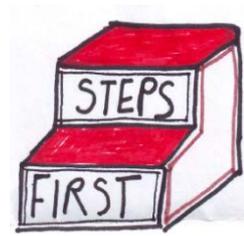


Process evaluation documents (Chapter 5)

1. Qualitative interview consent form
2. Participant information sheet
3. Participant interview topic guide
4. Family Nurse information sheet
5. Family Nurse interview topic guide



First Steps Randomised Trial of gFNP

Consent form for qualitative interview participants

(Please tick each box)

- 1 I confirm that I have read and understood the information sheet dated November 4, 2014 for the above study and have had the opportunity to ask questions and have had these answered satisfactorily.
- 2 I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without any of my legal rights being affected.
- 3 I agree to the interview being audio taped. I understand that I can ask for the recorder to be switched off at any time without giving a reason.
- 4 I understand that direct quotes may be used in the study write up but that they will be anonymised so that no individual or location can be identified.
- 5 I understand that the information which I provide will be treated in confidence and that it will not be shared with any person outside of the research team.
- 6 I agree to take part in the above study.

Name _____ (PLEASE PRINT) Date

Signature _____



First Steps Study

Participant, Qualitative Interview Information Sheet

The study

We are inviting you to take part in one additional part of the First Steps study. Before you decide it is important to understand why this part of the research is being done and what it would involve. Please take the time to read the following information carefully. It explains why this part of the research is being done and what it will mean for you. A researcher will go through it with you and answer any questions. Feel free to discuss it with friends, relatives, or anyone else you normally talk to. **Part 1** tells you the reason for the interview and what will happen if you take part. **Part 2** gives you more details about the way the study is managed.

Part 1

What is the purpose of the interviews?

The Group Family Nurse Partnership (gFNP) programme is a new service. To find out if this new service can make a difference we are comparing families receiving the support with others who were receiving usual services. The purpose of this part of the research is to give participating families the opportunity to tell us in more detail about the things that they like and found helpful about the service, and the things that were not so useful.

Why have I been invited to take part in the study?

After you agreed to be part of the First Steps study you were allocated to receive gFNP support. You have already been approached to complete up to three structured interviews as part of the study. We are now asking a small number of the mothers and their partners, including those with a range of different experiences of the programme, to talk to us in more detail about the experience of being offered the Group Family Nurse Partnership programme. Whether you chose not to attend the programme, just attended a few sessions, or attended a lot of sessions, we are interested in your views about the programme. There are no right or wrong answers; we would like to hear your views in your own words.

Do I have to take part?

It is up to you to decide whether to take part. You can keep this information sheet and you will be asked in a day or so if you would like to sign a consent form agreeing to take part in the

interview. If you do agree you are free to withdraw at any time, without giving a reason. Taking part will not affect the standard of medical or other care you receive.

What will happen to me if I take part?

If you decide to take part, one of the study researchers will visit you at your home or a location of your choosing at a time of your choosing, and will ask you what you thought about the material covered in the sessions, whether you thought they made any difference to the way you are bringing up your baby, your relationship with other group members, and any ideas that you have for improving this type of support. The interview will allow you to talk in your own words, as much or as little as you like and to mention any other topics that you think important and will take about 30-40 minutes depending on how much you have to tell us. To allow the interview to be more natural, and avoid note taking it will, with your agreement, be recorded and the conversation typed out later - with any names altered to make sure that they cannot be recognised. After the interview we will give you a £20 shopping voucher as a thank you for your time.

You may also be asked if you would share the name of your partner so that they can also be asked to take part in a similar interview, covering the same topics.

What are the possible disadvantages and risk of taking part?

There should not be any disadvantages or risks to you of taking part in the interview. We find that most mothers enjoy talking about their experiences during pregnancy and during the first few years of their child's life. If you do find any question difficult to answer you can stop the interview, or move on to other topics.

What are the possible benefits of taking part?

This is a new way of supporting mothers and fathers expecting a new baby so your views and experiences will be important in helping us to understand what parents found useful or not about gFNP.

What if there is a problem?

Any complaint about your experiences during the study or any possible harm you might suffer will be addressed. Details about this are given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We follow ethical and legal practice and all information about you will be handled in confidence. The details are included in part 2.

This completes Part 1. If the information in Part 1 about the interview study has interested you and you are thinking about taking part, please read Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the interview?

If you agree to take part and then do not want to carry on with the interview you can just tell the researcher, who will then stop the interview. You do not have to give a reason. You can also ask for the recording to be stopped at any time without giving a reason. Your health services and other services will not be affected.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the researchers who will do their best to answer your questions. You can do this by contacting Jacqueline Barnes at 0207 079 0837. If you remain unhappy and wish to complain formally you can do this by using the NHS complaints procedure <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/NHScomplaints.aspx> making your complaint to your local health trust.

