TRUST LOGO

Studying the Implementation of Midwifery Continuity of Carer

PARTICIPANT INFORMATION SHEET- (WOMEN/SERVICE USERS)

Version 2.0 6th December 2023

We are looking for individuals who have experience of receiving maternity care in the past 24 months, and would like to share their experience or thoughts with us and 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 would involve for you. If needed, one of our team can go through this information sheet with you to answer any questions you may have which may help you decide whether or not you would like to take part. Please do contact us if you have any questions or would like to discuss participation by emailing simca@cardiff.ac.uk We'd suggest this should take about 15 minutes to go through this information. Please feel free to talk to others about the study if you wish. Joining the study is entirely up to you.

This Participant Information Sheet tells you the purpose of the study and what will happen if you take part, it will also provide more detailed information about the conduct of the study. If anything is unclear, please do ask.

Study overview: During pregnancy, labour and early motherhood, most women/pregnant people receive care from different midwives. This is changing in some areas of England to ensure that a woman is cared for mainly by the same midwife throughout her pregnancy and birth. This model of care is called Midwifery Continuity of Carer (MCoC).

MCoC has been found to lead to improvements in outcomes for mothers and their babies. MCoC can also increase midwives' job satisfaction, but it can also increase job-related stress and unsociable working hours. Putting MCoC into practice (implementation) is progressing in different ways and different speeds across England: it is progressing well in some Trusts, but in many it is delayed, has been stopped, or is yet to start. This study will explore the implementation, of MCoC in England.

Research aims and outcomes: The aim of the research is 'to explore the factors influencing the implementation of MCoC in England, and to examine differences in how MCoC implementation has been operationalised, sustained, and **experienced'**.

The outcomes of this study are to identify various local, regional and national approaches to MCoC implementation. By reaching a better understanding of local, regional and national factors contributing to varying progress with MCoC implementation, the findings of the study can be used to inform future planning and management of change.

Participants: We are looking for individuals who have experience of **receiving** or providing maternity care and would like to share their experience or thoughts with us.

Expenses will not be paid for participation in the interviews.

Study setting: England (MCoC in NHS England sites).

Study duration: 1st March 2023 to 31st May 2025

What would it involve?

- We will arrange an informal interview at a time / location which suits you, this can be online (Microsoft Teams or in-person) or over the telephone if preferrable.
- The interview will last between 30 and 60 minutes
- The interview will be recorded and transcribed
- Questions will be flexible and open-ended
- There are no right or wrong answers to any questions
- Questions may be left unanswered if you do not want to answer them
- On the day of the interview, we will:

- Check that you understand the information and that you are still willing to take part
- If not previously completed online, we will ask you to sign a consent form or give verbal consent, which will be recorded

We will collect information about you including your name, NHS Trust from which you received care, and contact details. We will use this to make sure that we are interviewing the correct people for this study and are able to arrange an interview with you. People outside of the research team will not be able to see your name or contact details. We will write our reports in a way that no-one can work out that you took part in the study.

Benefits of taking part: Whilst there is no direct benefit to you resulting from participation, taking part in an interview will give you the opportunity to share your thoughts, experiences and opinions about MCoC implementation. Your interview will also contribute to debates about future changes to maternity services and how these changes are managed nationally, regionally and locally.

Risks of taking part: Potential risk or direct harm is extremely unlikely. It may however be distressing to recall and describe some pregnancy-related care. If at any time you are experiencing emotional distress during the interview, we will pause the interview and you will be offered the option of continuing, or terminating and recommencing the interview (or not) at a later time point. The research team will be able to signpost if support is required, either to existing staff support services within their organisation or a third sector organisation (e.g. Tommy's Baby Charity). Choosing not to take part will not affect your care or future care in any way.

