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ARM@DA: A REALIST INQUIRY INTO MATERNITY CARE @ A DISTANCE

RESEARCH PROTOCOL v.1

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SUMMARY OF RESEARCH

ARM@DA: A Realist Inquiry into Maternity Care @ a DistAnce

Background
The Maternity Transformation Programme in England aims to create safer, kinder, more personalised and family friendly care. A core work stream is 'harnessing digital technology'. The Covid-19 pandemic has radically altered and dramatically accelerated the context for this digital policy imperative. One of the most commonly reported Covid-related changes to all maternity services has been an increase in the use of remote/virtual consultations using telephone or video-calling. This shift was primarily implemented to support pandemic response objectives such as social distancing and service demand management. Going forward however, a key service challenge lies in how to 're-purpose' the use of digital clinical consultations to meet longer term quality, equity and productivity objectives. National guidance has been developed quickly to guide professional practice, but there has not, to date, been a comprehensive review of the evidence base to inform future service developments or research in this area of maternity care. Hence, although remote consultations may now be widespread, the ways in which they can be optimally scaled up and utilised in future along the maternity care pathway is unclear. This proposed project seeks to fill these gaps through an in-depth and theory-informed investigation of the evidence around implementation of digital clinical consultations.

Research Aim
To identify mechanisms to explain how digital consultations can work to support safe, personalised and appropriate maternity care and to clarify when they might be most appropriately used, for whom, when, and in what contexts.

Research Design and Methods
A realist synthesis will be conducted over an 18-month period in 4 highly iterative phases: (i) refining the review focus and generating initial programme theories, (ii) exploring and developing the programme theories in light of evidence, (iii) testing/refining the programme theories, and, (iv) constructing actionable recommendations in ways that can be rapidly adopted into practice and clearly define a future research agenda. The review will draw upon three sources of evidence: (i) literature (published and unpublished research, audit, evaluation and theory), (ii) stakeholder expertise and insights, and (iii) (limited) key informant interviews. The review will be registered on Prospero and will follow the RAMESES (Realist and Meta-narrative Evidence Synthesis Evolving Standards) quality procedures and will comply with RAMESES reporting guidance.

Research Team
The project includes extensive PPI at every stage. It includes a highly experienced multi-professional and multi-disciplinary team of academics, information scientists, service users and expert clinicians. This group will work closely alongside two expert stakeholder groups (NHS staff and community organisations/service users) designed to reflect a wide diversity of experience.

Dissemination and Impact
The review findings will be disseminated in formats relevant to different audiences, augmented and signposted through social media, including reports/publications, webinars, best practice infographics and implementation toolkits and an online education resource. The review output will be a theoretically-grounded explanatory framework for safe, appropriate and acceptable digital consultations in maternity care that can be used by NHS stakeholders to guide future service development, policy, practice and research.

BACKGROUND AND RATIONALE

This proposal is for a realist review to generate a theory- and evidence-informed framework to guide best practice in the implementation of digital clinical consultations in maternity care in the NHS. The project adopts an inclusive collaborative approach, involving diverse and extensive PPI and stakeholder engagement at every stage.

Maternity care in England is undergoing a substantive transformation programme whose overall aim is to support services to work across professional and service boundaries to become safer, kinder, more personalised, and more family-friendly.[1-3] A core work stream is 'harnessing digital technology'.[4, 5] The Covid-19 pandemic has radically altered and dramatically accelerated the context of this digital policy imperative.[6-9]

The 'Better Births' report highlighted that women are "savvy consumers" of online information and require digital information to empower them in their decision-making and help them feel more confident to discuss their care and ask for help during interactions with their care providers.[1] Women require trustworthy, clear, evidence-based and unbiased information to help them make decisions. Such information needs to be personalised, accessible and include locally relevant information. Digital interactions and information are being used to support and complement clinical consultations in maternity care. Text messaging and social media have been reported to disseminate health messages and answer non-urgent questions,[10] improve attendance at clinic appointments,[11] provide information and coaching to enhance postnatal care,[12] support antenatal smoking cessation[13] and weight management interventions.[14] Remote blood pressure and blood glucose self-monitoring and diabetes care has been widely implemented during the Covid-19 pandemic with published clinical guidance for implementation to support virtual clinics.[15] Many NHS trusts are providing or signposting women to remote support for breastfeeding, mental health and early parenting advice.[16]

One of the most commonly reported Covid-related changes to all forms of service provision in maternity care has been an increase in the use of remote/virtual consultations using telephone or video.[4, 7, 16, 17] For example, one recent survey of all 194 obstetric units in the country (42% response rate) found that 89% reported using digitally delivered consultation methods in antenatal care and 56.8% for postnatal care.[7] For antenatal services, the majority of these (87.7%) were conducted via the telephone whereas a smaller percentage were conducted using everyday video technology or specialist video technology (12% and 25.9% respectively). A national online survey of 524 women reported that 51.8% had experienced telephone or video consultations.[18] This trend towards digital consultation is likely to continue in the short term as an immediate response to Covid-19, but will also continue in the longer term as part of the existing digital strategy.[9, 19, 20]

As noted in a recent Health Foundation report,[21] the rapid shift to remote or digitally delivered clinical consultations was primarily implemented to support pandemic response objectives such as social distancing and service demand management. Going forward however, a key challenge for the NHS lies in how to 're-purpose' the use of remote consultations to serve longer term quality, equity and productivity objectives. Within maternity care, consultations have a wide range of potential purposes depending upon the individual circumstances and characteristics of the service user, clinical categorisation of the pregnancy (e.g. high risk or low risk) and stage of the maternity care pathway (e.g. antenatal care, assessment of early labour, postnatal care). Consultations may involve clinical (physical and mental health) assessment, safeguarding assessments, health promotion, information giving, education or therapeutic support. The interactions need to be

organised and implemented within multi-professional care pathways that promote continuity, personalisation and choice, recognise diversity and ensure safety.[9] Likewise, consultations need to be supported by auditable records that can be accessed by, and strengthen communications between, different providers and settings.

In maternity care, the rapid shift to remote consultations (due to Covid-19) has involved pragmatic changes to protocols and service patterns with relatively little understanding of which aspects of a consultation may, or may not, be most impacted by the change to a digitally-facilitated modality.[6] National guidance has been developed quickly to guide professional practice,[16, 17] but there has not, to date, been a comprehensive review of the evidence base to inform future service developments or future research in this area of maternity care.[6] Hence, although remote consultations may now be widespread in maternity services, the ways in which they can optimally be utilised in future along the care pathway remains unclear. This proposed project seeks to fill this gap through an in-depth and theory informed investigation of the evidence around implementation of digital clinical consultations. In doing so, it seeks to illuminate how digital consultations can work to support safe, personalised and appropriate maternity care and to clarify when they might be most appropriately used, for whom, when, and in what contexts.

Operational Definitions

Digitally-facilitated clinical communication has a highly diverse nomenclature, including terms such as telehealth, telemedicine, mobile health, e-health, virtual consultation, video consultations, digital consultation, remotely delivered care and online consultations (amongst many others). In spite of efforts by WHO in 2017 to standardise concepts and terminology, there is no internationally agreed or consistent set of terms, meanings or definitions.[22] A similar diversity is found in the rapidly evolving technologies and systems used to implement digitally-facilitated consultations. Key distinctions are that digital technologies can be utilised for: (i) direct 'live' clinical communication/consultation between a service user and a practitioner (synchronous), or (ii) direct communication that may happen at different time points (asynchronous), such as text messaging. This is in contrast to other digital care modalities such as remote monitoring systems (e.g. remote blood pressure monitoring), on-line triage algorithms, the use of Apps, wearable personal devices or electronic medical records which are usually asynchronous and do not involve direct interpersonal patient/practitioner communication (although these may be utilised to trigger, or to directly inform, consultations).

The focus of this project is on maternity care **consultations** that are facilitated through, and/or complemented by, digital technology. To capture this focus, we will use the term 'Digital Clinical Consultation' – henceforth referred to as 'DC-CON' (this term is an adaptation of the term 'Digital Clinical Communication' – DCC - utilised by a research team investigating a wider range of digital communication modalities between young people with chronic conditions and their healthcare providers).[23] The working definition for our project is outlined in Table 1 as follows:

Table 1: Operational Definition

Digital Clinical Consultation (DC-CON) *– Synchronous telephone or video consultations involving direct interaction between a service user and a maternity healthcare professional. It has two-way functionality and can be initiated by either party. It may be linked to, or complemented by, other digital technologies within the maternity care pathways.*

This definition recognises that the focus is on the consultation itself, but that this might be linked to, or informed by, other digital technologies. We have chosen to utilise the term DC-CON rather than

the term 'remote consulting' as used in several other research initiatives,[24] to avoid the potential impersonal connotations of the term 'remote'.

This project will investigate digital consultations across the maternity pathway, i.e. during pregnancy, the intrapartum period and early postnatal care (up to 10-14 days post-partum).

Why is this Research Needed Now?

