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An exploration of preconception care for people with health conditions using realist methodology: what works, for whom, and in what circumstances?

by

Heather Joy Hopper

A thesis submitted to the University of Plymouth

in partial fulfilment for the degree of

DOCTOR OF PHILOSOPHY

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Author's Declaration

At no time during the registration for the degree of Doctor of Philosophy has the author been registered for any other University award without prior agreement of the Doctoral College Quality Sub-Committee.

Work submitted for this research degree at the University of Plymouth has not formed part of any other degree either at the University of Plymouth or at another establishment.

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Glossary

- BMI Body Mass Index
- CDC Centers for Disease Control and Prevention
- CKD Chronic kidney disease
- CMOC Context, mechanism, outcome configuration
- GP General practitioner (medical doctor)
- HCP Healthcare professional
- IMD Index of multiple deprivation
- MBRRACE Mothers and Babies: Reducing Risk through Audit and Confidential Enquiries
- MS Multiple sclerosis
- NHS National Health Service
- NICE National Institute for Health and Clinical Excellence
- PCC Preconception care
- PHE Public Health England
- QOF Quality outcomes framework
- SGA Small for gestational age (baby)
- SLE Systemic lupus erythematosus
- UK United Kingdom
- US / USA United States / United States of America
- WHO World Health Organisation

Heather Joy Hopper

An exploration of preconception care for people with health conditions using realist methodology: what works, for whom, and in what circumstances?

Abstract

Background: People living with pre-existing physical or mental health conditions are over-represented in audits and confidential enquiries regarding maternal morbidity and mortality and thus often advised to stabilise or optimise their health prior to becoming pregnant. Preconception care may include medication or behaviour change, which can be effective but not always accessed by those who need it, and there is a lack of evidence demonstrating how this can be achieved. The aim of this study was therefore to explore what form of preconception care for people living with health conditions works, for whom, how do these approaches work, and in what circumstances.

Design: Realist methodology was used to identify causal explanations, involving consideration of unobservable processes or powers that can only be identified by their effects but may still have relevant impact on the outcomes of an intervention or programme. A realist review of literature was followed by a realist evaluation, which involved qualitative interviews with relevant stakeholders: women living with health conditions, their partners or supporting family members, and healthcare professionals.

Results: Thirteen refined middle-range theories, providing causal explanations of what works for whom, and how, were identified. These focused on information, knowledge and beliefs, therapeutic relationships, and social structures and healthcare services.

Theories were identified as relevant different points of a person's journey. Since pregnancy planning was identified as important for people living with health conditions, theories providing a causal explanation of how this can be enabled are important, in addition to theories that apply within the context of pregnancy planning.

Discussion: This is the first study of preconception care for people living with health conditions using a realist approach. A realist review followed by a realist evaluation has resulted in new knowledge about causal factors that promote access to preconception care and support for people in this group to improve their preconception health. Focusing on causality has identified important recommendations for health care professionals, public health messaging, and the organisation of healthcare. Implementation in practice will lead to a greater chance of pregnancy planning and support to optimise preconception health for people living with health conditions.

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Introduction

"The role of the midwife is to provide skilled, knowledgeable, respectful, and compassionate care for all women, newborn infants and their families. Midwives work across the continuum from pre-pregnancy, pregnancy, labour and birth, postpartum, and the early weeks of newborn infants' life."

(Nursing and Midwifery Council, 2019) p4.

As a midwife, I have provided skilled, knowledgeable, respectful, and compassionate care for birthing people and their families, with a focus on pregnancy, labour and birth, and the postpartum period, throughout my career. Whilst pre-pregnancy (preconception) care is within the scope of the midwife (Nursing and Midwifery Council (NMC), 2019), this area is not currently included in routine midwifery practice in the United Kingdom (UK) (Hughes et al., 2016). Midwives are familiar however, with the increase chance of complications among people living with health conditions both during and after pregnancy. Annual reports on UK maternal mortality (Mothers and Babies: Reducing Risk through Audit and Confidential Enquiries – MBRRACE-UK) highlight the over-representation of people with pre-existing physical and mental health conditions among those who died during or up to one year after pregnancy in the UK (Knight et al., 2023). The most recent MBRRACE-UK report identified that 56% of the women who died in 2019-2021 were living with pre-existing physical health conditions and 37% were living with pre-existing mental health condition, whilst 34% had a BMI of 30kg/m² or above (classified as living with obesity). Maternal deaths attributed to physical health conditions included cardiac conditions (n=33), epilepsy (n=17), diabetes and other endocrine disorders (n=14, including 8 with diabetes), haematological disorders (n=7), respiratory disorders (n=5, including 4 with asthma),

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and connective tissue disorders (n=2); 25 maternal deaths were attributed to mental health conditions (n=13 due to suicide) (Knight *et al.*, 2023).

Preconception care is therefore both within my professional scope of practice as a midwife, and an area in need of greater input, since improved preconception health can help improve health not just during pregnancy, but beyond pregnancy, for offspring, and for future generations (Public Health England (PHE), 2018).

Interventions to improve health *during* pregnancy have been found to have little effect on newborn and child health outcomes, which suggests that an earlier focus on preconception health is required (Stephenson *et al.*, 2018); this presents a challenge, however, in terms of identification of people who may be planning a pregnancy, and ensuring they have access to preconception care, advice and support (Stephenson *et al.*, 2018).

Whilst the impact of effective preconception care is known (Public Health England, 2018), there is currently a lack of evidence demonstrating how access to preconception care and support to improve preconception health is (or is not) achieved for people living with health conditions. The purpose of this PhD study is therefore to focus on causation, by using a realist approach; what works for whom and how, in order to inform services, reduce maternal mortality and improve the health of mothers, babies and future generations, including people living with *any* pre-existing physical or mental health condition.

A realist approach enables the researcher to consider powers or processes that are only observable through their effects and does not attempt to control for confounding factors since context can have a significant impact on outcome (Pawson and Tilley, 1997). This facilitates exploration of a complex system, such as preconception care,

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resulting in programme theories about how people might or might not access appropriate support.

Outline of the aim and objectives of the study

The aim of the study is to explore, among people living with pre-existing health conditions, what form of preconception care works, for whom, how these approaches work, and in what circumstances.

Objectives:

- To develop theory relating to contexts and mechanisms that are thought to explain how and why people with pre-existing health conditions
 - a. Seek and/or receive appropriate preconception care or advice, and
 - Engage in recommended behaviour change leading to improved preconception health
- 2. To identify types of preconception care that may be particularly beneficial and appropriate for different groups of people in different contexts
- To test and refine the identified theories with people experiencing a range of different health conditions, their partners or supporting family members, and healthcare professionals providing preconception care
- 4. To make recommendations for improvements in preconception care for people with health conditions

Aim:	To explore, among people with pre-existing health conditions, wha approaches work, and in w	• • •
Objectives:	 to develop theory relating to contexts and mechanisms that are thought to explain how and why people with pre- existing health conditions a) seek and/or receive appropriate preconception care or advice, and b) engage in recommended behaviour change leading to improved preconception health 	 3. to test and refine the identified theories with people experiencing a range of different health conditions, their partners or supporting family members, and healthcare professionals providing preconception care 4. to make recommendations for improvements in preconception care for people with health conditions
Phases:	1. Realist Review	2. Realist Evaluation
Process of theory building:	Development of programme theories Context – mechanism - outcome	Qualitative interviews to test theoriesAppraise findings and refine theoriesConceptual framework of preconception care

Figure 1. Overview of the study

Structure of the thesis

The thesis is divided into three parts, aligning with the overview of the study illustrated in Figure 1.

Part one introduces the subject area and chosen methodology, with chapter one providing an overview of preconception health and care, chapter two exploring health conditions and related preconception issues, and chapter three providing a rationale for the use of realism and realist methodology to answer the research question.

Part two concerns the realist review, with chapter four outlining the methods used and chapter five including the results; these programme theories are presented in the three groups that were identified as providing a significant contribution to effective preconception care for people living with health conditions. Chapter six provides a summary and conclusion from the realist review.

Part three concerns the realist evaluation, which involved theory testing and further refining, with chapter seven outlining the methods used. Chapter eight provides an overview of stakeholders who engaged in qualitative interviews and thus participated in the refinement of programme theories. Chapters nine, ten and eleven provide the results, showing how data from interviews contributed to the refined middle-range programme theories. These are presented in the three groups that were identified through analysis and synthesis of the data: chapter nine concerns information, knowledge and beliefs, chapter ten concerns therapeutic relationships, and chapter eleven concerns social structures and healthcare services.

The final chapter in part three (chapter 12) provides a discussion of results in relation to the current literature, along with a summary and conclusions from the realist

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evaluation. It also includes a conception framework of preconception care for people living with health conditions and provides recommendations for clinical practice and further research.

Terminology and inclusive approach used in this thesis

Where possible, inclusive gender-neutral terms such as "people" are used throughout this thesis. Since there is a biological basis of conception, requiring both male and female gametes however, the terms "woman" and "women" may be used to refer to the pregnant, or potentially pregnant person, when it is appropriate to differentiate within the text, without any intended discrimination. People who identify as transgender, non-binary or having a fluid gender identity are recognised as valued maternity service users by the author and respected as individuals with equal rights to excellent and appropriate preconception and maternity care.

Part I

Overview of Preconception Health and Care for People Living with Health Conditions, and Methodological Basis of this Study

Chapter 1

The Concept of Preconception Health and Care

In this chapter I will introduce preconception health and care, including definitions, where preconception advice might be accessed, and the concern that not all those who need support to improve their preconception health are accessing it.

1.1 Definitions of preconception health and care

Preconception health is defined as the health during reproductive age and includes both men and women (Centers for Disease Control and Prevention, 2023a; Public Health England, 2018). The preconception period exists before conception, and as such, can only be identified in retrospect, providing a challenge for healthcare professionals seeking to offer preconception care. To address this issue, Stephenson *et al.* (2018) presented three definitions of the preconception period, identifying a biological, an individual, and a population perspective. Hill *et al.* (2020) subsequently identified four perspectives, which can be used to define preconception populations: intentional, potential, public health, and life course perspectives.

1.1.1 Biological perspective

The biological perspective focuses on the period around conception, often referred to as the periconception period. During this time environmental factors impact gamete development and maturation, fertilisation, and early embryonic development. The minimum timeframe from this perspective is from 6 weeks before, extending to 3 weeks after conception (Stephenson *et al.*, 2018). This period, however, is based on recommendations concerning folic acid supplementation (Mastroiacovo and Leoncini, 2011) and is therefore focused on the potential pregnant person's perspective. Since human spermatogenesis takes 74 ± 2 days (Amann, 2008), a more accurate and gender inclusive biological timeframe would be between 11 weeks before and 3 weeks after conception. Others define the periconception period to include from 14 weeks before conception to 10 weeks after conception, covering earlier gametogenesis and later embryogenesis (Fazeli and Holt, 2017; Steegers-Theunissen *et al.*, 2013).

1.1.2 Individual perspective

The individual perspective (Stephenson *et al.*, 2018) requires a conscious decision to plan a pregnancy, aligning with the intentional preconception perspective identified by Hill *et al.* (2020). This perspective provides the opportunity for behaviour change, medical review and other elements that may be beneficial to improve preconception health (Stephenson *et al.*, 2018; Hill *et al.*, 2020). Data from 36 low and middle-income countries demonstrate a wide variation in the prevalence of unplanned pregnancies, with 25% overall reported as unintended (out of 43,763 pregnancies) (Bellizzi *et al.*, 2020); data from a smaller UK sample showed a similar prevalence of unplanned pregnancies, at 24%, with a further 3% resulting from an ambivalent approach to pregnancy (Stephenson *et al.*, 2014). In circumstances where a pregnancy is not planned, there is no preconception period from Stephenson *et al.*'s (2018) individual perspective. This is where the potential preconception perspective identified by Hill *et al.* (2020) is relevant as this includes people who are sexually active, with or without the use of effective contraception. This does not negate the biological or population perspective but highlights the importance of pregnancy planning to enable individuals to make improvements in their own preconception health.

1.1.3 Population perspective

At a population level, the issue of preconception health can be viewed from a public health perspective (Hill *et al.*, 2020; Stephenson *et al.*, 2018), with behaviours relating to diet, exercise, obesity, smoking and drinking embedded within culture and communities. Data show that and poorer preconception health correlates directly with increased levels of deprivation (Schoenaker *et al.*, 2023). This situation reflects the national picture in the UK, where data demonstrate a social gradient whereby people living in areas of greatest deprivation experience a "double whammy" of the poorest health and shortest life expectancy (Marmot *et al.*, 2020).

1.1.4 Perspective of a person living with one or more health condition

I propose an additional definition of the preconception period; one from the perspective of a person with one or more physical or mental health conditions. For this group of individuals, the preconception period starts at the point of diagnosis of their health condition and extends to the point when pregnancy is confirmed. The rationale for this timeframe is that it includes any medical interventions and individual choices that relate to the health condition/s and have an impact on current and/or future sexual and reproductive health for that individual. With about a quarter of people in the UK starting pregnancy with a pre-existing health condition (Schoenaker *et al.*, 2023), this perspective is highly significant and requires consideration by

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healthcare professionals who provide advice and support to people with health conditions. This aligns somewhat with the life course perspective identified by Hill *et al.* (2020) since it includes people prior to reproductive age, but my proposed definition specifically identifies people with health conditions.

Preconception care is relevant for both biological sexes; in the case of people living with obesity, for example, male fertility can be impaired in terms of both quality and quantity of sperm (Kort *et al.*, 2006), and for females, obesity can impact both fertility and result in increased chances of comorbidities in pregnancy (Poston *et al.*, 2016; Daly *et al.*, 2022a). Diabetes is similarly associated with impaired quality and quantity of sperm among males (Facondo *et al.*, 2022), and established preconception recommendations for females in view of increased chances of perinatal morbidity and complications during pregnancy and beyond, as well as higher chances of morbidity and valproate is strongly advised against, among both males and females under the age of 55, due to the known risk of birth defects and neurodevelopmental disorders following its use in pregnancy, with recent action taken in terms of advice regarding impaired fertility and abnormal sperm morphology in males (Tallon, O'Donovan and Delanty, 2021; Medicines and Healthcare products Regulatory Agency, 2022).

In conclusion, preconception health is an important consideration for anyone of reproductive age, and people with one or more physical or mental health condition should be given the opportunity to access appropriate information from the point of diagnosis, in view of the implications this may have for their own health and the health of any potential future offspring. The focus of this study concerns people with one or more physical or mental health condition.

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1.2 Where and when preconception advice might be accessed

People with health conditions may access or be offered preconception care through a variety of different approaches, sources, healthcare professionals and settings, both before and during reproductive age; these include:

- Clinics targeting people planning a pregnancy (Murphy *et al.*, 2010a); these clinics may not be available in all areas, and are likely to attract people (mainly targeted at women) who are willing to openly discuss their pregnancy intention with a healthcare professional
- Opportunistic counselling in primary or secondary care (Shannon *et al.*, 2014); this includes advice that is recommended for anyone with pre-existing health conditions, regardless of pregnancy intention, for example, people with type 1 diabetes (National Institute for Health and Care Excellence, 2020a) or epilepsy (National Institute for Health and Care Excellence, 2023a)
- Digital or web-based resources such as smart phone applications (apps)
 (Nwolise, Carey and Shawe, 2021; De Leo *et al.*, 2022) or condition-specific web sites; these may attract people who wish to find information about preconception care without openly discussing it with a healthcare professional.

1.2.1 Condition-specific preconception care clinics

Many health conditions are associated with poorer pregnancy and infant outcomes. Both type 1 and type 2 Diabetes Mellitus, for example, are associated with an increased chance of pre-eclampsia, macrosomia, prematurity and stillbirth (Newman *et al.*, 2022; Mackin *et al.*, 2018), with optimal preconception health recommended in

order to mitigate against both morbidity and mortality (National Institute for Health and Care Excellence, 2020a). Preconception care clinics for people (specifically women) with diabetes were established over 40 years ago; a clinic in Edinburgh, for example, was established in 1976, at which time the prevalence of diabetes amongst the pregnant population was considerably lower that it is today (Mackin et al., 2018). Attendance at this early preconception care clinic was associated with improved glycaemic control during the first trimester of pregnancy (Steel et al., 1982). More recently, a study by Gutaj et al. (2015) demonstrated a better metabolic profile among pregnant women in the first trimester who had attended a preconception care clinic and were using continuous subcutaneous insulin infusion in the preconception period, compared with those using multiple daily injections of insulin. Findings confirmed that preconception care was a significant element in achieving optimal metabolic control. Despite these positive outcomes, however, a Cochrane review undertaken by Tieu et al. (2017) identified insufficient randomised controlled trial data to assess the effects of preconception care for people with diabetes on health outcomes for parents and their infants, highlighting the need for further research into the effects of preconception care among people with diabetes.

The European Society of Cardiology (ESC) guidelines (Regitz-Zagrosek *et al.*, 2018) recommend pre-pregnancy counselling for people with congenital and acquired cardiac disease, noting that this facilitates informed decision making. Whilst the risk associated with pregnancy varies depending on cardiac diagnosis (using the modified World Health Organisation (mWHO) classification of maternal cardiovascular risk (Regitz-Zagrosek *et al.*, 2018)), the most recent MBRRACE report (Knight *et al.*, 2023) identifies cardiac disease as one of the most frequent indirect causes of maternal

death, highlighting the importance of access to preconception care for people with this health condition. Epilepsy, similarly, is associated with increased risk of maternal mortality (Knight *et al.*, 2023), therefore preconception care is recommended for this group (National Institute for Health and Care Excellence, 2023a).

Preconception care clinics are also available (in some areas) for people with other health conditions, with National Institute for Health and Care Excellence (2023c) preconception advice recommending specialist referral for people with the following: thyroid disease, diabetes, epilepsy, chronic cardiac disease, chronic hypertension, moderate / severe or poorly controlled asthma, renal disease, history of venous thromboembolism, rheumatological conditions (including systemic lupus erythematosus (Saulescu *et al.*, 2022)), inflammatory bowel disease, haemoglobinopathies (including sickle cell disease and thalassaemia), and severe mental health conditions (such as bipolar disorder and severe depression) (Howard *et al.*, 2014; Jones *et al.*, 2014).

Preconception care clinics are typically led by a condition specialist, team of specialists (Egan *et al.*, 2016), and/or obstetrician, and focus on optimising preconception health and reviewing medication, as appropriate (National Institute for Health and Care Excellence, 2023b). Referral pathways may be via a General Practitioner, condition specialist, or self-referral (examples: NorthEastLondonClinicalCommissioningGroup (2023); Somerset NHS Foundation Trust (2023)). Availability and provision of pre-conception care clinics vary widely across the UK, however, with evidence of no identified care pathway for preconception counselling in some areas, even when this is recommended (Taylor *et al.*, 2022).

