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Evaluation of the Family Nurse Partnership in Scotland: A methods paper on process and success of linkages

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Evaluation of the Family Nurse Partnership in Scotland: A Methods paper on process and success of linkages

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Executive summary

This paper presents the methods of using routinely collected health, education and social care data to evaluate the Family Nurse Partnership (FNP) in Scotland using a natural experiment methodology (case-cohort design). FNP is a licensed US programme which 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. The evaluation was commissioned by the Scottish Government.

The evaluation is structured around a well-specified programme logic model and the availability of routine data mapping onto key short, medium and long-term outcomes. The overarching aim of the evaluation is to compare first time young mothers enrolled and receiving the FNP programme (FNP Clients) to a comparable group of Controls over a range of outcomes covering maternal health, child health and development, and parental life course. Delivering the evaluation depends upon approval and successful linkage to routinely collected electronic health, education and social care records to evaluate a complex intervention already available in the population.

We have so far established the required model of data linkage to routine Scottish data in order to evaluate FNP using a natural experiment. Approvals were obtained to access data on over 3,000 FNP Clients and these cases were mapped to routine health data with little loss of records. The quality of the data used to identify the potential control sample was found to be high and had limited missingness. Over 5,000 Controls were successfully identified using routine health data. Both FNP Clients and Controls were linked to health data to characterise these young mothers.

The assessment of effectiveness in the evaluation is necessarily limited to outcomes available from routinely collected data. Study outcomes have been selected by matching routinely collected administrative data to the three main aims of the Scottish FNP logic model, which is based on the underlying programme theory. These aims are 1) to improve pregnancy outcomes, 2) to improve child health and development, and 3) to improve parents' economic self-sufficiency. The logic model translates these aims into outcomes, which were then matched to the routine data. This resulted in matches for about 50% of the outcomes detailed within the model. Therefore, the included outcomes have been selected on the basis that they are outcomes FNP aims to influence and for which there is routine data, rather than a set of specific outcomes where research indicates the most significant contribution.

This report therefore, describes the principal study objectives, the broad evaluation design including the detailed data flows, the required governance approvals and the identification of both cases (FNP Clients) and the control

group of young mothers. It describes the identification of study outcomes against available data sources and how they will be regarded in analysis. The proposed analysis is described in the main body of the report and the detailed statistical analysis plan is provided in an appendix. Progress in establishing the study database and descriptive summary statistics for the study population are included in this report. Full results will be reported in mid-2020.

Abbreviations

Acronym	Definition
A&E	Accident and Emergency
BMI	Body Mass Index
CHI	Community Health Index
CHSP-PS	Child Health Systems Programme - Pre-School
CHSP-S	Child Health Systems Programme - School
CI	Confidence Interval
CU	Cardiff University
DOB	Date of birth
DPA	Data Processing Agreement
DSA	Data Sharing Agreement
EAS	Education Analytical Services
eDRIS	electronic Data Research and Innovation Service
FNP	Family Nurse Partnership
FNP NU	FNP National Unit
FNP SIS	FNP Scottish Information System
FN	Family Nurse
HBs	Health Boards
ICD-10	International Classification of Disease version 10
LMP	Last menstrual period
MOU	Memorandum of Understanding

Acronym	Definition
MPID	Master Person ID
MRC	Medical Research Council
NES	NHS Education for Scotland
NRS	National Records of Scotland
NSS	National Services Scotland
OR	Odds Ratio
PBPP	Public Benefit and Privacy Panel
PIA	Privacy Impact Assessment
PSM	Propensity score matching
RCT	Randomised Controlled Trial
REML	Restricted Maximum Likelihood
SAP	Statistical Analysis Plan
SD	Standard Deviation
SG	Scottish Government
SILC	Scottish Informatics Linkage Collaboration
SIMD	Scottish Index of Multiple Deprivation
SMR	Scottish Morbidity Record
UPID	Unique Person ID

Key Definitions

- Case / FNP Client – young mothers in Scotland expecting their first child who were offered and received FNP.
- Control – young mothers in Scotland expecting their first child who were not offered FNP but would have been eligible if available.
- Data linkage – Data brought together from two different records considered to belong to the same person.

1. Introduction

1.1. The Family Nurse Partnership

Individual, social and economic circumstances faced by many young mothers present a challenge to a successful start in life for children and may interrupt the mother's longer term economic stability (1). 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 (2–5).

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 an intensive preventative home visiting intervention delivered by specially recruited and trained nurses (6), and was formally adapted for use under license in the UK. FNP traditionally 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 Clients are identified at booking via local maternity systems and contact information is passed on to FNP teams who make contact to offer participation in the programme and enrol the individual as a Client if appropriate.

Introduced into Scotland in 2010 for initial feasibility and acceptability testing in NHS Lothian, the service was extended to a further nine Health Boards (HBs). Scotland also opened eligibility to 20 to 24-year-old first time mothers and personalised the programme to the strengths and risks of each Client. Establishing the evidence base for what works, for whom and in what circumstances, is key to policy decision making. The clinical need and public borne intervention cost requires a robust evaluation of the programme's impact. An independent academic collaboration undertook an 'Evaluability Assessment' to consider options for evaluating impact of the programme in Scotland, the feasibility of these options and cost (7). It recommended data linkage as a preferred method for evaluating impact using a natural

experiment approach, on the basis of being far less expensive than a randomised controlled trial (RCT), and allowing data on all participants from the initiation of FNP in Scotland to be used to the point at which complete coverage was achieved. The well-specified programme logic model (Appendix 1) and the availability of routine data mapping onto key outcomes complements this recommendation.

1.2. Research aim

The aim of this study is to examine the association between the provision of FNP when added to existing services 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.

1.2.1. Objectives

The original objectives of the study were:

1. To obtain approval and link Client and Control identifiers to health, education, and social care data available in public sector records;

2. To identify families in receipt of FNP support at all relevant Scottish sites (FNP Clients) and a control sample of families who would meet criteria for FNP but did not receive support (Controls) from routine data;

3. To 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;

4. To examine the association between provision of FNP on a range of pre-specified outcomes and for key sample sub-groups;

5. To explore variation in effectiveness by geographical area and over time;

6. To explore variation in effectiveness by level of exposure to the intervention (such as the number of FNP visits).

1.2.2. Scope of this methodological paper

This paper describes the methods to addresss all six study objectives. It also describes the narrative and descriptive results of the first two objectives.

2. Methods

2.1. Study design

Following the Medical Research Council's (MRC) guidance on natural experiments, the FNP Programme in Scotland will be evaluated using a case-cohort design (8). We will generate a linked anonymised research database to compare routinely available health, education, and social care data between FNP Clients and Controls.

2.1.1. Natural experiments

Natural experiments encompass a range of observational study designs used to evaluate the impact of population health and policy interventions, usually when an RCT is not possible (8,9).

The key feature of natural experiments is that researchers do not have the ability to assign participants to 'treatment' and 'control' groups. Rather, divergences in law, policy or practice, across time and space, offer the opportunities for evaluation. These designs involve characterising periods of time or populations which have and have not been exposed to an intervention or policy. The validity of natural experiments depends on the ability that an observational design can create comparable 'treatment' and 'control' groups. A challenge with non-randomised exposures is that individuals/groups are often selected on the basis of need or risk factors associated with the outcome. As with other observational or quasi-experimental designs, natural experiments will never unequivocally determine causation because the researcher cannot randomly allocate populations exposed. However, these designs provide a useful inferential tool to evaluate interventions and policies which are not or cannot be randomised, for example existing services.

2.1.1. Data linkage in Scotland

Electronic Data Research and Innovation Service (eDRIS) provides a single point of contact to assist researchers in study design, approvals and data access for projects using routinely collected data in Scotland. The role of eDRIS is to advise on the application submitted to the Public Benefit and Privacy Panel (PBPP), liaise with the trusted third party indexing team and the various data controllers on behalf of the study. eDRIS also oversee all data transfer and linkage to create the study cohort within the the safe haven.

National Services Scotland (NSS) Safe Haven is a secure environment in which data are linked and stored. Access is provided either remotely or via a secure access point. Both access methods allow trusted and authorised researchers to analyse anonymised individual level data while maintaining confidentiality. Remote access to the safe haven is via Citrix using an accredited organisation's secure desktop / laptop.

2.2. Setting

FNP was implemented in January 2010 in one Health Board (HB) (NHS Lothian) to test the feasibility and acceptability of the programme within a local context. By the end of 2015, a total of 20 FNP teams/cohorts existed within 10 of the 14 NHS HBs in Scotland, delivering FNP at a local level. The participating HBs are shown in Table 1**.**

2.3. Study population

The study population will be all women who were eligible for the FNP Programme from 1st January 2009 to 31st March 2016 and their first-born child(ren). Cases will be defined as FNP Clients; all women (and first-borns) enrolled into FNP in the ten participating Scottish HBs since its initiation from 1st January 2010 to 31st March 2016. The Control population will be women eligible for enrolment in the FNP programme during a period when FNP recruitment was not offered in the same FNP catchment area:

i. in the 12 months prior to initiation of FNP recruitment [Pre-FNP] (starting 1st January 2009)
ii. in the 12 months post FNP recruitment [Post-FNP] (ending 31st March 2016)
iii. between periods of FNP recruitment (i.e. when recruitment was temporarily suspended due to caseload capacity being reached) [Interval].

Figure 1 shows the Cases and all potential Controls. Detail on the process of identification of Cases and Controls follows below.

Table 1: Participating Scottish NHS Health Boards with enrollment dates

Health Board	Geographical area	Team/Cohort	Date started enrolling	Date finished enrolling	Interval dates[1]
Ayrshire and Arran	East, North and South Ayrshire	A / 1	04/02/2013	03/02/2014	04/02/2014 to 09/03/2014
		Part-time nurse recruiting 17 Clients	10/03/2014	04/09/2014	05/09/2014 to 15/10/2015
		A / 2	16/10/2015	Ongoing recruitment[2]	N/A
Borders	Whole board	A / 1	01/08/2015	Ongoing recruitment[2]	N/A
Fife	Whole board, with specific percentages taken from each area	A / 1	01/08/2012	31/07/2013	01/08/2013 to 16/03/2014
	Whole board	B / 1	17/03/2014	31/03/2015	N/A (new notifications picked up by Team A)
	Whole board	A / 2	01/04/2015 (notifications picked up after Team B stopped recruiting)	May 2016	May 2016 to present and 2-3 week gap in March 2016
Forth Valley	Stirling, Clackmannanshire and Falkirk	A / 1	28/04/2014	21/05/2015	N/A
Grampian	Aberdeen City, Aberdeenshire and Moray	A / 1	18/05/2015	Ongoing recruitment[2]	N/A

[1] Interval dates are periods in between FNP recruitment when recruitment is temporarily suspended due to caseload capacity being reached

