STUDY PROTOCOL

The SIMCA Study Protocol: Factors influencing the implementation of the Midwifery Continuity of Carer (MCoC) model of care in NHS maternity care in England: A mixed methods cross case analysis involving clinicians, women and policy makers

[version 1; peer review: 2 approved, 1 approved with reservations]

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Abstract

Background

During pregnancy, labour and early motherhood, most women in the UK receive care from different midwives. NHS policy change in England sought to introduce a model of care whereby each woman is cared for by the same midwife throughout antenatal, intrapartum and postnatal periods, supported by a small team of midwives to cover off-duty periods. This model is called the Midwifery Continuity of Carer (MCoC). This study proposes to evaluate the implementation and delivery of MCoC across England, aiming to better understand the factors that result in different rates of progress with MCoC implementation.

Open Peer Review

Approval Status ? ✓ ✓

	1	2	3
version 1 16 Jan 2025	? view	✓ view	✓ view

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Any reports and responses or comments on the article can be found at the end of the article.

Aim

To identify the local, regional and national factors which contribute to variable progress with implementation of MCoC in the NHS in England?

Methods

A sequential mixed-methods study, informed by implementation science frameworks will be delivered over three work packages. Following a literature review of the challenges and successes of previous attempts to implement MCoC (work package 1), six case studies in NHS Trusts will be undertaken to better understand different rates of progress with MCoC implementation and people's experiences of MCoC implementation through: interview and questionnaire (maternity services staff); interviews (service-users); observation of relevant implementation meetings and organisational documentation collection (work package 2). Interviews will be undertaken with national and regional stakeholders relevant to MCoC implementation (work package 2). Data analysis will be conducted both inductively and deductively, informed by implementation science constructs (work package 3).

Dissemination

Study findings will be disseminated through peer-reviewed journals, conferences and events. Results will be of interest to the public, clinical and policy stakeholders in the UK and will be disseminated accordingly.

Plain Language Summary

Background

During pregnancy, labour, and early motherhood, most women in England receive care from different midwives. In 2016, NHS England introduced a policy aimed at ensuring that, by 2020, women would receive care from the same midwife (or a small team of midwives during off-duty periods) throughout their pregnancy and after birth. This model of care, called Midwifery Continuity of Carer (MCoC), has been introduced as there are strong claims that MCoC can improve the safety and quality of maternity care, especially for vulnerable women, babies, and those from minority ethnic communities or deprived areas. MCoC could also increase job satisfaction for midwives, although it might also lead to higher job-related stress and more unsociable working hours. While many midwives support the idea of MCoC, many also feel unable to implement it due to staffing shortages and other resource limitations, leading to mixed progress in England.

Aims

The study aims to understand the factors influencing the varied progress of MCoC implementation across England through three linked work packages (WPs).

Work packages

WP1: Conduct a literature review to understand the challenges and successes of previous MCoC implementation efforts.

WP2: Perform case studies in six NHS Trusts to explore different implementation rates and experiences. This includes interviews and surveys with maternity staff, service users, and stakeholders, as well as document reviews and observations of meeting.

WP3: Analyse data from the case studies to identify different approaches to MCoC implementation, including associated implementation factors, barriers and enablers, and patterns in MCoC outcomes.

Objectives:

- Review international literature on MCoC implementation challenges and successes.

- Evaluate how MCoC has been implemented and experienced in six diverse case sites.

- Explore the role of national and regional stakeholders in MCoC implementation.

- Synthesise findings to identify key implementation factors including barriers, facilitators and patterns in outcomes.

Keywords
Midwifery, maternity, continuity of carer, MCoC, continuity of care models, service delivery, patient safety, implementation.

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Introduction

Improving newborn and maternal health has long been a leading priority of UK and global policy makers[2,3]. Yet safety and quality of maternity services remains problematic worldwide[4]. Sub-optimal care in maternity services can result in death, serious disability and profound anguish for women, their children, and their families[5,6], placing significant burden on healthcare systems and infrastructure, including the costs associated with legal action[7]. The continuous and urgent need to enhance the quality and safety of care delivery is frequently linked to several factors, namely: multimorbidity, healthcare delivery complexities and a multitude of cultural and organisational challenges[6,8].