Meeting the Needs of a Digital Society and Digital NHS

According to the Office of National Statistics, 96% of households in the UK have access to the internet and 84% of adults own a Smartphone – increasing to 98% in the 18-24 age group.[25] As part of this trend, women are increasingly, and routinely, using digital technology and digital resources as an adjunct to their maternity care.[1] For example, a recent survey of 632 pregnant women in the UK found that women used 91 different digital resources; 97% used a Smartphone and only 0.5% reported no access to digital devices.[26] Alongside the imperatives to improve service quality and efficiency in maternity care,[2] it is likely that women will increasingly want and expect aspects of their care to be delivered through mobile digital technology.[1]

As part of the NHS Maternity Digital Transformation Programme, a 2018 national 'Digital Maturity Assessment' report found highly variable levels of digital maturity within maternity services across the country.[5] At the time, the report highlighted that the development of 'remote and assistive care' was still in its infancy, but was an aspirational area likely to see rapid growth and increasing demand from service users. The report found that 23% of all maternity services provided some form of remote/virtual service for women deemed to be at low risk. These services included telephone triage/helplines, telehealth and SKYPE consultations, text messaging (one- or two- way communication), email, social media, virtual tours of the maternity unit and electronic self-referrals. The report acknowledged that it is currently unclear which aspects of care are most appropriately delivered using digital technologies and specifically what role digitally delivered consultations might play.[5, 27] It concluded that evidence is urgently needed to inform further development in this area.[20]

Ensuring Equity within DC-CON Roll Out

The implementation of DC-CON needs to take account of a key priority for UK maternity services – namely how to address significant ongoing disparities in service access and clinical outcomes.[9] These concerns relate particularly to women from minority ethnic communities[28, 29] and women with complex social needs.[8, 30] Concerns regarding women from ethnic minority backgrounds have been amplified and made even more visible during the Covid-19 pandemic where figures show that a disproportionate number of pregnant women admitted to hospital with Covid-19 identify with an ethnic minority background.[31] The extent to which this extends to DC-CON-related service changes is currently unknown.[9]

In addition, it is well known that women with other vulnerabilities (some of which intersect with ethnicity/race) are also likely to experience poorer outcomes and challenges in accessing and engaging with care.[30, 32] A recent review suggests that this group includes women who are socially isolated, living in poverty/homeless, refugees/asylum seekers, non-native language speakers, victims of abuse, sex workers, young mothers, single mothers and women from the travelling community.[30] More complex, often multi-agency, input is also often required for women where there are safeguarding concerns, substance and/or alcohol abuse, physical or learning disability, female genital mutilation, HIV positive status and those with perinatal mental health issues.

An important issue for the roll out of DC-CON in maternity care therefore is to explore how best to achieve this in a way can improve, but at the very least does not worsen, existing inequalities.[21] In addition, it is essential that further digital innovations must be able to support the escalation of concerns, not impede multi-disciplinary working and fit within governance systems.[33] It is essential therefore that efforts to inform future DC-CON developments are guided by evidence that takes cognisance of the need to address inequalities.[9]

Existing Evidence on DC-CON in Maternity Care

There is a large and rapidly expanding literature associated with DC-CON in maternity care.[19] For simplicity, we conceptualise the purpose of DC-CON in two ways (while recognising significant overlap between the two). The first relates to DC-CON that is additional to usual care – where specialist support is required on a single issue where a specific need is identified (e.g. interventions to support perinatal mental health, breastfeeding or smoking cessation). There is now substantial evidence that such targeted interventions can be feasible, acceptable and effective to varying degrees, although these have still not been widely implemented in the NHS.[19, 27, 34-38]

The second DC-CON purpose relates to situations where DC-CON is already the main modality of care (e.g. in telephone helplines or triage for assessment of early labour).[39] It also refers to situations where standard care pathways are altered so that some in-person points of contact are replaced or supplemented DC-CON (as happened during the Covid-19 pandemic). DC-CON has been investigated with regard to antenatal care among both high[40] and low[41, 42] risk women. For example, a recent randomised control trial in the USA sought to compare standard in-person antenatal care with a new 'hybrid' system that included virtual consultations. This study found higher satisfaction with care, no difference in health outcomes and less anxiety in the hybrid care group.[41] A systematic review of telephone support for women in pregnancy and postpartum was less conclusive however, with results suggesting that telephone support may be associated with higher overall satisfaction with care while yielding uncertain impacts on clinical outcomes.[36]

<u>DC-CON Implementation Research</u>

To date, most research on DC-CON modalities in maternity care has evaluated relatively small-scale, carefully planned and controlled initiatives.[43, 44] The Covid—19 pandemic has provided additional evidence about 'real world' implementation issues that need to be synthesised and better understood in order to drive forward this agenda.[45]

Staff Perspectives

Policy guidance[16] and anecdotal reports from professionals and community based organisations have identified several concerns related to DC-CON as implemented during the Covid-19 pandemic,[46-48] including: (i) how to maintain privacy within a consultation when it takes place in shared accommodation, (ii) how to build rapport and encourage disclosure of concerns (including safeguarding issues) or anxiety when it is not possible to pick up on non-verbal cues, (iii) how to overcome language barriers for women for whom English is a second language, (iv) how to support breastfeeding when unable to 'see', and, (v) how to involve partners. However, benefits have also been articulated, including that DC-CON may be more convenient for some groups of women and may be particularly useful for situations where there are routine queries and non-complex issues.

These concerns and potential benefits are mirrored in prior research that has explored midwifery staff views about telephone triage and video calling.[39, 49, 50] These studies appear to suggest some perceived advantages of video calling over phone calls due to the ability to utilise non-verbal visual cues to build trust and foster communication. However, in one study, midwives expressed potential reluctance at 'being seen' during calls.[50] The studies also identify a perceived need for clear information governance and record keeping processes, technical support, staff training and clear systems for embedding DC-CON modalities within care protocols and organisational infrastructure.

In order to guide future developments in DC-CON, further work is clearly needed to understand how maternity professionals perceive, experience and utilise DC-CON, the mechanisms through which they feel DC-CON can be best deployed and the educational and training inputs required to support this.[51]

Women's Experiences

To date, the limited evidence available on women's experiences of DC-CON in maternity care during the Covid-19 pandemic in the UK NHS paints a mixed picture. For example, in one survey of 1,451 women, 62% thought that virtual consultations in the antenatal care context felt 'impersonal'.[52] Further disaggregation of the experience revealed several other concerns: 62% said that this modality affected the type of information they disclosed to health workers; 14% noted a particular difficulty in talking about mental health issues; 11% felt embarrassed to discuss mental health or sensitive concerns and some participants worried that important information or risks might be missed - noting that the appointment did not feel detailed enough. The study presented less information with respect to postnatal care but noted that women reported feeling concerned about lack of support for breastfeeding and reduced contact with the midwife.

In another survey of 524 women,[18] with regard to digital antenatal care, only 12.9% felt that their needs had been met entirely, and 23.3% felt that their needs were not met at all. Key concerns were that care felt poorly organised, impersonal and too brief, leading to worries that important issues might be missed. The situation was similarly problematic with respect to virtual postnatal contacts, with 28.4% reporting that these had not met their needs at all. Interestingly, very few participants (only 4.2%) reported any technical or other issues related to the technology itself.

Although the above findings are concerning, it is clear that women's experiences are variable. Not everyone reports a negative experience. Interestingly, studies from the USA and globally report much higher levels of satisfaction with similar Covid-19-related DC-CON service changes, suggesting that satisfaction may be associated with wider organisational or contextual factors.[40, 48, 53] Hence, a challenge for DC-CON implementation going forward lies in understanding what works well and why? and for whom?

