Protocol for First Steps Study

Administrative information

1. Scientific title
FIRST STEPS STUDY: 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

Public title
The First Steps Study: to determine the effectiveness of the Group Family Nurse Partnership (gFNP) programme in improving parenting outcomes

2. Trial registration, International Standard Randomised Controlled Trial Register
ISRCTN78814904

3. Protocol version
Issue date: 25 October
Protocol amendment number: 2

4. Funding
The research costs are funded by the UK NHS National Institute for Health Research. Funds to train the nurses delivering the intervention programme are provided by the Family Nurse Partnership National Unit. Funds to deliver the programme are met by commissioners supporting each local Family Nurse Partnership team.

5. Roles and responsibilities
a. Protocol contributors
Professor Jacqueline Barnes (JB) Birkbeck, University of London
Dipti Aistrop (DA) Family Nurse Partnership Supervisor, Sheffield
Dr. Elizabeth Allen (EA) London School of Hygiene and Tropical Medicine
Professor Jane Barlow (JBw) University of Warwick
Professor Diana Elbourne (DE) London School of Hygiene and Tropical Medicine
Professor Geraldine Macdonald (GM)
Professor Edward Melhuish (EM) Birkbeck, University of London
Professor Stavros Petrou (SP) University of Warwick
Dr. Joshua Pink (JP) University of Warwick
Dr. Claire Snowdon (CS) London School of Hygiene and Tropical Medicine
Professor Helen Spiby (HS) University of Nottingham
Dr. Jane Stuart (JS) Birkbeck, University of London
Joanna Sturgess (JSs) London School of Hygiene and Tropical Medicine

JB conceived the study and is the project director. JB, EA, JBw, DE, GM, EM and SP all contributed to the study design and are grant holders. EA and DE provided trials and statistical expertise and EA will supervise the randomisation and conduct the primary analysis. SP and JP will conduct the economic evaluation. DA is providing practitioner input into the trial. JS is the trial manager and JSs is the Data Manager. HS is a grant holder and will support the integration of the trial with midwifery services. CS is co-grant holder of the embedded sub-study focussing on currently or previously 'Looked After' participants and will manage those qualitative methods. All authors contributed to refinement of the study protocol and approved the final manuscript.

b. Roles and responsibilities - Trial sponsor
Birkbeck College, University of London
Contact: Professor Jacqueline Barnes, jacqueline.barnes@bbk.ac.uk

c. Role and responsibilities - Study sponsor and funders
The funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data or decision to submit results. The funder will actively monitor the progress of the trial and will be informed with at least 28 days notice of any publication or presentation.

d. Roles and responsibilities - Committees
Principal Investigator and Trial Manager
Day to day management of the study
Preparation or protocol and revisions
Overseeing the trial, delegation of roles and responsibilities
Preparation of study materials and administration
GCP and regulatory compliance
Compliance to protocol
Budget
Communication to ethics and R&D
Management/policing of informed consent and blinding procedures
Trial monitoring
Quality control
Safety reporting (serious adverse events).
Data protection, participant confidentiality.
Organisation of steering committee meetings
Managing smooth running of the recruitment and data collection
Publication of study reports

Trial Management Group
Members – see page 1 for members
Agreement of final protocol
Reviewing progress of study and if necessary agreeing changes to the protocol to facilitate smooth running of the study

Trial Steering Committee
Independent chair:
Meg Wiggins, Social Science Research Unit, Childhood, Families and Health, Institute of Education, University of London
Independent members:
Chris Cuthbert, Head of strategy and development for under-ones, NSPCC
Professor Angela Harden, Institute for Health and Human Development, University of East London
Gerry Richardson, Humber Centre for Health Economics University of York
Professor Helen Roberts, General Adolescent and Paediatrics Unit, UCL Institute of Child Health
Investigators:
Professor Jacqueline Barnes
Dr. Jane Stuart
Any TMG member, ex officio
Observer: Mary Griffiths, FNP National Unit

Overall supervision for the study on behalf of the study sponsor and funder and to ensure that the study is conducted to the rigorous standards set out in the Research Governance Framework. In particular the TSC will concentrate on progress of the study, adherence to the protocol, participant safety and the consideration of new information of relevance to the research question. The TSC should provide advice, through its chair, to the Principal Investigator, the study sponsor, and the study funder.

Data Monitoring Committee
Independent chair:
Rona McCandlish (CQC)
Independent members:
Pollyanna Hardy (CTU, NPEU, University of Oxford)
Mike Robling (SEWTU), School of Medicine, Cardiff University
Investigators:
Dr. Elizabeth Allen
The only body that has access to the study data, their role is to monitor the data and make recommendations to the TSC on whether there are any ethical or safety reasons why the study should not continue, with the safety, rights and well-being of the study paramount. The DMC considers the need for any interim analysis and may be asked by the TSC, study sponsor of study funder to consider data emerging.

Introduction
6. Background and Rationale
a. Research question and relevant studies
This study will examine if provision of the Group Family Nurse Partnership (gFNP) programme, compared to routine antenatal and postnatal services, can reduce risk factors for maltreatment in expectant mothers aged <20 with one or more previous live births or expectant mothers aged 20-24 with low/no educational qualifications and no previous live births.

Recent estimates show that suboptimal parenting of infants is a major public health issue. Infants (children aged up to one year) account for 13% of children who were subject to a child protection plan in the England at 31 March 2012 [1]. The most common initial category of abuse for infants was neglect (49%) followed by emotional abuse (22%) and physical abuse (16%). Infants also face four times the average risk of homicide, perpetrators being parents in most cases [2]. Non-accidental head injuries are high resulting in up to 30% mortality and significant neurological impairment for survivors [3]. Furthermore, abuse of very young children may be up to 25% higher than indicated by official estimates [4]. In addition to preventing child injury and abuse, sensitive caregiving during the first few years is important for promoting optimal child outcomes because brain development is rapid then and vulnerable to negative influences [5]. Trauma and adverse early parent-child interactions elevate cortisol, a strong indicator of greater stress that can subsequently lead to attachment difficulties, hyperactivity, anxiety and impulsive behaviour [6,7].

There is little hard evidence available about 'what works' to support vulnerable parents during pregnancy and infancy but a US developed nurse home visiting programme, Nurse Family Partnership (NFP) has been identified as a programme that has be shown to reduce the later risk of child abuse. It is commonly named when examples of programmes with high quality evidence for success are sought. For instance, the US coalition for evidence-based policy, responding to a Congressional directive that funds be directed to programmes with top tier evidence of effectiveness identified only two programmes for children aged 0 to 6 and their families that could be thus categorized, one of which was the NFP [8]. The Blueprints mission of the '*Center for the Study and*

Prevention of Violence' was charged with identifying outstanding violence and drug prevention programmes that meet a high scientific standard of effectiveness and, out of 800 with published research found 12, one of which was NFP [9]. A similar conclusion was reached by academics seeking evidence-based home-visiting programmes likely to reduce child abuse and neglect [10].