As a result, recent NHS England policy has introduced significant changes to improve the quality and safety of maternity care[1,3]. Implementation of the policy for safer and more personalised care across England is currently led by the Maternity Transformation Programme (MTP), consisting of a range of inter-connected interventions, including establishing Midwifery Continuity of Carer (MCoC) models of care. MCoC aims to ensure that women are cared for by a named midwife who coordinates and personally provides the majority of care, supported by a small MCoC team (a headcount of eight midwives or fewer), throughout pregnancy, birth and the postnatal period, supported by a linked obstetrician[9]. Although this evidence is still evolving and the extent of clinical advantages of the model have recently changed[10]. However, little is known about the factors, contexts, and conditions necessary for successful implementation of policy initiatives to improve service delivery and care quality within the distinctive setting of maternity care[11,12].

The question of implementing change in maternity services is particularly salient given the proliferation of priorities and initiatives introduced over the last five years within the 'maternity and neonatal safety improvement programme', coordinated by the MTP. Healthcare settings, which have similarly experienced a surfeit of interventions, have been described as 'policy thickets', which are defined as dense patches of overlapping goals that command substantial attention and resources, but where policy goals are unclear and external strategies may not link to local priorities[13]. Policy thickets should be of particular interest to implementation research projects such as this. For example, important questions include how the implementation of each individual initiative interacts with other initiatives, such as MCoC implementation. Similarly, while each national initiative is generally well described whether they cumulatively stack-up as a coherent whole at the regional and local level, is often overlooked. The accumulation of local, regional and national maternity interventions also raises questions regarding the potential for MCoC implementation to be affected by 'change fatigue' within the workforce[14].

Questions relating to de-implementation are also relevant, such as how service leaders and other stakeholders plan and experience the redesign and decommissioning of existing services in response to new priorities. Potential difficulties and unintended consequences related to parallel and simultaneous implementation/de-implementation processes within clinical settings and teams are largely overlooked in existing research and policy[15].

Progress in implementing MCoC across England has been highly problematic[16,17]. Initial targets to deliver MCoC to the majority of women by 2021, with an interim target of 20% of women receiving MCoC by March 2019, were not met. For example, NHS statistics[17] indicated that in 2020, 108 Trusts offered MCoC to 15.9% of pregnant women, falling short of the interim target and significantly below the target of the 'majority of women'. Implementation challenges were compounded by the COVID-19 pandemic, but this was not the only challenge with, a recent Health and Social Care Select Committee report rated the progress of MCoC implementation as highly variable and 'requires improvement'[17].

As a result, the implementation targets for MCoC have been regularly revised. Most recent amendments to MCoC implementation policy were issued in September 2022[18]. In response to the Ockenden report[6], NHS England directed all NHS Trust Chief Executives to 'review and suspend, if necessary, the existing provision and further roll out of MCoC' unless they could 'demonstrate staffing meets safe minimum requirements on all shifts.' Targets for implementation progress were also removed. Since autumn 2022 the MTP has maintained support for expansion of MCoC wherever possible. Some Trusts have successfully implemented MCoC, although the majority have partially implemented, or are yet to commence implementation. Progress with MCoC implementation is likely to remain variable for the foreseeable future, providing an opportunity to observe the challenges of implementation, as well as to describe the receptive context and the necessary conditions required for change.

Rationale

Unproductive implementation in healthcare can cause workforce stress and uncertainty, especially if changes lack clear communication, fairness, or appropriate speed[16,19]. Failed efforts can overload staff, reducing patient care quality and treatment effectiveness. Implementing change in the NHS[20,21], particularly in maternity services[4,22], is challenging. Studying the implementation of MCoC within this context, amidst various initiatives and operational hurdles, is crucial. While limited research exists on MCoC implementation in NHS England, early evidence indicates complexity and challenges. A recent Cochrane review suggests future research should focus on understanding the implementation and scaling up of midwife continuity of care[10].

Evaluating local, regional and national factors relevant to MCoC implementation will inform policy discussions and improve decision-making in maternity settings in England and beyond. The aim is to explore factors influencing MCoC implementation in England, examining variations in operationalisation, sustainability, and experience. The research question is: "What factors at local, regional and national levels contribute to variable progress in MCoC implementation in NHS England?"

Protocol

Objectives

1. Appraise the international literature to understand the factors contributing to the success and challenges of MCoC implementation.

2. Evaluate how implementation decisions have been operationalised, sustained and experienced in six case study sites representing contrasting progress with MCoC implementation.