[2] at 31/03/2016

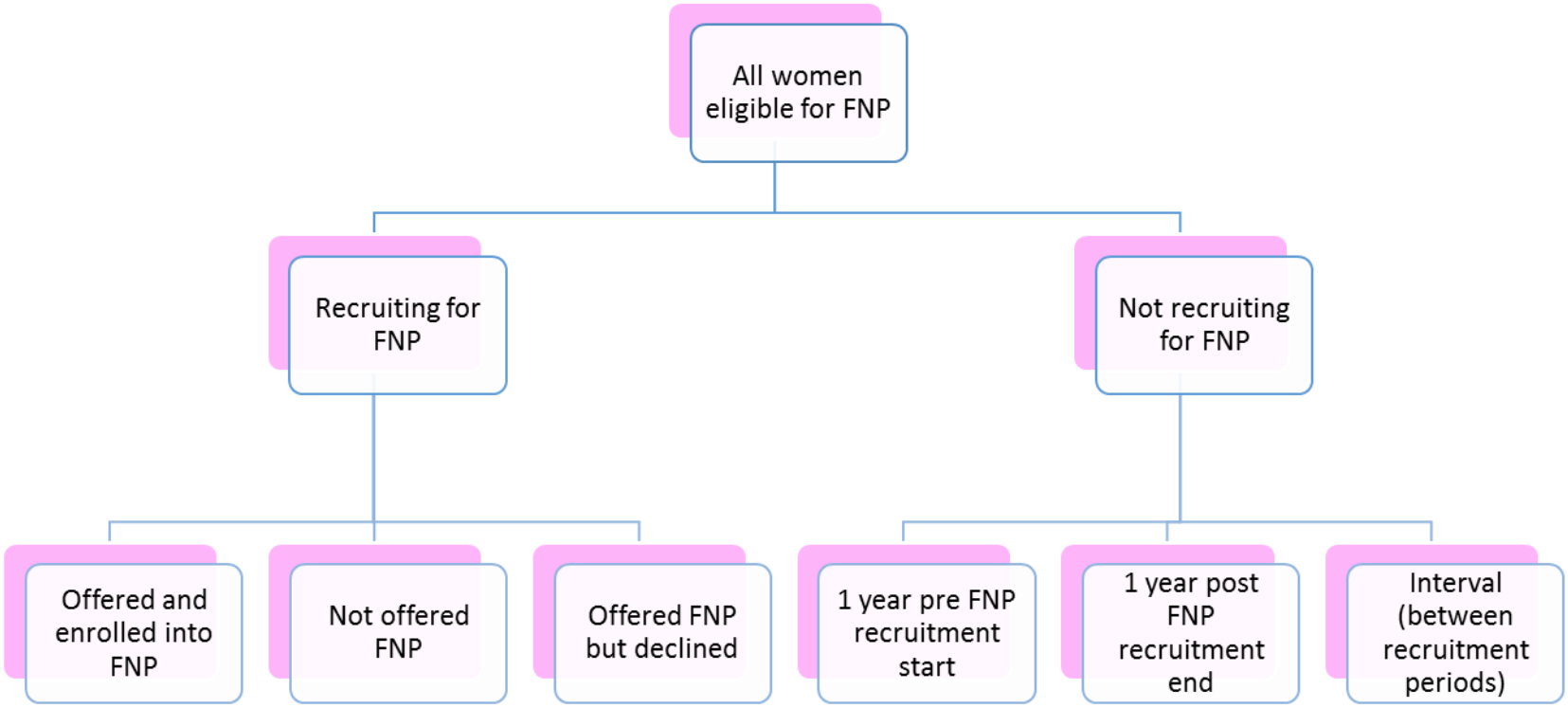
Health Board	Geographical area	Team/Cohort	Date started enrolling	Date finished enrolling	Interval dates[1]
Greater Glasgow and Clyde	Glasgow City, West Dunbartonshire, East Dunbartonshire	A /1	22/10/2012	01/11/2013	02/11/2013 to 18/10/2015
		A / 2	19/10/2015	Ongoing recruitment[2]	N/A
	East Renfrewshire, Inverclyde, Renfrewshire	B / 1	01/08/2014	28/01/2016	29/01/2016 to present
Highland	South and mid areas of Highland Council (Inner Moray Firth)	A/ 1	04/02/2013	26/05/2014	27/05/2014 to 31/12/2015
		A / 2	01/01/2016	Ongoing recruitment[2]	N/A
Lanarkshire	South Lanarkshire	A / 1	08/07/2013	15/10/2014	N/A
	North Lanarkshire	B / 1	08/07/2013	15/10/2014	N/A
Lothian	Edinburgh city	Pilot cohort	25/01/2010	31/10/2010	01/11/2010 to 31/08/2012
	Edinburgh city	A / 1 (not including pilot cohort)	01/09/2012[3] 25/09/2012[4]	24/09/2013	None (Overlap with Team B)
	West Lothian	A / 1 (not including pilot cohort)	01/03/2013	24/09/2013	None (Overlap with Team B)
	Edinburgh and West Lothian	B / 1	01/08/2013	31/07/2014	None (new notifications picked up by Team C)
	Mid Lothian	B / 1	01/04/2014	31/07/2014	None (new notifications picked up by Team C)

[3] Clients aged 16 and under only

[4] For all eligible Clients

Health Board	Geographical area	Team/Cohort	Date started enrolling	Date finished enrolling	Interval dates[1]
	Edinburgh, West and Midlothian	C / 1	01/08/2014	31/07/2015	None (overlap with other recruiting teams)
	Edinburgh, West and Midlothian	A/B/C Combined teams with rolling recruitment	01/04/2015	Ongoing recruitment[2]	N/A
Tayside	Whole board	A / 1	01/07/2011	30/09/2011	01/10/2011 to 18/10/2012
		A / 2	19/10/2012	20/11/2013	21/11/2013 to 31/12/2013
		A / 3	01/01/2014	Ongoing recruitment[2]	N/A
		A / 4	01/01/2016	Ongoing recruitment[2]	N/A

Figure 1: Identification of the study cohort



FNP Clients	✓					
Controls		x	x	✓	✓	✓

2.3.1. Identifying Cases

Cases will be defined as FNP Clients (and first-borns) enrolled into FNP in the ten participating Scottish HBs since its initiation from 1st January 2010 to 31st March 2016. This end date will give birth outcomes on women (and their first-borns) around the end of October 2016 (depending on gestation at recruitment). FNP Clients will be identified from the FNP Scottish Information System (FNP SIS), a national database based on FNP data forms and which is accessible to family nurse (FN) teams through a secure web-based portal. The FNP National Unit (FNP NU) within NHS Education for Scotland (NES) will provide Community Health Index (CHI) numbers and other identifiers (name, date of birth (DOB), postcode) for all FNP Clients to the electronic Data Research and Innovation Service (eDRIS) team, who will link to the SMR02 Maternity Inpatient and Day Case dataset and a flag will be added to identify them as FNP Clients. Table 2 shows the FNP eligibility criteria applicable to the period under observation.

Table 2: FNP eligibility criteria

Inclusion criteria
Women must be: • living in an FNP-recruiting NHS Health Board area • a first-time mother-to-be (women are eligible if a previous pregnancy resulted in a miscarriage, stillbirth or termination) • aged 19 years or younger at time of last menstrual period (LMP) • enrolled into FNP no later than 28 weeks.
Exclusion criteria
Women with an intention: • to relinquish the baby • to move outside FNP area

2.3.2. Identifying Controls

(a) Applying eligibility criteria

The identification of the remaining eligible population (potential Controls) using SMR02 will also be carried out by the eDRIS team. The SMR02 contains fields that map well to the FNP eligibility criteria (Table 3). The only field we have to use as a proxy to these eligibility criteria is gestation at time of antenatal booking instead of at time of enrolment into FNP. The process of identifying Controls will also exclude any pregnant women not registered on the SMR02 (i.e. women delivering at home or in non-NHS hospitals, around 1% of all births)(10). Ineligibility criteria (intention to relinquish the baby and / or moving outside FNP area) are applied to women during the FNP recruitment process but cannot be applied in the selection of Controls as they are not assessed in the SMR02 (or any other dataset).

Table 3: Eligibility criteria applied to the SMR02 dataset fields to identify eligible Control women

Inclusion criteria	**Criteria applied to SMR02 dataset**
Living in an FNP-recruiting NHS Health Board area	Postcode of mother at antenatal booking will be mapped to each FNP recruiting area[1]
A first-time mother-to-be (women are eligible if a previous pregnancy resulted in a miscarriage, stillbirth or termination)	A flag will be derived by eDRIS to confirm that the mother is a first time mother, examining any birth previous to the antenatal booking date.
Aged 19 years or younger at time of last menstrual period (LMP)	Estimated age (years) at LMP: Derived from maternal date of birth and LMP date
Enrolled into FNP no later than 28 weeks	Estimated gestation (weeks) at booking: Derived from date of booking and LMP date
Exclusion criteria	
Mother-to-be will relinquish baby at birth	Not measurable at recruitment – minimal risk to numbers
Moving outside of the FNP catchment area before programme end	Not measurable at recruitment – minimal risk

[1] Either Health Board level or smaller geographical area such as Community Health Partnership level or where a recruitment area was defined by travel time

(b) Applying recruitment area criteria

Controls will be women who were eligible for enrolment in the FNP programme (using their antenatal booking date as a proxy) during a period *when FNP recruitment was not offered* in the same FNP catchment area. To further identify the potential Controls, a FNP recruitment table was provided to eDRIS (Table 1). This included the start and end dates of recruitment including any intervals when cohorts ceased recruitment, the geographical coverage (either entire Health Boards/ Community Health Partnerships level or exact postcodes for areas defined by travel time) for each FNP team. This allowed eDRIS to identify and flag potential Controls from the same FNP areas of recruitment, and categorise them as such. It also allowed them to categorise Controls further into those with an antenatal booking date:

i. in the 12 months prior to initiation of FNP recruitment [Pre-FNP];

ii. in the 12 months post FNP recruitment [Post-FNP];

iii. between periods of FNP recruitment (i.e. when recruitment is temporarily suspended due to caseload capacity being reached) [Interval].

A second potential Control cohort exists consisting of women eligible for enrolment into the programme during a period of active FNP recruitment and who:

iv. were approached for FNP but not enrolled;

v. were not approached (e.g. insufficient capacity in team to offer to all eligible women; near end of recruitment period and caseloads nearly full).

Following advice from the Public Benefit and Privacy Panel (PBPP), it was not possible to access these potential Controls. However, it is important to note that these groups may have different demographic, social or personal characteristics from those that enrolled in the programme and may differ non-randomly from the Controls in (i) to (iii) for some variables. It would be beneficial to the evaluation to understand the characteristics of Controls (iv) and (v) above and so aggregate statistics will be provided by eDRIS.

2.3.3. Identifying children

A mother-child link is available within the SMR02 enabling a flag for any children born after the enrolment date (FNP Clients)/antenatal booking date (Controls) to be derived, typically between 15 to 35 weeks. Once the FNP

Clients and Controls and their first-born children are identified, the eDRIS team will send the Community Health Index (CHI) number and a “FNP Client / Control” and a “mother/child” flag to National Records of Scotland (NRS) Indexing team.

2.4. Data Access Approvals

2.4.1. Public Benefit and Privacy Panel (PBPP)

The PBPP is a governance structure of NHS Scotland with a remit to carry out information governance scrutiny of requests for linkage of and access to individual level health data on behalf of NHS Scotland. The full scope of the panel can be found here http://www.informationgovernance.scot.nhs.uk/pbpphsc/home/about-the-panel/.