NFP is offered now in England, known here as the Family Nurse Partnership (FNP) and is currently available in 50 locations with further expansion planned [11]. However, according to the US licence only low socio-economic status (SES) first-time mothers are eligible, identified in the UK as first-time mothers under 20 [12]. Group FNP (gFNP) is a newly developed programme, with the same theoretical basis and using the FNP curriculum but the provision is in a group, and the programme extends from early pregnancy only to the end of the first year of life. It is provided by trained nurses already skilled in providing FNP [13]. Following the success of group-based antenatal care such as the US Centering Pregnancy Model [14], reported to be preferred to traditional care [15,16,17] and leading to improved prenatal outcomes such as preterm births among high-risk women [18,19] the programme combines the provision of the FNP curriculum with midwifery care in pregnancy and infant health checks in infancy. Just like individual FNP, gFNP focuses on promoting secure mother-infant attachment, healthy lifestyles and increasing maternal confidence to make good decisions about relationships and life plans (e.g. whether to have another child, to take up education/employment, or to use other services)[13]. The use of the group context also helps mothers to develop social networks with other local mothers [20], and to benefit from peer-group learning. Meetings take place in Children's Centres helping families to become familiar with the other services and maintaining regular contact with other professionals when additional support is called for [21].

The NFP curriculum has strong theoretical underpinnings, both in terms of risk and protective factors, and mechanisms through which change may be produced [22] drawing from Ecological [23], Self-efficacy [24] and Attachment [25] theories. Ecological theory emphasises the importance of interactions between the characteristics of individuals and their contexts; self-efficacy theory concentrates on an individual's beliefs that they can successfully carry out behaviour required for good outcomes; and attachment theory highlights the importance of the mother-infant relationships. The cornerstone of the NFP model is the therapeutic nurse-client relationship. Beneficial outcomes found in US trials are: improved prenatal health, fewer childhood injuries, fewer subsequent pregnancies, increased interval between births, increased maternal employment and improved school readiness [26,27,28,29,30] and it has been shown to have the potential to be cost effective [31]. NFP is particularly beneficial for young and /or single women of low SES [32].

The NFP has been successfully implemented in the UK with evidence that the expected dosage and attrition can be attained [33,34,35]. While now offered in more than 50 sites in England with further expansion planned [11] there are mothers-to-be who might benefit from the FNP programme but who cannot receive the intervention, due to the eligibility criteria (no previous live births, low SES, under 20) [12]. Group FNP was developed in 2009, jointly by the Department of Health FNP National Unit and the US NFP National Office led by Professor David Olds as a way to use the expertise of the FNP nurses and the learning from the FNP to reach mothers who were as vulnerable but who were not eligible for FNP either through age (over 19) or parity (not first-time mother). In conjunction with a parallel process in the USA, the group FNP programme (gFNP) has been refined and piloted [13,20,21]. Implementation evaluation in England found that both the mode of delivery and materials were acceptable to clients and nurses [20,21]. Clients have, in addition to developing relationships with the FNs, developed close relationships with other group members and have used other services in the Children's Centres. The delivered content of gFNP has been close to NFP US National Office recommendations [36]. Thus the expectation is that gFNP is likely to be associated

with the same kinds of benefits as the individually delivered programme, which this trial is designed to demonstrate. However, in order to provide optimal information for service providers and commissioners, and to provide the most effective support for potentially vulnerable families, it is important that programmes be subject to rigorous randomised trials to provide evidence about efficacy and cost-effectiveness.

Risks and benefits for participants and society

There are no obvious risks to society of the study. While some expectant mothers will not receive the programme under investigation it is important to investigate whether it makes an identifiable impact. Up to this point the evaluation has been based on clients' perceptions of the impact but without a control group. It would be a greater risk to society to widely offer a programme without establishing that it has specific benefits. All research protocols will be developed with a view to promoting and protecting participant welfare including their dignity, rights, safety and well-being. A Clinical Advisory Group will be developed to ensure that the welfare of participants is paramount. The clinical advisory group will comprise individuals with appropriate specialist skills in terms of adult mental health and child protection. The advice of this group will be sought as regards all issues relating to the well-being of the study participants.

There will be benefits for the families involved whether they receive the programme or not. They will experience three research visits, with a small monetary recompense, plus one additional telephone contact, and will be able to talk about their early parenting. Any family thought to be in need of referral to specialist services will be urged by the research team to do this, through their GP or where relevant their Family Nurse and will be supported by the researchers.

b. Choice of comparator

The Healthy Child Programme Core Offer [37] is a substantial and universal service for expectant mothers and for their infants, for which there is a strong evidence base [38], supported by systematic review evidence and NICE guidance. It offers screening tests, immunisations, developmental reviews, information and guidance to support parenting. The latest version has a strong emphasis on pregnancy and the first year of life. Midwives and Health Visitors may provide or refer to a range of other community-based services designed to support young mothers but there is no consistently available comparator across England. A full record of all service use will be documented during the trial.

7. Research Objectives

Primary objective

To determine whether gFNP, compared to routine antenatal and postnatal services, can reduce risk factors for maltreatment in a vulnerable group, namely expectant mothers under 20 and a previous live birth or expectant mothers aged 20 to 24 with no previous live births and with low/no educational qualifications.

Secondary objectives

To determine whether provision of gFNP will enhance maternal physical and mental health in pregnancy and the experience of pregnancy and delivery for mothers and fathers and will enhance infant birth status and health status in infancy, breast feeding in the first two months, and immunisation take up during the first year.

To determine the feasibility and acceptability of gFNP and its cost-effectiveness as part of routine ante-natal and postnatal services.

8. Trial design
A multi-site randomised controlled trial in which eligible families are randomly allocated (stratified by site and maternal age group) to one of two arms i) gFNP delivered with 44 sessions over 76 weeks (N=100); ii) standard care (N=100). Mixed methods (quantitative and qualitative data) will be used to explore the experience of taking part in the trial.

Methods

9. Study setting
The gFNP programme is delivered in community settings such as Sure Start Children's Centres, located so that the amount of travelling necessary by group participants is kept to a minimum. Proximity to the location should enhance the rate of attendance and also foster the formulation of social networks. However, so that women from a potentially wider range of home addresses can be recruited to ensure the sample size, funds are available to reimburse intervention participants for travel by public transport to the intervention sessions. Child care is available for any older toddlers.

10. Eligibility criteria
Patients eligible for the trial must be expectant mothers prior to 23 weeks gestation with expected delivery dates (EDD) ideally within 6 to 8 weeks of each other, with the range of EDDs specified for each site in relation to the expected date of the first meeting so that the majority will have a gestation at identification of 13 to 20 weeks when the programme commences. Specific criteria beyond similar EDDs and gestation have been developed based on a formative evaluation [20, 21, 36] and on the requirement of the FNP National Unit that gFNP should only be offered to women not eligible for FNP, but who are likely to benefit from the content of programme, based on research in the USA [22,26]. Thus participants must be either <20 at LMP and having given birth to at least one child; or aged 20 to 24 at LMP with no previous live births and who do not have both Maths and English GCSE at C or higher or who have both English and Maths GCSE at Grade C or higher and no more than 2 other GCSEs at C or higher. To be entered into the trial, they must have given consent (see below).
Exclusions are: expectant mothers who have previously received home-based FNP, those with psychotic mental illness, those who are not able to communicate in English, and expectant mothers already enrolled in the study but who experienced fetal death and who are pregnant again during the recruitment period.

11. Planned intervention
The intervention is delivered by two members of the local FNP team of nurses, one also a qualified midwife, who have additional training for group work and are given additional supervision. The gFNP programme runs from the 16th week of pregnancy to when the babies are 12 months old, meeting weekly or fortnightly depending on the stage of the programme (14 pregnancy sessions and 30 infancy sessions), designed to end when infants reach their first birthdays. The group consists of between 8 and 12 women and partners are encouraged to attend. Each session last for 2 hours during which time specific curriculum content is covered and relevant routine medical checks according to NICE guidelines (mother in pregnancy, infant in infancy). Mothers are encouraged to take an active role in checking their own health and that of their infants.

