FACTORS INFLUENCING THE IMPLEMENTATION OF THE MIDWIFERY CONTINUITY OF CARER (MCoC) MODEL OF CARE IN ENGLAND: A MIXED METHODS CROSS CASE ANALYSIS

SHORT STUDY TITLE/ACRONYM

Studying **I**mplementation of **M**idwifery **C**ontinuity of C**a**rer (SIMCA)

PROTOCOL VERSION NUMBER AND DATE

Protocol version 3.0 17th April 2024

RESEARCH REFERENCE NUMBERS

Sponsor	University of Plymouth
Sponsor Reference	AM1001431
Funder	NIHR – Health and Social Care Delivery Research
Funder Reference	NIHR 151802
REC Reference	23/PR/1249
IRAS Number	327714
Website	https://plymouth.ac.uk/research/simca
ISRCTN	10635039
Q-Pulse Template Number	TPL/003/2

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement. I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor. I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

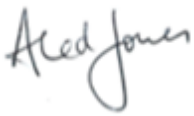
Signature: 

Name: Sarah Jones

Date: 22/04/2024

Position: Senior Research Integrity & Governance Manager

Chief Investigator:

Signature: 

Name: Aled Jones

Date: 22/04/2024

GENERAL INFORMATION

The CI and the co-investigators have all contributed to the protocol. In the 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 throughout the project, in particular with the Public and Patient Involvement (PPI) group.

This protocol describes the SIMCA study and provides information about the study. The protocol has been written with great care; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the project. Problems relating to the project should be referred, in the first instance, to CTR simca@cardiff.ac.uk and the CI aled.jones@plymouth.ac.uk.

CONTACT DETAILS CHIEF INVESTIGATOR AND CO-INVESTIGATORS

Name	Role	Organisation	Contact Details
Professor Aled Jones	Head of School Nursing and Midwifery and Professor of Patient Safety and Healthcare Quality.	Faculty of Health, University of Plymouth	aled.jones@plymouth.ac.uk
Dr Susan Channon (CU PI)	Senior Research Fellow	Centre for Trials Research, Cardiff University	channons2@cardiff.ac.uk
Professor Julia Sanders	Professor of Clinical Midwifery	School of Healthcare Sciences, Cardiff University	sandersj3@cardiff.ac.uk
Professor Sara Kenyon	Professor of Evidence-based Maternity Care	Institute of Applied Health Research, University of Birmingham	s.kenyon@bham.ac.uk
Miss Rebecca Milton	Research Associate / Trial Manager	Centre for Trials Research, Cardiff University	miltonr1l@cardiff.ac.uk
Mrs Tina Prendeville	Senior Clinical Research Midwife with Imperial College NHS Trust	Women's Health Research Centre, Imperial College London	tina.prendeville@nhs.net
Miss Susan Barry	Associate Director of Maternity	Women's, Children's and Clinical Support, Imperial College Healthcare NHS Trust	susan.barry4@nhs.net
Miss Kate Davies	Research and Policy Director	Tommy’s Baby Charity	KDavies@Tommys.org
Mrs Habiba Haque	Head of Community Programmes	The Mosaic Community Trust	habibahaque.mct@gmail.com

STUDY CO-ORDINATION

SIMCA is being co-ordinated by the Centre for Trials Research (CTR), Cardiff University, a Clinical Research Collaboration (UKCRC) registered studies unit. For **all queries** please contact the SIMCA study team through the main study email address simca@cardiff.ac.uk.

KEY STUDY CONTACTS

Chief Investigator	**Professor Aled Jones** Head of School Nursing and Midwifery and Professor of Patient Safety and Healthcare Quality, Faculty of Health, University of Plymouth aled.jones@plymouth.ac.uk PA Lilian Cheetham 01752 586700
Study Manager	**Rebecca Milton** Study Manager / Research Associate, Centre for Trials Research, College of Biomedical and Life Sciences, Cardiff University, 7th Floor, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS miltonrl1@cardiff.ac.uk 02920 687518
Sponsor	**Sarah C Jones** Senior Research Integrity and Governance Manager, Research Governance Specialist, Research and Innovation, University of Plymouth, Level 2, Marine Building, Drake Circus, Plymouth PL4 8AA
Funder(s)	NIHR Health and Social Care Services Delivery Research (Study ref: NIHR151802)
Key Protocol Contributors	Aled Jones (as above); Susan Channon channons2@cardiff.ac.uk and Rebecca Milton (as above)
Study Administrator	**Lorraine Craig** Study Administrator Centre for Trials Research, College of Biomedical and Life Sciences, Cardiff University, 7th Floor, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS simca@cardiff.ac.uk 02922 514076

KEY WORDS

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

CONTENTS

GLOSSARY OF ABBREVIATIONS

CFIR	Consolidated Framework for Implementation Research
CI	Chief Investigator
CTR	Centre for Trials Research
CU	Cardiff University
GCP	Good Clinical Practice
GP	General Practitioner
HEE	Health Education England
ISRCTN	International Standard Randomised Controlled Trial Number
MCoC	Midwifery Continuity of Carer
MTP	Maternity Transformation Programme
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NIHR	National Institute for Health and Care Research
NPT	Normalisation Process Theory
PAG	Project Advisory Group
PPI	Public and Patient Involvement
R&D	Research and Development
RA	Research Associate
RCM	Royal College of Midwives
RCOG	Royal College of Obstetricians and Gynaecologists
REC	Research Ethics Committee
SM	Study Manager
SMG	Study Management Group
SOP	Standard Operating Procedure
UoB	University of Birmingham
UoP	University of Plymouth

1 Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

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.
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	17/04/24	Addition of ISRCTN number. Removal of development of data management plan. Addition of incentive for service user interviews Updated section 23.

