



Newcastle Birthing Centre

Postnatal Infant Care (PInC) Trial

Information for parents planning on giving birth in Newcastle Birthing Centre

- We would like to invite you to take part in our research study.
- Joining the study is entirely up to you, this booklet will help you to understand why the research is being done and what it would involve for you.
- Please read this information booklet to help you decide if you may want to take part and if you have any questions.
- We suggest that it should take about 15 minutes.
- Please feel free to get in touch if have any questions or discuss the study with your midwife and other family members if you wish. You can find the contact details at the back of this booklet.

Aims

- We are trying to find out how parents look after their new-born babies in Newcastle Birthing Centre and how we might make this easier.
- In order to find out how parents care for their babies in the Birthing Centre we would like to record video and sound of parents looking after their babies after they've given birth. We are interested in looking at behaviours such as: feeding, sleeping , touching and crying.
- We would also like to find out whether using a portable cot or a standalone cot affects the way parents look after their babies in the Birthing Centre.
- Anyone who delivers their baby in Newcastle Birthing Centre and has some intention of trying to breastfed is able to take part in the study. If you sign up for the study but do not end up giving birth in the Birthing Centre, you will be automatically withdrawn and your personal details destroyed.

Overview of the project

If you agree to take part in the study and deliver your baby in Newcastle Birthing Centre you will receive either:

A portable cot for your baby (figure 1)

OR

A standalone cot for you baby (figure 2)

It doesn't matter which cot you are given the care that you receive will be **exactly the same**.

After you have given birth, you will be asked to turn on the video camera so that we may record how you care for your baby in the Birthing Centre. We would like you to keep the camera on for the whole time you are in the Birthing Centre however you will be able to turn the camera on and off if you wish throughout your stay. The video data we collect will only be seen by the research team. The trial fits in with your normal care, so there are no extra hospital visits and the care you receive will be exactly the same whether you take part in the study or not.



Image used with permission from The Newcastle Hospitals NHS Foundation Trust

Figure 1. Portable cot



Image used with permission from The Newcastle Hospitals NHS Foundation Trust

Figure 2. Standalone cot

Eligibility

In order to be able to take part in this study you must:



Be able to give birth in
Newcastle Birthing Centre



Be planning to give
birth for the first time



Have some intention to try and
breastfeed your baby

This study is being run in Newcastle Birthing Centre, so you will only be able to take part if you deliver your baby there. Please discuss your birth options with your midwife and decide if giving birth in Newcastle Birthing Centre is an option for you.

What does taking part involve?

1. If you decide that you want to take part you will need to fill in a consent form saying that you are happy to participate in the study. You should find a copy of the consent form in this booklet.
2. You will need to discuss participation in the study with the person who will be staying in the Birthing Centre after birth with you to see if they are happy to take part as well, they will need to sign a consent form too.
3. Once you've signed the consent form you should put it in your personal maternity record so that we can collect it when you are in labour. Don't worry if you lose or forget your consent form we can send you a new one or give you another one when you come into Newcastle Birthing Centre.

Study Participation:

Stage 1 - Immediately after birth

- After you have given birth you will be randomly given either a standalone cot **or** a portable cot for your baby.
- When you are ready you can turn the camera on and you can leave it recording for the rest of the time that you are in Newcastle Birthing Centre.
- Information about your birth and the postnatal period is routinely collected by midwives, with your permission we will access your maternity record to find out some of this information. We do this so we do not have to disturb you whilst you are staying in the Birthing Centre.

Stage 2 - Up to 1 week after your Birthing Centre stay

- A researcher will come and visit you before you are discharged from the Birthing Centre to ask you a few questions about your experience staying in the Birthing Centre.
- If it is not possible to visit you in the Birthing Centre then you will be contacted by phone to complete the interview about your experiences.
- This interview will be recorded by the researcher using a Dictaphone.

Stage 3 - 6-8 weeks after birth

- As part of your routine care a health visitor will visit you to check up on your baby at around 6-8 weeks after birth. Upon receipt of full consent, we will use this data to find out how your baby is fed.

You can stop taking part in the study at any time, without giving a reason.

