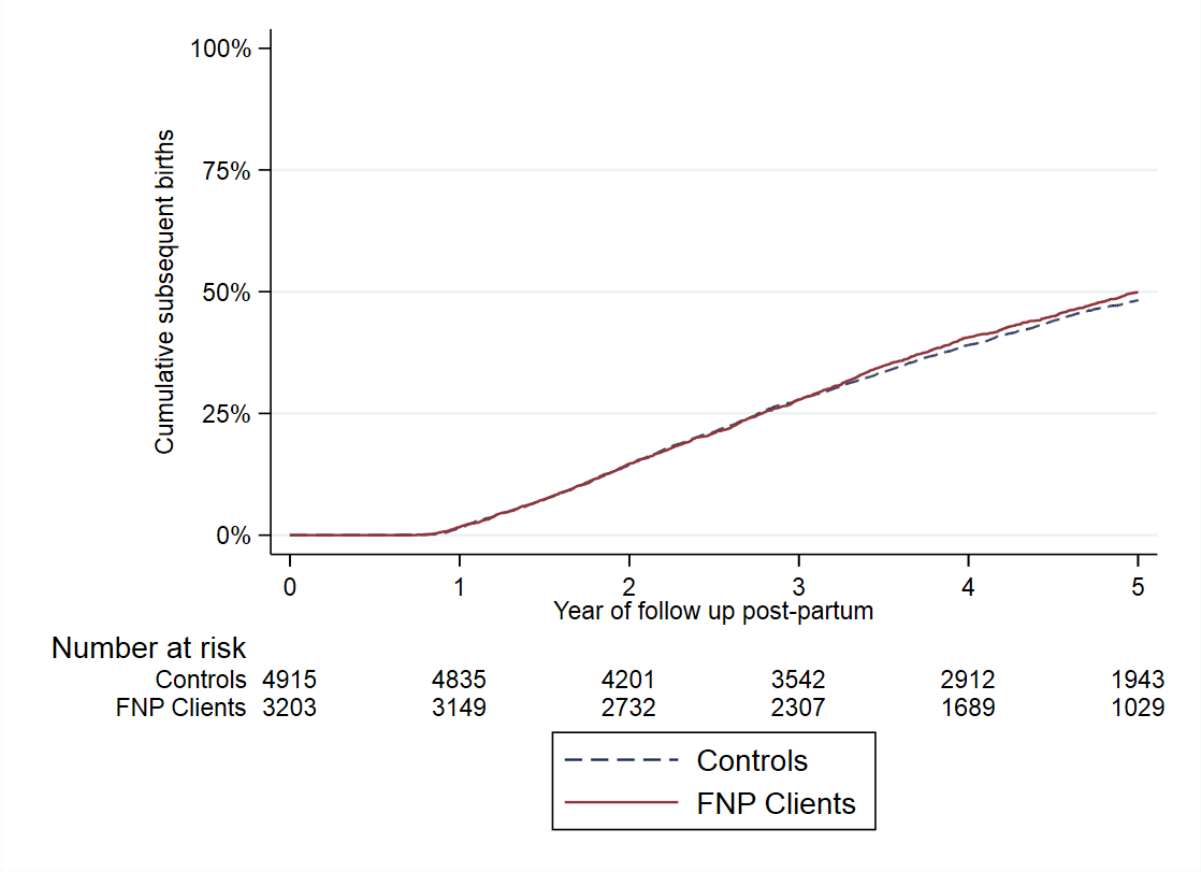
When the follow-up was truncated to less than 5 years to account for differential follow-up in the FNP Clients and Control groups, the median time to a subsequent birth was 2.7 years for FNP Clients and 2.7 for Controls (Table 5.7). The probability of not having a subsequent birth by different follow-up time points were comparable across groups (Table 5.7). There was no evidence of a difference in the time to subsequent birth, the adjusted hazard ratio (aHR) was 0.99 (95% CI: 0.92 to 1.07, p-value=0.800) (Table 5.7, Figure 5.3).

Table 5.7: Inter-birth interval (years) by FNP Clients and Controls

	FNP Clients N=3,203	Controls N=4,915	Adjusted[a] HR (95% CI)	p-value
Inter-birth interval (years), Median (IQR)	2.69 (1.82 to 3.56)	2.67 (1.82 to 3.65)	0.99 (0.92 to 1.07)	0.800
Probability of not having a subsequent birth[b] by:				
1 year follow-up	98.4	98.4		
2 years follow-up	85.4	85.6		
3 years follow-up	72.2	72.1		
4 years follow-up	59.3	61.0		
5 years follow-up	50.1	51.7		

CI=Confidence interval, HR=Hazard ratio, IQR=interquartile range
a adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced; b 'Survivor' functions (or in this case not having a subsequent birth) are presented at certain time points. The probability of 'surviving' the end of the k^{th} time-period is calculated by the probability of surviving to the end of the $(k-1)^{th}$ time-period, multiplied by the probability of surviving the k^{th} time-period.

Figure 5.3: Cumulative subsequent births during the 5 years post-partum by FNP Clients and Controls



Section 6: Child Outcomes

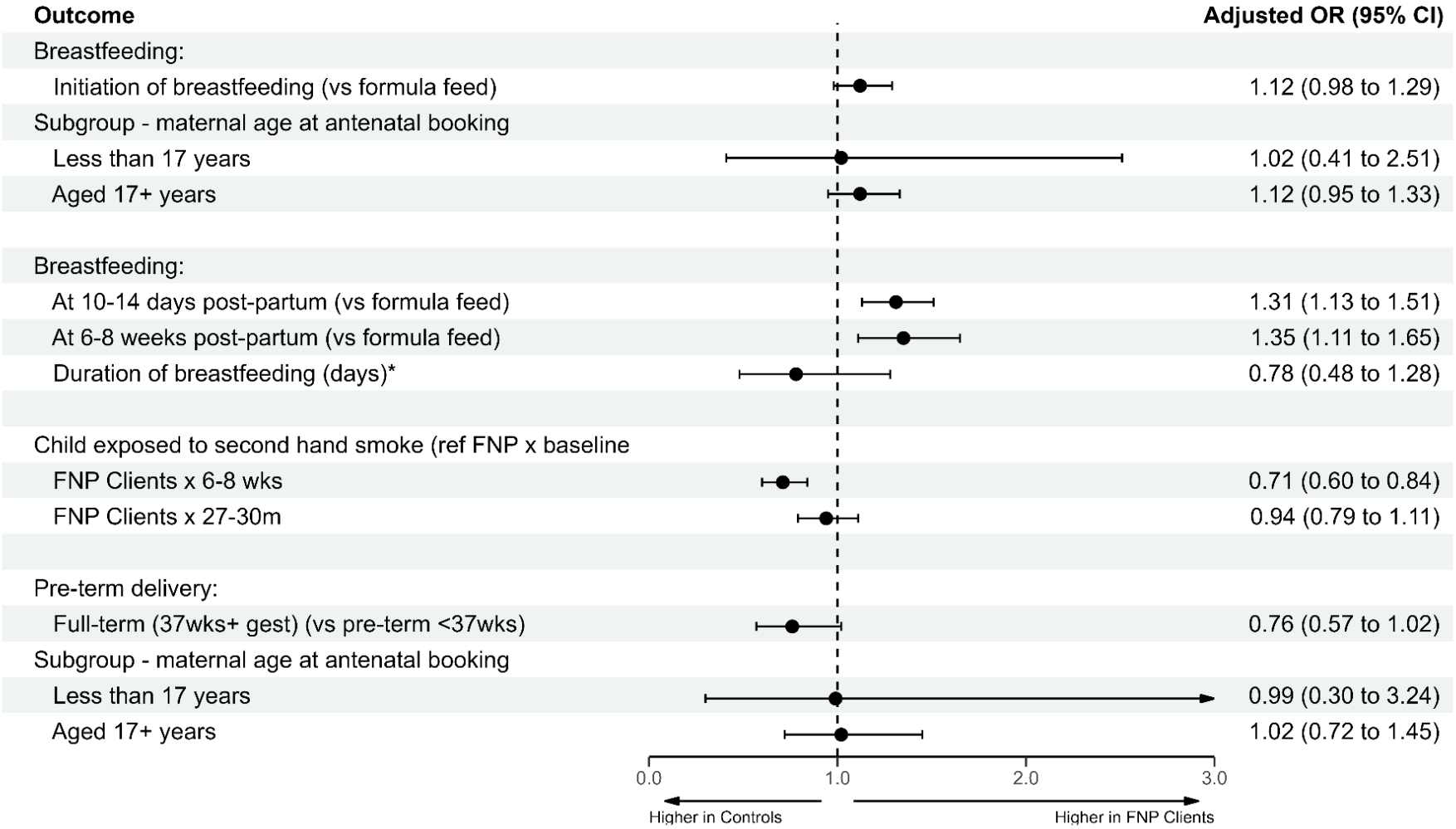
6.1 Competent parenting: child health

Key Findings

Tested outcomes:

- 40% of FNP Clients breastfed their babies at first feed following delivery compared to 37% of Controls, with no statistically significant difference between the groups in rates of breastfeeding initiation.
- At the 10-14 days post-partum child health assessment, breastfeeding was statistically significantly higher in the FNP group (22%) compared to the Controls (17%).
- Breastfeeding rates remained statistically significantly higher in the FNP group by the 6-8 weeks post-partum child health assessment (11% in FNP vs. 9% Controls)
- The percentage of mothers breastfeeding increased with the number of FNP visits received during the pregnancy period, with an 11-percentage points difference in breastfeeding rates between mothers with 5 visits or less compared to those with 16+ visits, at initiation and at 10-14 days post-partum. At 6-8 weeks, rates increased by 8 percentage points.
- In a small cohort of women recorded as breastfeeding at 10-14 days and/or 6-8 weeks, that had also reported stopping breastfeeding, the median (interquartile range) duration of breastfeeding (days) was 4.5 (1.75 to 15.3) for FNP Clients and 4 (2 to 10) in Controls.
- Rates of child exposure to second hand smoke substantially reduced between 10-14 days and 6-8 weeks post-partum with a statistically significantly larger reduction in rates observed in the FNP Clients (from 36.9% to 25.7%) compared to the Controls (from 34.2% to 30.3%). Rates of exposure for both groups at 27-30 months post-partum were similar (FNP Clients: 22.5%; Controls: 21.6%). The trend over time in rates of children exposed to second hand smoke in FNP Clients was significantly different to that observed in Controls, with a greater reduction in exposure to second hand smoke seen earlier in FNP (between 10-14 days and 6-8 weeks) compared to Controls (between 6-8 weeks and 27-30 months).

Figure 6.1: Forest plot of estimates from tested outcomes in the Competent Parenting child health and protection and Improved birth outcomes domains including subgroups



Data sources: Child Health Surveillance Programme (CHSP) Pre-School, SMR01-General / Acute Inpatient and Day Case, SMR02 – Maternity Inpatient and Day Case.

CI=Confidence interval, OR=Odds ratio
Note: OR compares outcomes for FNP Clients to Controls; an OR>1 indicates outcome is higher for FNP Clients; an OR<1 indicates outcome is lower for FNP Clients. Vertical dashed line represents no effect (ratio = 1). * Parameter estimate for duration of breastfeeding is an incidence rate ratio (IRR) from the negative binomial model.

Breastfeeding at initiation, 10-14 days and 6-8 weeks

Data source: *SMR02 – Maternity Inpatient and Day Case / Child Health Surveillance Programme (CHSP) Pre-School*

Hypothesised direction of FNP programme effect: *Increased initiation of breastfeeding, increased breastfeeding at 10-14 days and 6-8 weeks.*

Breastfeeding is defined as either exclusive breastfeeding or a mixture of breastfeeding and formula feeding. Breastfeeding initiation, measured by the first feed following delivery (as recorded in the SMR02) was marginally higher in FNP Clients compared to Controls (40.1% vs 37.3%), with no evidence of a difference after adjustment for measured confounders (aOR: 1.12, 95% CI: 0.98 to 1.29, p-value=0.096) (Table 6.1a). At the 10-14 days assessment (as recorded in the Child Health Surveillance Programme Pre-School), breastfeeding was more prevalent in FNP Clients (22%) than the Controls (17%) with evidence of significant differences between groups (aOR: 1.31, 95% CI: 1.13 to 1.51, p-value= <0.001). At the 6-8 week post partum assessment, breastfeeding was also more prevalent in FNP Clients (11%) compared to Controls (9%) (aOR: 1.35, 95% CI: 1.11 to 1.65, p-value=0.003).

When the rate of breastfeeding initiation was examined by the age of the mother (<17 years vs 17+ years), no difference in the effect of FNP was found in mothers aged less than 17 years compared to those aged 17 years and over (p-value =0.744) (Table 6.1b). No evidence of differential programme effects were found for any of the breastfeeding outcomes by year of antenatal booking (initiation: interaction p-value=0.951; 10-14 days: 0.999; 6-8 weeks: 0.984) nor between HBs (initiation: interaction p-value=0.117; 10-14 days: 0.109; 6-8 weeks: 0.427).

The number of FNP visits received during the pregnancy phase of the study was categorised to obtain sufficient numbers in each group. Based on the observed data in the FNP Clients only, the percentage of mothers initiating breastfeeding, breastfeeding at 10-14 days or 6-8 weeks increased as the number of visits increased (Table 6.1c). For example, 37% of women receiving 0-5 and 6-10 visits in pregnancy initiated breastfeeding, 44% of those receiving 11-15 visits, and 48% of those receiving 16 visits or more.

Table 6.1a: Breastfeeding by FNP Clients and Controls

	FNP Clients	Controls	Adjusted[a] OR (95% CI)	p-value
Breastfeeding initiation, n (%)				
Formula only	1,551 (59.9)	2,121 (62.7)	Reference	
Any breastfeeding	1,040 (40.1)	1,261 (37.3)	1.12 (0.98 to 1.29)	0.096
Exclusive	1,007 (38.9)	1,240 (36.7)		
Mixed	33 (1.2)	21 (0.6)		
Breastfeeding at 10-14 days, n (%)				
Formula only	2,449 (78.3)	3,940 (83.0)	Reference	
Any breastfeeding	677 (21.7)	809 (17.0)	1.31 (1.13 to 1.51)	<0.001
Exclusive	432 (13.8)	538 (11.3)		
Mixed	245 (7.8)	271 (5.7)		
Breastfeeding at 6-8 weeks assessment, n (%)				
Formula only	2,502 (89.1)	4,040 (90.8)	Reference	
Any breastfeeding	305 (10.9)	407 (9.2)	1.35 (1.11 to 1.65)	0.003
Exclusive	179 (6.4)	260 (5.8)		
Mixed	126 (4.5)	147 (3.3)		

CI=Confidence interval, OR=Odds ratio

a adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced.

Table 6.1b: Subgroup analysis – n (%) initiated breastfeeding by maternal age at antenatal booking (<17/17+ years) by FNP Clients and Controls

Subgroup	FNP Clients	Controls	Adjusted[a] OR (95% CI), p-value	Interaction p-value[b]
Maternal age <17 years	219 (36.0)	179 (31.6)	1.27 (0.96 to 1.67), 0.095	0.744
Maternal age ≥ 17 years	821 (41.4)	1,082 (38.4)	1.29 (1.13 to 1.47), <0.001	

CI=Confidence interval, OR=Odds ratio
a adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced;
b Overall p-value from the interaction term (group x maternal age) in the main model. Assesses whether the effect of FNP is different in one strata to another strata (e.g maternal age <17 years vs 17 years+).

Table 6.1c: Breastfeeding by FNP visits received in pregnancy phase

FNP visits	N mothers	N (%) breastfeeding initiation	N mothers	N (%) breastfeeding at 10-14 days	N mothers	N (%) breastfeeding at 6-8 weeks
0-5	269	99 (36.9)	354	61 (17.2)	320	24 (7.5)
6-10	1,099	402 (36.6)	1,358	261 (19.2)	1,207	122 (10.1)
11-15	1,175	516 (43.9)	1,361	340 (25.0)	1,229	151 (12.3)
16+	48	23 (47.9)	53	15 (28.3)	51	8 (15.7)
Total	2,591	1,040 (40.1)	3,126	677 (21.7)	2,807	305 (10.9)

Duration of breastfeeding

Data source: *Child Health Surveillance Programme (CHSP) Pre-School*
Hypothesised direction of FNP programme effect: *Increased duration of feeding (days)*

Duration of breastfeeding could only be examined in a reduced cohort of women who had been recorded as breastfeeding at either the 10-14 day or 6-8 week child health assessment (or at both) or those detailing the duration (in days and weeks) that they had ceased feeding. Breastfeeding was reported as the feeding method at either the first and/or 6-8 week visit or provided the week/days that breastfeeding had stopped (indicating that breastfeeding had occurred) for 831 (25.6%) of the FNP Clients and 931 (20%) of the Controls (Table 6.1d). The remainder of children either had missing feeding data (10.8% vs 9.0% respectively) or there was evidence to suggest that they had never breastfed (reported using formula at both visits) (63.3% vs 72.0% respectively). Of those that had reported breastfeeding at any visit (current feeding method or dates stopped), the majority had not provided stopping dates. Duration of any breastfeeding was examined in a cohort of 263 women (FNP: 170 vs Controls: 93) who had detailed the duration (in days and weeks) that they had ceased feeding. A total of 170 FNP Clients breastfed for a median of 4.5 days (IQR=1.75 to 15.25 days) compared to a median of 4 days (2 to 14 days) in 93 Controls, with no significant differences between the two groups (IRR: 0.78, 95% CI: 0.48 to 1.28, p-value=0.328).

Table 6.1d: Duration of breastfeeding in women that ever breastfed (days) by 6-8 weeks FNP Clients and Controls

	FNP Clients	Controls
Missing data at one or both visits (any valid data states Formula feeding), n (%)	345 (10.8)	441 (9.0)
Never breastfed (based on reporting formula at both child health visits), n (%)	2,024 (63.3)	3,531 (72.0)
Breastfeeding reported at any visit and date stopped feeding recorded (indicating BF), n (%)	831 (25.9)	931 (20.0)
Breastfed but stopped[a], n (%)	170 (20.5)	93 (10.0)
Median (IQR) duration of BF (days)	4.5 (1.75 to 15.25)	4 (2 to 14)

IQR=interquartile range. a Evidenced by a recording of a day/week stopped breastfeeding in the child health visit.

Exposed to second hand smoked

Data source: *Child Health Surveillance Programme (CHSP) Pre-School*
Hypothesised direction of FNP programme effect: *Reduced exposure to second hand smoke*

Exposure to second hand smoke was measured at the child health visits at 10-14 days, 6-8 weeks and 27-30 months using the question “Child exposed to second hand smoke (Y/N)”. At the 10-14 days assessment, around a third of FNP Clients and Controls had been recorded as being exposed to second hand smoke (36.9% vs 34.2% respectively) (Table 6.2a). Rates of child exposure to second hand smoke reduced between the 10-14 day and the 6–8-week assessment (11.2 percentage points in the FNP Clients and 3.9 percentage points in Controls). Between the 6–8-week assessment and the 27–30-month review, FNP Clients reduced a further 3.2 percentage points (to 22.5%), and Controls reduced rates of child exposure to second hand smoke by 8.7 percentage points (to 21.6%). There was evidence that the trend in children exposed to second hand smoke in FNP Clients was different to that observed in Controls, with a larger reduction in FNP Clients at an earlier timepoint between 10-14 days and 6-8 weeks, and a larger reduction in Controls at the later timepoint between 6-8 weeks and 27-30 months (interaction term: p=0.0002) (Table 6.2a).

Table 6.2a: Child exposed to second hand smoke over time by FNP Clients and Controls

n (%) child exposed to second hand smoke	FNP Clients	Controls
10-14 days assessment	934 (36.9)	1,331 (34.2)
6-8 weeks assessment	534 (25.7)	1,026 (30.3)
27-30 month review	578 (22.5)	831 (21.6)

Rates of children exposed to second hand smoke over time in mothers who were current smokers at antenatal booking were compared to mothers who were recorded as being non/former smokers. Rates of children exposed to second hand smoke was higher in mothers defined as current smokers at antenatal booking compared to non/former smokers over all time points (Table 6.2b). However, there was no evidence of a differential effect in children exposed to second hand smoke over time between FNP Clients and Controls, when current and non-/former smokers were compared (interaction p-value = 0.663).

Table 6.2b: Subgroup analysis – n (%) exposure to second hand smoke over time by smoking status at booking and FNP Clients and Controls

	Non / Former smoker		Current smoker	
	FNP Clients	**Controls**	**FNP Clients**	**Controls**
10-14 days assessment	369 (24.3)	534 (22.2)	533 (57.9)	730 (57.4)
6-8 weeks assessment	227 (18.1)	478 (22.9)	284 (37.9)	467 (42.3)
27-30 months review	230 (15.1)	348 (14.8)	328 (34.4)	436 (33.2)

6.2 Improved birth outcomes

Key Findings

Tested outcomes:

- Rates of pre-term delivery (babies born before 37 weeks) were similar across study groups (FNP Clients 8.8% vs Controls 7.8%) with no statistically significant difference between groups. For FNP Clients, there was an observable relationship between the number of FNP visits during pregnancy and the proportion of pre-term deliveries, with a reduction of pre-term delivery for those that received 11-15 visits during pregnancy (3.7%).
- There was no differential programme effect observed in mothers aged less than 17 years at antenatal booking when compared to mothers aged 17 years and over.

Descriptive outcomes:

- Birth weights were comparable between babies of FNP Clients and Controls, of 3266 grams and 3284 grams respectively.
- Using the Customized Gestation Related Optimal Weight (GROW) centiles (which adjusts for maternal height and weight, ethnicity, gestational age, parity and sex of baby), nearly one in ten of babies were small for gestational age (FNP Clients 9.3% vs Controls 10.3%) and under 5% were large for gestational age in both groups with no observable differences between groups.