The PBPP operates on a two-tier structure utilising the proportionate governance method:

- Tier 1: Assesses the more technical, security and legalistic aspects of requests for data
- Tier 2: Considers the wider privacy issues relating to the use of health and social care data

An application was made to PBPP to access individual level data from national datasets held by NHS NSS, FNP data from individual NHS Scotland health boards and linking these to education and social care datasets provided by the Scottish Government Education Analytical Services (EAS). Approval was sought to access individual level data from health boards via a Data Sharing Agreement (DSA) and from EAS via a data access application.

2.4.2. Education Analytical Services (EAS)

The EAS Division plays a key and leading role in the collection, analysis and publication of analytical evidence across the School Education and Young People sector. The EAS Data Access Panel is formed by the Head of the EAS Division - the ‘Information Asset Owner’ of data held by the EAS Division, the Divisional Data Access Officer, and other senior officials holding relevant datasets. The purpose of the panel is to assess the objectives and data protection implications of data request applications as well as the security arrangements for the data requested. The application is assessed using the privacy risk matrix template to determine if the application is a simple or complex request.

An application was made to access individual level data held by EAS such as school and social care datasets and to link to the health datasets made available via eDRIS.

2.4.3. Requirements

In addition to the applications submitted to PBPP and EAS, the following governance and contractual aspects were considered and actioned as appropriate. These requirements were either outlined as required by the data access panels or were subsequently conditions of approval once considered by the panel.

Ethical approval: Advice about ethical requirements was sought from South East Scotland Research Ethics Service.Their recommendation was that under the terms of the governance arrangements for research ethics committees ethical approval was not required. This is because the project is an evaluation limited to using data obtained as part of usual care.

A *Privacy Impact Assessment* (PIA) was required by PBPP to identify and assess risk where data are being processed

A new *information leaflet* to be handed to all new FNP Clients about how their data will be stored and used was requested by PBPP and developed and issued by Scottish Government (SG) / FNP (2).

PBPP also requested assurances around the methodologies in the form of independent peer review. The study has an independent study steering committee (SSC) and a letter from the chair of this committee was submitted to respond to this request. The SSC provides on-going scientific scrutiny (i.e. consistent with this request).

All researchers are required to be *approved researchers*, defined by eDRIS as having completed appropriate information governance training (e.g. ‘MRC safe researcher’); have appropriate approvals in place; have read the NHS Confidentiality Code of Practice; affiliated with an Approved Organisation; and have read and signed the eDRIS User Agreement.

Secure all required *data sharing and processing agreements* between all data controllers and data processors (See Table 4).

Table 4: Required agreements for this data linkage study

Data	Data Controller	Share with	Processed by	Agreements required
FNP data	Health Board (x10) (Table 1)	Scottish Government		10 x Data Sharing Agreements (DSA)
			eDRIS | NHS Services Scotland (NSS)	10 x Memorandum of Understanding (MOU)
			National Records of Scotland (NRS)	10 x Data Processing Agreements (DPA)
NHS Scotland Health data	NHS Services Scotland (NSS)	Scottish Government	eDRIS | NHS Services Scotland (NSS)	Data Sharing Agreement (DSA)
Education Analytical Service	Scottish Government	Scottish Government	National Records of Scotland (NRS)	Data Processing Agreement (DPA)
Study Data	Scottish Government	Scottish Government	Cardiff University (CU)	Data Processing Agreement (DPA)

2.5. Datasets

Table 5 lists the datasets requested for use for this study alongside the Data Controller and the relevant panel to approve data access.

Table 5: Requested datasets

Dataset	Data Controller	PBPP	EAS
Scottish Morbidity Record (SMR) 00 – Outpatient Attendance	NHS NSS	✓	
SMR01 – General/Acute Inpatient and Day Case	NHS NSS	✓	
SMR02 – Maternity Inpatient and Day Case	NHS NSS	✓	
SMR04 - Mental Health Inpatient and Day Case	NHS NSS	✓	
Community prescribing and dispensing	NHS NSS	✓	
National Record for Scotland (NRS): deaths	NHS NSS	✓	
Community Health Index (CHI): demographics	NHS NSS	✓	
Unscheduled Care: Accident and Emergency (A&E)	NHS NSS	✓	
Child Health Systems Programme Pre-School (CHSP –PS): Health Visitor first visit; 6-8 week review; 27-30 month review; unscheduled review	NHS NSS	✓	
Child Health Systems Programme School (CHSP-S): Primary 1 - screening and assessment	NHS NSS	✓	
FNP Scottish Information System	Local Health Boards via FNP SIS	✓	
School/Pupil Census	SG		✓
Attendance, Absence and Exclusions	SG		✓
School Leavers (Summer and Christmas)	SG		✓
Skills Development Scotland: destinations	SG		✓
Children and Young People: Looked after children	SG		✓
Children and Young People: Child protection register	SG		✓
Scottish Credit and Qualifications Framework	SG		✓
Achievement of Curriculum for Excellence levels collections	SG		✓

SG - Scottish Government; NHS NSS - NHS National Services Scotland
PBPP – Public Benefit and Privacy Panel; EAS - Education Analytical Services

2.6. Data flow

2.6.1. The Population Spine

The Population Spine contains the personal identifiers of all individuals in Scotland who have been in contact with NHS Scotland. It is an existing set of records that covers most of the population, and has been linked to a high standard. The pupil census (data collected from publicly funded schools and their pupils on a set date each year) is matched to the spine to create an anonymised “read-through” index key which NRS and EAS hold at a person-level. When the cohort is identified on the spine the read-through keys will be sent from the indexing team to EAS to identify the cohort.

The pupil census is matched to the spine using only DOB, sex and postcode. This means that where there is more than one spine record with the same credentials the precision of these matches (in around 2-3% of cases, and mainly resulting from multiple births) will be around 50%.

The data linkage process for this project is shown in Figure 2, based on the Scottish Informatics Linkage Collaboration (SILC) procedure.

1 CHI numbers (plus other identifiers) for all FNP Clients are provided by FNP to the eDRIS team, who link to the SMR02 dataset and add a flag to identify them as FNP Clients. The identification of the remaining eligible population (potential controls) using SMR02 is also carried out by the eDRIS team.

2 The controls are further restricted by FNP team recruitment areas and flagged accordingly (Pre-FNP, Post-FNP, Interval) and are given an anonymous ID and made available via the safe haven for the research team.

3 Once the final set of FNP Clients and controls are identified, eDRIS will identify the first-borns for each mother and send CHI number and a “case/control” and a “mother/child” flag to National Records of Scotland (NRS) Indexing team.

4A NRS have a population spine which contains CHI number and where relevant, an Education identifer for each individual in Scotland. Using CHI number, NRS will identify all individuals on their spine. NRS will then generate a different unique index along with CHI number and the mother/child flag to each of the health data providers.

4B Similarly, NRS will return the education identifier from their spine and a different unique index for each education / social work dataset will be sent to EAS. NRS will also construct a master control file which links together the different index numbers a person has in each dataset. This control file is sent to the safe haven.

5 Each data provider will extract the required data from their data set (using CHI / education identifier). The index provided by NRS will be attached to the extract, CHI / education identifiers will be dropped and the files sent to the safe haven.

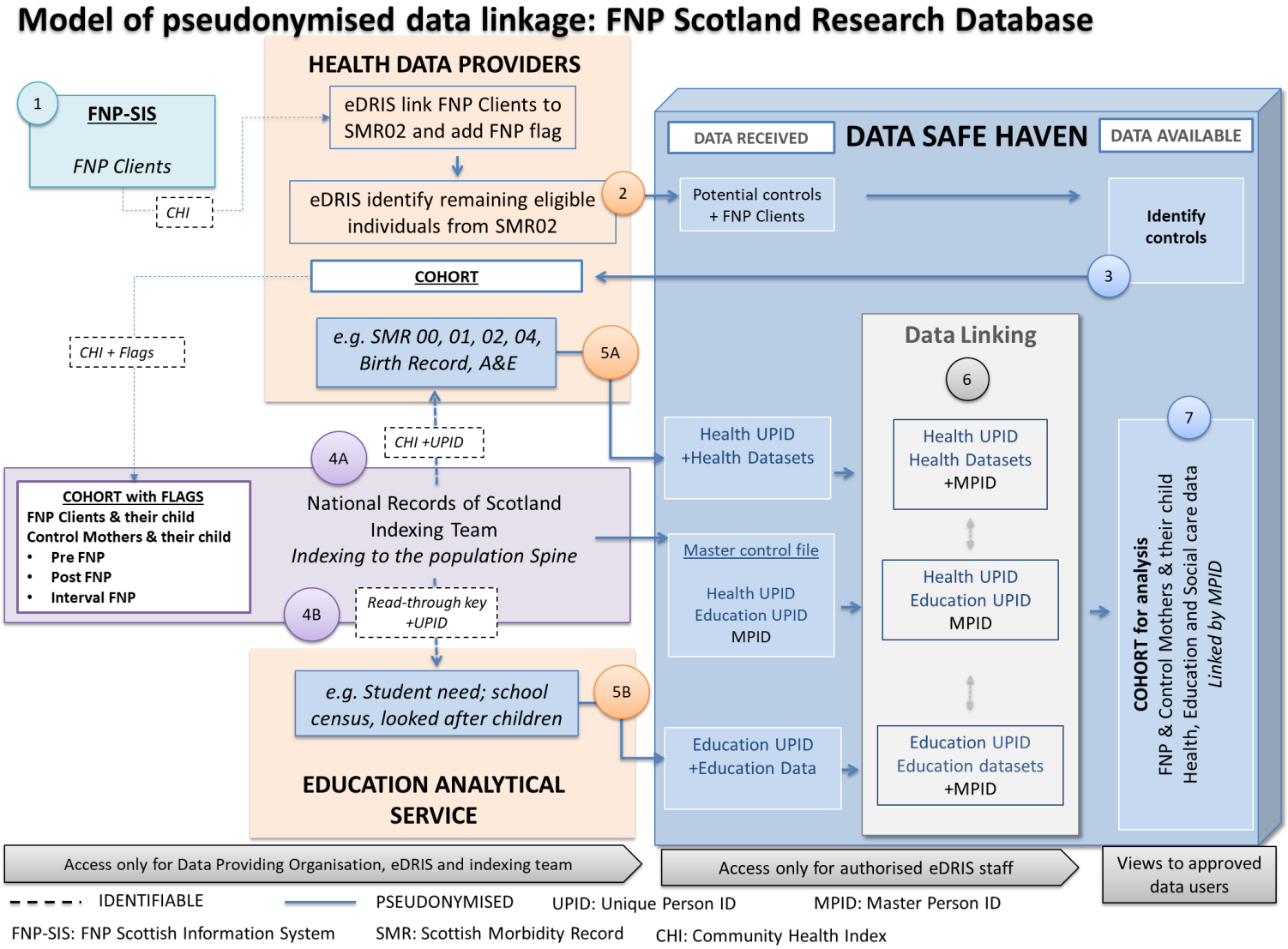
6 An automated script called the linkage agent is then run on all files in the safe haven to replace the different index numbers in each dataset with a master index number that is common across all datasets.