Will my taking part in this study be kept confidential?

Information about you will be kept strictly confidential and any identifying information such as your name and address will be removed so that you cannot be recognised. Participants are identified in computer records only by a number. No one outside the research team is given access to the information. According to Data Protection guidelines after research reports are written and published the information is kept for five years, then disposed of securely by shredding paper documents and cleaning computer storage. Audio recordings made during the research will be used only for analysis. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.

No information about you will be shared with any other agency except where UK law requires otherwise. What this means is that if you say something to the researcher in the interview that suggests you or your infant are at risk of harm or in immediate danger, or if you tell them about thoughts of harming yourself, then the research team will need to share this information with a professional involved in your care so that additional help can be arranged. You will be told if this occurs.

What will happen to the results of the research study?

The results of the study should be available about six months after the study ends. This will probably be in the Autumn of 2016. We will keep you informed about progress and share the main findings, through newsletters, twitter or other electronic means, and local meetings. The results will be presented in government reports, in academic journals and in other formats for non-academic audiences.

Who is organising and funding the research?

The Institute for the Study of Children, Families and Social Issues at Birkbeck, University of London is leading the research and the NHS National Institute for Health Research is

funding the research. If you have any questions please do not hesitate to contact us at the telephone number or address given below.

Who has reviewed the study?

Before funds were given for the study the NIHR obtained independent expert reviews of the plans. All research in the NHS is also looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. It was approved in May 2013 by the South West Frenchay Committee in Bristol.

Thank you for reading this.

Institute for the Study of Children, Families and Social Issues

Birkbeck, University of London

Malet Street, London WC1E 7HX

020 7079 0823, fax 020 7079 0827

For any enquiries e-mail: firststepsinfo@bbk.ac.uk

Intervention participant qualitative interview topic guide

Interview to be structured around the topics below but allowing for conversation to be as natural as possible. Questions designed to guide the conversation rather than to be followed as a question and answer process.

1. Attendance at gFNP sessions

- Were you able to attend the group?
- *[If none attended]* Can you tell me a bit about why you did not go to any gFNP sessions?

- *[If any sessions attended]* Approximately how many sessions did you go to (or until what stage, pregnancy or after baby born)?
- Did your partner attend at all? If so, about how many sessions did he go to?
- Was there anything that made it more or less likely he would go to sessions?
- Were there any particular reasons when you missed a session?
- Did you have any transport difficulties, getting to the group?

- *[If stopped attending part-way through]*
 - Can you tell me why you stopped attending the gFNP sessions?
 - Have there been other services or support that you have used since you stopped attending the gFNP groups?
 - How about family members or friends? Have they given support?
 - Can you tell me something about how any other types of support compare with what you experienced with gFNP?
 - Did this meet your needs?
 - Did you think about returning to gFNP at any time, for example, once your baby was born if you stopped in pregnancy, or once our baby became more active in infancy?

IF NO ATTENDANCE AT gFNP THEN SKIP TO QUESTION 7

2. Views on group activities

- Are there any topics or activities that you have found to be particularly useful and/or enjoyable?
- Have you been able to raise issues that you are particularly concerned about in the group? Such as your baby becoming upset if you leave him/her with another adult, or problems with weaning or eating solids?
- Could you be honest in the group, saying what you were really thinking?
- Have you mentioned things there that you have not told other people before?

3. Overall impact of the programme

- Have any of the topics influenced the way you or your partner are with your baby, or ways that you have coped with things such as crying, sleeping, weaning or any other behaviour?
- Have any of the topics influenced the way that you think about parenting in general, about bringing up children and how things might be in the future?

4. On a scale from 1 to 10 can you rate the difference going to the group has made to the way you are looking after your baby?

1 = not at all, not learned anything new and have lots of other support anyway

10 = made all the difference in the world, it has helped me to be much more confident in the way that I care for my baby than I might have been

1 _____ 2 _____ 3 _____ 4 _____ 5 _____ 6 _____ 7 _____ 8 _____ 9 _____ 10

Can you tell me a bit more about why you made that rating?

For example

- Are there things you would have liked to learn about that were not covered?
- Are there things about caring for a baby that you were worried about before you went to gFNP sessions?

5. Relationships in the group

- Now that you have finished your involvement in the gFNP programme, what do you think about:
 - The Family Nurses running the group, what has your relationship with them been like over time? Was there any difference in your relationship with the Family Nurse midwife and the other Family Nurse?
 - And your relationship with other mothers or fathers in the group?
 - Do you have any special friends among the group members? If yes are you still in touch with them?
- What do you think about the way that the group works? For example are there any members who took up a lot of the time talking about their own issues, so you did not get a chance to say what you wanted?
- Are there things about being with other mums with similar aged babies that make the group especially helpful?