Pre-term delivery

Data source: *SMR02 – Maternity Inpatient and Day Case*

Hypothesised direction of FNP programme effect: *Reduced pre-term delivery*

Pre-term delivery (before 37 weeks) was observed in 8.8% of deliveries to FNP Clients and 7.8% of Controls, with no evidence of a programme effect after adjustment for groups (aOR: 0.76, 95% CI: 0.57 to 1.02, p-value=0.069) (Table 6.3a). In mothers aged less than 17 years of age at antenatal booking, 9.1% of children born to mothers enrolled in FNP were preterm births (born before 37 weeks) compared to 7.8% of children born to Controls. In mothers aged 17 years and over preterm births were 8.7% vs 7.8% respectively. When these two subgroups were compared, there was no differential effect (interaction p-value=0.526). There was also no differential effect in preterm rates over time (interaction p-value=0.276) or between HBs (interaction p-value=0.499). For FNP Clients, there was an observable relationship between the number of FNP visits during pregnancy and the proportion of pre-term deliveries, with a reduction of pre-term delivery for those that received 11-15 visits during pregnancy (3.7%) (Table 6.3b).

Table 6.3a: Pre-term delivery by FNP Clients and Controls

	FNP Clients N=3,225	Controls N=4,941	Adjusted[a] OR (95% CI)	p-value
Gestational age at birth (weeks), n (%)				
Preterm (<37 weeks)[b]	284 (8.8)	386 (7.8)	Reference	
Full term (37 weeks+)	2,941 (91.2)	4,555 (92.2)	0.76 (0.57 to 1.02)	0.069
			Absolute difference[c] (95% CI)	
Gestational age at birth (weeks), n (%)				
<28 weeks (extremely preterm)	20 (0.6)	25 (0.5)	0.1 (-0.2 to 0.5)	
28 to <32 weeks (very preterm)	29 (0.9)	39 (0.8)	0.1 (-0.3 to 0.6)	
32 to <37 weeks (moderately to late preterm)	235 (7.3)	322 (6.5)	0.8 (-0.3 to 1.9)	
Full term (37 weeks+)	2,941 (91.2)	4,555 (92.2)	-0.1 (-2.3 to 2.2)	

	FNP Clients N=3,225	Controls N=4,941	Adjusted[a] OR (95% CI)	p-value
Subgroup analysis – n (%) pre-term deliveries (<37 weeks) by maternal age at antenatal booking				Interaction p-value[d]
Maternal age <17 years	68 (9.1)	67 (7.8)	1.01 (0.56 to 1.79)	
Maternal age ≥ 17 years	216 (8.7)	319 (7.8)	0.81 (0.62 to 1.06)	0.526

CI=Confidence interval, OR=Odds ratio
a Adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced; b For babies missing gestational age at birth (n=16), data was imputed using formula: Child date of birth – booking date + gestational age at booking; c FNP Clients minus Controls; d From the interaction term (group by age).

Table 6.3b: Dosage–FNP visits during pregnancy and pre-term delivery rates

FNP visits	Total mothers (N)	N (%) <37 weeks	N (%) 37 weeks +
0-5 visits	375	61 (16.3)	314 (83.7)
6-10 visits	1,407	166 (11.8)	1,241 (88.2)
11-15 visits	1,388	51 (3.7)	1,337 (96.3)
16+ visits	55	6 (10.9)	49 (89.1)

Birth weight

Data source: *SMR02 - Maternity Inpatient and Day Case*
Hypothesised direction of FNP programme effect: *Uncertainty in direction of effect- descriptive*

Babies' birth weights (grams) were comparable; 3,266 grams in children born to FNP Clients vs 3,284 grams in children born to Controls, a difference of 18.2 grams (FNP Clients minus Controls) (95% CI: -44.9 to 8.2 grams) (Table 6.4). Using the customised Gestation Related Optimal Weight (GROW) centiles which adjusts for maternal height and weight, ethnicity, gestational age, parity and sex of baby (GROW does not adjust for maternal smoking status). The majority of babies were a healthy weight for gestational age (between the 5th and 95th centiles) but nearly 10% were small for gestational age (<5th centile). There did not appear to be any differences in maternal age by each of these centile categorisations.

Table 6.4: Birth weight (grams) by FNP Clients and Controls

	FNP Clients N=3,225	**Controls N=4,941**
Birth weight (grams) Mean (SD)	3266.1 (609.2)	3284.3 (595.9)
Birth weight, n (%)	N=3,212	N=4,938
Small for gestational age (<5th centile)	300 (9.3)	507 (10.3)
Healthy (5th to 95th centile)	2,764 (86.1)	4,210 (85.3)
Large for gestational age (>95th centile)	148 (4.6)	221 (4.5)
Subgroup analysis – Maternal age by birthweight		
Maternal age <17 years, n (%)		
Small for gestational age (<5th centile)	81 (10.8)	77 (9.0)
Healthy (5th to 95th centile)	624 (83.4)	743 (86.5)
Large for gestational age (>95th centile)	43 (5.7)	39 (4.5)
Maternal age ≥ 17 years, n (%)		
Small for gestational age (<5th centile)	240 (9.7)	409 (10.0)
Healthy (5th to 95th centile)	2,126 (86.0)	3,481 (85.5)
Large for gestational age (>95th centile)	106 (4.3)	181 (4.4)

SD=Standard deviation

6.3 Improved child health and competent parenting

Key Findings

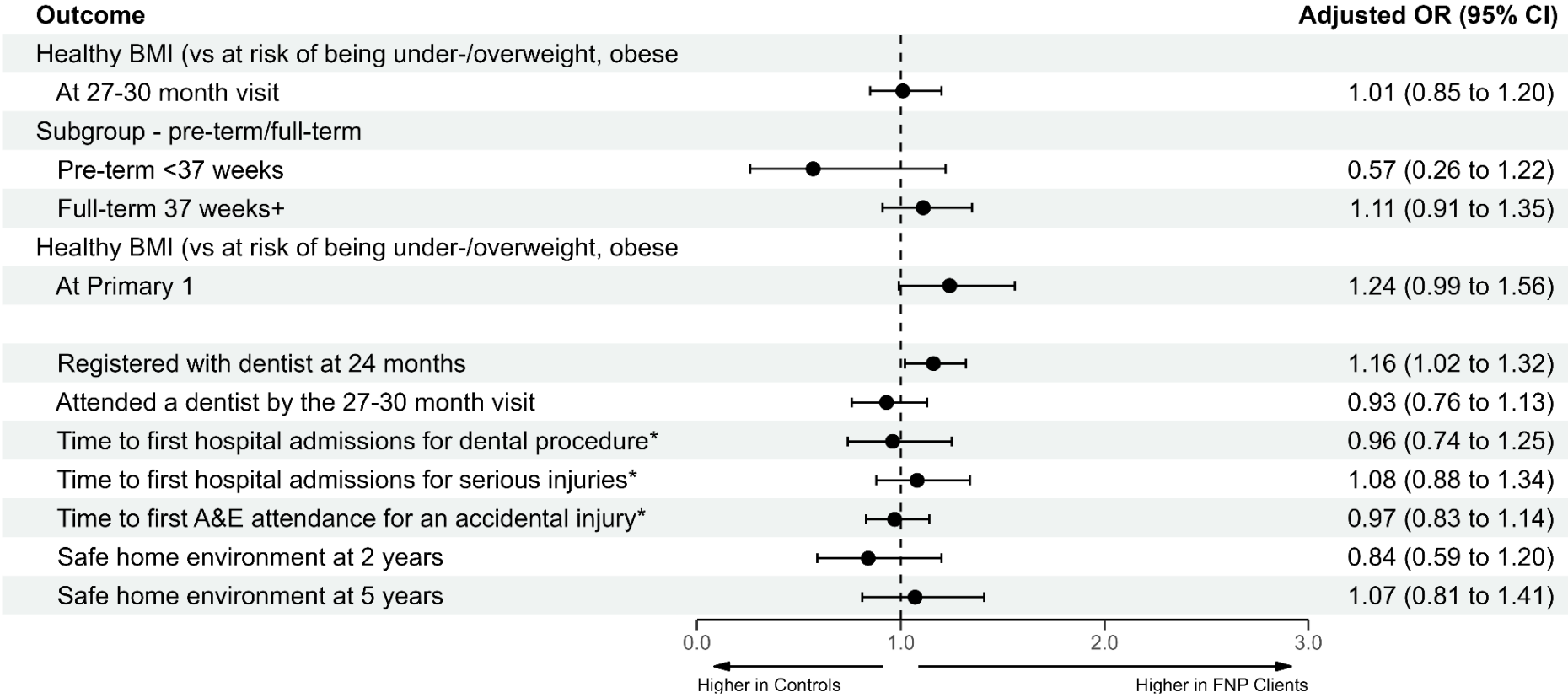
Tested outcomes:

- No statistically significant differences in rates of children with a healthy BMI were found between the study groups at the 27-30 months and the Primary 1 review. At the 27-30 months review: 68% (FNP) and 69% (Controls) of children had a healthy BMI. However, at the Primary 1 review, the proportion of FNP children (71%) having a healthy BMI increased while the proportion of children in the Controls having a healthy BMI (67%) fell.
- A statistically significantly higher proportion of children in the FNP group were registered with a dentist by age 24 months, with differential effect across HBs.
- The rate of children attending a dentist by 27-30 months was the same across study groups and a comparable time to first hospital admission for a dental procedure was observed.
- There were no statistically significant differences between study groups in the time to first hospital admission for a serious injury or to first A&E attendance for an accidental injury.
- There was no evidence of a statistically significant difference in hospital admissions for unintentional injuries in the home between FNP Clients and Controls.
- There was no evidence of a statistically significant difference in the proportion of children with at least one hospital admission due to an unintentional injury in the home by two years and by five years.

Descriptive outcomes:

- Unadjusted rates of admission for accidental injuries were similar across study groups at six months, one, two and five years. Injuries to the head were the main reason for admissions in both groups.
- Unadjusted rates of attendances to A&E (for any reason) were slightly higher in the FNP group compared to Controls with soft tissue injuries/wounds and head injuries being the main nature of attendances. The same pattern is seen for rates of attendances to A&E specifically for accidental injuries.

Figure 6.2: Forest plot of estimates from tested outcomes in the Competent Parenting: child health and child protection domain including subgroups



Data sources: Child Health Surveillance Programme Pre-School (27-30m) / School (Primary 1), SMR01 - General/Acute Inpatient and Day Case, Accident and Emergency.

CI=Confidence interval, OR=Odds ratio
OR compares outcomes for FNP Clients to Controls; an OR>1 indicates outcome is higher for FNP Clients; an OR<1 indicates outcome is lower for FNP Clients. Vertical dashed line represents no effect (ratio = 1). * The parameter estimate for time to event analyses is presented as a hazard ratio (HR); a HR>1 indicates that the FNP Clients experience a higher event probability within any given period than the Controls; a HR<1 indicates that the Controls experience a higher event probability within any given period than the FNP Clients.

Physical development at 27-30 months and Primary 1 review

Data source: *Child Health Surveillance Programme (CHSP) Pre-School (27-30m) / School (Primary 1)*
Hypothesised direction of FNP programme effect: *Increased children with healthy BMI*

Recorded height and weight data was available for 50% of children at the 27-30 month review. Just over two-thirds of these children had a healthy BMI (birth weight between 2nd and 85th centile) at the 27-30 month child health review (FNP Clients: 68.0% vs Controls: 69.3%) (Table 6.5). By the Primary 1 review, the groups diverge with the proportion of children with a healthy BMI rising to 71.4% in FNP Clients but reducing to 67.0% in the Controls. It should be noted that less children had data recorded at Primary 1 with a smaller proportion from FNP enrolled mothers assessed than Controls (21% vs 42% respectively). No statistically significant difference in BMI centiles was observed between FNP Clients and Controls at either 27-30 month review or the Primary 1 review.

There was no differential effect in healthy BMI by gestational age (full term: 37 weeks+ vs pre-term <37 weeks) (interaction p-value=0.443). There were also no differential effects seen across the HBs (interaction p-value at 27-30m: 0.131; interaction p-value at Primary 1: 0.819) or over time (27-30m: 0.128; Primary 1: 0.080).

Table 6.5: Physical development outcomes – BMI at 27-30 months review and at primary 1 by FNP Clients and Controls

	FNP Clients	Controls	Adjusted[a] OR (95% CI)	p-value
BMI recorded at 27-30 month review	N=1,627	N=2,462		
BMI Category, n (%)				
Child at risk of being underweight (<2nd centile), overweight, or obese (85th centile+)	520 (32.0)	756 (30.7)	Reference	
Underweight (<2nd centile)	*52 (3.2)*	*55 (2.2)*	-	
Overweight (85th to <95th centile)	*264 (16.2)*	*384 (15.6)*	-	
Obese (95th+ centile)	*204 (12.5)*	*317 (12.9)*	-	
Healthy BMI (2nd to 85th centile)	1,107 (68.0)	1,706 (69.3)	1.01 (0.85 to 1.20)	0.946

	FNP Clients	Controls	Adjusted[a] OR (95% CI)	p-value
Subgroup – Pre-term delivery % healthy				
Pre-term <37 weeks	85 (67.5)	124 (70.9)	0.57 (0.26 to 1.22)	0.443
Full-term 37 weeks+	1,022 (68.1)	1,582 (69.2)	1.11 (0.91 to 1.35)	
BMI recorded at Primary 1 review	N=667	N=2,069		
BMI Category, n (%)				
Child at risk of being underweight, (<2nd centile) overweight, obese[b], (85th centile+)	191 (28.6)	683 (33.0)	Reference	
Healthy BMI (2nd to 85th centile)	476 (71.4)	1,386 (67.0)	1.24 (0.99 to 1.56)	0.067

BMI=Body mass index, CI=Confidence interval, OR=Odds ratio
a Taken from non-imputed model and adjusted for maternal age, maternal mental health, asthma, diabetes, deprivation quintile, previous pregnancy, gestation at delivery, smoking at booking, Maternal BMI, ethnicity, birthweight, Health Board and year of booking; b data not broken down as above categories due to small numbers.

Dental registrations and attendances by 27-30 months

Data source: *Child Health Surveillance Programme (CHSP) Pre-School, SMR01 - General/Acute Inpatient and Day Case*

Hypothesised direction of FNP programme effect: *Increased registrations to dentist and uptake of dental care*

Overall, over 60% of children had been registered at the dentist by the age of 24 months, as reported on the 27-30 month child health review. A higher proportion of FNP Clients registered compared to Controls (61.8% vs 60.7% respectively), with a significant statistical difference found between the two groups after adjusting for confounders (OR: 1.16, 95% CI: 1.02 to 1.32, p-value=0.020) (Table 6.6a). Over 76% of children had been reported as attending a dentist by the 27-30 month child health review (FNP Clients: 76.1% vs Controls: 76.9%), with no significant statistical difference between groups (0.93, 0.76 to 1.13, p-value=0.479).

Table 6.6a: Dental outcomes by FNP Clients and Controls

	FNP Clients	Controls	Adjusted[a] OR (95% CI)	p-value
Registered with dentist at 24 months, n (%)	N=3,068	N=4,583		
No	998 (38.2)	1,545 (39.3)	Reference	
Yes	1,614 (61.8)	2,385 (60.7)	1.16 (1.02 to 1.32)	0.020
Attended a dentist by 27-30 month, n (%)	N=3,068	N=4,583		
No	383 (23.9)	539 (23.1)	Reference	
Yes	1,219 (76.1)	1,794 (76.9)	0.93 (0.76 to 1.13)	0.479

CI=Confidence interval, OR=Odds ratio
a adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced

There was a differential programme effect found in the proportion of children registered at the dentist by the age of 24 months by HBs (interaction p-value=0.0005) but not year of antenatal booking (0.588). Significant differences in rates of children registered with a dentist were observed between FNP Clients and Controls in NHS Tayside, Fife, Forth Valley, and Highland (Table 6.6b), with FNP Clients' children more likely to be registered in these health board areas compared to controls. No differential effect was found in the proportion of children attending a dentist by the 27-30 month child health review either by health board (0.611) or year of antenatal booking (0.855).

Table 6.6b: Number (%) of children registered with dentist at 24 months by health board

NHS Health Board	FNP Clients	Controls	Adjusted[a] OR (95% CI)
Ayrshire and Arran	138 (67.3)	253 (61.3)	1.46 (0.78 to 2.72)
Borders	10 (62.5)	26 (65.0)	Could not be estimated
Fife	241 (75.1)	243 (67.5)	0.81 (0.49 to 1.35)
Forth Valley	59 (73.8)	124 (55.9)	2.22 (1.02 to 4.83)
Grampian	39 (57.4)	82 (56.2)	0.79 (0.32 to 1.97)
Greater Glasgow and Clyde	228 (64.0)	724 (64.4)	0.91 (0.54 to 1.53)
Highland	79 (87.8)	101 (62.0)	4.63 (0.72 to 29.97)
Lanarkshire	131 (60.6)	409 (64.1)	0.89 (0.56 to 1.39)
Lothian	346 (54.4)	250 (54.3)	0.86 (0.54 to 1.36)
Tayside	343 (55.0)	173 (47.5)	1.40 (0.91 to 2.16)

CI=Confidence interval, OR=Odds ratio
a adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced

There was no evidence of an increase in the proportion of children either registered with a dentist at 24 months or those attending a dentist by 27-30 months in FNP Clients, as the total number of FNP visits received increased (Table 6.6c).

Table 6.6c: FNP visits by dental outcomes recorded at 27-30 month child health review

Total FNP visit[a]	Number of children	Registered with dentist at 24m	Number of children	Attended a dentist by 27-30m
1-10	151	88 (58.3)	87	66 (75.9)
11-20	90	56 (62.2)	55	39 (70.9)
21-30	238	126 (52.9)	124	99 (79.8)
31-40	608	349 (57.4)	347	257 (74.1)
41-50	1031	641 (62.2)	638	257 (74.1)
51-60	419	304 (72.6)	301	232 (77.1)
60+	72	48 (66.7)	48	36 (75.0)

a FNP visits received by FNP clients over the whole programme (pregnancy, infancy and toddlerhood)

Admissions for dental procedures

Data source: *Child Health Surveillance Programme (CHSP) Pre-School, SMR01 – General/Acute Inpatient and Day Case*

Hypothesised direction of FNP programme effect: *Reduced admissions/increased time to dental procedures*

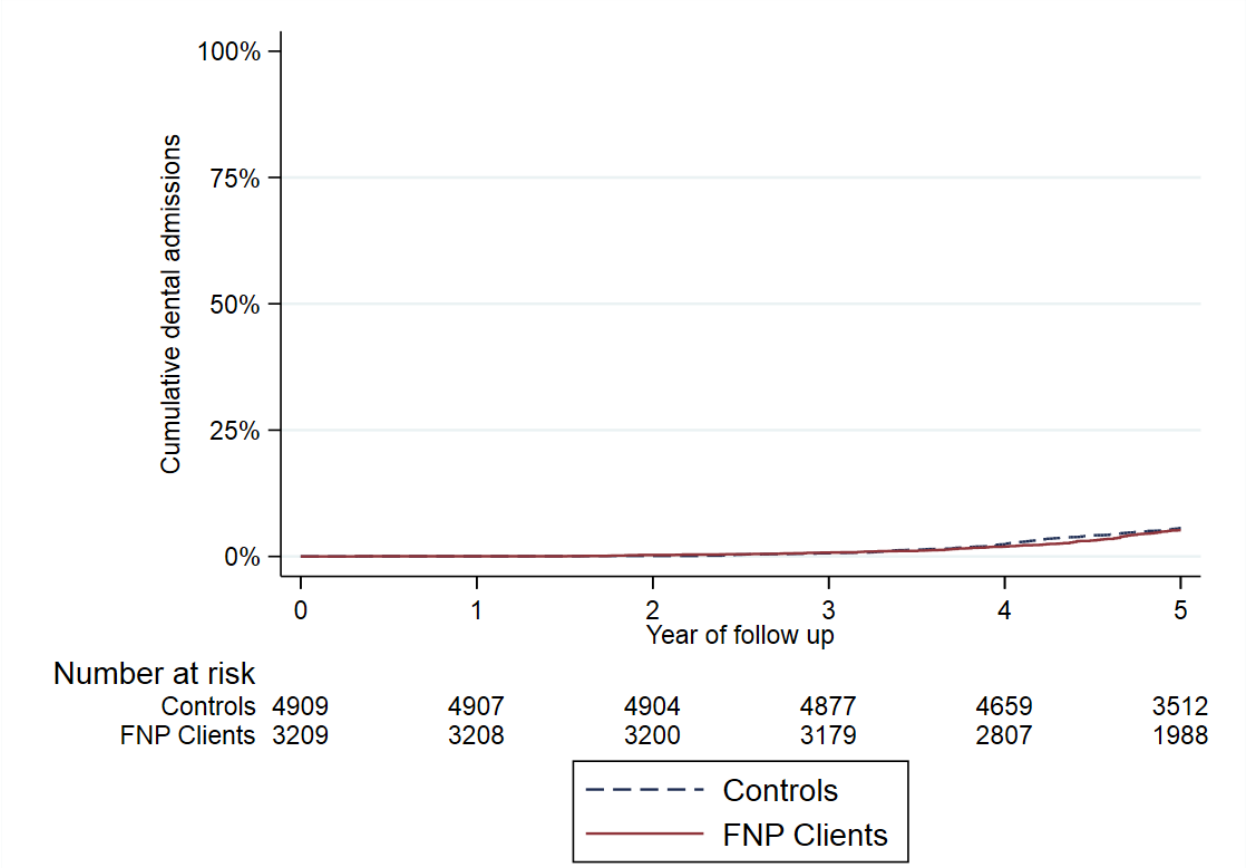
Time to first dental admission was measured as the duration in years between the child's date of birth and their first admission to hospital for a dental procedure. When the follow-up was truncated to 5 years to account for differential follow-up in FNP Clients and Controls, the median duration to first dental admission for children of FNP Clients was 4.2 years and 4.0 years in Controls (Table 6.7). The probability of children not being admitted to hospital for a dental procedure were comparable at each time point (Table 6.7). There was no evidence of a difference found between groups, with an adjusted hazard ratio (aHR) of 0.96 (95% CI: 0.74 to 1.25, p-value=0.773) (Table 6.7, Figure 6.3).