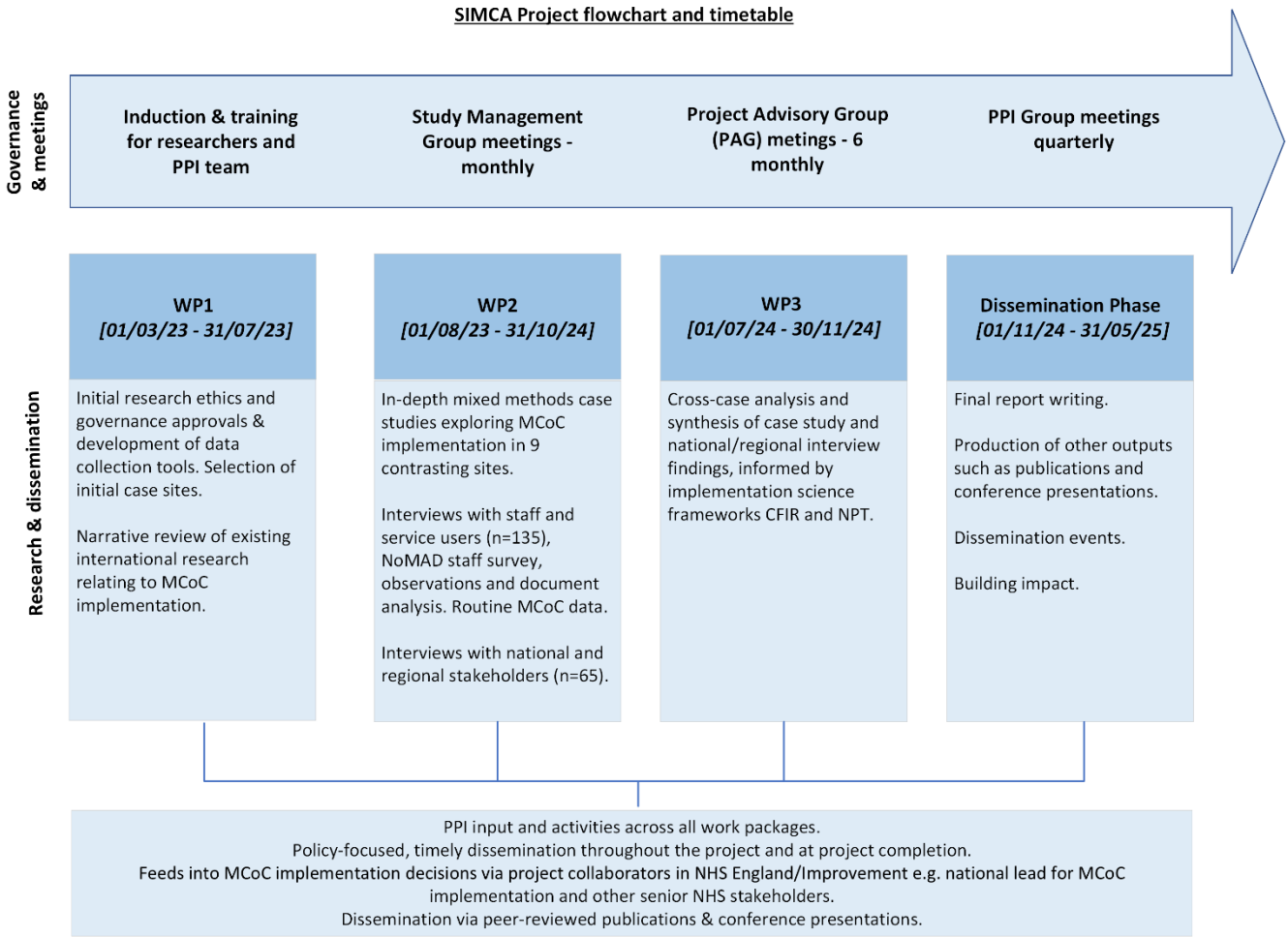
2 Synopsis

Study title	Factors influencing the implementation of the Midwifery Continuity of Carer (MCoC) model of care in England: a mixed methods cross case analysis
Short title/acronym	Studying Implementation of Midwifery Continuity of Carer (SIMCA)
Study design	Mixed methods cross case analysis
Study participants	Staff working in or professionally connected to midwifery services in nine case study sites. They will be from across professional groups, and junior and senior positions, including midwives and obstetricians. Women/service-users enrolled in MCoC from across the nine case study sites. National and regional stakeholders whose professional role has brought them into contact with the discussions about and/or implementation of MCoC in the UK.
Planned sample/data collection	Nine 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 study participants (NHS staff and women/service-users) and stakeholders, a semi-structured survey, documentary review and observations: • NoMAD Survey distributed electronically to all maternity services staff working within the case study sites. The survey will be distributed to staff in a range of junior and senior positions and professional groups. • National and regional stakeholder interviews (n=65) • 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). These will be referred to as participants throughout. • Guided non-participant observations at MCoC implementation meetings and related activities at each case site. • Local documentation and data accessed via the stakeholders including routinely collected MCoC outcome data, anonymised patient safety data, MCoC operational policies and service specifications, completed local audits and/or evaluations, and related grey literature.
Follow up duration	N/A
Planned study period	27 months 01/03/23 – 31/05/25
Research question/aim(s)	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.
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.

Primary objectives	1. Critically appraise the international literature to understand the contexts and factors contributing to the success and challenges of MCoC implementation. 2. Rigorously evaluate how implementation decisions have been operationalised, sustained and experienced in nine case study sites representing contrasting progress with MCoC implementation. 3. Describe and explore the role played by national and regional stakeholders in MCoC implementation decisions and progress. 4. Synthesise the findings of objectives 1 to 3 to identify various approaches to MCoC implementation, the key implementation factors and relationships, and any discernible patterns between implementation factors and routinely reported MCoC outcomes. 5. Disseminate recommendations throughout the project timeline to inform ongoing implementation of MCoC in England and contribute to debates about future changes to maternity services.
Primary outcomes	The main outcomes of the study are to identify various regional and national approaches to MCoC implementation, the key implementation factors and relationships and any discernible patterns between implementation factors and routinely reported MCoC outcomes. By reaching a better understanding of 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 contribute to debates about future changes to maternity services.

3 Study Summary and Schema

3.1 Study Schema



3.2 Plain English Summary

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.

The study aims to better understand the factors that result in different rates of progress with MCoC implementation in England 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 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.

4 Background

Improving newborn and maternal health has long been a leading priority of UK and global policy makers.[1,2] Yet the safety and quality of maternity services remains problematic worldwide.[3] Sub-optimal care quality in maternity services can result in death, serious disability and profound anguish for women, their children, and their families,[4,5] and imposes substantial burdens on health systems, including the cost associated with litigation.[6] The ongoing and pressing need for improvement in the quality and safety of care delivery is often attributed to several factors including: multimorbidity, the complexity of healthcare delivery and a variety of cultural and organisational challenges.[5,7]

Considering this, recent NHS England policy has introduced significant changes to improve the quality and safety of maternity care.[2,8] Implementation of the policy vision for safer and more personalised care across England is currently coordinated within the Maternity Transformation Programme (MTP). The MTP consists of a range of inter-connected interventions, including establishing the MCoC model 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 (eight midwives or fewer), throughout pregnancy, birth and the postnatal period.[9] Research evidence[10–12] and several policy directives[2,8] support the introduction of MCoC, the implementation of which represents a radical change to maternity services. 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.[11,13]

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', these 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.[14] Policy thickets are of particular interest to implementation research projects such as this. For example, important questions include how the implementation of each individual initiative interacts with others, 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.[15]

Questions relating to de-implementation are also relevant here, 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.[16]

Progress in implementing MCoC across England has been highly problematic.[17,18] 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[18] 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'. Furthermore, a recent Health and Social Care Select Committee report rated the progress of MCoC implementation as highly variable and 'requires improvement'.[18]

As a result, the implementation targets for MCoC have been regularly revised. Most recent amendments to MCoC implementation guidance were issued on April 1st 2022. In response to the Ockenden report,[5] NHS England directed all 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'. Currently, the MTP maintains 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.