3. Describe and explore the role played by national and regional stakeholders in MCoC implementation.

4. Synthesise findings to identify various approaches to MCoC implementation, key implementation factors and relationships, and any discernible patterns between implementation factors and routinely reported MCoC outcomes.

Theoretical/conceptual framework

MCoC is conceptualised as a complex intervention, e.g. one that comprises many inter-dependent components across multiple systems from the macro level (e.g. NHS England), to meso (e.g. Regional Midwifery Boards) and micro levels (e.g. Local Maternity Services)[23]. These complex organisational levels are 'nested'[24], such that each level simultaneously interacts with multiple other systems. For example, MCoC implementation will occur alongside pre-existing micro-level employee relationships and experiences, as well as the characteristics of the maternity unit (e.g., size and setting). A range of contextual and organisational preconditions also exist at the meso-level, such as organisational/managerial structures, policies, processes, and hierarchies, which can shape the local implementation. In addition, public, policy and governmental interest in MCoC adds a social and inter-institutional macro level dimension to the implementation, which may be experienced from an institutional standpoint as external social and policy pressure and risk[25].

Given the complex nature of MCoC implementation and the contexts within which the intervention is being implemented, Normalisation Process Theory (NPT)[26,27] and the Consolidated Framework for Implementation Research (CFIR)[25] offer appropriate and complementary frameworks to guide the study. NPT and CFIR are often used in combination with other theories to explore multiple facets of implementation[27,28].

CFIR is not intended to be applied wholesale, but rather offers numerous constructs to consider when investigating implementation of complex interventions[28]. In particular, CFIR constructs focussing on the interaction between the inner and outer settings within which an intervention is implemented are useful, given the complexity and national profile of MCoC. Generally, the outer setting includes the wider national/regional economic, political, and social context within which an organisation resides, and the inner setting includes features of local organisations' structural, political, and cultural contexts through which the implementation process proceeds[25].

NPT seeks to explain how complex interventions work by focusing on factors promoting and inhibiting their transformation into routine ways of working[29]. NPT consists of four main components, or generative mechanisms: coherence, cognitive participation, collective action and reflexive monitoring[26].

Methods

Patient and Public Involvement

Since study inception there has been active involvement and engagement from patient and public members. The Patient and Public Involvement (PPI) members of SIMCA are named co-applicants on the grant and have contributed to the development of the study. There is an established PPI group which meets regularly, similarly the PPI members participate as full members of the monthly Study Management Group (SMG). The Project Advisory Group (PAG) which meets six monthly has a PPI representative as a core member. The aim of this active engagement from inception is to ensure that patient and public views are integrated throughout the lifetime of the project as well to help the research team take a broader look at the context of maternity services, trying to understand the wider system of healthcare (e.g., the interface of maternity services and primary care), how national and regional decisions and systems reflect the needs of communities and individuals, and how these might impact on MCoC.

PPI members will focus on ensuring that the study is appropriately designed and delivered; e.g. contributing to developing the analysis, exploring findings and dissemination from a public/patient perspective.

PPI members will also contribute directly to dissemination. Dissemination will have significant public reach through the close involvement in the project of Tommy's Baby Charity and The Mosaic Community Trust.

Preparation of research information will include input from our PPI team, to ensure culturally appropriate content is distributed. Similarly, the PPI co-applicants will provide cultural sensitivity and awareness training to all members of the research team as specialist input for those undertaking interviews with women.

Work packages

The project consists of the three inter-related work packages (WPs).

Work Package 1: Narrative evidence synthesis

The aim of WP1 is to undertake a narrative evidence synthesis approach which addresses objective 1. We will use a textual approach to generate an interpretive synthesis of any relevant 'theories of change'[30], contextual factors and organisational mechanisms that influence (for better or worse) the implementation of MCoC.

Results of selected studies will be gathered into a framework informed by CFIR constructs and supplemented by NPT (such as the focus on internal and external implementation factors). The framework approach ensures that the review

focusses on the factors influencing implementation of MCoC, rather than reviewing the results of MCoC interventions per se. The final stage of WP1 will produce a synthesis of the results which will directly inform all subsequent work packages.

Work package 2: Comparative case studies and national and regional stakeholder interviews

WP2 addresses research objectives 2 and 3. 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[31] as well as explore the perspectives of key national and regional stakeholders on the implementation of MCoC.

Study setting

WP2 will be conducted across six NHS settings in England.