Table 6.7: Time to first dental admission (years) by FNP Clients and Controls

	FNP Clients N=3,209	Controls N=4,909	Adjusted[a] HR (95% CI)	p-value
Time to first dental admission (years), Median (IQR)	4.18 (3.45 to 4.64)	4.02 (3.45 to 4.45)	0.96 (0.74 to 1.25)	0.773
Probability of a child not having a dental admission[b] by:				
1 year follow-up	*	*		
2 years follow-up	*	*		
3 years follow-up	99.3	99.4		
4 years follow-up	98.1	97.6		
5 years follow-up	94.8	94.4		

CI=Confidence interval, HR=Hazard ratio. * number of children with a dental admission is <10; cells suppressed.
a Adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced; b 'Survivor' functions (or in this case not having an admission to hospital for a dental procedure) are presented at certain time points. The probability of 'surviving' the end of the k^{th} time-period is calculated by the probability of surviving to the end of the $(k-1)^{th}$ time-period, multiplied by the probability of surviving the k^{th} time-period.

Figure 6.3: Proportion of children with a dental procedure over time by FNP Clients and Controls



Hospital admissions for serious injuries

Data source: *SMR01 - General/Acute Inpatient and Day Case*

Hypothesised direction of FNP programme effect: *Admissions for serious injuries present later*

Time to first event was measured as the duration in years between the child's date of birth and their first admission to hospital for a serious injury. When the follow-up was truncated to 5 years to account for differential follow-up in FNP Clients and Controls, the median age at first hospital admission for children of FNP Clients was 1.38 years and 1.88 years in Controls (Table 6.8a). The probability of a child having no admission for a serious injury at 1 year was 98% in FNP and 98% in Controls; at 5 years the probability of a child not having an admission was equivalent (93% in both arms). There was no evidence of a difference between groups (aHR: 1.08, 95% CI: 0.88 to 1.34, p-value=0.478) (Table 6.8a, Figure 6.4).

Table 6.8a: Time to first admissions for serious injuries (years) by FNP Clients and Controls

	FNP Clients N=3,209	Controls N=4,909	Adjusted[a] HR (95% CI)	p-value
Time to first admissions for serious injuries (years), Median (IQR)	1.38 (0.83 to 2.06)	1.88 (1.05 to 2.66)	1.08 (0.88 to 1.34)	0.478
Probability of a child with no admission for a serious injury[b] by:				
1 year follow-up	97.8	98.4		
2 years follow-up	95.1	96.3		
3 years follow-up	94.1	94.4		
4 years follow-up	93.6	93.6		
5 years follow-up	93.3	93.1		

* number of children with a dental admission is <10; cells suppressed.

a Adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced; b 'Survivor' functions (or in this case not having an admission to hospital for a dental procedure) are presented at certain time points. The probability of 'surviving' the end of the k^{th} time-period is calculated by the probability of surviving to the end of the $(k-1)^{th}$ time-period, multiplied by the probability of surviving the k^{th} time-period.

Figure 6.4: Proportion of children with hospital admissions for serious injuries over time by FNP Clients and Controls

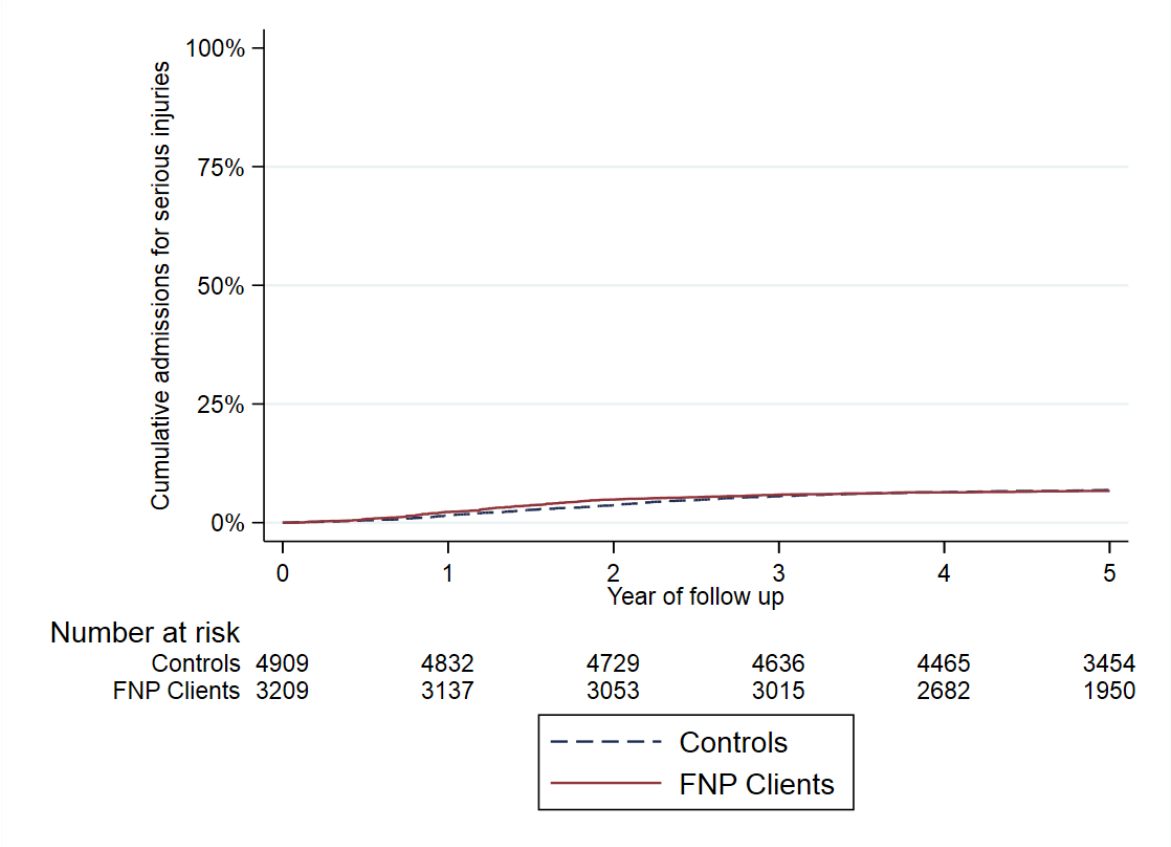


Table 6.8b shows the descriptive results for hospital admission for serious injuries including the proportions of children with at least one admission for serious injuries, the number of admissions by cause of admission, and the length of stay at four separate time points: by 6 months, 1 year, 2 years, and 5 years. Around 1% of children (FNP Clients: 1.1% vs Controls: 1.2%) were admitted by 6 months old, rising to 2% in both groups by the age of one, 4% in both groups by the age of two and to 8-9% by the age of five. At each time point, injuries to the head are the main reason for admissions. Length of stay were mainly comparable between the two groups including all admissions and also excluding the same day admissions.

Table 6.8b Hospital admissions for serious injuries – at 6 months, 1, 2 and 5 years and type of attendance by FNP Clients and Controls

	FNP Clients N=3,209	Controls N=4,909	Absolute difference[a] (95% CI)
Children with hospital admissions for serious injuries at 6 months (unit=child), n (%)			
No admissions	3,173 (98.9)	4,848 (98.8)	
At least one admission	36 (1.1)	61 (1.2)	-0.1 (-0.6 to 0.4)
Number of admissions (unit=admission)	N=40	N=67	
Nature of injury, n (%)			
Injuries to the head	22 (55.0)	46 (68.7)	
Other causes (Injuries to other body areas, burns, poisoning, Effects of foreign body entering through natural orifice, toxic effects of substances, other unspecified external causes)	18 (45.0)	21 (31.3)	
Length of stay (days), Median (IQR)			
All admissions	2.0 (1.0 to 3.75)	1.0 (0.0 to 2.0)	
Excluding same day admissions	2.5 (1.0 to 4.0)	2.0 (1.0 to 4.0)	
Length of stay, n (%)			
0 (same day admission)	8 (20.0)	30 (44.8)	
1 day	11 (27.5)	14 (20.9)	
2 days or more	21 (52.5)	23 (34.3)	
Children with hospital admissions for serious injuries by 1 year of age (unit=child), n (%)			
No admissions	3,143 (97.9)	4,798 (97.7)	
At least one admission	66 (2.1)	111 (2.3)	-0.2 (-0.8 to 0.5)
Number of admissions (unit=admission)	N=76	N=131	
Nature of injury, n (%)			
Injuries to the head	47 (61.8)	82 (62.6)	
Injuries (other locations)	12 (15.8)	24 (18.3)	
Other causes (Effects of foreign body entering through natural orifice/Burns and corrosions/Poisoning by drugs, medicaments and biological substances/Toxic effects of substances chiefly nonmedical as to source)	17 (22.4)	25 (19.1)	

	FNP Clients N=3,209	Controls N=4,909	Absolute difference[a] (95% CI)
Length of stay (days), Median (IQR)			
All admissions	1.0 (0.0 to 3.0)	1.0 (0.0 to 2.0)	
Excluding same day admissions	2.0 (1.0 to 3.5)	2.0 (1.0 to 4.0)	
Length of stay, n (%)			
0 (same day admissions)	27 (35.5)	64 (48.9)	
1 day	21 (27.6)	33 (25.2)	
2 days or more	28 (36.8)	34 (27.0)	
Children with hospital admissions for serious injuries by 2 years of age (unit=child), n (%)			
No admissions	3,070 (95.7)	4,691 (95.6)	
At least one admission	139 (4.3)	218 (4.4)	-0.1 (1.0 to 0.8)
Number of admission (unit=admission)	N=167	n=253	
Nature of admission, n (%)			
Injuries to the head	80 (47.9)	131 (51.8)	
Injuries (other locations)	24 (14.4)	45 (17.8)	
Effects of foreign body entering through natural orifice/ Other and unspecified effects of external causes	13 (7.8)	17 (6.7)	
Burns and corrosions	21 (12.6)	12 (4.7)	
Poisoning by drugs, medicaments and biological substances	19 (11.4)	22 (8.7)	
Toxic effects of substances chiefly nonmedical as to source	10 (6.0)	26 (10.3)	
Length of stay (days), Median (IQR)			
All admissions	1.0 (0.0 to 1.0)	0.0 (0.0 to 1.0)	
Excluding same day admissions	1.0 (1.0 to 3.0)	1.0 (1.0 to 3.0)	
Length of stay, n (%)			
0 (same day admissions)	79 (47.3)	138 (54.5)	
1 day	50 (29.9)	70 (27.7)	
2 days	12 (7.2)	13 (5.1)	
3 days or more	26 (15.6)	32 (12.6)	

	FNP Clients N=3,209	Controls N=4,909	Absolute difference[a] (95% CI)
Children with hospital admissions for serious injuries by 5 years of age (unit=child), n (%)			
No admissions	2,943 (91.7)	4,471 (91.1)	
At least one admission	266 (8.3)	438 (8.9)	-0.6 (-1.9 to 0.6)
Number of admission (unit=admission), n (%)	N=333	N=515	
Nature of admission, n (%)			
Injuries to the head	138 (41.4)	227 (44.1)	
Injuries (other locations)	97 (29.1)	144 (28.0)	
Effects of foreign body entering through natural orifice/ Other and unspecified effects of external causes	12 (3.6)	31 (6.0)	
Burns and corrosions	34 (10.2)	17 (3.3)	
Poisoning by drugs, medicaments and biological substances	35 (10.5)	59 (11.5)	
Toxic effects of substances chiefly nonmedical as to source	17 (5.1)	37 (7.2)	
Length of stay (days), Median (IQR)			
All admissions	0.0 (0.0 to 1.0)	0.0 (0.0 to 1.0)	
Excluding same day admissions	1.0 (1.0 to 2.0)	1.0 (1.0 to 2.0)	
Length of stay, n (%)			
0 (same day admissions)	188 (56.5)	293 (56.9)	
1 day	91 (27.3)	145 (28.2)	
2 days	18 (5.4)	24 (4.7)	
3 days or more	36 (10.8)	53 (10.3)	

CI=Confidence interval, IQR=interquartile range

a FNP Clients minus Controls

Any attendance to Accident & Emergency

Data source: *Accident and Emergency (A&E)*

Hypothesised direction of FNP programme effect: *Uncertainty in direction of effect – descriptive only*

As there was uncertainty over how to interpret direction of effect with any attendances to A&E for children, the results for this outcome are descriptive. Table 6.9 shows the children with at least one attendance to A&E by the age of 6 months, 1, 2, and 5 years of age and the nature of the attendance. Rates of A&E attendance for any reason were by six months 1.8% (FNP Clients) 1.0% (Control), by 1 year 5.0% (FNP Clients) 2.8% (Control), by 2 years 11.7% (FNP Clients) 7.8% (Control) and by 5 years 16.4% (FNP Clients) 14.4% (Control). The nature of attendances was mainly head and soft tissue/wound injuries.

Table 6.9: Attendances to A&E for any cause – at 6 months, 1, 2 and 5 years and nature of attendance by FNP Clients and Controls

	FNP Clients N=3,101	Controls N=4,602	Absolute difference[a] (95% CI)
Children with at least one attendance to A&E by 6 months old, n (%)			
No attendances	3,046 (98.2)	4,558 (99.0)	
At least one attendance	55 (1.8)	44 (1.0)	0.8 (0.3 to 1.4)
Total number of attendances	N=56	N=47	
Nature of attendance, n (%)			
Head injury	29 (51.8)	27 (57.5)	
Soft tissue injury/Wounds[b]	16 (28.6)	12 (25.5)	
Other reasons (burn, scald, poisoning, fractures)	11 (19.6)	8 (17.0)	
Children with at least one attendance to A&E by 1 year old, n (%)			
No attendances	2,946 (95.0)	4,471 (97.2)	
At least one attendance	155 (5.0)	131 (2.8)	2.2 (1.3 to 3.1)
Total number of attendances	N=174	N=147	
Nature of attendance, n (%)			
Head injury	81 (46.6)	72 (49.0)	
Soft tissue injury/Wounds[b]	50 (28.7)	41 (27.9)	
Burn/Scalds/Blisters	24 (13.8)	18 (12.2)	

	FNP Clients N=3,101	Controls N=4,602	Absolute difference[a] (95% CI)
Other reasons	19 (10.9)	16 (10.9)	
Children with at least one attendance to A&E by 2 years old, n (%)			
No attendances	2,739 (88.3)	4244 (92.1)	
At least one attendance	362 (11.7)	358 (7.8)	3.9 (2.5 to 5.3)
Total number of attendances	N=465	N=483	
Nature of attendance, n (%)			
Head injury	187 (40.2)	171 (35.4)	
Soft tissue injury/Wounds[b]	166 (35.7)	177 (36.6)	
Burn/Scalds/Blisters	49 (10.5)	50 (10.4)	
Fracture/Dislocation/Bone/joint injury	24 (5.2)	33 (6.8)	
Other reasons	39 (8.4)	52 (10.8)	
Children with at least one attendance to A&E by 5 years old, n (%)			
No attendances	2,591 (83.6)	3,940 (85.6)	
At least one attendance	510 (16.4)	662 (14.4)	2.1 (0.4 to 3.7)
Total number of attendances	N=820	N=1,104	
Nature of attendance, n (%)			
Head injury	284 (34.6)	329 (29.8)	
Soft tissue injury/Wounds[b]	323 (39.4)	450 (40.8)	
Burn/Scalds/Blisters	63 (7.7)	77 (7.0)	
Poisoning	16 (2.0)	26 (2.4)	
Closed fracture	49 (6.0)	84 (7.6)	
Dislocation/Bone/joint injury	14 (1.7)	30 (2.7)	
Bite (animal/insect)	10 (1.2)	20 (1.8)	
Other reasons	61 (7.4)	88 (8.0)	

CI=Confidence interval

a FNP Clients minus Controls; a includes abrasion, laceration, contusion, and avulsions

Attendances to Accident and Emergency (A&E) for accidental injuries

Data source: *Accident and Emergency (A&E)*

Hypothesised direction of FNP programme effect: *Attendances to A&E for accidental injuries present later*

Time to first attendance for an accidental injury was measured as the duration in years between the child's date of birth and their first attendance. When the follow-up was truncated to 5 years to account for differential follow-up in FNP Clients and Controls, the median age at first attendance (years) for children of FNP Clients was 1.40 years and 1.86 years in Controls (Table 6.10). The probability of a child with no attendance for an accidental injury by 1 year was 95% (FNP) and 97% (Controls) and 84% and 86% by 5 years. There was no evidence to suggest that attendances for accidental injuries presented later (aHR: 0.97, 95% CI: 0.83 to 1.14, p-value=0.698) (Table 6.10, Figure 6.5).

Table 6.10: Time to first attendances for an accidental injury (years) by FNP Clients and Controls

	FNP Clients N=3,101	Controls N=4,602	Adjusted[a] HR (95% CI)	p-value
Time to first attendances for an accidental injury (years), Median (IQR)	1.40 (0.88 to 2.15)	1.86 (1.13 to 2.80)	0.97 (0.83 to 1.14)	0.698
Probability of a child with no attendance for an accidental injury[b] by:				
1 year follow-up	95.1	97.2		
2 years follow-up	88.7	92.4		
3 years follow-up	85.8	89.0		
4 years follow-up	84.6	87.2		
5 years follow-up	83.9	85.8		

CI=Confidence interval, HR=Hazard ratio, IQR=Interquartile range

a adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced; b 'Survivor' functions (or in this case not having an attendance to hospital with an accidental injury) are presented at certain time points. The probability of 'surviving' the end of the k^{th} time-period is calculated by the probability of surviving to the end of the $(k-1)^{th}$ time-period, multiplied by the probability of surviving the k^{th} time-period.

Figure 6.5: Proportion of children with accidental injury over time by FNP Clients and Controls

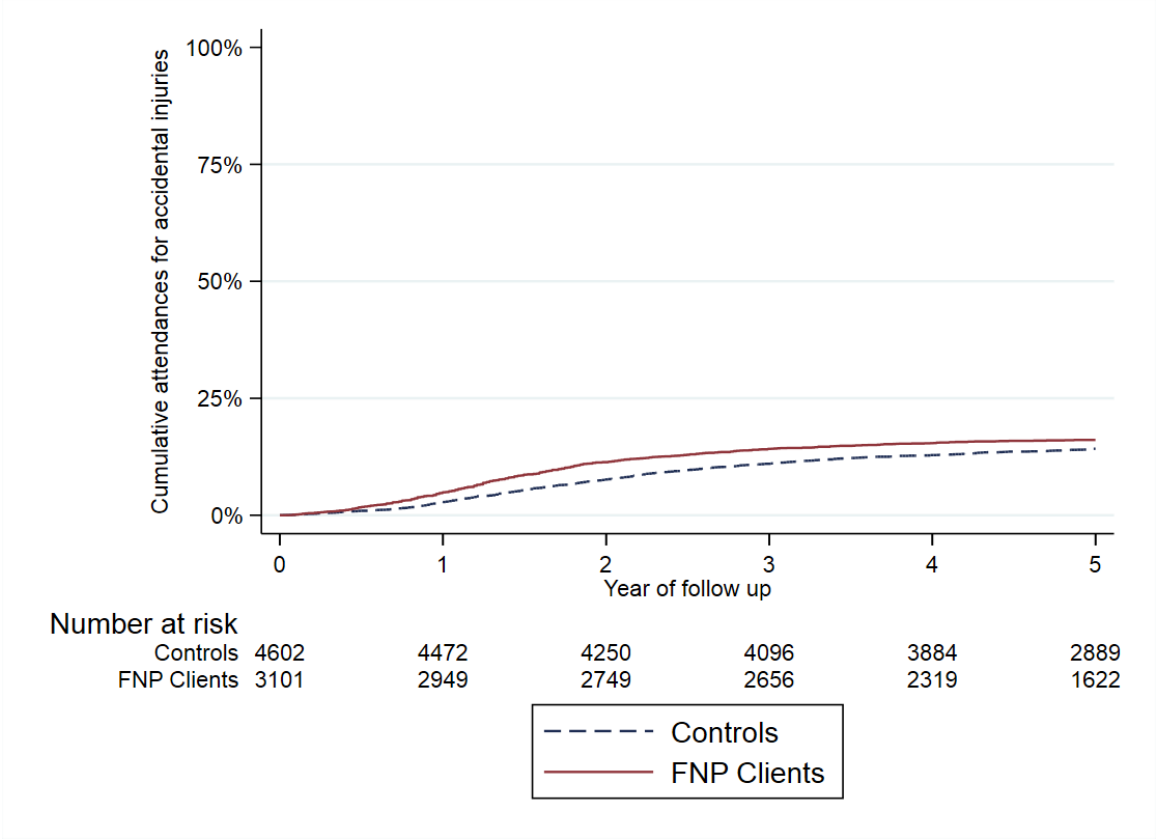


Table 6.11 shows the children with at least one attendance to A&E for an accidental injury by the age of 6 months, 1, 2, and 5 years of age and the nature of the attendance. Rates of A&E attendance for an accidental injury were by six months 1.1% (FNP Clients) 0.7% (Control), by 12 months 3.1% (FNP Clients) 1.8% (Control), by 24 months 7.6% (FNP) 4.9% (Control) and by 5 years 11.5% (FNP Clients) 9.6% (Control). The nature of attendances was mainly head and soft tissue/wound injuries.

