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Research Article

What Approaches to Peri-Conception Care for Women with Pre-Existing Medical Conditions Work, for Whom and in What Circumstances? A Protocol for A Realist Review

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Abstract

Women with pre-existing medical conditions are at increased risk of complications during pregnancy that can affect the immediate and long-term health of themselves and their offspring. Evidence suggests that preparation in the peri-conception period, before and during very early pregnancy, is effective but not all women are aware of, or able to undertake, the advised condition-specific behaviour change prior to pregnancy. Improving outcomes for these women requires a greater understanding of what approaches work, for whom they work, in what context and how. This protocol outlines how realist review methods can be used to synthesize evidence on peri-conception care for women with pre-existing medical conditions. The review will be conducted in two phases using electronic database and supplementary searching to find relevant evidence to develop and test program theories about how peri-conception care works. Phase 1 will focus on initial theory development, specifically the context and mechanisms that may explain how it works. Phase 2 will then be undertaken to test and refine these program theories. Experts and women with relevant lived experience will be consulted at each phase of the review to ensure it is grounded in real-life. The findings will be disseminated locally, nationally and internationally to peri-conception care networks. This realist review will explore how and for whom peri-conception care works, in order to support decisions regarding how to implement effective peri-conception care for women with pre-existing medical conditions and thus improve the lives of affected families. The findings will also inform a realist evaluation of peri-conception care, with the aim to further refine program theory and explore different methods of implementation of peri-conception care.

Introduction

The period before and during very early pregnancy is referred to as "peri-conception" [1]. The precise period used is dependent on the perspective from which this concept is viewed, which may be biological (4 weeks either side of conception), individual (from the point at which a couple decide they want to have a baby) or population level (from adolescence through to the end of the reproductive life stage) [2]. For the purpose of this review, a combination of all three will be included, to address the issues of both planned and un-planned pregnancy, and in recognition of the fact that some conditions (such as raised obesity) may take several months or even years of behavior change to address.

It is well known that parental factors, including nutrition, lifestyle habits and medication, can influence embryo development and the subsequent long-term health and development of offspring [1,3]. Many of these factors are modifiable, and parents who are planning pregnancy are likely to quit or reduce both smoking and alcohol intake due to public awareness of the risks associated with these substances [4].

Care during the peri-conception period is particularly important for women with pre-existing medical conditions; these include diabetes, epilepsy, cardiac conditions, hypertension, hypothyroidism and severe mental health problems [5,6]. This is due to the increased risk of morbidity and mortality for both mothers and babies in these groups [7-12]. This is demonstrated in the most recent report on maternal mortality in the United Kingdom (UK), which highlighted that two thirds of women who died in 2013-15, during or up to six weeks after giving birth or the end of

pregnancy had pre-existing physical or mental health problems [13]. The report stated that forward planning could have prevented many of these deaths. These findings emphasize the importance of this area of care, which has been somewhat neglected to date in terms of both research and policy [1], hence the focus of our proposed review upon peri-conception care for women with pre-existing medical (including physical and mental health) conditions.

There is evidence that some women lack knowledge despite planning a pregnancy [14], with the percentage of women who plan a pregnancy in the UK reported at 73% [4]; although this research was limited to one area in North London, the authors reported that participants were from range of socio-economic and ethnic backgrounds. Findings showed that 34% of the women surveyed (total n=1173) reported having acquired no information about pre-conception health; the figure amongst women with a relevant medical condition was 32%. However, those who had received pre-conception advice from a health care professional were more likely to be those with pre-existing medical conditions and were more likely to adopt positive behavior changes. In another study, involving women with type 1 diabetes (an example of a pre-existing medical condition), similar figures were identified; 36% of these women self-reported having received no pre-pregnancy counselling [15]. This is despite national recommendations to do so [16] and evidence of improved pregnancy outcomes for women with type 1 diabetes who receive appropriate peri-conception care [15,17,18]. These findings highlight the need to make peri-conception care available to all women with pre-existing medical conditions, whether they report planning a pregnancy or not.

Several different approaches to peri-conception care, for women with pre-existing medical conditions, have been identified in the literature including:

- face-to-face clinics targeting women planning a pregnancy [17]; these clinics may not be available in all areas, and are likely to attract women who are willing to openly discuss their pregnancy intention with a healthcare professional
- opportunistic counselling in primary or secondary care [19]; this includes advice that is recommended for all women with pre-existing medical conditions, regardless of pregnancy intention, for example, women with type 1 diabetes [16] and
- digital or web-based resources such as smart phone applications (apps) [20]; these may attract women who wish to find information about peri-conception care without openly discussing it with a healthcare professional.