Study participants

We aim to conduct up to 65 national and regional stakeholder interviews and 90 participant interviews across the six case sites; 15 interviews per site (n=10) purposively sampled participants including those directly involved in MCoC implementation, for example, managers, midwives, obstetricians and (n=5) women enrolled in MCoC.

Sampling and selecting national and regional stakeholders

For the purposes of this study, we define stakeholders as individuals and/or organisations who directly affect, or are affected by, MCoC implementation. National and regional stakeholders can have considerable influence over MCoC implementation by directly controlling resources and informing/taking key decisions. Individuals will be purposively sampled to recruit respondents with knowledge of MCoC, and/or involved in policy/strategy implementation. Potential participants include those contributing to MCoC and MTP implementation nationally within NHS (E/I) and NHS Health Education England (HEE). Stakeholders will be identified, contacted and recruited via accessing publicly available information from professional bodies (e.g. Royal Colleges), third sector organisations (e.g. Maternity Action), national and regional NHS representative bodies and national maternity voices programme (who support the co-production of maternity and neonatal services with service-users) for example. Regional NHS stakeholders will be geographically linked to the location of each case site and are likely to include representatives from regional maternity boards and regional MCoC and workforce planning leads. The research team's extensive existing networks will also be utilised and referral from those contacted or recruited using the above methods.

Data collection and management

Recorded semi-structured interviews with regional and national leads (up to 65): Candidate questions and interview schedules will be prepared as outlined above for case study interviews, with a particular focus on regional and national decision-making, implementation and de-implementation strategies and boundary working with local maternity settings. All participants taking part in interviews will be offered the choice of online applications (e.g., MS Teams) or face-to-face and recorded with permission. Interviews will be transcribed in full by an authorised external transcription company.

Sampling and selecting case studies

Six case study sites will be selected following further examination of NHS England (NHSE) MCoC implementation data and discussion with key MCoC implementation leads at NHSE. The purposive sampling strategy will be informed by:

- 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.
- Identifying 'positive deviants', defined as 'organisations, teams or individuals that a consistently demonstrate high performance in an area of interest'[32].

Positive deviance will be identified in a range of ways, including reviewing NHSE data on Trusts who have a high percentage of women placed on MCoC pathway by 28 weeks' gestation. 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 lower percentage of women placed on the MCoC pathway.

Data collection and management

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

Observations: researchers will undertake guided non-participant observations at MCoC implementation meetings and related activities at each case site.

Local documentation and data: The researchers will access local documents via the stakeholders. These may include:

- Routinely collected MCoC implementation data.
- Anonymised patient safety data (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.
- Related grey literature.

Staff survey: the survey 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.

Descriptive analysis of the survey responses will initially explore how answers are distributed. In line with the guidance provided by the tool's creators[33], total scores for the survey will not be calculated. Cronbach α testing will be conducted on all four NPT components, to measure the internal consistency of the constructs within the context of this study. Each NPT component will be derived as the mean score of the four questions in the survey that correspond to that NPT component. Components will then be summarised and examined for potential associations by various roles or organisational characteristics. Descriptive statistics and bar charts will help visualise the 'shape' of the data within and eventually across case sites. These steps will help identify interesting or anomalous features within the data and prove useful in then generating cross-tabulations and scattergrams of the relationships between implementation factors and other variables. Survey analysis will be undertaken via SPSS.

Recorded semi-structured interviews in six case study sites (n=c.90): At each case site semi-structured interviews (n=15) will be conducted with purposively sampled participants including those directly involved in MCoC implementation, for example, managers, midwives, obstetricians (n=10) and women enrolled in MCoC (n=5).

Interview schedules will be informed by the staff survey 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 their respective toolkits[34,35]. Questions will be included on:

- How services are organised and delivered.
- Any effect on implementation of the interplay between the 'outer domain' (regional and national priorities and incentives) and the 'inner domain' (maternity services).
- Organisational readiness and the 'implementation climate' related to MCoC.
- The coherence of MCoC implementation to staff and women.
- Resources allocated to embedding and sustaining the MCoC model of care.
- The effect of MCoC on other maternity services and how existing services are decommissioned/de-implemented.

All participants taking part in interviews will be offered the choice of online applications (e.g., MS Teams) or face-to-face and recorded with permission. Interviews will be transcribed in full by an authorised external transcription company.