Preconception clinics offering condition-specific advice and support for people with a health condition are therefore recommended, but not necessarily available in all areas. Additionally, access to such clinics requires planning and referral, so at least 27% of people in the UK will not access them in view of unplanned (24%) or ambivalent approach (3%) to pregnancy (Stephenson *et al.*, 2014). Other opportunities for people in these groups are therefore required.

1.2.2 Opportunistic preconception advice

Clinical guidelines for health conditions that are congenital or diagnosed in childhood often include the need for sexual and reproductive health advice or education. For instance, NICE guidance for epilepsy includes the recommendation that contraceptive advice should be given to women and girls before they become sexually active, in view of anti-epileptic drug use, which may reduce the effectiveness of oral contraceptives or be teratogenic (National Institute for Health and Care Excellence, 2023a). NICE guidance for diabetes in pregnancy (including management from preconception to the postnatal period) states that diabetes education in adolescence should include the importance of planning a pregnancy (National Institute for Health and Care Excellence, 2020a). The European Society of Cardiology (ESC) guidelines (Regitz-Zagrosek *et al.,* 2018) also recommend that pregnancy is first discussed, with people who have both congenital and acquired cardiac disease, in adolescence.

The underlying message, when reading such clinical guidelines, is that a health condition can impact every area of life, including sexual and reproductive health. This, therefore, presents a challenge to condition specialists, who are tasked with a long list of educational needs among their patient population. Guidance that recommends discussing contraception before a person becomes sexually active begs the question of when this might be, and how a health professional might know that. Research confirms that healthcare professionals can find such conversations difficult to incorporate into routine appointments due to a number of factors including time constraints, lack of knowledge, and ethical dilemmas / discomfort (M'Hamdi H *et al.*, 2017; Kohn *et al.*, 2018). A qualitative study involving interviews with general practitioners, consultant obstetricians, and nurse practitioners (in the USA) identified additional barriers to the delivery of preconception care, including that people generally do not request this information, and may be unwilling or unable to change their behaviour (Nacev *et al.*, 2022). With preconception care perceived by some participants as outside of their normal clinical practice, further understanding of the impact of structural inequalities on preconception health and behaviour was noted (Nacev *et al.*, 2022).

More structured opportunities to offer sexual and reproductive (including preconception) health advice have demonstrated greater success in terms of the provision of advice; these include the use of "One Key Question" (Stulberg *et al.*, 2019), and specific programmes such as "READY-girls" (Charron-Prochownik *et al.*, 2013; Fischl *et al.*, 2010) and other targeted projects (Yamamoto *et al.*, 2018). Identified outcomes include improved knowledge of the benefits of pregnancy planning (Charron-Prochownik *et al.*, 2013), improved access to contraception (Stulberg *et al.*, 2019), and improved preconception health (including appropriate folic acid intake and improved HbA1c levels) (Yamamoto *et al.*, 2018).

Opportunistic preconception advice as part of routine health care is therefore recommended, and was reported as acceptable by most people of reproductive age in

a recent survey (Daly *et al.*, 2022b), but appears to be challenging to deliver and may require a structured, rather than ad hoc approach to ensure that everyone with a health condition has access to appropriate information.

1.2.3 Digital or web-based resources

In their integrative review regarding motivation to engage in preconception care, De Leo et al. (2022) found that the internet and social media influenced people's motivation to seek preconception care, both through information searching online, and increased use of mobile applications (apps). Google searches were sources of information mentioned by people interviewed regarding sources of preconception information in more than one qualitative study (McGowan et al., 2020; Khan et al., 2019). Another survey by Daly et al. (2022b) identified that preconception health websites and apps were acceptable for preconception health information for 99.5% of respondents. In a qualitative study involving focus groups and including both sexes, McGowan et al. (2020) identified generally poor or superficial knowledge of preconception care. Social media, however, was acknowledged to be an acceptable source of information, with positive messages and quizzes having appeal. Participants identified NHS websites as sources of information, in addition to Instagram, which was agreed to be less reliable. The ability to seek information without face-to-face interaction was identified as a benefit of online information, with younger males highlighted as preferring to remain anonymous when accessing advice from a health professional (McGowan et al., 2020). Whilst these findings were from the general population, not just those with health conditions, they do highlight the rising use of the internet to access information among people of reproductive age.

The potential for people with diabetes to access more personalised information via a mobile app was explored by Nwolise, Carey and Shawe (2021). A co-created preconception and diabetes information app was found to be acceptable, useful and informative, with further development and evaluation required at the point of publication.

Digital and web-based resources, therefore, show promise in terms of providing preconception advice for people with health conditions, especially when people would prefer to remain anonymous. Further work appears to be ongoing in this area, and endorsement by trusted health professionals is required.

1.3 Access to preconception care

Despite the range of approaches and sources of preconception care and advice, access to these is limited for people with health conditions. A scoping review of 31 studies identified fewer than 50% of people with type 1 diabetes attended preconception care appointments prior to pregnancy (Ferry *et al.*, 2023). Retrospective analysis of electronic patient records in one large teaching hospital in the UK found that only 66.8% of the pregnant population known to their cardiology services attended prepregnancy counselling (during 2014 – 2020) (Hamilton *et al.*, 2021). In addition to the issue of unplanned pregnancy, significant barriers to care have been identified; these include poor relationships with healthcare professionals, perceived unrealistic expectations and a desire for less medicalised pregnancies among people with health conditions (Ferry *et al.*, 2023; Murphy *et al.*, 2010b). In addition, people may have a

poor understanding of why pregnancy planning is important for them and may also be embarrassed to ask for advice (Spence *et al.*, 2010).

In the UK, among 994 women of reproductive age who responded to an online survey (not limited to those with health conditions), of those who were "trying", "thinking" or "maybe thinking" about becoming pregnant, only 50% were taking folic acid and 15% stated that they would take action to improve health once they found out they were pregnant (Stewart and Hall, 2023). 19% of their partners were not aware of anything they should be doing to improve preconception health (Stewart and Hall, 2023). Data from another survey, involving questionnaires from 835 women of reproductive age (who were not pregnant at the time, again, not limited to those with health conditions) demonstrated low preconception health knowledge, including poor awareness of the need for folic acid supplementation (Daly *et al.*, 2022b). These findings demonstrate a lack of knowledge in the general population (among both males and females) regarding the importance of preconception health.

Whilst the published literature indicates an awareness of the need to improve access to preconception care and some of the barriers to achieving this, a recent call to action by Public Health England (2018), shows that there is a lack of systematic consideration of what approaches to preconception care for people with health conditions work, for whom, and in what circumstances.

1.4 Conclusion

In this chapter I have outlined different definitions and perspectives of preconception health and care. For the purpose of this study, however, I will focus on the perspective of a person with one or more physical or mental health conditions. Preconception care may be accessed from a range of different people and sources, but despite this, there is a low uptake of preconception care among this group. In the next chapter I will explore a range of health conditions that are mentioned in this study and are relevant since people living with these conditions are recommended to access preconception care in order to optimise their preconception health.

Chapter 2

Health Conditions

In this chapter I will explore the prevalence of health conditions among people of reproductive age who have the potential to become pregnant. I will also provide an outline and preconception implications of some common health conditions that will be referred to in this thesis. These include type 1 and type 2 diabetes, epilepsy, cardiac conditions, obesity, chronic kidney disease, cystic fibrosis, systemic lupus erythematosus, and mental health conditions.

I will be using the term obesity since this is a medical term used by the World Health Organisation (World Health Organisation, 2021) and other national and international health organisations (Centers for Disease Control and Prevention, 2023b; The Association for the Study of Obesity, 2022; National Health Service, 2023; National Institute for Health and Care Excellence, 2023c). I acknowledge that this term can generate negative emotional responses (Brown and Flint, 2021) but this is not intended; my intentions throughout are to act with compassion, and reduce bias, discrimination, and stigma for people whatever their condition, characteristics, background or beliefs.

2.1 Prevalence of health conditions in the pregnant population

People of reproductive age (defined for women by World Health Organisation (2023b), as 15-49 years) are generally assumed to be healthier compared with those in an older age bracket. Whilst health data support an increase in the prevalence of long-term

conditions with age, however, they also highlight a relatively high level of some conditions (especially mental health conditions) among people of reproductive age (Office for National Statistics, 2020). It is therefore important to be aware of the prevalence of health conditions in people of reproductive age, and for them to access preconception care.

It is acknowledged that data regarding the prevalence of health conditions in the pregnant population is used here as a proxy for the prevalence of health conditions in the preconception population, which requires some clarification. Firstly, these data only relate to people with the potential to become pregnant; not their partners, whose gametes also contribute to the developing offspring. Secondly, it may not provide a true reflection of the preconception population as some people may be infertile, others may choose not to have children, and others may experience fetal loss. The purpose of this information, however, is to give an approximation of health condition prevalence and is therefore considered sufficiently accurate for this purpose.

Depression (23.43%) and anxiety (18.98%) were the most prevalent health conditions among pregnant people in the UK, identified by Lee *et al.* (2022) in their populationbased cross-sectional study (based on primary care data for pregnant people aged 15-49 with conception date 01/01/2018 – 31/12/2018; n=37,641), with the prevalence of depression noted to increase with deprivation. The lower levels of mental health conditions (9.3%) identified in cross sectional analysis using national maternity service data from England (booking appointments April 2018 to March 2019; n=652,880) by Schoenaker *et al.* (2023), may be due to a reluctance to disclose a mental health condition to a midwife at booking, which is the first point of contact with maternity

services. Further comparison between primary care data and maternity service data at booking would be required to verify this.

Lee *et al.* (2022) found that 24.2% of pregnant people in the UK experienced multimorbidity (more than one active health condition in the year prior to pregnancy), with mental health conditions highly prevalent and representing 70% of multimorbidity. Schoenaker *et al.* (2023) identified that 24.3% of pregnant people had at least one mental or physical health condition (Schoenaker *et al.*, 2023), although did not differentiate between single and multimorbidity.

Table 1 below shows the prevalence of health conditions among the pregnant population. Both data sources referred to above are included; one taken from the national maternity data set in England (booking appointments April 2018 to March 2019; n=652,880), published by the office for health improvement and disparities (Office For Health Improvement and Disparities, 2023), based on work undertaken by Schoenaker *et al.* (2023). The other data source is the clinical practice research datalink (CPRD) (based on primary care data for pregnant people aged 15-49 with conception date 01/01/2018 - 31/12/2018; n=37,641) (Lee *et al.*, 2022). Not all health where appropriate, to provide comparative groups.

These levels of pre-existing health conditions among people of reproductive age challenge assumptions of health in this age group, and highlight the need to provide appropriate preconception care, advice, and support, especially when research by The Nuffield Trust (2023) showed that fewer younger people with long-term health conditions felt supported to manage their condition (58% in age bracket 16-24) compared with people in older age groups (74% in age bracket 75-84). These data also

justify the inclusion of both mental and physical health conditions in this study; just focusing on physical health conditions would exclude a significant number of people from this important area of research.

Table 1. Prevalence of health conditions from England maternity data set and UK primary care data set

Health condition	Maternity data set	Primary care data set	
	(England, n=652,880	(CPRD, UK, n=37,641)	
	(April 2018 – March	(Jan – Dec 2018)	
	2019)	(Lee <i>et al.,</i> 2022)	
	(Office For Health		
	Improvement and		
	Disparities, 2023)		
Obesity (BMI ≥ 30 kg/m ²)	22.29%	19.07%	
Mental health condition	9.34%	-	
Anxiety	-	18.59%	
Depression	-	23.43%	
Post-traumatic stress	-	0.76%	
disorder			
Bipolar disorder /	-	0.47%	
affective psychosis			
Schizophrenia / non-	-	0.33%	
affective psychosis			
Eating disorder	-	1.88%	
Personality disorder	-	1.09%	
Physical health condition	19.10%		
Diabetes (type 1 and 2	0.97%	0.99%	
combined)			
Hypertension	1.03%	0.87%	
Cardiac disease	0.79%	1.26%	
Renal disease	0.79%	0.71%	
Thromboembolic	0.60% 0.65%		
condition			
Hepatitis B	0.15%	-	
Cancer	0.17%	0.51%	

Inflammatory bowel	-	0.60%
disease		
Irritable bowel	-	7.97%
syndrome		
Polycystic ovarian	-	4.66%
syndrome		
Endometriosis	-	1.68
Systemic lupus	-	0.09%
erythematosus		
Inflammatory arthritis	-	1.46%
Migraine	-	12.71%
Epilepsy	-	1.44%
Multiple sclerosis	-	0.15%
Asthma	-	14.63%
Cystic fibrosis	-	0.02%
Thyroid disorder	-	3.34%
Marfan syndrome	-	0.03%

2.2 Overview of health conditions and preconception advice

A range of health conditions are outlined below, with a brief overview of the condition and outline of the impact this may have during the preconception period and pregnancy, including outcomes for both the person who is pregnant, and their offspring. This is not a comprehensive list of health conditions but provides examples illustrating the importance of preconception care for people with health conditions. These conditions have been selected due to the significant impact that the condition and / or treatment may have on preconception health, and they provide a representative a sample of the conditions referred to in this study.

2.2.1 Diabetes (Type 1 and type 2) (0.99%)

Diabetes mellitus (DM) is a group of endocrine disorders, involving a disfunction within the endocrine (hormone) system, specifically the pancreas, which secretes insulin that in turn is involved in glucose regulation (Evans, Lintner and de Veciana, 2014). With either insufficient insulin release (type 1 DM) or impaired response to insulin (type 2 DM and maturity-onset DM of the young; MODY)), hyperglycaemia occurs along with other clinical signs and symptoms. Diabetes is also described as a metabolic disease (World Health Organisation, 2023a), due to the disruption caused to the metabolism of glucose. Inability to metabolise glucose from the diet causes an increase in glycogen breakdown and gluconeogenesis, and increase in ketone production and urea formation as the body is unable to deliver sufficient glucose to tissues that need it, despite a build-up of glucose in the blood stream. Excessive blood glucose is filtered out by the kidneys, resulting in glycosuria and increased thirst due to the osmotic

potential of glucose and resulting dehydration (Rankin, 2017c). Over time, diabetes causes serious damage to organs, including the heart, blood vessels, eyes, kidneys and nerves, leading to increased morbidity and mortality among people with the condition (World Health Organisation, 2023a).

Diabetes affects approximately 422 million people worldwide (World Health Organisation, 2023a), many of whom live in low and middle-income countries, with higher rates of morbidity and mortality due to poorer access to healthcare services. Data from primary care in the UK (Lee *et al.*, 2022) and national maternity data sets in England (Office For Health Improvement and Disparities, 2023) for 2018 show the prevalence of pre-existing diabetes (type 1 and 2) among pregnant people is approximately 1%. With a steadily rising prevalence of diabetes globally, predominantly due to a rise in type 2 diabetes (World Health Organisation, 2023a), this is likely to increase to become an even greater concern for preconception health.

The impact of hyperglycaemia in early pregnancy is a ninefold increase in the chance of congenital abnormalities in offspring (Temple *et al.*, 2002). This highlights the importance of good glycaemic control in the periconception period, continuing throughout pregnancy. Preconception care focuses on achieving optimum glycaemic control, and as a result leads to reduced congenital abnormality rates and perinatal mortality (Wahabi *et al.*, 2020).

In addition to achieving targets for blood glucose (4-7 mmol/litre before meals) and HbA1c levels (below 48 mmol/mol, or 6.5%) before pregnancy, preconception care for people with diabetes (National Institute for Health and Care Excellence, 2020a) includes the following:

- Support regarding diet, weight and exercise, including weight reduction if BMI above 27 kg/m²; this threshold is lower for people with South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background, due to greater cardiometabolic risk even at lower BMI (National Institute for Health and Care Excellence, 2023c)
- Diabetic retinopathy and nephropathy assessment before pregnancy
- Use of contraception until HbA1c target has been achieved
- Medication review (and change if any are teratogenic / not recommended in pregnancy)
- 5mg/day folic acid until 12 weeks gestation

Optimum glycaemic control in the periconception period can be a challenge to achieve, requiring support from healthcare professionals and diligence, commitment, and determination on behalf of the person with diabetes (Murphy *et al.*, 2018). Multiple daily injections of insulin may not result in adequately lowered periconception HbA1c levels for people with type 1 diabetes, but use of continuous subcutaneous insulin infusions (CSII) has demonstrated improved results (better metabolic profiles in the first trimester of pregnancy) (Gutaj *et al.*, 2015; Murphy *et al.*, 2018; NHS Digital, 2023).

The National Institute for Health and Care Excellence (NICE) is an organisation that provides evidence-based best practice and value for money guidance for health and care providers. The most recent guidance regarding diabetes in pregnancy, including the preconception period, (National Institute for Health and Care Excellence, 2020a) does not recommend offering continuous glucose monitoring and CGII until the antenatal period, which may be too late for those people who struggle to achieve appropriate HbA1c levels, using multiple daily injections of insulin, around the time of conception and early embryo development (the periconception period).

Recommendations following audit of pregnancy in diabetes in England and Wales (2021-2022), however, reflect rapid improvements in diabetes technology and include the use of continuous glucose monitoring and hybrid closed-loop systems for all people of reproductive age with the potential to become pregnant, in view of an associated reduction in serious adverse pregnancy outcomes (NHS Digital, 2023). With fetal organs developing early on, before awareness of pregnancy, the critical period for glucose control (preventing hyperglycaemia) is before and during conception (periconception), and providing opportunities to optimise glucose control for everyone of reproductive age will support optimal preconception health for both planned and unplanned pregnancies.

Murphy *et al.* (2018) also identified the need for improved medication review (reducing use of teratogenic medication and prescribing of 5mg folic acid) among people with type 2 diabetes in the periconception period. Required improvements in care for people with type 2 diabetes were also noted in a recent audit conducted in England and Wales (2021-2022) (NHS Digital, 2023). People with both type 1 and type 2 diabetes could therefore experience better pregnancy outcomes with improved access to preconception care and support to achieve the recommended behaviour changes to improve preconception health.

A Cochrane review of preconception care for women with diabetes for improving maternal and infant health only identified three randomised controlled trials that were eligible for inclusion (Tieu *et al.*, 2017). Participants were adolescent girls who were not planning pregnancy at the time of the intervention, and no data were reported

regarding pregnancy or offspring outcome measures. Tieu *et al.* (2017) concluded that there was no evidence to guide practice on the provision of specialised care for people with diabetes before they become pregnant, in terms of their health and the health of their future babies.