<u>Inequalities in the DC-CON Evidence Base</u>

Much of the existing evidence around DC-CON in maternity settings comes from relatively homogenous samples that fail to represent the diversity found in real life.[45] This is exemplified in recent studies on women's experiences of maternity care during the Covid-19 pandemic.[40, 53] For example, in a UK national survey of women's experiences (n=1,451), 91.9% identified as White/White British and 80.8% had a degree or higher degree qualification. Likewise, in another survey of women (n=524),[18] only 4.2% of respondents were from ethnic minority communities. It is critical, therefore, that future work on DC-CON is fully inclusive, intentionally seeks out the perspectives of diverse, vulnerable or marginalised groups and considers how to tackle poorer outcomes.[28]

Evidence Gap and Conceptual Framework: DC-CON as a Complex Intervention

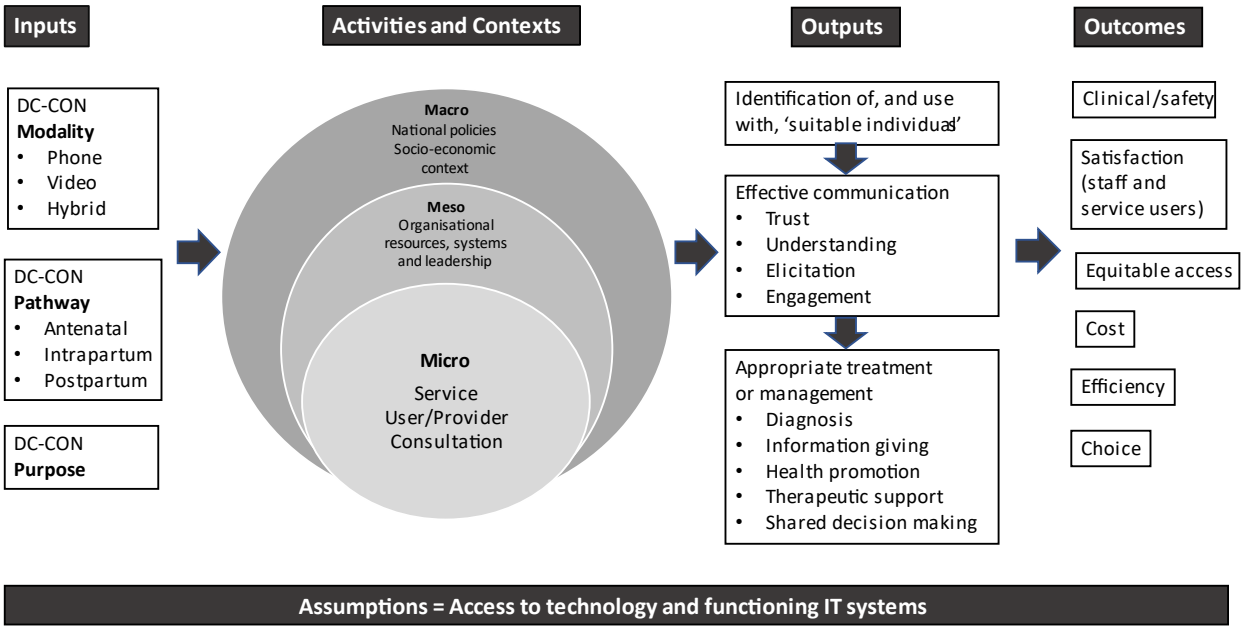
Existing research on DC-CON in maternity care shows it can be safe and acceptable in controlled conditions[27, 34, 35, 40, 42].[11, 41] Existing research also shows that experiences for staff and women vary widely.[7, 39, 49, 52] A gap remains however in understanding the conditions required for safe and acceptable DC-CON implementation and in understanding the factors that underpin variation in experience. Such variation is problematic, as it is implementation in real world contexts, at scale, that needs to be understood for the systems-wide transformation as envisaged in the NHS Maternity Transformation Programme.[2, 20, 54] It is this gap that the proposed project will address.

In order to develop a rigorous evidence base for DC-CON implementation in maternity care, we argue that DC-CON constitutes a complex intervention. Complex interventions draw upon implementation science theories[55] and are defined by the Medical Research Council as: "*1) including several interacting components; 2) sensitive to the context in which they are delivered; 3) having a causal chain linking the intervention to outcomes; 4) having a range of possible outcomes.*"[56] These criteria are applicable to DC-CON as they constitute a multiplicity of potential intervention modalities needing to be introduced into complex healthcare systems. Prior research suggests that DC-CON implementation and outcomes are mediated through 3 different but interlinked pathways:[57] (i) at the micro level (through individuals with varying skills sets, norms, resources and values), (ii) at the meso level (through organisations and organisational processes, including IT systems, leadership and resources), and, (iii) at the macro level (e.g. national policy imperatives to digitise systems and the wider socio-economic context).

A large body of implementation science literature demonstrates that adoption of technology-based solutions in healthcare is rarely straightforward, often results in failure and is best understood using (broadly) constructionist theoretical approaches (e.g. Actor-Network Theory[58] or Normalisation Process Theory[59]).[60] Several studies of DC-CON implementation in non-maternity clinical settings have drawn upon these and related theories.[23, 57, 60, 61] These studies show that DC-CON outcomes are strongly influenced by the nature of the relationship that can be established between provider and patient, the nature of the clinical issue, and the extent to which DC-CON 'fits' with, or changes, existing patient and professional norms, cultures, routines and processes.[60, 62, 63] Key findings include that: (i) DC-CON can be valued and utilised well for patients/situations that are 'suitable' (e.g. patients who are already known to a service and with whom a relationship already exists, and for patients with routine, straightforward or transactional queries), (ii) DC-CON is challenging for patients with complexities where elicitation, rapport and engagement is required, (iii) DC-CON frequently requires 'work-arounds' to fit the technology into existing IT systems, work patterns and protocols and does not necessarily lead to greater efficiency, (iv) DC-CON can have unanticipated consequences (e.g. becoming used as an additional adjunct to in-person care rather than replacing routine contacts, thereby increasing workload and cost), and, (v) DC-CON implementation requires strong organisational support and leadership.

An understanding of potential factors that may be critical for successful DC-CON implementation in maternity care can, therefore, be inferred from theories of implementation science and from implementation research in other clinical areas.[60] A key strength of a realist evidence synthesis, as proposed in this project, is that it is able to draw upon these additional sources (as well as evidence directly related to DC-CON in maternity care settings). This makes it a particularly suitable methodology to answer the research questions posed below. An initial logic model to guide the inquiry has been developed (see Figure 1).

Figure 1 Initial Project Logic Model



AIMS AND OBJECTIVES

Research Question

How can digital clinical consultations be implemented in a clinically safe, appropriate and acceptable way in maternity care in the UK NHS? For whom? In what settings? And for what purposes?

Research Objectives

1. To work collaboratively with key stakeholders to map, define and understand best practice in use of digital clinical consultation at different points of the maternity care pathway
2. To work collaboratively with key stakeholders to identify the mechanisms through which digitally delivered consultations can lead to safe, acceptable, high quality and personalised maternity care
3. To investigate how professional and organisational contexts mediate the impact of these mechanisms to promote or hinder safe, acceptable, personalised and high-quality delivery of digital clinical consultations in maternity care
4. To explore how the context of digital clinical consultations for different groups of women (e.g. ethnic minority groups, migrant women, women with psychological needs, women from socio-economically disadvantaged backgrounds, women with neuro-diversity) may (or may not) impact on equity of access, service use and quality
5. To explore how digital information can best be used to complement, inform and support DC-CON
6. Through a comprehensive, stakeholder-informed dissemination strategy, to provide policy and practice guidance on implementation of digital clinical consultation in maternity care in the UK NHS

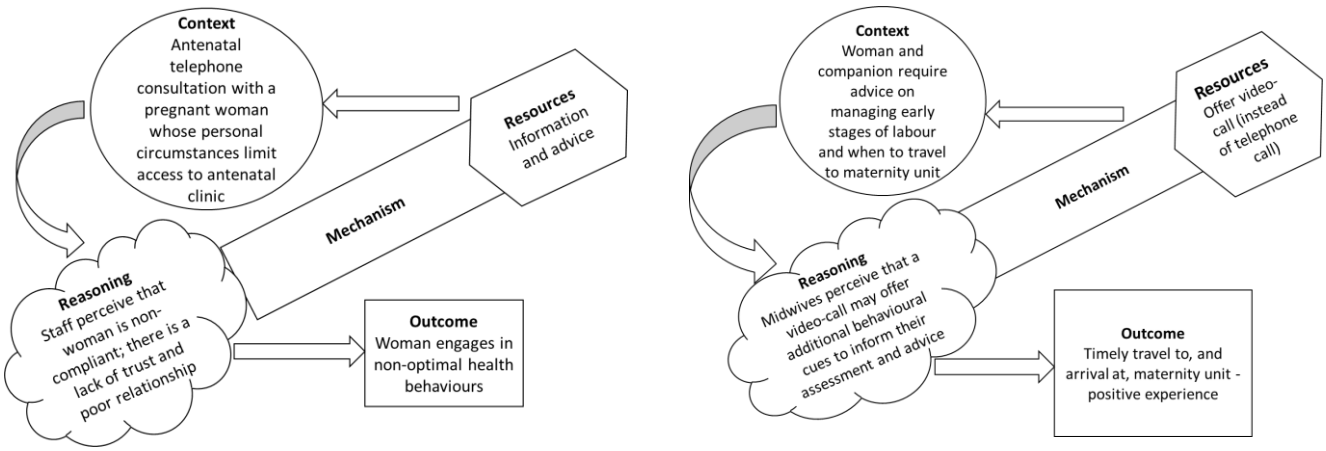
RESEARCH PLAN

Overall Approach

We will address the research question by undertaking a realist synthesis in which PPI and diverse stakeholder participation is embedded at every stage.[64] Realist syntheses seek to investigate the relationships between what can be observed and experienced, human interpretation of this reality and 'unseen' underlying social structures.[65-67] Increasingly, realist approaches are applied in health research to investigate the complexity of health-related behaviour and to explore how behaviours are shaped by human agency via intersecting social structures that manifest differently in different contexts.[68] Realist approaches are particularly well suited to investigating complex interventions such as DC-CON. This is because realist inquiry seeks to establish causal relationships - expressed as 'programme theories' - between intersecting intervention components, contexts and outcomes.[69] When applied to evidence synthesis, a realist approach focuses on understanding *how* particular interventions lead to particular outcomes under particular contexts (i.e. 'how does A lead to B'? and 'how might B be affected when A is implemented through contexts C, D or E'?).[70] This contrasts with the linear or deterministic approaches adopted by conventional systematic reviews which ask: 'does A lead to B'? (e.g. an effectiveness review) or: 'is A acceptable or meaningful to a particular group of individuals in a particular context'? (e.g. a qualitative review).[64]