4.1 Rationale

Unproductive implementation in healthcare can cause workforce stress and uncertainty, especially if changes are poorly communicated, are considered unfair and take place too quickly or too slowly.[17,19] 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,[20,21] and maternity services specifically,[3,22] can prove problematic. It is imperative to study the implementation of 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 suggest similar difficulties have been experienced, making the research questions in this study relevant and timely.

A Cochrane review[10] of the outcomes of MCoC' recommended future research should evaluate the process of implementing MCoC, including generating 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 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.

5 Study Objectives/Endpoints and Outcome Measures

The aim of this study 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 research question is ‘What regional and national factors contribute to variable progress with implementation of MCoC in NHS England?’

5.1 Primary Objectives

1. Critically appraise the international literature to understand the contexts and factors contributing to the success and challenges of MCoC implementation.
2. Rigorously evaluate how implementation decisions have been operationalised, sustained, and experienced in nine case study sites representing contrasting progress with MCoC implementation.
3. Describe and explore the role played by national and regional stakeholders in MCoC implementation decisions and progress.
4. Synthesise the findings of objectives 1 to 3 to identify various approaches to MCoC implementation, the key implementation factors and relationships and any discernible patterns between implementation factors and routinely reported MCoC outcomes.
5. Disseminate recommendations throughout the project timeline to inform ongoing implementation of MCoC in England and contribute to debates about future changes to maternity services.

5.2 Primary Outcomes

The primary outcomes of the study are to identify various regional and national approaches to MCoC implementation, the key implementation factors and relationships and any discernible patterns between implementation factors and routinely reported MCoC outcomes. By reaching a better understanding of 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 contribute to debates about future changes to maternity services.

6 Study Design and Setting

6.1 Theoretical Framework

We conceptualise MCoC as a complex intervention. Complex interventions are conventionally defined as interventions that are difficult to implement as they consist of several interacting and interlocking components, which span a number of organisational levels, 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] so that each level can be thought of as simultaneously sitting above and below (and interacting with) other systems of different scale. 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]. Both approaches have been usefully combined and deployed in previous and current NIHR projects undertaken by the CI (HSDR 16/116/25; HTA17/85; NIHR151811) and co-applicants Channon and Sanders (HTA 17/130/05).

The 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, which help identify the social processes underpinning the implementation of complex interventions (see Table 1).[26]

Table 1: Normalisation Process Theory – Overview of Generative Mechanisms

NPT component	**Explanation of the component and how it may be enacted in the context of MCoC**
Coherence or sense-making	Sense-making work undertaken individually and collectively to operationalise MCoC model of care. The 'success' of this depends on the perceived workability and integration of the various elements of the care model into everyday practice.
Cognitive Participation	The incorporation of MCoC within the workplace depends on relevant individuals' capacity to resource, cooperate and co-ordinate their actions.
Collective Action	NHS Trusts will be more disposed towards normalising MCoC into practice if there is individual and collective intention and commitment to operationalising the role in practice.
Reflexive Monitoring	The appraisal work that people do to assess and understand the ways that MCoC affects them and others around them.

6.2 Summary of the Work Packages

The project consists of the three inter-related WPs outlined in Table 2.

Table 2: Three Inter-Related Work Packages

Work Package	Objectives	Months	Methods
WP1: Narrative evidence synthesis	1	01/03/23 to 31/07/2023 (five months)	Narrative evidence synthesis of findings relevant to MCoC implementation, to inform data collection and interpretation of WP2 and WP3 findings.
WP2: Comparative case studies in nine sites. National and regional stakeholders' interviews	2 & 3	01/08/2023 to 31/10/2024 (three sites every five months, totalling 15 months).	**Quantitative data collection methods:** NoMAD implementation survey; MCoC outcomes **Qualitative data collection methods:** Semi-structured interviews with participants (NHS staff and service-users) in nine cases (n=c.135) and with regional and national maternity stakeholders (n=c.65 e.g. policy makers, senior managers, professional bodies, etc). Observations/meetings; documents. **Concurrent data analysis:** Descriptive quantitative analysis and qualitative thematic analysis, informed by CFIR/NPT.
WP3: Cross-case analysis	4	01/07/2024 to 30/11/2024	Cross-case analysis and synthesis of findings, informed by CFIR/NPT.
Dissemination Phase: Final report writing and dissemination	5	01/11/2024 to 31/05/2025	Dissemination will occur throughout. The study will follow the NIHR threaded publication format. Insights will contribute to current and future implementation of complex initiatives within maternity and other NHS services.

6.2.1 Work Package 1: Narrative Evidence Synthesis

The aim of WP1 is to undertake a narrative evidence synthesis approach[9] which addresses objective 1: *Critically appraise the international literature to understand the contexts and factors contributing to implementation and sustainability of MCoC models of care*.

Narrative synthesis refers to an approach that relies primarily on the use of words and text to summarise, synthesise and explain research findings. 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. The review will be registered with PROSPERO.

The search terms, inclusion and exclusion criteria for the review will be determined by the project team, the Project Advisory Group (PAG) and a library information specialist. An exhaustive literature search of healthcare and medical databases will be undertaken by the RAs. This will involve scoping searches to help identify appropriate keywords, synonyms, spelling variations; searches using both free text and database-specific subject headings e.g. MeSH. Advanced Boolean truncation, 'explode' and other search techniques will be deployed where necessary. We will also supplement the search of databases with additional 'snowball' search strategies, including reference list checking and 'asking around' through contact with experts.

Titles and abstracts of articles retrieved will be initially read by two team members and assessed against inclusion criteria, with a third reviewer consulted to resolve any disagreement. Next full text versions of the selected papers will be retrieved and screened against inclusion criteria. To ensure robustness, a screening tool will be developed to select studies congruent with the review aim and inclusion criteria. Overall quality of the research will be appraised using relevant CASP checklists (https://casp-uk.net/casp-tools-checklists/).

Data from all included papers will be extracted into a table which describes the attributes of the studies and relevant results. In addition, the results of selected studies will be gathered into a framework informed by NPT and supplemented by CFIR constructs (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.

6.2.2 Work Package 2: Comparative Case Studies and National and Regional Stakeholder Interviews

WP2 addresses objectives 2 and 3: *Rigorously evaluate how implementation decisions have been operationalised, sustained, and experienced in nine case study sites representing contrasting progress*

with MCoC implementation and describe and explore the role played by key national and regional stakeholders in MCoC implementation decisions.

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]

6.2.2.1 Sampling and Selecting Case Studies

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' [32]

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 lower percentage of women placed on the MCoC pathway.

6.2.2.2 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). 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 HEE leads. Other 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. The research team's extensive existing networks will also be utilised and referral ('snowballing') from those contacted or recruited using the above methods.

6.2.2.3 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: The two Research Associates (RAs) will undertake guided non-participant observations at MCoC implementation meetings and related activities at each case site. Observations will be recorded in cotemporaneous '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. The meetings observed by researcher will be policy operational meetings only – for example Maternity Improvement and Transformation meetings are held to discuss progress with maternity policy changes and related service improvements. No patient data are discussed at these meetings. The attendance at these meetings will be at the discretion and management of the NHS site. We have discussed attending such meetings directly with case sites and others NHS maternity professionals involved in the study as co-applicants or advisors. They agree that our presence observing meetings that are occurring regardless of our presence will not burden the services being observed and will greatly benefit the overall quality of the research being undertaken.