The type of preconception care included in the review by Tieu et al. (2017), however, could be described as structured educational input, but this is still essentially opportunistic counselling, with the aim to improve knowledge of the benefits of pregnancy planning and improve preconception health, as participants were not actively planning pregnancy at the time. It would not be ethically acceptable to conduct a randomised controlled trial involving condition-specific preconception clinics for people planning pregnancy, in view of the evidence supporting this intervention (Wahabi et al., 2020) and existing guidance to provide support (National Institute for Health and Care Excellence, 2020a). This highlights the complexity of the provision of preconception care for people with health conditions, and the importance of the research question in this study using a realist approach: "what works for whom, in what circumstances, and how?". It is anticipated that some programmes will work for some people in some contexts; further identification and refinement of programme theories providing causal explanation of what contributes to improved access to preconception care and improved preconception health is therefore required.

2.2.2 Epilepsy (1.44%)

Epilepsy is not one, but a group of neurological conditions that cause abnormal electrical discharges from neurones (brain cells), resulting in seizures; in many cases, the cause of these is unknown (idiopathic) (Bothamley and Boyle, 2020). Treatment

with anti-epileptic drugs (AEDs) is mostly effective (at reducing or stopping seizures), but some are not recommended during pregnancy due to teratogenicity, and some reduce the effectiveness of hormonal contraceptives (Bothamley and Boyle, 2020). Whilst many people with epilepsy have a healthy pregnancy, there is a small but significant increase in the chance of complications including spontaneous miscarriage, antepartum haemorrhage, postpartum haemorrhage, hypertensive disorders, induction of labour, caesarean section, preterm birth and fetal growth restriction (Viale *et al.*, 2015). There is also a risk of death during pregnancy and up to a year afterwards, with Sudden Unexpected Death in Epilepsy (SUDEP) being the leading cause of death among people with epilepsy during this period (Knight *et al.*, 2023). Achieving seizure control is important; uncontrolled convulsive seizures present the greatest risk to both the fetus and pregnant person during pregnancy and immediately afterwards (Leach *et al.*, 2017).

Preconception care from an epilepsy specialist team is therefore recommended for people with epilepsy who are planning pregnancy, with the aim to become seizure free on AEDs that are as safe as possible prior to becoming pregnant (Knight *et al.*, 2023; National Institute for Health and Care Excellence, 2023a; Leach *et al.*, 2017). A 5mg dose of folic acid is also recommended for people with epilepsy (National Institute for Health and Care Excellence, 2023a). Some people, however, experience extreme difficulties changing medication, due to the physical, social and psychological impact that seizures can have on a person's everyday life, freedom and choices (Lawther *et al.*, 2018), and others stop taking prescribed AEDs against medical advice (Askarieh *et al.*, 2022). Other challenges include the level of unplanned pregnancy among people with

epilepsy (approximately 50%), the impact of social deprivation, and limited access to specialist epilepsy services (Leach *et al.*, 2017).

Opportunistic preconception care is therefore important, in addition to specialist advice and support when a person is known to be planning pregnancy. This includes prescribing choices on diagnosis and medication review, in addition to broader sexual and reproductive health advice, such as discussing contraceptive options in view of drug interactions (National Institute for Health and Care Excellence, 2023a).

Preconception care for people with epilepsy is an area that requires improvement (Taylor *et al.*, 2022; Askarieh *et al.*, 2022). Knowing what works, for whom, in what circumstances, and how, is therefore important in this area, and will contribute to recommendations for service improvement.

2.2.3 Cardiac conditions (1.26%) and hypertension (1.03%)

The changes that occur in the cardiovascular system during pregnancy are significant. These changes are required to meet increased demands from the uteroplacental circulation and developing fetus. Pregnancy requires a greater circulating blood mass and volume (up to 50%), compared with the non-pregnant state, and involves decreased peripheral resistance alongside increased body weight (Rankin, 2017b). Increased circulating volume and cardiac output (up to 40%, resulting from both an increase in both heart rate and stroke volume) results in a higher demand on the heart, which is a complex organ comprising of muscle, connective tissue, valves and tendons encased in a fibro-serous sac that protects it and facilitates its constant pumping activity. Even without cardiac disease, pregnancy may cause signs, such as

breathlessness on exertion and oedema, usually associated with cardiac disease; as such it provides a "stress test" of the cardiovascular system. Thus, any pre-existing cardiac conditions that reduce cardiac function present an increased chance of morbidity and, or mortality during pregnancy and immediately after the birth (Rankin, 2017a; Al Khalaf *et al.*, 2023). In addition, pregnancy may reveal previously undiagnosed cardiovascular disease (Al Khalaf *et al.*, 2023).

Cardiac conditions can be divided into congenital heart disease (CHD) and acquired disease. The majority of people with cardiac disease considering pregnancy will have CHD, due to the low prevalence of acquired heart disease in people of reproductive age (Hamilton *et al.*, 2021; Neff, Hunt and Shawe, 2020). Deaths during pregnancy due to acquired heart disease, however, have become more likely, due to people becoming pregnant at an older age (\geq 40), and co-morbidities such as BMI \geq 30 kg/m² and hypertension increasing among people of reproductive age (Knight *et al.*, 2022; Al Khalaf *et al.*, 2023).

Pre-existing chronic hypertension is becoming more common in people of reproductive age (Neff, Hunt and Shawe, 2020), and is associated with an increased chance of pre-eclampsia, preterm birth, caesarean section, neonatal unit admission and perinatal death (Bramham *et al.*, 2014). These findings are from a systematic review and meta-analysis of US studies (using US population data as a comparison) conducted up to 2013. With some studies dating back to 1983, variation and improvements in both a medical and maternity services may therefore limit the generalisation of findings to the present day. Indeed, an in-depth review of deaths during pregnancy and up to a year afterwards (2019 – 2021 inclusive) in the UK and (Knight *et al.*, 2022) shows that none of the people who died due cardiac causes had

essential (pre-existing) hypertension. A more recent longitudinal cohort study using UK data (1.2 million individuals; 12,698 of whom had chronic hypertension and were pregnant between 1997-2016), however, showed that pregnant people with preexisting chronic hypertension had a significantly increased chance of developing cardiovascular disease later in life (Al Khalaf *et al.*, 2023). People with chronic hypertension who had experienced adverse pregnancy outcomes (including hypertensive disorders of pregnancy, preterm birth and a small for gestational age infant), had an increased chance of developing future heart failure (10-fold higher risk) and coronary heart disease (8-fold higher risk), which was evident in the first 5 years of follow-up (Al Khalaf *et al.*, 2023). This demonstrates the serious implication of this health condition and the impact that pregnancy can have on the cardiovascular system.

Eight out of the 33 people who died during pregnancy and up to a year after birth due to cardiac disease, during the 2019-2021 triennium, had known pre-existing cardiac problems (Knight *et al.*, 2023); a reduction from the previous triennium. More detailed exploration of deaths due to cardiac causes, and lessons learnt, was included in the report published in 2022 (Knight *et al.*, 2022), during which there were 61 deaths in this category. Of these 61, only 10% had a recognised pre-existing cardiac problem, but it was noted that pregnant people aged 40 or over, and those living in the most deprived areas of the UK (IMD quintile V) had an increased chance of death from cardiovascular causes (Knight *et al.*, 2022). Compared with people aged 25-29, those aged 40 or over had a relative risk of 6.6 (i.e. were 6.6 times more likely to die due to cardiac disease) and compared with people living in the least deprived areas (IMD

quintile 1), those living in the most deprived areas (IMD quintile V) had a relative risk of 2.19 (i.e. were 2.19 times more likely to die from cardiac disease).

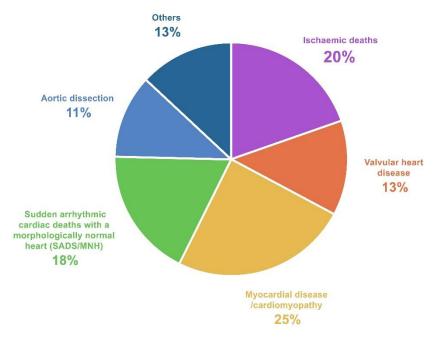


Figure 2. Causes of cardiovascular deaths in the UK and Ireland during 2018-2020

adapted from 2022 MBRRACE report (Knight et al., 2022)

Figure 2 shows the causes of deaths due to cardiac disease during pregnancy and up to a year after birth. With only 10% of these people known to have cardiac disease at booking, signs and symptoms of cardiac disease during pregnancy and after birth need to be appropriately investigated; these may be existing, but unknown conditions that are aggravated by pregnancy and/or childbirth, or conditions that are associated with or acquired during that period.

Appropriate preconception advice and support for people with pre-existing cardiovascular disease (including hypertension), includes medication review and assessment, with a view to achieving optimal cardiovascular function prior to pregnancy; this will depend on individual circumstances (Neff, Hunt and Shawe, 2020; Regitz-Zagrosek *et al.*, 2018). Anyone with a family history of aortopathy and channelopathy should also have a cardiac assessment before pregnancy (Knight *et al.*, 2022). Whilst pregnancy may present a high chance of complications for some, many people with cardiac conditions will experience a healthy pregnancy with positive outcomes (Regitz-Zagrosek *et al.*, 2018). The modified World Health Organisation (mWHO) classification of maternal cardiovascular risk provides an assessment tool that is appropriate for use in developed countries and should be used to guide individual decision making for people with cardiac conditions planning pregnancy (Regitz-Zagrosek *et al.*, 2018).

People with known cardiac conditions and chronic hypertension should therefore access preconception care prior to pregnancy. With one retrospective study of people known to a cardiology unit in the UK reporting only 66.8% of their pregnant population having received pre-conception counselling, there is scope for improvement in order to enable informed decision making (Hamilton *et al.*, 2021). Identification and refinement of programme theories providing causal explanation of what contributes to improved access to preconception care for people with cardiac conditions is therefore required.

2.2.4 Obesity; BMI ≥ 30 kg/m² (22.29%)

In their robust umbrella review of systematic reviews, Daly *et al.* (2022a) identify moderate-certainty evidence that people living with obesity have a greater chance of developing complications in pregnancy. These complications include gestational diabetes mellitus, pregnancy-induced antenatal hypertension and pre-eclampsia, fetal distress, shoulder dystocia, and fetal macrosomia (Daly *et al.*, 2022a). A retrospective cohort study using a Spanish perinatal database (2013 – 2017), comparing perinatal and neonatal outcomes among people living with obesity (BMI \ge 30 kg/m²) (n=2207) with people living with a healthy weight (BMI 20-24.9 kg/m²) (n=9778), also found a higher chance of pre-eclampsia and fetal macrosomia, as well as additional perinatal complications (Melchor *et al.*, 2019). These additional complications included rectovaginal group B streptococcus colonisation, induction of labour, caesarean section, and admission to neonatal intensive care unit. A further large retrospective cohort study using Scottish medical record databases identified similar outcomes among people living with obesity (n=25,173) compared with people living with a healthy weight (n=71,538) (Doi *et al.*, 2020). Results identified that people living with obesity had a greater chance of developing gestational diabetes, gestational hypertension and pre-eclampsia, macrosomia, induction of labour and caesarean section.

The 2023 MBRRACE report (Knight *et al.*, 2023), providing an overview of maternal deaths during 2019-2021 (inclusive) showed that 34% of the women who died during that triennium (n=82) had a BMI \geq 30 kg/m². This statistic shows an over-representation of people living with obesity among those who died due to either direct or indirect causes during pregnancy and up to a year after the birth of their child. In addition to these perinatal and neonatal complications, the offspring of people living

with obesity have a greater chance of longer-term health consequences. The mechanisms causing these metabolic changes in offspring are epigenetic and multifactorial (based on animal studies), but the consequences observed in humans have concerning public health implications in view of the increased chance of coronary heart disease, stroke, type 2 diabetes and asthma, in addition to BMI \geq 30 kg/m² and

some evidence of an increased chance of neurodevelopmental disorders (Godfrey *et al.*, 2017).

Obesity is not necessarily recognised as a health condition in itself; in the UK, the National Health Service (2023) describes it as a "health concern", whereas in the USA, the Centers for Disease Control and Prevention (2023b) describes it as a "chronic disease". In addition, the possibility that some people living with obesity have an eating disorder should not be overlooked (Bogaerts *et al.*, 2020). The evidence regarding the impact that obesity has on health during pregnancy and childbirth, and the impact that obesity has on future generations, however, provides the rationale for including it as a chronic health condition in this study.

Preconception advice and recommendations for people with living with obesity is essentially to lose weight (National Institute for Health and Care Excellence, 2010), and take a higher dose of folic acid, based on high-certainty evidence that this reduces the chance of neural tube defects and pregnancy terminations for fetal anomaly (Daly *et al.*, 2022a). Body weight, however, is a product of complex biopsychosocial components, and whilst people who desire to lose weight identified lack of knowledge, time constraints and affordability as being barriers to weight loss (Benton *et al.*, 2021), sustained weigh loss can take time and be difficult to achieve, even in a highly motivated population (Bogaerts *et al.*, 2020; Hanson *et al.*, 2017). Ongoing studies are therefore exploring innovative interventions, including a combination of eHealth and face-to-face coaching for people between pregnancies (Bogaerts *et al.*, 2017), and effective world-wide guidelines to address this growing public health epidemic are still required at both a population level (Ng *et al.*, 2014) and for people planning pregnancy (Devlieger *et al.*, 2016).

Increasing numbers of people considering pregnancy are finding bariatric surgery to be effective in terms of weight reduction, but nutrient deficiency after surgery can lead to concerning impacts on offspring, and people need specialised care regarding reproductive health following this surgery (Shawe *et al.*, 2019). There have also been advances in weight loss medication, which shows promise and is now available to some people living with obesity as part of a package of care (National Institute for Health and Care Excellence, 2023d). Preconception weight reduction is therefore challenging, and the question "what works, for whom, in what circumstances, and how?", is particularly pertinent for people seeking to lose weight in order to improve their preconception health.

2.2.5 Chronic kidney disease (0.79%)

Chronic kidney disease is defined as any structural or functional kidney damage resulting in loss of the ability to effectively clear waste products, lasting for more than three months (Bothamley and Boyle, 2020). Normal physiological changes due to pregnancy include increased kidney size, dilation of ureters, increased renal blood flow and glomerular filtration rate, increased protein excretion and increased potential for infection (Bothamley and Boyle, 2020). With these increased demands during pregnancy, the impact of pregnancy on already compromised kidney function and vice versa is therefore proportionate to individual disease severity.

A retrospective cohort study of 84 pregnant people with CKD in the Czech Republic (who delivered live born infants 2004-2019), demonstrated an increased chance of preterm birth and small for gestational age (SGA) infants among this group (Dvořák *et al.*, 2021). A larger Italian retrospective cohort study (n=508 births with CKD and

n=839 low-risk births in a comparison group) also identified that people with CKD had a greater chance of experiencing preterm birth and SGA infants, noting that the likelihood of adverse outcomes increased with increasing severity of CKD (classified as stages 1-5) (Piccoli *et al.*, 2015). People with severe kidney disease (stages 3-5) were identified as having a 98% birth rate, in a retrospective cohort study in the UK (participants with CKD n=159 2003-2017); of these 56% experienced preterm birth, with chronic hypertension being the strongest prediction of this (Wiles *et al.*, 2021); people also experienced a decline in renal function during pregnancy.

In addition to potential impacts of CKD on maternal and infant outcome, people with CKD may also be taking teratogenic medication, requiring review when planning pregnancy (Wiles *et al.*, 2015). Whilst pregnancy in people with stage 3-5 CKD may have been discouraged in the past, this is no longer the case, and preconception care is a welcomed intervention that provides support for people to make informed decisions based on individual assessment (He *et al.*, 2022; Wiles *et al.*, 2021; Wiles *et al.*, 2015). Knowing what works, for whom, in what circumstances, and how, is therefore important in this area, and will contribute to recommendations for service improvement.

2.2.6 Cystic fibrosis (0.02%)

Cystic fibrosis (CF) is an autosomal recessive disorder that affects transmembrane transport of chloride and sodium ions, resulting in respiratory, gastrointestinal and reproductive tract problems due to viscous secretions (Patel *et al.*, 2015). In the early 1990's, CF was viewed as a paediatric disease, with few people surviving into adulthood; this has changed with therapeutic advances over recent years, and some people with CF in countries with well-established CF care are living into their 60's (Burgel *et al.*, 2023). This has led to further challenges for adults with CF, including sexual and reproductive health issues and the possibility of pregnancy (Kazmerski *et al.*, 2018; Jain *et al.*, 2022).

Pregnancy outcomes, for people with CF, were analysed by Patel *et al.* (2015), using US hospital database records. Data showed a linear increase in the number of pregnancies achieved between 2000 and 2010, with 1119 pregnancies in people with CF during 2008-2010. Pregnant people with CF were more likely to have significant medical comorbidities (including diabetes mellitus), and an increased chance of morbidity and mortality during pregnancy and immediately afterwards, compared with people without CF (Patel *et al.*, 2015). A more recent literature review confirmed the increase in number of people with CF experiencing pregnancy, with many achieving good outcomes despite associated complexities requiring multidisciplinary support (Jain *et al.*, 2022).

Discussions regarding sexual and reproductive health, including pregnancy planning, should therefore be part of comprehensive multi-disciplinary CF health care (Kazmerski *et al.*, 2018). Pregnancy planning for people with CF involves health assessment, medication review, genetic counselling and informed decision making (Jain *et al.*, 2022). Access to preconception care is critical for this group, so identifying what works, for whom, in what circumstances, and how, is important.

2.2.7 Systemic lupus erythematosus (0.09%)

Systemic lupus erythematosus (SLE) is an autoimmune disease, characterised by the presence of a range of antibodies, affecting connective tissue. The condition mainly affects people assigned female at birth, of reproductive age (and lifelong), and can be unpredictable with periods of relapse (flares) involving profound fatigue, pain, and potential major organ damage (particularly kidneys) (Bothamley and Boyle, 2020). Treatment involves a range of medications, including immunosuppressants, anti-inflammatory drugs, and corticosteroids, some of which are not advised during pregnancy.

Pregnancy is thus only recommended during periods of remission, although deterioration during pregnancy is still possible, and people with SLE are more likely to experience complications during pregnancy compared with people without SLE. Complications include pre-eclampsia, preterm birth, small for gestational age infants, and intrauterine death (resulting in stillbirth) (Saulescu *et al.*, 2022; Kroese *et al.*, 2017). Pregnancy planning is therefore important, involving medication review and optimising health prior to conception to reduce the chance of adverse effects to either pregnant person or their offspring (Saulescu *et al.*, 2022).

Multi-disciplinary preconception care is recommended, with a low-flare rate during pregnancy attributed to close collaboration between rheumatologists and gynaecologists in a study conducted in the Netherlands by Kroese *et al.* (2017). In addition to careful pregnancy planning, opportunistic preconception care is recommended, and indeed welcomed by people newly diagnosed with SLE, who mostly felt it should be provided face-to-face from their rheumatologist (SLE

specialist), with some people deciding against pregnancy in view of potential complications (Blomjous *et al.*, 2021).