Data analysis

Thematic analysis of qualitative data sources, underpinned by methodological rigour[35], will be undertaken by the core project team, concurrent with data collection in each case site. NPT and CFIR constructs will iteratively inform each step of the analysis to provide rich understanding of the operational context and implementation of MCoC. Separate analysis of each case study and the regional and national stakeholder interviews will commence with data familiarisation, initial inductive and theoretical coding drawing on findings from WP1, and the identification of themes. All analysis will be overseen by a senior researcher. Other members of the team, including the PPI members, will also periodically review transcripts to ensure consistency and contribute to analysis via online and face-to-face team meetings.

The combined WP2 analytic process will involve:

- Using the latest version of the NVivo qualitative data analysis software (https://lumivero.com/products/nvivo/) and SPSS (www.ibm.com/spss) for the survey data to organise and store data ready for analysis.
- In-depth and iterative familiarisation of interview transcripts and field-notes followed by inductive thematic analysis[35]. The analysis will identify a range of respondents' views including local (micro level), regional (meso level) and national (macro level) participants.
- Methodological rigour will be ensured through standard procedures of reflexivity[36]. Regular analysis meetings will be held within and between the teams in Cardiff University and University of Plymouth.
- Convergent analysis[31], via triangulation of the quantitative (survey) and qualitative datasets, will establish patterns of within-case similarities and differences regarding MCoC implementation.
- A comparative, cross-case synthesis will then follow in WP3 (see below), though we have also scheduled a period into the WP2 timeline to explicitly plan and prepare for our transition from within-case to cross-case analysis.

Work Package 3: Cross-case analysis and synthesis of findings

WP3 addresses objective 4. This objective will be achieved by comparing and contrasting factors influential to each case study's approach to the development, organisation, and implementation of the MCoC model of care. The process of cross-case analysis and synthesis will follow a matrix approach[37], consisting of a 'tabular format that collects and arranges data for easy viewing in one place and permits cross-case analysis'. Specifically, to integrate findings across cases an inductive 'data condensation' process, foreshadowed by the overall research question and objectives, will initially be used to select, focus and simplify relevant findings from each site. Extracted findings will populate a series of cross-case thematic tables informed by NPT and CFIR frameworks, in order to map and understand the range of views and experiences across sites. Local implementation decisions will also be considered alongside the findings of the national and regional stakeholder interviews and the findings of the WP1 narrative synthesis of MCoC implementation.

Table 1 presents an overview of protocol and study related information. Table 2 displays the protocol amendments to date.

Table 1. Dataset.

Data category	Information
Primary registry and trial identifying number	ISRCTN10635039
Date of registration in primary registry	18th March 2024
Source(s) of monetary or material support	NIHR Health and Social Care Delivery Research
Primary sponsor	University of Plymouth
Contact for public queries	simca@cardiff.ac.uk
Contact for scientific queries	simca@cardiff.ac.uk / aled.jones@plymouth.ac.uk
Public title	Factors influencing the implementation of the Midwifery Continuity of Care (MCoC) model of care in England: A mixed methods cross case analysis
Countries of recruitment	England
Health condition(s) or problem(s) studied	Implementation of the Midwifery Continuity of Care (MCoC)
Intervention(s)	N/A
Key inclusion and exclusion criteria	Inclusion criteria: - Individuals who directly affect, or are affected by, MCoC implementation. - Are associated with a case site. Exclusion criteria: - No groups are to be excluded from participating, unless there are clinical grounds barring participation following discussion with the midwifery team.
Study type	A mixed methods cross case analysis
Date of first enrolment	19/07/2023
Target sample size	90 (semi-structured interviews)
Recruitment status	Open
Primary outcome(s)	The main outcomes of the study will be to identify various local, regional and national approaches to MCoC implementation and key implementation factors and relationships and any discernible patterns between implementation factors and routinely reported MCoC outcomes. Through 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 ongoing implementation of MCoC in England, and elsewhere and contribute to debates about future changes to maternity services.

Table 2. Protocol amendments.

Amendment No.	Protocol version no.	Date issued	Summary of changes made since previous version
1	1.1	29/08/23	Comments and suggestions implemented from University of Plymouth's review process.
2	1.2	28/09/23	Addition of recruitment details for service users in section 9.1. Updated milestones table (section 21) to reflect study set up delays.
3	1.3	10/10/23	Add website to page 1. Added in statement re. UoP granting ethical approval (section 17.1). Updated Appendices section with new file names.