Local documentation and data: The RAs 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
- and related grey literature

Staff survey: NoMAD, a free-to-use validated 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. Consent to participate in the survey will be presumed when staff complete the survey. 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 others such as 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 (such as two “blanket” reminders via staff/team email accounts) where increased response rate/coverage is required.

Recorded semi-structured interviews in nine case study sites (n=c.135): At each case site semi-structured interviews (n=15) will be conducted by the RAs 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). Participants will be offered the choice of interviews using 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. On receipt of transcription a member of the research team will check the transcript for accuracy and undertake a pseudonymisation of any individuals and organisations named within the transcript.

The participant information sheet will identify that the purpose of the interview is 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 their respective toolkits.[33,34] Questions will be included on:

i) how services are organised and delivered

ii) any effect on implementation of the interplay between the ‘outer domain’ (regional and national priorities and incentives) and the ‘inner domain’ (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

Recorded semi-structured interviews with regional and national leads (n=c.65): Stakeholders will also be offered the choice of interviews using online technology or face-to-face recording. 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.

To ensure privacy face-to-face interviews will be conducted in a private room. Online interviews will be conducted within university offices or other spaces (home offices) where only the researcher or other members of the research team will be present. Participants will also be encouraged to consider the privacy of their location when participating in interviews, to ensure the discussion is not overheard by others. However, the nature of remote/online interviewing means that the location of the participant is completely within their discretion.

All data collected will be saved on secure CU Microsoft Teams channels. Files will be password protected, and accessible only to relevant members of the research team. Recordings will be

transcribed and pseudonymised in line with Centre for Trials Research (CTR) Standard Operating Procedures.

6.6.2.4 Data Analysis

Survey data: Descriptive analysis of the NoMAD survey responses will initially explore how answers are distributed. In line with the guidance provided by the tool's creators,[35] total scores for the NoMAD 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.

Qualitative data: Inductive thematic analysis of qualitative data sources, underpinned by methodological rigour,[34] will be undertaken by the core project team, concurrent with data collection in each case site. For regional and national stakeholder interviews this will enable critical assessment of whether data is of sufficient quality to meet study aims and will help inform subsequent data collection strategies. 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 coding, and the identification of emergent themes within and then across teams situated in CU and UoP. 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.

Specifically, the combined WP2 analytic process will involve:

1. Using the latest version of the NVivo qualitative data analysis software and SPSS for the survey data to organise and store data ready for analysis.
2. In-depth and iterative familiarisation of interview transcripts and field-notes followed by inductive thematic analysis.[34] The analysis will identify a range of respondents' views regarding factors such as organisational commitment, resources allocated, barriers to and enablers of MCoC implementation as perceived by local (micro level), regional (meso level) and national (macro level) participants.
3. Methodological rigour will be ensured through standard procedures of reflexivity.[36] Regular analysis meetings will be held within and between the teams in CU and UoP. Emerging and final themes will be discussed and agreed across both teams and the PPI team to ensure consistency 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.

4. Convergent analysis,[31] via triangulation of the quantitative (survey) and qualitative datasets, will establish patterns of within-case similarities and differences regarding MCoC implementation. Analysis will result in descriptions of the factors influencing each case site's approach to MCoC implementation, with subsequent interpretation and delineation of why such patterns may be occurring. Emergent patterns will also be cross-referenced to findings extracted from the WP1 narrative synthesis.
5. 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.

6.2.2.5 Service-users as Research Participants

The study involves service-users as research participants in WP2, where maternity service users who have experienced recent maternity care within the case study sites will be interviewed (n=45) for approximately 45 to 60 minutes. Furthermore, representatives from third sector organisations who represent pregnant women and new mothers in the UK will be interviewed as national stakeholders, such as Maternity Action the maternity rights charity.

To maximise opportunities for involvement, we will offer a choice of online or face-to-face interviews to service-users at a time and place which suits their needs. We will also offer a £25 gift voucher as an acknowledgement of their participation and a gesture of thanks.

6.2.2.6 Research Material

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.

6.2.3 Work Package 3: Cross-Case Analysis and Synthesis of Findings

WP3 addresses objective 4: *Synthesise the findings of objectives 1 to 3 to identify various approaches to MCoC implementation, the key implementation factors and relationships and any discernible patterns between implementation factors and routinely reported MCoC outcomes.*

Objective 4 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. This methodological approach to conducting within-case analysis, followed by cross-case analysis and synthesis, is founded on earlier NIHR-funded projects on which the CI has led and collaborated. 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.

6.2.4 Dissemination Phase

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.

The NPT/CFIR informed cross-case analysis and synthesis will not only feed into the final report but will also act as the foundation of a range of outputs such as accessible summaries, articles and presentations and workshops aimed at academics, policy makers, managers and practitioners working at local, regional and national levels within the NHS, as further detailed in section 6 (Study design and setting).

We will notify research participants that they will be able to track study progress and access findings via a range of social media and web platforms as well as the study website.

7 Risk Assessment

A study risk assessment has been completed by UoP to identify the potential hazards associated with the study and to assess the likelihood of those hazards occurring and resulting in harm. This risk assessment includes:

- The known and potential risks and benefits to human subjects
- How high the risk is compared to normal standard practice
- How the risk will be minimised/managed

This study has been categorised as low risk. The study does not impact the level of care received. A copy of the study risk assessment may be requested from the Study Manager or study sponsor.

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. In the event of a participant experiencing emotional distress during an interview, the interview will initially be paused and the option of continuing or terminating and recommencing the interview (or not) at a later time/date discussed. A support structure for debriefing distressed participants will be established prior to data collection. Specifically, distressed participants will be debriefed by the research team and encouraged to seek support/advice via existing staff support services within their organisation or a third sector organisation (e.g. TBC) of which details will be given. Participants will also be reminded of their right to

withdraw from the study, as well as their right not to answer some questions, without giving reason. 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. Direct benefits to participants are minor, however their opinion and thoughts are being recorded and could contribute to future policy making, change/implementation management and ways of working.

8 Participant Selection

Participants are eligible for WP2 of the study if they are able to contribute to the aims of the study and provide informed verbal or written consent, this is fully detailed in section 6.2.2.

8.1 Inclusion Criteria

- Individuals who directly affect, or are affected by, MCoC implementation.
- Are associated with a case site.

8.2 Exclusion Criteria

- No groups are to be excluded from participating, unless there are clinical grounds barring participation following discussion with the midwifery team.

9 Recruitment and sampling

Detailed recruitment and sampling for the case studies and stakeholder interviews are fully described in section 6, an overview is provided in this section.

9.1 Recruitment

Within each case study site, sampling will be purposive and iterative, to ensure a range of views are gathered from those with relevant experience and that data saturation is achieved as far as possible. We will start by identifying and interviewing participants in order to map the core components of midwifery services and MCoC provision within the organisation. These data will inform our initial sampling strategy and enable us to identify relevant stakeholders, documents, meetings, and situations in which MCoC is enacted or discussed. Hereafter, data generation and analysis will be undertaken concurrently to build up an understanding of each case.

