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FIRST STEPS: a trial of the effectiveness of the Group Family Nurse Partnership (gFNP) programme compared to routine care in improving outcomes for high risk mothers and preventing abuse

Submission date
17/05/2013

Recruitment status
No longer recruiting

Registration date
17/05/2013

Overall study status
Completed

Last Edited
15/01/2018

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Child abuse and neglect is a major public health problem and infants are a high-risk group accounting for up to 13% of child protection registrations in the UK, and a significant number of deaths. The provision of sensitive caregiving during the first few years is important because brain development is rapid at this time, but also very vulnerable to negative influences. A nurse home visiting programme, Family Nurse Partnership (FNP) which starts early in pregnancy and extends until infants are 24 months old has been identified as one with strong evidence that it reduces the later risk of child abuse. It is now offered widely in England but is only available to first-time mothers under 20. Group Family Nurse Partnership (gFNP), a newly developed programme, based on the FNP curriculum and strength-based approach, is delivered in a group context to 8-12 women with similar expected delivery dates, starting in pregnancy and lasting until infants are 12 months old. Partners are also encouraged to attend the group sessions. Following the success of group-based antenatal care such as the US Centering Pregnancy Model, preferred by many to traditional care and leading to improved prenatal outcomes among high-risk women, the gFNP programme combines the provision of the FNP curriculum with midwifery care in pregnancy and infant health checks in infancy. Women are encouraged to monitor their own health. The aim of this study is to examine if provision of the gFNP programme, compared to routine antenatal and postnatal services, can reduce risk factors for maltreatment.

Who can participate?
The gFNp programme is being offered in England to women currently not eligible for FNP but who are likely to benefit from the support, namely in expectant mothers <20 years with one or more previous live births or expectant mothers aged 20-24 with low/no qualifications and no previous live births. Ideally they will recruit when they are between 12 and 16 weeks gestation.

What does the study involve?
After initial identification by community midwifery in pregnancy, informed consent will be gained by a local researcher in the participant's home and participant will complete an interview. Participants will then be randomly allocated either to receive the gFNP programme or routine antenatal and postnatal services. Those receiving gFNP will take part in up to 44 gFNP sessions, each lasting about 2 hours and delivered in a local centre by two specially trained Family Nurses, one of whom is also a registered midwife. All study participants will be visited by a researcher in their home when infants are 2 and 12 months of age, with an additional telephone research contact when infants are 6 months old.

What are the possible benefits and risks of participating?
There will be potential benefits for the study participants whether they receive the programme or not. They will experience three research visits, with a small monetary reward, plus one additional telephone contact, and will be able to talk about their parenting experiences. Any family thought to be in need of referral to specialist services will be urged by the research team to do this, through their general practitioner (GP) and will be supported by the researchers. There are no obvious risks of participating. While some expectant mothers will not receive the programme under investigation it is first important to investigate whether the program under investigation has a beneficial impact.

Where is the study run from?
The First Steps Study has been set up by Birkbeck, University of London with collaboration from the London School of Hygiene and Tropical Medicine, the University of Warwick, Queen's University Belfast and the University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in mid 2013, extending over 6 to 7 months and taking place in 6-7 locations throughout England. Each location will offer the programme to two groups, with start times approximately 3 months apart. Participants will be enrolled in the study for 20 months. Given the phased nature of enrolment and programme delivery, from the start of recruitment the entire study will extend over 30 months.