The importance of preconception care contributing to informed choice and optimal preconception health for people with SLE is therefore established; identifying what works, for whom, in what circumstances, will contribute to improvements in healthcare provision that will promote access to this support.

2.2.8 Mental health conditions (23.43%)

Mental health conditions are common among people of reproductive age, as reflected in studies by both Lee et al. (2022) and Schoenaker et al. (2023), based on the pregnant population (outlined in section 2.1). Physical health conditions are also more common among people with mental health conditions, as highlighted by Tosh et al. (2023). This study used data from "Tommy's" online pregnancy planning tool. "Tommy's" is a UK charity working to save babies' lives through information, support, research, and other activities; the pregnancy planning tool is a web-based public-facing free tool providing information and health improvement advice for people considering future pregnancy. The advice provided is based on people's responses to 26 questions regarding health and lifestyle; responses provided between 22nd June 2018 and 31st July 2019 (n=131,182 after duplications removed) were used in the study. Tosh et al. (2023) found that 17.8% of respondents reported a current or previous mental health condition, and 4.2% of respondents reported both a physical and mental health condition. Fewer people with a mental health condition (8.9%) had discussed pregnancy planning with a doctor or specialist compared with people with a physical health condition (41%), and even those who reported both a physical and mental

health condition, fewer reported having a preconception discussion regarding mental health (16.9%), compared with physical health (39.4%). Similar levels of access to preconception care (less than 50%) were identified by Ferry *et al.* (2023) in their scoping review of preconception care for people with diabetes (a physical health condition). These findings highlight the concern that fewer than half of people with physical health conditions access preconception care, and the greater concern that less than a one in ten people with mental health conditions access preconception care.

Mental health conditions range from severe mood disorders, such as bipolar disorder, which carries a high chance (1 in 5) of recurrence of severe postnatal illness requiring hospitalisation, to less sever conditions such as mild to moderate depression and anxiety, with lower but still significant potential for exacerbation during both pregnancy and the postnatal period (Howard and Khalifeh, 2020). People with mental health conditions also have a higher chance of experiencing additional preconception risk factors leading to suboptimal reproductive outcomes, including BMI \geq 30 kg/m², physical health conditions, medication use, addiction issues, domestic violence, increased levels of deprivation, poor diet and low levels of physical activity (Dennis *et al.*, 2022; Tosh *et al.*, 2023; Sūdžiūtė *et al.*, 2020; Knight *et al.*, 2023).

Pregnancy and neonatal outcomes for people with mental health conditions reflect the increased levels of preconception risk factors. A study using birth records from Lithuania compared outcomes from 131 people with mental health conditions (excluding twin pregnancies), with matched controls (n=228) (Sūdžiūtė *et al.*, 2020); this study found a higher chance of premature birth, stillbirth congenital abnormalities and low birth weight babies among people with mental health conditions. A similar matched controlled cohort study conducted in the UK among people with psychotic

disorders (199 cases and 787 controls, following birth in 1996-1998) showed an increased chance of stillbirth and neonatal death among cases (Howard *et al.*, 2003).

37% of people who died during pregnancy and up to a year after birth, during the triennium 2019–2021 (n=82), were known to have a mental health condition (Knight *et al.*, 2023), with suicide being the cause of death for 19% of those who died between six weeks and one year; suicide is thus the leading cause of death during this time period in the UK. Whilst direct causes of death during and up to a year following pregnancy have declined over recent decades, death due to psychiatric causes has not (Knight *et al.*, 2023), so continues to be an area for improvement.

Preconception care for people with mental health conditions should include opportunistic support and advice, such as consideration of pregnancy intention at the point of prescribing, in addition to medication review at any time a person discloses pregnancy planning (Howard *et al.*, 2014; Jones *et al.*, 2014; National Institute for Health and Care Excellence, 2020b). Anyone planning a pregnancy with a past or current severe mental health condition should be referred to specialist perinatal mental health service for preconception counselling (National Institute for Health and Care Excellence, 2020b). With evidence suggesting that fewer than 10% of people with mental health conditions access preconception care, however (Tosh *et al.*, 2023), this is not always achieved. Anecdotal evidence from my own experience suggests that people planning their first pregnancy may not seek preconception care, whereas a person who has experienced a severe perinatal mental health episode with effective support from a perinatal mental health service, will seek preconception care prior to subsequent pregnancies. Further exploration of what works, for whom, in what

circumstances, and how, is therefore appropriate for people with mental health conditions in order to identify how better to improve their preconception health.

2.3 Conclusion

In this chapter I have explored the prevalence of health conditions among people of reproductive age, providing further information relevant to conditions included as part of our study. The level of mental and physical health conditions among this population is significant, particularly in view of implications for health during pregnancy and health of future generations. Multimorbidity, involving both physical and mental health conditions, adds to the health complexity seen at an individual level (Lee *et al.*, 2022; Tosh *et al.*, 2023), providing compelling evidence of the need for preconception care.

Table 2 below provides a very broad overview of the types of preconception care that are recommended for each health condition explored in this chapter. This demonstrates similarities between health conditions, providing a rationale for including any health conditions in this study, rather than focusing on just one. This table particularly highlights similarities between mental and physical health conditions, with both requiring medication review, consideration of behaviour change and additional health checks. This is important in view of evidence suggesting that preconception care is less likely to be accessed for mental health conditions than for physical health conditions (Tosh *et al.*, 2023), despite the fact that mental health is a significant cause of death during and up to a year following childbirth (Knight *et al.*, 2023).

Condition	Types of preconception care that are recommended					
	Medication review, which may involve changes and/or dose optimisatio n	Achieving optimum preconceptio n health through behaviour change	5mg / day Folic Acid (requiring prescriptio n)	Additional health checks / assessme nt	All general PCC advice (diet, drugs, exercise, smoking, immunisatio n etc.)	
Diabetes (type 1 and 2)	 ✓ 	 ✓ 	 ✓ 	 ✓ 	 ✓ 	
Epilepsy	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	
Cardiac conditions and hypertension	\checkmark	\checkmark		 ✓ 	✓	
BMI ≥ 30 kg/m ²	\checkmark	\checkmark	\checkmark	\checkmark	 ✓ 	
Chronic kidney disease	V	\checkmark		 ✓ 	✓	
Cystic fibrosis	\checkmark	\checkmark		✓	\checkmark	
Systemic lupus erythematos us	\checkmark	\checkmark		V	~	
Mental health conditions	V	~		✓	✓	

Table 2. Types of preconception care that are recommended according to healthcondition

Another theme that is consistent across all health conditions, is the need to promote

informed choice through the provision of preconception care, and the recognition that

different individuals will make different choices, that may not be in line with healthcare recommendations (Blomjous *et al.*, 2021). This suggests that preconception care is a complex intervention involving people, society, culture, healthcare services, information, and other factors that are both part of what may be offered as well as outside of it on a personal or wider societal level.

The complex nature of preconception care for people with health conditions provides a rationale for the use of realist methodology in this study. Realist research is exploratory and may involve a range of methods in order to identify causal explanations of what works, for whom, in what circumstances, and how (Pawson and Tilley, 1997). Using a realist approach has enabled me to construct theories explaining why what is observed or experienced occurs, based on causal powers or processes, recognising how different contexts can lead to different outcomes given the same intervention.

Having provided a background to the subject matter of this study in this chapter, I will provide an overview of realist philosophy and methodology, which underpins this study, in the next chapter.

Chapter 3

Realism and Realist Research

In chapters one and two I outlined the complex situation regarding preconception care for people living with health conditions. Some people experience healthy pregnancies and families, either with or without support from healthcare professionals to improve their preconception health. Others may be unaware of the availability and/or benefit of preconception care, and some may find it difficult or even impossible to improve their preconception health for a variety of reasons. As outlined in chapter one, preconception care is offered in different forms, and each intervention is designed to meet a particular need or offer a particular resource that is deemed to be beneficial to the person concerned. There is, therefore, a theory underpinning each intervention of preconception care that is offered, even if that theory is not made explicit, and this evidently works for some people, works to some extent for others, and there may be another group for whom it may not work at all.

3.1 Rationale for using a realist approach

Realist research focuses on theory; uncovering theory, elaborating on theory, refining theory. This assists researchers in their efforts to identify causal explanations of what works for whom, in what circumstances, and how (Pawson and Tilley, 1997). Pawson and Tilley (1997), in their seminal book "Realistic Evaluation", describe social programmes as involving interaction between both the individual and an institution and including complexities of structure and agency. This reflects the situation involving preconception care; a range of programmes offered to people with particular

needs, experiences, perceptions and preferences, and range of situations that impact their ability to make choices; by health care services, which in the case of the UK are part of an extremely complex organisation known as the National Health Service (NHS).

I therefore identified that a realist approach was appropriate to explore what works for whom, in what circumstances and how, in relation to preconception care for people with health conditions. Realism, as opposed to empiricism, does not prioritise observable reality, but allows for the consideration of powers (or processes) that are unobservable; their presence can only be identified due to their effects, through a process referred to by realists as retroduction (Jagosh, 2020). This approach helped to capture the complexity if the situation outlined in chapters one and two without oversimplifying it and enabled me to engage with and consider preconception care at multiple levels (including individual and structural), to draw out elements that might be having relevant impact.

Philosophical differences exist between critical realism and scientific realism (Mukumbang, De Souza and Eastwood, 2023), stemming mainly from the differences between natural and social sciences, although Porter (2015) argues that they are not as different as some may claim. I have used the approach outlined by Pawson and Tilley (1997) in this study, which although stems from and has similarities with critical realism, is referred to as scientific realism (Jagosh, 2020). Critical and scientific realism diverge in their views regarding the role and nature of generative theory; this includes transitive (that which can be altered by human action) and intransitive (that which human action cannot change) dimensions of reality in critical realism, whereas theory is considered to capture the nature of reality (semantic notion) and be approximately

true of the world (epistemic notion) in scientific realism (Mukumbang, De Souza and Eastwood, 2023) (see Figure 3 below).

Scientific realism acknowledges that it is not possible to use an experimental approach, involving an intervention group and a control group, to explore complex social programmes, so evaluation of an open system (without any attempt to control confounding factors) is required to try and identify causal explanations of how and why a particular programme may or may not work. Using realist research has been a useful and appropriate lens through which to view and explore preconception care, uncover programme theories, and make recommendations to improve preconception health for people with existing health conditions based on identified programme theories that consider social systems (including healthcare systems) and individual choices (agency). Further exploration and explanation of realist philosophy and methodology is therefore briefly outlined below.

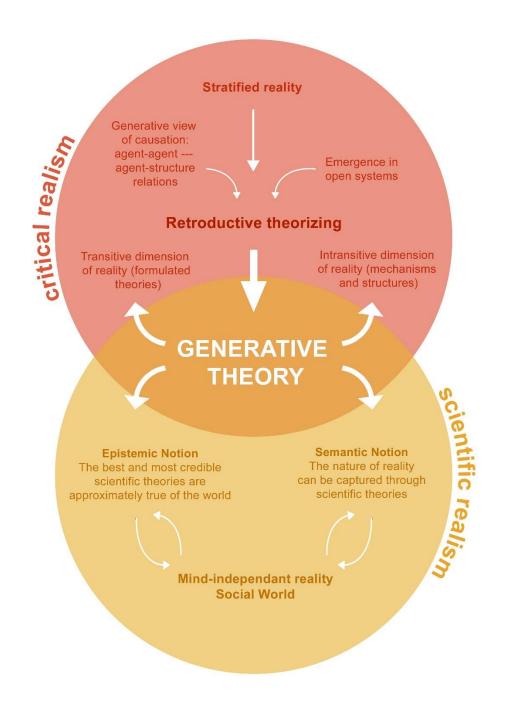


Figure 3. Contributions of the different realism tenants to retroductive theorising and the nature of generative theory.

Adapted from Mukumbang, DeSouza and Eastwood (2023)

3.2 Ontology and epistemology in realism

Ontology: how the world is and how it works, is of primary importance to the realist researcher (Bhaskar, 2016). The nature of reality, in critical realism, is described by Bhaskar (2016), as stratified. His stratification of reality consists of the empirical (which can be observed), the actual (which exists whether or not it is either material or has been experienced), and the real (this includes both of the above, plus causal factors that can have real effects / impact, known as mechanisms); Table 3 below illustrates this. Scientific realism draws on Bhaskar's stratification of reality (which is referred to by Pawson and Tilley (1997)), but often refers to mind-independent reality that includes observable and unobservable reality, rather than stratified reality that includes the empirical, the actual and the real (Mukumbang, De Souza and Eastwood, 2023).

	Empirical	Actual	Real
Experiences	\checkmark	\checkmark	\checkmark
Events		\checkmark	\checkmark
Mechanisms			\checkmark

Table 3. Domains of reality, adapted from Bhaskar (2016)

Realism acknowledges that the social world is continually evolving as people learn and change; for example, the historical changes regarding acceptable roles for individuals (e.g. women) within society, which have a direct impact on aspiration and achievement. Real things can therefore change, but in contrast with constructivist philosophy, can exist independently of an individual's knowledge or experience of them. Realist philosophy also accepts things that cannot be directly observed can nevertheless be real, in contrast with positivist philosophy (Bhaskar, 2016; Mukumbang, De Souza and Eastwood, 2023).

Epistemology; what we can know and how we can know it, is therefore more important for researchers using positivist and constructivist approaches (Bhaskar, 2016); indeed some realist researchers have suggested that epistemology and ontology are simply reflections of each other and therefore one, not two entities (Maxwell, 2012). Whilst there is logic in this approach, since what is real, according to the stratification of reality (Bhaskar, 2016), includes things that can be observed, things that can be experienced and things that have causal effect, it is also helpful for the researcher to define epistemology within realist research. Maxwell (2012) clearly states, in the preface to his book, that realist research uses a constructivist epistemology; meaning that our knowledge of the world is constructed and can never be entirely objective.

These philosophical positions provide the basis for realist methodology and provide a framework for the researcher in their search for underlying theory about what works, for whom, in what circumstances, and how.

3.3 Methodology

Realist research includes both realist reviews and realist evaluations, encompassing a multitude of methods, as appropriate. Realist research is exploratory in nature, requiring the construction of theories, including those explaining why what is observed or experienced (empirical and actual reality), occurs, based on causal powers or processes that are also real (mechanisms). Realist research also explores how

different contexts can lead to different outcomes following the same intervention. Thus, exploration of the observable and the unobservable is involved. The basic realist formula is: mechanism + context = outcome (Pawson and Tilley, 1997), as illustrated in Figure 4 below.

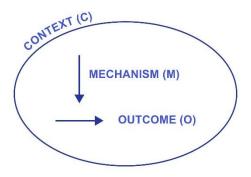


Figure 4. The basis of realist explanation

adapted from Pawson and Tilley (1997)

Key principles underpinning scientific realist methodology that reflect the ontological and epistemological positions outlined above include the following (Pawson and Tilley, 1997):

- a. Human activity is embedded within and inherently part of social reality,
 therefore assumptions, cultures and people involved will shape any programme
 or intervention (which is referred to in realist research as a programme)
- Underlying explanatory mechanisms in social interventions involve a combination of resources (what is offered by the intervention / programme) and reasoning (an individual's response)

- c. Programmes occur within existing social contexts, which contribute to the success or failure of a programme by enabling or disabling the underlying mechanism
- d. The purpose of realist inquiry is to explain outcomes (sometimes referred to as regularities), which are a result of mechanisms within particular contexts
- e. Change occurs over time; the challenge is to identify the underlying mechanisms that cause the change, triggered by a programme, and how they counteract existing social processes (that would otherwise prevent change)

Since mechanisms (b) and contexts (c) are important concepts in realist methodology, I have provided further explanation and analysis of these below.

3.3.1 Mechanisms

Mechanisms (in the realist sense) are causal processes or powers, they generate an outcome but operate at a different level within the system from the outcome; they therefore require different methods to identify or observe them (Westhorp, 2018). Since they have real causal effects, mechanisms themselves are real (Bhaskar, 2016); examples include self-esteem and understanding. Because mechanisms must be causal, a description of the components of the system, relationship between those components, and the interactions between them that result in the outcome, is required to fully define a mechanism (Westhorp, 2018) (why / how do self-esteem or understanding cause a behaviour change?). The important point here, is that consideration of mechanisms enables the researcher to move beyond a description of a situation, to an explanation of the situation (why something is the way it is) (Williams, 2018).

Mechanisms are generally hidden (you cannot see them), are complex, dynamic and are socially constructed; they are descriptions of reality, but due to being complex and dynamic, may not always be completely accurate, and may be over-simplistic. Despite and because of these challenges, realist researchers try to identify the important aspects about them (Williams, 2018).

Mechanisms can comprise of both resources and reasoning (Pawson and Tilley, 1997; Dalkin *et al.*, 2015) (information may enable understanding of the importance for change in an individual, for example), although Westhorp (2018) points out that whilst this works for theories that involve participant decision making, this may not be appropriate in all programmes. In some cases, mechanisms can also be powers and liabilities, forces, interactions and feedback or feedforward processes (Westhorp, 2018). Mechanisms may operate at different levels and over different timescales; either immediately or over time (possibly requiring repeated action) and are dependent on interactions between people or things (Westhorp, 2018). In the case of preconception care for people with health conditions, this involves an intervention or series of interventions over time, that require a response, reaction or behaviour change from an individual, thus the concept of mechanisms involving both resources and reasoning (sometimes referred to as responses) (Dalkin *et al.*, 2015) is appropriate, as it is likely to have causal effect.

Mechanisms can cause an effect, referred to as outcome, in one context but not in another (information may be provided, but an individual's context may prevent them from being able to make appropriate behaviour change). Mechanisms can also provide a context where a programme involves a number of steps or processes. What started as an outcome can then become a mechanism (for instance, understanding the

importance of preconception care may be the outcome of an early intervention, and then at the point of planning a pregnancy, that becomes the mechanism for seeking further preconception support). This illustrates the complexity and relational importance of components contributing to a particular programme; what realist researchers are looking for are causal explanations; how and why something occurs, or does not occur (Westhorp, 2018). Context is therefore important.

Since mechanisms cause an effect (outcome) in one context, but not another, Pawson and Tilley (1997) describe mechanisms as being triggered (or not) within a context. They use the gunpowder analogy, where gunpowder (the mechanism) causes and explosion (the outcome) only in the correct conditions (the context). Dalkin *et al.* (2015) provide an appropriate addition to this model, which is particularly relevant when human volition is an inextricable part of an intervention. Their "dimmer switch" analogy acknowledges a continuum of activation as opposed to a binary "all or nothing" approach. A continuum of activation (of a mechanism) is likely to be appropriate for some programme theories related to preconception care, particularly where trust or anxiety are involved (Dalkin *et al.*, 2015).