As applied to our research question, the logic of a realist review proposes that different types of interventions (e.g. a video call or a phone call) supply particular resources into a situation that prompt diverse possible reactions and responses (also referred to as 'reasonings') from women and health professionals.[71] The interaction between the resource and the response constitutes a 'mechanism.'[71] Mechanisms are influenced by differences in how an intervention is delivered but also by the context of particular women's lives or different service configurations – see Figure 2 for potential exemplars of this dynamic.[71] This means that the acceptability and outcomes of DC-CON may be highly contextually contingent.[72] A realist approach seeks to identify certain patterns ('demi-regularities'[65]) between types of resource (e.g. a phone call), how individuals respond and how a particular context may alter these responses. Hence, a realist review is focused on identifying and testing programme theories that can account for the contingent nature of intervention implementation.[73]

Figure 2 - CMOc diagram from Dalkin et al, 2015[71]



In a realist review, the identification and testing of relevant programme theories takes place through an ongoing and iterative process of stakeholder consultation, evidence retrieval and evidence synthesis. Increasingly, key informant interviews are also utilised in a limited manner as part of these approaches in order to 'fill in the gaps' (if relevant evidence is lacking) and to help test and refine the final theories.[64, 73]

In the early stages, the review team identifies potential programme theories (or draws upon existing programme theories – 'candidate theories') that might identify and explain key mechanisms that need to be generated for an intervention to work in particular contexts and that will lead to particular outcomes.[64] These programme theories are expressed as context-intervention-mechanism-outcome (CIMO) configurations.[73] The initial CIMO configurations are then tested and refined through iterative cycles of evidence identification, analysis, stakeholder consultation and (if required), key informant interviews.[64] This ongoing process enables the identification of the most relevant causal mechanisms, making it possible to generate propositions (referred to as 'mid-range theories') about how interventions work in different contexts. These mid-range explanatory theories are a principal output from a realist review. Their insights make a substantive contribution to health service innovation because, by taking context into account, they are able to directly inform the development of new interventions and practice guidance. A realist review is appropriate for our research question, as interventions for DC-CON in maternity care are being developed at pace in many different contexts, yet currently lack a theoretically informed evidence base.[45]

Scoping searches of PROSPERO, Medline and the Cochrane Library have not identified any similar reviews currently being undertaken. Based on the results of these initial scoping searches, the research team is confident that sufficient evidence is available for the project.

Study Design

Our proposed realist synthesis will be conducted in 4 phases over an 18 month period designed to: (i) refine the review focus and generate initial programme theories, (ii) explore and develop the programme theories in light of evidence, (iii) test/refine the programme theories and (iv) construct actionable recommendations for future research and practice. The review will follow the RAMESES (Realist and Meta-narrative Evidence Synthesis Evolving Standards) quality procedures[73] and, subsequently, will comply with RAMESES reporting guidance.[74] Each phase of the review (with its associated search approaches) is described sequentially below, although in practice there is considerable iteration between them. Each phase of the review potentially draws upon three sources of evidence: (i) literature (published and unpublished research, audit, evaluation and theory), (ii) diverse stakeholder expertise and insights, and (iii) key informant interviews. The review will be registered with PROSPERO and Open Science Framework. A protocol will be finalised after completion of Phase 1 (see below) and submitted for publication.

METHODS

The project stages (outlined in detailed below) will be facilitated through 4 groups:

- Core Research Team

  This includes all applicants on the bid, including the PPI co-applicant (Candice Sunney/CS)
- PPI/Core Stakeholder Groups

  These are community organisations (representing diverse groups of service users) and health professionals (with diverse roles) with a formal mandate to be involved in all stages of the project, including dissemination. There are two core stakeholder groups: community

organisation stakeholder group (COSU-SG) and health professional stakeholder group (HP-SG)

- Associated Stakeholders

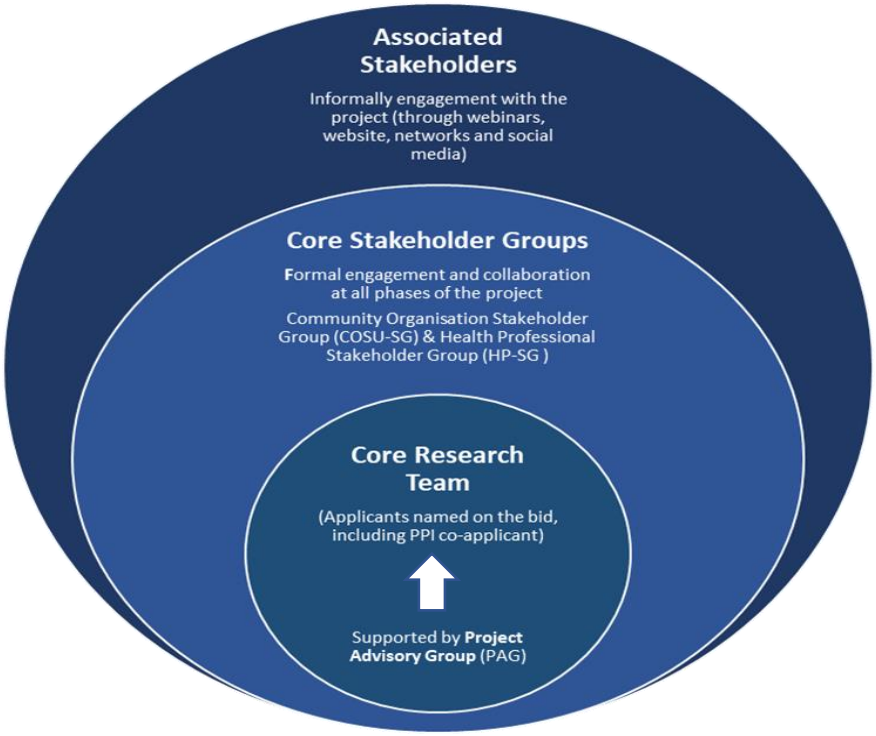
These include a wider group of service user, community organisation and professional stakeholders to ensure full and inclusive representation of perspectives into the project

- Project Advisory Group

This comprises a small senior group of professionals and community advocates whose role is to advise the core research team

See diagram below for an illustration of the project structure

Figure 3 – Project Management and Stakeholder Structure



PPI

This project has been informed by PPI from its outset and seeks to follow the NIHR UK Standards for Public Involvement in Research.[75] Public involvement in the project will be reported following the GRIPP2 reporting checklist.[76]

The research question originated directly from a collaborative research priority setting exercise undertaken in late 2020 in the Nottingham/Nottinghamshire area.[77] This initiative involved members of the current research team, maternity care professionals, commissioners and service users (women who were pregnant or had recently given birth) from the Nottingham and Nottinghamshire Maternity Voices Partnership (NMVP) and the Nottingham Maternity Research Network (NMRN). The NMRN is a maternity research-focused PPI group founded by members of the academic research team. The NMVP and NMRN assisted in developing an on-line survey and distributed this through their networks. Identifying types of maternity care interactions which can be delivered safely and effectively via digital and remote methods was rated as high priority by all respondents.[77] The NMRN has continued to be instrumental in shaping the current project. For

example, they identified a need to increase the diversity of PPI within the project. As a result, two other organisations were invited to become involved: (i) Women, Health and Family Services (based in east London serving deprived communities in an ethnically and linguistically diverse area and which runs an award winning 'Maternity Mates' community volunteer service), and (ii) the National Autistic Society (this has national representation and has been undertaking several recent projects on neuro-diversity and pregnancy/motherhood).

Within the project structure, these 2 organisations have been grouped together with the NMRN to form a 'Community Organisation and Service User Stakeholder Group' (COSU-SG). The COSU-SG enables a wide spectrum of socio-economic, geographical, ethnic and neuro-diversity amongst women to be represented. Each of the 3 organisations has a named lead for involvement in the project. Up to 3 individuals from each organisation will attend project stakeholder events (the organisational lead and 2 others). The organisational leads will be responsible for selecting the most appropriate individuals from their organisations to engage with project events. They will also facilitate consultation and engagement with their wider networks where required (e.g. through social media or email lists or by suggesting particular individuals as key informants). The project core research team includes a PPI co-applicant, Candice Sunney (CS), who is an established member of the NMRN. She will be supported by Professor Helen Spiby (HS) and her role is to ensure that PPI is embedded into all project processes and at all project stages (see 'PPI section' on the application form for full details of PPI training and support).

