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Studying the implementation of midwifery continuity of carer

Submission date
13/06/2023

Recruitment status
No longer recruiting

Registration date
18/03/2024

Overall study status
Completed

Last Edited
08/07/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
During pregnancy, labour and early motherhood, most women receive care from different midwives. This is changing across NHS England to ensure that a woman is cared for by the same midwife throughout, whilst supported by a small team of midwives to cover off-duty periods. This model of care is called the Midwifery Continuity of Carer (MCoC). This study proposes to evaluate the implementation and delivery of MCoC in England. MCoC can lead to improvements in the safety and quality of maternity care, particularly for vulnerable women and babies and those from minority ethnic communities and deprived neighbourhoods. MCoC can also increase midwives' job satisfaction yet can also increase job-related stress and unsociable working hours. Most midwives support the idea of MCoC but many do not want to change their model of care to MCoC due to current staff shortages. Implementation progress of MCoC is mixed; progressing well in some Trusts, but in many, it is delayed, or yet to start. This study aims to better understand the factors that result in different rates of progress with MCoC implementation in England.

Who can participate?
For work package two, prospective participants include service providers from within one of the nine case study sites and maternity service users. Service providers will be identified via publicly available information enabling identification of staff names and roles and contact details (e.g. Director of Midwifery, Head of Midwifery). Printed advertisements will also be placed in NHS units, the study will be publicised at unit meetings and information disseminated to Royal Colleges, professional networks and opportunistic encounters. Maternity service users will be identified via lay networks including those on social media (such as NHS or service-user social media platforms), printed advertisements on notice boards at NHS sites, as well as opportunistic encounters. Our study co-applicants Mosaic Community Trust and Tommy’s Baby Charity can also generate lay interest in the study via their reach locally and nationally to large groups of women from a range of diverse backgrounds.

What does the study involve?
The study aims will be addressed through three linked work packages (WPs):
WP1: Literature review focussing on understanding the challenges and successes of previous attempts to implement MCoC.

WP2: Case studies in nine NHS Trusts, to better understand different rates of progress with MCoC implementation and people's experiences of MCoC implementation through:
(a) interview and questionnaire (maternity services staff)
(b) interview (service users)
(c) observe meetings, collect documents and data related to MCoC
(d) interviews with national and regional stakeholders
WP3: Compare data from all nine sites to identify different approaches to MCoC implementation and the associated factors and relationships. Compare findings to results of WP1.
Project reports and papers will be produced detailing findings and recommendations, and training materials to be developed for use in other maternity services and other NHS services.

What are the possible benefits and risks of participating?
Direct benefits to participants are minor, however, participant's opinions and thoughts are being recorded and could contribute to future policy making, change/implementation management and ways of working.

The potential risk of direct harm to participants is minor. Although unlikely, some participants may find it distressing to recall and describe work-related events or pregnancy-related care. A potential burden to participants would be a time-related burden, that their involvement in the study impinges on their personal or working time. We will not make any assumptions or requests for participation outside of working hours, or at unsociable times, although may respond positively if such times are suggested by participants.

Where is the study run from?
University of Plymouth is the study sponsor, and the study is supported by the Centre for Trials Research at Cardiff University.

When is the study starting and how long is it expected to run for?
The study started in March 2023 and the end date is 31st May 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (NIHR151802)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327714

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 327714, NIHR 151802, CPMS 59153

Study information

Scientific Title
Factors influencing the implementation of the midwifery continuity of carer (MCoC) model of care in England: A mixed methods cross-case analysis

Acronym
SIMCA

Study objectives
Rationale: Unproductive implementation in healthcare can cause workforce stress and uncertainty, especially when changes are poorly communicated, are considered unfair and take place too quickly or too slowly. The ramifications of failed implementation efforts can be serious and far-reaching; the additional workload required by implementation efforts can add significant staff burden, which can reduce the quality of patient care and may even impact treatment efficacy, if interventions disrupt workflow.

Implementing change within the NHS generally, and maternity services specifically, can prove problematic. It is imperative to study the implementation of midwifery continuity of carer (MCoC) within the wider context of numerous other local, regional and national initiatives and the acute operational challenges confronting maternity services and the NHS nationally. Existing research has not evaluated the implementation of MCoC models across such a large and variable setting as NHS England. Nevertheless, the limited literature suggests that the process of implementing MCoC is complex and fraught with difficulty. Early evidence regarding the delayed MCoC implementation in England suggests similar difficulties have been experienced, making the research questions in this study relevant and timely.