3.3.2 Context

Contexts can be social and cultural preferences or norms; such conditions can either enable or inhibit a causal mechanism (Pawson and Tilley, 1997). Since people with health conditions live within different cultures, levels of deprivation, beliefs and values, both within the UK and globally, the context in which preconception care is offered varies widely. In view of this, I would suggest that context provides a

significant and extremely challenging contribution to the success or failure of a preconception care programme.

The impact that context has on health is illustrated by Marmot *et al.* (2020); their work shows that people living in the UK have shorter life expectancy and fewer healthy years of life (disability free life expectancy) with increasing levels of deprivation. This social gradient demonstrates the close connection between health and the conditions in which people are born, live, work and grow old; the context of their lives. It also demonstrates inequalities in resources, money and power, which contribute to social determinants of health (Marmot *et al.*, 2020).

Bronfenbrenner's bioecological theory (Hayes, O'Toole and Halpenny, 2017) (see Figure 5 below) provides further insight into social determinants of health, exploring complex dynamic processes and interactions that influence children's lives. Bronfenbrenner's theory highlights the many influences that shape our lives, including the macrosystem (social and cultural beliefs and values), exosystem (factors influencing parental stress, for example), micro system (family, siblings and peers) within which children develop, and also the chronosystem (changes across time) (Hayes, O'Toole and Halpenny, 2017). Bronfenbrenner believed that these influences determine a child's behavioural disposition (including motivation and persistence), resource characteristics (including knowledge, skill and experience) and demand characteristics (including temperament, influencing reactions from others), all of which shape health behaviours and therefore directly impact health.

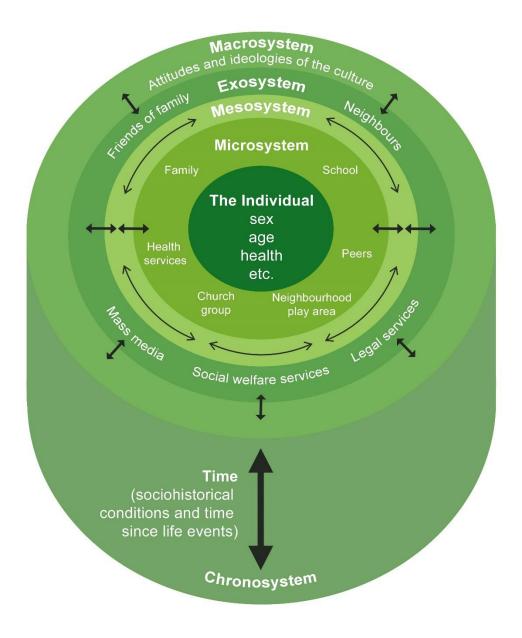


Figure 5. Brofenbrenners bioecological model of development

adapted from Hayes, O'Toole and Halpenny (2017, p15).

Returning to preconception health, it follows that health inequalities seen in wider society by Marmot *et al.* (2020) are reflected in the preconception population, and are determined throughout life, even from before their own birth (generational influences). This is evident in work by Schoenaker *et al.* (2023), which showed that people living in the most deprived areas in England, had the most indicators of suboptimal preconception health; this included smoking around conception, living with obesity, and having at least one health condition (both physical and mental health; in this case obesity was not considered a medical condition). Notably, a social gradient was evident with each indicator and each identified health condition (except for cancer, which may partly be due to age profile). This demonstrates not just a difference between the extremes of rich and poor, but the causal effects of deprivation through a clear picture of declining health between each quintile of deprivation, from least (quintile 5) to most (quintile 1).

Context is therefore highly significant. In some cases, where this involves systemic, structural, or macro contexts (as above), they cannot be changed by a programme of preconception care, but they need to be recognised and considered in programme design and delivery. In other cases, context may be more malleable; teaching about sexual and reproductive health at school, or language barriers, for instance (on more of a micro/meso level), can be changed if required. Due to the impact this may have, enabling better understanding of the rationale for optimal preconception health, for example, context is not just important, but an integral part of programme theory.

3.3.3 Programme theories

At this point it may be helpful to reiterate that realist research focuses on theory. The above factors contribute to an understanding of how programmes work, in what ways they work, and that is articulated through theory (how, why, for whom and to what extent something works or does not work). Identifying mechanisms and context in relation to outcomes of interest may involve observations, interviews, document review, literature review, and discussion of ideas (Marchal, Kegels and Van Belle, 2018). This results in initial programme theories (descriptions of how programmes *might* work, or not), which are the starting point for realist research; once initial programme theories have been identified, they can be tested and refined. In this study, I identified initial programme theories by undertaking a realist review of published and grey literature; I outline the methods involved in the next chapter. I then tested and refined the theories further using realist evaluation; I outline this in part 3 of this thesis.

Realists refer to different types of theory; I have therefore provided a brief explanation of some of these here (Rameses II Project, 2017b).

Formal (or substantive theory) – These theories are well established theories within a specific discipline, that have been tested over time and are often referred to by name. Examples include the health belief model, which has been used to develop interventions for adolescent women with type 1 diabetes, to influence their reproductive health behaviours (Charron-Prochownik *et al.,* 2001).

Initial programme theory – Realist researchers start by identifying initial programme theories, which may be based on stakeholder experience, beliefs,

documents, or literature. These descriptions and/or ideas about how a programme is thought to work (or not), may not initially include all the elements required in a realist explanation (context, mechanism and outcome), but the initial programme theories can be tested and refined to gain a more accurate insight into why something may or may not work, including identification of context, mechanism and outcome (Wong *et al.*, 2016).

Programme theory – Realist researchers develop, test, refine and programme theories. They should describe how they do this, for transparency, which may involve a range of methods. Since many programme theories may exist, researchers may focus on just one aspect of a programme (or intervention); the programme theories can be used to evaluate a project or inform future changes (Wong *et al.*, 2016).

Middle-range theory – This term is used for a theory that clearly explains reality and is at a level of abstraction between an initial programme theory and a formal theory. The term originates in sociology, where middle-range theories aligned closely with empirical reality, as opposed to intellectual speculation (Merton, 1949), and as such they can be tested. A middle-range theory may explain how and why an aspect of an intervention works, and may also apply across other interventions that are similar. Middle-range theories thus provide a level of abstraction that achieves a balance of application and relevance (Rameses II Project, 2017b; Westhorp, 2018).

3.4 Conclusion

In this chapter I have provided an overview of the underpinning philosophical position of realism, including ontological and epistemological principles that form the basis of realist research. This provides an understanding of the nature of realist research, which is not experimental, but uses a range of methods to unearth programme theories within open systems involving social structures and individual agency. In this study, the outcomes of interest are access to preconception care and support to achieve improved preconception health. I have explored the concepts of mechanism and context, providing an overview of the complex way in which these elements (within the C+M=O model) interact in preconception care and can be used to develop programme theories. Programme theories can provide the best and most credible explanation of the real world, and can therefore shed light on areas for improvement, involving both social structures and individuals' choices. In parts two and three of this thesis I will outline the realist review and realist evaluation I have undertaken; both use realist methodology and each part starts with an overview of methods used.

Part II

Realist Review

Chapter 4

Methods used in the Realist Review

Part two of this thesis concerns the realist review; in this chapter I will start by outlining and critically analysing the methods used in the realist review. Chapter five will provide an outline of the results, followed by a discussion of these in chapter six. Realist reviews are also sometimes referred to as realist syntheses; perhaps a more accurate description would be "realist review and synthesis" since the process involves both a review of literature and synthesis of extracted data (Rycroft-Malone *et al.*, 2012). A realist approach is appropriate since the aim is to provide an explanation of how something works (or doesn't work), rather than a judgement about effectiveness (Pawson *et al.*, 2005). Conventional systematic reviews seek to identify whether or not a particular intervention works, based on a synthesis of existing literature, but the problem with this approach is that the answer is often "sometimes" (Pawson, 2006). This is because an intervention might work on one context, but not another, which is why it is important to identify an explanation of how and why the intervention works.

The aim of a realist review is to review and synthesise existing literature to identify and test programme theory, by examining interactions between context, mechanism, and outcome (Rycroft-Malone *et al.*, 2012). This approach has been used effectively in the area of healthcare (Rycroft-Malone *et al.*, 2010), and is appropriate when exploring complex healthcare interventions, which involve social systems and individual agency (choice and behaviour).

4.1 Aims of the realist review

The aim of this review was

- To develop theory relating to contexts and mechanisms that are thought to explain how and why people with pre-existing health conditions
 - a. Seek and/or receive appropriate preconception care or advice, and
 - Engage in recommended behaviour change leading to improved preconception health
- 2. To identify types of preconception care that may be particularly beneficial and appropriate for different groups of people in different contexts

4.2 Literature searching

As with other realist reviews and in keeping with RAMESES guidelines (Rameses II Project, 2019), the review was conducted in two main phases: firstly, systematic searches led to the development of initial programme theories (from evidence related to preconception care) and secondly, targeted searches were conducted to test and refine these theories (using evidence from other interventions that share the same programme theories). As in other realist reviews, stakeholder involvement was embedded throughout this process (Husk *et al.*, 2020), with an international expert advisory group including health professionals, researchers, and people with lived experience, involved in each phase. Consultation was either face-to-face or by email.

4.3 Phase 1: Initial programme theory development

4.3.1 Electronic searches

The first phase of literature searching was comprehensive and aimed to capture all available relevant published literature. This aligned with the approach described by Rycroft-Malone *et al.* (2012), and was achievable within the resources available, in consultation with the expert advisory group. The first search was developed iteratively, with support from an information specialist, based on a known set of key articles. These key includable articles had been identified in an earlier targeted literature search; if they were not returned from a draft search strategy, it was amended until the team was satisfied with the search. The result was a "broad brush" approach that captured all types of preconception care. Terms included: preconception, peri-conception, pre-gestational, pre-pregnancy, and inter-conception (see appendix 1).

Databases searched were MEDLINE, Embase, PsycINFO, Cochrane Library, British Nursing Database and CINAHL. Included studies were those written in English and based in the Organization for Economic Co-operation and Development (OECD) countries (The Organization for Economic Cooperation and Development, 2021), to select those with similar approaches to healthcare and economic status. There were not an unmanageable number of studies and so no date limit was applied; the search was undertaken in August 2018. Search results were de-duplicated and saved using EndNote X8.

After further discussion with a member of the international expert advisory group, the term "family planning" was added; this was because preconception care was identified

as an element of what is referred to as family planning, in the United States of America (USA). This presented a challenge, since the initial systematic search of published literature was already complete at this stage, and family planning includes a much wider field of contraception advice and support, that we were not interested in. Following consultation with the core supervisory team, however, it was agreed that this search was appropriate and necessary. In this search, however, terms relating to specific health conditions were included (based on results from the initial database search), in conjunction with "family planning", to focus on preconception care for people with health conditions, and exclude many items solely related to contraception. The results of these two searches were then combined, and duplicates removed. This demonstrates one of the strengths of this review, which involved input from appropriate stakeholders and an iterative approach (Rycroft-Malone *et al.*, 2012).

4.3.2 Searching other sources

The review included multiple types of information and evidence, including guidelines and unpublished work; as part of phase 1 searches, a further approach involving supplementary searches was therefore undertaken to ensure relevant evidence was included (Cooper *et al.*, 2018). Strategies used included emailing authors of identified studies, conducting Google and Google Scholar searches, backwards and forward citation chasing, searching relevant United Kingdom websites (including relevant professional body websites, charity websites specific to a range of health conditions, and NICE guidelines), and the British Library EThOS online service.

The search for relevant evidence from such "grey literature" incorporated quality assessment, as I was looking for explanations of why an intervention might work,

during this more targeted search. All relevant evidence from these supplementary searches was therefore included in the review.

4.3.3 Screening to identify relevant evidence

Relevant evidence, from a variety of sources, contributed to theory building. Evidence was included when there were descriptions of who was receiving preconception care, under what circumstances, and what resources were on offer to them. This is important in a realist review, as data about context and mechanism, in relation to outcome, are required to identify programme theory (Wong *et al.*, 2013a).

Initial screening of titles and, where available, abstracts identified in the database searches, was conducted by two team members independently using the web-based citation management application Rayyan (Ouzzani *et al.*, 2016). Where these met the inclusion criteria, the full text was obtained and screened again by the same two team members. Any disagreements were resolved through discussion, and a third researcher was available but not needed.

4.3.4 Population inclusion criteria

The population inclusion criteria were people who had any type of self or clinicianidentified chronic physical or mental health condition, and who were seeking or receiving preconception care. This may have been part of routine primary or secondary care related to their condition, or specifically because they were considering planning a pregnancy. Some people in this group may have previously experienced

pregnancy, and some may have experienced pregnancy loss, complicated pregnancy, or neonatal loss. Evidence was not restricted by health condition.

4.3.5 Intervention inclusion and exclusion criteria

We included evidence concerning a range of preconception care packages aimed specifically at people with pre-existing health conditions. Some of these targeted anyone of reproductive age, and others were designed for people who were planning a pregnancy. Despite there being more evidence in the literature regarding preconception care for women (people assigned female at birth as opposed to male), our search included care offered to both sexes including care offered to same-sex couples. The following interventions were excluded: any aimed specifically at people experiencing fertility problems, seeking advice regarding contraception or delaying pregnancy, and any aimed at people seeking termination of pregnancy or prepregnancy genetic screening.

4.3.6 Types of study

As with other realist reviews (Wong *et al.*, 2013b), evidence that provided descriptions of preconception care using a broad variety of methods was included; both qualitative and quantitative studies as well as non-empirical studies. Since numerous studies were identified, these were prioritized based on relevance and rigor (Pearson *et al.*, 2015) (see below).

4.3.7 Outcomes

The outcomes relating to preconception care for people with health conditions included a) access to any experiences of preconception care, advice or support, and b) appropriate health behaviour change(s) dependent on the individual person's health condition(s) or circumstances. The outcomes for health care professionals included any awareness and involvement in preconception care. Including perspectives of people with health conditions and of healthcare providers offering preconception care provided a robust approach to capture as much relevant data as possible.

4.3.8 Quality assessment

In line with requirements for realist review, the quality of the data was based on relevance (to the programme theory; based on the above inclusion and exclusion criteria) and rigor (credibility and trustworthiness of the methods used) (Wong *et al.*, 2013b) using a hybrid tool classifying sources as "conceptually-rich, thick or thin" (Pearson *et al.*, 2013) (see Table 4 below). Papers identified as conceptually rich or thick were included in the review (see Table 5 in section 5.1). This enabled focus on stronger sources, such as systematic reviews or qualitative studies, without exclusion of relevant weaker ones, such as guidelines or opinion pieces.

Table 4. Criteria used for assessing richness of papers (adapted from Pearson et al.,2013)

Conceptually Rich	Conceptually Thick	Conceptually Thin
Includes clear and well	Includes clear description	Insufficient description of
described theoretical	of programme studied,	programme to identify
concepts contributing to	with	underpinning theoretical
programme theory,	sufficient detail to enable	concepts
including clear	some underpinning	
explanation of links	theoretical concepts to be	
between these	identified	
Context, mechanisms, and	Context and mechanisms	Unable to identify context
outcomes identifiable	not clearly described, but	or mechanisms
	some identifiable	
Concepts backed up by		
appropriate evidence,		
including cited literature		

The process of assessing data quality of papers identified through database searches, was undertaken after selection of included studies. As the main researcher I undertook this process initially, reading through the included papers to assess conceptual richness based on the above table. Where I was uncertain, I consulted my supervisory team, who were familiar with the requirements of the review. Relevance, rigor, and richness was re-assessed during data extraction, as we discussed and engaged with the data. This again, demonstrates the iterative nature of realist research (Rycroft-Malone *et al.*, 2012).

4.3.9 Data extraction

The realist approach of "engaging with" the data was used initially, rather than formal data extraction; this involved note-taking, annotation, conceptualization and revision based on team discussion and review of the data (Pearson *et al.*, 2015). This initially took place during face-to-face meetings, using paper to physically move data into different groups as key concepts were surfaced. NVivo 12 Pro (QSR International Pty Ltd., 2018) was also used to extract and group relevant data from the selected (conceptually rich and thick) papers; this provided an efficient and effective tool for data management and storage during the extraction, analysis, and synthesis process. Specifically, a variety of types of preconception care and factors (including both mechanisms and contexts) contributing to identified intended and un-intended outcomes were examined.

4.3.10 Synthesis

Iterative examination of the data by the team resulted in the identification of three broad areas that were found to contribute significantly to both access and behaviour change in relation to preconception care. Data relevant to each of these areas were grouped together and reviewed; recurring patterns were then identified. Further data examination led to the identification of prominent recurring patterns (demiregularities), which were explained using "if X – then Y" structured statements (Husk *et al.*, 2020).

These statements were iteratively refined through discussion and data review by the team together with input from the expert advisory group, resulting in 35 statements of

how preconception care works (initial programme theories – see Table 6 in section 5.2). Refinement of statements involved tools described in realist literature, in which synthesis is described as gaining a greater understanding of how and why an intervention works (Pawson, 2006; Wong *et al.*, 2013b). This involved discussion with members of the expert advisory group and identification of chains of inference (connections that can be made across articles based on themes identified), induction, deduction, and retroduction (Rycroft-Malone *et al.*, 2012; Rameses II Project, 2017a), to identify hidden causal forces behind observable patterns. Documentation of the reasoning processes used and applied during synthesis promoted transparency throughout the process (Wong *et al.*, 2013b).

Due to time and financial constraints, we were unable to refine all 35 statements further robustly and so undertook a web-based nominal group technique prioritisation (Murphy *et al.*, 1998; Husk *et al.*, 2020) with our expert advisory group, using a democratic process whereby all participants have an equal private vote and were asked to rank statements in order of preference for further investigation (see appendix 2 for extract from online survey). This resulted in 10 statements (initial programme theories) for further testing in phase 2 of the review.

4.4 Phase 2: Program theory testing and refinement

4.4.1 The search for empirical evidence to assess plausibility of initial program theories

An important element of a realist review is iterative testing and refinement of initial programme theory using empirical findings, drawing on any appropriate analytic

technique (Wong *et al.*, 2013a). Conducting a second phase of searches enabled this, leading to refinement of theories that can be classified as middle-range, through similar analysis and synthesis techniques as outlined above.

The second phase therefore started with 10 targeted searches, using search terms specific to each of the 10 initial programme theories identified for further investigation. Use of one large abstract and citation database, Scoups (Elsevier, 2021), enabled identification of relevant empirical evidence related to each program theory to assess plausibility; this was not intended to be an exhaustive systematic search. This effective approach was therefore described as purposive due to the use of specific programme theory-related terms and is often referred to as a "spear-fishing" approach (Pawson, 2006) (detail of search strategy available in appendix 3). During this phase I included both qualitative and quantitative studies; I included any primary studies, from any discipline (not necessarily related to preconception care), that provided apposite evidence on the theories that we had been identified in phase one and required testing and refining in phase two (see Table 8 in section 5.3). Evidence was again tested for relevance and rigor prior to data extraction and synthesis (Pawson, 2006), with conceptually rich papers contributing to the review.