Stakeholder Involvement

PPI and stakeholder involvement are integral to each Phase of this project. In addition to the COSU-SG, the project will also be informed by a health professional stakeholder group (HP-SG). The HP-SG will include between 7-10 obstetricians, digital midwives, frontline and managerial midwifery staff from different maternity settings. Group membership is not bounded and fixed, however, but may evolve as the project progresses to ensure that appropriate expertise and insights are accessed. Due to the rapidity of service developments and potential turnover of staff, volunteers for the HP-SG will be sought nearer the project start date and will be recruited via professional networks and pre-existing special interest groups and forums (e.g. the Digital Maternity Network Forum). As noted further below, the core stakeholder groups will be involved through formal events (e.g. project workshops and training events), but also more informally (e.g. by consulting individuals or just one organisation) at specific points in the project where their particular expertise would be valuable.

The two stakeholder groups (COSU-SG and HP-SG) are the project's 'core' stakeholders and will be involved formally in the project at each step. In addition, in order to maximise representation and inclusion from other service user or professional constituencies, we will develop a wider network of 'Associated Stakeholders'. The project will seek to actively engage associated stakeholders through social media, through communication within professional and third sector networks, through the personal networks of project team members and through two national webinars at different points in the project (see below). Associated stakeholders will be individuals (e.g. experts in digital inclusion) or groups (e.g. community organisations advocating for a particular population – e.g. hearing impaired, ethnic minority group or teenage mothers). Associated stakeholders will be involved through project communications, through invited participation in two webinars and via key informant interviews (more detail below).

Key Informant Interviews

Data sources for the project may also involve a small number of key informant interviews. Within a realist review, the purpose of these is to provide additional insights to confirm, refute or refine proposed programme theories.[64] These are most likely to be part of Phase 3 (see below) but may also take place in the other Phases if additional data is required to support programme theory development. Potential interviewees may include NHS staff or service users. Interviewees will be recruited purposively using contacts from the research team's own professional networks or through contacts identified by the core and associated stakeholder groups. The aim of the key informant interviews is to provide new insights or test the transferability of programme theories (e.g. describing experiences of utilising digital technology in a specific rather than generalist setting - such as a perinatal mental health service or testing a theory in relation to a specific characteristic such as the use of DC-CON with those who are hearing impaired). The specific function of the interviews within a realist review means that only a small number are usually required – we anticipate no more than ten. The interviews will be transcribed by a professional transcribing service. If interviews are needed in languages other than English, relevant materials (e.g. participant information sheet, consent form) will be translated. Likewise, during the interview, professional interpreters would be employed if required. Interviews will be analysed by the research team using a framework approach,[78] mapping the data to the CIMO configurations. It is envisaged that interviews will be conducted via video-calls, but the modality will be flexible depending upon participant preference. Service users agreeing to an interview will be provided with a £25 Amazon voucher to recognise their time contribution.

Overarching Approach to Literature Searching

Within this realist review, the overall search approach will follow the only published systematic approach to the "realist search", as lead authored by AB.[79, 80] This approach extends and enhances the Task and Time Template for a realist review advanced by Pawson.[65] It outlines 4 separate and distinct phases of searching using different retrieval techniques and targeted at different evidence bases (conducting the background search, searching for programme theory, searching for empirical studies, searching to refine programme theory and identify relevant mid-range theory), "topped" and "tailed" by precise question formulation and meticulous documentation.[79]

The search strategies within each Phase will be developed and operationalised by experienced information specialists (AB & MC). The search recognises that the concept of DC-CON is populated by multiple synonyms and so will analyse existing systematic reviews to generate an exhaustive list of Intervention search terms. It acknowledges that relevant terms for the Context will include overarching concepts, each with multiple synonyms (such as "pregnancy", "midwifery care", "obstetric care" and "maternity care"), related to specific stages and sub-stages of the maternity care pathway (e.g. antenatal, intrapartum postnatal) and linked to specific stakeholder groups (e.g. midwives, service users, obstetricians). Following Phase 1 (below), broad 'hedges' of search terms related to 'Context' may be linked to specific topics (e.g. perinatal mental health, infant feeding, hypertension, diabetes), procedures and processes (e.g. monitoring, screening, information giving). In line with current best practice we will not specifically detail Outcomes (which are poorly indexed) or Mechanisms (which are described within full texts) in the search strategy. Instead these will become apparent and be compiled once full texts are examined.[79] The search dates will be restricted to papers from 2010 to the present to reflect the need for contemporary data. Likewise, inclusion of evidence will be limited to papers in the English language and in high-income settings (OECD countries) to maximise retrieval of evidence of relevance to the UK NHS.

The search approach will engage the project advisory group and stakeholders throughout, consulting them where required to provide advice (for example clarifying the terminology used at service level) and help with identifying relevant literature (including, for example, cascading requests to identify literature and policy/practice documents through their associated social media sites and websites).

Review Phases

The flowchart (Appendix 1) provides a detailed visual representation of the review Phases and associated search approaches.

Phase 1: Refining the Review Scope and Developing Initial Programme Theories

This phase aims to identify and make explicit (through CIMO configurations) an initial set of programme theories that may explain how DC-CON in maternity care can be utilised to achieve optimal outcomes, for whom and in what contexts? Given the potential variability of modality and use of DC-CON in maternity care, an important part of this process will be to focus and prioritise the most important questions and outcomes. This phase comprises extensive stakeholder engagement to refine the review questions and to shape the associated search strategies. Phase 1 involves 3 inter-linked stages (A-C).

Stage A – Refining the Review Scope - Consultation and Formulation of the Focused Question

The project will begin with a workshop for the project advisory group, the research team and core stakeholder groups. This event will be designed to foster team building and to familiarise everyone with realist review methodology and with the project plan. Team members will be asked to share their own stories and experiences of DC-CON and to consider what best practice looks like for particular contexts and for different groups of women and how (i.e. through which mechanisms) they feel best practice can be achieved. They will be asked to prioritise the key questions and outcomes they feel are most relevant as lines of enquiry for DC-CON implementation. The output of this initial consultative work will be a set of refined research questions and an initial set of programme theories. This consultative work will be informed by a series of broad background searches that will enable the review team to assess the breadth, depth and range of evidence available.

Stage B – Searching to Identify and Develop Initial Programme Theories

This stage will utilise the insights from Stage A to search for, and identify, key papers (of any study design) on DC-CON implementation that can yield insights for programme theory development. The search is iterative, utilising searches on electronic databases, grey literature sources, suggestions from stakeholder suggestions, citation tracking and reference list searching of conceptually rich index papers. This stage will include, but will not be restricted to, maternity care settings as we know from pre-protocol scoping that relevant theories have been developed regarding the implementation of DC-CON in other clinical settings.[23, 57, 59, 61] Each included paper will be scrutinised to elucidate how 'best practice' in DC-CON is defined and to identify the mechanisms through which successful consultations are purported to work in relation to different contextual configurations and population groups. Details of key theories ('candidate theories') that have been used to explain implementation mechanisms will be extracted. Excel will be used to extract the key characteristics of each paper and NVivo will be used to code the key findings related to implementation. Where possible, findings will be coded and analysed in relation to possible context, mechanism and outcome configurations, helping to generate initial ideas around relevant programme theories. The coding and analysis templates for the reviews in this stage will

be developed and piloted by several members of the review team. The majority of the coding will be undertaken by one reviewer, with a second reviewer completing a random sample of approximately 20% to monitor quality and consistency. The findings of this stage will be presented using tables, figures, flow charts and narrative summaries to highlight the key features of the evidence and to describe potential programme theories.

The output of this step will be a summary report to be shared with the whole project team to inform ongoing work.

Stage C – Consultations and Development of Initial Programme Theories

This stage will broaden out the consultative process and include a webinar to which a wider network of 'associated stakeholders' are invited. The preliminary focus areas and analyses will be presented and critically discussed. Suggestions for further inclusion or prioritisation of potential programme theories and relevant literature will be invited. Additional searches and analysis may then take place.

The final stage of Phase 1 will comprise a second workshop for the research team and core stakeholder groups in which the findings of the theory-identification searches and analyses will be presented and discussed. The group will then validate and refine the key focus of the review and propose a refined set of initial programme theories. These will then be tested and explored in Phase 2.

Phase 2: Evidence Retrieval, Review and Synthesis

The aim of Phase 2 is to determine whether the initial programme theories are supported by empirical evidence and to analyse this evidence to elaborate, refine, adjust and test the theories. This Phase continues the iterative process of literature searching, data extraction and analysis.