7 A project specific account is created in the safe haven and approved data users at Cardiff University can access via a secure remote gateway via their own computer (11). The master index number allows the person analysing the data to see and link all the records belonging to an individual across all datasets without the need for access to personal identifiers. Data cannot be removed or transferred from the safe haven until it has been disclosure checked by eDRIS.

2.6.2. The pseudonymised dataset

The data used for analysis will not contain any identifiable fields (e.g. participant names and CHI numbers). This was agreed in the application to PBPP. Disclosive geographical areas such as postcodes at antenatal booking were only used by eDRIS for linking FNP Clients to SMR02 and to identify Controls. Health board, Community Health Partnership area, an anonymous FNP team ID, and Scottish Index of Multiple Deprivation (SIMD) quintile were the only geographical data required for analysis. All de-identification (such as changing date of birth to week and year of birth, postcode to deprivation quintile) and deriving variables from identifiable data (e.g. time to event instead of dates of events) will be carried out by eDRIS prior to the data being available to researchers (11).

Figure 2: Data flows



3. Outcome measures

3.1. Outcomes

The evaluation specification 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 (Appendix 1). A brief list of outcomes to be included in the evaluation is provided in Table 6 below and a full listing of all 54 outcomes is provided as an online supplement.

Outcomes are listed according to the logic model and the following information provided:

- the data source
- the variables to be used
- whether the outcome is specifically mentioned in the logic model
- the hypothesised direction of FNP programme effect
- the outcome to be analysed with the main method
- any pre-defined sensitivity analyses such as adjustment for FNP dosage or sub-group analyses to be performed.

Also included in this supplement are all data sources and outcomes considered but subsequently not used, and any identified gaps where it is indicated in the logic model but no data source is available.

3.1.1. Categorisation of outcomes

The ability to report on outcomes will depend on several factors: geographical and study cohort coverage, data quality (e.g. completeness), and possible bias in outcomes (such as FNP nurses carrying out child health assessments). As a result, the outcomes have been categorised into either short-term, medium-term, or descriptive.

Short term outcomes (n=20): These map well to the logic model, are known to have good data quality, and coverage across Scotland and our study cohort (thus maximising the number that can be formally analysed using statistical methods). These outcomes are likely to be associated with the pregnancy and birth period, and up to the child's 2nd birthday (e.g. child health outcomes). These outcomes will be formally analysed using statistical methods

Medium-term outcomes (n=14): These outcomes rely on data only measured in the period after the 2nd birthday (e.g. school based outcomes at age 4 years of age onwards) and the population included in the analysis would be restricted as a result. These outcomes will also be formally analysed using statistical methods. Medium term outcomes also include those where the

analysis would incorporate a time to event approach that would use our study cohort.

Descriptive outcomes (n=20): We will describe outcomes where the direction of the FNP effect is either uncertain, where outcomes are rare, or where the data are classed as experimental statistics (i.e. a type of official statistic that is undergoing development e.g. child attainment).

Table 6: Maternal and child outcomes and follow-up time points

		FOLLOW-UP TIME POINTS							
	Outcome Type[1]	During pregnancy	At birth	Post-partum assessments					
				10 days	6-8 weeks	2 years	27-30 months	4-5 years	5-6 years
Maternal Outcomes									
Positive health behaviour									
Alcohol/substance misuse during pregnancy	ST	✓							
Improved parental life-course									
Childcare use	D						✓		
Return to education	ST					✓			
Highest educational attainment for all school leavers	D								✓
Subsequent birth (live/still)	ST					✓			
Inter-pregnancy/birth interval (2 outcomes)	MT								up to ✓
Child Outcomes									
Competent parenting in terms of child-health									
Breastfeeding (3 outcomes: initiation, at 6-8 weeks, duration)	ST		✓	✓	✓				
Birthweight[2]	D		✓						
Passive smoking	ST			✓	✓		✓		
Competent parenting: child protection									
Safe home environment	ST					✓			
Safe home environment	MT								✓
Improved birth outcomes									

[1] ST - Short term outcome; MT - Medium term outcome; D - Descriptive outcome;

[2] Birthweight appropriate for gestational age and adjusted for gestational age, maternal height, maternal weight at booking, parity and ethnic group - Gestation Related Optimal Weight GROW [24]

	Outcome Type[1]	FOLLOW-UP TIME POINTS							
		During pregnancy	At birth	Post-partum assessments					
				10 days	6-8 weeks	2 years	27-30 months	4-5 years	5-6 years
Pre-term delivery (<37 vs 37+ weeks)	ST		✓						
Pre-term delivery (<28, 28 to <32, 32 to <37,37+ weeks)	D		✓						
Improved child health									
Physical development: Healthy Body Mass Index (BMI)	ST						✓		
Physical development: Healthy BMI	MT							✓	
Gross motor skills concern	ST				✓		✓		
Fine motor skills concern	ST						✓		
Registered with dentist at 24 months	ST						✓		
Attended a dentist by 27-30 month visit	ST						✓		
Hospital admissions for dental procedure	MT					✓			up to ✓
Hospital admissions for serious injuries	MT					✓			up to ✓
Any attendance to Accident and Emergency (A&E)	D					✓			✓
Accidental injuries	MT					✓			up to ✓
Improved child development									
Any child development concern[3]	ST				✓		✓		
Any new child development concern at 27-30 months	ST						✓		
Any student need concern	MT							✓	

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

		FOLLOW-UP TIME POINTS							
	Outcome Type[1]	During pregnancy	At birth	Post-partum assessments					
				10 days	6-8 weeks	2 years	27-30 months	4-5 years	5-6 years
(a) Personal/social & (b) Emotional/ behavioural concern	ST				✓		✓		
Social, emotional, and behavioural difficulty	MT							✓	
Speech, language, and communication concern	ST				✓		✓		
Language or speech disorder/Communication Support Needs	MT							✓	
Physical or motor impairment	MT							✓	
Vision concern	ST				✓		✓		
Vision impairment	MT							✓	
Hearing concern	ST				✓		✓		
Hearing impairment	MT							✓	
Other student need[4]	MT							✓	
More able pupil	D							✓	
Child attainment	D								✓
Improved child protection									
Child protection (CP) investigation	D					✓			✓
Age at first CP investigation	D								✓
Number of CP investigations	D								✓
Investigation requiring a CP Case Conference (CPCC)	D					✓			✓
Type of concern identified at CPCC	D					✓			✓
Length of time on CP register	D					✓			✓
Child registered as a result of conference	D					✓			✓

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

		FOLLOW-UP TIME POINTS							
	Outcome Type[1]	During pregnancy	At birth	Post-partum assessments					
				10 days	6-8 weeks	2 years	27-30 months	4-5 years	5-6 years
Child de-registered	D								
Looked after status	D			✓	✓		✓		
Children with a looked after status	D					✓			✓
Time spent in first placement	D								✓
Placement type	D								✓
Placed for adoption	D								✓

4. Analysis

4.1. Power calculation

The previous 'Evaluability Assessment' estimated around 3000 births in FNP cohorts between 2010 and 2015 and around 6000 in the Controls (7). This large sample size would permit very precise estimation of overall intervention effects for a primary or co-primary outcomes. However as, there is no pre-specified prioritization of the 34 short- or medium-term outcomes for the main report, no power calculation is necesary.

Section 4.2 will cover analyses relating to the first three objectives and will be reported here in this document.

4.2. Identification of FNP Clients and Controls

4.2.1. FNP Clients

The number of FNP Clients identified and received from FNP SIS and matched to the SMR02 dataset by eDRIS will be reported using a flow chart. Additional checks will be made on the eligibility of FNP Clients. The SMR02 fields will be compared against the fields recorded in the FNP SIS for the FNP Clients (Table 7). This will allow us to measure the robustness of these fields used to identify the Controls.

Table 7: Maternal variables required from FNP and SMR02 datasets assessing eligibility criteria

FNP SIS field	SMR02 field
Age at enrolment	Maternal age at booking (derived)
Age at LMP (years)	Age at LMP (years)
Gestational age at enrolment	Gestational age at booking

4.2.1. Controls

After eDRIS have identified all eligible Controls based on the FNP eligibility criteria (Table 2), and recruiting periods (Table 1), several checks will be made on the data similar to those described for FNP Clients. Based on the SMR02 fields, we will check that Controls are eligible for FNP.

A well-conducted RCT would provide a precise, unbiased estimate of the effectiveness of FNP due to the process of treatment allocation via

randomisation. In a natural experiment, to enable an unbiased comparison of cases and controls, measured risk factors associated with outcomes (known as covariates) should be sufficiently similar (and thus balanced) for both exposure groups (i.e. FNP Clients and Controls).

As the potential Controls would have been eligible for enrolment on FNP during a period of active recruitment, they are already a more homogenous comparison population. It is likely, therefore, that the controls will be sufficiently similar to FNP Clients. However a possible threat to an unbiased comparison is the enrolment of mothers into FNP on criteria other than area, age, and parity (for example, an additional subjective judgement of clinical need). If mothers who were approached but not enrolled to participate in FNP differ from FNP clients in a manner that is associated with variation in outcomes, comparisons with all eligible Controls may under- or overestimate any effect of FNP.

One way to address this is to match the population on further maternal characteristics (such as smoking, co-morbidities, etc.) as it may provide a more valid estimate of effect because only women with similar observed characteristics are included, thus the results are more comparable. The disadvantages of this matching would be that not all cases would be matched to controls which would risk the exclusion of cases and reduce the sample size. It also only gives a solution to short-term outcomes where the cohort is maximized; matching would provide balance based on the whole cohort but as the sample reduces over time due to loss to follow up, the characteristics of the sample will also change and risk of imbalance is again present.

One of the approaches to matching of controls considered was propensity score matching (PSM) where the ability to examine, quantify and balance the recorded characteristics between the exposed and non-exposed groups can be easily implemented and a large number of measureable covariates can be adjusted for. Key to this method is that the propensity score (the predicted probability of enrolment obtained via regressing FNP enrolment on all available covariates) can be generated without sight of outcome, eliminating any possible bias in selecting the best match that provides the most favourable result (akin to randomisation and assessing outcome measures in a trial). However, PSM is sensitive to missing data and to be able to perform matching on imputed datasets, outcome data on all eligible Controls are required to obtain a pooled intervention effect over imputed datasets (12).

Therefore, given the possibility of a homogeneous comparison group and considerations such as the feasibility of gaining approval for the additional data required for PSM, a pragmatic approach was adopted to use all available controls. Using all controls, results will be more generalizable, and will result in higher power.

4.2.2. Descriptive analysis: FNP Clients and Controls

Measurable pre-recruitment/at booking maternal demographics and socioeconomic covariates associated with the FNP enrolment and outcomes were decided in advance (Table 8). Covariates should be variables that are not affected by exposure and measured before recruitment into FNP. The maternal characteristics will be described in the FNP Clients and all Controls using summary statistics (e.g. N (%), mean (standard deviation (SD))). In addition key summary characteristics of women offered but not enrolled in FNP or not offered FNP in an FNP recruiting period will be supplied by eDRIS using a subset of characteristics from Table 8 (deprivation quintile, ethnic group, age at LMP, gestation at antenatal booking, BMI at booking, history of smoking, drug use, previous pregnancies).