Some barriers to care, however, have been identified [21] and these may include poor relationships with healthcare professionals, perceived unrealistic expectations and a desire for less medicalized pregnancies. In addition, women may have a poor understanding of why pregnancy planning is important for them and may be embarrassed to ask for advice [22]. An initial literature search has identified an awareness of these issues and a recent call to action in this area by Public Health England [6]. There is, however, a lack of systematic consideration of what approaches to peri-conception care work, for whom, and in what circumstances.

We plan to undertake a realist review to explore why different approaches to peri-conception care for women with pre-existing medical conditions might work in certain circumstances for certain groups of women. We therefore aim to understand why outcomes of interventions occur through different mechanisms and contexts [23]. The application of this method will facilitate identification of underlying causal mechanisms that influence women's decisions, behaviour and the resulting outcomes of peri-conception care. Identifying underlying mechanisms that lead to appropriate behaviour change under certain conditions will form "Context, Mechanism, Outcome" (CMO) configurations, which can be tested and refined.

Working with stakeholders, we will ensure that the resulting program theory informs health policy and influence commissioning decisions, resulting in improved access to effective peri-conception care for this group of women. Any subsequent change in service delivery can then be evaluated to measure the impact, with the aim of improving the morbidity and mortality of mothers and babies.

Review aim and objectives

The aim of this review is to use a theory-driven evidence synthesis to explore, amongst a group of women with pre-existing medical conditions, what form of peri-conception care works for whom, how these approaches work, and in what circumstances. Following the initial literature search, we will conduct the review in two main phases: firstly, we will conduct systematic searches to develop initial program theories, and secondly, we will conduct targeted searches to test and refine these theories (see "methods" section). The objectives of this two-phase review are listed below:

1. To develop theory relating to the main factors or mechanisms that are thought (both scientifically and experientially) to explain why women (and their partners) with pre-existing medical conditions a) seek or receive appropriate condition-specific peri-conception care or advice and b) engage in recommended behaviour change prior to pregnancy (we are defining "engagement in recommended behavior change" as engagement in at least one condition-specific behaviour change, which is known to reduce morbidity or mortality for either mother or baby prior to conception)
2. To identify types of peri-conception care that may be particularly beneficial and appropriate for different groups of people in different contexts

Methods

Since the nature of peri-conception care is complex, involving a wide variety of contextual circumstances and factors, and we are aiming to explore what works for whom and how, the methods of realist review methodology are most suitable [24]. The aim of realist

Table 1: Possible intended outcome based on context of pre-existing medical condition.

Context	Possible intended outcomes				
(pre-existing medical condition)	Optimization of medication	Specialist pregnancy / birth / postnatal planning	Optimal glycemic control (HbA1c level)	Prescription of high-dose folic acid supplement	Referral for genetic counseling
Diabetes	x	x	x	x	
Epilepsy	x	x		x	
Cardiac disease	x	x			x
Severe mental health conditions	x	x			

inquiry is explanation-building, and this is achieved through an iterative theory-driven interpretive approach using evidence from a range of sources [25]. We will therefore use an interlinked four-phase approach [26].

1. Prototype program theory development
2. Evidence location, retrieval, data extraction
3. Program theory testing and refinement
4. Development of actionable recommendations

Stakeholder involvement is embedded throughout this process; therefore, we will engage a group of experts and involve them in each phase; these experts will include health professionals involved in a newly established peri-conception clinic, researchers with specialist knowledge and interest in this topic, and service users with appropriate lived experience. Consultation will be face-to-face and by email.

Phase 1: Initial program theory development

Electronic searches

We will iteratively develop a search, based on a known set of target articles and consultation with stakeholders and an information specialist and use this to conduct a systematic search of the literature. In line with realist review methodology, the purpose of the first phase of literature searching will be to develop program theories that will explicate underlying mechanisms explaining how approaches to peri-conception care are thought to work for different groups of people in different contexts [25]. A "broad brush" approach will therefore be applied to the search in order to capture all types of peri-conception care outlined above, including all terminology that we identify as relating to this topic. The draft search strategy to be used in MEDLINE is: (("preconception" or pre-conception or periconception or peri-conception or pregestational or pre-gestational or prepregnancy or pre-pregnancy or interconception or inter-conception) adj4 (counsel?ing or advice or care or planning or clinic? or program*)).ti,ab,kw. Other databases that we will search are Embase, PsycINFO, Cochrane Library, British Nursing Database and CINAHL. We will include studies written in English (to avoid the need for translation), from the Organization for Economic Co-operation and Development (OECD) member countries, to select those with similar approaches to healthcare and economic status. Initially, we will not limit the publication date of studies, as searches are not anticipated to result in high numbers of hits. Search results will be saved as EndNote files for screening.