Table 6.11 Attendances for accidental injury – at 6 months, 1, 2 and 5 years and type of attendance by FNP Clients and Controls

	FNP Clients N=3,101	Controls N=4,602	Absolute difference[a] (95% CI)
Children with at least one accidental injury by 6 months, n (%)			
No accidental injuries	3,068 (98.9)	4,572 (99.3)	
At least one accidental injury	33 (1.1)	30 (0.7)	0.4 (0.02 to 0.9)
Number of attendances to A&E for accidental injuries	34	31	
Nature of attendance, n (%)			
Head injuries	18 (52.9)	22 (71.0)	
Other injuries (includes soft tissue injuries, wounds[b], poisoning, burn/scalds, fractures)	16 (47.1)	9 (29.0)	
Children with at least one accidental injury by 1 year, n (%)			
No accidental injuries	3,006 (96.9)	4,517 (98.2)	
At least one accidental injury	95 (3.1)	85 (1.8)	1.2 (0.5 to 2.0)
Number of attendances to A&E	107	93	
Nature of attendance, n (%)			
Burns/scalds	15 (14.0)	11 (11.8)	
Head injuries	51 (47.7)	50 (53.8)	
Soft tissue injuries/Wounds[b]	32 (29.9)	25 (26.9)	
Other injuries (includes poisonings, closed fractures, 'other')	9 (8.4)	7 (7.5)	
Children with accidental injuries by 2 years, n (%)			
No accidental injuries	2,865 (92.4)	4,376 (95.1)	

	FNP Clients N=3,101	Controls N=4,602	Absolute difference[a] (95% CI)
At least one accidental injury	236 (7.6)	226 (4.9)	2.7 (1.6 to 3.9)
Number of attendances to A&E	308	294	
Nature of attendance, n (%)			
Burns/scalds	28 (9.1)	33 (11.2)	
Head injuries	130 (42.2)	113 (38.4)	
Soft tissue injuries/Wounds[b]	118 (38.3)	105 (35.7)	
Fractures	14 (4.5)	17 (5.8)	
Other injuries (includes bites, poisonings, dislocations, dental injuries, 'other nature of injury')	18 (5.8)	26 (8.8)	
Children with accidental injuries by 5 years, n (%)			
No accidental injuries	2,744 (88.5)	4,158 (90.4)	
At least one accidental injury	357 (11.5)	444 (9.6)	1.9 (0.5 to 3.3)
Number of attendances to A&E	588	718	
Nature of attendance, n (%)			
Burns/scalds	41 (7.0)	51 (7.1)	
Head injuries	210 (35.7)	232 (32.3)	
Soft tissue injuries/Wounds[b]	237 (40.3)	289 (40.3)	
Fractures	45 (7.7)	71 (9.9)	
Poisonings	13 (2.2)	21 (2.9)	
Other injuries (includes bites, dislocations, needlestick, dental injuries, 'other nature of injury')	42 (7.1)	50 (7.0)	

a includes abrasion, laceration, contusion, and avulsions

Safe home environment at 2 and 5 years of age

Data source: *SMR01 - General / Acute Inpatient and Day Case*

Hypothesised direction of FNP programme effect: *Reduced hospital admissions for unintentional injuries in the home*

The rate of children with a hospital admission for an unintentional injury where the injury occurred in and around the home by two, were 2.2% in those born to FNP Clients and 2.6% in Controls with no evidence of a difference in unintentional injury in the home between the two groups (aOR: 0.84, 95% CI: 0.59 to 1.20, p-value=0.342) (Table 6.12). By five years, the rate of unintentional injury in the home had increased to 5.7% and 5.5% respectively, again with no differences found between the two groups when adjusted for confounders. Neither was there evidence of a differential effect by year or by HBs at two years (interaction p-value=0.458 and 0.776 respectively) or at five years (interaction p-value=0.532 and 0.736 respectively). Of the children that had experienced at least one unintentional injury in the home, 58% (FNP Clients) and 62% (Controls) occurred in children aged under two. Falls were the most commonly occurring injuries recorded followed by poisonings. No dosage effect was examined due to small numbers in these two outcomes (12 and 13).

Table 6.12: Children with an emergency admission to hospital due to an unintentional injury in the home by FNP Client and Control

	FNP Clients N=3,209	Controls N=4,909	Adjusted[a] OR (95% CI)	p-value
By 2 years, n (%)				
No unintentional injuries in the home	3,119 (97.8)	4,764 (97.4)	Reference	
At least one unintentional injury in the home	70 (2.2)	129 (2.6)	0.84 (0.59 to 1.20)	0.342
All unintentional injuries in the home (unit=admission)[b]	N=76	N=130		
Type of unintentional injury in the home by 2 years, n (%)				
Falls	27 (35.5)	60 (46.2)		
Poisonings	18 (23.7)	29 (22.3)		
Struck by, against/ crushing	12 (15.8)	18 (13.8)		

	FNP Clients N=3,209	Controls N=4,909	Adjusted[a] OR (95% CI)	p-value
Scalds/Accidental exposure/Other category[b]	19 (25.0)	23 (17.7)		
By 5 years, n (%)				
No unintentional injuries in the home	2,001 (94.3)	3,537 (94.5)	Reference	
At least one unintentional injury in the home	121 (5.7)	207 (5.5)	1.07 (0.81 to 1.41)	0.650
All unintentional injuries in the home (unit=admission)[c]	N=137	N=223		
Type of unintentional injury in the home by 5 years, n (%)				
Falls	50 (36.5)	90 (40.4)		
Struck by	12 (8.8)	24 (10.8)		
Crushing	11 (8.0)	12 (5.4)		
Poisonings	32 (23.4)	56 (25.1)		
Scalds/Accidental exposure	20 (14.6)	16 (7.2)		
Other category[b]	12 (8.8)	25 (11.2)		
Age at first unintentional injury in the home, n (%)				
Age 0 to <1 years	29 (24.0)	55 (26.6)		
Age 1 to <2 years	41 (33.9)	74 (35.7)		
Age 2 to <3 years	25 (20.7)	42 (20.3)		
Age 3 to <4 years	14 (11.6)	17 (8.2)		
Age 4 to <5 years	12 (9.9)	19 (9.2)		

CI=Confidence interval, OR=Odds ratio
a adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced; b Admission type code 33 and other ICD10 codes in the range V01-X59 Y85-Y86 that are not included in any of the other categories in the table; c some children had more than one admission.

6.4 Improved child development

Key Findings

Tested outcomes:

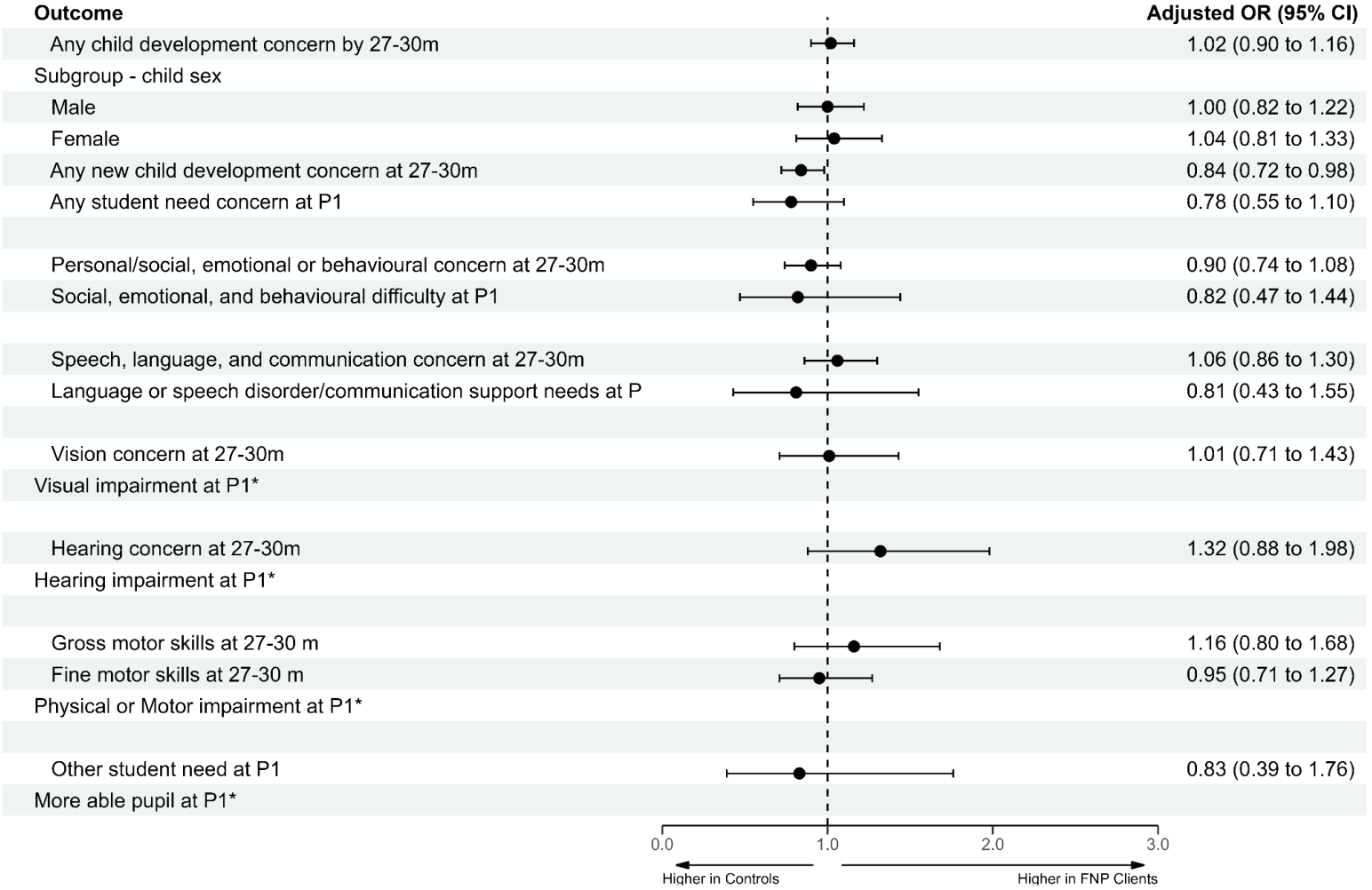
Child development

- There was evidence to suggest a statistically significant difference between study groups in any new child development concerns recorded at 27-30 months, with a higher proportion in the Controls (FNP Clients: 19.2% vs Controls: 21.7%). There was some indication of a dosage effect for any child development concerns by 27-30 months.
- 28% of children in both groups were found to have at least one child development concern by 27-30 months with no evidence of a statistically significant difference between groups.
- Under 5% of children in both groups were identified with either a gross or fine motor skill concern by the 27–30-month child health review and rates were comparable for FNP Clients and Controls.
- A higher proportion of children in the Control group (13.4%) had a concern recorded for social/emotional development at 27-30 months compared to the FNP group (11.0%) but there was no evidence of a statistically significant difference between groups.
- 17% of children in both groups had a concern recorded for speech/language with no evidence of a statistically significant difference between groups.
- For vision and hearing concerns and for additional support needs in Primary 1 there were no statistically significant differences between groups.

Child attainment

- There were no significant differences in the proportion of children achieving their age-related Curriculum for Excellence (CfE) Level (P1 or P4) for any of the subjects overall (Reading, Writing, Listening and Talking, Numeracy and Literacy).
- There was evidence of a differential programme effect for pupils achieving the expected CfE Levels in Writing and Literacy by HBs.
- Girls consistently outperform the boys across all subjects although no significant differences between FNP children and Controls were observed by child sex.
- Sensitivity analyses on age related achievement of the P1 Level, supported the findings of the primary analysis but found a significant differential FNP programme effect in Reading for child sex, and by HB and in Writing by HB.

Figure 6.6: Forest plot of estimates from tested outcomes in the Child Development domain including subgroups



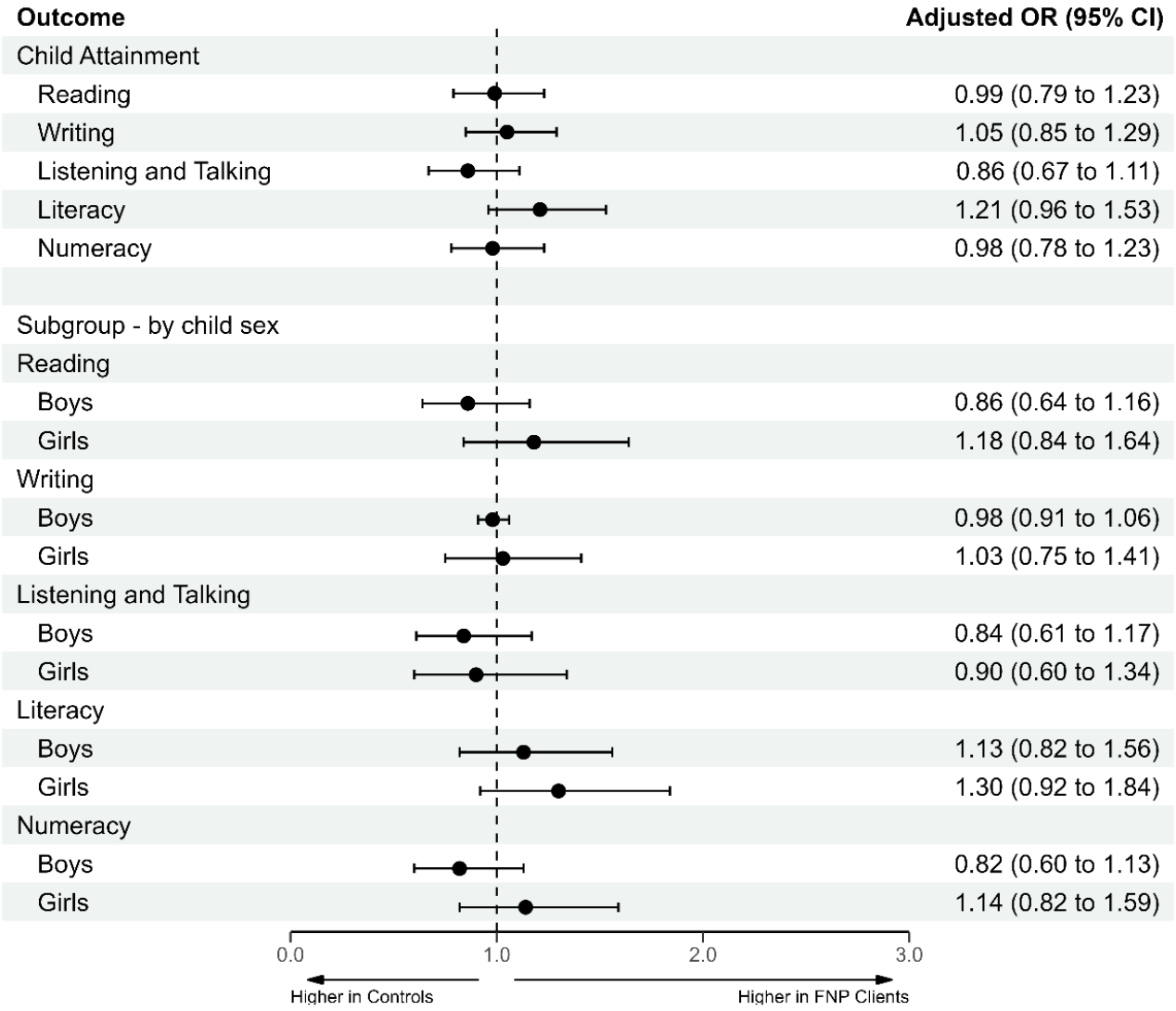
Data sources: Child Health Surveillance Programme (CHSP) Pre-School/ School

CI=Confidence interval, OR=Odds ratio

Note: OR compares outcomes for FNP Clients to Controls; an OR>1 indicates outcome is higher for FNP Clients; an OR<1 indicates outcome is lower for FNP Clients. Vertical dashed line represents no intervention effect (ratio = 1).

* Events for physical or motor impairment, visual impairment, and hearing impairment and more able pupil at Primary 1 were too rare to be modelled.

Figure 6.7: Forest plot of estimates from tested outcomes for child attainment including subgroups



Data sources: Achievement of Curriculum for Excellence Levels.
CI=Confidence interval, OR=Odds ratio

Note: OR compares outcomes for FNP Clients to Controls; an OR>1 indicates outcome is higher for FNP Clients; an OR<1 indicates outcome is lower for FNP Clients. Vertical dashed line represents no effect (ratio = 1). Literacy defined as achievement in all three Reading, Writing, Listening and Talking assessments

Child developmental outcomes

Data source: *Child Health Surveillance Programme (CHSP) Pre-School/ School (Primary 1)/School pupil census*

Hypothesised direction of FNP programme effect: *Reduced concerns and need*

The child development outcomes are examined and tested at two time points: at the 27-30 month child health review and again at the Primary 1 (P1) review. There was evidence to suggest a difference between study groups in any new child development concerns recorded at 27-30 months, with a higher proportion in the Controls (FNP Clients: 19.2% vs Controls: 21.7%) (aOR: 0.84, 95% CI: 0.72 to 0.98, p-value=0.030). Across all other child development outcomes, there were no significant differences between FNP Clients and Controls once adjusted for confounders (Figure 6.8; Table 6.12a). Around 1% of child development concerns were recorded at the 6-8 week assessment; by the 27-30 month review, 28% of children were found to have a child development concern recorded (including previously recorded concern at 6-8 weeks), with a higher proportion of concern in boys compared to girls but no differential intervention effect. The most prevalent concern was regarding speech, language and communications at 27-30 months with 17.3% (FNP) and 16.7% (Control) but by the P1 school pupil census the proportion of children with a need identified for speech and language is the same in both groups (2.4%). For personal/social, emotional, or behavioural concern at 27-30 months 11.0% of FNP Clients children and 13.4% of Controls had a developmental concern; once adjusted for confounders there was no statistical difference between study groups. By P1, the proportion of children in each group with a Social, emotional, and behavioural difficulty is comparable (2.7% FNP vs. 2.9% Controls). Under 5% of children were identified with either a gross or fine motor skill concern by the 27-30 month child health review and rates were comparable for FNP Clients and Controls. No differential effects were found for concerns between HBs or over time.

Table 6.12a: Child development outcomes at 6-8 weeks, 27-30 months and Primary 1 assessment by FNP Client and Controls

	FNP Clients	Controls	Adjusted[a] OR (95% CI)	p-value
Any child development concern at 6-8 weeks, n (%)				
No concern	2,764 (98.9)	4,358 (99.4)	-	-
With concern	30 (1.1)	28 (0.6)	Descriptive	-
Any child development concern by 27-30 months[b], n (%)				
No concern at either 6-8 weeks or 27-30 months	1,654 (71.3)	2,550 (71.8)	Reference	
Concern by 27-30 months	665 (28.7)	1,002 (28.2)	1.02 (0.90 to 1.16)	0.783
Subgroup – Child sex, n (%)				
Boys	440 (35.3)	625 (34.8)	1.00 (0.82 to 1.22)	0.718[c]
Girls	225 (21.0)	377 (21.5)	1.04 (0.81 to 1.33)	
Any newly suspected child development concern at 27-30 months[d], n (%)				
No concern at 27-30 months/Previous concern	2,064 (80.8)	3,005 (78.3)	Reference	
No concern	*1,900 (74.3)*	*2,843 (74.1)*	-	
Previous concern	*164 (6.4)*	*162 (4.2)*	-	
New concern at 27-30 months	492 (19.2)	832 (21.7)	0.84 (0.72 to 0.98)	0.030
Any additional student need at P1, n (%)				
None	710 (91.0)	1,949 (91.3)	Reference	
Yes	70 (9.0)	185 (8.7)	0.78 (0.55 to 1.10)	0.161

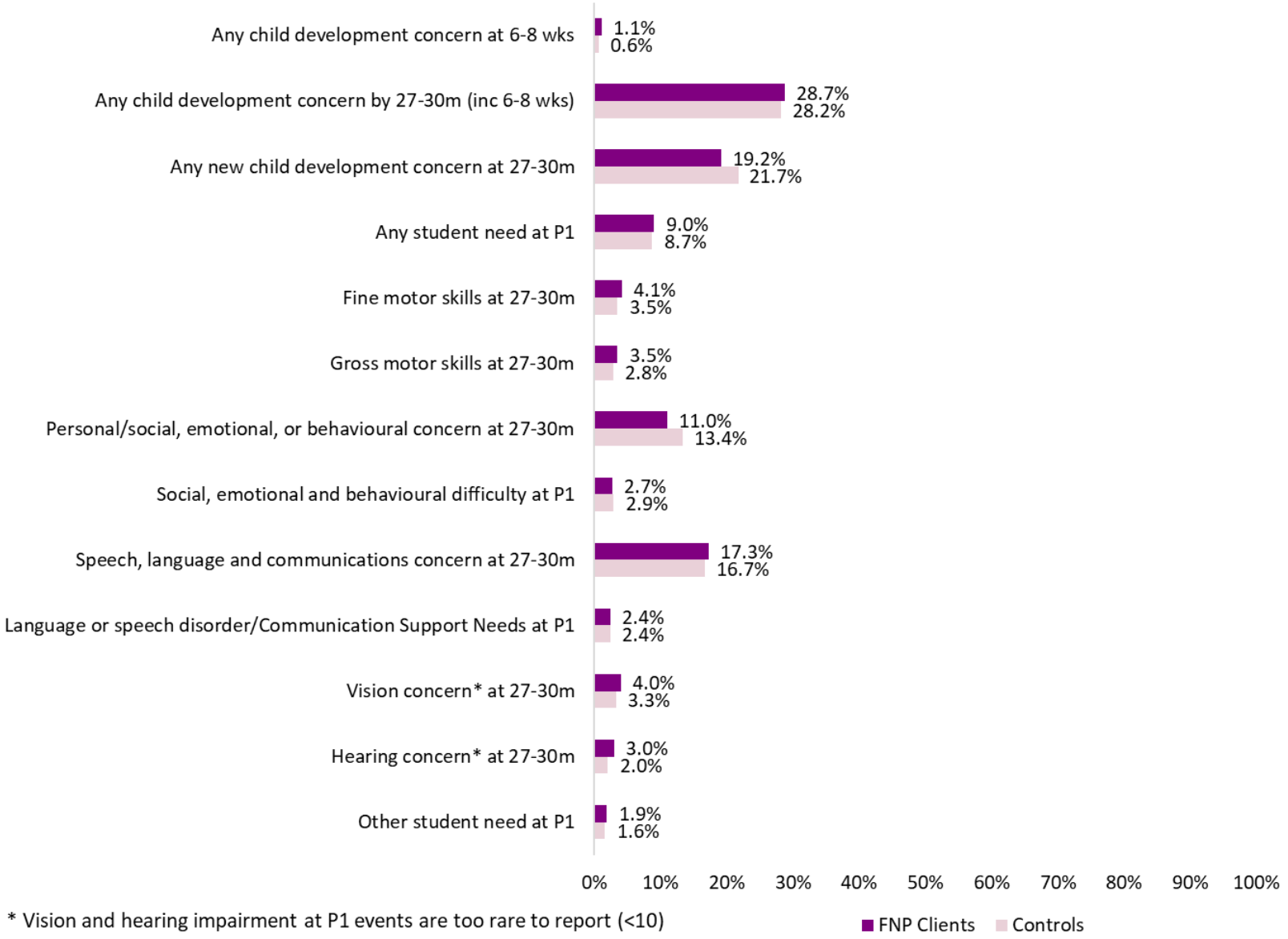
	FNP Clients	Controls	Adjusted[a] OR (95% CI)	p-value
Gross motors skills at 27-30m, n (%)				
No concern	2,430 (96.5)	3,621 (97.2)	Reference	
With concern	87 (3.5)	104 (2.8)	1.16 (0.80 to 1.68)	0.435
Fine motor skills concern at 27-30 months, n (%)				
No concern	2,406 (95.9)	3,577 (96.5)	Reference	
With concern	102 (4.1)	131 (3.5)	0.95 (0.71 to 1.27)	0.774
Personal/social, emotional, or behavioural concern at 27-30 months, n (%)				
No concern	2,258 (89.0)	3,305 (86.6)	Reference	
With concern	279 (11.0)	512 (13.4)	0.90 (0.74 to 1.08)	0.251
Concern previously identified	*77 (3.0)*	*92 (2.4)*		
Concern newly suspected	*202 (8.0)*	*420 (11.0)*		
Social, emotional, and behavioural difficulty at P1, n (%)				
No concern	759 (97.3)	2,073 (97.1)	Reference	
With concern	21 (2.7)	61 (2.9)	0.82 (0.47 to 1.44)	0.495
Speech, language and communications concern at 27-30 month, n (%)				
No concern	2,073 (82.7)	3,144 (83.3)	Reference	
With concern	434 (17.3)	631 (16.7)	1.06 (0.86 to 1.30)	0.611
Concern previously identified	*116 (4.6)*	*98 (2.6)*		