Table 8: Maternal baseline characteristics at (or before) date of antenatal booking/enrolment

Dataset/s	Variable (units or categories)
SMR02	Health Board based on postcode at antenatal booking date
SMR02	Scottish Index of Multiple Deprivation (SIMD) quintile
SMR02	Ethnic Group (White/Other)
SMR02	Age at antenatal booking (years)
SMR02/FNP SIS	Age at LMP (years)
SMR02/FNP SIS	Completed weeks of gestation at antenatal booking/FNP enrolment date
SMR02	Maternal Height/Weight/Body Mass Index (BMI) at booking date
SMR02	Booking Smoking History (never/non-smoker/current/former)
SMR02	Smoker during pregnancy recorded at booking (never/non-smoker/former/current)
SMR02	Drug misuse at any time during pregnancy reported at booking (yes/no)
SMR02	Illegal drugs/inappropriate injection of prescribed drugs at booking (yes/no)
SMR02	Typical weekly alcohol consumption at booking (units)

SMR02	Diabetes (pre-existing, gestational, yes but time of diagnosis unknown/no diabetes during this pregnancy)
Dispensing[1]	Drugs ever dispensed for asthma (yes/no)
Dispensing[1]	Drugs ever dispensed for mental ill health (yes/no)
SMR02	Previous pregnancy (yes/no)
SMR02	Outcome of pregnancy (live/stillbirth)
SMR02	Births (singleton/multiple)
Looked after child (LAC)	LAC status at booking (yes/no)
Child protection	Ever been on child protection register (yes/no)
Pupil/School level census	Ever had a student need (yes/no)
Pupil/School level census	Ever had Free School Meals (yes/no)
Attendances, Absences, Exclusions	Ever been excluded (yes/no)
School leavers	Left school at booking date (yes/no)

[1]Appendix 3 for BNF codes used to define dispensing of medications

4.2.3. Main analyses

With no primary outcome, equal importance will be given to each short and medium term outcome. All comparative analyses will be pre-specified and conducted on an intention to treat (ITT) basis. ITT in this study means that the analysis will include everyone who started the programme, according to their original 'allocation'. This means that the intervention group will be all women enrolled in FNP regardless of the treatment (intervention) they actually received.

All outcomes will be described by group (FNP Clients or Controls) and using summary statistics such as the number per group (percentage of all group), mean (alongside standard deviation) or median (alongside 25th to 75th centiles). All analyses will compare outcomes between women receiving FNP and those in the control group. Multilevel regression models will be used to allow for potential clustering of outcomes within NHS HBs and with the FNP teams/cohort. This means the analysis will take into account that possibility

that similar outcomes occur because women live within the same area or receive support within the same team/cohort.

Depending on the outcome, the effect of FNP (the difference for an outcome between FNP Clients and Controls) will be estimated and presented alongside a 95% confidence interval (CI) and p-value. This will show the certainty of the effect estimates. A wide confidence interval means that the difference between Cases and Controls could be much higher or lower than the difference estimated. In contrast, a small confidence interval provides a much more precise estimate of the real difference. A full technical description of the statistical analysis plan is in Appendix 4.

Before sight of any outcome data, a detailed statistical analysis plan (SAP) will be written and signed off by the co-lead for the project. The reporting and presentation of results will be in accordance with the GUILD, STROBE, RECORD and TREND guidelines to ensure the comprehensive reporting of this evaluation (13–16). The statistical packages SPSS and Stata will be used for all analyses (17,18). We will adhere to the NSS Statistical Disclosure Control protocol (11,19).

5. Results

5.1. Application process

Applications were made to PBPP and EAS and approved on 21st Dec 2016 and 28th October 2016 respectively. The EAS application was submitted, considered and approved within 1 month. The PBPP application was submitted 30th September 2016, considered at Tier 1 on 2nd November 2016 (comments responded to on 16th November 2016); Tier 2 approval granted 21st December 2017 (~2.5 months). Two additional amendments were then submitted. The first on 21st April 2017, following the addition of data fields and sources, with approval given 12th June 2017. The second amendment on 1st March 2018, extended the project duration and added data fields and sources, with final approval on 1st May 2018.

5.2. Population

5.2.1. FNP Clients

Identifiers for FNP Clients from the ten HB areas were sent from FNP SIS and pilot data were extracted separately from Lothian systems. FNP Clients who had transferred from one FNP area to another were kept in their originally assigned site. Where an FNP Client had enrolled into FNP more than once, the first episode was discarded and the more recent one included. These accounted for very small numbers.

Figure 3 shows the flow chart of the FNP Clients. A total of 3,277 FNP Clients were received by eDRIS from FNP SIS. Of these, six Clients were excluded (0.2%) and 3271 (99.8%) were eligible to be linked with the SMR02 maternity record. A total of 48 women could not be linked to the SMR02; 23 were missing an SMR02 record indicating that the CHI number was not present in the SMR02 dataset (possibly due to inaccuracies in CHI number) and 25 without a delivery record. 3,223 cases with a delivery record (live or stillbirth) remained and were imported alongside their maternal characteristics data into the eDRIS portal to be considered for inclusion in the evaluation.

Further data cleaning found an additional 18 women who were not eligible for FNP based on the fields in either the FNP SIS or the SMR02 dataset. 11 women were recorded as greater than 19 years of age at enrolment into FNP (from FNP SIS). Seven women were found to be outside the gestation criteria of 28^{+6} weeks. 3,205 FNP Clients (97.8% of the initial cohort) remained for analysis. Comparison of age at LMP between the two data sources for FNP Clients showed some small discrepancies with a median age of 18.4 years (SMR02) vs 18.1 years (FNP SIS) but a high correlation between the two ($r = 0.862$, $p<0.001$) (Table 9). Age at booking/enrolment was also very similar.

Gestation at enrolment in to FNP was on average nearly seven weeks after the gestation at booking with the FNP Clients and this is to be expected.

All eligibility criteria based on SMR02 fields had no or very low missing data, demonstrating that the SMR02 fields are robust enough to identify Controls.

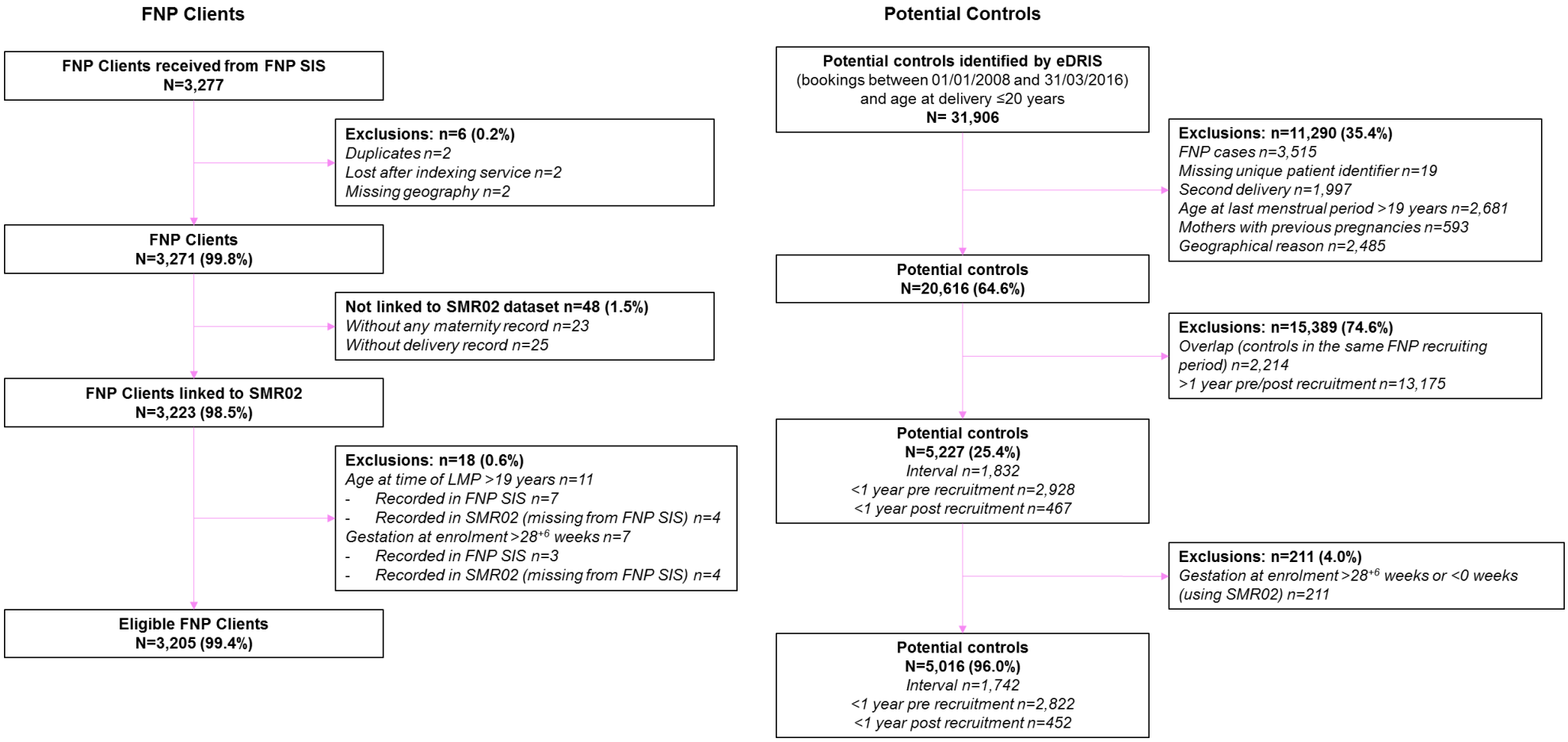
Table 9: Comparison of SMR02 vs FNP SIS datasets for FNP Clients

	Data source	
	SMR02 N=3,205	**FNP SIS N=3,205**
Age at LMP (years)		
Mean (sd)	18.30 (1.41)	17.91 (1.28)
Median (25th to 75th centiles)	18.4 (17.3 to 19.3)	18.1 (17.0 to 19.0)
Gestation (weeks)	**at booking** N=3,200	**at enrolment into FNP** N=3,205
Mean (sd)	10.82 (6.37)	17.84 (4.24)
Median (25th to 75th centiles)	10.0 (8.0 to 12.0)	16.7 (15.0 to 20.1)
Age (years)	**at booking** N= 3,205	**at enrolment into FNP** N=3,205
Mean (sd)	18.14 (1.22)	18.23 (1.29)
Median (25th to 75th centiles)	18.3 (17.2 to 19.2)	18.4 (17.3 to 19.2)

5.2.2. Controls (eDRIS)

eDRIS identified a total of 31,906 potential women whose age at delivery was ≤20 years from the period 1st January 2008 to 31st March 2016 based on SMR02 fields (Figure 3). From this figure 3,515 women were identified as being FNP Clients, 19 without a unique patient identifier, and the remainder of reasons were due to being outside the eligibility inclusion criteria.
After deleting Controls found to be in the recruiting period (2,214) and those with a booking date more than one year pre or post the recruiting periods (n=13,175), 5,227 Controls remained. A further 211 were identified with a gestation at enrolment >28^{+6} week, leaving 5016 controls for the evaluation.