A Cochrane review recommended future research should evaluate the process of implementing MCoC, including generating a better theoretically informed understanding of any connection between implementation processes and MCoC outcomes. In short, reviewers have reported a high degree of confidence that MCoC led to improved outcomes, but found no explanation regarding the strategies and processes that led to the successful implementation of MCoC.

This rigorous evaluation of national and regional factors relevant to the implementation of MCoC will directly inform ongoing policy discussions regarding MCoC implementation in England. Additionally, the study will contribute to better understanding and decision-making within existing and future implementation of other complex interventions within maternity settings in England. In the medium to longer term, the study will inform decisions regarding MCoC in devolved UK nations and internationally.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/12/2023, Nottingham 2 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; None provided; nottingham2.rec@hra.nhs.uk), ref: 23/EM /0272

Study design
Mixed methods cross-case analysis study

Primary study design
Observational

Secondary study design
Case crossover study

Study setting(s)
Community, Home, Hospital, Internet/virtual, Medical and other records, University/medical school/dental school, Workplace, Other

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
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.

Interventions
To capture complex change occurring within case study sites a mixed methods study design was devised. In consultations with users of maternity services during the development of this study we discussed their preferred terminology. Following this discussion, we have opted to refer to 'service users' and 'women', but will review them throughout the project, in particular with the PPI group.

Timeline:
WP1
• Initial research ethics and governance approvals and development of data collection tools. Selection of initial case sites.
• Narrative review of existing international research relating to MCoC implementation.
WP2
• In-depth mixed methods case studies exploring MCoC implementation in 9 contrasting sites.
• Interviews with staff and service users (n = 135), NoMAD implementation survey with staff, observations and document analysis. Routine MCoC data.
• Interviews with national and regional stakeholders (n = 65).
WP3
• Cross Case analysis and synthesis of cross-case findings with national and regional stakeholder findings.
• Informed by implementation science frameworks CFIR & NPT

Dissemination Phase
What procedures will be in place to detect and compensate for any possible "researcher effects" and "researcher bias":
During data collection, researchers will reinforce to all participants that their role is to undertake data collection to better understand the implementation of MCoC, rather than to establish or judge whether certain approaches to midwifery care are better, or worse than others. Time spent within case study sites will also benefit the acceptance of researchers as neutral rather than judgmental presence. Familiarisation with researchers increases the likelihood that participants will practice in their usual ways, rather than alter their behaviours due to an awareness of being observed.

Bias during the analysis will be mitigated by methodological rigor, ensured through standard procedures of reflexivity. Regular analysis meetings will be held within and between the research teams in Cardiff and Plymouth. Emerging and final themes will be discussed and agreed upon across both teams and the PPI team. The introduction of across-researcher/team scrutiny

of emergent and final themes will guard against researcher bias and ensure inter-researcher consistency/reliability is maximised across the dataset. Any discrepancies or issues with analysis will be resolved by discussion within a team and if this is not possible, by the wider research team.

The sampling and sample sizes for the project, including how participants will be identified, approached and sampled, and whether they are sufficient for the intended analysis: Purposive sampling will be used within the case sites to identify key informants, documents and stakeholders involved in the implementation of and delivery of MCoC. Following ethical and governance approval, but before data collection, an initial visit to each site will be arranged to discuss plans for data collection, including how attendance at meetings as an observer can be achieved without the researcher's presence being intrusive. An activity planning document will be completed in conjunction with key individuals within each case site, which will help identify information on events/meetings and key individuals who may subsequently be recruited for interview. An initial two-week introductory and orientation period will also help to establish rapport between researchers and other staff, enabling an early sense of the midwives' and maternity unit's work in each case site.

There are three main routes for recruiting research participants:
a) NOMAD survey: Background introductory information about the study and a link to the web survey instrument will be emailed to the NHS email account of those working in the relevant midwifery unit/maternity unit/birth centre/hospital.
b) Semi-structured interviews with staff: (n = 10) Midwives and other staff in key positions relevant to the implementation of MCoC will be approached, e.g. Heads and Deputy Heads of Midwifery, Director of Midwifery, Midwifery Transformation Leads, midwives, maternity support workers, Obstetricians, Chief Nurse, trade union representatives. The names and contact details of many of these individuals are in the public domain. Midwives and maternity support workers will become known to researchers during periods of observation and may be initially approached to participate in interviews following an observation period. In all cases, the recruitment process will formally begin with the research team sending an introductory email and participant information sheet. Those wishing to participate in the study will reply to the email indicating their willingness to be contacted by the research team to arrange further discussion of the study and potential date/time/place for the interview.
c) Semi-structured interviews with staff: Posters to alert employees of the study and our wish to recruit those with experience in MCoC implementation. Those interested in participating will inform the research team via phone or email or can consent through the website, details of which will be on the posters.
d) Women recently (within the past 24 months) or currently using maternity services (n = 5) will be identified via lay networks and opportunistic encounters.