	FNP Clients	Controls	Adjusted[a] OR (95% CI)	p-value
Concern newly suspected	*318 (12.7)*	*533 (14.1)*		
Language or speech disorder/Communication Support Needs at P1, n (%)				
No concern	761 (97.6)	2,083 (97.6)	Reference	
With concern	19 (2.4)	51 (2.4)	0.81 (0.43 to 1.55)	0.531
Vision concern at 27-30 month, n (%)				
No concern	2,375 (96.0)	3,444 (96.7)	Reference	
With concern	98 (4.0)	116 (3.3)	1.01 (0.71 to 1.43)	0.970
Concern previously identified	*54 (2.2)*	*60 (1.7)*		
Concern newly suspected	*44 (1.8)*	*56 (1.6)*		
Visual impairment at P1	*	*		
Hearing concern at 27-30 month, n (%)				
No concern	2400 (97.0)	3474 (98.0)	Reference	
With concern	73 (3.0)	72 (2.0)	1.32 (0.88 to 1.98)	0.174
Concern previously identified	*27 (1.1)*	*28 (0.8)*		
Concern newly suspected	*46 (1.9)*	*44 (1.2)*		
Hearing impairment at P1	*	*		
Other student need at P1, n (%)				
No	765 (98.1)	2100 (98.4)	Reference	

	FNP Clients	Controls	Adjusted[a] OR (95% CI)	p-value
Yes	15 (1.9)	34 (1.6)	0.83 (0.39 to 1.76)	0.629
Physical/Motor impairment at P1	*	*		
More able pupil		**		

CI=Confidence interval, OR=Odds ratio; a adjusted for year of antenatal booking, maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced; b including those previously identified at 6-8 weeks; c p-value is for measurement of the interaction between study group and sex subgroup; d does not include concerns previously identified at 6-8 weeks. * Events for physical/motor impairment, visual impairment and hearing impairment at P1 were <10 across both groups and hypothesis testing was not possible. ** Unable to summarise data as events were <10

Figure 6.8: Percentage of children with at least one developmental concern or additional support need



* Vision and hearing impairment at P1 events are too rare to report (<10)

There was some indication of a dosage effect for any child development concerns by 27-30 months; 17% of children that had received under 10 FNP visits over the duration of the programme had a concern recorded compared to 35% of children that received over 60 FNP visits (Table 6.12b). A similar pattern was observed for personal/social, emotional, or behavioural concern (from 8% (<10 visits) to 24% (60+ visits)).

Table 6.12b: Child development concerns at 27-30 months by total number of FNP visits received over the entire program, n (%)

	Child development concern at 27-30 months				
Number of FNP visits	**Any child development concern**	**Personal/social, emotional, or behavioural**	**Speech, language and communications**	**Vision**	**Hearing**
1-10	26 (17.1)	12 (8.2)	18 (12.5)	16 (3.7)	11 (2.5)
11-20	29 (33.3)	11 (12.9)	19 (22.1)		
21-30	56 (24.2)	32 (14.0)	27 (11.9)		
31-40	148 (25.0)	50 (8.5)	96 (16.4)	24 (4.2)	15 (2.6)
41-50	257 (25.3)	101 (10.0)	176 (17.7)	37 (3.7)	27 (2.7)
51-60	114 (27.9)	55 (13.6)	82 (20.9)	21 (4.4)	20 (4.2)
60+	25 (34.7)	17 (23.6)	15 (20.8)		
Total	655 (25.7)	278 (11.0)	433 (17.3)	98 (4.0)	73 (3.0)

Child attainment

Data source: *Achievement of Curriculum for Excellence (CfE) Levels*
Hypothesised direction of FNP programme effect: *Increased attainment*

Child attainment examines the proportion of children achieving the expected Curriculum for Excellence (CfE) level in the Early Level/Primary 1 (P1, 5-6 year olds), and First level/Primary 4 (P4, 8-9 year olds). Five subjects are assessed: Reading, Writing, Listening and Talking, Literacy (defined as achievement in all three Reading, Writing, Listening and Talking assessments), and Numeracy. The Achievement of Curriculum for Excellence Levels (ACEL) data provided for children of FNP Clients and Controls reflects what they achieved by the end of the school year in June 2019 and refers to the school years 2016/17, 2017/18 and 2018/19. It therefore only contains data for a proportion of the children with achievements recorded for assessments in P1 or P4. Excluded from these assessments are children that are not assessed usually due to a school move, or children that are following their own milestones, where children had not yet reached the appropriate age for school entry and therefore Early Level assessment (ages 5-6 years), or where the records could not be linked.

A total of 3,370 (41.3%) child attainment records were received with a smaller proportion from FNP enrolled mothers assesses than Controls (29.7% vs. 48.8% respectively) (Table 6.13a). Children without ACEL data were more likely to be younger (median age 4.3 years, IQR: 3.6 to 4.9 years), compared to children with data (6.6 years, 6.1 to 7.4 years) and did not differ according to characteristics such as ethnicity, sex, deprivation quintile, or maternal age at booking.

The data provided contained information on whether the child had achieved the Early Level at Primary 1 (P1=E) or not (P1=00), or in some cases achieving the First Level (P4=01) or not (P4=00 or E). For this analysis we defined children as achieving as either achieving age relevant Early Level (P1=E) or achieved age relevant First Level (P4=01). Children not achieving were defined as either not achieving the age relevant Early Level (P1=00), not achieving the age relevant First Level (P4=00), or achieving Early Level P1 but not achieving the age relevant First Level (P4=E). Table 6.13a shows the numbers and proportions of children by FNP Clients and Control groups achieving Early or First Level (P1/P4) or not for each subject. The percentage of pupils achieving relevant CfE Levels for age by both groups, was below that reported for Scotland in 2018/19 (P1-Early Level: 82% for Reading, 79% for Writing, 87% Listening & Talking, 76% Literacy, 85% for

Numeracy)[40]. No statistically significant differences were found between FNP Clients and Controls for any of the subjects. There was evidence of a differential FNP programme effect for pupils achieving in Writing and Literacy by HBs (Table 6.13c and 6.13d) (interaction p-value=0.018 and 0.046 respectively) but no other differences by HBs, nor by year of booking (Table 6.13b). Significant differences in rates of children achieving relevant CfE Levels for Writing were observed in Fife and Glasgow and Clyde HBs (Table 6.6c), with higher rates observed in children in the FNP group compared to Controls. Similarly, significant differences in rates of children achieving relevant CfE Levels for Literacy were observed in Fife HB (Table 6.6d).

Girls consistently outperform the boys across all subjects; a post-hoc subgroup analysis of attainment by child sex showed no significant differential FNP programme effects. There appeared to be no association with achievement levels and the number of FNP visits (Table 6.13e).

Sensitivity analysis restricting to achievement for P1 Level or not, supported the findings of the primary analysis but found a significant differential FNP programme effect in Reading for child sex and HB, and in Writing by HB (Table 6.13f).

Table 6.13a: Pupils achieving the expected Curriculum for Excellence (CfE) Levels by subject and FNP Clients and Controls

	FNP Clients N=3,225	Controls N=4,941	Adjusted[a] OR (95% CI)	p-value
Valid ACEL data, n (%)	957 (29.7)	2,413 (48.8)		
Pupils achieving expected Curriculum of Education Levels in:				
Reading, n (%)				
Not achieved relevant level for age[b]	269 (28.4)	659 (27.7)	Reference	
P1 or P4=00 (not achieved Early or First level)	*239*	*561*		
P4=E (achieved P1 but not P4)	*30*	*98*		
Achieved relevant level for age[c]	677 (71.6)	1,717 (72.3)	0.99 (0.79 to 1.23)	0.898
P1=E (achieved Early level)	*610*	*1514*		
P4=01 (achieved First level)	*67*	*203*		
Writing, n (%)				
Not achieved relevant level for age[b]	311 (32.9)	761 (32.0)	Reference	
P1 or P4=00 (not achieved Early or First level)	*272*	*634*		
P4=E (achieved P1 but not P4)	*39*	*127*		
Achieved relevant level for age[c]	635 (67.1)	1,615 (68.0)	1.05 (0.85 to 1.29)	0.653
P1=E (achieved Early level)	*569*	*1442*		
P4=01 (achieved First level)	*56*	*173*		
Listening and Talking, n (%)				
Not achieved relevant level for age[b]	184 (19.5)	421 (17.7)	Reference	

	FNP Clients N=3,225	Controls N=4,941	Adjusted[a] OR (95% CI)	p-value
P1 or P4=00 (not achieved Early or First level)	*159*	*367*		
P4=E (achieved P1 but not P4)	*25*	*54*		
Achieved relevant level for age[c]	762 (80.5)	1,956 (82.3)	0.86 (0.67 to 1.11)	0.247
P1=E (achieved Early level)	*690*	*1,707*		
P4=01 (achieved First level)	*72*	*249*		
Literacy, n (%)				
Not achieved relevant level for age in reading, writing, and listening and talking[d]	342 (36.2)	847 (35.7)	Reference	
Achieved relevant level for age in reading, writing, and listening and talking[e]	604 (63.8)	1,526 (64.3)	1.11 (0.90 to 1.36)	0.328
Numeracy, n (%)				
Not achieved relevant level for age[b]	246 (26.0)	564 (23.8)	Reference	
P1 or P4=00 (not achieved Early or First level)	*219*	*450*		
P4=E (achieved P1 but not P4)	*27*	*114*		
Achieved relevant level for age[c]	701 (74.0)	1,809 (76.2)	0.98 (0.78 to 1.23)	0.850
P1=E (achieved Early level)	*632*	*1,622*		
P4=01 (achieved First level)	*69*	*187*		

CI=Confidence interval, OR=Odds ratio. Note: The Gaelic results are combined with the English. a adjusted for year of antenatal booking (index year), maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced, child dob month and child sex; b P1=00 (did not achieve the age relevant Early Level), P4=00 (did not achieve the age relevant First Level), P4=E (achieved Early Level P1 but did not achieve age relevant First Level); c P1=E (achieved age relevant Early level), P4=01 (achieved age relevant First Level); d To not achieve in Literacy, children had to have not achieved in at least one of reading, writing, or listening and talking. e To achieve in Literacy, children had to have achieved across all three subjects (reading, writing, and listening and talking).

Table 6.13b: Subgroup analysis – n (%) pupils achieving the expected Curriculum for Excellence (CfE) Levels by FNP Clients and Controls and by child sex

	FNP Clients	Controls	Adjusted[a] OR (95% CI)	Sex	Health Board	Year of booking
Reading				0.116	0.055	0.632
Boys	318 (66.3)	824 (70.1)	0.86 (0.64 to 1.16)			
Girls	359 (77.0)	893 (74.4)	1.18 (0.84 to 1.64)			
Writing				0.773	**0.018**	0.252
Boys	293 (61.0)	741 (63.0)	0.98 (0.91 to 1.06)			
Girls	342 (73.4)	874 (72.8)	1.03 (0.75 to 1.41)			
Listening and Talking				0.754	0.125	0.589
Boys	362 (75.4)	922 (78.3)	0.84 (0.61 to 1.17)			
Girls	400 (85.8)	1,034 (86.2)	0.90 (0.60 to 1.34)			
Literacy				0.460	**0.046**	0.369
Boys	275 (57.3)	701 (59.7)	1.08 (0.82 to 1.43)			
Girls	329 (70.6)	825 (68.9)	1.13 (0.84 to 1.54)			
Numeracy				0.484	0.089	0.804
Boys	340 (70.7)	877 (74.6)	0.82 (0.60 to 1.13)			
Girls	361 (77.5)	932 (77.8)	1.14 (0.82 to 1.59)			

CI=Confidence interval, OR=Odds ratio

a adjusted for year of antenatal booking (index year), maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced, and child dob month.

Table 6.13c Subgroup analysis – n (%) pupils achieving expected Curriculum for Excellence (CfE) Levels for Writing by health board

NHS Health Board	FNP Clients	Controls	Adjusted[a] OR (95% CI)
Ayrshire/Arran	48 (57.1)	147 (73.9)	0.40 (0.07 to 2.10)
Borders[b]	-	-	-
Fife	94 (79.0)	192 (69.6)	3.16 (1.51 to 6.61)
Forth Valley[b]	-	-	-
Grampian[b]	-	-	-
Glasgow and Clyde	94 (74.0)	266 (68.4)	2.22 (1.01 to 4.56)
Highland	10 (43.5)	50 (64.9)	0.44 (0.01 to 14.14)
Lanarkshire	c	c	0.79 (0.26 to 2.43)
Lothian	156 (60.0)	456 (63.3)	0.89 (0.58 to 1.36)
NHS Tayside	223 (70.3)	253 (71.9)	1.24 (0.80 to 1.91)

Table 6.13d Subgroup analysis – n (%) pupils achieving expected Curriculum for Excellence (CfE) Levels for Literacy by health board

NHS Health Board	FNP Clients	Controls	Adjusted[a] OR (95% CI)
Ayrshire/Arran	46 (54.8)	139 (69.8)	0.13 (0.02 to 0.88)
Borders[b]	-	-	-
Fife	89 (74.8)	181 (65.6)	2.47 (1.11 to 5.49)
Forth Valley[b]	-	-	-
Grampian[b]	-	-	-
Glasgow and Clyde	89 (70.1)	251 (64.5)	2.36 (0.89 to 6.27)
Highland	9 (39.1)	41 (53.9)	0.41 (0.01 to 10.2)
Lanarkshire	c	c	1.19 (0.34 to 4.14)
Lothian	148 (56.9)	435 (60.5)	0.83 (0.54 to 1.29)
NHS Tayside	213 (67.2)	240 (68.2)	1.28 (0.82 to 2.00)

CI=Confidence interval, OR=Odds ratio
a adjusted for year of antenatal booking (index year), maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced, child dob month and child sex. b No attainment data in Borders, Grampian (both FNP and Control group) and in Forth Valley (FNP group only); c cells suppressed due to small numbers.

Table 6.13e: Pupils achieving the expected Curriculum for Excellence (CfE) Levels by total number of FNP visits received over the whole FNP programme

		n (%) pupils achieving				
N FNP visits	**N of children**	**Reading**	**Writing**	**Listening and Talking**	**Numeracy**	**Literacy**
1-10	60	47 (78.3)	45 (75.0)	52 (86.7)	46 (76.7)	44 (73.3)
11-20	29	22 (75.9)	21 (72.4)	24 (82.8)	23 (79.3)	20 (69.0)
21-30	78	59 (75.6)	57 (73.1)	70 (89.7)	62 (79.5)	54 (69.2)
31-40	216	160 (74.1)	151 (69.9)	180 (83.3)	162 (75.0)	143 (66.2)
41-50	380	271 (71.3)	251 (66.1)	302 (79.5)	281 (73.8)	238 (62.6)
51+	168	111 (66.1)	105 (62.5)	126 (75.0)	120 (71.4)	100 (59.5)
Total	931	670 (72.0)	630 (67.7)	754 (81.0)	694 (74.5)	599 (64.3)

Table 6.13f: Pupils achieving the expected Curriculum for Excellence (CfE) in P1 Levels by FNP Clients and Controls - Sensitivity analysis

		Interaction p-value		
	Adjusted[a] OR (95% CI), p-value	**Sex**	**HB**	**Year**
Reading - Main analysis	1.00 (0.78 to 1.29), 0.972		**0.048**	0.469
Subgroup analysis		**0.036**		
Boys	*0.80 (0.57 to 1.13)*			
Girls	*1.33 (0.90 to 1.95)*			
Writing - Main analysis	1.16 (0.91 to 1.47), 0.234		**0.018**	0.323
Subgroup analysis		0.419		
Boys	1.14 (0.82 to 1.57)			
Girls	1.16 (0.81 to 1.66)			
Listening and Talking- Main analysis	0.94 (0.71 to 1.25), 0.672		0.152	0.413
Subgroup analysis		0.304		
Boys	0.82 (0.56 to 1.18)			
Girls	1.16 (0.73 to 1.84)			
Literacy - Main analysis	1.21 (0.96 to 1.53), 0.101		0.053	0.323
Subgroup analysis		0.196		
Boys	1.13 (0.82 to 1.56)			
Girls	1.30 (0.92 to 1.84)			
Numeracy - Main analysis	0.99 (0.77 to 1.29), 0.974		0.073	0.688
Subgroup analysis		0.164		
Boys	0.74 (0.52 to 1.06)			
Girls	1.31 (0.89 to 1.93)			

CI=Confidence interval, HB=NHS Health Board, OR=Odds ratio
Note: The Gaelic results are combined with the English.
a adjusted for year of antenatal booking (index year), maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced, child dob month and child sex.

6.5 Improved child protection

Key Findings

Tested outcomes:

- Around a third of children had two or more child protection investigations in the first five years of life (33% FNP vs 29% Controls), with no difference between groups after adjustment for confounders.
- In the FNP Clients, the median age of the child's first child protection investigation (by five years of age) was 2.2 years (IQR 0.1 to 3.9 years) compared to 3.4 years (1.9 to 4.3), in the Controls. After adjusting for confounders, no differences were found between the two groups.
- For all children deregistered, the mean (SD) number of days on the child protection register was 220 days (142) in the FNP group and 225 days (116) in the Control group with no evidence of a statistical difference between the two groups.

Descriptive outcomes:

- The proportion of children that were subject to a child protection investigation before the age of two were rare (FNP: 2.2%; Control: 0.8%) rising to 4.9% and 3.2% respectively, by the age of five.
- In the FNP group, 67% of children required a child protection case conference (CPCC) compared to 57% in the Control group, with 50% of case conferences resulting in the registration of a child, following an initial or pre-birth review.
- The most prevalent concern identified at CPCC investigations for FNP Clients were domestic abuse (FNP: 67% vs Controls: 46%) and non engaging family or other concerns (66% vs 20% respectively). The most prevalent concerns identified in the Controls were emotional or physical abuse (34% vs 57% respectively).
- In the FNP group, at least 30 of 35 (86%) registered children had been deregistered by five years old follow up compared to 41 of 56 (73%) in Controls.
- The proportion of children looked after was 1.0% and 1.1% (FNP, Controls).
- Children were placed in care earlier in the FNP group compared to the Control group (median age: 31 vs 37 months respectively).
- A similar proportion of children in both Clients and Control group were initially placed at home with parents, or with friends or relatives (60-66%).
- A higher proportion of children in the FNP group had a destination accommodation not with their biological parents (55% FNP vs 18% Controls).

Child protection

Data source: *Child Protection Register Database*

Hypothesised direction of FNP programme effect: *Children are investigated sooner, reduction in the number of investigations*

The Child Protection Register Database is linked using the Scottish Candidate Number (SCN) that is allocated to children upon entry to Primary 1. Therefore, the data that could be used for this outcome is limited, mainly descriptive and should not be over-interpreted. Any child with episodes of care completed prior to school entry and for whom there were no subsequent episodes after school entry, were not able to be linked and included in the analysis. If a child was linked, then retrospective records could be accessed on the child. Child protection investigations were recorded in 22 (2.2%) (FNP Clients) and 20 (0.8%) (Controls) children before the age of two, with a total number of child protection investigations of 29 and 26 (Table 6.14a). A further breakdown of the number of investigations per child before the age of two including the proportion of children subject to a case conference, could not be reported due to small numbers.