4.4.2 Data extraction and synthesis

Data extraction in phase two of this review involved annotation of papers, collation of evidence aligned to the initial programme theories identified in phase one, using NVivo 12 Pro (QSR International Pty Ltd., 2018), and reportage, using extracts of evidence to identify the basis of inferences used for synthesis (Pawson, 2006). The data were used to clarify and explore contexts, mechanisms, and outcomes in order to test and refine

programme theory indicating causal explanations regarding how and why effective preconception care occurred, and thus contributed to the final synthesis stage. Synthesis followed the strategy outlined in phase one above, with the purpose of refining initial program theory developed during phase one in the light of evidence and analysis of findings from a broader range of empirical studies identified in phase two. This refinement of theory is referred to as abstraction, where the theory still provides an explanation of what is happening in a particular scenario but can also be applied more generically in other similar situations, such as among people with different health conditions; at this stage, the theory is often referred to as "middle-range theory" (Wong *et al.*, 2013b).

4.5 Conclusion

In this chapter I have outlined and analysed the methods used in the realist review. There are significant differences between traditional systematic review methods and realist review methods, including the two-phase process, the prioritization of descriptions of programme theory over traditional data, the assessment of those descriptions, and the inclusion of all types of evidence that incudes those programme descriptions. This makes a realist review a complex, time-consuming and humanresource intensive exercise (Rycroft-Malone *et al.*, 2012). The aim of a realist review, however, is to gain an explanation of how something works, not a judgement of its effectiveness, and that explanation is generally not simple due to the interaction of mechanisms and context and the involvement of social systems and individual agency. As stated by Rycroft-Malone *et al.* (2012), I found the process challenging due to the complexity involved and the need to think flexibly. I learnt to use realist principles and tools that suited me, the team, and the topic, rather than a prescribed approach, due to the specific nature and scope of the review. This review was very broad, covering any pre-existing health condition and any form of preconception care. This resulted in identification of a wide range of relevant literature that contributed to the review, but also enabled similarities to be identified between different health conditions, leading to relevant middle range theories. I will outline the results of the realist review in the next chapter (five), and then provide further discussion and conclusions in chapter six. The results from the realist review provide a framework for further analysis, and as such it is a useful and important starting phase for the realist evaluation, in which programme theories are further tested and refined. I will present the realist evaluation in part three of this thesis.

Chapter 5

Results from the Realist Review

In this chapter I will present the results of the realist review, using the methods outlined in the previous chapter, in line with RAMESES II reporting standards (Wong *et al.*, 2013a). The realist review was published and is in the public domain as an open-access article (Hopper *et al.*, 2023).

I will include a document flow diagram from the first phase of searching, document characteristics and main findings in the form of programme theories. The 35 identified initial programme theories will be outlined, of which 10 were selected by the expert advisory group as being of most interest. All 35 initial programme theories will be taken forward into the realist evaluation, involving primary research using qualitative interviews with stakeholders to gather data and further refine relevant theories; this will be outlined in part three of this thesis. In this chapter I will present relevant data contributing to the 10 refined middle-range programme theories identified through analysis and synthesis in the realist review following the second phase of searching. Further discussion regarding these theories and conclusions from the realist review will be presented in chapter six.

5.1 Search results from phase 1

After removal of duplicates, 2,873 unique citations were identified from the database search using the terms pre-conception, peri-conception, pre-gestational, pre-pregnancy, and inter-conception (see appendix 1). A further 288 citations were

identified from the literature search using terms relating to specific health conditions, in conjunction with "family planning", which was added after stakeholder consultation. The total number of citations identified in the first phase of database searching was therefore 3,161.

2,957 of these citations were excluded as they did not meet the inclusion criteria following screening of titles and abstracts by two reviewers. 196 papers from the database search were screened at full text, (by two reviewers), 71 were excluded as they did not meet the inclusion criteria, and 125 were included. Given the number of included studies and the aim of the review, in keeping with other realist reviews these were prioritised to identify those with conceptually rich and thick descriptions. This involved one reviewer assessing the 125 included paper for quality; specifically, relevance, richness, and rigour, in line with the realist approach (see chapter 4); 37 of these were identified as conceptually rich (n=4) or conceptually thick (n=33), and therefore included in the synthesis. Conceptually thin papers (n=36) were not included as they contained insufficient descriptions of the programmes involved and it was therefore not possible to identify underpinning theoretical concepts from these papers.

Thirty-seven papers from the database searches therefore contributed to the synthesis, alongside 15 additional citations from the grey literature searches, which had already been read in full (by one reviewer) and identified as including conceptually thick or rich descriptions; Figure 6 shows the progress and flow of sources through the review. Most evidence from the first phase searches related to people with Diabetes (type 1 and type 2). Other health conditions identified included obesity, epilepsy, HIV, hypertension, mental health conditions, chronic kidney disease, cystic fibrosis and

inflammatory bowel disease; Table 5 below details characteristics of documents from

first phase searches contributing to 35 initial programme theories.

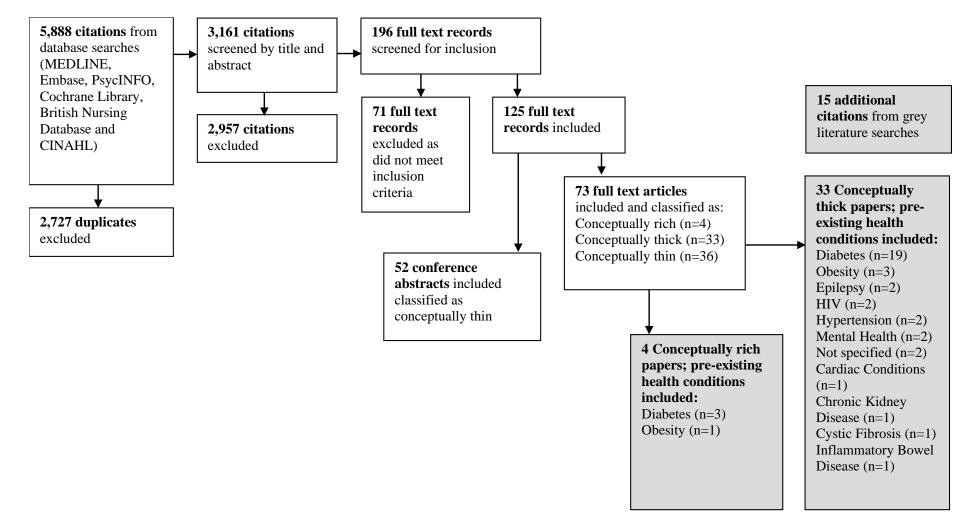


Figure 6. First phase searches: progress and flow of sources through the review

Table 5. Characteristics of documents from first phase searches contributing to initial programme theories

E

Database – conceptually rich papers				
Reference	Country	Type of Preconception care (PCC)	Study/paper type	Health condition
Doss, J. (2017). Reducing Pregnancy Risk by Motivation Overweight and Obese Women to Make Preconception Changes to Diet and Physical Activity Behavior: A Pilot Study. (PhD). Georgia State University. https://scholarworks.gsu.edu/nursing_diss/48	USA	Supporting behaviour change before pregnancy	Controlled	Obesity
Forde, R., Patelarou, E. E., & Forbes, A. (2016). The experiences of prepregnancy care for women with type 2 diabetes mellitus: a meta-synthesis. <i>International Journal of Women's Health, 8</i> , 691-703.	UK (range in review)	PCC for women planning pregnancy	Systematic review	Type 2 Diabetes
Komiti, A., Jackson, H. J., Nankervis, A., Conn, J., Allan, C., & Judd, F. (2014). Psychosocial influences on glycemic control in women with pre-existing diabetes preparing for pregnancy. <i>Canadian Journal of Diabetes, 38</i> (6), 439-443.	Australia	PCC for women planning pregnancy	Retrospective analysis – comparing women who had received PCC and those who had not	Type 1 and type 2 Diabetes
D'Higgins, S., McGuire, B. E., Mustafa, E., & Dunne, F. (2014). Barriers and facilitators to attending pre-pregnancy care services: the ATLANTIC-DIP experience. <i>Diabetic Medicine,</i> 31(3), 366-374	Ireland	PCC for women planning pregnancy	Qualitative	Type 1 and type 2 Diabetes

Database – conceptually thick papers					
Reference	Country	Type of Preconception care (PCC)	Study/paper type	Health condition	
Agricola, E., Pandolfi, E., Gonfiantini, M. V., Gesualdo, F., Romano, M., Carloni, E., Mastroiacovo, P. & Tozzi, A. E. (2014). A cohort study of a tailored web intervention for preconception care. <i>BMC Medical Informatics & Decision</i> <i>Making, 14</i> (33).	Italy	Web-based for women planning pregnancy	Cohort study – uncontrolled before and after	All	
Charron-Prochownik, D., Sereika, S. M., Becker, D., Jacober, S., Mansfield, J., White, N. H., Hughes, S., Dean-McElhinny, T. & Trail, L. (2001). Reproductive health beliefs and behaviors in teens with diabetes: application of the Expanded Health Belief Model. <i>Pediatric Diabetes</i> , <i>2</i> (1), 30-39.	USA	Opportunistic as part of routine care for medical condition	Controlled	Type 1 Diabetes	
AND Charron-Prochownik, D., Ferons-Hannan, M., Sereika, S. and Becker, D. (2008) Randomized efficacy trial of early preconception counseling for diabetic teens (READY-girls). <i>Diabetes Care</i> . 31(7) 1327-30.					
AND					
Charron-Prochownik, D., Sereika, S. M., Becker, D., White, N. H., Schmitt, P., Powell, A. B., 3rd, Diaz, A. M., Jones, J., Herman, W. H., Fischl, A. F., McEwen, L., DiNardo, M., Guo, F. & Downs, J. (2013). Long-term effects of the booster- enhanced READY-Girls preconception counseling program on					

intentions and behaviors for family planning in teens with diabetes. <i>Diabetes Care, 36</i> (12), 3870-3874.				
De Lima, A., Zelinkova, Z., Mulders, A. G. and Van der Woude, C. J. (2016) Preconception Care Reduces Relapse of Inflammatory Bowel Disease During Pregnancy. <i>Clinical</i> <i>Gastroenterology & Hepatology</i> 14(9) 1285-1292.	The Netherlan ds	PCC for women planning pregnancy	Controlled	IBD
Devido, J. (2015). Exploring the role of the parish nurse in providing diabetes education and preconception counseling to African American women using a community-engaged mixed methods approach. <i>Dissertation Abstracts International:</i> <i>Section B: The Sciences and Engineering, 76</i> (1)	USA	Opportunistic PCC & for women planning pregnancy	Qualitative	Type 1 and type 2 Diabetes
Earle, S., Tariq, A., Komaromy, C., Lloyd, C. E., Karamat, M. A., Webb, J., & Gill, P. S. (2017). Preconception care for women with type 1 or type 2 diabetes mellitus: a mixed-methods study exploring uptake of preconception care. <i>Health</i> <i>Technology Assessment (Winchester, England), 21</i> (14), 1-130.	UK (range in review)	Opportunistic PCC & for women planning pregnancy	Systematic review	Type 1 and type 2 Diabetes
Echenique, M., Bookman, R. S., Rodriguez, V. J., LaCabe, R. P., Potter, J. E., & Jones, D. L. (2017). HIV is always with me: men living with perinatally acquired HIV and planning their families. <i>Open Access Journal of Contraception, 8</i> , 35-43.	USA	Sexual and Reproductive Health (SRH) including PCC for men	Qualitative	HIV
Fischl, A. F., Herman, W. H., Sereika, S. M., Hannan, M., Becker, D., Mansfield, M. J., Freytag, L. L., Milaszewski, K., Botscheller, A. N. & Charron-Prochownik, D. (2010). Impact of a preconception counseling program for teens with type 1	USA	Opportunistic as part of routine care for medical condition	Controlled	Type 1 Diabetes

diabetes (READY-Girls) on patient-provider interaction, resource utilization, and cost. <i>Diabetes Care</i> , <i>33</i> (4), 701-705.				
Frieder, A. (2010). Preconception counseling for women with schizophrenia. <i>Current Women's Health Reviews, 6</i> (1), 12-16.	USA	Proactive SRH care, including PCC, and advice as part of routine care	Opinion	Schizophrenia
Grady, C. M., & Geller, P. A. (2016). Effects of Self-Efficacy and Locus of Control on Future Preconception Counseling Plans of Adult Women With Type 1 Diabetes. <i>Diabetes Spectrum</i> , <i>29</i> (1), 37-43.	USA	SRH and PCC as part of routine care	Survey	Type 1 Diabetes
Holmes, V. A., Spence, M., McCance, D. R., Patterson, C. C., Harper, R., & Alderdice, F. A. (2012). Evaluation of a DVD for women with diabetes: impact on knowledge and attitudes to preconception care. <i>Diabetic Medicine, 29</i> (7), 950-956.	UK	SRH and PCC as part of routine care – via DVD	Uncontrolled before and after	Type 1 and type 2 Diabetes
Holmes, V. A., Hamill, L. L., Alderdice, F. A., Spence, M., Harper, R., Patterson, C. C., Loughridge, S., McKenna, S., Gough, A., & McCance, D. R. (2017). Effect of implementation of a preconception counselling resource for women with diabetes: A population based study. <i>Primary care diabetes</i> , <i>11</i> (1), 37-45.	UK	SRH and PCC as part of routine care – via DVD	Controlled	Type 1 and type 2 Diabetes
Janz, N. K Herman, W. H., Becker, M. P., Charron- Prochownik, D., Shayna, V. L., Lesnick, T. G., Jacober, S. J., Fachnie, J. D., Kruger, D. F. and	USA	PCC for women planning pregnancy	Controlled	Type 1 Diabetes

Sanfield, J. A. (1995) Diabetes and pregnancy. Factors associated with seeking pre-conception care. <i>Diabetes Care</i> . 18(2) 157-65.				
Kazmerski, T. M., Gmelin, T., Slocum, B., Borrero, S., & Miller, E. (2017). Attitudes and Decision Making Related to Pregnancy Among Young Women with Cystic Fibrosis. <i>Maternal & Child</i> <i>Health Journal, 21</i> (4), 818-824.	USA	SRH and PCC as part of routine care	Qualitative	CF
Klein, J., Boyle, J. A., Kirkham, R., Connors, C., Whitbread, C., Oats, J., Barzi, F., McIntyre, D., Lee, I., Luey, M., Shaw, J., Brown, A. D. H. & Maple-Brown, L. J. (2017). Preconception care for women with type 2 diabetes mellitus: A mixed- methods study of provider knowledge and practice. <i>Diabetes</i> <i>Research & Clinical Practice</i> , <i>129</i> , 105-115.	Australia	Opportunistic as part of routine care for medical condition	Mixed methods	Type 2 Diabetes
Komiti, A., Jackson, H. J., Nankervis, A., Conn, J., Allan, C., & Judd, F. (2014). Psychosocial influences on glycemic control in women with pre-existing diabetes preparing for pregnancy. <i>Canadian Journal of Diabetes, 38</i> (6), 439-443.	Australia	PCC for women planning pregnancy	Cross-sectional study / Evaluation	Type 1 and type 2 Diabetes
Lawther, L., Dolk, H., Sinclair, M., & Morrow, J. (2018). The preconception care experiences of women with epilepsy on sodium valproate. <i>Seizure, 59</i> , 82-89.	UK	PCC for women planning pregnancy	Qualitative	Epilepsy
Lopez, K. N., Karlsten, M., Bonaduce De Nigris, F., King, J., Salciccioli, K., Jiang, A., Marelli, A., Kovacs, A. H., Fordis, M. & Thompson, D. (2015). Understanding Age-based Transition Needs: Perspectives from Adolescents and Adults with Congenital Heart Disease. <i>Congenit Heart Dis, 10</i> (6), 561-571.	Canada	SRH and PCC as part of routine care for medical condition	Qualitative	Congenital Heart Disease

McCorry, N. K., Hughes, C., Spence, D., Holmes, V. A., & Harper, R. (2012). Pregnancy planning and diabetes: a qualitative exploration of women's attitudes toward preconception care. <i>Journal of Midwifery & Women's Health</i> , <i>57</i> (4), 396-402.	UK	Any type of PCC	Qualitative	Type 1 Diabetes
Mittal, P., Dandekar, A., & Hessler, D. (2014). Use of a modified reproductive life plan to improve awareness of preconception health in women with chronic disease. <i>Permanente Journal, 18</i> (2), 28-32.	USA	Reproductive life plan counselling	Uncontrolled before and after	Diabetes (type not specified) / hypertension / obesity
Mortagy, I., Kielmann, K., Baldeweg, S. E., Modder, J., & Pierce, M. B. (2010). Integrating preconception care for women with diabetes into primary care: a qualitative study. <i>British Journal of General Practice, 60</i> (580), 815-821.	UK	PCC in primary care	Qualitative	Type 1 and type 2 Diabetes
Murphy, H. R., Temple, R. C., Ball, V. E., Roland, J. M., Steel, S., Zill. E., Huma, R., Simmons, D., Royce, L. R. & Skinner, T. C., on behalf of the East Anglia Study group for Improving Pregnancy Outcomes in women with Diabetes. (2010). Personal experiences of women with diabetes who do not attend pre- pregnancy care. <i>Diabetic Medicine</i> , <i>27</i> (1), 92-100.	UK	PCC prior to pregnancy	Qualitative	Type 1 and type 2 Diabetes
Nguyen, T., Brooks, J., Frayne, J., Watt, F., & Fisher, J. (2015). The preconception needs of women with severe mental illness: a consecutive clinical case series. <i>Journal of</i> <i>Psychosomatic Obstetrics & Gynecology, 36</i> (3), 87-93.	Australia	PCC for women planning pregnancy	Qualitative	Women with severe mental illness
Pashley, S., & O'Donoghue, M. F. (2009). The safety of anti- epileptic drug regimens: a qualitative study of factors	UK	Any type of PCC	Qualitative	Epilepsy

determining the success of counselling women before conception. <i>Journal of Family Planning & Reproductive Health</i> <i>Care, 35</i> (3), 153-156.				
Poels, M., Koster, M. P., Boeije, H. R., Franx, A., & van Stel, H. F. (2016). Why Do Women Not Use Preconception Care? A Systematic Review On Barriers And Facilitators. <i>Obstetrical &</i> <i>Gynecological Survey, 71</i> (10), 603-612.	The Netherlan ds (range in review)	PCC prior to pregnancy	Systematic review	Type 1 and type 2 Diabetes
Schwarz, E. B., Santucci, A., Borrero, S., Akers, A. Y., Nikolajski, C. andGold, M. A. (2009) Perspectives of primary care clinicians on teratogenic risk counselling. <i>Birth Defects</i> <i>Research</i> . 85(10) 858-63.	USA	Proactive SRH and PCC in view of medication	Qualitative	Any requiring teratogenic medication
Shannon, G. D., Alberg, C., Nacul, L., & Pashayan, N. (2014). Preconception healthcare delivery at a population level: construction of public health models of preconception care. <i>Maternal & Child Health Journal, 18</i> (6), 1512-1531.	UK (range in review)	Any type of PCC	Systematic review	Any
Simone, J., Hoyt, M. J., Storm, D. S., & Finocchario-Kessler, S. (2018). Models of HIV Preconception Care and Key Elements Influencing These Services: Findings from Healthcare Providers in Seven US Cities. <i>AIDS Patient Care & Stds</i> , <i>32</i> (7), 272-281.	USA	Any type of PCC	Qualitative	HIV
Spence, M., Alderdice, F. A., Harper, R., McCance, D. R., & Holmes, V. A. (2010). An exploration of knowledge and attitudes related to pre-pregnancy care in women with diabetes. <i>Diabetic Medicine</i> , <i>27</i> (12), 1385-1391.	UK	Any type of PCC	Qualitative	Type 1 and type 2 Diabetes