Prospective participants for WP2 will be identified through various routes. 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 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.

All potential participants will be requested to contact the research team to receive more information through a variety of methods, such as posters with a QR code to link to the website. The website provides the study information, contact details, participant information sheet and the opportunity to provide informed consent.

Researchers will approach staff members to invite them to take part, and members of the clinical team will approach service-users and lay representatives to invite them to take part, emphasising that participation is voluntary. Contact details of those willing to participate will be passed onto the research team. Researchers will then individually contact those willing to participate via email, or work phone/WhatsApp, where available/in accordance with participant preferences.

9.2 Sampling

The study will be publicised throughout the unit (e.g. via posters and at NHS unit meetings) and via local networks, and potential participants requested to visit the study website or to contact the research team to receive information. The researchers will liaise with site contacts to set up a meeting with local lay representatives (e.g. Maternity Voices/Maternity Services Liaison Committee/NHS Trust Facebook pages), to include women who have given birth recently.

Researchers will be introduced to participants initially through key informants and thereafter purposively selected, with agreement, in light of the emerging findings.

9.3 Recruitment Rates

For the semi-structured interviews in WP2 across nine sites we aim to recruit (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).

9.4 Informed Consent

All participants will be provided with a Participant Information Sheet (PIS) which will be available online via the study website or paper-based on request. On reviewing the PIS participants will be given time to consider whether they would like to participate in the study. The PIS will clearly outline the nature and objectives of the study and possible benefits and risks associated with participation. Participants will also be offered the opportunity to ask questions about the study prior to consenting to participate, with a final opportunity to ask questions immediately prior to the interview itself. Participants have the right to refuse to participate in the study at any time without giving a reason.

All interview participants will need to provide consent using the study consent form (online or paper-based) prior to the start of the interview. Participants will be asked to initial each consent statement and

provide a signed copy of the form to the researcher (in person or online). Where online 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. For paper-based consent forms one copy will be kept by the participant, and another kept by the researcher. Participants have the right to refuse to participate in the study without giving a reason. Once consent has been obtained, electronic copies of consent forms will be held on password-protected computers and paper copies will be stored in secure, lockable cabinets at the CTR. A participant management database/consent log will be kept in a restricted-access MS Teams folder (accessible to study team members only, as detailed on the study delegation log).

To enable the linking of individual participants with their responses, participants will be allocated a unique numerical study identifier prior to data collection. Each organisation and participant's name/role will be stored along with their unique study identifier in a secure document/spreadsheet. This document will be saved in a separate folder from data documents (such as sound files and transcripts) and only made accessible to the project lead and members of the research team directly involved in data collection.

10 Withdrawal

Participants have the right to withdraw consent for participation in any aspect of the study at any time. The participant's care will not be affected at any time by declining to participate or withdrawing from the study. If the participant decides to withdraw from the study, this could be during or after an interview, semi-structured survey or the data collected during documentary review and observations. If a participant wishes to withdraw permission to use data already collected a withdrawal form will need to be completed and this withdrawal will need to take place within two weeks of data being collected. This will be detailed in the PIS.

In all instances participants who consent and subsequently withdraw should complete a withdrawal form or the withdrawal form should be completed on the participant's behalf by the researcher based on information provided by the participant. This withdrawal form should be sent to *simca@cardiff.ac.uk* Any queries relating to potential withdrawal of a participant should be forwarded to simca@cardiff.ac.uk.

11 Study procedures

Participants will have the opportunity to participate in a semi-structured interview in order to share their experiences of MCoC implementation and the factors influencing the development, organisation and normalisation of MCoC in each site. The interview schedules will be informed by the findings from NoMAD, in addition to views of the PAG and PPI team, the findings of the narrative synthesis and the application of CFIR and NPT via the their respective toolkits.[47,48] Questions will be included on:

i) how services are organised and delivered

ii) any effect on implementation of the interplay between the 'outer domain' (regional and national priorities and incentives) and the 'inner domain' (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.

Participants will be offered the choice of interviews using 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. On receipt of transcription a member of the research team will check the transcript for accuracy and undertake a pseudonymisation of any individuals and organisations named within the transcript.

All data collected will be saved on secure CU Microsoft Teams study channel. Files will be accessible only to relevant members of the research team. Recordings will be transcribed and pseudonymised in line with CTR Standard Operating Procedures.

Key themes emerging from the interviews will be summarised and coded using qualitative thematic analysis approach by the research team. Pseudonymised quotes will be drawn out from the key themes to support the analysis and highlight specific issues. Participants are expected to participate in one interview, lasting approximately one hour.

12 Safety

This study has been classed as low risk with minimal participant contact, no clinical or medical interventions and no changes to care as a result of the study. As such it is highly unlikely that participants will experience any adverse events/serious adverse events as a result of participating in this study. Therefore, there will be no process in place for collecting adverse events/serious adverse events. Although unlikely, some participants may find it distressing to recall and describe work-related events or pregnancy-related care. In the event of a participant experiencing emotional distress during an interview, the interview will initially be paused and the option of continuing or terminating and recommencing the interview (or not) at a later time/date discussed. A support structure for debriefing distressed participants will be established prior to data collection. Specifically, distressed participants will be debriefed by the research team and encouraged to seek support/advice via existing staff support services within their organisation or a third sector organisation (e.g. TBC) of which details will be given. Participants' will also be reminded of their right to withdraw from the study, as well as their right not to answer some questions, without giving reason.

Study team members will follow CTR's Lone Working standard operating procedure to ensure safety of the researchers when collecting data alone. Lone working has been assessed as presenting a low risk to researchers in this study.

13 Data Management

All procedures for data storage, processing and management will comply with CTR Standard Operating Procedures, and the GDPR.

A study MS Teams folder will be set up and managed by the SM; this will allow all study members to access and upload documents and pseudonymised data. MS Teams is of a sufficient standard for UK Data Protection legislation 2018, and is supported by Cardiff University as is underpinned by OneDrive. Study team members will be able to access material at any time, although permissions for restricted access will be set per folder or document where required (permissions will be recorded on the study delegation log). Any identifiable data e.g. consent forms will be securely stored on password-protected computers (in restricted access folders) and/or in secure, lockable cabinets located at the CTR and study sites. Identifiable data (consent forms, recordings) will be stored separately from study data.

Participants will be assigned a unique identifier and a password-protected participant management database/consent log, located on the study MS Teams channel, will be used to keep a record of consented participants and link unique identifiers to participant names and contact details. This will be maintained and managed by relevant study team members.

NoMAD survey will be hosted by UoP with data being stored on the study MS Teams platform.

Interviews will be recorded through MS Teams and/or CU owned encrypted recording devices and saved on secure CU servers (recordings will be deleted from encrypted devices once uploaded to secure CU servers). Files will be password protected, and accessible only to relevant members of the research team. Recordings will be transcribed and pseudonymised in line with CTR Standard Operating Procedures.