Amendment No.	Protocol version no.	Date issued	Summary of changes made since previous version
4	2.0	11/12/23	Change to section 9.1 in relation to members of the clinical team approaching service-users obtaining consent to contact.
5	3.0	17/04/2024	Addition of ISRCTN number. Removal of development of data management plan. Addition of incentive for service user interviews Updated section 23
6	4.0	19/06/2024	Reduce the number of case study sites from nine to six and alter subsequent sample sizes.

Ethics and consent

Throughout this study we will follow the principles of good practice set out in the UK Policy Framework for Health and Social Care Research (Health Research Authority *et al.*, 2021). Ethical issues in this project arise in WP2: Comparative Case Studies and National and Regional Stakeholder Interviews. The primary ethical and research governance issues here are consent, anonymity, confidentiality, data protection and the safety of participants and researchers. Regarding consent, we will follow standard ethical procedures for gaining written informed consent from participants prior to them participating in the interview and subsequent them reading and considering the participant information sheets. In relation to data protection, all data we collect will be confidential to the project and stored securely in line with current University and NHS research governance and general data protection regulations. Any identifiable data will be anonymised prior to analysis in line with good research practice. In the context of participant safety and wellbeing, researchers will be trained in good interview practice as well as the use of distress protocols (including immediately ceasing the interview if participants become upset and providing avenues for support) and a disclosure protocol. All researchers accessing participants will be DBS checked. Regarding researcher safety, we will follow the relevant University's lone working policy.

This study protocol has been approved by NHS, East Midlands – Nottingham 2 Research Ethics Committee and Health Research Authority, REC reference 23/EM/0272, approval date 14th December 2023. The national and regional stakeholder interviews were approved by University of Plymouth Faculty Research Ethics and Integrity Committee, approval date was 24th March 2023.

Dissemination

Dissemination will occur throughout the project. Insights will contribute to current and future implementation of complex initiatives within maternity and other NHS services. Dissemination outputs will include clear, actionable, lessons to advance implementation decision making of national, regional, and local policy makers and practitioners. Findings will also be disseminated via international peer reviewed journals and conferences. PPI is embedded into each WP and a range of public engagement and dissemination events are planned throughout the project's duration. The report will follow the NIHR threaded publication format. Project report and papers will be produced detailing findings and recommendations, training materials to be developed for use in other maternity services and in other NHS services. Results will be of interest to clinicians, practitioners and policy makers in the UK.

Data availability

No data are associated with this article.

Extended data

Figshare: SIMCA Study Material, Doi: https://doi.org/10.6084/m9.figshare.27831345.v1[38]

This project contains the following extended data:

- 20230317SIMCAStakeholdersConsentFormONLINEv2_0.pdf
- SIMCA CASE SITE INTERVIEW GUIDE Board level.docx
- SIMCA CASE SITE INTERVIEW GUIDE Midwifery management.docx
- SIMCA CASE SITE INTERVIEW GUIDE Midwives.docx
- SIMCA CASE SITE INTERVIEW GUIDE Women and other service users.docx
- SIMCA Consent Form - Service Providers - v1.2 240124.docx
- SIMCA Consent Form - Service Users - v1.3 17042024.pdf
- SIMCA Participant information sheet - Service Providers - v2.1 240124.pdf
- SIMCA Participant information sheet - Service Users - v3.0 17042024.pdf
- SIMCA PIS - Stakeholders v3.0 17032023.docx
- SIMCA Poster - Service Providers - v1.1 240124.pdf

- SIMCA Poster - Service Users - v3.0 170424.pptx
- SIMCA STAKEHOLDER INTERVIEW GUIDE - National regional midwives.docx
- SIMCA STAKEHOLDER INTERVIEW GUIDE – NHSE.docx
- SIMCA STAKEHOLDER INTERVIEW GUIDE - Service user orgs and reps.docx

Reporting guidelines

Figshare: SPIRIT reporting guidelines[39,40] "The SIMCA Study Protocol: Factors influencing the implementation of the Midwifery Continuity of Carer (MCoC) model of Care in England: A mixed methods cross case analysis." Doi: https://doi.org/10.6084/m9.figshare.27831891.v1.

Author contributions

RM, AJ, SC, JS and SK have contributed to conceptualisation, funding acquisition, methodology, writing (original draft preparation and review and editing). AM and HS have contributed to methodology, writing (original draft preparation and review and editing) and SB, TP, LC and KD have contributed to funding acquisition, writing (original draft preparation and review and editing). All authors have reviewed the final draft.