The curriculum content domains mirror those of individual FNP, namely: personal health, maternal role, family and friends, life course, and environmental health. The relative time spent on each varies between pregnancy and infancy. The programme also focuses on links with other services. The mode of delivery is non-judgemental and positive, building on mothers' aspirations, using communication strategies based on motivational interviewing so that mothers can gain confidence in their capacity to parent and to plan their lives. The aims of the gFNP programme are to improve

birth outcomes, develop a warm and authoritative parenting style underpinned by good attachment and knowledge of babies' development and needs, effective local support networks through contact with other parents; increase take-up of local services and greater parental self-efficacy to make positive life choices and plan for the future. Any out-of-hours antenatal care is managed by the community midwifery team and intrapartum care is managed by the hospital/birth centre midwifery team.

Community-based services including those provided at Sure Start Children's Centres will be available to families in both arms antenatally and postnatally.

12. Outcomes (see Table 1 for summary of timings)
Primary outcomes (12 months postpartum)
i) The Adult-Adolescent Parenting Inventory-revised [39] is a 40 item self-report measure known to discriminate between abusive and non-abusive parents and includes the subscales 'inappropriate expectations of children, parental empathy to children's needs, use of corporal punishment, parent-child family roles and children's power and independence.
ii) The observational CARE-Index [40,41], based on a video recording of 3 minutes mother-child play, which measures three aspects of maternal behaviour (sensitivity; covert and overt hostility; unresponsiveness) and four aspects of infant behaviour (cooperativeness; compulsive compliance; difficultness; and passivity). These are highly correlated with attachment (Strange situation) and differentiate abusing from neglecting, abusing and neglecting, marginally maltreating, and adequate dyads. Scores range from 0 to 14, higher scores indicating better sensitivity and/or co-operation.

Secondary outcomes
i) Maternal depression (baseline, 2, 6 and 12 months postpartum) using the Edinburgh Postnatal Depression Scale [42], a well-validated 12 item measure of postnatal depression with high reliability (0.88) and internal consistency (0.87), 86% sensitivity and 78% specificity.
ii) Parental stress (2 and 12 months postpartum) using the Abidin Parenting Stress Index, Short Form [43], a well-validated measure of perceived stress in the parenting role with sound test–retest reliability (r = .84) and internal consistency (a = .91). High scores on the PSI have been associated with abusive parenting [44,45] with recent studies finding that parenting stress is higher in women with five or more risk factors for child abuse [46].
iii) Incidence of child abuse (maternal report) for: number of case conferences; children with Child Protection Plan in place; children removed from the home.
iv) Attendance at hospital A&E departments for non-accidental injuries or ingestions of toxic substances using HES data and data from GP records extracted at 12 months postpartum.
v) Maternal health-related quality of life using the EuroQol EQ-5D-3L [47] measure at baseline, 2, 6 and 12 months postpartum.
vi) Social support (baseline and 12 months) using the MOS Social Support Survey [48].
vii) Parenting sense of competence assessed with the PSOC [49] at 2 and 12 months.
vii) Use of local resources using questionnaires designed specifically for this study.
xi) Qualitative interviews conducted after completion of the programme with a sub-sample of intervention arm participants will explore acceptability of the programme and perceived benefits.
x) Qualitative interviews conducted after completion of the programme with a sub-sample of control and intervention arm participants and partners who have experience of being 'looked after' by their local authority will explore their perceptions of the programme, or any impacts, and other support needs.

13. Participant timeline

Figure 1 provides details of the timeline for each participant, which will extend from the time that they book in with their midwife to report their pregnancy (on average at 8 to 12 weeks gestation) through to the end of the study, when their infants are at least 12 months old. The specific time will vary depending on their gestation at booking but will range from 82 to 86 weeks. The intervention arm will experience the gFNP programme for 76 weeks on average (from 16 weeks gestation to infant 12 months).

14. Sample size

The sample size was calculated on the basis of Scores on the Adult Adolescent Parenting Inventory (AAPI-2) [39]. The standard deviation (SD) of the AAPI-2 is 10, with differences of 6.7 identified in the normative sample between abusive and non-abusive adult females [39]. For this individually randomised trial, we propose to recruit sufficient mothers and babies (families) to allow the trial to detect a difference between groups of 0.5 standard deviations, with 90% power at a significance level of 0.05 (2-tailed); this is considered to represent a moderate size of effect [50]. Very conservatively assuming a correlation of 0.4 between pre and post intervention scores we would need at least 71 families in each arm of the trial to detect this difference. Conservatively, allowing for an expected 30% drop out rate (based on the first two applications of the programme in England) we would therefore need to recruit a minimum of 84 families per arm of the trial. We therefore propose to recruit 100 families per arm. In the intervention arm this will consist of 10 groups of (generally) 10 families (N=100). Based on the assumption that uptake will be in the region of 1:3 and, on the basis of recruitment at two pilot sites, there will need to be 60 eligible women to take part in the study at each participation centre for each group. Prior to becoming a site for the study each area have provided information on births to women in the target age group/parity over the previous year so that it could be demonstrated that there are likely to be sufficient for the recruitment of between 8 and 12 women to each arm of the trial over a period of 8 weeks.

The proposed sample size would similarly allow us to detect a change of approximately 0.5 standard deviations in the CARE index. The standard deviation for the CARE index is expected to be around 2.3 [51]. We would therefore expect to be able to detect a difference at follow up between arms of the trial of approximately 1.2 with 90% power and a 5% level of significance.

15. Recruitment

Recruitment will be time-dependent in that a minimum number of trial participants must be recruited in each centre for each group, namely at least 16 and ideally 20 (8-10 intervention and 8-10 control) participants over a period of 8 weeks, with expected delivery dates (EDDs) that are within 10 weeks of each other as a maximum spread, ideally a smaller range. The success of recruitment to the trial will depend on a number of factors including existing effective enrolment pathways from community midwifery and other relevant sources (e.g. GPs) for the home-based Family Nurse Partnership programme in each local centre, community midwives who are willing and able to identify eligibility based on age and parity, and ideally to ask 20 to 24 year olds about their educational qualifications, effective processes for timely communication between midwives and researchers and a willingness of local professionals to participate in a research programme. To ensure that this is likely, meetings have been held between the research PI, the lead for gFNP from the FNP National Unit and local professionals including the FNP team, midwifery managers, commissioners and R&D representatives. The main focus of discussion has been on estimating local numbers of women who are likely to meet criteria and ways to strengthen information sharing in a timely manner. Feedback has been variable about the extent to which midwifery staff will be able or open to asking a question not usually covered in the booking-in process, that of educational qualifications. Thus the researchers will establish this aspect of eligibility for 20 to 24 year olds.

The research team re-visited each centre to arrange meetings with midwifery staff, managers and other relevant staff to explain both the gFNP programme and the purpose of the trial. The researchers will be local so that they can communicate regularly with local midwifery and other potential referral sources about any issues in terms of information sharing

In the recruitment process, the main strategy was that midwives would identify women at each clinic using the initial criteria of age, parity and gestation To this end they were provided with 'aide memoire' cards specifying the age and parity criteria and the EDD range for their site. Proximity to the location should enhance the rate of attendance. However, so that women from a wider range of home addresses can be recruited, funds are available to reimburse intervention participants for travel to the group sessions.