Interviews will be transcribed by a commercial transcription service which will be required to sign a study specific contract between UoP and the organisation.

All essential documents generated by the study will be kept in the electronic Study Management File and managed by the SM. UoP's Research Data Policy will be adhered to. Cardiff University demonstrates compliance with current information governance requirements as set out in the Department of Health Policy with standards being met 2021/22 for the Data Security and Protection Toolkit.

14 Protocol/GCP Non-Compliance

Any non-compliance to the study protocol or the conditions and principles of Good Clinical Practice should be reported to the CTR in writing as soon as they become aware of it.

Protocol compliance will be monitored by the study team and any team member identifying any deviations will contact the SM as soon as they become aware of them. Any deviations will be documented using the relevant forms and the CI and Sponsor will be notified immediately. Compliance, deviations and changes to the protocol will be recorded in the project management meetings with actions and minuted.

15 End of Study Definition

The end of the study is defined as the date of final data capture to meet the study endpoints.

CI or Study Manager must notify the main REC of the end of a clinical study within 90 days of its completion or within 15 days if the study is terminated early.

16 Archiving

The Study Management File and any Study Site Files containing essential documents will be archived at an approved external storage facility for a minimum of 10 years as per sponsor policy. Dependent on site requirements any site files will be archived on approval from Sponsor, the responsibility will be with the site Principal Investigator. Essential documents pertaining to the study shall not be destroyed without permission from the Sponsor.

17 Regulatory Considerations

17.1 Ethical and Governance Approval

Approval will be sought for this protocol from a Research Ethics Committee (REC) that is legally recognised by the United Kingdom Ethics Committee Authority for review and approval, Health Research Authority. This study protocol will be submitted through the relevant permission system for global governance review. We have sought University of Plymouth's ethics approval through the Faculty Research Ethics and Integrity Committee. This approval was obtained on 2nd October 2023 and is subject to HRA/REC approval. The project reference is: 4556.

UK Policy Framework for Health and Social Care Research and UoP research governance procedures will be followed. This guidance set out the professional standards and basic requirements that are fundamental to all research, as well as the ethical and external regulations that govern research.

Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

All correspondence with the REC will be retained.

The CI will produce the annual reports and submit them to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.

The CI will notify the REC of the end of the study. If the study is ended prematurely, the CI will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the CI will submit a final report with the results, including any publications/abstracts, to the REC.

17.2 Data Protection

We will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Any identifiable data will be pseudonymised prior to analysis in line with good research practice. All data collected will be confidential to the project and stored securely in line with current CU research governance and data protection standards and regulations. All researchers will be trained in good interview practice and in the use of distress protocols (including immediately pausing/ceasing the interview if participants become upset and providing avenues for support).

All procedures for data storage, processing and management will comply with comply with CTR guidance and the General Data Protection Regulation. Data will be stored in a secure manner and will be registered in accordance with the General Data Protection Regulation 2018 and the UK Data Protection legislation 2018. The data processor for this study is CU, the data controller is UoP and overall responsibility for data management is allocated to the CI (AJ) .

All electronic data will be stored on a secure CU Microsoft Teams channel, with restricted access to named study team members only. Access to files will be through password protected PCs/laptops and only accessible to named researchers. All essential documents generated by the study will be kept in the electronic Study Master File (with any paper copy consent forms scanned) (on Microsoft Teams).

The online survey will be hosted on a secure university server and access password protected. A member of the research team will act as administrator.

Interview recordings will be transferred to the secure Microsoft Teams folder allocated only for interview recordings and accessed only by those leading data analysis. A sound-only file will be forwarded for transcription to the selected transcription service.

Issues of anonymity, confidentiality and informed consent will be addressed in the recruitment of all participants, data collection processes and data storage. The principles of beneficence and non-malfeasance will be adhered to. The team is experienced in managing large-scale NIHR funded research studies and applying for NHS/University Research Ethics and R&D approvals applications and ethical practices in terms of accessing and recruiting participants, and data collection via remote/online interviews.

To enable the linking of individual participants with their responses, participants will be allocated a unique numerical study identifier prior to data collection. Each organisation and participant's name/role will be stored along with their unique study identifier in a document/spreadsheet. This document will be saved in a separate folder from data documents (such as sound files and transcripts) and only made accessible to the project lead and members of the research team directly involved in data collection.

17.3 Indemnity

The UoP (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

17.4 Study Sponsorship

The study sponsor and contracting organisation is UoP, who shall be responsible for ensuring that the study is performed in accordance with the following:

- Conditions and principles of GCP.
- Declaration of Helsinki (1996)
- UK Policy Framework for Health and Social Care Research
- The General Data Protection Regulation (2016)
- Other regulatory requirements as appropriate

Contact details:
Email: plymouth.sponsor@plymouth.ac.uk
Telephone: 01752 588959

17.5 Funding

SIMCA is funded by NIHR, Health and Social Care Delivery Research, funders reference: 151802. The funder will have no direct role in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The funder has no direct control over the final decision regarding any of these aspects of the study, but the PAG (via the Chair) will communicate any concerns or issues to the funder accordingly.

18 Study Management

UoP:

- Aled Jones (AJ) Chief Investigator. AJ will be responsible for oversight of the project budget, progress, and timely study completion overall. AJ will also be responsible for the identification of case study sites; contribute to data collection and analysis; synthesis of data and report writing.
- Research Associate will be responsible for the identification of case study sites; contribute to data collection and analysis; synthesis of data and report writing.

CU:

- Sue Channon (SC) (site PI for CU), SC will be responsible for oversight of the project budget, progress, and timely study completion from CU perspective and to contribute to identification of case study sites; data collection, data analysis; synthesis of data and report writing.

- Julia Sanders (JS) will contribute to identification of case study sites; sampling and recruitment of participants; data collection, data analysis; synthesis of data and report writing.
- Rebecca Milton (RM) (Study Manager) will be responsible for day-to-day management of the study, contribute to identification of case study sites; sampling and recruitment of participants; data collection, data analysis; synthesis of data and report writing.
- Research Associate will contribute to identification of case study sites; sampling and recruitment of participants; data collection, data analysis; synthesis of data and report writing.
- Administrator will be responsible for the day-to-day administration of the project.

UoB:

- Sara Kenyon (SK) will contribute to identification of case study sites, stakeholders for interview, data analysis, synthesis of data and report writing.

Imperial College London:

- Tina Prendeville (TP) will provide clinical and PPI expertise throughout the course of the study.
- Susan Barry (SB) will provide clinical expertise throughout the course of the study.

PPI Members:

- Kate Davies (KD) PPI co-lead from TBC.
- Lena Chaoudary-Salter (LCS) PPI co-lead and lead for community engagement from MCT

The study will be conducted via UoP and CU's CTR, with additional support from UoB. The universities will collaborate in undertaking all aspects of the study. The teams in CU and UoP will lead the case studies (five sites and four sites respectively). To promote efficiency, cross-team scrutiny, and opportunities for supportive working, we will seek research governance permission for each team to collect data in all nine sites.