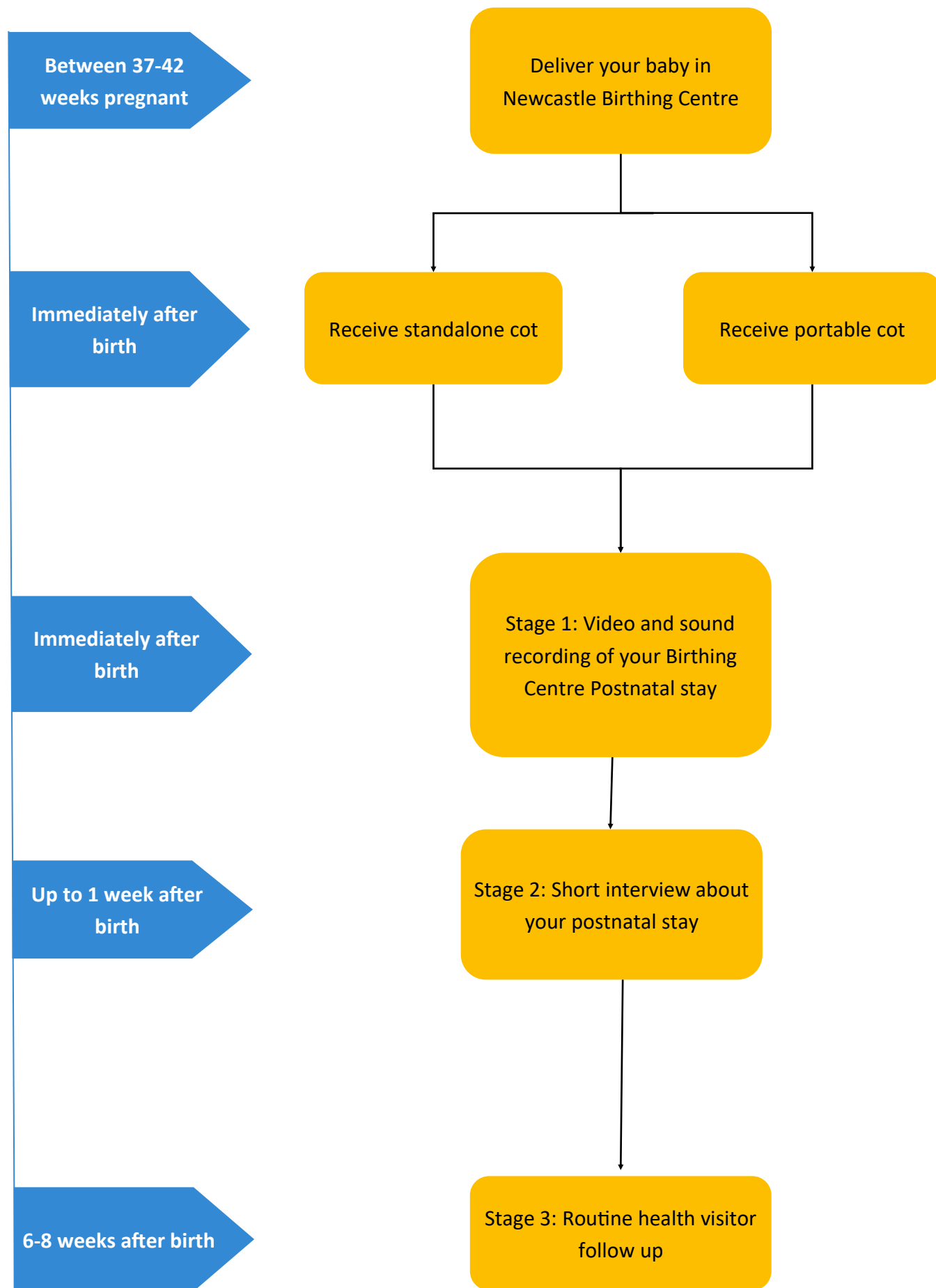


Figure 3. Timeline of your participation in the study

Why do we use video and sound recording?

Using video and audio to record behaviour can be useful because it allows us to see what people are actually doing rather than relying on what they can remember when they are tired after birth. Previously, video studies have been useful in understanding how people look after their babies, enabling health professionals to support parents where they really need it.