Midwives will give standard information about research happening in the clinic, providing a brochure describing the First Steps study and ask women for agreement to give their names and contact details to the local researcher as part of a staged consent process, using an 'agreement to contact' form.

The first phase of recruitment revealed that most community midwives, for a range of different reasons, did not tell women about the study and provided contact details for very few participants. To address this in the first instance FNP midwives and CLRN or trust research nurses with access to midwifery records accessed booking records, located potentially eligible women, telephoned then and gained oral agreement for the research team to be contacted. This amendment to procedure has been supported by the Study Steering Committee and approved by the Study Sponsor's Ethics Committee and the decision conveyed to the REC.

In addition, researchers have obtained letters of access from PIC sites (where these are different to the Service delivery Trusts for which they already have letters of access) and will sit in waiting rooms for pregnancy scan clinics and pregnancy booking clinics, handing out study leaflets to generate interest in the study. Any interested mother-to-be will be asked to complete and sign an 'agreement to contact' form in the same way as the approved procedure so that they can subsequently be telephoned by the researcher to arrange a home visit.

Amendments to be submitted to the REC include placing a poster in locations where women meet with community midwives (GP practices, Children's Centres, hospitals) and involving CLRN and PCRN research nurses in the process of checking booking appointments to identify potentially eligible women. In one site the CLRN nurses will, once permission is gained, take full informed consent for the study.

One result of this new strategy is that the start of all groups has had to be delayed and will not take place until October and November 2013 (see Table 2). Second, to allow for careful plans to be made for alternative strategies for the second round of recruitment, the second groups will not start until March and April 2014, making a delay in total for the start of all groups of three months. The whole timeline has been revised accordingly. This change will necessitate fieldworkers being employed for 30 months rather than the 28 in the current budget. Other costs for the project team will also need adjusting by 2 months with the completion of the final report by March 2016 instead of January 2016, and the total time 38 rather than 36 months.

Those agreeing to be contacted will be telephoned by the local researcher. If necessary the researcher will screen 20 to 24 year olds for educational qualifications. Those not eligible are

thanked for their time. Those who are eligible will be given further information about the trial, and time to think about participation. After at least 24 hours, the researcher will telephone and if telephone agreement is given the researcher will make a home visit, gain written consent and collect baseline data. The local researcher will then provide information about what services are available in their area (usual care) reminding all to maintain contact with community midwifery and remind about future data collection points. A card will be left with a prepaid envelope so that the participant can inform the research team of any change of address or other change in circumstances.

Randomisation will allow secure blind allocation of eligible participants to one or other arm of the study. The local researcher will telephone the central randomisation service provided by Health Services Research Unit (HSRU) Aberdeen to randomise the participant, giving identifying details and sufficient prognostic detail to allow randomisation. Minimisation criteria will be used to ensure a balance of key prognostic factors using the following two criteria: site and age group. Following random allocation the local researcher will be given the study number but will remain blind to allocation. Allocation will be conveyed securely from HSRU Aberdeen to LSHTM CTU. LSHTM CTU will inform all participants by first class post of their allocation to the intervention or control arm of the study.

For women in the intervention arm, the LSHTM team will inform the relevant FNP team by fax, confirmed by fax, of the women in the intervention arm so that the gFNP intervention can be initiated. This process will continue until at least 16 and no more than 24 women have been recruited in each site for the first delivery of gFNP.

If a second group is to be offered in the same location, a second round of recruitment will take place 2-3 months later repeating the same procedure.

16. Allocation to groups
a. Consenting mothers-to-be will be randomly allocated to one of two arms. The allocations will be computer generated by HSRU Aberdeen and overseen by the LSHTM CTU. Allocation will be minimised by centre and by age group (<20, 20-24) at LMP.
b. The allocation will be generated by telephone but the researcher will remain blind to allocation, being given only a study number.
c. The allocation to the intervention or control arm will be generated by the HSRU Aberdeen and conveyed securely to London School of Hygiene and Tropical Medicine CTU.

17. Blinding
This is a partially blinded study. Allocation is concealed for recruitment and for all data collectors. The families cannot be blind.

18. Data collection methods
a. Quantitative data (summarised in Table 1) will be collected for both the intervention and control arms of the study by field workers blind at baseline to the study group, in the participants' homes, when their gestation is between 10 and 16 weeks. The data will comprise a range of self-report questionnaires. Further home visits will be made when participants' infants are 2 and 12 months old with a telephone contact when infants are 6 months old. At 12 months postpartum, data collection will also include independent video-recorded observations of the mother and infant. Researchers will administer questionnaires orally where required with the anticipation that some participants may have low levels of literacy. Response cards will be used for questions that have a range of possible responses. Researchers will be trained together to ensure that similar methods are used in

all locations and the Trial Manager will accompany them on a percentage of home visits throughout the study to maintain quality.

At the end of the study, routinely collected hospital episode statistics (HES) data will be accessed for information on all hospital health service activity during the period between randomisation and 12 month postpartum. HES data cover hospital in-patient, outpatients, and accident & emergency attendances.
Missing data in longitudinal studies of vulnerable populations are often associated with frequent changes of address. In a trial of a less intensive intervention targeting a similar population of pregnant women with risk factors [52], the intervention and control arms had high (and roughly equivalent) retention drop-out rates from baseline to follow-up at 12 months (97% intervention; 91% controls). In the proposed study there will be three contacts during the child's first year, which should maximise retention of the control group without unduly influencing the outcomes. In both intervention and control groups, participants will be asked to notify the research team using a provided change of address card, and contact details of a close relative will be requested.

As a further strategy to limit attrition, both intervention and control group participants will be given 'High Street' vouchers for £20 at each home-visit data collection point (baseline, 2 months postpartum and 12 months postpartum) and a £10 voucher after the 6 month telephone contact as acknowledgement of their contribution, and to promote compliance. The team has extensive experience of discussions with ethics committees about this issue, with agreement that provision of vouchers is both appropriate and acceptable (e.g. for National Evaluation of Sure Start, FNP, and Home-Start). This will not have an impact on any state benefits received.

In addition, details of changes of address of intervention group families will be maintained through contact with the intervention administrative staff. Reasons for all forms of attrition from the intervention will be carefully documented. Although maximum attendance rates would increase the likelihood of finding an impact of the programme, it is not the role of the research team to ensure attendance at the groups. Nevertheless, this is part and parcel of gFNP; any mother not attending a meeting is contacted by the FNP nurses to encourage maximum attendance and given any assistance necessary. Also gFNP nurses contact the routine universal care providers to ensure that any women dropping out of the programme then accesses the Healthy Child Programme. If a research contact reveals that a mother has dropped out, and has not informed the gFNP team, then they will contact the relevant gFNP supervisor.

b. For the intervention arm only, data are collected by the Family Nurses as part of programme delivery, documenting attendance, involvement in the sessions, and both timing and reasons if the mother decides to stop using the service. This information, anonymised, will be shared electronically with the research team throughout programme delivery.

c. Qualitative interviews will be conducted throughout the study with selected professionals in the local areas to ascertain the extent to which the referral pathways could be strengthened, the likelihood that the service may be successfully embedded in the area and its likely sustainability. These interviews will take place after all recruitment has taken place in each local area through semi-structured recorded interviews with professionals likely to be involved in making referrals to the programme (in total at least 5 community midwives and at least 5 other relevant health professionals such as GPs). At the completion of programme delivery in each area interviews will also be conducted with at least 5 commissioners of children's services and with 10 professionals who are providers of care for 'looked-after' young people.