Figure 3. Flow of eligible FNP Clients and potential Controls



5.2.2.1 Maternal characteristics

Table 10 describes the maternal characteristics of the FNP Clients and the Controls identified from the 1-year pre and post recruitment periods and within intervals where recruiting stopped and also the standardised differences between FNP Clients and the Controls. Of the data requested, the education and social care data were not available. Imbalance between the FNP Clients and Control group can be observed in some maternal characteristics such as ethnicity, dispensing of medication for asthma and depression, age and gestation at booking. FNP Clients were on average younger (recorded at booking) and had a lower gestation at booking when compared to the Control population. However, age at last menstrual period was comparable (18.30 vs 18.22 years respectively). FNP also appear to recruit a higher proportion of white women (87.6% vs 78.7% respectively), with a higher proportion of drug misuse, and dispensing for asthma and depression.

Table 10. Maternal characteristics *All results are n(%) unless otherwise stated*

	FNP Clients N=3,205		**Controls N=5,016**	
Health board of residence				
NHS Ayrshire/ Arran	227	7.1	483	9.6
NHS Borders	24	0.8	42	0.8
NHS Fife	380	11.9	450	9.0
NHS Forth Valley	100	3.1	263	5.2
NHS Grampian	93	2.9	172	3.4
Greater Glasgow and Clyde	404	12.6	1391	27.7
NHS Highland	100	3.1	197	3.9
Lanarkshire	250	7.8	722	14.4
Edinburgh	895	27.9	862	17.2
NHS Tayside	732	22.8	434	8.7
Missing	*0*	*0*	*0*	*0*
Ethnicity				

	FNP Clients N=3,205		Controls N=5,016	
White	2,724	87.6	3,573	78.7
Other	384	12.4	969	21.3
Missing	*97*	*3.0*	*474*	*9.4*
Scottish Index of Multiple Deprivation Quintile				
1 - most deprived	1,532	47.9	2,478	49.4
2	821	25.7	1,221	24.3
3	441	13.8	643	12.8
4	264	8.3	459	9.2
5 least deprived	140	4.4	215	4.3
Missing	*7*	*0.02*	*0*	*0*
Age at last menstrual period (LMP) (years) (SMR02)				
Mean (SD)	18.30 (1.41)		18.22 (1.23)	
Median (25th to 75th centiles)	18.4 (17.3 to 19.3)		18.4 (17.4 to 19.2)	
Missing	*0*	*0*	*0*	*0*
Age at antenatal booking (years) (SMR02)				
Mean (SD)	18.14 (1.22)		18.45 (1.22)	
Median (25th to 75th centiles)	18.3 (17.2 to 19.2)		18.7 (17.6 to 19.5)	
Missing	*0*	*0*	*0*	*0*
Gestation at antenatal booking (weeks) (SMR02)				
Mean (sd)	10.86 (6.25)		11.53 (4.69)	
Median (25th to 75th centiles)	10.0 (8.0 to 12.0)		11.0 (8 to 13)	
Missing	*9*	*0.3*	*0*	*0*

	FNP Clients N=3,205		Controls N=5,016	
Body mass index (BMI) (kg/m^2) at antenatal booking				
Mean (SD)	23.94 (5.0)		24.3 (5.1)	
Median (25th to 75th centiles)	22.9 (20.4 to 26.4)		23.2 (20.6 to 27.0)	
Missing	*51*	*1.6*	*483*	*9.6*
BMI category at antenatal booking				
Underweight	259	8.2	325	7.2
Healthy	1840	58.3	2585	57.0
Overweight	680	21.6	1005	22.2
Obese	375	11.9	618	13.6
History of smoking during pregnancy				
No	1,891	61.4	3,036	64.3
Yes	1,191	38.6	1,684	35.7
Not known/missing	*123*	*3.8*	*299*	*6.0*
Smoking history at antenatal booking				
Never smoked, non-smoker/former smoker	1,856	59.1	3,000	62.9
Never smoked, non-smoker	*1,254*	*39.1*	*2,212*	*46.4*
Former smoker	*602*	*18.8*	*788*	*16.5*
Current smoker	*1,285*	40.9	1,767	37.1
Not known/Missing	*64*	*2.0*	*249*	*5.0*
Drug misuse at any time during the current pregnancy				

	FNP Clients N=3,205		Controls N=5,016	
No	2,788	94.7	3,768	96.8
Yes	156	5.3	123	3.2
Not known/Missing	*260*	*8.1*	*1,125*	*22.6*
Ever injected illegal drugs				
No	2,927	99.8	3,856	99.7
Yes (during /prior to current pregnancy / yes but not know when)	7	0.2	13	0.3
Not know/Missing	*270*	*8.4*	*1,147*	*22.0*
Number of units of alcohol consumed in the course of a typical week at antenatal booking				
None	2897	94.9	4174	95.4
At least one unit	156	5.1	203	4.6
Missing	*152*	*4.7*	*639*	*12.7*
Patient has diabetes or not				
Yes (pre-existing, gestational, time of diagnosis unknown)	43	1.4	48	1.0
No (no diabetes during this pregnancy)	3,119	98.6	4,836	99.0
Unknown/Missing	*43*	*1.3*	*132*	*2.6*
Ever dispensed medication for asthma				
No	2,504	78.1	4,431	88.3
Yes	701	21.9	585	11.7

	FNP Clients N=3,205		Controls N=5,016	
Missing[1]	*0*	*0*	*0*	*0*
Ever dispensed medication for depression				
No	2,614	81.6	4,598	91.7
Yes	591	18.4	418	8.3
Missing	*0*	*0*	*0*	*0*
Previous pregnancy				
No	2,350	74.0	3,716	74.1
Yes	827	26.0	1,296	25.9
Missing	*28*	*0.9*	*4*	*0.1*
Births				
Singleton	3,184	99.3	4,989	99.5
Multiple (2+ births)	21	0.7	27	0.5
Missing	*0*	*0*	*0*	*0*
Total Babies	**n=3,227**		**n=5,043**	
Outcome				
Live births	3,210	99.5	5,010	99.3
Still births	17	0.5	33	0.7

5.2.2.2 Missing data

Table 11 shows the completeness of the variables used to describe the maternal characteristics. The dataset provided had a higher degree of missing data than anticipated in 11 important maternal characteristics (possibly associated with outcomes in the evaluation e.g. smoking, drug use, BMI,

[1] Women with no medication flag were not linked to medications data and thus are assumed not to have any medication

alcohol use, ethnicity etc.) thus rendering the propensity score matching method as unusable.

Table 11: Completeness of maternal characteristic variables

Variable	N	Categorised as 'Not known'	Missing (%)
Exposure (FNP/Control)	11,638	0	0
Health Board of residence	11,638	0	0
SIMD quintiles (least to most deprived)	11,631	0	7 (0.06%)
Ethnicity (White/Other)	10,469	0	1,169 (10.0%)
Age at booking (SMR02 only) (years)	11,638	0	0
Age at LMP (SMR02 only) (years)	11,638	0	0
Gestation at booking (SMR02 only) (weeks)	11,629	0	9 (0.09%)
BMI (kg/m^2) at booking	10,580	0	1,058 (9.1%)
History of smoking during pregnancy	11,002	636 (5.5%)	0
History of smoking recorded at booking	11,135	496 (4.3%)	0
Drug misuse (yes/no)	9,664	1,872 (16.1%)	102 (1.0%)
Injected (yes/no)	9,625	1,910 (16.4%)	103 (1.0%)
Alcohol or not (yes/no)	10,276	0	1,362 (11.7%)
Diabetes (yes/no)	11,385	253 (2.2%)	0
Asthma meds (yes/no)	11,638	0	0
Antidepressant (yes/no)	11,638	0	0
Previous pregnancy (yes/no)	11,601	0	37 (0.3%)
Births (singleton/multiple)	11,638	0	0
Outcome of birth (live/still)	11,638	0	0

5.3. Controls offered FNP but not enrolled or not offered FNP

Table 12 shows selected characteristics for women who were eligible for FNP but did not enroll in the FNP programme compared to women who did enroll (FNP Clients) and Controls. Women who were offered FNP but not enrolled appeared to be more likely to be of ethnic background, a non-smoker and less likely to misuse drugs. All other characteristics such as deprivation profile, age at last menstrual period, BMI and rate of previous pregnancy were comparable.

Table 12: Controls offered FNP but not enrolled or not offered FNP

	FNP Clients N=3,205		**Controls N=5,016**		**Women offered FNP but not enrolled or not offered FNP N=2,214**	
Ethnicity						
White	2,724	87.6	3,573	78.7	1,733	78.3
Other	384	12.4	969	21.3	360	16.3
Missing	*97*	*3.0*	*474*	*9.4*	121	5.5
Scottish Index of Multiple Deprivation Quintile						
1 - most deprived	1,532	47.9	2,478	49.4	992	44.8
2	821	25.7	1,221	24.3	588	26.6
3	441	13.8	643	12.8	316	14.3
4	264	8.3	459	9.2	214	9.7
5 least deprived	140	4.4	215	4.3	101	4.6
Missing	*7*	*0.02*	*0*	*0*	3	0.1
Age at last menstrual period (LMP) (years) (SMR02)						
Mean (SD)	18.30 (1.41)		18.22 (1.23)		18.4 (2.20)	

	FNP Clients N=3,205		Controls N=5,016		Women offered FNP but not enrolled or not offered FNP N=2,214	
Median (25th to 75th centiles)	18.4 (17.3 to 19.3)		18.4 (17.4 to 19.2)		18.7 (1.7)	
Missing	*0*	*0*	*0*	*0*	*0*	*0*
Body mass index (BMI) (kg/m^2) at antenatal booking						
Mean (SD)	23.94 (5.0)		24.3 (5.1)		24.4 (5.1)	
Median (25th to 75th centiles)	22.9 (20.4 to 26.4)		23.2 (20.6 to 27.0)		23.3 (6.3)	
Missing	*51*	*1.6*	*483*	*9.6*	*87*	*3.9*
Smoking history at antenatal booking						
Never smoked, former smoker	1,856	59.1	3,000	62.9	1,389	62.7
Never smoked	*1,254*	*39.1*	*2,212*	*46.4*	*1,048*	*47.3*
Former smoker	*602*	*18.8*	*788*	*16.5*	*341*	*15.4*
Current smoker	*1,285*	40.9	1,767	37.1	739	33.4
Not known/Missing	*64*	*2.0*	*249*	*5.0*	*86*	*3.9*
Drug misuse at any time during the current pregnancy						
No	2,788	94.7	3,768	96.8	1,866	84.3
Yes	156	5.3	123	3.2	59	2.7
Not known/Missing	*260*	*8.1*	*1,125*	*22.6*	289	13.1
Previous pregnancy						
No	2,350	74.0	3,716	74.1	1,656	74.8

	FNP Clients N=3,205		Controls N=5,016		Women offered FNP but not enrolled or not offered FNP N=2,214	
Yes	827	26.0	1,296	25.9	555	25.1
Missing	*28*	*0.9*	*4*	*0.1*	*3*	*0.1*

5.4. Final cohort

Consistent with our commitment to minimum processing by using only those Controls that are required, we will only use the Controls identified within one year pre and post recruitment and in the interval period. This means that we would require outcome data on 3,205 FNP Clients and 5,016 Controls (approximately a 1:1.56 ratio) mothers for this evaluation and we should expect data on 3227 and 5043 children respectively.