Table 6.14a. Children with a child protection investigation (up to 2 years of age)

	FNP Clients	Controls
Children with an SCN to enable linkage, n (%)	978	2,451
Number of children by 2 years old with at least 1 child protection investigation, n (%)	22 (2.2)	20 (0.8)
Total number of child protection investigations recorded by 2 years old[a], n	29	26
Investigation requiring a Case Conference by 2 years old	≥10/29	≥10/26

Child protection investigations were recorded in 48 (4.9%) (FNP Clients) and 80 (3.2%) (Controls) children respectively by the age of five, with a total number of child protection investigations of 70 and 115 respectively (Table 6.14b). Around a third of children had two or more investigations in the first five years of life (33.3% FNP vs 29.1% Controls), with no difference between groups in the number of investigations after adjustment for confounders (adjusted IRR: 0.97, 95% CI: 0.67 to1.40, p-value=0.862). The median age of the child's first child protection investigation (by five years of age) was 2.2 years (IQR 0.1 to 3.9 years) in the FNP Group compared to 3.4 years (1.9 to 4.3), in the Controls, with no difference between groups (adjusted mean difference: -0.52, 95% CI: -1.43 to 0.38, p-value=0.256). A higher proportion of children were first investigated sooner (under 2 years

of age, including pre-birth), in the FNP group (45.8%) compared to in the Control group (25.0%), with 75% of children in the Control group first identified between the ages of 2 to 5 (54.2% in the FNP group).

Table 6.14b. Children with a child protection investigation (up to 5 years of age)

	FNP Clients	Controls	Adjusted[a] parameter estimate (95% CI), p-value
Children with an SCN to enable linkage	978	2,451	
Number of children by 5 years old with at least 1 child protection investigation[b], n (%)	48 (4.9)	80 (3.2)	
Total number of child protection investigations recorded by 5 years old, n (%)	70	115	0.97[c] (0.67 to 1.40), 0.862
Children with 1 investigation	*32 (66.7)*	*57 (70.9)*	
Children with 2 or more investigations	*16 (33.3)*	*23 (29.1)*	
	N=48	**N=80**	
Age at first investigation (years), Median (IQR) (by 5 years old)	2.2 (0.1 to 3.9)	3.4 (1.9 to 4.3)	-0.52[d] (-1.43 to 0.38), 0.256
Age group, n (%)			
Pre-birth to <2 years	22 (45.8)	20 (25.0)	
Between age 2 and <5 years	26 (54.2)	60 (75.0)	
2 to <4 years	*16 (33.3)*	*33 (41.3)*	
4 to <5 years	*10 (20.8)*	*27 (33.8)*	

CI=Confidence interval, IQR=interquartile range
a adjusted for year of antenatal booking (index year), maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever been excluded, left school at booking, ever been on the child protection register, ever care experienced. b includes pre-births; c incidence rate ratio; d mean difference.

Of all investigations recorded in the first 5 years of life, 67.1% of children in the FNP group were subject to a case conference compared to 57.4% in the Control group, with roughly 50% of case conferences resulting in the registration of a child, following an initial or pre-birth review. For these investigations in which the child was registered, the types of the concern were noted (a child could be coded with more than one concern); the majority of concerns in the FNP group were due to domestic abuse or non engaging family or other concerns not specified (65.7% for each) compared to the Control group (46.4% and 19.6% respectively). A higher proportion of concerns for emotional or physical abuse were found

in the Control group (57.1% vs 34.3% in FNP group). Neglect and parental alcohol/drug misuse were comparable between groups. For all children that had been deregistered (therefore recorded with a registered and a deregistered date), the mean (SD) number of days on the child protection register was 220.1 days (141.8) in FNP group and 225.0 days (116.3) in the Control group with no evidence of a statistical difference between the two groups (adjusted mean difference: 10.05, 95% CI: -61.7 to 81.8, p-value=0.783).

Table 6.14c. Children with a child protection investigation up to 5 years of age

	FNP Clients	Controls	Adjusted[a] parameter estimate (95% CI), p-value
Total number of child protection (CP) investigations recorded by 5 years old	N=70	N=115	
Investigations being the subject of a CP case conference (CPCC), n (%)	47 (67.1)	66 (57.4)	
CPCC in which the child is registered	35 (50.0)	56 (48.7)	
Type of concern (note: a child could be coded with more than one concern), n (%)	N=35	N=56	
Domestic abuse	23 (65.7)	26 (46.4)	
Emotional /Physical abuse	12 (34.3)	32 (57.1)	
Sexual abuse/child sexual exploitation	<10	<10	
Neglect	11 (31.4)	19 (33.9)	
Non engaging family / Other concern	23 (65.7)	11 (19.6)	
Parental alcohol/drug misuse	14 (40.0)	21 (37.5)	
Parental mental health	14 (40.0)	16 (28.6)	
Investigations in which the child is registered, n (%)	35/70 (50.0)	56/115 (48.7)	
child was deregistered before end of follow-up[b]	>30 (>86)	41 (73.2)	
child still registered at end of follow-up	<5 (<14)	15 (26.8)	
In children that have been deregistered:	N≥5	N=41	
Days on Child Protection register - Mean (SD)			
Including pre-births	220.1 (141.8)	225.0 (116.3)	10.1[b] (-61.7 to 81.8), 0.783
Excluding pre-births	222.4 (154.4)	228.1 (117.0)	

IQR=interquartile range, SD=Standard deviation
a adjusted for year of antenatal booking (index year), maternal age at booking, ethnic group, Scottish Index of Multiple Deprivation quintile, health board, gestational age at booking and delivery (weeks), previous pregnancy, maternal BMI, medication ever dispensed for asthma or mental ill health, diabetes, smoking history at booking, drug misuse at booking, typical weekly alcohol consumption at booking, ever been in receipt of a free school meal, ever had a student need, ever

been excluded, left school at booking, ever been on the child protection register, ever care experienced, child dob month and child sex; b Adjusted mean difference

Care experienced children

Data source: *Looked After Children Longitudinal (CLAS) dataset*
Hypothesised direction of FNP programme effect: *Children experience care earlier and less time spent in placement*

Children having an experience of care was measured using data from the Looked After Children Longitudinal (CLAS) dataset. This dataset is linked using the Scottish Candidate Number (SCN) that is allocated to children upon entry to Primary 1. Therefore the data that could be used for this outcome is limited. Data from the First Visit time point (10-14 days post partum) also could not be used due to quality issues. Any children with episodes of care that were completed prior to school entry and for whom there were no subsequent episodes after school entry were not able to be linked and included in the analysis. If a child was linked then retrospective records could be accessed on the child. Data from the child health reviews at 27-30 months were deemed as not fit for purpose due to issues with over-recording of the Looked After Child (LAC) variable between 2013/14 and 2015/16 [41].

Approximately 1% of children in both arms had at least one care placement recorded in the CLAS data; due to these small numbers, no further descriptive results could be produced e.g., the proportion of children care experienced by age 2 and 5 years. Children from FNP mothers appeared to have been placed in care at an earlier age than those from Controls (mean age 774 vs of 956 days respectively). Duration of the first placement was comparable with an average of 192.5 days. A similar proportion of children in both Clients and Control group were initially placed at home with parents, or with friends or relatives (FNP: 60% vs Controls: 66%). A higher proportion of children in the Controls had a destination accommodation at home with biological parents (45% vs 82% respectively) while a higher proportion of children in the FNP group had a destination accommodations not with their biological parents (55% vs 18% respectively). The other placement and destination categories could not be disaggregated further due to small numbers.

Table 6.15: Care experienced child by FNP Clients and Controls

	FNP Clients	Controls	Absolute difference[a] (95% CI)
Children with an SCN to enable linkage, n (%)	978 (30.3)	2,451 (49.6)	
Children with at least one care placement, n (%)	10 (1.02)	28 (1.14)	-0.1 (-0.8 to 0.8)
First placement, n (%)			
Age at first placement (days), Mean (SD) (truncated to 5 years)	774 (601)	956 (596)	-182 (-630 to 266)
Duration of first placement (days), Median (IQR)	192.5 (78.7 to 532)	192.5 (94.5 to 469)	
Total placements, n (ratio children:placements)	20 (1:2)	44 (1:1.6)	
Placement Type, n (%)			
At home with parents, with friends/relatives	12 (60.0)	29 (65.9)	
Foster carer, permanent placement with prospective adopters, Other residential	8 (40.0%)	15 (34.1)	
Destination Accommodation, n (%)			
Home with biological parents	9 (45.0)	36 (81.8)	
Home with newly adopted parents, Friends/relatives, Kinship care order	11 (55.0)	8 (18.2)	

CI=Confidence interval, IQR=Interquartile range, SCN=Scottish Candidate Number, SD=Standard deviation

a FNP Clients minus Controls

Section 7: Discussion

Principal findings

The principal findings are summarised below by outcome domain. Findings are reported for outcomes modelled statistically and those assessed only descriptively and distinguished where appropriate. An overview of the statistically tested findings is listed in Table 7.1, alongside existing evidence of programme effect from randomised controlled trials (RCTs).

Table 7.1: Principal findings of the FNP Scotland evaluation, alongside existing evidence of effects

Outcome	Estimate type[a]	Adjusted estimate (95% CI), p-value (where <0.05)	Existing RCT evidence of effect[b]
Alcohol use / substance misuse during pregnancy	OR	0.94 (0.50 to 1.75)	
Childcare use	D	-	-
Return to education	D	-	-
Highest educational attainment	D	-	-
Subsequent birth (live/still)	OR	1.01 (0.87 to 1.18)	
Inter-pregnancy interval	HR	0.97 (0.90 to 1.04)	
Inter-birth interval	HR	0.99 (0.92 to 1.07)	
Breastfeeding initiation (first feed)	OR	1.12 (0.98 to 1.29)	
Breastfeeding at 10-14 days post-partum	OR	**1.31 (1.13 to 1.51), <0.001**	
Breastfeeding at 6-8 weeks post-partum	OR	**1.35 (1.11 to 1.65), 0.003**	M,TN[c]
Duration of breastfeeding	IRR	0.78 (0.48 to 1.28)	
Exposure to second hand smoke	OR	**Interaction p-value=0.0002**	TN
Pre-term delivery (<37 vs 37+ weeks)	OR	0.76 (0.57 to 1.02)	
Pre-term delivery (<28, 28-<32, 32-<37,37+ weeks)	D	-	-
Babies with appropriate birth weight	D	-	-
Healthy Body Mass Index (BMI) at 27-30 months	OR	1.01 (0.85 to 1.20)	
Healthy BMI at Primary 1	OR	1.24 (0.99 to 1.56)	

Outcome	Estimate type[a]	Adjusted estimate (95% CI), p-value (where <0.05)	Existing RCT evidence of effect[b]
Registered with dentist at 24 months	OR	**1.16 (1.02 to 1.32), 0.020**	No existing evidence
Attended a dentist by 27-30 month visit	OR	0.93 (0.76 to 1.13)	
Hospital admissions for dental procedure	HR	0.96 (0.74 to 1.25)	
Hospital admissions for serious injuries	HR	1.08 (0.88 to 1.34)	
Any attendance to Accident and Emergency (A&E)	D	-	-
Attendance to A&E for accidental injuries	HR	0.97 (0.83 to 1.14)	
Safe home environment at 2 years	OR	0.84 (0.59 to 1.20)	
Safe home environment at 5 years	OR	1.07 (0.81 to 1.41)	
Any child development concern by 27-30 months	OR	1.02 (0.90 to 1.16)	
Any new child development concern at 27-30 months	OR	**0.84 (0.72 to 0.98), 0.030**	D, TN, En
Any student need at P1	OR	0.78 (0.55 to 1.10)	
Gross motor skills concern at 27-30m	OR	1.16 (0.80 to 1.68)	
Fine motor skills concern at 27-30m	OR	0.95 (0.71 to 1.27)	
Personal/social, emotional or behavioural concern at 27-30m	OR	0.90 (0.74 to 1.08)	
Social, emotional, and behavioural difficulty at P1	OR	0.82 (0.47 to 1.44)	
Speech, language, and communication concern at 27-30m	OR	1.06 (0.86 to 1.30)	
Language or speech disorder/ Communication Support Needs at P1	OR	0.81 (0.43 to 1.55)	
Physical or motor impairment at P1	OR	na	
Vision concern at 27-30m	OR	1.01 (0.71 to 1.43)	
Vision impairment at P1	OR	na	
Hearing concern at 27-30m	OR	1.32 (0.88 to 1.98)	
Hearing impairment at P1	OR	na	
Other student need at P1	OR	0.83 (0.39 to 1.76)	
More able pupil	D	-	-
Child attainment (5 outcomes)			

Outcome	Estimate type[a]	Adjusted estimate (95% CI), p-value (where <0.05)	Existing RCT evidence of effect[b]
Reading	OR	0.99 (0.79 to 1.23)	
Writing	OR	1.05 (0.85 to 1.29)	
Listening and Talking	OR	0.86 (0.67 to 1.11)	
Literacy	OR	1.21 (0.96 to 1.53)	
Numeracy	OR	0.98 (0.78 to 1.23)	
Child protection (CP) investigation	D	-	-
Age at first CP investigation	MD	-0.52 (-1.43 to 0.38)	
Number of CP investigations	IRR	0.97 (0.67 to 1.40)	
Investigation requiring a CP Case Conference (CPCC)	D	-	-
Type of concern identified at CPCC	D	-	-
Length of time on CP register	MD	10.05 (-61.7 to 81.8)	-
Child registered as a result of conference	D	-	-
Child deregistered	D	-	-
Care experience status	D	-	-
Children with a care experience status	D	-	-
Time spent in first placement	D	-	-
Placement type	D	-	-
Placed for adoption	D	-	-

CI=Confidence interval, RCT=Randomised controlled trial

a D-Descriptive; OR=Odds ratio; HR=Hazard ratio; MD=Mean difference; IRR=Incidence rate ratio; b Comparative findings shown for tested outcomes with a statistically significant difference in current study (i.e. not including those presented above as Descriptive statistics or non-significant). Summaries show statistically significant findings (p<0.05) where analysis was of the whole trial sample only: E (Elmira), M (Memphis), D (Denver), TN (The Netherlands), En (England). Previously assessed but non-significant findings are not included. Summarised findings relate to relevant domains but may not always be precise equivalent outcomes, including time-frame of assessment. c Domain of breastfeeding (i.e. Outcomes 8-10) summarised under third listed outcome only.

Maternal outcomes

There was no statistically significant difference between groups in the number of women attending an emergency department or being admitted due to alcohol / substance misuse during pregnancy or with a firstborn child with fetal alcohol syndrome. There was no statistically significant difference between groups in the number of women with a subsequent birth within 24 months of the first baby being born. Similarly, the study groups were not significantly different in the time between first child being born and subsequent pregnancy or birth across the follow-up period. Subsequent births within 24 months across study groups were not affected significantly by deprivation, maternal age, health board, year of antenatal booking and, assessed descriptively for FNP Clients, number of nurse visits.

A higher proportion of children born to FNP Clients attended any childcare by the 27–30-month review compared to children born to women in the Control group (59.8% and 56.1% for FNP Clients and Controls respectively) (descriptive only). The proportion of children attending nursery was higher for children of FNP Clients (42.1% vs 36.0% respectively), whilst children attending a playgroup was higher for children of women in the Control group (8.3% vs 11.1% respectively). There were few women who left school after their antenatal booking date (FNP Clients: n=227, Control: n=250). These represent 9.2% (FNP Clients) and 7.2% (Control) where a leaving date could be determined or inferred. FNP Clients that were recorded as leaving school after their antenatal booking date remained in school for a longer duration than Controls, 193 days (86 to 410) and 151 days (70 to 331) for FNP Clients and Controls respectively.

Birth outcomes

There was no difference in birth weight between study groups for either observed weight or when using the customised Gestation Related Optimal Weight (GROW) centiles which adjusts for maternal height and weight, ethnicity, gestational age, parity and sex of baby (GROW does not adjust for maternal smoking status). Rates of pre-term delivery (<37 vs 37+ weeks gestation) were not significantly different across study groups and there were no differential programme effects by maternal age, year of booking or health board. The rate of pre-term babies was around 8%, similar to the rate in Scotland for mothers under 20 years old [37].

Competent parenting (child health and protection)

There was no statistically significant difference between study groups in rates of initiation (first feed) of any breastfeeding (combination of exclusive breastfeeding and mixed feeding). Breastfeeding rates at 10-14 days and 6-8 weeks post-partum were statistically significantly higher in the FNP group compared to the Control group (10-14 days: adjusted odds ratio (aOR): 1.31, 95% confidence interval (CI): 1.13 to 1.51; 6-8 weeks: 1.35: 1.11 to 1.65). The percentage of any breastfeeding increased with FNP visits received during the pregnancy period, although this was not tested. Programme impact on rates of breastfeeding initiation did not differ significantly by maternal age. Similarly, breastfeeding rates at both 10-14 days and 6-8 weeks were not significantly affected by adjustment for health board or year of booking. A smaller cohort of women reported stopping breastfeeding (recorded within the child health visits at 10-14 days and 6-8 weeks). Of the small group that reported stopping breastfeeding; FNP Clients breastfed for a median of 4.5 days (IQR: 1.75 to 15.25 days) compared to 4 days (2 to 14 days) in Controls, with no statistically significant difference between the two groups.

There was a statistically significantly greater reduction in exposure to second hand smoke over time (10-14 days, 6-8 weeks, 27-30 months) in the FNP group compared to the Control group (interaction p-value=0.0002). Exposure to second hand smoke rates were 36.9% (10-14 days) and 25.7% (6-8 weeks) in the FNP Clients and 34.2% (10-14 days) and 30.3% (6-8 weeks) in the Control group.

Child development

There was evidence to suggest a difference between study groups in any newly suspected child development concerns recorded at 27-30 months, with a higher proportion of new concerns in the Control group (aOR: 0.84, 95% CI: 0.72 to 0.98). There were no significant differences between study groups at 27-30 months post-partum in rates of children recorded with a gross or fine motor skill concern, any personal/social, emotional or behavioural concern or any speech, language or communication concern, or for any vision or hearing concern. At the P1 assessment, there were no significant differences between study groups in rates of children recorded with any student need, any social, emotional or behavioural difficulty, any language or speech disorder / communication support needs or ‘other student need’. The small numbers of cases at P1 for physical or motor impairment, visual impairment and hearing impairment meant the groups could not be compared statistically.

Child health

There were no statistically significant differences in the rates of children with a healthy weight at 27-30 months post-partum or at the Primary 1 (P1) review. A significantly higher proportion of children in the FNP group were registered with a dentist by aged 2 years (aOR: 1.16, 95% CI: 1.02 to 1.32). The effect of FNP on registration differed across HBs but not by year of booking. The rate of children attending a dentist by 27-30 months was not significantly different between study groups. The rate of dental procedures between study groups was not significantly different after adjusting for the differences in follow-up time in the FNP Clients and Controls. There was no significant difference between study groups in the time to first hospital admission for a first serious injury. Rates for at least one hospital admission were at six months 1.1% (FNP), 1.2% (Control), at one year 2.1% (FNP), 2.3% (Control), and at two years 4.3% (FNP) 4.4% (Control).

Rates of A&E attendance for any reason were by six months 1.8% (FNP Clients) 1.0% (Control), by 1 year 5.0% (FNP Clients) 2.8% (Control), by 2 years 11.7% (FNP Clients) 7.8% (Control) and by 5 years 16.4% (FNP Clients) 14.4% (Control). Rates of A&E attendance for an accidental injury were by six months 1.1% (FNP Clients) 0.7% (Control), by 12 months 3.1% (FNP Clients) 1.8% (Control), by 24 months 7.6% (FNP) 4.9% (Control) and by 5 years 11.5% (FNP Clients) 9.6% (Control). There was no statistically significant difference in the time to first accidental injury between the study groups (adjusted hazard ratio (aHR): 0.97, 95% CI: 0.83 to 1.14).

There were no significant differences between study groups in the proportion of children with at least one hospital admission due to an unintentional injury in the home by 2 years and by 5 years (2 years - FNP: 2.2%, Control: 2.6%; 5 years - FNP: 5.7%, Control: 5.5%). There were also no significant differences by health board or year of booking.

Child attainment

The proportion of children achieving their age relevant Curriculum for Excellence (CfE) level at P1 (Early Level: 5-6 year-olds) or P4 (First Level: 8-9 year olds) for Reading, Writing, Listening and Talking, and for Numeracy were similar between the FNP Client and Control study groups with no statistically significant differences after adjusting for confounders including child sex and month of birth. There was evidence of a differential programme effect for Writing and Literacy by HBs (interaction p-value=0.018) but there were no other differences in intervention effect by HBs, nor year of booking. Girls outperformed boys consistently across all assessments. A post-hoc subgroup analysis of

attainment by child sex found no evidence of a differential FNP programme effect for any subjects. Sensitivity analyses on age related achievement at the P1 Level, supported the findings of the primary analysis but found a significant differential FNP programme effect in Reading for child sex and HB, and in Writing by HB.

Improved child protection

Unadjusted rates of children ever being subject to child protection investigation up to the age of two were 2.2% (n=22/978) in the FNP group and 0.8% (n=20/2,451) in the Control group. By the age of five they had risen to 4.9% and 3.2% respectively. A higher proportion of children were first investigated sooner (under 2 years of age, including pre-birth), in the FNP group (45.8%) compared to in the Control group (25.0%), with 75% of children in the Control group first identified between the ages of 2 to 5 (54.2% in the FNP group).The median (IQR) age at first investigation was 2.2 years (0.1 to 3.9 years) for those in FNP group and 3.4 years (1.9 to 4.3 years) for those in the Control group. After adjustment for confounders, there was no evidence of a significant difference in the age at the child's earliest investigation (different in means: -0.52, 95% CI: -1.43 to 0.38). The median (interquartile range) duration of first placements were 192.5 (78.7 to 532) days for FNP and 192.5 (94.5 to 469) days for the Control group.