6. Overall thoughts about gFNP

- Would you recommend Group FNP to others?
- If you could change anything about the way that the group is organised or the programme delivered what would it be?
- If you were asked to tell someone else about the group FNP programme, what would you say?

7. Support offer as part of a research trial

- You may remember that we are offering the group sessions as part of a large research project and that, at the moment, this is the only way that people can take part in this type of group. Do you think that joining and/ or taking part in the groups would be different if groups were routinely available for young pregnant women?

8. Final thoughts

- Is there anything else that you would like to say about gFNP, or any of the other support that you have received while you were pregnant or up to your child's first birthday?



First Steps Study

Family Nurse Qualitative Interview Information Sheet

The study

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it will involve for you. A researcher will go through the information sheet with you and answer any questions you have. This should take about 5 to 10 minutes. You may want to talk to others about the study. Part 1 of this sheet tells you the purpose of the study and what will happen if you take part. Part 2 gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear.

Part 1

What is the purpose of the study?

The research study is an evaluation of the impact of offering the Family-Nurse Partnership programme in a group, comparing families offered the support with those receiving usual services. The study is completely independent and separate from the actual service provision. If you do not wish to take part in the research, your employment as a Family Nurse will not be affected in any way.

Why have I been chosen?

You have been involved in delivering the Group Family Nurse Partnership programme in one of the seven sites that have been part of the First Steps study. The delivery of gFNP for the First Steps Study has now been completed in your location.

Do I have to take part?

No. You do not have to take part in this research, which is completely independent and separate from the service provision. If you agree to take part you can withdraw at any time without having to give a reason and your decision will not affect your ongoing employment as a Family Nurse. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form to indicate that you agree to being interviewed.

What will happen to me if I take part?

If you agree you will be asked to take part in one interview lasting about 45 minutes to one hour. It can take place at the FNP team office or at any other convenient location of your choice. Questions will be open-ended so that you can talk in your own words, as much or as little as you like. You will be asked about recruiting participants, your thoughts on the Family Nurse Partnership group and the way it

works, how the group participants responded to the group setting, any changes that you perceived in parents or children and its strengths and weaknesses in your opinion. Questions will also cover your thoughts on reasons why some participants may have left the group and the potential for gFNP to be provided in the future. **We will not ask you to discuss named individuals.**

To allow the interview to be more natural, and avoid note taking, it will be audio-recorded and the conversation typed out later – with any names altered to make sure that individuals cannot be recognised. You can ask for the audio recording to be stopped at any time without having to give a reason. The information provided in your interview will not be shared with your employer or with your co-workers. Instead themes will be drawn out to assist in understanding the results of the First Steps study.

What are the possible disadvantages and risks of taking part?

There should not be any disadvantages or risks to you. We find that most practitioners enjoy talking about their work experiences. If you do find any question difficult to answer you can stop the interview, or ask to move on to other topics.

What are the possible benefits of taking part?

This is a new way of supporting mothers expecting a new baby and you are among the first practitioners in this role so your views will be important in finding out how the service is working and what its potential impact may be for parents and children. This should be of benefit to other practitioners and families in the future, guiding policy and practice.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in part 2.

This completes Part 1

If the information in Part 1 has interested you and you are thinking about taking part, please read the additional information in Part 2 before making any decision.

First Steps RCT study of Family Nurse Partnership Groups

Family Nurse Participant Information Sheet

Part 2

What will happen if I don't want to carry on with the study?

If you sign the consent form and then do not want to carry on then let the researcher know and you will not be contacted for an interview. If you start the interview and then want to stop then let the researcher know. You do not have to give a reason and your employment with the Trust as a Family Nurse will not be affected in any way.

What if there is a problem?

If you have a concern about any aspect of this study you can contact the study Director Jacqueline Barnes at 0207 079 0837. If you remain unhappy and wish to complain formally you can do this through your NHS Trust, first contacting your local FNP supervisor and then your Human Resources department.

Is the information confidential?

Information about you will be kept strictly confidential and will have any identifying information such as your name removed. Participants are described in all research information only by a number and no one outside of the research team is given access to the information. Information is kept until research reports are written and published and then retained for five years after the completion of the study, at which time it is disposed of securely by shredding any paper documents and cleaning computer storage. No information about you will be shared with any other agency.

What will happen to the results of the study?

The results of the study should be available a few months after all the groups have finished in each of the seven sites of the study, which will probably be in the Autumn of 2016. All quotes and other information will be anonymised so that the respondent cannot be identified. Results of the study will be presented in professional journals and in other formats for non-academic audiences.

Who is organising and funding the research?