Reference	Country	Type of Preconception care	Study/paper type	Health condition
Grey literature			·	·
Wiles, K. S., Bramham, K., Vais, A., Harding, K. R., Chowdhury, P., Taylor, C. J., & Nelson-Piercy, C. (2015). Pre-pregnancy counselling for women with chronic kidney disease: a retrospective analysis of nine years' experience. <i>BMC</i> <i>Nephrology</i> , <i>16</i> , 28.	UK	PCC for women planning pregnancy	Service evaluation	Kidney Disease
Steel, A., Lucke, J., & Adams, J. (2015). The prevalence and nature of the use of preconception services by women with chronic health conditions: an integrative review. <i>BMC</i> <i>Women's Health</i> , <i>15</i> , 14.	Australia (range in review)	Any type of PCC	Systematic review	Any
Spence, M., Harper, R., McCance, D. R., Alderdice, F. A., McKinley, M. C., Hughes, C., & Holmes, V. A. (2013). The systematic development of an innovative DVD to raise awareness of preconception care. <i>European Diabetes Nursing</i> , <i>10</i> (1), 7-12b.	UK	DVD	Qualitative	Type 1 and type 2 Diabetes

Reference	Country	Type of Preconception care (PCC)	Study/paper type	Health condition
Barker, M., Baird, J., Lawrence, W., Vogel, C., Strommer, S., Rose, T., Inskip, H., Godfrey, K. & Cooper, C. (2016). Preconception and pregnancy: opportunities to intervene to improve women's diets and lifestyles. <i>Journal of</i> <i>Developmental Origins of Health and Disease, 1</i> (4).	UK	Digital/Healthy conversations to promote behaviour change	Opinion	Obesity
Brennand, J., Northridge, R., Scott, H., Walker, N., (2016) Addressing the Heart of the Issue. Good clinical practice in the	UK	Opportunistic PCC as part of primary and secondary care	Other - guideline	Cardiac

shared obstetric and cardiology care of women of childbearing age. Royal College of Physicians and Surgeons of Glasgow.				
North West of England Adult Congenital Heart Disease Strategic Board, (2012) Cardiac Disease in Pregnancy. Regional clinical guidance and referral protocol for the management of congenital and acquired cardiac disease from preconception to the postnatal period.	UK	Proactive SRH care, including PCC, and advice as part of secondary care	Other - guideline	Cardiac
NICE (2015). Diabetes in pregnancy: management from preconception to the postnatal period. National Institute for Health and Care Excellence guideline [NG3]. https://www.nice.org.uk/guidance/ng3	UK	Proactive SRH care, including PCC, and advice as part of primary and secondary care	Other - guideline	Type 1 and type 2 Diabetes
National Institute for Health and Clinical Excellence. (2012) The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care. NICE clinical guideline 137. London: NICE; 2012.	UK	Proactive SRH care, including PCC, and advice as part of primary and secondary care	Other - guideline	Epilepsy
Royal College of Obstetricians and Gynaecologists, (2011) <i>Cardiac Disease and Pregnancy</i> . Good Practice No 13.	UK	Proactive SRH care, including PCC, and advice as part of secondary care	Other - guideline	Cardiac
Health Education England, (2017). Perinatal Mental Health Competency Framework. https://perinatalcompetency.e- lfh.org.uk/	UK	Any - principles	Other – competency framework	Mental Health
Lawther, L. (2016) <i>The Preconception Care Experiences of Women with Epilepsy: a qualitative study.</i> PhD Thesis. Ulster University.	UK	PCC clinic for women planning pregnancy with specialist nurse	Qualitative	Epilepsy

Public Health England, (2018). Making the Case for Preconception Care. Planning and preparation for pregnancy to improve maternal and child heath outcomes. https://assets.publishing.service.gov.uk/government/uploads /system/uploads/attachment_data/file/729018/Making_the_ case_for_preconception_care.pdf	UK	All	Other - PHE recommendations	All
Knight, M., Nair, M., Tuffnell, D., Shakespeare, J., Kenyon, S., & Kurinczuk, J. J. E. (2017). Saving Lives, Improving Mothers' Care. Lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2013–15. https://www.npeu.ox.ac.uk/mbrrace- uk/reports	UK	Opportunistic PCC as part of primary and secondary care	Other – Audit and recommendations	All
Unpublished conversation with Specialist diabetes nurse, 2019	UK	PCC clinic for women planning pregnancy with specialist nurse	Other – opinion	Type 1 and type 2 Diabetes
King, P. (2019) PROCEED Preconception Care for Diabetes in Derby / Derbyshire. A "teams without walls" approach to preconception care. (paper and poster)	UK	Integrated PCC clinic for women planning pregnancy	Other – service improvement project	Diabetes (type not specified)
Royal College of Obstetricians and Gynaecologists, (2016) <i>Epilepsy in Pregnancy</i> . Green-top Guideline No. 68.	UK	PCC for women planning pregnancy	Other - guideline	Epilepsy
Winterbottom, J. (2012). <i>Women with Epilepsy Preparing for</i> <i>Pregnancy: A qualitative Analysis</i> . (PhD). University of Liverpool,	UK	PCC for women planning pregnancy	Qualitative	Epilepsy

5.2 Thirty-five initial programme theories identified

Thirty-five "if, then" statements were identified as initial programme theories from iterative data analysis and synthesis following phase 1 searches (as outlined in section 4.3.10 in chapter four). These are listed in full below, in Table 6. These 35 statements were divided into three broad areas that were found to contribute significantly to if and how access to preconception care and behaviour change prior to pregnancy takes place, for people with chronic health conditions. These three areas: the intervention (including provider characteristics, content and delivery mechanisms), people's beliefs (including perceptions of self, perceptions of support and perceptions of pregnancy planning) and the process (including guidelines and pathways, and accessibility of services), are interconnected, as illustrated in Figure 7.

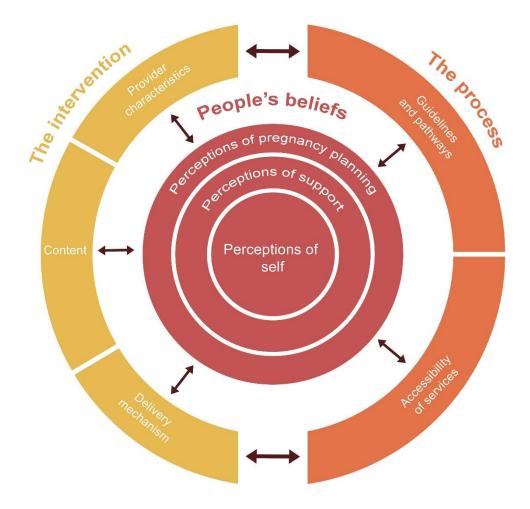


Figure 7. Subdivisions and connections between the three areas that were found to contribute significantly to both access and behaviour change in relation to preconception care

Table 6. Initial programme theories identified from phase 1 of the realist review

	Theories about the intervention			
Provider	1	IF HCPs have appropriate knowledge and skills regarding SRH / PCC in relation to health	Survey question 1:	
Characteristics		conditions THEN they will include appropriate SRH advice and recommend PCC to the people	ranked 5th	
		in their care		
	2	IF HCPs have a positive, non-judgemental, respectful attitude towards people THEN people	Survey question 1:	
		are more likely to trust HCPs and feel empowered and supported to make informed and	ranked joint 2nd	
		appropriate choices / behaviour change		
	3	IF there is continuity of carer, and this experience is positive THEN people are more likely to	Survey question 1:	
		trust their HCP and feel empowered and supported to make appropriate choices / behaviour	ranked 1st	
		change		
	4	IF people have been attending clinics since childhood (due to their condition) THEN they may	Survey question 1:	
		view HCP's as parental figures with whom they feel uncomfortable / consider it	ranked 6th	
		inappropriate discussing sexual practices		

Dellisser	-	IF the intervention is delivered in a DVD (Mak beaud / makile platforms TUEN) seconds who	Commence and a string 1.			
Delivery	5	IF the intervention is delivered via a DVD/ Web based / mobile platform THEN people who	Survey question 1:			
mechanism	echanism feel anxious or unable to discuss issues related to SRH with others for social / cultural / othe					
	reasons will be able to access information regarding PCC and are less likely to perceive the					
	information as including any human assumptions or value judgements					
	6	IF the intervention provides an app for monitoring a condition / progress whilst planning (i.e.	Survey question 1:			
		prior to) a pregnancy THEN people are more likely to monitor their behaviour change and be	ranked 4th			
		encouraged or act on this information to sustain behaviour change prior to pregnancy				
Content	7	IF people have access to accurate information about pregnancy risks and benefits of	Survey question 2:			
		behaviour change that increase their perceived personal threat to themselves and their	ranked 8th			
		unborn child THEN they are more inclined to make appropriate behaviour changes due to a				
		shift in "decisional balance" and motivation				
	8	IF PCC is considered as part of a broader SRH continuum in relation to a person's medical	Survey question 2:			
		condition THEN relevant aspects of SRH on the continuum of contraception / pregnancy	ranked 3rd			
		planning are likely to be discussed and they are more likely to seek / be receptive to PCC				
	9	IF people are specifically asked "do you want a baby in the next 12 months?" (Rather than	Survey question 2:			
		"are you planning a pregnancy?) at each annual check-up THEN pregnancy intention is easier	ranked joint 6th			

	to assess, and appropriate support and advice based on response (yes / no / don't know) can be given	
10	IF interventions focus on and promote improvements in self-efficacy rather than self-blame THEN people are more likely to develop a positive relationship with their HCP and perceive PCC as positive and beneficial	Survey question 2: ranked 4th
11	IF people have support from their partners / family THEN they are more likely to seek / be receptive to PCC and adopt appropriate behaviour to optimise pregnancy	Survey question 2: ranked 9th
12	IF peer support networks are available THEN people are more likely to feel emotionally / socially supported and will be more inclined to engage with the medical advice and support they are offered	Survey question 2: ranked 1st
13	IF psychological counselling and support is available as part of PCC, if required, THEN people are more likely to be able to engage in PCC and appropriate behaviour change	Survey question 2: ranked 2nd
14	IF people have multiple health issues THEN they will need greater strategies for limiting loss to follow-up and maintaining engagement in behaviour change	Survey question 2: ranked 5th

	15	Survey question 2: ranked 6th	
		change	
		Theories about people's beliefs	
Perceptions of	16	If people are resilient, motivated, resourceful and able to implement evidence-based tools	Survey question 3:
self		and techniques for behaviour change THEN they will be likely to seek PCC when planning a	ranked 3rd
		pregnancy and are more likely to adopt appropriate behaviour change	
	17	IF people feel unable to maintain control or are labelled as "high risk" in terms of pregnancy	Survey question 3:
		THEN they may not engage in PCC since they may wish to avoid additional knowledge in	ranked joint 7th
		order to avoid anxiety	
	18	IF people are anxious / fearful / guilty about reproductive capacity and risks for self and baby	Survey question 3:
		THEN they may not engage in PCC since they may wish to avoid additional knowledge in	ranked joint 9th
		order to avoid increased anxiety	
	19	IF people feel respected, regarding their personal / cultural / religious beliefs and that any	Survey question 3:
		difficulties they may experience whilst making changes in preparation for pregnancy are	ranked joint 4th

Perceptions of		recognised / acknowledged THEN they are more likely to trust their HCP and are more likely	
support		to seek / be receptive to PCC and adopt appropriate behaviour change	
	20	IF people feel judged / stigmatised / looked down on / criticised etc by their HCP they are	Survey question 3:
		more likely to feel scared and pressurised and may actively avoid PCC	ranked joint 9th
	21	IF people perceive PCC as normal THEN they are more likely to seek / be receptive to PCC	Survey question 3:
		and adopt appropriate behaviour to optimise pregnancy	ranked 1st
Perceptions of	22	IF people believe that their medical condition reduces fertility and/or their use of	Survey question 3:
pregnancy		contraception is suboptimal THEN they have a greater chance of unplanned pregnancies	ranked 2nd
planning	23	IF people are ambivalent towards pregnancy (believe "it just happens") or their social and	Survey question 3:
		cultural norms include an expectation of pregnancy THEN they have a greater chance of	ranked 6th
		unplanned pregnancies and may lack time to optimise health before pregnancy	
	24	IF there is a shared understanding (between people and clinicians) of what is meant by	Survey question 3:
		"planning a pregnancy" THEN people are more likely to prepare for pregnancy in advance of	ranked joint 4th
		trying to conceive	

	25	IF a person's cultural / religious / personal beliefs prevent them discussing SRH / PCC with	Survey question 3:			
		their HCP (eg it would be inappropriate, or it is considered a private issue) THEN they may	ranked joint 7th			
	not be receptive to the PCC that is offered (eg gender issues)					
	<u> </u>	Theories about the process				
Guidelines	26	IF discussions about issues around SRH (including PCC), in view of a person's health	Survey question 4:			
and pathways		condition, are a routine part of on-going care THEN they are more likely to seek / access PCC	ranked 1st			
		having received "cues to action"				
	27	IF provision is integrated across specialities and across both primary and secondary care	Survey question 4:			
		THEN a shared vision for pre-conception care will result in consistently better provision of	ranked 2nd			
		PCC				
	28	IF a multidisciplinary model of PCC is used (a number of HCP's involved in each consultation)	Survey question 4:			
		THEN this promotes autonomy and provides an immediate resource of expertise ("one stop	ranked 5th			
		shop")				
	29	IF pre-conception clinics are led by a specialist nurse, midwife or dietitian THEN the	Survey question 4:			
		consultant physician can provide an overview of the service and clinical mentorship to	ranked 3rd			
		promote an efficient and consistent PCC service				

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	30	IF clear guidelines and protocols for PCC for people with pre-existing health conditions are	Survey question 4:
		available for HCPs to follow THEN HCPs are more likely to offer PCC to these people	ranked equal 6th
	31	IF HCPs in primary care are prompted to discuss SRH by the system/pathways/protocols they	Survey question 4:
		use THEN they are more likely to include discussions around PCC in routine appointments	ranked 9th
	32	IF GP's are incentivised (not financially penalised) to provide PCC to people with pre-existing	Survey question 4:
		health conditions THEN HCPs are more likely to offer PCC to these people	ranked 8th
Accessibility	33	IF people have socio-economic factors such as now income, needing to take time off work,	Survey question 4:
of services		needing to pay for transport to or parking at appointments, needing childcare etc. THEN	ranked equal 6th
		they may find it difficult to attend appointments and may not access PCC	
	34	IF flexibility and variety / choice of opportunity (time and location) to access PCC is available	Survey question 4:
		THEN there will be more opportunity for people to access PCC at a place or time they feel	ranked 4th
		comfortable with	
	35	IF translation / interpreters are not available at appointments for people who do not speak	Survey question 4:
		English THEN they may not be aware of the need for, or be able to access PCC	ranked 10th

5.3 Search results from phase 2

Phase 2 targeted searches focused on the ten statements (initial programme theories) that had been prioritised by the expert advisory group, as outlined in section 4.3.10 (see chapter four) (for ranking see Table 6 above). Ten targeted searches were undertaken to demonstrate plausibility of the programme theories from the existing literature (search terms included in appendix 3), resulting in a total of 4,228 hits, with 38 contributing to context, mechanism, outcome (CMO) configurations. Table 7 below provides the number of search results related to each of the ten prioritised statements.

Table 7. Phase 2 targeted searches

The Intervention:		Hits (SCOPUS)	Included			
Provider	Continuity of Carer	731	5			
characteristics and delivery mechanism	Respectful attitude	77	5			
	Web-based	220	4			
The Intervention:		Hits (SCOPUS)	Included			
Content	Preconception care part of broader Sexual and Reproductive Health	61	4			
	Peer support	661	6			
	Psychological counseling	361	4			
People's beliefs		Hits (SCOPUS)	Included			
Perceptions of	Perceived as normal	83	2			
pregnancy planning	Health beliefs	212	2			
The Process		Hits (SCOPUS)	Included			
Guidelines and	Part of routine care	43	3			
pathways	Integrated services	1,779	3			
38 papers contributing to CMO configurations						

Table 8 below shows characteristics of each of the papers included following phase 2 searching. Data extracted from these papers contributed to further analysis and synthesis, resulting in refinement of the ten prioritised theories (see section 4.4.2).