18.1 Project Team

Weekly project team meetings between CU and UoP will be chaired by the SM. These will be attended by all CU and UoP team members. The aim of these meetings is to direct and co-ordinate the work of the study team, oversee project progress and management.

18.2 Study Management Group (SMG)

A Study Management Group (SMG), comprising the CI, co-applicants, CU and UoP study team members and PPI members will meet monthly online to regularly review study milestones. SMG members will be required to sign up to the remit and conditions as set out in the SMG Charter. The CI will chair the SMG meetings, input will be sought from each team member and PPI leads.

18.3 Project Advisory Group

Study oversight will be provided by the PAG, which will have a national focus. The PAG will be independently chaired by Dame Cathy Warwick, former Chief Executive of the Royal College of

Midwives (RCM) and Chair of Trustees of the British Pregnancy Advisory Service. The PAG will meet six monthly to advise the project team on all aspects of the work. Members will be independent, and invited based on their varied perspectives, from: professional organisations (e.g., RCM, RCOG), charities with national reach; groups focussed on inequalities; maternity/midwifery senior researchers/academics, PPI representatives and NHS policy-makers. PAG members will be required to sign up to the remit and conditions as set out in the PAG Charter.

18.4 Public and Patient Involvement Group

Group membership and structure: The PPI group will meet every four months, chaired by either of the PPI co-applicants from TBC or MCT. The meetings will either be in-person or online (via MS Teams) attended by PPI representatives and members of the research team.

The PPI members will participate as full members of the monthly SMG and the PPI representative from TBC will represent PPI at the six monthly PAG meetings. This will ensure that patient and public views are integrated throughout the lifetime of the project. All PPI activities, travel and subsistence have been fully costed in accordance with NIHR guidance.

PPI work is led by TBC and MCT, both of whom are funded co-applicants. TBC run a UK-wide and international online midwifery-led pregnancy hub, supporting families through their pregnancy reaching around two million people. The MCT aims to empower diverse, socially and economically disadvantaged communities to influence public services. SC from the project team will support and co-ordinate PPI activities. The GRIPP2 short-form checklist will be used to capture the impact of the PPI work within the study and reviewed on a six monthly basis.

Activities: Overall, the PPI group will help the 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. During the analysis phase PPI members will periodically review pseudonymised transcripts to contribute to analysis via online and face-to-face team meetings. Emerging and final themes will be discussed and agreed with the PPI members. Particularly important during analysis will be PPI contribution to an understanding of the service-users' perspectives, by informing emergent analytical themes which academics and practitioners might otherwise overlook.

PPI members will also contribute directly to dissemination. Dissemination will have significant public reach through the close involvement in the project of TBC.

Approach to PPI activities: The approach of MCT and TBC to the PPI activity will reflect their existing engagement models with their respective communities and draws on their previous experiences of engaging with researchers. For example, MCT's public engagement and involvement throughout the project will be achieved via their Health and Wellbeing advocates, who work directly with vulnerable and disadvantaged Black, Asian and minority ethnic women and communities. As part of their practice to encourage community participation and activism in health and social care issues, MCT regularly hold community gatherings for people to share experiences. This project includes funding for similar gatherings, focussed on maternity services, where people in the community will come together to discuss their experiences and views.

For TBC, where much of the work is conducted online, it is anticipated that these equivalent discussions will happen virtually with the funding allocated to attendees of virtual discussion groups.

19 Quality Control and Assurance

19.1 Monitoring

The clinical study risk assessment has been used to determine the intensity and focus of central and on-site monitoring activity in the SIMCA. This study does not require a study monitoring plan, due to its low risk and overall aims/objectives having no risk to participants or researcher.

19.2 Audits and Inspections

The study is participant to inspection by the Health Research Authority as the regulatory body. The study may also be participant to inspection and audit by UoP under their remit as Sponsor.

20 Publication Policy

All dissemination of NIHR funded research is closely overseen and scrutinised by the NIHR study managers and colleagues and guided by NIHR policy. All publications and presentations relating to the study will be authorised by the Project Team and communicated to the PAG. Dissemination of the study results will also occur online via the NIHR Journals Library; outputs will also include open access 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 report will follow the NIHR threaded publication format. The co-applicants will disseminate the results of the study through professional and lay, local, national and international meetings, workshops and conferences. Study 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. All investigators will be authors of the final study report as per the International Committee of Medical Journal Editors guidance and NIHR policy.

21 Milestones

Table 3: Milestones

Milestones	Target completion date
Initial research ethics and governance approvals	31/07/2023
Development of data collection tools	31/07/2023
Selection of initial case sites	30/07/2023
Narrative review of existing international research relating to MCoC implementation	31/10/2023
In depth mixed methods case studies exploring MCoC implementation in nine contrasting sites	31/10/2024
Interviews with staff and service users (n=135)	31/10/2024
NoMAD staff survey, observations and document analysis, routine MCoC data	31/10/2024
Interviews with national and regional stakeholders (n=65)	31/10/2024
Cross Case analysis and synthesis of cross-case findings with national and regional stakeholder findings informed by implementation science frameworks CFIR and NPT	30/11/2024
Final report	31/05/2025
Output production	31/05/2025

22 References

1. World Health Organisation. *WHO Recommendations on Maternal Health*.; 2017. Accessed May 30, 2023. https://www.who.int/publications/i/item/WHO-MCA-17.10
2. NHS England. *The Long Term Plan*.; 2019. www.longtermplan.nhs.uk
3. Liberati EG, Tarrant C, Willars J, et al. Seven features of safety in maternity units: a framework based on multisite ethnography and stakeholder consultation. *BMJ Qual Saf*. 2021;30(6):444-456. doi:10.1136/bmjqs-2020-010988
4. Andreasen S, Backe B, JØrstad RG, Øian P. A nationwide descriptive study of obstetric claims for compensation in Norway. *Acta Obstet Gynecol Scand*. 2012;91(10):1191-1195. doi:10.1111/j.1600-0412.2012.01409.x
5. Great Britain. Department of Health & Social Care., Great Britain. Independent Maternity Review. *Findings, Conclusions and Essential Actions from the Independent Review of Maternity Services at The Shrewsbury and Telford Hospital NHS Trust : Ockenden Report - Final*.; 2022. Accessed May 30, 2023. https://www.gov.uk/government/publications/final-report-of-the-ockenden-review
6. Magro M. *Five Years of Cerebral Palsy Claims: A Thematic Review of NHS Resolution Data*.; 2017. Accessed May 30, 2023. https://resolution.nhs.uk/wp-content/uploads/2017/09/Five-years-of-cerebral-palsy-claims_A-thematic-review-of-NHS-Resolution-data.pdf
7. Barber J, Wienand-Barnett S. Royal College of Obstetricians and Gynaecologists Workforce Report 2022. Published online 2022. Accessed May 30, 2023. https://www.rcog.org.uk/careers-and-training/starting-your-og-career/workforce/og-workforce-report-2022/
8. NHS England. *BETTER BIRTHS: Improving Outcomes of Maternity Services in England - A Five Year Forward View for Maternity Care*.; 2016.
9. NHS England. *Delivering Midwifery Continuity of Carer at Full Scale*.; 2021. Accessed May 30, 2023. https://www.england.nhs.uk/publication/delivering-midwifery-continuity-of-carer-at-full-scale-guidance-21-22/
10. Sandall J, Soltani H, Gates S, Shennan A, Devane D. Midwife-led continuity models versus other models of care for childbearing women. *Cochrane Database of Systematic Reviews*. 2016;2016(4). doi:10.1002/14651858.CD004667.pub5
11. Medley N, Vogel JP, Care A, Alfirevic Z. Interventions during pregnancy to prevent preterm birth: An overview of Cochrane systematic reviews. *Cochrane Database of Systematic Reviews*. 2018;2018(11). doi:10.1002/14651858.CD012505.pub2
12. Care Quality Commission. *Maternity Services Survey 2019*.; 2019. Accessed June 6, 2023. https://nhssurveys.org/surveys/survey/04-maternity/year/2019/
13. Fernandez Turienzo C, Rayment-Jones H, Roe Y, et al. A realist review to explore how midwifery continuity of care may influence preterm birth in pregnant women. *Birth*. 2021;48(3):375-388. doi:10.1111/birt.12547
14. Dixon-Woods M, Baker R, Charles K, et al. Culture and behaviour in the English National Health Service overview of lessons from a large multimethod study. *BMJ Quality & Safety Journal*. 2014;23:106-115.