After the completion of programme delivery in each centre, so that the research does not influence their experience of the intervention, at least 1 Family Nurses will be interviewed per centre and each FNP supervisor will be interviewed about their thoughts on delivering the programme and its likely sustainability. They will also be asked about the particular relevance of the gFNP programme for women or men who have a 'looked-after' history or who are currently under the care of social services.

After completion of programme delivery in each group, so that the research does not influence their experience of the intervention or their responses to outcome measures, participant views about the acceptability of the programme will be assessed using semi-structured face-to-face interviews with a purposive sample (informed by programme delivery data) of 20 woman who were allocated to receive gFNP support and 5 of their partners.

After completion of programme delivery in each group, so that the research does not influence their experience of the intervention or their responses to outcome measures, interviews will be conducted with up to 10 women allocated to receive gFNP (excluding those specified in the previous paragraph) who are or who have a history of being looked after and, if available, their partners, and a similar number of women allocated to standard care.

All qualitative interviews for the main study will be transcribed and analysed thematically, using content analysis [53]. For the interviews with women and their partners with a look-after history using a computer aided qualitative data analysis package, working in the tradition of interpretive phenomenology which seeks to represent the experiences of the research participants in context [54].

19. Data management

Signed consent forms and contact details of participants will be stored initially in a locked drawer in researcher's homes. Consent forms will be brought to Birkbeck by hand monthly at which time they will be stored in numerical order in a secure and accessible place. They will be retained in storage for a period of 3 years after completion of the study. Contact details will be stored in an on-line, password protected, database.

All LSHTM data will be managed and stored in compliance with ICH GCP 1996 following trial specific standard operating procedures (SOP) as given in the trial master file, and in accordance with LSHTM Information Management and Security Policy and LSHTM Data Protection Policy.

Anonymised original paper study forms will be scanned and pdf files stored on encrypted data stick and the originals sent from the local researchers to the Data Coordinating centre at LSHTM. Data will be entered into a database and validated through double entry. Queries will be recorded, logged and tracked until resolution in line with the data management SOP. Encrypted data sticks will be brought to London by hand at intervals and files deleted once it has been established that the data have been received by LSHTM.

Anonymised data will be stored securely at the LSHTM and separately from any information identifying participants. Paper forms will be stored in numerical order in a secure and accessible place and will be maintained in storage for a period of 3 years after completion of the study.

Electronic data will be stored as csv files and Stata data files (.dta) in LSHTM data centres which provide appropriate levels of environmental and physical security on servers that are managed in accordance with LSHTM Systems Management Policy. Confidential information will be registered with LSHTM Archivist and Records Manger and data will be stored on a secure server which

maintains an audit trail demonstrating system access. A centralised network backup service is used. All data will be stored in accordance with LSHTM Data Protection Policy.

20. Statistical methods

a. Outcomes

Statistical analysis will be carried out at the individual level. Every effort will be made to obtain outcome measures on participants, even if some drop out during the course of the group sessions.

The primary analysis will use intention-to-treat where all participants are included in the group to which they were assigned. A complier average causal effect (CACE) analysis will also be carried out [55]. The CACE analysis will estimate a measure of the effect of the intervention on those participants who received it as intended by the original allocation. Although intention-to-treat analysis is recognised as the gold standard approach to the analysis of randomised controlled trials, a CACE analysis is a useful addition to assess effectiveness

Tabulation of demographic and other characteristics will be done using the intention-to-treat datasets. No significance tests will be performed to test for differences at baseline. Descriptive statistics for continuous variables will include the mean, standard deviation, median, range and the number of observations. Categorical variables will be presented as numbers and percentages.

The data will be analysed by multiple regression modelling, with appropriate generalised linear models (GLMs) used to examine the effect of the intervention, fitting baseline measures of outcomes as covariates, where available. A small number of secondary analyses based on explicit hypotheses, e.g. subgroup (including 'looked after' history)/explanatory analyses (considering compliance with the interventions) will be specified in advance. The secondary analyses will include an analysis in which the small groups in which the intervention is delivered will be fitted as a random effect.

Sensitivity analyses will be conducted for all primary outcomes. Inverse probability weighting would be considered if missing data were larger than expected and/or there was differential attrition between the trial arms. Additionally reasons for the differential attrition would be fully explored

b. Economic evaluation

A prospective economic evaluation, conducted from a NHS and personal social services perspective, will be integrated into the trial. The economic assessment method will, as far as possible, adhere to the recommendations of the NICE Reference Case [56]. Primary research methods will be followed to estimate the costs of the delivering gFNP, including development and training of accredited providers, the cost of delivering the group sessions, participant monitoring activities, and any follow-up/management. Broader resource utilisation will be captured through two principal sources: (i) routine health service data collection systems described above; and (ii) patient questionnaires administered at baseline, 2 months postpartum, and 12 months postpartum with a telephone contact at 6 months to minimise loss of information due to recall difficulties. Unit costs for health and social care resources will largely be derived from local and national sources and estimated in line with best practice. Primary research using established accounting methods may also be required to estimate unit costs. Costs will be standardised to current prices where possible.

Maternal health-related quality of life, measured at baseline, 2 months postpartum, 6 months postpartum and 12 months postpartum using the EuroQol EQ-5D-5L [47] will be converted into health utilities using established utility algorithms [57] for the purposes of quality-adjusted life year

(QALY) estimation. The results of the economic evaluation will primarily be expressed in terms of incremental cost per QALY gained. Non-parametric bootstrap estimation will be used to derive 95% confidence intervals for mean cost differences between the trial groups and to calculate 95% confidence intervals for incremental cost effectiveness ratios [58]. A series of sensitivity analyses will explore the implications of uncertainty on the incremental cost-effectiveness ratios and will consider the broader issue of the generalisability of the results. One such analysis will adopt a societal perspective incorporating direct costs to trial participants and their partners, informal care provided by family and friends, and productivity losses. In the baseline analysis, and for each sensitivity analysis, cost-effectiveness acceptability curves will be constructed using the net benefits approach [59]. More extensive economic modelling using decision-analytic methods will extend the time horizon of the economic evaluation, drawing on best available information from the literature together with stakeholder consultations to supplement the trial data. Parameter uncertainty in the decision-analytic model will be explored using probabilistic sensitivity analysis. Longer term costs and consequences will be discounted to present values using discount rates recommended for health technology appraisal in the United Kingdom [56]. Given the plethora of outcome measures across several domains for the mother, child and broader family, a separate discrete choice experiment (DCE) will be conducted. The possibility of combining the outputs of the DCE with cost estimates and changes in relevant outcomes within a cost-benefit analysis framework will be explored.

c. Process

Additional statistical analyses will focus on the process evaluation. Specifically any available characteristics of study participants and those who gave agreement for a contact but declined to participate will be identified and contrasted with those of the wider population in the study areas. The representativeness of recruited families will be assessed by analysing anonymised data for each expectant woman who potentially could have been approached (i.e. irrespective of whether they gave agreement for their name to be given to the researcher): age; parity; in relation to their acceptance or rejection of the agreement for researcher contact.

The uptake rate of women who agree to the intervention will involve an assessment of the ratio of women randomised to receive the intervention who then attend at least one session relative to those who either refuse after meeting with the Family Nurse or who agree but never attend any sessions.