The sample size and the purposive sampling approach for semi-structured interviews reflect a number of overlapping considerations, primarily obtaining depth and diversity of viewpoints from the maternity/midwifery workforce (n = 10) and women (n = 5). Depth in this respect refers to the richness, detail, and complexity of the data collected from participants. Achieving depth of data involves collecting diverse, comprehensive and nuanced information about participants' experiences and perspectives of MCoC implementation, and the social and workplace contexts within which implementation decisions are deployed. Such depth will enable the research team to gain a thorough understanding of MCoC implementation and uncover intricate patterns, meanings, and themes within the data.

Qualitative sampling is often discussed in terms of data saturation, where recruitment and sampling decisions are predicated on whether new information emerges, or not. However, in the

case of MCoC implementation, we believe that theoretical saturation better informs our sampling. Focussing on theoretical saturation is preferable, in this instance, to data saturation as theoretical saturation involves the development of a coherent and comprehensive theoretical framework that explains experiences and perceptions of implementation. Achieving theoretical saturation requires a deeper integration of multiple data points and sources with existing theories, concepts, and literature.

The number of participants recruited, therefore, also needs to be considered alongside other data generated and collected, including the survey, observations and documents. The variety of data collection methods deployed enables a more complete picture of MCoC implementation within and across case sites than would be possible by only undertaking interviews. Depth is crucial in providing a rich and detailed description of the research topic, generating meaningful insights, and supporting theory development to support future implementation of complex interventions within midwifery/maternity services.

Study Design: The project consists of the four inter-related work packages (WP)

WP1: Narrative evidence synthesis, WP1 aims to undertake a narrative evidence synthesis approach which addresses objective 1: Critically appraise the international literature to understand the contexts and factors contributing to the implementation and sustainability of MCoC models of care.

WP2: Case studies and national and regional interviews. WP2 addresses objective 2: Rigorously evaluate how implementation decisions have been operationalised, sustained and experienced in nine case study sites representing contrasting progress with MCoC implementation. Nine NHS Trusts will be selected to better understand different rates of progress with MCoC implementation. To better understand different rates of progress and people's experiences of MCoC implementation we will:
(a) Interview and use a questionnaire with maternity services staff
(b) Interview women using maternity services
(c) Observe meetings, collect documents and data related to MCoC
(d) Interview people working in regional and national NHS organisations involved in MCoC implementation or representing groups such as pregnancy charities and Royal Colleges (not for consideration with this REC)

Comparative case study methodology will be used to facilitate the in-depth exploration of complex organisations, such as maternity services. This is achieved through combining a range of data collection methods, including surveys, interviews, observations and documents, with a variety of sampling techniques, to gain an in-depth understanding of the implementation factors and processes within each study site.

A total of nine case study sites will be selected following further examination of NHS England and Improvement (E/I) MCoC implementation data and discussion with key MCoC implementation leads at NHS E/I. Progress with MCoC implementation continues to be variable across England.
A key measure of implementation progress within the NHS is the 'number of women placed on the CoC pathway by 28 weeks gestation'. This measure will be used to purposively sample NHS Trusts to ensure case studies (n = 9) represent the full range of MCoC implementation progress. The sampling strategy will also include: i) consideration of the regional and geographical settings of case study sites to ensure that case studies are undertaken in different regions of England and in rural, urban and inner-city areas, ii) identifying 'positive deviants', defined as 'organisations, teams or individuals that consistently demonstrate high performance in an area

of interest', Positive deviance may be identified, as outlined above, as a characteristic of Trusts who have a high percentage of women placed on MCoC pathway by 28 weeks gestation. However, we will also incorporate a more rounded conception of positive deviance, by looking beyond outcome data produced by Trusts. For example, we will not discount the possibility that local pockets of high performance can also exist in Trusts that may have a lower percentage of women placed on the MCoC pathway.