Intervention delivery (FNP Client group)

Details of the infrastructural core model elements required under FNP licensing conditions fall outside the scope of the current evaluation. Instead, we have focused on the fidelity targets intended to support high quality delivery of the programme as these data were available from the FNP SIS. This section, therefore, relates only to the FNP Client group in this study. Overall, 52% of FNP Clients included in the current study sample were enrolled to the programme by the end of the 16th week of pregnancy (the fidelity target is 60%). There was variability between sites, with some recording higher rates (e.g. 75% in Borders and 60% in Lothian). It is possible that the smaller number of clients in Borders and the longer experience of programme delivery in Lothian (which was the first test site for FNP in Scotland) may contribute to these rates being higher than the overall average. In the NHS Lothian evaluation which covered the period from January 2010 to April 2013, only 42% of clients were enrolled by 16 weeks, a rate similar to that reported in the Building Blocks trial in England for non-trial clients (41.6%) [23,42]. The median (IQR) number of valid visits received per phase were Pregnancy: 10 (8 to 12), Infancy: 19 (16 to 22) and Toddlerhood: 14 (10 to 17). While the maximum number of scheduled visits per phase are 28 (infant) and 22 (toddlerhood), gestation at enrolment and programme departure are used to modify

the expected visit numbers in the pregnancy phase [43]. Furthermore, benchmarks are set for the proportion of these number of visits received per phase (80%, 65% and 60% respectively). The number of valid visits reported here are very similar to those reported in the Building Blocks trial in England (mean (standard deviation): Pregnancy: 9.71 (3.45), Infancy: 18.63 (6.04), Toddlerhood: 13.22 (1.49) [42]. Comparability of rates probably reflect the pragmatic nature of the trial, the observational nature of the natural experiment, with both underpinned by the structured nature of the programme. Nevertheless, there was evidence of some variation in visit delivery between sites in Scotland (e.g. median visits in the Infancy phase was 16 in Forth Valley and 23 in both Borders and Highland).

Core model elements are intended to replicate the original US research conditions. Targets for the proportion of scheduled visits achieved in practice are set for each phase of delivery (Pregnancy: 80%, Infancy: 65%, Toddlerhood: 60%). These goals were met for 73.8%, 57.3% and 52.7% of women commencing each respective delivery phase. This compares to rates of 52%, 55% and 83% reported in the NHS Lothian process evaluation and rates of 57.7%, 53.1% and 43.5% in the English cohort enrolled in the Building Blocks trial [23,42].

While recorded fidelity in our study sample may add little to what is already known about programme delivery in Scotland, it provides a benchmark for understanding how fidelity compares to other evaluations. In this natural experiment, metrics on some of the fidelity measures demonstrate what is possible for a programme being delivered at scale and the relevant context for assessing the outcomes reported here. In addition, it has allowed the opportunity to explore descriptively dosage effects for selected outcomes.

Interpretation and comparison to other studies

The overall rate of alcohol and substance misuse during pregnancy observed in the study was low, in part reflecting the severity of the presentation detectable using routine health records (i.e. A&E attendance or Inpatient admissions). This limited the opportunity to examine dosage effects. With no overall study group difference nor any differential effects by deprivation, over time or across health boards there is no evident programme effect based on this outcome. Alcohol and drug use during pregnancy were not assessed in the US trials of FNP nor in the Building Blocks trial. Only longer-term (i.e. at 24 months post-partum) alcohol and / or drug use were assessed in both the Building Blocks trial and trial of VoorZorg [17,44]. Therefore, there is little high quality evidence for programme effects on such substance misuse during pregnancy.

The lack of difference between study groups for any pregnancy or birth outcomes mirrors what was found in the Building Blocks trial and the Dutch trial of VoorZorg [16,20]. The main evidence for programme effects for birth weight (which was treated as a descriptive outcome in this study), and gestational age are found in the original Elmira trial for specific subgroups of the trial sample (younger women). We had no data available through routine sources to establish a programme effect on maternal smoking during pregnancy.

Exposure to second hand smoke reduced to a significantly greater extent after 10-14 days post-partum in the FNP compared to the Control group, with the results showing that the FNP arm reduced passive smoking earlier than the Control arm. The trial of VoorZorg found differences in passive smoking at two months post-partum based on maternal report [20]. Although data on passive smoking captured at Health visitor first visit at 10-14 days post partum and at 6-8 week review were recorded by either family nurses or health visitors depending upon study group, a potential source of bias which is discussed further below (under Strengths and Weaknesses). In addition, evidence from the US Elmira trial suggested that FNP Clients may be more accurate in their reporting of smoking behaviour than women in the Control group [12]. In the Building Blocks trial a validation and calibration process using urinary cotinine was used to enhance the measurement of changes in maternal smoking during pregnancy [45]. Cotinine informed assessment of smoking was used in the Denver trial of FNP where reductions in smoking during pregnancy were found [11]. The earlier Elmira trial found programme associated reductions in smoking during pregnancy for women smoking at baseline [12]. Click or tap here to enter text.

Like the Building Blocks trial, this study shows that FNP has no overall impact on subsequent pregnancy rates in the two years following a mother's first child being born. This was unaffected by maternal age or deprivation level when tested. This contrasts with the three US trials of the programme, all of which have found reductions in subsequent pregnancies in more vulnerable subgroups (for example, poor unmarried women in Elmira). A retrospective cohort study of 3,844 FNP Clients and a control group of 10,938 women in Pennsylvania found no programme effect in the first three years of its introduction but some benefits over a longer period of implementation, mainly in younger women (aged 18 years and under) and clients living in rural locations [46]. In the present study, neither year of booking nor health board had any impact on pregnancy rates across study groups. In the process evaluation for Building Blocks, family nurses described the challenges of competing with existing socio-cultural norms and that clients in receipt of good support from their family nurse felt more confident in having a second child. Whether

a longer period of programme implementation than available in the present study may lead to an incremental programme impact on pregnancy rates remains to be determined. However, strong cultural factors and differences in social and financial support for young families across evaluation settings may be important drivers in determining such outcomes.

The Memphis trial of NFP found higher maternally reported rates of attempted breastfeeding but not duration when assessed by interview at six months post-partum. While the Dutch trial of VoorZorg reported superior rates of breastfeeding at six months post-partum for women in the intervention group [13,20]. The Building Blocks trial in England found a higher proportion of women in the FNP arm intending to commence breastfeeding but no difference in actual feeding practice [17]. The higher rates of breastfeeding at 10-14 days and 6-8 weeks for FNP Clients in the current study would therefore fit the broad pattern from previous trials. National data across Scotland from the 6-8 weeks review show any breastfeeding rates for mothers under 20 years old rose from 8.7% in 2009/10 to 11.8% (2016/17) [47], which is aligned to the period of incremental FNP roll-out in Scotland. Whilst these rates for mothers under 20 years old exceed those observed in the current study, temporal changes (reflecting the longer period of coverage in this natural experiment i.e. 2009 to 2016) and differences in geographical coverage may explain some of the variation.

In Scotland overall, dental registration rates for all children aged up to 2 years old are below 50% (in 2016 48.1%, in 2019 47.4%) with variation across the regions covered by the current study sample (in 2016, registration rates were 40.1% in Tayside and 52.3% in Lanarkshire) but then rise to approximately 90% in ages 3-5 years [48,49]. The higher rate of registration with a dentist by age 2 years for children in the study's FNP group (62%) would be consistent with family nurses supporting access to health and social care services. Nevertheless, this difference was not matched with a higher level of attendance at the dentist by the time of the 27-30 months review (which records attendance in the preceding twelve months). The Building Blocks trial also recorded uptake of dental care and found no difference in rates of children attending a dentist for a routine check-up by 2 years[17]. Overall rates of attending a dentist were higher in the current study at nearly 77% compared to approximately 67% in the Building Blocks trial. The later census point in the current study (27-30 months post-partum) compared to 24 months in Building Blocks which may explain some of this difference.

The US Elmira and Memphis trials of FNP provided evidence of programme impact upon child abuse and neglect through reductions in emergency room visits and reduction in inpatient stays following injuries and ingestions, in particular for women at baseline with lower psychological resources, household income and higher levels of poverty [13,14]. Safety in the home environment was examined firstly in the current study by looking at data from the SMR01 records for children attending the general / acute hospital setting by 2 years and then by 5 years. Overall rates were the same across study groups for both timepoints. Rates of attendance at an emergency department for any reason were examined descriptively and were slightly higher in the FNP group compared to Controls. For accidental injuries, the slightly higher but untested rates of attendance amongst children in the FNP group up to two years of age would be consistent with family nurses supporting appropriate access to supportive healthcare (although when tested, time to first attendance for an accidental injury did not differ between study groups). This matches a similarly non-significant pattern reported in the Building Blocks trial of children attending emergency departments for an injury or ingestion by six months and by 24 months [17].

While rates of children admitted to hospital following a serious injury by six months were similar between study groups, children in the FNP group stayed longer, although this unadjusted difference was not tested. Longer durations of stay have been suggested as a more objective measure for examining child maltreatment than, for example, child protective services records. Duration of stay was associated with programme impact by two years of age for children in the Memphis trial [13]In England, a shorter duration of stay was not found for children in the FNP trial arm, and the authors noted the potential for factors other than objective clinical severity (e.g. health service or social factors) to influence duration of hospital stay [18].

While the difference between groups in time to first child protection investigation was not statistically different, the pattern of investigation timing (earlier in FNP group) would be consistent with early intervention by Family Nurses in close and frequent contact with families. Although data on category of abuse for FNP Clients and Controls are reported, these numbers are very small and in combination with being unadjusted rates, should be cautiously interpreted.

Work from the Elmira trial of FNP has indicated that intervention from child protective services may occur at lower levels of concern for FNP enrolled children than for families not under the care of a family nurse, driven by greater levels of contact with families and nurses promoting earlier access to relevant services [50].

The study provides evidence of little difference in early child development outcomes between study groups based on child health reviews at 27-30 months and at the P1 assessment. However, the higher rate of any newly identified child development concern at 27 – 30 months in the Control group is consistent with findings in the Denver trial of NFP which reported programme benefits for child mental development at 24 months within the maternal low resource sub-group [11]. A higher rate of cognitive developmental concerns at 24 months postpartum were also reported in the Control group of the Building Blocks trial in England, which additionally found higher language scores at 24 months postpartum in the FNP group [17]. In the Building Blocks trial, maternally reported language outcomes also differed between arms at 12 and 18 months, although these maternally reported outcomes may be at greater risk of reporting bias than the standard health visitor reviews and P1 assessments in the current study. Finally, rates of internalising and externalising behaviour were assessed at 24 months for children in the trial of VoorZorg and found to be significantly higher in the control group for the former and not different between groups for the latter [21].

School achievement outcomes

The achievement of expected Curriculum for Excellence (CfE) Level data are based on the professional judgements of teachers who undertake assessments against set benchmarks [40]. Four domains are assessed, three of which (Reading, Writing, Listening and Talking) also contribute to an overall Literacy assessment. At a population level there is a substantial attainment gap between least and most deprived areas and also between girls and boys [51]. The latter effect is evident in the current study where girls perform better across all domains. In this study, the higher rate of achievement in Writing for children in the FNP group did not reach statistical significance for children in Early and First Level (ages 4 to 5 years and 8 to 9 years old respectively), although a differential effect by HB was found. Similarly, in the English trial cohort at Key Stage 1 (ages 6 to 7 years old) this group difference was on the cusp of statistical significance after adjustment for confounders (OR=1.30, 95% CI= 1.00 to 1.69, p-value=0.050)[18]. In the English trial cohort, group differences for Reading reached statistical significance after adjusting for month of birth unlike the present study where no such overall difference was found between the two groups although diferential effects were found by child sex and HB. The absence of a difference for Numeracy is also matched by the lack of difference for Maths at KS1 in the trial cohort in England.

Differences over time and across health boards

In recommending a natural experiment to evaluate FNP in Scotland, the evaluability report highlighted the utility of the large sample to explore variation in programme impact over time and across sites [25]. As FNP teams become better established at sites and gain greater experience, it is certainly possible that this could lead to more effective practice, including increasingly effective integration with other services and better family outcomes. Such experience and potential to learn will also accrue collectively across sites as well as within sites. The potential to examine such temporal effects will be greater in this type of natural experiment compared to a trial where programme implementation will often be for a much shorter duration of time and at smaller scale.

However, no interaction effects by year of booking were found where tested. For some outcomes with few events (e.g. maternal alcohol or substance misuse) the scope for looking at differences over time would have been limited but for others, such as a subsequent pregnancy that would not have been the case. Within sites delivering the programme over the relatively short period of time covered by this study (e.g. NHS Lanarkshire) the scope for making changes would have been limited compared to those enrolling clients over a much longer period (e.g. NHS Lothian).

Similarly, there were few differences between health boards in outcomes. Exceptions to this were found for the proportion of children registered with a dentist at 24 months post-partum (a difference of 20% in registration rates for children in the FNP group between the sites with the lowest and highest registration rates) and for the proportion of children achieving the expected level in Writing and Literacy (Early Level and First Level) and Reading (Early Level) . It is possible that improvements in delivery over time or variation in delivery across sites will just be too small to be reflected in observable differences in routine data when set against the structured programme and other client characteristics that may influence outcomes.

Dosage effects

In this study, the association between number of visits received and selected outcomes was assessed descriptively only. Overall, there appeared to be little evidence of dosage effects although such unadjusted rates may provide a modest indicator of any underlying association. For outcomes such as child attainment there appears to be no clear pattern across different levels of dosage for any of the five outcomes. The exception may be for the highest level of visits where child attainment was lower in most cases. However, the

number in receipt of this highest level of visitation was very small and not a strong basis for inferring any effect. Similarly, children in families receiving the highest number of visits also had highest numbers of overall (any) child development concerns and the same was true for Personal/Social/ emotional of behavioural concerns. Again, the numbers in this category were very small. The same pattern was observed for the mothers with a subsequent birth by 24 months post-partum. Subsequent births reduced as visits peaked at 21-30 visits but gradually increased for women who received 60 visits or more), but suggestive of a potential dosage effect. For all these examples, where more visits are reported for children with poorer outcomes also suggests the hypothesis that greater FNP input is being provided to support families in greatest baseline need.

For other outcome domains such as safe home environment, events were too few to examine possible associations. More visits in the pregnancy phase are recorded for women delivering their baby at term), peaking at 11-15 visits. However, wider evidence shows women booking later than 14 weeks are at risk of a pre-term birth, both of which would limit the number of potential nurse visits and could equally explain any apparent dosage effect [52]. Rates of breastfeeding initiation were higher in women with more recorded pregnancy visits (for example, 36.6% for n=1,099 women receiving 6-10 visits, 43.9% in n=1,175 women receiving 11-15 visits). A similar pattern is also evident for rates of breastfeeding at 10-14 days and at 6-8 weeks. An association between more visits in pregnancy and higher rates of breastfeeding initiation seems plausible. Further exploration of this hypothesis should assess and control for the potential for competing explanations independent of the role of the Family Nurse.

Subgroups

FNP in Scotland is delivered at a population level (for mothers 19 years and under) across each Health Board site. Accordingly, the evaluation focused on main treatment effects across study group. Nevertheless, exploratory subgroup analyses assessing programme effects for selected outcomes were undertaken reflecting previous trial evidence of added benefit for families experiencing particular baseline disadvantage. In our evaluation, we explored effects that may vary by maternal age, deprivation quintile and smoking history at booking and by sex of child and whether the child had a pre-term delivery.

We found little evidence of subgroup effects. Maternal age made no difference to programme impact in terms of pre-term delivery, breastfeeding initiation, or subsequent births by 24 months. Similarly, baseline deprivation level made no difference to

programme impact for alcohol/substance use during pregnancy, or subsequent births by 24 months. Whether a child was delivered pre-term or not made no difference to programme impact on BMI at 27-30 months review, while sex of child also makes no difference to programme impact on rates of child development concern at the same time-point. For none of these outcomes was there an overall group difference, which could limit the potential for discernible subgroup differences, although these analyses demonstrate that such differences were not being masked. Exposure to second hand smoke was higher in current smokers compared to non-/former smokers as recorded at antenatal booking, at all time points (10-14 days, 6-8 weeks, 27-30 months). We found no differential effect in children exposed to second hand smoke over time between FNP Clients and Controls, when current smokers and non-/former smokers were compared.

A post-hoc analysis of child attainment for PI and P4 by sex showed no differences in programme effects between boys and girls comparable to the English trial cohort where no differences by child sex were observed for the three Key Stage 1 assessments evaluated (Reading, Maths, Numeracy) [18]. There was evidence of a differential FNP programme effect for pupils achieving in Writing and Literacy by HBs. Sensitivity analyses on achieving age related P1 Level found a significant differential programme effect in Reading for child sex and by HB and also in Writing by HB.

Strengths and weakness

Data linkage, balance between study groups and sample representativeness

The absence of match rates provided for linkage of FNP and Control group records to health and education datasets limits our understanding of the representativeness of the study cohort and may overestimate denominators for some outcomes. This is likely to be less problematic for health data as SMR02 data were provided for all women and children (and therefore, likely to be the case for other health datasets) but not so for education and child protection data supplied by EAS. Several factors were associated with a lower rate of linkage including year of booking (lower rate in years 2009 to 2011), older at booking, of ethnic background other than white, experiencing a previous pregnancy, drug misuse during pregnancy.

Data contributing to the study are generally returned and collated nationally which greatly aids coverage and consistency. Nevertheless, reliance on routine data meant that its

availability and consistency over time could change. For example, of the CHSP-PS forms, the 27-30 month review was started in April 2013 and then forms for all existing reviews were updated in 2015, being implemented in 2016 [53]. Some outcome data were available for only a proportion of the study sample, for example child attainment outcomes which were originally experimental statistics, became subsequently established for use in 2018/19. This led to coverage for only 41.3% of the sample and a large difference in coverage between groups (29.7% FNP Clients, 48.8% for Controls), due to the length of follow-up. There was also variation across sites in routine data collection, for example, in when and what data for exposure to second hand smoke is recorded via two fields in the child health data (Primary carer current smoker/Child exposed to second hand smoke). In this case we undertook a sensitivity analysis which included just examining the exposed to second hand smoke fields which reduced the observed rate of smoking but did not change conclusions about study group differences. Similar sensitivity analyses were applied where there were differences over time in data collected (e.g. the exclusion of earlier periods of study where there were higher rates of missing data).

Whilst the two study groups were well balanced on several baseline characteristics, there were some key differences on recorded characteristics of clients. FNP Clients exhibited higher rates of health and social care need and were more likely to include women of white ethnicity than found for women in the control group. Women eligible but not enrolled to FNP were more frequently of an ethnicity other than white, less frequently within the most deprived quintile, marginally older and less commonly a current smoker than women who were enrolled. These factors are likely to be interrelated and reasons for eligible women's non-enrolment may reflect women's self-perceived need for additional support and differences in family and social support. Adjusting for observed confounders had a large impact on the size and occasionally direction of effect. The impact of unobserved confounders such as self-efficacy, employment, family / social support and household structure is not known.

Study outcomes included those captured in the Child Health System Programme – Pre School (CHSP-PS) dataset. For the 'Health Visitor first visit' (at around 10-14 days after birth) and the '6-8 week review', these reviews would have been completed by family nurses for women in the FNP group and by health visitors for women in the Control group. Data captured at the 10-14 day and 6-8 week reviews included breastfeeding and exposure to second hand smoke. The 6-8 week review additionally included several child development outcomes. Whilst a common form was used for data collection across study

groups, these reviews are at risk of both response bias and interviewer bias. These biases may operate differentially across study groups due to the relationships established between mothers and family nurses and health visitors. For example, mothers may present more favourably on positive behaviours such as breastfeeding and underplay negative behaviours such as exposure to second hand smoke – a form of response bias (social desirability). A more established and secure relationship between a mother with her family nurse (compared to a health visitor) may lead to differences in how such biases may operate. For the 27-30 months review conducted by health visitors (for both FNP Clients and Controls in this study) concerns previously identified separately by family nurses or health visitors at 6-8 weeks are still reflected in the assessment, although any retained bias may be expected to be small. With no data available on visits received from health visitors outwith the child health assessments, for women in the control group, it is not known whether their prescribed schedule of visits was delivered. Nevertheless, any systematic difference in visit dosage, intensity and duration could further confound the group comparison. Furthermore, work from the Elmira trial of FNP suggested programme clients may be more accurate reporters of some health behaviours, independent of the data collector [12]. Therefore, the validity of such data and comparison across groups must be treated with some caution. A systematic bias in one or other direction could either under or over-estimate a treatment affect. Bias operating, but in no overall direction, would add variability to the treatment effect and an associated loss in precision. However, this risk reduces with later reviews (e.g. 27-30 months) by which time care for FNP Clients would have transitioned to health visiting.

Rates of pregnancies and birth within 24 months of the birth of a first child were much lower than reported in the Building Blocks trial (e.g. a subsequent pregnancy rate of 66.2%) [16]. In this study the primary data source was the SMR02 Maternity Inpatient and Day case dataset. These data revealed an overall pregnancy rate of 25% (FNP: 25.0%; Controls: 25.3%). This is similar to the subsequent pregnancy rate identified from the inpatient dataset alone in England for mothers in the Building Blocks trial (21%) [42]. Other sources of information about pregnancy were used in that study to develop a derived outcome (i.e. any evidence of pregnancy from maternal self-report, abortion statistics, outpatient or GP records). In the Building Blocks trial, only using one or other of the different sources of information about pregnancies would have led to different conclusions about rates. Understanding fully the nature and source of any one routine data source is essential to interpreting study outcome and supporting comparisons.

Adjustment for multiple comparisons

An important risk to manage in this natural experiment with the large number of outcomes of interest and a large sample size is the increased likelihood of reporting spurious group differences. The tender that informed our design specified that no outcomes were prioritised. The implication for this approach was that the originally planned total of 34 short or medium outcomes meant an increased risk of finding a significant result by chance (false-positive error) i.e. given a 0.05 alpha there was an 82% ($1-0.95^{34}$) chance that at least one of the tests was statistically significant by chance when the conclusion was not true in the population. For transparency, we have reported the actual p-values without correction and then indicated the number of tests and Bonferroni-threshold so the reader can assess evidence as compared with both the conventional nominal threshold and the Bonferroni-corrected threshold [27,54].