6. Discussion

6.1. Establishing the evaluation framework

We have established the framework for evaluating FNP using data linkage and routine Scottish data. The required governance approvals were obtained and eDRIS successfully received and mapped FNP Clients to the SMR02 with little loss of records. The majority of women excluded were due to no CHI number or delivery record. The quality of the fields from the SMR02 used to identify the potential control sample was found to be high with few missing values. Controls were successfully identified using the SMR02 dataset. Both FNP Clients and Controls were linked to health data and descriptive data for both groups were summarised. Education and social care data (e.g. women ever in care or need) were not received to examine at baseline. Therefore, the impact of these data and possible imbalances will be examined once the remainder of the data is received. Any such imbalances will be adjusted for in the analysis. eDRIS also successfully identified a potential control sample of eligible women who would meet criteria for FNP but were not enrolled to receive the FNP programme. Approval was not gained from Public Benefit and Privacy Panel to use this group. Even though these women were not FNP Clients and would not be included in the evaluation, it was vital to understand how they might differ from the women enrolled in FNP. As such, it is important to take ethnicity into account during analysis since the proportion of white women in this group were comparable to the Controls.

We were unable to match FNP Clients to Controls using propensity score matching methods due to the proportion of missing data. For propensity scores to have been generated and used for matching, outcome data would have had to have been sought beforehand. This was outside of the scope of this study. Instead, the cohort of eligible Controls identified in the one-year pre and post recruitment and within interval periods where recruitment ceased will be used. This still maximizes the study cohort of mothers and children (8,221 and 8,270 respectively) and will provide results that will be more generalisable and result in higher statistical power. Any imbalances in important confounders will be adjusted for by modelling.

6.2. Scope of evaluation outcomes

The assessment of effectiveness in the evaluation is limited to outcomes available from routinely collected data. The outcomes for this study have been selected by matching routinely collected administrative data to the Scottish FNP logic model based on the underlying programme theory. FNP has three main aims in Scotland: 1) to improve pregnancy outcomes; 2) to improve child

health and development; and 3) to improve parents' economic self-sufficiency. The breadth of these aims is intended to capture the complexity of the intervention. Translated into outcomes within the logic model, these aims were matched to the available routine data. This resulted in data matches or proxy data matches for around 50% of the outcomes detailed within the model.

Therefore, the included outcomes have been selected on the basis that they are outcomes FNP aims to influence and for which there is routine data, rather than a set of specific outcomes where research indicates the most significant contribution. Where there is a clear hypothesis for why FNP will contribute to a specific outcome this has been described. The remaining outcomes will be regarded as exploratory outcomes, pre-specified but not hypothesised. In addition, special consideration will be given to outcomes where bias may have been incorporated in their reporting. An example of this is child health assessments up to 24 months, which are carried out by different health professionals depending upon which group (FNP clients or Controls) women are in.

There are no primary outcomes selected for this evaluation. This approach is consistent with some previous trials of FNP (for example, the original Elmira trial) and with other evaluations of home visiting programmes (20), where impact is expected to arise across multiple domains and over multiple time-points. A consequence of this approach is that the large number of statistical tests performed will increase the risk of finding a significant result by chance (false-positive error). Given a 0.05 alpha there is an 83% ($1-0.95^{34}$) chance that at least one of these tests are statistically significant by chance when the conclusion is not true in the population. Recently, James Heckman and colleagues re-assessed the findings of the Memphis trial of NFP using a 'step-down' approach to address the challenge of multiple significance testing (21). Although in Heckman's re-analysis fewer treatment effects survived corrections for multiple hypothesis testing they observed strong effects for boys, sustained until age 12. For individual studies, other correction methods such as Bonferroni have been suggested but are likely to prove overly conservative and risk the possibility of Type II error (i.e. incorrectly concluding no effect when one does actually exist).

The numbers of available FNP Clients are in the region reported in the Evaluability Assessment (estimated around 3000 births in FNP cohorts between 2010 and 2015) but the number of Controls are lower than expected (7). One reason for this might be that Controls were defined as 'First births to mothers aged <20 at conception' where as our cohort of Controls were further restricted to gestational age and previous births. They also included projected numbers for 2013/14-2014/15, based on an assumption of a 6% annual fall in the number of such births. Nevertheless we have an adequate ratio of FNP Clients to Controls for the evaluation.

As currently, we haven't performed any matching to EAS, we do not know how well it will be done or who will be matched. As already noted, the matching of Education data to the Population Spine presents a 50% chance of matching error for twins. For this evaluation, this means that outcomes from Education and Health on an individual level may not relate to the correct twin. However, on a population level, this should not impact on the overall results as both would have recieved FNP or not.

6.3. Legal & Ethical considerations

This study has been considered a service evaluation as it is limited to using data obtained as part of usual care. This was confirmed by the South East Scotland Research Ethics Service. The principal legal consideration is of unintentional identification of individuals. Such a risk could be increased through the combination of clinical and socio-demographic attributes from a single or multiple datasets[41].This risk is managed through the de-identification of sensitive and personally identifiable data items before matching and before being made available for analysis as well as the disclosure controls placed on all outputs from the safe haven. There are various governance and contractual requirements placed on this study, many of which were identified and required by the PBPP and/or EAS panel before final approval. All researchers have completed the information governance training required by eDRIS to evidence their "approved researcher" status. Thirty-three data sharing and/or data processing agreements were set up between HBs, NSS, NRS, EAS and SG to allow the transfer, processing and storage of data for this study. The study has a steering committee to provide independent oversight of the study, this was set up by the study team and their remit is to provide independent advice on the study including ensuring retaining scientific robustness.

7. Conclusions

An approved framework for evaluating FNP in Scotland using a natural experiment design and routine data has been established. This includes the identification of both FNP clients and a control group of young mothers drawn from the same health boards. A set of study outcomes has been agreed which collectively address about half of the potential domains within the programme logic model. Defined short and medium term outcomes will be analysed using statistical methods. Outcomes where either the direction effect is uncertain, the outcome is rare or data are classed as experimental will be reported descriptively only. The governance approvals secured and numbers of successfully identified and linked study cases and controls lays the foundation for a pre-specified main analysis which will efficiently use routine data to produce generalisable results about FNP programme impact in Scotland.

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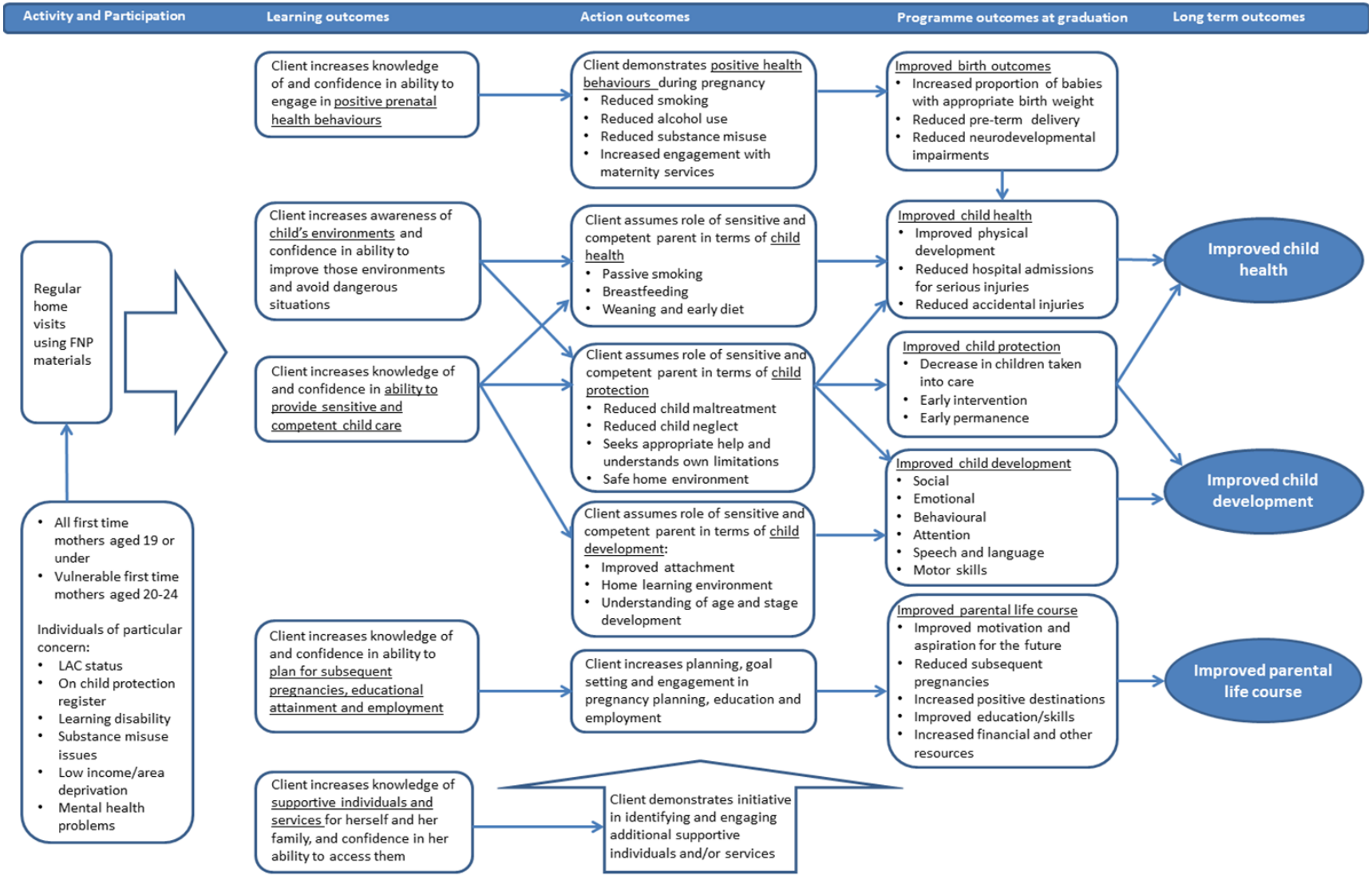
9. Appendices

Appendix 1: Logic model



Appendix 2: FNP leaflet

This is for anyone who has enrolled on the Family Nurse Partnership (FNP) programme in Scotland.

Just like other services within the NHS, information is routinely collected about you and your baby whilst you are on FNP. This will include personal information that identifies you such as your name, address and date of birth. This information will also be linked to, for example:

- information about care or treatment you or your baby have had,
- information about the health and lifestyle of you and your baby, and
- any results of tests you or your baby may have had.

This information is kept in records. These can be paper or on computer or both. In FNP in Scotland this information is often held on both paper and computer. This information is accessed by your family nurse and by their supervisor to plan the best service for you and your baby.