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Open Peer Review

Current Peer Review Status: ? ✓ ✓

Version 1

Reviewer Report 10 March 2025

https://doi.org/10.3310/nihropenres.14929.r34586

✓ **Jane Sandall**
Kings College London, London, London, UK

Its important to have the overall aim consistently described in study materials. For example, The aim of the research is described differently in different study materials. The aim in the protocol is 'To identify the local, regional and national factors which contribute to variable progress with implementation of MCoC in the NHS in England?' In the study materials I see two aims and these need to be aligned. "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 design and methods are informed by implementation science frameworks in three work packages. The rational for the choice of the two frameworks guiding the Normalisation Process Theory (NPT) and the Consolidated Framework for Implementation Research (CFIR) could be explained more. A literature review that has been published. Six case studies in NHS Trusts looking at MCoC implementation. I am not sure that data analysis is a separate work package or integral to WP2. Case study site selection in WP2 is described but has not included criteria to ensure some sites have had experience of settling down implementation. All organisational change has teething problems and needs time to embed, it is hoped that some sites will fulfill the criteria.

It is also important to interview those who have had experience of implementation. This is not clear as for example in SIMCA Board level interview guide, one question asks 'do you believe it improves care'. Rather than asking what an individual hypothesizes, it would be more helpful to ask them of any evidence or experience they have of intended or unintended impacts on women and staff or system. Belief also implies an ideology, rather than a factual question regarding impact on care (good or bad).

Staff surveys are notorious for poor response rates. It is hoped this is about real word experiences rather than what staff have heard from colleagues either in their own trust or elsewhere. Pre-organisational change, there is always staff anxiety, far better to hear from their actual experiences. Similarly, it is important to interview some women who have experienced MCOC.

How will predicted survey response be improved, and how will women whose voices are not heard be engaged.

This is an experienced team and the findings grounded in an implementation science framework should provide useful and relevant information for decision makers.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: maternity service delivery

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 21 February 2025

https://doi.org/10.3310/nihropenres.14929.r34582

Linda Sweet
Deakin University Geelong, Victoria, Australia

Thank you for the opportunity to review this study protocol. It is a timely and much-needed study. The team is strong, and the work packages are achievable.
There are a few acronyms used before being qualified and some minor anthropomorphic statements such as 'This study proposes .."
In WP2, the first sentence for study participants is confusing at first read and is one very long sentence.
I look forward to following the outcome of this work.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Midwifery

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 17 February 2025

https://doi.org/10.3310/nihropenres.14929.r34730

?

Vidanka Vasilevski
Deakin University, Burwood, Victoria, Australia

Thanks for inviting me to review this paper. It is well established that MCoC improves a range of outcomes for women, babies, and the healthcare system, however, successful implementation remains a significant challenge. Understanding MCoC implementation, and the various factors that influence it, will contribute knowledge that can support broader implementation of MCoC internationally. Overall, this is a very clear and well written protocol, however a bit more detail is required in the methods. Please see my queries related to specific sections of the paper below:

Abstract: Nice summary of the overall study
Introduction: Great introduction, covering background and rationale to the study. A minor point, generally you would not start a sentence with an acronym, but with the full term.

Theoretical/conceptual framework: The following sentence 'CFIR is not intended to be applied wholesale...' I don't think 'wholesale' is the right term here.

WP2:
Study setting: Could more details about the NHS settings in England be provided, are they from areas with similar demographics or are they diverse?

Study participants: '15 interviews per site (n=10)' The (n=10) placements appears as if you are including 10 sites, possibly move it after managers, midwives etc., and then (n=5) after women

enrolled in MCoC.
How many participants are you aiming for the surveys? Consider sample size calculation if appropriate.

Data collection and management: What is 'Speak Up Guardians' please define for the non-UK audience.
Please describe the tools you are using in more detail, are they validated tools or tools designed specifically for this project?
You state that components will be summarised and examined for potential associations, what outcomes will you be looking for specifically?

Recorded semi-structured interviews in six case study sites: n=90? Stated above n=65, please clarify. The detail here is also repetitive of the above, decide where it fits better.

Data analysis:
There is no mention of what statistical tests are anticipated to be used for the survey component.

Overall: There are many acronyms used throughout, which impact the flow of reading when they are not familiar, consider minimising the number of acronyms used.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Maternity service research

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.