For the main analyses in this evaluation, with 39 main comparisons statistically tested, applying a $p<0.05$ significance level we would have expected two significant group differences to occur by chance; we found five significant group differences (breastfeeding at 10-14 days and 6-8 weeks, exposure to second hand smoke over time, dental registrations, and any new child concern at 27-30 months) (Table 7.1). Applying a conservative Bonferroni correction and using a threshold of <0.00128 (0.05 divided by 39) to deem outcomes as significant, only breastfeeding at 10-14 days post-partum and exposure to second hand smoke over time remained. Even though the Bonferroni correction for multiple testing is conservative (concluding no effect when one does actually exist), similar results are given using more powerful approaches that preserve type I error such as the Holm, Hochberg and Dunn-Sidak adjustments [29,30,55]. The only adjustment where three outcomes (exposure to second-hand smoke, breastfeeding at 10-14 days and at 6-8 weeks) remain significant when using the Benjamini-Hochberg adjustment [28]. Dental registrations, and any new child concern at 27-30 months are consistently rejected.

Principal changes to the analysis plan

To respond to emerging external evidence about programme impacts, some additional analyses were agreed to be added to the statistical analysis plan for the natural experiment (51). These were principally in the domains of child attainment (Reading, Writing, Listening and Talking, Numeracy) and child protection (e.g. age at first child protection investigation, number of child protection registrations, time registered or with experience of care). In each case this involved testing group differences rather than reporting solely using descriptive statistics.

Conclusions

In this natural experiment, we found statistically significant differences between FNP Clients and Controls on five of the 39 tested outcomes assessed. No statistically significant differences were found for pregnancy or birth outcomes, other child health outcomes or for all but one of the child development outcomes. Of the positive programme effects, fewer new developmental concerns were identified at 27-30 months in children of families visited by family nurses. Families visited by family nurses were more likely to have their child registered with a dentist by 24 months post-partum, an effect consistent with a programme goal of linking families to supportive healthcare services. Differences for breastfeeding and child exposure to second hand smoking were also found to be statistically significant but these comparisons must be considered in the context of potential response and interviewer bias for the reviews undertaken at 10-14 days and 6-8 weeks. Formally adjusting to account for the large number of comparative tests reduces these to two programme effects (exposure to second hand smoking and breastfeeding at 10-14 days). As the study used only routine data, other outcomes of relevance to FNP could not be assessed but remain of importance.

Re-use of the data

Applications to re-use the data in this study should be made to the Public Benefit and Privacy Panel (PBPP) for Health and Social Care and the Education Analytical Services (EAS).

How to access background or source data

The data collected for this <statistical bulletin / social research publication>:
☐ are available in more detail through Scottish Neighbourhood Statistics

☐ are available via an alternative route <specify or delete this text>

☐ may be made available on request, subject to consideration of legal and ethical factors. Please contact <email address> for further information.

☒ cannot be made available by Scottish Government for further analysis as Scottish Government is not the data controller.

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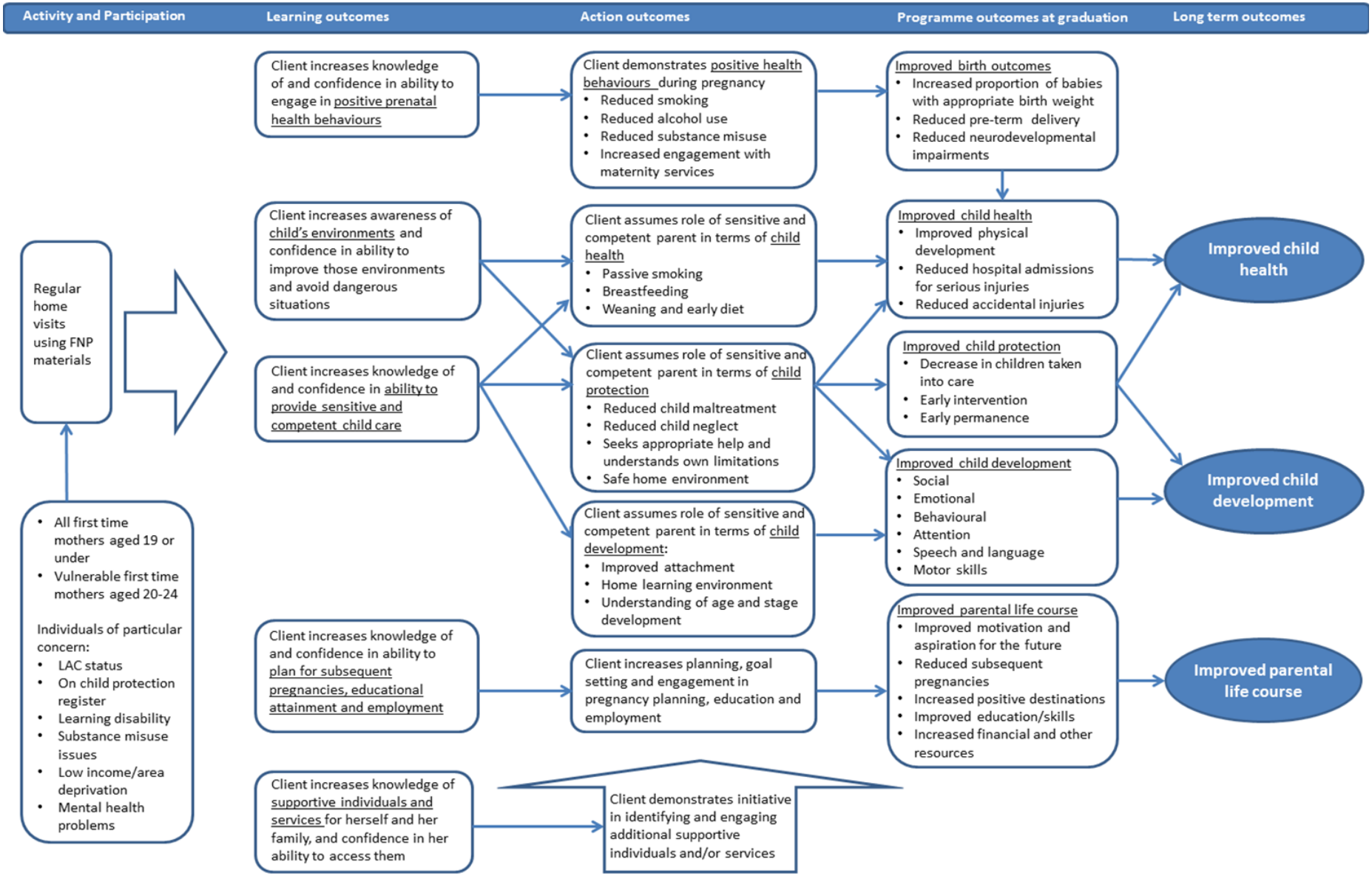
Appendices

Appendix 1: Logic model



Appendix 2: Hospital admissions for Alcohol and Substance misuse during pregnancy[9]

Data source: Accident and Emergency		
Field	**National code**	**Description**
Alcohol and Substance-related		
Diagnosis	02	Alcohol and/or substance use problems
External cause of injury	03B	Alcohol
External cause of injury	03D	Illegal drugs
Objects/Substances Involved in Producing injury	15C	Street/recreational drug
Objects/Substances Involved in Producing injury	15D	Alcohol
Referred to 1,2,3,	06	Drug/alcohol service
Data source: SMR01/02/04		
Substance-related admissions	**ICD-10 code**	**Description**
Main Condition/Other conditions	F10	Mental and behavioural disorders due to alcohol
	F11	Opioid related disorders
	F12	Cannabis related disorders
	F13	Sedative, hypnotic, or anxiolytic related disorders
	F14	Cocaine related disorders
	F15	Other stimulant related disorders
	F16	Hallucinogen related disorders
	F18	Inhalant related disorders
	F19	Other psychoactive substance related disorders
	O35.5*	Maternal care for (suspected) damage to fetus by drugs

[9] Alcohol and substance misuse: https://www.isdscotland.org/Health-Topics/Drugs-and-Alcohol-Misuse/Publications/2016-10-25/2016-10-25-ARHS-Report.pdf; http://orca.cf.ac.uk/88615/1/FullReport-phr04030.pdf; https://bmjopen.bmj.com/content/5/2/e006079; Drug misuse in pregnancy: https://isdscotland.scot.nhs.uk/Health-Topics/Maternity-and-Births/Publications/2015-11-24/2015-11-24-Births-Report.pdf

Data source: Accident and Emergency		
	P04.4*	Newborn affected by maternal use of drugs of addiction
	P96.1*	Neonatal withdrawal symptoms from maternal use of drugs of addiction
	P96.2*	Withdrawal symptoms from therapeutic use of drugs in newborn
Alcohol-related admissions and conditions		
Main Condition/Other conditions	F10	Mental and behavioural disorders due to the use of alcohol
	K70	Alcohol Liver Disease
	T51.0, T51.1, T51.9	Toxic effect of alcohol
	I42.6	Alcohol cardiomyopathy
	K29.2	Alcoholic gastritis
	K85.2 & K86.0	Alcohol-induced pancreatitis
	E24.4	Alcohol-induced pseudo-Cushing syndrome
	E51.2	Wernicke encephalopathy
	G31.2	Degeneration of nervous system due to alcohol
	G62.1	Alcoholic polyneuropathy
	G72.1	Alcoholic myopathy
	R78.0	Finding of alcohol in blood
	X45	Accidental poisoning by and exposure to alcohol
	X65	Intentional self-poisoning by and exposure to alcohol
	Y15	Poisoning by and exposure to alcohol, undetermined intent
	Y57.3	Alcohol deterrents
	Y90	Evidence of alcohol involvement determined by blood alcohol level
	Y91	Evidence of alcohol involvement determined by level of intoxication
	Z50.2	Alcohol rehabilitation

Data source: Accident and Emergency		
	Z71.4	Alcohol abuse counselling and surveillance
	Z72.1	Alcohol use
	O35.4	Maternal care for (suspected) damage to fetus from alcohol
	P04.3	Newborn affected by maternal use of alcohol
	Q86.0	Fetal alcohol syndrome dysmorphic
	K73	Chronic hepatitis, not elsewhere classified
	K74	Fibrosis and cirrhosis of liver (excluding K74.3 - K74.5 biliary cirrhosis)
SMR02		
Alcohol and Substance-related		
Drug Misuse during this pregnancy	1	Yes
Drugs used 1-4	any code 0 to 70	
Ever injected illicit drugs	1	Yes - during pregnancy
Typical weekly alcohol consumption	1	At least one

Appendix 3: Subsequent pregnancies and births

Data source: SMR01/SMR02

	Description
International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD10) codes	
O60-O75	Complications of labour and delivery
O60	*Preterm labour and delivery*
O80-O84	Delivery
O00-O08	Pregnancy with abortive outcome
O10-O16	Oedema, proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium
O20-O29	Other maternal disorders predominantly related to pregnancy
O30-O48	Maternal care related to the fetus and amniotic cavity and possible delivery problems
O85-O92	Complications predominantly related to the puerperium
O94-O99	Other obstetric conditions, not elsewhere classified
P072	Extreme immaturity
P590	Neonatal jaundice associated with preterm delivery
P95	Fetal death of unspecified cause
P964	Termination of pregnancy, affecting fetus and newborn
Z321	Pregnancy confirmed
Z33	Pregnancy state, incidental
Z34	Supervision of normal pregnancy
Z35	Supervision of high-risk pregnancy
Z36	Antenatal screening
Z37	Outcome of delivery
Z38	Liveborn infants according to place of birth
Z39	Postpartum care and examination
OPCS Classification of Interventions and Procedures codes	
R14	Surgical induction of labour

	Description
R15	Other induction of labour
R17	Elective caesarean delivery
R18	Other caesarean delivery
R19	Breech extraction delivery
R20	Other breech delivery
R21	Forceps cephalic delivery
R22	Vacuum delivery
R23	Cephalic vaginal delivery with abnormal presentation of head
R24	Normal delivery
R25	Other methods of delivery
R27	Other operations to facilitate delivery
Maternity tail codes	
delprean	Anaesthetic given during labour or delivery
delposn	Anaesthetic given post-labour or delivery
antedur	Antenatal days of stay
dobbaby	Birth date (baby)
birorder	Birth order
birweit	Birth weight
delchang	Delivery place change reason
delmeth	Delivery method
delplac	Delivery place (actual)
delinten	Delivery place (intended)
anasdate	First antenatal assessment date
anagest	Gestation period in weeks at first antenatal assessment
gestat	Length of gestation
birstat	Birth status

	Description
delonset	Labour / delivery onset method
matage	Mother's age at delivery
postdur	Postnatal stay
biresus	Resuscitation method
sexbaby	Sex of baby
delstat	Status of person conducting delivery
gestat <24	Gestational age at birth <24 weeks
gestat <37	Length of gestation
epitype	3: Birth event
	6: Other birth event
admimeth	82: Other: babies born in health care provider
	83: Other: babies born outside the health care provider, except when born at home as intended
startage	7001: <1 day
	7002: 1-6 days
neocare	0: Normal care
	1: Special care
	2: Level 2 intensive care
	3: Level 1 intensive care
birordr>1	Birth order
numbaby>1	Number of babies
birstat=2-4	Birth status
dismeth=5	Method of discharge
N01	Neonates – died <2 days old
N02	Neonates with multiple minor diagnoses
N03	Neonates with one minor diagnosis
N04	Neonates with multiple major diagnoses

	Description
N05	Neonates with one major diagnosis

Appendix 4: Hospital admissions for dental procedures[10]

Data source: SMR01

Field: Main Condition/Other conditions	
ICD-10 code	**Description**
K021	Implantation of tooth
K025	Surgical removal of tooth
K028	Simple extraction of tooth
K029	Preprosthetic oral surgery
K040	Surgery on apex of tooth
K045	Restoration of tooth
K046	Orthodontic operations
K047	Other orthodontic operations
Field: Main operation A /B	
OPCS code	**Description**
F08	Implantation of tooth
F09	Surgical removal of tooth
F10	Simple extraction of tooth
F11	Preprosthetic oral surgery
F12	Surgery on apex of tooth
F13	Restoration of tooth
F14	Orthodontic operations
F15	Other orthodontic operations
F16	Other operations on tooth
F17	Operations on teeth using dental crown or bridge
F63	Insertion of dental prosthesis

[10] https://www.gov.uk/government/publications/hospital-tooth-extractions-of-0-to-19-year-olds

Appendix 5: Hospital admissions for serious injuries[11]

Data source: SMR01

ICD-10 code	Description
S00-S09	Injuries to the head
S10-S19	Injuries to the neck
S20-S29	Injuries to the thorax
S30-S39	Injuries to the abdomen lower back, lumbar spine and pelvis
S40-S49	Injuries to the shoulder and upper arm
S50-S59	Injuries to the elbow and forearm
S60-S69	Injuries to the wrist and hand
S70-S79	Injuries to the hip and thigh
S80-S89	Injuries to the knee and lower leg
S90-S99	Injuries to the ankle and foot
T00 - T07	Injuries involving multiple body regions
T08-T14	Injuries to unspecified part of trunk, limb or body region
T15-T19	Effects of foreign body entering through natural orifice
T20–T32	Burns and corrosions
T33–T35	Frostbite
T36–T50	Poisoning by drugs, medicaments and biological substances
T51-T65	Toxic effects of substances chiefly nonmedicinal as to source
T66-T78	Other and unspecified effects of external causes
T73	*effects of deprivaton*
T74	*maltreatment syndromes*

[11] Herbert A, Gilbert R, González-Izquierdo A, et al. Violence, self-harm and drug or alcohol misuse in adolescents admitted to hospitals in England for injury: a retrospective cohort study. BMJ Open 2015;5:e006079. doi: 10.1136/bmjopen-2014-006079; Risk of emergency hospital admission in children associated with mental disorders and alcohol misuse in the household: an electronic birth cohort study - The Lancet Public Health

ICD-10 code	Description
T79	Certain early complications of trauma, not elsewhere classified
T80-T88	Complications of surgical and medical care, not elsewhere classified
V01–V99	Transport accidents
W00–X59	Falls, exposure to inanimate objects,
X40-X49	*Accidental poisoning by and exposure to noxious substances*
X60–X84	Intentional self-harm
X85–Y09	Assault
X85 - Y03	*Other types of assault*
Y08-Y09	*Other types of assault*
Y04-Y05	*Assault by bodily force and sexual assault*
Y06-Y07	*Perpetrator of neglect, and other maltreatment syndromes*
Y10–Y36	Event of undetermined event
Y20-Y34	
Y85-Y86	Sequelae of transport and other accidents
Z04.5	Examination and observation following other inflicted injury
Z04.8	Examination and observation for other reasons

Appendix 6: Accident and Emergency (A&E) attendance with injury /ingestion

Data source: Accident and Emergency Dataset

Code	Description
01	Laceration
021	Contusion
022	Abrasion
03	Soft tissue inflammation
041	Concussion
042	Other head injury
051	Dislocation
052	Open fracture
053	Closed fracture
054	Joint injury
055	Amputation
06	Sprain/ligament injury
07	Muscle/tendon injury
08	Nerve injury
09	Vascular injury
101-104	Burns and scalds (electric/thermal/chemical/radiation)
11	Electric shock
12	Foreign body
13	Bites/stings
141-144	Poisoning (inc overdose) (prescriptive/proprietary/controlled drugs, other, inc alcohol)
15	Near drowning
16	Visceral injury

Appendix 7: Safe home environment: Emergency admissions to hospital as a result of an unintentional injury

Admission type code = 33 Patient injury (home incident) (up to 2013)

ICD10 4 digit codes (2014 onwards). From the 2014 publication onwards we have used the fourth digit of the ICD10 codes W000-X599 to denote 'place of occurrence' using the following categories:

ICD10 code	Description
V01-X59, Y85-Y86	All Unintentional Injuries
X40-X49	Poisonings
W00-W19	Falls
W20-W22, W50-W52	Struck by, against
W23	Crushing
X10-X19	Scalds
X58-X59	Accidental exposure
	Other

Emergency hospital admission[12]

Data source: SMR01

The SMR01 codes used for identifying emergency hospital admissions due to an unintentional injury and assault are outlined below

Admissions unintentional injury	SMR01 admission code and ICD10 code
All Unintentional Injuries	SMR01 emergency admission type code 33-35 and ICD10 V01-X59, Y85-Y86
Poisonings	Admission type code 33 and ICD10 codes X40-X49
Falls	Admission type code 33 and ICD10 codes W00-W19
Struck by, against	Admission type code 33 and ICD10 codes W20-W22, W50-W52
Crushing	Admission type code 33 and ICD10 code W23
Scalds	Admission type code 33 and ICD10 codes X10-X19
Accidental exposure	Admission type code 33 and ICD10 codes X58-X59

[12] https://www.isdscotland.org/Health-Topics/Emergency-Care/Publications/2017-03-07/2017-03-07-UI-Report.pdf

Admissions unintentional injury	SMR01 admission code and ICD10 code
Other	Admission type code 33 and other ICD10 codes in the range V01-X59 Y85-Y86 that are not included in any of the other categories in the table

Admissions assault	SMR01 admission code and ICD10 code
All assaults	SMR01 emergency admission type code 33 and ICD10 X85-Y09
Assault by sharp object	SMR01 emergency admission type code 33 and ICD10 X99
Other	Admission type code 33 and other ICD10 codes in the range X85-Y09 that are not included in any of the other categories in the table

Appendix 8: The RECORD statement – checklist of items, reported in observational studies using routinely collected health data.

	Item No.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Title and abstract					
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 1	RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included. RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract. RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.	Not possible in title Page 1 Not possible in title
Introduction					
Background rationale	2	Explain the scientific background and rationale for the investigation being reported	Section 1: pages 15-18		
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 18		
Methods					
Study Design	4	Present key elements of study design early in the paper	Page 18		

Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 19		
Participants	6	*(a) Cohort study* - Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study* - Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study* - Give the eligibility criteria, and the sources and methods of selection of participants *(b) Cohort study* - For matched studies, give matching criteria and number of exposed and unexposed *Case-control study* - For matched studies, give matching criteria and the number of controls per case		RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided. RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided. RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage.	Details are provided in the protocol paper and methods report
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	Pages 20-26	RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided.	Appendix 2-7
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement).	Pages 20-26		

		Describe comparability of assessment methods if there is more than one group			
Bias	9	Describe any efforts to address potential sources of bias	Page 26		
Study size	10	Explain how the study size was arrived at	Details are provided in the protocol paper and methods report		
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	Page 38		
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) *Cohort study* - If applicable, explain how loss to follow-up was addressed *Case-control study* - If applicable, explain how matching of cases and controls was addressed *Cross-sectional study* - If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	Page 27-38		
Data access and cleaning methods		..		RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population.	Page 31/32

				RECORD 12.2: Authors should provide information on the data cleaning methods used in the study.	
Linkage		..		RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided.	Page 32
Results					
Participants	13	(a) Report the numbers of individuals at each stage of the study (*e.g.*, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed) (b) Give reasons for non-participation at each stage. (c) Consider use of a flow diagram		RECORD 13.1: Describe in detail the selection of the persons included in the study (*i.e.,* study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram.	Page 31-33
Descriptive data	14	(a) Give characteristics of study participants (*e.g.*, demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) *Cohort study* - summarise follow-up time (*e.g.*, average and total amount)	Pages 38-43		

Outcome data	15	*Cohort study* - Report numbers of outcome events or summary measures over time *Case-control study* - Report numbers in each exposure category, or summary measures of exposure *Cross-sectional study* - Report numbers of outcome events or summary measures	Sections 5 and 6		
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Sections 5 and 6		
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Sections 5 and 6		
Discussion					
Key results	18	Summarise key results with reference to study objectives	Pages 126-131		
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision.		RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of	Pages 140-142

		Discuss both direction and magnitude of any potential bias		misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported.	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Pages 142-143		
Generalisability	21	Discuss the generalisability (external validity) of the study results	Pages 140-141		
Other Information					
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 8		
Accessibility of protocol, raw data, and programming code		..		RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code.	Page 145

*Reference: Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, the RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLoS Medicine* 2015; in press.

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