Who is funding the study?
National Institute of Health Research (UK)

Who is the main contact?
Prof. Jacqueline Barnes
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
14520

Study information

Scientific Title
FIRST STEPS: a randomised controlled trial of the effectiveness of the Group Family Nurse Partnership (gFNP) programme compared to routine care in improving outcomes for high risk mothers and preventing abuse

Acronym
FIRST STEPS

Study objectives
Child abuse and neglect is a major public health problem and infants are a high-risk group accounting for up to 13% of child protection registrations in the UK. The provision of sensitive caregiving during the first few years is important because brain development is rapid at this time. A nurse home visiting programme, Family Nurse Partnership (FNP) which starts early in pregnancy and extends until infants are 24 months old has been identified as one with strong evidence that it reduces the later risk of child abuse. In England it is only available to first-time mothers under 20. Group FNP, a newly developed programme, based on the FNP curriculum and strength-based approach, is delivered in a group context to 8-12 women with similar expected delivery dates, starting in pregnancy and lasting until infants are 12 months old. Partners are also encouraged to attend the group sessions. The gFNP programme combines the provision of the FNP curriculum with midwifery care in pregnancy and infant health checks in infancy. Women are encouraged to monitor their own health. The aim of this study is to examine if provision of the Group Family Nurse Partnership (gFNP) programme, compared to routine antenatal and postnatal services, can reduce reduce risk factors for maltreatment.

After initial identification by community midwifery in pregnancy, informed consent will be gained by a local researcher in the participant's home and a baseline interview completed. Participants will then be randomly assigned either to receive the gFNP programme or routine antenatal and postnatal services. All study participants will be visited by a researcher in their home when infants are 2 and 12 months of age, with an additional telephone research contact when infants are 6 month old.Those receiving gFNP will take part in up to 44 gFNP sessions, each lasting approximately 2 hours.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West - Frenchay, 28/05/2013, ref: 13/SW/0086

Study design
Randomised interventional prevention trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Disease: All Diseases

Interventions
1. Group Family Nurse Partnership, Delivered by two Family Nurses one is also a qualified midwife. The group consists of between 8 and 12 women with EDDs within 6 weeks of each other, and partners are encouraged to attend. Routine midwifery care in pregnancy and infant health checks in infancy according to NICE guidelines are undertaken during the gFNP session with encouragement for mothers to conduct the necessary checks themselves. Groups meet from 16 weeks pregnancy until infants are 12 months old (total of 44 sessions).
2. Usual antenatal and postnatal services.

Follow Up Length: 18 months
Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Phase I

Primary outcome(s)
Adult Adolescent Parenting Inventory (AAPI-2); Timepoints: Baseline (10-14 weeks gestation) and 18 months later when infants are 12 months

Key secondary outcome(s))
1. CARE index; Timepoints: Infant 12 months
2. Edinburgh Postnatal Depression Scale; Timepoints: baseline (10-14 weeks gestation), infant 2 months, infant 6 months, infant 12 months
3. EQ-5D 5L quality of life; Timepoints: Baseline (10-14 weeks gestation), infant 2 months, 6 months, 12 months
4. Medical Outcomes Study (MOS) social networks measure; Timepoints: Baseline (10 to 14 weeks gestation) and infant 12 months
5. Parenting Stress Index (short form); Timepoints: Infant 2 months and infant 12 months
6. Perceived Parenting Competence (PSOC); Timepoints: Infant 2 months, infant 12 months
7. Service use; Timepoint(s): Infant 2 months, 6 months and 12 months

Completion date

31/07/2016

Eligibility

Key inclusion criteria
1. Aged <20 with one or more previous live births, or
2. Aged 20-24 with low/no educational qualifications and no previous live births.

Low educational qualifications is defined as not having both Maths and English GCSE at grade C or higher or, if they have both of these GCSEs, no more than 4 GCSEs in total at grade C or higher.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Expectant mothers who have previously received home-based FNP
2. Expectant mothers with psychotic mental illness
3. Expectant mothers who are not able to communicate in English

Date of first enrolment
22/08/2013

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birkbeck, University of London
London
United Kingdom
WC1E 7HX

Sponsor information

Organisation
University of London (UK)

ROR
https://ror.org/04cw6st05

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) ref: PHR 11/3002/02

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Jacqueline Barnes (Jacqueline.barnes@bbk.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2017		Yes	No
Results article	results	01/11/2017		Yes	No

Protocol article	protocol	08/09/2013		Yes	No
HRA research summary			28/06/2023	No	No