Searching other sources

We will undertake supplementary searches, using strategies including emailing authors of identified studies, conducting Google and Google Scholar searches, hand searching relevant journals and conference proceedings, backwards and forward citation chasing, and searching for theses and dissertations on the British Library EThOS online service. We will also search additional websites for data, including the Department of Health, the National Institute of Health and Care Excellence (NICE), Royal College of Obstetricians and Gynecologists (RCOG) and relevant condition-specific third sector websites such as those belonging to Diabetes UK, the British Heart Foundation and Epilepsy Action.

Screening to identify relevant evidence

In the first phase, relevant evidence will contribute to theory building, and we will include a variety of sources of evidence, including, but not limited to editorials, opinion pieces, communications, primary studies, process evaluations and systematic reviews. The purpose of screening will therefore be to identify and include any evidence where there are descriptions of who is receiving peri-conception care, under what circumstances, and what resources are on offer to them, in order to develop an understanding of how peri-conception care might work. We will also search for descriptions of reactions to this information or care and include any descriptions of why people might choose not to access or accept this form of care.

Initial screening of titles and where available, abstracts of studies identified in the database searches, will be conducted by two team members independently using the web-based citation management application Rayyan [27]. Where these appear to be relevant, given the inclusion criteria outlined below, the full text will be obtained and, again, screened by two team members. Any disagreement will be resolved by discussion, with involvement of a third researcher, where necessary, to aid consensus.

Population inclusion criteria

The population inclusion criteria will be women of reproductive age and / or their partners, who have any type of pre-existing medical (including physical and mental health) condition, and who are seeking or receiving peri-conception care. This may be part of routine primary

or secondary care related to their condition, or specifically because they are considering planning a pregnancy. Some women in this group may have previously experienced pregnancy, and some may have previously experienced a pregnancy loss, complicated pregnancy, or neonatal loss; others will not have experienced any of these events. We will not initially restrict evidence to any particular medical or mental health condition, but we may iteratively focus on one or more specific conditions in response to findings from our initial search phase.

Intervention inclusion and exclusion criteria

We will include evidence concerning a range of peri-conception care packages aimed specifically at women with pre-existing medical conditions. Some of these will target all women of reproductive age and others will target women who are planning, or considering planning, a pregnancy. Although the evidence is likely to be scarce, our search will include care offered to men, as well as women, and include care offered to same-sex couples. Any form of peri-conception intervention will be included in the first phase; this may include face-to face clinics, telephone advice, video recordings or internet-based resources including web and mobile applications (apps). Intervention inclusion in the second phase is likely to focus on face-to-face clinics and mobile apps, but we may iteratively focus on another area in response to initially identified evidence, resulting in a shift or expansion in scope. Interventions that will be excluded, include any aimed specifically at women experiencing fertility problems, seeking advice regarding contraception or delaying pregnancy, women seeking termination of pregnancy or pre-pregnancy screening.

Comparator

Since the testing of program theories will involve a range of study designs, including evaluations and qualitative research, comparator criteria in both phases will mainly be applied to comparative effectiveness studies. In these studies, comparator criteria will be women with pre-existing medical conditions who have not received any peri-conception care. Comparator criteria may also be applied to studies involving similar types of care where access or engagement may differ resulting in significant differences in outcome.

Types of study

We will include evidence that provides descriptions of peri-conception care using a broad variety of methods. This will include both qualitative and quantitative studies as well as non-empirical studies. We will therefore include any studies that provide a detailed account of a peri-conception care intervention as outlined above. If numerous studies are identified, these will be prioritized based on relevance and rigor (see below).

Outcomes

We anticipate that the outcomes will be context specific and may emerge during both phases of the review process. However, the likely outcomes relating to peri-conception care for this population group include, but are not limited to, the following:

1. Health care professionals' awareness and delivery of appropriate peri-conception care
2. Health care professionals' awareness of and referral to appropriate peri-conception care
3. Women's (and/or their partners') recollection of peri-conception advice as part of normal primary or secondary care related to their medical condition
4. Women's (and/or their partners') initial attendance at a peri-conception clinic
5. Women (and/or their partners) downloading or accessing specific peri-conception advice / mobile app
6. Women's (and/or their partners') engagement in appropriate health behaviour change

Appropriate health behavior change will be dependent on the individual woman's circumstances or "context" related to her pre-existing medical condition. Some potential condition-specific intended outcomes (in terms of behavior change) are outlined in table 1. However, in this review we are interested in how context may influence the firing of mechanisms, rather than the effectiveness of the intervention (peri-conception care), which, in many cases, has been explored elsewhere.

Quality assessment

In line with requirements for realist review, we will assess the quality of data based on relevance (to the program theory) and rigor (credibility and trustworthiness of the methods used) [28]. This will be achieved in the first phase of the review by using a hybrid classification tool, which classifies sources as "conceptually-rich" or "thin" [29]. This enables focus on stronger sources without exclusion of weaker ones.