WP2 Data collection: Access to undertake fieldwork in the case study sites will be negotiated with key local stakeholders. In each case study, data will be generated via:

Observations: The two RAs will undertake guided non-participant observations at MCoC implementation meetings and related activities at each case site. Observations will be recorded in contemporaneous 'free text' field notes, later elaborated upon, finalised and word-processed. Field-note recording and transcribing conventions will ensure comparability of the data across all sites.

Local documentation and data: The RAs will access local documents via the stakeholders. These will include: Routinely collected MCoC outcome data (via the publicly available Maternity Services Data Set); anonymised patient safety data where MCoC is a known factor (e.g. serious incidents and events reports, staff concerns via Speak Up Guardians); local documents (for example, MCoC operational policies and service specifications), MCoC service use, completed local audits and/or evaluations, and related grey literature.

Staff survey: NoMAD, a free-to-use NPT-informed survey instrument, will be used to collect the perceptions and experiences of maternity staff about the implementation of MCoC in the maternity services within which they work. It will be distributed electronically by the project team to all maternity services staff working within the case study site. The survey will be distributed to staff in a range of junior and senior positions e.g., director of midwifery to band 5 midwives, consultant to junior doctors and professional groups, such as: midwives, obstetricians, anaesthetists, paediatricians, sonographers and support workers. Response rates and coverage will be closely monitored to ensure the survey is completed across the workforce and strategies deployed where increased response rates/coverage are required.

Recorded semi-structured interviews: At each case site semi-structured interviews (n=15) will be held by the RAs with purposively sampled participants including those directly involved in MCoC implementation, for example, managers, midwives, obstetricians (c.10 in total) and women (c.5 in total) enrolled in MCoC. Participants will be offered the choice of interviews using online applications (e.g., MSTeams) or face-to-face and recorded with permission. Interviews will be transcribed in full by an authorised external transcription company.

The participant information sheet will identify the purpose of the interview to explore participants' experience of MCoC implementation and the factors influencing the development, organisation and normalisation of MCoC in each site. Interview schedules will be informed by NoMAD findings, in addition to views of the PAG and PPI team, the findings of the narrative synthesis and the application of CFIR and NPT via respective toolkits.

Questions will be included on:
i) how services are organised and delivered,
ii) any effect on the implementation of the interplay between the 'outer domain' (regional and national priorities and incentives) and the 'inner domain' (local maternity services),
iii) organisational readiness and the 'implementation climate' related to MCoC
iv) the coherence of MCoC implementation to staff and women;

v) resources allocated to embedding and sustaining the MCoC model of care vi) the effect of MCoC on other maternity services and how existing services are decommissioned / de-implemented.
All data collected will be saved on secure Cardiff University servers. Files will be password-protected and accessible only to relevant members of the research team. Recordings will be transcribed and anonymised in line with CTR Standard Operating Procedures.

Intervention Type
Other

Primary outcome measure
1. Anonymous perceptions and experiences of the maternity service staff of the implementation of MCoC at the nine case study sites measured using the Normalization Measurement Development questionnaire (NoMAD) at one timepoint
2. Perceptions and experiences of the implementation of MCoC at the nine case sites measured using semi-structured interviews (n=10 maternity service staff and n=5 maternity service users) at one timepoint

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/03/2023

Completion date
31/05/2025

Eligibility

Key inclusion criteria
Individuals who directly affect, or are affected by MCoC implementation

Participant type(s)
Patient, Health professional, Employee, Service user

Age group
All

Sex
Both

Target number of participants
Six case study sites representing a variety of organisations will be used to explore the implementation of MCoC. The methods of data generation will be via qualitative interview with key stakeholders, a semi-structured survey, documentary review and observations: NoMAD Survey distributed electronically to all maternity services staff working within the case study site. The survey will be distributed to staff in a range of junior and senior positions and professional groups. • Semi-structured interviews: (n=c.135) purposively sampled participants including those directly involved in MCoC implementation, for example, managers, midwives (n=c.10 in total per site) and service users (n=c.5 in total per site) = 135

Total final enrolment
264

Key exclusion criteria
Inability to communicate in English

Date of first enrolment
21/02/2024

Date of final enrolment
12/03/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

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Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact and peer-reviewed publication
Conference presentations
Policy-focused, timely dissemination throughout the project and at project completion

Intention to publish date
31/05/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	06/12/2023	24/01/2024	No	Yes
Participant information sheet	version 2.0	06/12/2023	24/01/2024	No	Yes