Withdrawal: If at any point after your interview you wish to withdraw from the study (e.g. have your data deleted), you are able to do so up to two weeks after your interview, please email simca@cardiff.ac.uk with the subject: 'withdrawal'. If this request is made more than two weeks after your interview we will not be unable to delete your data. You do not need to give any reasons for your request to withdraw and this does not impact you in any way, you will be asked to complete a withdrawal form.

Consent process: All participants will need to provide consent using the study consent form prior to the start of the interview. Electronic consent will be obtained via the study website (or emailed on request). For those opting for a face-to-face interview, it is preferrable the consent form is completed prior to the start of the interview, but this can be done at the time of the interview if preferred. Where electronic

completion has not been possible, for whatever reason, the consent statements will be read out at the start of the interview and consent will be recorded. Participants have the right to refuse to participate in the study at any time without giving a reason.

Consent forms will be securely stored either online or in locked cabinet at Cardiff University and only relevant team members will have access.

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Name
- Contact details
- NHS Trust where you received care

This information will be held by Cardiff University for the research and will be used to carry out the research. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Data collected during the interviews will be transcribed by a commercial transcription service and the company has already signed a project specific confidentiality agreement.

It should also be noted that, in the event of information provided during the interviews suggesting that either malpractice or harm to patients, the public or workplace colleagues has occurred, we may be obliged to disclose these details to others (internally or externally) who may wish to take further action. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have if beyond two weeks following your interview (see withdrawal section).
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.plymouth.ac.uk/your-university/governance/information-governance
- at www.hra.nhs.uk/information-about-patients/
- leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to the Data Protection Officer: dpo@plymouth.ac.uk
- by ringing us on 01752 588959
- by reviewing privacy notices at www.plymouth.ac.uk/your-university/governance/information-governance/privacy-notices

How long will my data be stored? Our university policy states that we must keep all other research data securely on file for 10 years in order that study findings can be checked. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Data Protection: Whilst there is a small risk of identifiable data being accidently disclosed both Cardiff University and University of Plymouth have substantial data protection processes in place to prevent this from happening. Identifiable data will only be accessible to researchers directly involved in data collection and analysis.

Future research: Anonymised data may be used in the future to support other research projects, and therefore shared with other researchers.

Study results: Will be disseminated tin a variety of ways, for example, via the NIHR Journals Library and publications in high calibre journals. A plain English summary and the full report will also be placed on institutional/University websites, when the results are in the public domain. The co-applicants will disseminate the results of the study through professional and lay, local, national, and international meetings, workshops and conferences. Participants will be provided with details of the NIHR Journals Library resource as a means of accessing outcomes of the study (anticipated 8-12 months following study completion) and all other related publications and study documents, which will variously appear over the course of the study's duration.

Public and patient involvement: Has been fundamental to the development of the grant application and of the running of this study. Members of the core study team are public and patient representatives and we meet on a regular basis.

Who has reviewed this 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 favourable opinion by _____Research Ethics Committee.

Study contact details:

Study manager: simca@cardiff.ac.uk

Chief Investigator: Professor Aled Jones: aled.jones@plymouth.ac.uk

Study Sponsor: Mrs Sarah C Jones, University Sponsor Representative, University of Plymouth, Research and Innovation, Level 2, Marine Building, Drake Circus, Plymouth, PL4 8AA

Email: plymouth.sponsor@plymouth.ac.uk

Telephone: 01752 588959

Complaints: If you have any concerns or complaints about the ethical conduct of this study, please contact the Research Administrator, Faculty of Health Research Ethics and Integrity Committee, University of Plymouth, Level 2, Marine Building, Drake Circus, Plymouth, PL4 8AA. Email: FOHEthics@plymouth.ac.uk

Indemnity/Insurance: The University of Plymouth (as the sponsor) maintains insurance and/or indemnity to meet the potential legal liability of the sponsor for harm to participants arising from the management of the research.

The University has in force a Public Liability Policy and the activities here are included within that coverage: www.plymouth.ac.uk/about-us/university-structure/service-areas/procurement/insurance-certificates

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Thank you for reading this information.