Search Strategy

At the core of the search approach is the search for empirical studies that can provide data with which to explore and elaborate the initial programme theories. The search strategy will be iterative, proceeding with carefully formulated searches based on sub-sets of literature constructed using terms associated with the initial programme theories (CIMO frameworks) and key concepts.[79, 81] Searches are initially broad but may then be narrowed down to focus more specifically on evidence associated with particular mechanisms. As an example, in our review, we may construct an initial search using sets of terms derived from our programme theories combined using the 'AND' Boolean operator:

- Context (from the initial programme theory) – antenatal care
- Interventions/phenomenon of interest (from the initial programme theory) – video-based consultation

A follow up search might then focus more specifically on the influence of a mechanism (e.g. trust or 'relationships') in relation to an outcome (e.g. positive health behaviours). In the first instance, the main focus of the search for evidence will be for literature related directly to maternity settings. However, in a realist review, the focus of analysis is the programme theory (or mechanism of action) – hence we may also draw upon wider literature to seek opportunities for transferable learning. In the example above, we might, therefore, seek evidence related to 'trust' in the context of video consultations from other clinical settings such as primary care to confirm or refute our emerging theories.

The searches will include systematic reviews and empirical research of any study design, including service evaluation, audit and quality improvement projects. The searches will also include existing policies and practice guidelines surrounding DC-CON in maternity care in the UK. This is because the recommendations set out in policy or practice guidance rest upon implicit or explicit theoretical assumptions regarding implementation. Moreover, the inclusion of policy documents will help to ensure that governance issues are considered alongside implementation so that the review is appropriately contextualised.

As in Phase 1, search sources will include electronic databases, grey literature and expert stakeholders (see Table 2 below). Additional search approaches will include reference list searching, citation tracking, identification of sibling papers (linked papers from a single study) as well as cluster searching[81] which involves building up rich 'cases' of different models of DC-CON in order to grow a cluster of related reports around named or identifiable initiatives to offer both richness and detail. Unlike a conventional systematic review search, searches in a realist review are not necessarily exhaustive but follow the principles of theoretical saturation, ceasing when programme theories are deemed to be sufficiently explained, supported or refuted by the empirical evidence.[73, 79] Likewise, additional targeted searches may be undertaken to explore new mechanisms or other aspects of programme theory that may be identified during the review.[73, 79]

Table 2: Sources of Evidence

Electronic Databases (2010-present)	Grey Literature Sources	Stakeholders
• Cochrane Central Register of Controlled Trials • Cochrane Database of Systematic Reviews • JBI Library • MEDLINE Ovid • Embase Ovid • PsycINFO Ovid • ASSIA Cambridge Scientific Abstracts (Applied Social Sciences Index and Abstracts) • CINAHL Plus EBCSCOhost (Cumulative Index to Nursing and Allied Health Literature) • MIDIRS Ovid	• Google Scholar • Websites (e.g. RCOG, RCM, RCN, NCT, NHS Trusts, NHS^X, Health Foundation, WHO) • Conference proceedings • OpenGrey • ProQuest Dissertations & Theses • EThOS – British Library Electronic Theses Online	• Project Advisory Group • Stakeholder groups • Others (e.g. via social media requests, email list serves)

Selection and Appraisal

Records will be imported into EndNote and duplicates removed. Study screening and selection will be undertaken by two reviewers independently, with recourse to other team members in cases of ambiguity or disagreement. To aid transparency and consistency, once the initial programme theories have been formulated, an 'inclusion criteria flow chart' will be constructed in which key concepts are operationalised and against which each potential study can be assessed.[82]

Records will initially be screened by title and abstract. All seemingly relevant papers will then be examined in full-text and reasons for exclusion noted in a table. In line with realist methodology, records will be screened for inclusion based on relevance, rigour and richness.[64, 73] An assessment of relevance considers the extent to which a paper can directly contribute to theory building or theory testing.[73] An assessment of rigour considers whether the methods used to generate the relevant data are credible and trustworthy. Richness refers to the extent to which study findings are fully elaborated through 'thick description', grounded in the data and provide explanatory insights.[83] In a realist review, the process of quality assessment refers to the specific data that is relevant to the particular programme theory being examined rather than on the basis of a global evaluation of overall study quality.[84] Hence for each key finding, a sophisticated judgment will need to be made about the plausibility and coherence of the methods used to generate it.[74] For each included paper,

the team will follow the process outlined by Rycroft Malone *et al*,[70] asking: "*is the evidence provided in this theory area good enough and relevant enough to be included?*". These judgements will be articulated and recorded for each study as part of the screening and data extraction process (see below).

Data Extraction, Analysis and Synthesis

Data will be extracted from the included studies in two ways. First, information about study characteristics will be extracted into a summary table (as is the case with a conventional systematic review). This will include information on features such as study setting, design, methods, details of intervention modality and technology, participants, outcomes and stage of maternity care pathway. Second, a bespoke data extraction form will be developed based on the initial programme theories, and as noted above, will include sections in which to note assessments of relevance, richness and rigour. Theory-based data extraction enables the coding and charting of relevant data so that elements of the theory can become populated to investigate what works, for whom, how and in what contexts. The analytical process involves both deductive and inductive coding. Deductive coding will involve extracting data that appears to be directly related to aspects of the programme theory. Where it is possible to make relevant inferences, the data will also be coded in relation to contexts, mechanisms or outcomes. However, the evidence may also reveal new contexts, mechanisms or outcomes which will be identified and coded inductively.

The data extraction templates and associated analytical process will be developed collaboratively amongst the core research team and extensively piloted. Once the team feel they have achieved a clear and consistent approach, the remaining data extraction will be undertaken by one reviewer, with a second reviewer checking approximately 20%. The outputs of this stage will be a set of evidence tables. There will be one overarching table representing the key characteristics of all the studies included in the review. Then there will be series of tables organised to represent the different bodies of literature and findings related to each initial programme theory. Thus, each theory area will have its own evidence table.

The process of data analysis will be ongoing and iterative. The evidence will be reviewed within and across the theory areas to explore how it builds upon, refutes or provides alternative explanations for the initial CIMO configurations. The analytical process will involve asking questions such as: "*What does this evidence suggest about this aspect of our theory? Does it support it? Does it disprove it? Does it suggest an amendment to it*?"[73] This analytic process involves both abductive and retroductive reasoning – i.e. making new observations from the evidence, inferring plausible explanations related to the programme theory, seeking to understand the cause of perceived events beyond what can be observed and seeking to identify over-arching patterns. Wong *et al*[73] propose a series of 'conceptual tools' (derived from Pawson, 2005[65]) which will be employed by the review team in this complex process, as indicated in Table 3 below.

Table 3: Analytic Process of a Realist Review

• Juxtaposition of sources of evidence—for example, where evidence about outcomes in one study allows insights into evidence about outcomes in another study; • Reconciling of sources of evidence—where results differ in comparable circumstances, these will be examined further to find possible reasons for the different results; • Adjudication of sources of evidence—based on methodological strengths or weaknesses; • Consolidation of sources of evidence—where outcomes differ in particular contexts, an explanation will be constructed on how and why these outcomes occur differently; • Situating sources of evidence—when outcomes are different in particular contexts, a possible explanation will be developed as to why they differ

This stage of the review is highly resource intensive, involving much deliberation during frequent meetings of the review team and additional literature searches to test new insights, adjustments or elaborations made to the theoretical propositions. Our stakeholder groups will continue to be consulted at different points to seek their views and test out new ideas.

Accounting for Temporality in the Synthesis

An important feature of the analysis will be to explore the issue of temporality and sustainability within the evidence. For example, it might be expected that evidence on Covid-19-related DC-CON implementation might include different experiences depending upon the stage of the pandemic and the length of time that staff and service users have had to adjust to changes in service delivery models. Likewise, even in non-Covid-related studies, experiences with new technologies vary depending upon the length of time since introduction, with many studies focusing upon the early stages of implementation rather than exploring how and why technologies become embedded, normalised or sustainable.[59, 85]

In this project, we will endeavour to take temporality into account in two ways. The first, relates to evidence that is specifically concerned with changes made during the Covid-19 pandemic. Here, we will ensure that our data extraction template explicitly acknowledges the time period of data collection, extracting and mapping data to the stages of the pandemic and then transparently considering these stages as part of the analysis. Likewise, working with our advisory and stakeholder groups, we will attempt to develop a clearer picture of how digital consultations were initially introduced in different settings and how their use and implementation may have adapted and changed as the pandemic progressed. The second issue relates to the fact that not all of the evidence that we anticipate including in the review will come from the pandemic context. We will endeavour to include temporality as an aspect of our analysis for **all** the evidence by explicitly considering the stage of implementation of an innovation that is reported and by considering data related to change and adaptation over time (where reported). We plan to draw upon concepts from the Dynamic Sustainability Framework[86] to help 'sensitise' the team to issues of temporality. The framework focuses attention to the constantly changing evidence-base, the multi-level context in which interventions are delivered, and the broader ecological system within which the maternity care exists and operates

The output of Phase 2 will be comprehensive set of evidence tables and refined programme theories linked to associated sets of working papers organised by DC-CON type, purpose and (where relevant) temporality in relation to different points in the maternity care pathway.