The study attrition rate will be estimated in terms of the proportion of women who drop out relative to those who continue in either arm of the trial and also those who may or may not take part in research visits but cease to receive the intervention, based on information provided by the nurses delivering the programme. The extent to which the programme is being delivered with integrity: will be assessed though analysis of anonymised data from the programme's standardised data forms documenting attendance, the content domains covered in each session and participants' responses to the content, comparing the information with recommendations for delivery from the US National Office and from the UK FNP National Unit.

21. Data monitoring

An independent Data Monitoring Committee (DMC) has been established, whose remit is to review the trial's progress. Interim analyses will be supplied, in strict confidence, to the DMC, as frequently as its Chair requests. The terms of reference and a DMC charter [60] will be agreed at their first meeting. Meetings of the committee will be arranged periodically, as considered appropriate by the Chair. In the light of interim data on the trial's outcomes, adverse event data, accumulating evidence from other trials and any other relevant evidence (including updated overviews of the relevant

randomised controlled trials), the DMC will inform the Trial Steering Committee (TSC) if in their view there is proof beyond reasonable doubt that the data indicate that any part of the protocol under investigation is either clearly indicated or contra-indicated, either for all infants or for a particular subgroup of trial participants. Unless modification or cessation of the trial is recommended by the DMC, the TSC, investigators, collaborators and administrative staff (except those who supply the confidential information) will remain ignorant of the results of the interim analysis. Collaborators and all others associated with the study may write to the DMC via the Trial Co-ordinating Centre, to draw attention to any concern they may have about the possibility of harm arising from the treatment under study.

22. Harms
Serious adverse events (fetal death, neonatal death, infant death, any hospitalisation of mother or infant other than for delivery, congenital anomaly or birth defect, persistent or significant disability, death, maternal death) will be recorded using the NHS National Patient Safety Agency form and reported by the PI to the DMC and the Multicentre Research Ethics Committee who gave a favourable opinion. Mothers who suffer a fetal or infant death will be sent a letter offering condolences, thanking for their contributions thus far, asking whether they wish to receive the results when available, and whether or not they wish to continue to provide data for the trial. The data collection forms will be modified appropriately.

23. Auditing
Regular audits will be conducted to confirm consent processes and study procedures are followed and all consent forms are properly signed, dated, and stored at the study main site (Birkbeck), and that good clinical practice standards are maintained.
All data are monitored using central statistical monitoring for consistency, viability and quality.

Ethics and dissemination

24. Research ethics approval has been given (28 May 2013) by the NRES Committee South West – Frenchay.
25. Protocol amendments will be communicated to the NIHR and to the Research Ethics Committee giving approval.

26. Consent
Local researchers employed by the trial sponsor, Birkbeck, University of London and given all the necessary training, with full CRB clearance, Good Clinical Practice certificates and with appropriate Trust approval prior to working with the study population including a research passport, will gain written consent from trial participants.
Participants will be informed that they can withdraw at any time without giving a reason. Outcome data will continue to be collected from participants who wish to withdraw from the intervention unless specifically requested otherwise; similarly, outcome data which have already been collected from participants who wish to withdraw from further involvement in the study will continue to be used in the analysis, unless specifically requested.

27. Confidentiality
For the purpose of recruitment local researchers and the Trial Manager at Birkbeck will, with the consent of the mother, store their names and any other identifying detail in an on-line password-protected database which will be the only data linking participants to the study ID number.

Electronic outcome data will be stored at LSHTM in a password protected electronic database in which the mother and baby will be identified only by a study specific number.
When data are shared with The University of Warwick for economic analysis, at the end of data collection, those data will also be stored in a password protected electronic database in which the mother and baby will be identified only by a study number.
All participants will be informed that their responses will not be shared with local service providers or any other professionals but that be made aware that we are obliged by the requirements of the Children Act (1989) to inform the appropriate authorities in the event that any member of the research team is made aware of any dangers to a participating infant/child. NHS staff engaged in providing care to participants in the trial will continue to follow local guidelines for clinical care and safeguarding policies.

28. Declaration of interests
None of the study investigators has any financial interests in the outcome of the trial.

29. Access to data
In due course, will we make the data available on an open access site such as http://datadryad.org/pages/depositing so that it links with the published paper.

30. Dissemination policy
To safeguard the scientific integrity of the trial, data from this study will not be presented in public before the main results are published without the prior consent of the TSC. When the results of the trial have been established the findings will be published in peer reviewed journals according to CONSORT guidelines [61, 62] and disseminated to all the study participants in a format that is accessible.

Abbreviations

A&E	Accident and Emergency unit in hospital
CQC	Care Quality Commission
CTU	Clinical Trials Unit
CRB	Criminal Records Bureau
DCE	Discrete choice experiment
DH	Department of Health
DMC	Data Monitoring Committee
EDD	Expected delivery date
FN	Family Nurse, trained to deliver FNP
FNP	Family Nurse Partnership home-visiting programme (UK)
GCP	Good clinical practice
GCSE	General Certificate of Secondary Education
gFNP	Group-based Family Nurse Partnership
GP	General Practitioner
HES	Hospital Episode Statistics
HSRU	Health Services Research Unit
ISRCTN	International Standard Randomised Controlled Trial Number
LAC	Looked after child, in care of Social Services
LMP	Last menstrual period
LSHTM	London School of Hygiene and Tropical Medicine
MOS	Medical Outcomes Study
NICE	National Institute for Health and Clinical Excellence
NFP	Nurse Family Partnership, the original US developed home visiting programme, renamed FNP in the UK
NHS	National Health Service
NIHR	NHS National Institute for Health Research
NPEU	National Perinatal Epidemiology Unit
NSPCC	National Society for the Prevention of Cruelty to Children
PI	Principal Investigator
QALY	Quality adjusted life year
RCT	Randomised Controlled Trial
SES	Socioeconomic Status
SOP	Standard operating procedures
TMG	Trial Management Group
TSC	Trial Steering Committee
UCL	University College London