The Institute for the Study of Children, Families and Social Issues at Birkbeck, University of London is conducting the research and the NHS National Institute of Health research, Public Health Programme is funding the research. If you have any questions please do not hesitate to contact us on firststepsinfo@bbk.ac.uk or 0207 079 0823.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the South West (Frenchay) Research Ethics Committee.

Thank you for reading this

Topic Guide, Qualitative Interview, Family Nurse

Interview to be conducted in a conversational style, covering the topics listed below but letting the discussion be as natural as possible.

A. Participation

We are interested in what might influence participation and retention over the course of the gFNP programme

1. What has attendance been like?

For the women? For their partners?

2. What are your views about a realistic attendance rate and a realistic group size?

3. Can you identify any client or partner characteristics or situations that have led to more or less attendance?

Prompts: Physical health; Mental health; Target child's health/behaviour; Other children in family; Other family responsibilities; Employment

4. What other factors do you think had an impact on attendance?

Prompts: Weather; Time of year; Location; Availability of transport public/private; Topics being covered; Other group members

5. Have you had to take any specific actions to increase retention? If so which do you think were the most effective?

Prompts: Home visits to clients; Telephone calls to clients; Arranging transport; Change of venue/adaptation of venue; Change of day or time; Adapting content

B. Encouraging Self care

One aspect of the Centering Pregnancy approach incorporated into gFNP is that women are considered to be active contributors in the sessions in order that they can learn from each other.

6. What was your experience of the women being active in their routine midwifery care?

Prompts: What do you think about this aspect of gFNP? Did you encourage this? How did the clients in your groups respond? Did anything surprise you about this aspect of gFNP? Is there anything else that you want to mention about self-care in pregnancy?

7. And once the babies were born, what are your thoughts about encouraging mothers and fathers to be involved in checking their baby's development?

Prompts: How well did this work in your groups? Were there any difficulties? Do you think there are some benefits to this, and could there be any drawbacks?

C. Possible impacts of gFNP

8. What are your thoughts about providing midwifery care in the groups. Do you think this had any impact for group members on antenatal health, or their experience of labour and delivery?

Was there any aspect of the midwifery care that was particularly relevant?

Prompts: Encouraging women to carry out checks? Seeing one midwife regularly?
Knowing they could contact their FN midwife with queries?

9. Have you noticed ways that taking part in gFNP has contributed to mothers' confidence with their infants? (details)

And to fathers' confidence? (details)

10. Are there any materials or other resources that were particularly relevant to any perceived impacts on confidence?

If specific resources are names, ask why they seemed especially effective?

11. Can you now think about the ways mothers (and fathers) managed any aspect of their infants' behaviour (e.g. crying, sleeping, feeding, weaning, misbehaviour)?

Are there ways that you think gFNP materials or discussions had an impact you have noticed on parents dealing with these or other aspects of their child's behaviour?

If so which materials or other resources content of the sessions, comments from other members of the group, were particularly relevant to having an impact?

12. Were any impacts you noticed on parenting related to specific parent characteristics (e.g. age, whether partner attended, first time parent etc.)

13. As well as parenting, the programme is designed to have an impact on child health and development. In your opinion has taking part in gFNP contributed to the health and development of the infants?

Prompts infant health: Infections; Immunisations; Appropriate weight; Healthy diet; Smoke free home; Safety, accidents

Prompts infant development: Language; Gross motor skills (e.g. more outdoor play); Cognitive (e.g. more stimulation); Sociability (e.g. able to play with other children); Behaviour

14. Are there any other impacts that you have noticed for the parents, or the infants?(details)

D. Delivery and Sustainability

15. Can you sum up what the experience of delivering gFNP has been like for you?

Prompts:

Did the training cover the issue of having couples in the group?

Did the training prepare you for other circumstances (e.g., parent with Looked After history; parent who had experienced domestic violence; parent with mental health difficulties?)

Did you feel well prepared for gFNP after your training?

How has the delivery of this programme compared with other group work that you have done in the past?

Have you been able to encourage all group members to participate orally?

Have you been able to engage the partners?

Have you been able to respond spontaneously to clients while at the same time maintaining the coverage for the session?

Are there any of the materials that stand out as working really well, and as such generate much discussion in the group?

Are there some clients who are very well suited to this kind of support?

Are there some clients who would have been better served with a different kind of support?

16. What are your thoughts about how gFNP using this model of delivery (two FNP Family Nurses, one of whom is also qualified as midwife) or the Phase 3 model (one FN, with community midwife followed by Family Support worker) could be integrated more smoothly with other services and mainstreamed?

Prompts: Recruitment pathway; Numbers of potential clients; Links with midwifery to cover midwifery care if the FN is not available; Restriction in sites that can offer gFNP; Staffing, e.g. to cover absence or sickness

17. Finally, is there anything I have not covered that you would like to talk about?

Many thanks for your time.