<u>Phase 3: Test and Refine Programme Theories (Validation)</u>

The purpose of this Phase is to test and further refine the programme theories. This is done in three interlinked ways.

First, as part of an ongoing recursive approach, new literature searches will be undertaken to find, test and empirically explore any new theories identified during the review process.[79] This may also include a need to re-visit and re-code previously identified papers. As noted by Booth et al,[79] this stage may involve searches for specific named theories that have been identified in Phase 2 and that are considered worthy of further empirical exploration.

Second, further in-depth consultation with the project's core stakeholder groups will be undertaken to test and refine proposed theories. This phase will include a third workshop to discuss the findings from Phase 2. Our core stakeholder groups will be asked to consider the proposed

theories in relation to their own experiences (additional participants or stakeholder groups may also be invited to attend this workshop to ensure that all aspects of the review findings can be debated). Particular attention will be paid to clarifying the key mechanisms that are required to produce desired outcomes and to identify the key links between these mechanisms and different contexts. Prior to the workshop, the stakeholders will be asked to identify several examples based on their own or others' experiences of where digital clinical consultations were perceived to have worked extremely well and where adverse events or negative experiences had been reported. These exemplars will be used to interrogate the proposed CIMO configurations to see if they can explain what happened. Through this process we will identify 'gaps' that may remain in our understanding and identify the essential elements of intervention and context that need to be place to ensure that the appropriate mechanisms can be triggered.

Third, as described above, we will undertake a limited number of key informant interviews to test aspects of the programme theories and to evaluate their plausibility, credibility and transferability.[64]

The output of this Phase will be a theoretically-grounded explanatory framework for safe, appropriate and acceptable DC-CON in maternity care that can be used to guide intervention development, policy and practice.

Phase 4: Development of Actionable Recommendations

The purpose of this Phase is to generate actionable recommendations from the review. We will do this in two ways.

First, we will hold a second on-line national webinar to which our wider range of 'associate stakeholders' will be invited. The purpose of this webinar will be to share and 'sense-check' the review findings and to solicit suggestions for recommendations, actions and strategies for dissemination. Second, we will hold further meetings to discuss, develop and finalise recommendations appropriate to a range of constituents (researchers, commissioners, service leads, professionals, women, community organisations) and feasible for implementation in a UK NHS context. We will consider short, medium and long term implications and actions and finalise a plan for dissemination. In line with the MRC complex interventions framework,[56] we will also seek to identify key theories, interventions or mechanisms that require further testing through robust research.

Ensuring Timeliness, Currency and Relevance of The Review

Research and service developments related to DC-CON are both very rapidly evolving fields. There is need therefore to ensure that the review includes the most recent evidence and takes cognizance of new service innovations. The project team will endeavour to address these issues in several ways (listed below), and, in the process, will explore ways in which realist review approaches can become more 'rapid' and 'live':[87, 88]

- As noted above, a key feature of realist methodology is the iterative nature of the process and the fact that searching is conducted in stages, repetitively and over time. We would expect to continue the various search approaches until the final 3 months of the project. In this way, we will seek to become aware of potentially relevant evidence as soon as it is available.
- We will set up weekly 'alerts' on the major databases, including medRxiv (the Health Sciences pre-print server that is being increasingly commonly used) to identify newly published studies.
- Our extensive searches of the grey literature will harness website and grey literature database searches. We will supplement these with ongoing advice from our project advisory group,

stakeholder groups and social media for relevant evidence. In this way, we will use systematic strategies to find current best evidence of key relevance to the programme theories that are identified.

- In addition, we will secure an ongoing commitment from our stakeholder groups and project advisory group to horizon-scan for relevant new evidence and to report key changes to service or policy that the team may need to take into account.
- In Phases 1 and 2, we will explore with our Project Advisory and stakeholder groups whether, amongst the emerging programme theories, there are one or two areas that require more immediate attention (e.g. in areas relating to clinical safety) in order to support faster dissemination. These areas would then be addressed first, with other programme areas being give attention later in the review cycle
- As well as being a challenge, the imperative for 'currency' presents an important opportunity for methodological innovation. We will seek to generate debate within the 'realist' community on this topic by hosting a methodologically focused webinar and will seek to incorporate any lessons learned into our review process.
- Throughout, we will engage strategies of reflexivity and maintain detailed records of our actions and decision-making processes.

DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

As listed below, we will adopt a range of dissemination strategies aimed at different audiences, augmented and signposted through social media. Our PPI co-applicant and core stakeholder groups will play an integral role in influencing and co-producing **all** dissemination strategies and resources. To maximise relevance and timeliness of the review, where possible, we will include strategies that enable interim outputs or interim insights to be shared with practitioners and policy makers. We are confident that the project will influence key groups to support best practice in DC-CON and will form the foundation for future research in this critical and rapidly evolving aspect of NHS care:

- **Website:** we will develop a user-friendly website for project information and updates. The website will be used as a key source of information about the project but also as one (of several) vehicles for sharing key project outputs and related resources. For example, we will create a website section entitled '**Evidence**' where we will share the evidence (i.e. the references or websites) that we identify on an ongoing basis, categorised into key themes or topic areas. We will also have a '**Blog**' section on the website where we will provide regular reflective updates on methodological issues/challenges as well as on key insights being generated by the project. We will also have a '**Resources**' section and a '**Training**' section where we will make available any powerpoint presentations and all the other dissemination and training resources developed for the project. We will have a function on the website for people to register an interest in the project and will include those individuals in invitations to online stakeholder engagement events and webinars and for dissemination of project outputs. We will use Social Media to draw attention to the website and all relevant project updates and webinars on an ongoing basis
- **Report**: we will submit a final project report to the NIHR for publication in the HS&DR library
- **Publications in peer reviewed journals**: we aim to publish 3 open access outputs from this work - the realist review protocol, the final realist synthesis and a methodological paper on our approach to constructing a 'living' realist review.
- **Publications in practice journals**: to ensure that project findings reach practising professionals as well as academics, we will publish an overview of the key findings and implications in a practice-focused journal (e.g. The Practising Midwife).

- **Short report**: specifically for obstetricians, to be circulated to RCOG members and Fellows
- **Infographics**: working with our PPI/core stakeholder groups, we will produce three infographics for different audiences and purposes: one will be constructed to disseminate the key review findings and recommendations via social media; two will be constructed to provide 'top tips' on getting the most out of DC-CON (one aimed at professionals and one at service users). The service user infographic will be also be audio-recorded and translated in up to 5 different languages
- **Conference**: we will present the findings at a national (e.g. RCM Research Conference) and international conference (e.g. RCOG World Congress)
- **Webinars**: we will hold a series of on-line webinars aimed at different audiences to share the review findings and debate the key recommendations
- **Online educational resource for practitioners, educators and students**: We will produce an open access Re-useable Learning Object (RLO) to be developed by the University of Nottingham's award-winning Health E-Learning and Media team. RLO development is based on a model of co-production, hence we will continue to work together with our stakeholder groups to ensure that material is engaging and directly relevant to practice
- **Best practice implementation toolkit**: A best practice guide will be produced alongside a power-point slide set that can be used in practice areas to inform discussions about implementation of remote consultations.

ETHICS APPROVALS

Ethical approval for the key informant interviews will be sought from the University of Nottingham Faculty of Medicine and Health Sciences Ethics Committee. NHS ethical approval will not be required as healthcare professionals will be recruited through membership of professional organisations (e.g. RCM e-lists) and service users will be recruited as 'healthy volunteers' through community-based stakeholder groups.

PROJECT MANAGEMENT

The PI (CE) and co-applicants (including the PPI co-applicant) constitute the core research team. We are a highly experienced team with a strong track record of previous collaboration, PPI engagement and demonstrable ability to successfully execute and disseminate high quality review projects. The PI will have overall accountability for meeting project deliverables and adhering to the time frame, with other members responsible for contributing specific expertise and inputs, including liaison with, and support of, the stakeholder engagement process. The Research Fellow will be supervised by the PI through weekly meetings. Their career development will be further supported through training and mentorship provided through the University of Nottingham's 'Researcher Academy'. HS will be responsible for liaison with the two core stakeholder groups and for support of our PPI co-applicant (CS). The Research Fellow (supported by the research team) will be responsible for ongoing engagement with the 'Associated Stakeholder' groups (through updates on the website, webinars and social media). The core research team will meet online monthly or more often as required.