References

1. Department for Education (DfE): *Statistical first release SFR27/2010.* London: Department for Education; 2012.
2. Home Office: *Crime in England and Wales 2001/2002: Supplementary volume*. London: Home Office; 2003.
3. Dias MS, Smith K, de Guehery K, Mazur P, Li V, Shaffer ML: **Preventing Abusive Head Trauma Among Infants and Young Children: A Hospital-Based, Parent Education Program**. *Pediatrics 2005,* **115:**470-7.
4. Sidebotham PD and the ALSPAC study team. **Patterns of child abuse in early childhood, a cohort study of the "Children of the Nineties**. *Child Abuse Review*. 2000, **9:**311-320.
5. Allen G. *Early intervention: the next steps*. London: Cabinet Office, 2011.
6. Gunnar MR, Donzella B. **Social regulation of the cortisol levels in early human development.***Psychoneuroendocrinology* 2002,**27:**199-220.
7. Schore AN. **Attachment and the regulation of the right brain** *Attach Hum Dev* 2000,**2:**23-47.
8. Council for Excellence in Government (CEG) [Internet] 2009 *Coalition for evidence-based policy. Top tier evidence initiative: evidence summary for the Nurse-Family Partnership*.[http://ceg.files.cms-plus.com/Evidence/NFP%20-%20Summary%20for%20website%2012.3.08.pdf]
9. Blueprints [Internet]. *Model Programs*. Denver, Colorado: Centre for the study and prevention of violence; University of Colorado 2010. [http://www.colorado.edu/cspv/blueprints/modelprograms.html]
10. Macmillan HL, Wathen CN, Barlow J, Fergusson DM, Leventhal JM, Taussig HN: **Interventions to prevent child maltreatment and associated impairment**. *Lancet* 2009,**373:**250-66.
11. Department of Health (DH)*:* **More help for disadvantaged families**.in press.[http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_121040]
12. Hall D, Hall S. ***The "Family-Nurse Partnership": developing an instrument for identification, assessment and recruitment of clients***. Research report DCSF-RW022. London: DCSF 2007.
13. Barnes J. Evaluation of a group support program based on the Nurse Family Partnership model. Paper presented at: R.E. Ross Trust and Murdoch Children's Research Institute conference Empowering parents, empowering communities. Using evidence in family-centred practice. 2011 Apr 15, Melbourne, Australia.
14. Rising S. **Centering pregnancy: in interdisciplinary model of empowerment**. *J Nurse Midwifery* 1998,**43:**46-54.
15. Ickovics JR, Kershaw TS, Westdahl C et al. **Group prenatal care and preterm birth weight: results from a matched cohort study at public clinics.** *Obstet Gynaecol* 2003,**102:**1052-7.
16. Ickovics J, Kershaw T, Westdahl C, Magriples U, Reynolds H, Rising S. **Group prenatal care and perinatal outcomes: a randomized controlled trial**. *Obstet Gynaecol* 2007,**110**:330-9.
17. Robertson B, Aycock DM, Darnell LA .**Comparison of Centering Pregnancy to traditional care in Hispanic mothers**. *Matern Child Health J* 2009,**13**:407-14.
18. Grady MA, Bloom KC. **Pregnancy outcomes of adolescents enrolled in a Centering Pregnancy program**. *J Midwifery and Women's Health* 2004,**49:**412–20.
19. Williams KJ, Zolotor A, Kaufmann L. **Does group prenatal care improve pregnancy outcomes?** *JFP 2009*,**58**:384a-c.
20. Henderson J, Barnes J. Interim report on recruitment and the pregnancy phase of the formative evaluation of the group-based antenatal care project. Unpublished report to the Department of Health. London: Birkbeck University of London, 2010.
21. Henderson J, Barnes J. Interim report on early infancy phase of the formative evaluation of the group-based antenatal care project. Unpublished report to the Department of Health. London: Birkbeck, University of London, October 2010.

22. Olds D,Kitzman H,Cole R,Robinson J**. Theoretical foundations of a program of home visitation for pregnant women and parents of young children.** *J Com Psych* 1997**, 25:**9-25.
23. Bronfenbrenner U. *The ecology of human development: experiments by nature and design.* Cambridge, MA: Harvard University Press, 1979.
24. Bandura A. **Self-efficacy: toward a unifying theory of behavioural change.** *Psychological Review,*1977, **84**:191-215.
25. Bowlby J. *Attachment and loss. Volume 1. Attachment.* New York: Basic Books; 1969.
26. Olds DL. **The Nurse-Family Partnership: an evidence-based preventive intervention.** *Inf Mental Hlth J* 2006, **27:**5-25.
27. Olds DL, et al**. Long-term effects of home visitation on maternal life course and child abuse and neglect. Fifteen-year follow-up of a randomized trial.** *JAMA* 1997, **278:**637-43.
28. Kitzman H, et al. **Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing. A randomized controlled trial.** *JAMA* 1997, 278, **8**:644-52.
29. Eckenrode J, et al. **Long-term effects of prenatal and infancy nurse home visitation on the life course of youths 19-Year follow-up of a randomized trial**. *Arch Pediatr Adolesc. Med*, 2010, **164:**9-15.
30. Olds DL, et al. **Effects of home visits by paraprofessionals and by nurses: age-four follow-up of a randomized trial**. *Pediatrics* 2004,**114**:1560-8.
31. Aos S, Lieb R, Mayfield J, Miller M, Pennucci A. *Benefits and costs of prevention and early intervention programs for youth.* Olympia WA: Washington State Institute for Public Policy; 2004.
32. Olds DL, Henderson CR Jr, Chamberlin R, Tatelbaum R. **Preventing child abuse and neglect: a randomized trial of nurse home visitation.** *Pediatrics* 1986,**78:**65-78.
33. Barnes J, Ball M, Meadows P, McLeish J, Belsky J, FNP Implementation Research Team. *Nurse-Family Partnership: First year pilot sites implementation in England. Pregnancy and the post-partum period*. London: DCSF; 2008.
34. Barnes J, Ball M, Meadows P, Belsky J, FNP Implementation Research Team. *Nurse-Family Partnership Programme: Second year pilot sites implementation in England. The infancy period*. Research report DCSF-RR166. London: DCSF; 2009.
35. Barnes J, Ball M, Meadows P, Howden B, Jackson A, Henderson J, Niven L. *The Family-Nurse Partnership Programme in England: Wave 1 implementation in toddlerhood and a comparison between Waves 1 and 2a of implementation in pregnancy and infancy*. London: DH; 2011.
36. Barnes J, Henderson J. Summary of the formative evaluation of the first phase of the group-based Family Nurse Partnership programme. London: Department of Health, 2012.
37. Shribman S, Billingham, K. Healthy Child Programme. **Pregnancy and the first five years. London:** Department of Health, 2009.
38. Hall D, Elliman D: *Health for all children* (4th Ed.) Oxford: Oxford University Press; 2006.
39. Bavolek SJ. (1999) Research and Validation report. Adult-Adolescent Parenting Inventory. Park City, Utah: Family development resources.
40. Crittenden PM. CARE-Index: Coding Manual. Unpublished manuscript, Miami, FL.
41. Crittenden PM. **Abusing, neglecting, problematic, and adequate dyads: Differentiating by patterns of interaction.** *Merrill - Palmer Q* 1981, **27:** 201-218.
42. Cox JL, Holden JM, Sagovsky R: **Detection of postnatal depression: Development of the 10-item Edinburgh postnatal depression scale**. *B J Psych* 1987, **150:**782-6.
43. Abidin R. *Parenting Stress Index (3rd Edition): Professional Manual*. Lutz, Florida: *PAR*, Inc. 1995.
44. Lacharite C, Ethier LS, Couture G: **Sensitivity and specificity of the Parenting Stress Index in situations of child maltreatment.** *Canad J Behavioral Science* 1999, **31:**217–20.