15. Taylor B, Hewison A, Cross-Sudworth F, Morrell K. Transformational Change in maternity services in England: a longitudinal qualitative study of a national transformation programme 'Early Adopter.' *BMC Health Serv Res*. 2022;22(1). doi:10.1186/s12913-021-07375-3
16. Williams I, Harlock J, Robert G, Kimberly J, Mannion R. Is the end in sight? A study of how and why services are decommissioned in the English National Health Service. *Sociol Health Illn*. 2021;43(2):441-458. doi:10.1111/1467-9566.13234
17. Royal College of Midwives. The RCM's stance on continuity of carer. *Midwives*. 2021;24.
18. Care Committee S. *The Health and Social Care Committee's Expert Panel: Evaluation of the Government's Progress against Its Policy Commitments in the Area of Maternity Services in England First Special Report of Session 2021-22*.; 2021. www.parliament.uk/hsccom
19. Nilsen P, Schildmeijer K, Ericsson C, Seing I, Birken S. Implementation of change in health care in Sweden: A qualitative study of professionals' change responses. *Implementation Science*. 2019;14(51). doi:10.1186/s13012-019-0902-6
20. Dixon J. Improving the quality of care in health systems: towards better strategies. *Isr J Health Policy Res*. 2021;10(15).
21. Marshall M, Davies H, Ward V, et al. Optimising the impact of health services research on the organisation and delivery of health services: a mixed-methods study. *Health and Social Care Delivery Research*. 2022;10(3). doi:10.3310/HFUU3193
22. Liberati EG, Tarrant C, Willars J, et al. How to be a very safe maternity unit: An ethnographic study. *Soc Sci Med*. 2019;223:64-72. doi:10.1016/j.socscimed.2019.01.035
23. Skivington K, Matthews L, Simpson SA, et al. Framework for the development and evaluation of complex interventions: Gap analysis, workshop and consultation-informed update. *Health Technol Assess (Rockv)*. 2021;25(57):i-132. doi:10.3310/HTA25570
24. Hannigan B. Connections and consequences in complex systems: Insights from a case study of the emergence and local impact of crisis resolution and home treatment services. *Soc Sci Med*. 2013;93:212-219. doi:10.1016/j.socscimed.2011.12.044
25. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science*. 2009;4(1). doi:10.1186/1748-5908-4-50
26. May C. Towards a general theory of implementation. *Implementation Science*. 2013;8(1). doi:10.1186/1748-5908-8-18
27. May CR, Cummings A, Girling M, et al. Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: A systematic review. *Implementation Science*. 2018;13(1). doi:10.1186/s13012-018-0758-1
28. Damschroder LJ. Clarity out of chaos: Use of theory in implementation research. *Psychiatry Res*. 2020;283. doi:10.1016/j.psychres.2019.06.036
29. Murray E, Treweek S, Pope C, et al. Normalisation process theory: A framework for developing, evaluating and implementing complex interventions. *BMC Med*. 2010;8. doi:10.1186/1741-7015-8-63

30. Davidoff F, Dixon-Woods M, Leviton L, Michie S. Demystifying theory and its use in improvement. *BMJ Qual Saf*. 2015;24(3):228-238. doi:10.1136/bmjqs-2014-003627
31. Yin R. *Case Study Research and Applications: Design and Methods*. 6th ed. Sage Publications; 2018.
32. May CR, Finch T, Ballini L, et al. Evaluating complex interventions and health technologies using normalization process theory: Development of a simplified approach and web-enabled toolkit. *BMC Health Serv Res*. 2011;11. doi:10.1186/1472-6963-11-245
33. CFIR Research Team. The Consolidated Framework for Implementation Research. Published 2022. Accessed May 30, 2023. https://cfirguide.org/tools/
34. Bradley EH, Curry LA, Devers KJ. Qualitative data analysis for health services research: Developing taxonomy, themes, and theory. *Health Serv Res*. 2007;42(4):1758-1772. doi:10.1111/j.1475-6773.2006.00684.x
35. Finch TL, Girling M, May CR, et al. Improving the normalization of complex interventions: Part 2 - Validation of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT) 17 Psychology and Cognitive Sciences 1701 Psychology. *BMC Med Res Methodol*. 2018;18(1). doi:10.1186/s12874-018-0591-x
36. Simpson A, Hannigan B, Coffey M, et al. Cross-national comparative mixed-methods case study of recovery-focused mental health care planning and co-ordination: Collaborative Care Planning Project (COCAPP). *Health Services and Delivery Research*. 2016;4(5):1-190. doi:10.3310/hsdr04050
37. Mannion R, Freeman T, Millar R, Davies H. Effective board governance of safe care: a (theoretically underpinned) cross-sectioned examination of the breadth and depth of relationships through national quantitative surveys and in-depth qualitative case studies. *Health Services and Delivery Research*. 2016;4(4):1-166. doi:10.3310/hsdr04040

23 Appendices

- Participant information sheet, service users. (File name: SIMCA Participant information sheet - Service Users - v3.0 17042024)
- Participant information sheet, service providers. (File name: SIMCA Participant information sheet - Service Providers - v2.1 240124)
- Consent form, service users. (File name: SIMCA Consent Form – Service Users – v1.3 17042024)
- Consent form, service providers. (File name: SIMCA Consent Form – Service Providers – v1.2 240124)
- Advert for maternity service users. (File name: SIMCA Poster – Service Users - v3.0 170424).
- Advert for maternity service providers (File name: SIMCA Poster – Service Provider – v1.1 240124).