The core team will be advised by a Project Advisory Group (PAG), chaired by HS. The PAG will meet the core team at three time points during the project and will act as a source of expert advice to shape the project focus, to provide a senior policy perspective, to help identify relevant literature and to support the dissemination strategy. The PAG currently has the following membership:

- **Coralie Rodgers**, Lead Midwife for Digital and Achieving Equity, Lancashire & South Cumbria Maternity and Newborn Alliance
- **Dr Sunita Sharma**, Consultant Obstetrician and Gynaecologist, Chelsea & Westminster Hospital NHS Foundation Trust, Advisor to the NICE Guideline Committee on postnatal care; NHS Clinical Entrepreneur; Winner of multiple awards for digital innovations, including the Mum & Baby App
- **Danni Burnett** - Deputy Chief Nurse, Nottingham and Nottinghamshire CCG
- **Victoria Komolafe** – Professional Advisor, Midwife (Digital), Royal College of Midwives (RCM)
- **Professor Gina Higginbottom** - Maternity Stakeholder Group; NHS Race and Health Observatory
- **Amanda Mansfield** – Consultant Midwife, London Ambulance Service
- **Juliet Albert** – FGM Specialist Midwife

Supporting a Positive and Inclusive Team Culture

This project involves many diverse groups and team members with varying levels of familiarity with clinical or research processes. An essential part of project management will be to build and support a positive team culture where all members feel valued and respected. The project team is firmly committed to a collaborative and non-hierarchical approach where all stakeholder groups are equally valued and where all have an opportunity to share their views and to be heard. As such, we anticipate that the meetings and workshops will yield different experiences and different perspectives. We will facilitate project interactions by encouraging a confidence in articulating diverse view-points together with a project culture of respect and humility. Collectively, we will promote an ethos of '**creative synthesis**' – explicitly recognising that the whole is greater than the sum of its parts – and that each part is important and needs to be visible and valued.

We will do this by explicitly setting out and repeating 'ground rules' of inclusivity, receptiveness to difference, trust and respect in project meetings. We will also do this by encouraging project and group members to get to know each other, to build a shared vision for the project and to build capacity (which in turn facilitates confidence).

Currently, we plan for all three groups (project advisory group, core research team, core stakeholder groups) to meet together in an initial team building 'kick off' meeting, intended to be face to face, to enable networking and relationship building. We will use this meeting to ensure that all stakeholders develop a clear and shared understanding of the project aim, objectives and methods and also of their respective roles and responsibilities. At this meeting (and through smaller informal discussions) we will also identify specific training needs (e.g. more information on realist approaches, training on EDI or the digital transformation agenda). We will then deliver some training inputs at different time points (for all, or for specific groups, as required) to ensure that all stakeholders feel knowledgeable, empowered and equipped to fully participate in the project. As the project progresses, we will review and remain sensitive to respectful inclusion and be flexible in terms of adopting strategies to ensure that all can participate (e.g. by having a pre-meeting or a smaller follow up meeting with a particular stakeholder or group if required). An email list and Whatsapp group (or similar) will be established for each stakeholder group (HP-SG and COSU-SG). This will help to facilitate communication and to target requests for engagement and support. In addition, prior to project meetings, we will ensure that relevant materials are sent to the groups well in advance (and include additional information to aid accessibility where relevant).

After the initial project workshop, we expect that the two core stakeholder groups will work together as engaged participants in the remaining project workshops (rather than treating them as part of separate groups). We are mindful however that there may need to be some flexibility around this if timings, work/life pressures or Covid-19 disrupt plans – so separate smaller meetings may be needed at times – but avoided if possible. The 'Project Timetable' section below provides further detail on how often, and in what modality, project meetings will take place.

In terms of dealing with potential conflict, we recognise that differences of opinion may occur. Having established a positive project working culture, we would strive to facilitate a process where agreement and consensus can be achieved and, if not, where all will nonetheless feel respected. By having multiple groups engaged with the project, we hope that areas of contention can be resolved through engagement with experts (both professional and service user experts) and by bringing in outside additional expertise where required. As noted in the Methods section above, Phase 4 of the project will include a webinar and meetings to 'sense check' the review findings and solicit recommendations. We expect that this process will also help to clearly indicate a consensus of where the project needs to focus.

PROJECT/RESEARCH EXPERTISE AND CONTRIBUTIONS

The core research team reflects the diverse service user, clinical, methodological, information science, theoretical and policy expertise required to successfully implement this project. The team (listed below) has a strong commitment to, and significant experience of PPI and of working in partnership with stakeholders to ensure the integrity and credibility of the review outputs.

- **Dr Catrin Evans (CE)** - Principal investigator, 20%FTE – Co-Director of the Nottingham Centre for Evidence Based Healthcare and member of the School of Health Sciences' Maternal Health and Wellbeing Research Group. Experienced PI and systematic reviewer.
- **Research Fellow (RF)** – 100%FTE. The RF will support all aspects of the project, but will focus primarily on study screening, selection, data extraction, synthesis and report writing.
- **Professor Helen Spiby (HS)** – 10%FTE. Professor of Midwifery, Lead of the School of Health Sciences' Maternal Health and Wellbeing Research Group. Expert in evidence-based Midwifery. HS established, and provides ongoing support to, the Nottingham Maternity Research Network (NMRN) PPI group. HS will contribute expert midwifery input to all project stages. HS will be responsible for liaison with, and support of, the PAG, our PPI co-applicant and the two stakeholder groups.
- **Candice Sunney (CS)** – 10%FTE. PPI co-applicant and member of the NMRN. CS will provide PPI input to every stage of the project and will work with HS to support the community/service user stakeholders.
- **Dr Kerry Evans (KE)** – 5%FTE. NIHR-funded clinical-academic midwife, member of the Nottingham Maternal Health and Wellbeing Research Group. Experienced systematic reviewer. Has particular expertise in digital interventions for maternity care. KE will contribute particularly to programme theory development and dissemination.
- **Dr Andrew Booth (AB)** – 5%FTE. Co-Director of the NIHR HS&DR Sheffield Evidence Synthesis Centre and member of the Cochrane Qualitative and Implementation Methods Group. AB has particular expertise in realist synthesis and realist methodology and will act as senior methodological advisor for the project.
- **Professor Stephen Timmons (ST)** – 5%FTE. Sociologist and member of the Centre for Healthcare Innovation and Leadership (CHILL). ST has particular expertise in implementation science as applied to technology implementation in the NHS and will provide particular input around programme theory development.

- **Dr Nia Jones (NJ)** - 2%FTE, Associate Clinical Professor in Obstetrics and Gynaecology at Nottingham University Hospital Trust with a special interest in digital interventions. She will provide a medical perspective and will liaise with national obstetric networks. She is the CRN East Midlands representative for Reproductive Health and Childbirth.
- **Mark Clowes (MC)** – 20%FTE (for 9 months) – MC is an experienced information scientist and systematic reviewer at ScHARR. MC will develop and implement the search strategies.
- **Benash Nazmeen (BM)** – Consultant. BM is a specialist cultural liaison midwife with Bolton NHS Foundation Teaching Trust and co-founder of the Association of South Asian Midwives. She is co-Chair of the Birthrights Inquiry into Racial Injustice in Maternity Services in the UK and Chair of the Shared Decision-Making Council within the NHS Maternity Transformation Programme. BM will ensure the team integrate EDI principles into all aspects of the project.
- **Administrator** – 2%FTE – will provide logistical support to the team, particularly with respect to financial arrangements and organising meetings.

PROJECT/RESEARCH TIMETABLE

The project will be undertaken over 18 months, as outlined in the GANTT chart below. For ease, this has been depicted in a linear manner. As noted previously however, many of the project stages are iterative rather than linear, hence there will be overlaps and recursive loops between the stages (see uploaded project flowchart).

Currently, as per the GANTT chart, there will be four formal meetings where both stakeholder groups will be involved – ideally together and at the same time (although we recognise we may need to be flexible as per stakeholder requirements):

- Two meetings in Phase 1 (one face to face and one on-line)
- One face to face meeting in Phase 3
- One face to face meeting in the dissemination phase for co-production of project outputs

In addition, the core stakeholder groups will be invited and expected to be a key part of the online webinars with the wider associated stakeholder groups in Phase 2 and Phase 4.

SUCCESS CRITERIA AND BARRIERS TO PROPOSED WORK

Success will be assessed against timely completion of the key milestones within each Phase of the review. These will be monitored in the monthly meetings of the core research team. Possible barriers and potential solutions are presented in Table 4 below.

Table 4: Project Risks and Potential Solutions

Potential Barriers/Risks	Potential Solutions
Disruption due to new waves of Covid-19 pandemic	Project meetings would take place virtually. A more flexible meeting/consultation approach would be taken to ensure affected stakeholders (e.g. health workers) could remain involved
Sickness of a team member	As a highly experienced team in substantive posts, with multiple transferable skills, team members would be able to cover for each other
Rapid change in NHS maternity and digital policies and infrastructure	Our project advisory and stakeholder groups have senior representatives from relevant NHS bodies, allowing changes to be identified and fed into the review process where relevant
Ongoing engagement of the stakeholder groups during a long project	We have a designated lead (HS) for stakeholder engagement. We will utilise social media and regular project updates and communications to keep in close contact with all stakeholders and to provide support and training where required
Some programme theories may have insufficient direct evidence from maternity care settings	These will be identified as areas requiring further research. Grey literature and examples of current practice will be actively pursued. Indirect evidence from non-maternity settings will be utilised to provide initial findings to inform the future research agenda

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APPENDIX 1: PROJECT FLOWCHART