

First Steps Recruitment documents - agreement for contact form, study information sheet, and consent forms



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AGREEMENT FOR CONTACT DETAILS TO BE SHARED

I agree to my contact details being shared with Birkbeck, University of London so that I can be approached to hear more about the First Steps study.

Name [please print] _____

Signature _____

Today's date _____

Date of Birth _____

ADDRESS [including full postcode]

Home telephone _____

Mobile _____



First Steps Study

Participant Information Sheet

The study

We are inviting you to take part in a research study. Before you decide it is important to understand why the research is being done and what it would involve. Please take the time to read the following information carefully. 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. It explains why the research is being done and what it will mean for you. **Part 1** tells you the reason for the study 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 study?

The Group Family Nurse Partnership (gFNP) programme is a new service where two nurses give information, support and medical care to a group of about 10 young mothers, starting in pregnancy and going on until their babies are one year old. Partners are also encouraged to attend. Since it is new it is important to find out if it can make a difference before deciding if it should be offered to more families. A team at Birkbeck, University of London is leading a study to answer this question. The study will compare two groups. Some will have the usual NHS care; others will have usual NHS care and will also receive gFNP support.

The nurses providing gFNP are known as Family Nurses and work only with young families.. The support begins when mothers are around 16 weeks pregnant, meetings are weekly for four weeks then every fortnight until the babies are born. Then meetings are weekly again for six weeks and fortnightly until babies are one year old. Routine medical care is provided in pregnancy by the Family Nurses if one is also a midwife, or by a community midwife who attends the group in pregnancy. They encourage mothers to learn how to

understand their own care, for example by listening to their baby's heartbeat. After babies are born routine infant health checks such as weighing are provided by both Family Nurses. Since everyone in the group is due at about the same time, parents can learn together.

It is important to understand that if you agree to be part of the study you will not be able to choose which group you are in. You may be in the group that has the usual NHS care and you may be in the other group that has the usual NHS care and also the gFNP programme. This decision is made by a random computer process (a bit like flipping a coin) which helps to make sure that both groups are very similar to start with. Doing the study this way means that we can be surer that any differences between the groups when babies are one year old are because one group has received the gFNP programme.

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

You live in one of the seven areas around England where gFNP is being made available and you are in the right age group. Either you were aged under 20 when you became pregnant and have already had one or more children, or you were 20 to 24 when you became pregnant and you are expecting your first child.

Do I have to take part?

It is up to you to decide. 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 research. If you do consent 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 take part there will be one interview with a researcher at your home lasting about 40 minutes getting background information. She will tell you whether you will receive the gFNP programme or usual NHS care. If you are in the group receiving gFNP your contact details will be given to the local gFNP team who will contact you with details of when and where the gFNP sessions will take place. These would start when you are about 16 weeks pregnant and continue until your baby is 12 months old.

Everyone in the study in both groups is contacted again for a second research interview when their babies are 2 months old to see how they are coping with their new baby. This will also last about 40 to 45 minutes. When babies are about 6 months old, there will be a telephone interview lasting about 20 to 25 minutes. At the end of the study, after your baby's first birthday we will make one last visit. At this time, in addition to an interview lasting about 40 to 45 minutes we will ask you to sign a second form saying that you agree to a short video being made of you and your baby playing together.

After each of the three home interviews we will give you a £20 shopping voucher to show our appreciation for your time and after the telephone interview we will send you a £10 shopping voucher.

Some mothers will also be asked, after their baby is one year old, whether they would agree to take part in a more open-ended conversational interview that will be audio-recorded. Another voucher for £20 will be given after this interview.

What are the possible disadvantages and risk of taking part?

There should not be any disadvantages or risks to you. We find that most mothers enjoy talking about their experiences during pregnancy and as they raise their new baby. 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 working out if gFNP can make a difference. Without that information it is not likely to be made available to more families across the country.

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 is handled in confidence. The details are included in part 2.

This completes Part 1.

If the information in Part 1 about the 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 study?

If you agree and then do not want to carry on in the study, let the researcher know. You do not have to give a reason. Your health 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, 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. Any audio and/or video 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 an 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.

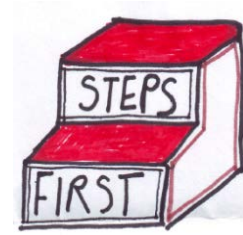
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First Steps Study

Consent form for research participants

(Participant id number for this study: _____)

(Please tick each box)

1. I confirm that I have read and understood the information sheet
2. I confirm that I am willing to take part in this research study
3. I understand that my participation in the study is voluntary
4. I understand that when my baby is one year old I will be asked to give my permission for the researcher to make a short video (3 minutes) of me playing with my child
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 understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the research team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records for the purpose of monitoring the research.

Name _____ (Please print) Date _____

Signature _____



First Steps Study



Additional consent form for videoing research participants (to be completed at 12 month visit)

(Participant id number for this study: _____)

As part of this study, we would like to make a short video tape (3minutes) of you playing with your baby.

If you decide to take part in this part of the study, we will give you a copy of the video that we make.

(Please tick each box)

1. I confirm that I am willing to take part in making a short video tape
2. I understand that my participation is voluntary
3. I give permission for the researcher to make a short video (3 minutes) of me playing with my child after his/her first birthday
4. I would like a copy of the video once it has been made
5. I understand that the video which I provide will be treated in confidence and that it will not be shared with any person outside of the research team.

Name _____ (Please print)

Date _____

Signature _____