All NHS staff including all those working in FNP have a legal duty to keep your information confidential and to store it safely and securely.

This information is only shared if it is relevant, in an emergency or if the law says it must.

For further information contact your local FNP team:

1.1 January 2017

Designed and typeset by the NES Design Team.

NHS Education for Scotland

Family Nurse Partnership™ National Unit Scotland

How we use your information

How is my information used in FNP?

Just like the NHS, FNP uses your information to make sure you get what you need from being part of the programme. This could include referring you to another service or agency.

Sometimes FNP may use your, and your child's information, from FNP and other sources to carry out research, statistics or evaluation to help improve FNP or other health services or the health of the public.

This may include for example:

- to check that FNP is providing a good service,
- to find out how many people choose to have FNP and how many people decide not to enrol,
- to help train family nurses, student health visitors and other staff.

Lots of information is created when people come in contact with services like FNP and if we can connect this in a way that does not breach someone's privacy we can use the information to get a better understanding of how FNP makes a difference and how we can make it better.

In FNP we may ask you, either whilst you are receiving the FNP programme or even after you have graduated from the programme, to be involved in helping us develop a deeper understanding about FNP.

If you are still on the FNP programme it will be your Family Nurse that discusses this with you.

What happens to my data once I have graduated from FNP?

FNP, like other parts of the NHS, holds information for as long as necessary to help us provide our services and in line with local policy and any requirements of the law.

If research is being carried out, and you have left the FNP programme you may be contacted by a researcher via your local GP Practice.

As with all research you do not have to take part and can stop at any point.

This will have no impact on you being on the FNP programme or make any difference to your care and treatment.

Appendix 3: BNF Codes for dispensing

(a) Mental Ill Health

BNF code	Drug name	BNF code	Drug name
040101000	Other Hypnotic Preps	0403010H0	Desipramine Hydrochloride
0401010AA	Sodium Bromide	0403010I0	Amineptine Hydrochloride
0401010AB	Methaqualone & Diphenhydramine HCl	0403010J0	Dosulepin Hydrochloride
0401010AC	Sodium Oxybate	0403010L0	Doxepin
0401010AD	Melatonin	0403010N0	Imipramine Hydrochloride
0401010B0	Chloral Hydrate	0403010P0	Nomifensine Hydrogen Maleate
0401010C0	Cloral Betaine	0403010Q0	Iprindole
0401010D0	Clomethiazole Edisilate	0403010R0	Lofepramine Hydrochloride
0401010F0	Clomethiazole	0403010S0	Maprotiline Hydrochloride
0401010I0	Flunitrazepam	0403010T0	Mianserin Hydrochloride
0401010L0	Flurazepam Hydrochloride	0403010V0	Nortriptyline
0401010N0	Loprazolam Mesilate	0403010W0	Protriptyline Hydrochloride
0401010P0	Lormetazepam	0403010X0	Trazodone Hydrochloride
0401010Q0	Midazolam Maleate	0403010Y0	Trimipramine Maleate
0401010R0	Nitrazepam	0403010Z0	Viloxazine Hydrochloride
0401010S0	Potassium Bromide	0403020C0	Iproniazid
0401010T0	Temazepam	0403020H0	Isocarboxazid
0401010V0	Triazolam	0403020K0	Moclobemide
0401010W0	Zaleplon	0403020M0	Phenelzine Sulphate
0401010X0	Triclofos Sodium	0403020Q0	Tranylcypromine Sulphate
0401010Y0	Zolpidem Tartrate	0403030	Fluoxetine Hydrochloride
0401010Z0	Zopiclone	0403030D0	Citalopram Hydrobromide
0401020	Chlordiazepoxide Hydrochloride	0403030L0	Fluvoxamine Maleate
040102000	Other Anxiolytic Preps	0403030P0	Paroxetine Hydrochloride
0401020A0	Alprazolam	0403030Q0	Paroxetine Hydrochloride
0401020B0	Buspirone Hydrochloride	0403030X0	Escitalopram
0401020C0	Clotiazepam	0403030Y0	Duloxetine Hydrochloride (old)
0401020D0	Chlordiazepoxide	0403030Z0	Citalopram Hydrochloride
0401020F0	Chlormezanone	040304000	Other Antidepressant Preps
0401020G0	Bromazepam	0403040B0	Bupropion Hydrochloride
0401020K0	Diazepam	0403040F0	Flupentixol Hydrochloride
0401020L0	Ketazolam	0403040M0	5-Hydroxytryptophan
0401020P0	Lorazepam	0403040N0	Minaprine Hydrochloride
0401020Q0	Medazepam	0403040R0	Oxitriptan
0401020R0	Meprobamate	0403040S0	Tryptophan
0401020T0	Oxazepam	0403040T0	Nefazodone Hydrochloride
0401020U0	Prazepam	0403040U0	Reboxetine

0401020V0	Clorazepate Dipotassium	0403040W0	Venlafaxine
0403010	Amitriptyline Embonate	0403040X0	Mirtazapine
0403010B0	Amitriptyline Hydrochloride	0403040Y0	Duloxetine Hydrochloride
0403010C0	Amoxapine	0403040Z0	Agomelatine
0403010D0	Butriptyline		
0403010F0	Clomipramine Hydrochloride		
0403010G0	Dibenzepin Hydrochloride		

(b) Asthma

BNF code	Drug name
0301011	Formoterol Fumarate
0301011B0	Bambuterol Hydrochloride
0301011C0	Clenbuterol Hydrochloride
0301011F0	Fenoterol Hydrobromide
0301011J0	Pirbuterol Hydrochloride
0301011K0	Pirbuterol Acetate
0301011M0	Reproterol Hydrochloride
0301011P0	Rimiterol Hydrobromide
0301011R0	Salbutamol
0301011U0	Salmeterol
0301011V0	Terbutaline Sulphate
0301011W0	Tulobuterol Hydrochloride
0301011X0	Indacaterol Maleate
030101200	Other Andrenoceptor Agonist Preps
0301012A0	Adrenaline
0301012F0	Ephedrine Hydrochloride
0301012J0	Isoetarine Hydrochloride
0301012N0	Isoprenaline Sulphate
0301012Q0	Methoxyphenamine Hydrochloride
0301012S0	Orciprenaline Sulphate
0301020A0	Atropine Methonitrate
0301020B0	Atropine Sulphate
0301020I0	Ipratropium Bromide
0301020P0	Oxitropium Bromide
0301020Q0	Tiotropium
0301020R0	Aclidinium Bromide
030103000	Other Theophylline Preps
0301030A0	Acefylline Piperazine
0301030B0	Aminophylline
0301030C0	Aminophylline Hydrate
0301030D0	Aminophylline With Antacid
0301030H0	Choline Theophyllinate
0301030K0	Diprophylline

0301030N0	Proxyphylline
0301030S0	Theophylline
0302000C0	Beclometasone Dipropionate
0302000G0	Betamethasone Valerate
0302000K0	Budesonide
0302000N0	Fluticasone Propionate (Inh)
0302000R0	Mometasone Furoate
0302000T0	Triamcinolone Acetonide
0302000U0	Ciclesonide
0303010D0	Ketotifen Fumarate
0303010J0	Nedocromil Sodium
0303010Q0	Sodium Cromoglicate
0303020G0	Montelukast
0303020Y0	Zileuton
0303020Z0	Zafirlukast

Appendix 4: Statistical analysis plan.

With no primary outcome, equal importance will be given to each short and medium term outcome. All comparative analyses will be pre-specified and conducted on an intention to treat (ITT) basis. ITT in this study means that the analysis will include everyone who started the programme, according to their original 'allocation', i.e. the intervention group will be women enrolled in FNP regardless of the treatment (intervention) they received.

All analyses will compare outcomes (intervention effect) between the two groups (Cases and Controls) using multilevel regression models, to allow for clustering of outcome within NHS HB, and FNP team/cohort (where more than one team runs within a HB). Intervention effects will also be examined over time and between different geographical areas (HB and team/cohort) by fitting multilevel models and interactions (group x year). Alongside the estimate of effect, for all outcomes a 95% confidence interval (CI) and p-value will be presented. Sensitivity analyses will explore the effect of multiple comparisons and also adjustment for any hypothesized confounders of outcomes at baseline.

Binary outcomes will be modelled using a logistic model and presented as odds ratios comparing the odds of an event in a case compared with the Control. For continuous outcomes a multilevel linear model will be fitted and results presented as a difference in means (Case minus Control group). Time to event analyses (e.g. cessation of breastfeeding, time to subsequent birth) will be analysed using a proportional hazards regression model and results presented as hazard ratios. We will ascertain if the proportional hazards assumption has not been violated by inspecting the log (−log(survival)) plot and Schoenfeld residuals. Count data will be analysed using a Poisson multilevel model. If the distribution of events display signs of over dispersion (greater variance than might be expected in a Poisson distribution), then a Negative Binomial model will be used. Results will be presented as the incidence rate ratio in the case arm compared to the Control group. The impact of FNP visits (dosage of intervention) on outcomes will be explored as a sensitivity analysis. Adherence will be defined as the number of FNP visits that a Client received during their programme enrolment overall or by phase (pregnancy, infancy, toddler), dependent on outcome.

Subgroup analyses

We will examine the effect of FNP on pre-specified outcomes by modelling interactions between FNP uptake and pre-specified maternal baseline characteristics such as ever been on the child protection register/ looked after child, substance misuse issues and child demographics such as gender. Effect sizes alongside 95% CIs and p-values will be reported.

Sensitivity analyses

We plan to conduct several sensitivity analyses:

- Adjustment for any imbalance in confounders (pre-exposure maternal and baby characteristics). Note that these will be assessed for the differing denominators (study populations) dependent on outcome;
- Adjustment for multiple testing;
- The impact of FNP visits (dosage of intervention) on outcomes will be explored as a sensitivity analysis. Adherence will be defined as the number of FNP visits that a client received during FNP enrolment overall or by phase (pregnancy, infancy, toddler), depending on the outcome. We will use 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.
- For certain outcomes such as smoking status and drug use, there may be missing data. Multiple imputation using chained equations accounting for the clustered nature of the data will be performed in addition to a complete case analysis(23).
- For outcomes that may have variable follow-up times (such as 27-30 month health visitor review) and in outcomes that variable length of follow-up might have an impact, such as in development, we will examine the average length of time of follow-up between cases and Controls and where imbalanced, further adjust.
- For outcomes with known constraints on data quality, such as mandatory drug and alcohol questions at booking since April 2011, analyses will be restricted to consider these quality issues for example excluding years where data is known to be of variable quality.

Intervention effects will also be examined over time (e.g. year of recruitment), site maturity (e.g. if outcomes are more improved for second cohorts within a given site) and between different geographical areas (HB and team/cohort) by fitting interactions (group x year). These analyses are essentially exploratory and will require cautious interpretation. Effect sizes alongside 95% confidence intervals and p-values will again be reported.

How to access background or source data

The data collected for this social research publication:

☐ are available in more detail through Scottish Neighbourhood Statistics

☐ are available via an alternative route

☐ 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.

social research

The views expressed in this report are those of the researcher and do not necessarily represent those of the Scottish Government or Scottish Ministers.

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