Using video as a research tool means that we can understand how you and your baby are behaving without having to disrupt you in an important time. It also helps us to understand how you and your baby behave when you are sleeping. We record sound so that we can hear the noises that your baby makes, such as fussing, crying and suckling.



Figure 3. The camera that we use is a small CCTV camera which will be attached to the ceiling in Newcastle Birthing Centre.

What do we do with your video and sound recordings?

If you wish you will be able to watch your video and you may ask for sections to be removed if you do not want them to be included in the study. If you feel like you are not happy with your video being used in the study at all you can withdraw your consent at any time and we will delete your video from our records.

Once we've recorded your video it will be stored on secure password-protected Durham University computers and they will be analysed using computer software. After the study has ended your personal data will be destroyed however anonymised video data will be retained for the purposes of possible further analyses by our research team for up to 10 years.

We may use still images from your video recording in publications or presentations but all images will be fully anonymised, with faces blurred and covered to ensure that you or your baby cannot be identified. We will also ask if you would be happy with us using small clips from your video in scientific presentations. This is entirely up to you and if you do not want us to show anyone your video clips we will **never** show them. This is not a requirement of participating in the study and if you do not want us to show them in presentations you can still take part in the study.

We will also be recording the sound from your postnatal interview, this means that the researcher doesn't have to make lots of notes whilst you are talking. The recordings will be transcribed and written quotes from your interview may be used in published material. All quotes will be anonymised and no personally identifiable quotes will be used.

Benefits and risks of talking part in the study

- + Taking part in the study provides you with the chance to influence how postnatal care is provided at Newcastle Birthing Centre and you can help improve the experience for future users.
- The risks of taking part in the study are very low. Some people may find the use of video intrusive. We are hoping by using video to collect data we can minimise the disruption to you and your baby after you have given birth. You will be told how to turn the cameras on and off and you will be able to stop taking part at any time.

Confidentiality

Your confidentiality is very important to us. All information we collect will be stored safely and will not be shared with anyone. We will not identify you or your baby in any publications. In any reports we may write, information will be summarised so you cannot be identified.

The information that you share with us will be kept confidential, unless we receive information that we believe indicates someone is at risk. If you or your baby is thought to be at risk, then we are legally obliged to inform your midwifery staff, health visitor, and/or GP so that they may be of assistance.

Data Protection

Durham University is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Durham University will keep identifiable information about you until the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Alice Keegan.

Durham University will keep your name and contact details confidential and will not pass this information to anyone else. The study team will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from regulatory organisations may look at your research records to check the accuracy of the research study. These organisations will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. Durham University will keep identifiable information about you from this study until this study has finished.

How do I take part?

If you are interested in taking part in the study please complete the consent form inside this booklet and put it in your maternity record book. We will collect it when you come into the Birthing Centre for labour.

It is important that anyone staying with you in the Birthing Centre after you have given birth is also happy to be involved in the study, so please share this with your partner.

Who is organising and funding the research?

This is PhD research project led by Alice Keegan of Durham University and supervised by Professor Helen Ball and Dr Nick Embleton (Consultant Neonatal Paediatrician). This project has been approved by the NHS Research Ethics committee. This research is funded by the Economic and Social Research Council (ESRC) and sponsored by Durham University.

Thank you

As a thank you for taking part in this research you will be provided with a participation certificate. If you wish, we can produce a photo book with still images or a short video compilation from your observation footage.

What if there is a problem?

If you wish to withdraw from the study you can contact Alice Keegan the study co-ordinator (details below)

Complaints: If you wish to complain, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted Freephone: 0800 032 0202.

Harm: Durham University insurance covers claims of non-negligent harm.

How to contact us

If you have any questions about this study or would like to take part, please get in touch with Alice Keegan, the study co-ordinator:

Alice Keegan

PhD Candidate & Study co-ordinator

Tel: 07828743146

Email: pinc.trial@dur.ac.uk

Results from this study can be found on the study webpage when they become available:

<https://www.dur.ac.uk/sleep.lab/current/pinc>

You can register your interest for the study at: <https://durham.onlinesurveys.ac.uk/pinc>