Standard quality assessment tools will also be used in the review. This includes the Cochrane Collaboration's tool for assessing risk of bias in studies of effectiveness [30] and the Wallace criteria for appraisal of qualitative studies [31]. Appraisal of studies during both phases will be undertaken by two reviewers independently, with any disagreement being resolved through discussion and, where necessary, a third reviewer.

Data extraction

The first phase of this review will use the realist approach of "engaging with" the data, rather than formal data extraction; this involves note taking, annotation and conceptualization [29]. Specifically, we will examine a variety of types of peri-conception care and factors contributing to identified intended and un-intended outcomes. The process will be continually refined based on discussion, with the aim of developing program theory for further refinement in phase two.

Synthesis

We aim to develop an understanding of how different approaches to peri-conception care might work for women with pre-existing medical conditions by identifying how specific outcomes are generated by relevant mechanisms, which are triggered in particular contexts. We will seek recurring patterns across the data. A similar strategy will be used for both phases, following realist methodology, which may involve some of the following tools [25,28].

1. Juxtaposition of sources of evidence, for example when evidence about implementation in one source enables insights into evidence about outcomes in another source
2. Reconciling of sources of evidence, when results differ in apparently similar circumstances, further investigation is appropriate in order to find explanations for why these different results occurred
3. Adjudication of sources of evidence, based on methodological strengths or weaknesses
4. Consolidation of sources of evidence, when evidence about mechanisms and outcomes is complementary and enables a multi-faceted explanation to be built
5. Situating sources of evidence, when outcomes differ in particular contexts, an explanation can be constructed of how and why these outcomes occur differently

Transparency will be achieved by documenting the reasoning processes used and applied during synthesis as outlined above. In phase one we will organize studies according mechanisms and contextual factors, such as type of pre-existing medical condition and demographics. We will tabulate the data to explore combinations of contexts, mechanisms and outcomes and develop a series of "if, then" statements around mechanisms, which we will refine through discussion. The resulting theoretical explanatory model, including CMO configurations, will be used as a theoretical framework for phase two of the review.

Phase 2: Program theory testing and refinement

The search for empirical evidence

Having developed initial program theories in phase one of the review, the second phase will involve searching for empirical evidence that can be used to test and refine these theories; "testing" in this case will constitute adjudicating between 2 rival theories, or more where applicable [25]. Searching will be purposive (based on the theoretical framework) and iterative as the review evolves; searching will stop when saturation is reached. Search terms for database searches in this second stage will depend on results from the first phase and will be discussed within the review team and wider stakeholder advisory group for sense checking and completeness.

However, a "snowballing" approach to identifying empirical studies will also be used, in view of the identified effectiveness of this method [25]. During this phase we will include both qualitative and quantitative studies; we include any primary studies, from any discipline, that provide apposite evidence on the theories that have been identified in phase one and require testing and refining in phase two. Evidence will be tested for relevance and rigor prior to data extraction and synthesis, although further assessment of rigor will be undertaken as each study enters the synthesis stage [25].

Data extraction and synthesis

Data extraction in phase two of this review will involve annotation of papers, collation of evidence using a bespoke data extraction form (based on the theoretical framework identified at the end of phase one) and reportage, which involves the use of extracts of evidence to identify the basis of inferences used for synthesis [25]. Data will be extracted by one reviewer and checked by another. The data will be used to clarify and explain the mechanisms and refine program theory, and as such, data will not simply be classified, but used to develop a line of argument that feeds into the final synthesis stage. Synthesis will follow the strategy outlined in phase one above; with the purpose of refining program theory developed during phase one in the light of evidence and analysis of findings from phase two.

Dissemination

We will produce a briefing document for stakeholders and commissioners outlining our findings. This will be a two-page summary of purpose, aims, findings and implications of the review that are relevant and user-friendly. We will disseminate the findings of this review to relevant local, regional, national and international groups. These include the local expert group and stakeholders involved in this review, who have recently established a pre-conception clinic; the regional maternity clinical network, upon which one member of the research team sits as a member of their expert reference group; and the European Preconception network, which includes two members of the research team.

We will submit the results of the review to a high-impact, peer-reviewed journal for international dissemination; any paper will follow the RAMESES publication standards for realist syntheses [32]. We also plan to present our findings at the 4th Preconception Health and Care conference organized by the European Preconception network.

Discussion

This realist review will explore how, for whom and in what circumstances peri-conception care for women with pre-existing medical conditions works. In addition, the findings will inform a realist evaluation of peri-conception care, with the aim to further refine program theory and explore different methods of implementation of peri-conception care. If successful, the findings will offer innovative approaches to peri-conception care that result in reduced morbidity and mortality rates amongst women with pre-exiting medical conditions.

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