45. Mash,EJ, Johnston C, Kovitz K. **A comparison of the mother-child interactions of physically abused and non-abused children during play and task situations**. *J Clin Child Psychol* 1983,**12**:337-346.
46. Nair P, Schuler ME, Black MM, Kettinger L, Harrington D. **Cumulative environmental risk in substance abusing women: Early intervention, parenting stress, child abuse potential, and child development**. *Child Abuse & Neglect* 2003, ***27***:997-1017.
47. Brooks R. EQ-5D, the current state of play. *Health Pol* 1996, 37: 53-72.
48. Sherbourne CD, Stewart AL. **The MOS social support survey.** Soc Sci Med 1991, **32**:705-14.
49. Johnston, C. & mash, E.J: **A measure of parenting satisfaction and efficacy**. *J. Clin Child Psychol. 1989, **18:**167-175.*
50. Cohen J. *Statistical Power Analysis for the Behavioral Sciences, Second edition*. Hillsdale, N.J.: Erlbaum; 1988.
51. Cramer B, Robert-Tissot C, Stern DN et al: **Outcome evaluation in Brief Mother-Infant Psychotherapy: a preliminary report.** Inf Mental Hlth J 1990, **11**:278-300.
52. Barnes J, MacPherson K, Senior R. (2006) **The impact on parenting and the home environment of early support to mothers with new babies.** *J Child Services*, **4**:: 4-20.
53. Robson C: *Real World Research. 3rd Edition.* Chichester: John Wiley & Sons; 2011.
54. Lopez KA, Willis DG. **Descriptive Versus Interpretive Phenomenology: Their Contributions to Nursing Knowledge**. *Qual Health Res* 2004, 14:726-735.
55. Dunn G, Maracy M, Tomenson B. **Estimating treatment effects from randomised clinical trials with non-compliance and loss to follow-up: the role of instrumental variable methods.** *Stat Methods Med Res* 2005, 14:369-396.
56. NICE. *Guide to the Methods of Technology Appraisal*. London: NICE, 2013.
57. Dolan P: **Modelling valuations for EuroQoL health states**. *Med Care* 1997,**35:**1095-108.
58. Barber JA, Thompson SG: **Analysis of cost data in randomized trials: an application of the non-parametric bootstrap**. *Stat Med* 2000, **23**:3219-36.
59. Stinnett AA, Mullahy J. Net health benefits: a new framework for the analysis of uncertainty in cost-effectiveness analysis. *Med Decis Making* 1998, 18(2 Suppl):S68-80.
60. Damocles Study Group. A proposed charter for clinical trial data monitoring committees: helping them to do their job well. *Lancet*. 2005, **365**:711-722.
61. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010, **340**:c332.
62. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol* 2010, **63**:e1-37.

Table 1: Details and Timing of Data Collection

Measure	**Baseline, gestation 10-14 weeks**	**Infant 2 months, home visit**	**Infant 6 months, telephone interview**	**Infant 12 months, home visit**
Demographics	X	X (update)	X (update)	X (update)
Adult-Adolescent Parenting Inventory (AAPI-2)	X			X
Edinburgh Postnatal Depression Scale (EPDS)	X	X	X	X
Quality of Life (EQ-5D 5L)	X	X	X	X
Smoking and Alcohol use	X	X (update)		X (update)
Drug use	X	X (update)		X (update)
Infant feeding	X (plans)	X	X	
Relationship violence	X			X
Social networks (MOS)	X			X
Service use		X	X	X
Parenting Stress Index Short Form (PSI)		X		X
Immunisations		X		X
Perceived Parenting Competence (PSOC)		X		X
CARE index				X

Figure 1. (Flow of Participants)

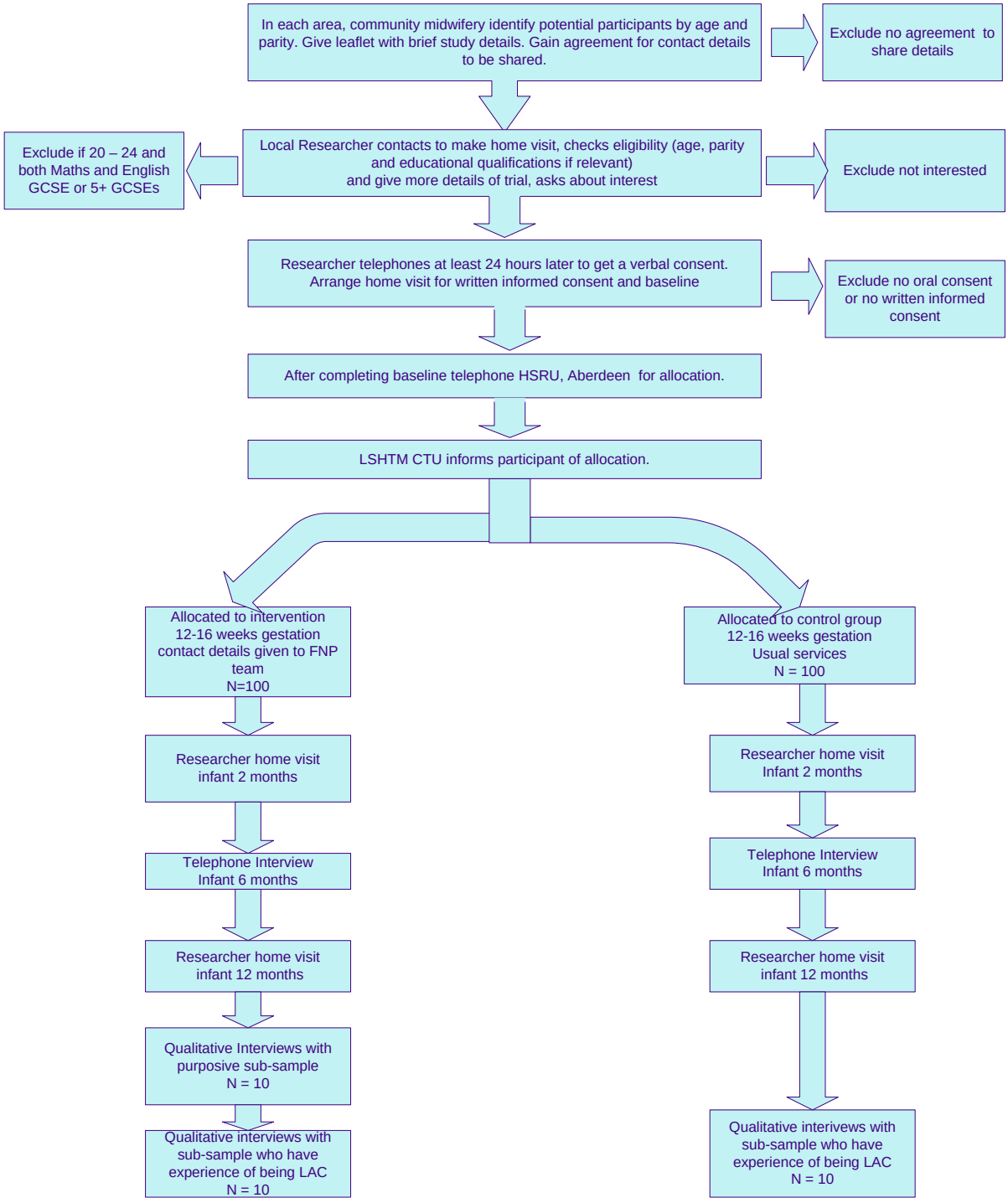

Figure 2. Work flow - First Steps Study, RCT of Group Family Nurse Partnership

	2013											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Finalise measures, NHS REC												
NHS R&D												
Recruitment and Baseline												
(gFNP Programme begins) group #										1 - 4	5 -7	
Consolidate recruitment pathways												
Milestone						1			2			
	2014											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Recruitment and Baseline												
(gFNP Programme begins) group #			8 - 11	12 -14								
Interviews, recruitment professionals												
Analyse recruitment data												
(Births) group #			1 - 4	5 - 7				8 - 11	12 - 14			
2-3 m home interviews, group #					1 - 4	5 - 7				8 - 11	12 - 14	
6 m telephone interviews, group #									1 - 4	5 - 7		
Data cleaning												
Milestone			3			4					5	

	2015											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
6 m telephone interviews, group #		8 - 11	12 - 4									
(gFNP Programme ends) group #			1 - 4	5 - 7				8 -11	12- 14			
12-13 m home interviews, group #			1 - 3	4 - 6	7			8 -10	11 - 13	14		
Interviews, FNs & supervisors												
Client qualitative (2 subsamples)												
Interviews with professionals, LAC												
Data coding cleaning												
Analysis and report writing												
Milestone										6		
	2016											
Complete and submit final report												
Milestone			7									