Continuity of Carer Author / Country Aim / objective(s) Methodology Participants date / studies reviewed Barker et UK To assess whether Cross sectional 230,472 al, 2017 continuity of carer study patients with a general aged 62-82 practitioner is associated with hospital admissions for ambulatory care sensitive conditions for older patients McLachlan Australia To determine Randomised 2314 et al, 2012 whether primary **Controlled Trial** pregnant women midwife care (caseload midwifery) decreases the caesarean section rate compared with standard maternity care Parker et UK To assess how 10 studies Qualitative, with al, 2011 specific projects had narrative analysis progressed conceptualisation and measurement of continuity, focusing on two questions: what is continuity of care and what influences it? Van To identify and Systematic review Canada 18 studies Walraven summarise all et al, 2010 methodological studies that measure the association between continuity of care and patient outcomes Waibel et Spain To improve the Meta-synthesis 25 studies al, 2012 knowledge on patients' perceptions of relational,

Table 8. Characteristics of papers from phase 2 targeted secondary searches

informational and

		management		
		continuity across		
		care levels		
	Resp	ectful and non-judgem	ental attitude	
Author / date	Country	Aim / objective(s)	Methodology	Participants / studies reviewed
Brener et al, 2013	New Zealand	To assess the role of a Hepatitis C community clinic in improving health outcomes, knowledge, lifestyle practices and psychosocial functioning of the target population	Qualitative study (semi-structured interviews)	24 clients and 24 health professionals
Holt et al, 2018	Mexico	To investigate women's preferences for contraceptive counselling to inform efforts to improve service quality	Applied qualitative research (focus groups)	43 women
Lor et al, 2016	USA	To explicate and compare four conceptual care models: person-, patient-, family- centred, and culturally competent care	Comparative concept analysis	32 nursing research articles
Stenner et al, 2011	UK	To explore the views patients with diabetes have about their consultations with nurse prescribers and any impact this may have on their medications management	Qualitative study (semi-structured interviews)	41 patients with diabetes
Sword et al, 2012	Canada	To explore women's and care providers' perspectives of quality prenatal care to inform the development of	Qualitative study (semi-structured interviews)	40 pregnant women and 40 prenatal care providers

		items for a new		
		instrument, the		
		quality of prenatal		
		care questionnaire.		
	<u> </u>	Mobile or web-ba	sed	l
Author /	Country	Aim / objective(s)	Methodology	Participants
date			methodology	/ studies reviewed
Jeffrey et al, 2019	Australia	To evaluate firstly the experiences, barriers and facilitators to app	Qualitative (Semi- structured interviews)	People with type 2 diabetes: 16 app users and 14 non-
		usage among people with Type 2 Diabetes Mellitus and secondly determine recommendations to improve usage of diabetes apps.		app users
Kelly et al, 2018	UK	To understand the impact of using web- based and mobile technologies to support the management of type 2 diabetes	Qualitative (in- depth interviews)	15 People with type 2 diabetes
Madrigal and Escoffery, 2019	USA	To explore: 1. The differences in technology use, 2. Web-based health information seeking and use behaviours, 3. Attitudes towards seeking health information on the web, and 4. The level of eHealth Literacy between adults aged 18 and 64 years with and without chronic disease	A cross-sectional internet survey	401 adults
Reen et al, 2019	UK	To synthesize the usability of specific health information websites. These findings were mapped onto the adolescent	Systematic review	25 studies totalling 2621 participants

		Γ		,
		neurodevelopmental profile, and a design brief based on the findings was developed to tailor future websites for specific adolescent requirements		
Precor	ception care a	is part of sexual and rej	productive health co	ntinuum
Author / date	Country	Aim / objective(s)	Methodology	Participants / studies reviewed
Dean et al, 2014	Pakistan- studies from a range	To ascertain the possible impact of preconception care for adolescents, women and couples of reproductive age on maternal new- born and child health	Systematic review and meta-analysis	168 studies
Liu et al, 2016	USA - studies from a range	To provide a concept analysis of reproductive life planning using Walker and Avant's method as an organizing framework	Literature review and concept analysis	20 articles, 4 white papers, 2 conference proceedings and 5 other related studies
Mittal et al, 2014	USA	To test the use of a reproductive life plan to improve knowledge of preconception and contraception health in women with chronic diseases	Pre- and post- intervention surveys	27 women with chronic disease
Skogsdal et al, 2019	Sweden	To evaluate the effect of reproductive life plan counselling among women attending contraceptive counselling. Outcomes were knowledge about fertility and awareness of	RCT with pre and post intervention questionnaire	1,198 women

		preconception		
		health, use of		
		contraception and		
		women's experience		
		of reproductive life		
		plan counselling		
		Peer support		
Author /	Country	Aim / objective(s)	Methodology	Participants
date	country		Wethodology	/ studies reviewed
Davidson	USA	To review what is	Review of	unclear
et al, 2012		known about peer	evidence and	
,		support within	experience	
		mental health		
		community-based		
		practice; firstly,		
		through a review of		
		existing evidence		
		based, and secondly		
		by describing		
		experiences		
Gagliardino	Argentina	To compare clinical,	RCT with pre- and	198 people
et al <i>,</i> 2013		metabolic and	post- intervention	with type 2
		psychological	questionnaires	diabetes
		outcomes in people		
		with type 2 diabetes		
		1 year after		
		attending a		
		structured diabetes		
		education		
		programme		
		implemented by		
		professional		
		educators versus the		
		same programme		
		implemented by		
		trained peers with		
		diabetes that also		
		provided ongoing		
		support		
Gillard et	UK	To model the	Qualitative;	71 peer
al, 2015		change mechanisms	grounded theory	workers,
		underlying peer	B ounded theory	service
		worker interventions		
				users, staff
		(in mental health		and
		services)		managers
Naslund et	USA	To offer a	Commentary,	unclear
al, 2016		perspective on how	with proposed	
		online peer to peer	conceptual model	
		111		

	1			
		connections among		
		people with serious		
		mental illness could		
		advance efforts to		
		promote mental and		
		physical wellbeing in		
		this group		
Piette et al,	USA	To examine whether	RCT	212 people
2013		improvements in		with type 2
		insulin uptake and		diabetes
		perceived diabetes		
		social support		
		mediated the		
		intervention's		
		(guided diabetes		
		peer-support		
		intervention) impact		
		on A1c		
Schmied et	Australia	To examine	Metasynthisis	31 studies
al, 2011		women's	,,	
- , -		perceptions and		
		experiences of		
		breastfeeding		
		support, either		
		professional or peer,		
		to illuminate the		
		components of		
		support that they		
		deemed supportive		
		Psychological couns	elling	
Author /	Country	Aim / objective(s)	Methodology	Participants
date date	country		incence acrossy	/ studies
uute				reviewed
Armitage	UK	To test the efficacy	RCT	72
et al, 2014	UK	of a very brief	NCT	overweight
et al, 2014		psychological		people
		intervention that		people
		could be used as an		
		adjunct to standard		
		-		
		weight loss		
		programmes to		
		support increased		
		weight loss in an		
		overweight sample	Deview reserve	20 (lists d)
Harvey,	UK	To provide an	Review paper	28 (listed)
2015		overview of		
		psychologically		
		based interventions		
		with some		

				1
		discussion of their		
		basis in		
		psychological theory		
Lunn et al,	UK	To review the	Case study	1 team
2017		contribution of a		
		psychologist in		
		addressing the		
		biopsychosocial		
		needs of a		
		chronically unwell		
		population		
		(respiratory disease)		
Uchendu	UK –	To establish the	Systematic review	9 studies
and Blake,	studies	effectiveness of CBT	and meta-analysis	
2017	from a	on glycaemic control	,	
	wider range	and comorbid		
		diabetes-related		
		distress, depression,		
		anxiety and quality		
		of life in the short,		
		medium and longer		
		term among adults		
		with diabetes		
		Perceived as norm	 nal	
Author /	Country	Aim / objective(s)	Methodology	Participants
date	country		Withouology	/ studies
uale				reviewed
Atkinson et	UK	To invostigato	Qualitative:	
	UK	To investigate whether women's	•	7 women
al, 2016			interpretative	experiencing
		experiences of	phenomenological	their first
		pregnancy indicate	analysis	pregnancy
		that they would be		
		receptive to		
		behaviour change		
		during this period.		
Genuis and	Canada	To explore the	Sense-making	Study 1: 28
Bronstein,		following questions:	methodology	women;
2017		How were notions of	using a social	study 2: 634
		normality expressed	construc-	items posted
		by, and what might	tionist approach	on online
		these expressions		fora
		mean for people		
		who are engaged in		
		information		
		behaviours related		
		to life disrupting		
		health challenges?		
		And how might the		
		search for normality		
		search for normancy		

		1 11 1 11 11		
		be theorized in the		
		context of sense		
		making theory?		
	Country	Health Beliefs		Deuticinente
Author / date	Country	Aim / objective(s)	Methodology	Participants / studies reviewed
Jones et al, 2014	UK – studies mainly from USA	To explore barriers to early presentation and diagnosis with breast cancer among black women	Systematic review	18 studies (6183 participants)
Spencer et al, 2012	UK	To explore patient and provider illness perceptions and barriers to effective management of gout in general practice	A qualitative study involving semi-structured face-to-face interviews with patients and health professionals	20 gout sufferers and 18 health professionals
		Part of routine ca	ire	
Author / date	Country	Aim / objective(s)	Methodology	Participants / studies reviewed
Johnson et al, 2021	USA	To develop a theoretical model that reflects contraceptive decision-making and behaviour in the setting of diabetes mellitus	Qualitative – semi-structured interviews	17 women with type 1 or type 2 diabetes
Keyworth et al, 2018	UK	 To examine awareness of the "making every contact count" policy and To examine prevalence of "making every contact count"- related practice in relation to a) perceived patient benefit, b) how often healthcare professionals deliver 	Cross-sectional national survey of healthcare professionals	1387 healthcare professionals

r		• •		ر ۱
		interventions during routine		
		consultations		
		and c) the time		
		spent on this		
		activity		
Nelson et	UK	To conduct an initial	Qualitative –	12
al, 2013		evaluation of a	Indepth	stakeholders
ai, 2015		behaviour change	interviews	from a range
		programme called	Interviews	of
		"making every		professional
		contact count"		backgrounds
		Integrated servic	<u> </u>	backgrounds
Author /	Country	Aim / objective(s)	Methodology	Participants
date	country		wiethouology	/ studies
uute				reviewed
Kruis et al,	The	To evaluate the	Systematic review	26 trials
2013	Netherlands	effects of integrated	(Cochrane)	involving
2010	– studies	disease		2997 people
	from a	management		across 11
	range	programmes or		countries
	Tunge	interventions in		countries
		people with COPD		
		on health related		
		QoL, exercise		
		tolerance and		
		number of		
		exacerbations		
Ling et al,	UK	To identify barriers	Qualitative	213 staff
2012		and facilitators to	analysis of	interviews
		successful	Indepth	
		integration of care	interviews +	
			systematic	
			comparison with	
			findings from	
			previous	
			systematic review	
Nuno et al,	Spain –	To highlight the	Literature review	Number not
2012	studies	current relevance of		specified
	from a	the innovative care		
	range	for chronic		
		conditions		
		framework, as a		
		model for change in		
		health systems		
		towards better care		
		for chronic		
		conditions, as well		
		as to assess its		
	1	115	1	

	impact on health	
	policy development	
	and healthcare	
	redesign to date	

5.4 Results: the ten refined programme theories

In this section I now present the prioritised programme theories as "if then" statements, together with evidence supporting these from phase 1 searches, and identified papers that provided empirical evidence supporting the plausibility of the theories from phase 2 targeted searches.

Programme theories related to the intervention (provider characteristics):

5.4.1 If there is continuity of carer, and this experience is positive, THEN people are more likely to trust their healthcare professional, feel empowered and thus supported to make appropriate choices / behaviour change.

Nine studies (Devido, 2014; Earle *et al.*, 2017; Echenique *et al.*, 2017; King *et al.*, 2012; McCorry *et al.*, 2012; Mortagy *et al.*, 2010; Murphy *et al.*, 2010b; O'Higgins *et al.*, 2014; Spence *et al.*, 2010) were included in the review that referred to continuity of carer, or relational continuity; most reported its value. This was both in terms of accessing preconception care, and for on-going support for behaviour change prior to pregnancy.

"Our data demonstrates how the nature and quality of existing relationships with health professionals may impact reproductive behaviours such as seeking preconception care among women with diabetes.... Relational continuity was highly valued by our participants..." (McCorry et al., 2012 p400)

What people gained from such continuity was described in several ways:

"Reassurance and support... trusted expert guidance... feeling cared for... moral and medical support... professional support and understanding..." (O'Higgins et al., 2014 p370) Relational continuity can, therefore, improve care through trust in a healthcare professional that is established over time and based on knowledge and understanding of an individual. To develop a truly empowering partnership approach to care, however, mutual respect between both parties is required:

"Participants who had developed a strong relationship with their professional carers and had expertise in their diabetes mellitus talked about care as a partnership..." (Earle et al., 2017 p86)

"... women expressed a desire to get advice from an 'approachable' individual who understood their 'real life' and their difficulty of living with diabetes." (Spence et al., 2010 p1388)

Studies highlighted that continuity of carer alone is not sufficient, but continuity must be accompanied by mutual respect (Devido, 2014; Earle et al., 2017; McCorry et al., 2012; Murphy et al., 2010; O'Higgins et al., 2014; Spence et al., 2010). The extract below illustrates how people feel when the health care professional does not appear to care about them:

"... they don't even let you speak, they just tell you to shut it there that's it ..." (Earle et al., 2017 p87)

Healthcare professionals need to listen and acknowledge that people may be willing to

sacrifice their own health in order to fulfil their dreams and goals. The extract below

highlights the negative impact of perceived disapproval from health care professionals:

"... she would not seek advice as her health professional was opposed to the prospect of further pregnancies ... I don't want to hear you telling me I can't have more children, so I just went ahead." (Spence et al., 2010 p1388)

"Another woman admitted not communicating with her CF provider that she had been trying to get pregnant for a year because 'he was already mad about it.'... Some participants were advised against pregnancy due to poor health. ...Participants often perceived disapproval towards childbearing from their CF providers." (Kazmerski et al., 2017) Continuity of carer over time may result in additional barriers, as one study highlighted, if health care providers are viewed as parental figures. A paternalistic approach suggests lack of mutual respect and is therefore unlikely to result in feelings of support and empowerment.

"Most men in this study had been attending the clinic their entire lives and could have viewed providers as parental figures, such that discussions of sexual practice were uncomfortable or could have been considered inappropriate or to stimulate disapproval." (Echenique et al., 2017 p41)

In the broader targeted (secondary) searches (for search terms see appendix 2), I sought to establish the plausibility of this theory in other fields. Studies show that continuity of carer can improve outcomes for individuals in both general practice and maternity care (Barker, Steventon and Deeny, 2017; McLachlan *et al.*, 2012; Parker, Corden and Heaton, 2011; Sandall *et al.*, 2016; Van Walraven *et al.*, 2010), supporting the resulting middle-range theory. These studies showed improved patient safety and reduced mortality rates, with relational continuity, as well as improvement in both patient and health care provider satisfaction.

5.4.2 IF healthcare professionals have a positive, non-judgemental, respectful attitude towards people seeking support, and adopt a partnership approach THEN people will develop trust in their healthcare professional and are likely to feel empowered and supported to make informed and appropriate choices / behaviour change. As identified above, a positive and respectful attitude towards people seeking support, by healthcare professionals, has been recognised as paramount. The nature of interactions with healthcare professionals was mentioned in 18 studies included in the review (Devido, 2014; Earle *et al.*, 2017; Echenique *et al.*, 2017; Health Education England, 2017; Public Health England, 2018; Forde, Patelarou and Forbes, 2016; Frieder, 2010; Kazmerski *et al.*, 2017; Klein *et al.*, 2017; Lawther *et al.*, 2018; McCorry *et al.*, 2012; Mittal, Dandekar and Hessler, 2014; Murphy *et al.*, 2010b; Nguyen *et al.*, 2015; O'Higgins *et al.*, 2014; Poels *et al.*, 2016; Spence *et al.*, 2010; Winterbottom, 2012), highlighting that health care professionals' behaviour can affect how people perceive they are viewed, and this in turn impacts their behaviour and therefore the outcome of the intervention. One study highlighted how this can affect clinic attendance:

"...women are more likely to want to attend clinics when they feel they are treated with respect and dignity." (Earle et al., 2017 p87)

Some studies highlighted the issue of control, resulting from an authoritative and paternalistic communication style (Earle et al., 2017). Studies also reported how lack of respect can make people feel they are not valued:

"... felt 'judged' by the health professional and perceived them to be controlling and directive ... one woman preferred to shy away from advice as she felt doctors attributed all her problems to obesity and made her feel like she was unimportant. (Spence et al., 2010 p1388).

"Some participants reported feeling as if doctors did not care about their patients.." (Echenique *et al.,* 2017)

Whilst healthcare professionals may have an opinion on what is right, they must recognise that people have autonomy and agency. Healthcare professionals must adopt a partnership rather than a paternalistic approach:

"The advice one woman gave to [healthcare] providers was, "Don't let [your patient] just assume they're never going to have a baby. Whether you think it's good for their health or not, it's [your patient's] decision." (Kazmerski et al., 2017 p821)

The targeted, broader, secondary searches showed that this middle-range theory is well supported in other fields. Meaningful relationships between individuals and their health care providers, characterised by trust, is a recurrent theme of effective health care in a range of settings (Brener *et al.*, 2013; Holt *et al.*, 2018; Lor, Crooks and Tluczek, 2016; Stenner, Courtenay and Carey, 2011; Sword *et al.*, 2012). Many studies refer to this as personalized care (Deeny, Thorlby and Steventon, 2018; National, Health and Service, 2019) or a person-centred approach (McCormack and McCance, 2006).

Programme theories related to the intervention (delivery mechanism):

5.4.3 IF information and/or support is internet-based or available via a mobile phone THEN people can use this to increase knowledge about their condition / progress, which is both empowering and supports a partnership approach between the patient and their healthcare professional.

Four studies included in the review referred to online or internet-based preconception information (Agricola *et al.*, 2014; Barker *et al.*, 2016; Lopez *et al.*, 2015; O'Higgins *et*

al., 2014). In some cases, it was noted that this could be used to complement a faceto-face discussion with a health care professional:

"... talking to a doctor is the preferred way to receive information ... However, searching for information online was seen as a complementary way to receive information and also helped in preparing for their conversation with a doctor." (Lopez et al., 2015 p567)

The use of online platforms (web sites, social media, or mobile applications) to improve pre-pregnancy health through sustained behaviour change has shown promise, with one study identifying how a digital intervention tool can tailor content to meet individual needs (Barker et al., 2016). People who used the tool received regular reminders, tips and feedback, which may have contributed to motivation and empowerment to maintain healthy behaviors. Adding human interaction, however, may result in increased engagement and effectiveness of the online intervention:

"... adding an element of human interaction in the form of telephone coaching increased engagement with, and effectiveness of, the [digital] intervention when compared with a condition where there was no telephone coaching." (Barker et al., 2016 p332)

In the targeted, broader, secondary searches, it was evident that online platforms are useful sources of information for some individuals with underlying health conditions, which can empower them through increased knowledge and understanding (Kelly, Jenkinson and Morley, 2018; Madrigal and Escoffery, 2019; Reen, Muirhead and Langdon, 2019). Digital interventions (such as mobile applications) increased selfefficacy and self-management of glycaemic control for some individuals with diabetes; an example of beneficial preconception health behaviour change (Jeffrey *et al.*, 2019). Recommendation and involvement of the healthcare professional in use of the mobile application showed increased effectiveness through a partnership approach to care (Kelly, Jenkinson and Morley, 2018).

This middle-range theory is therefore supported, with evidence suggesting that a combination of non-judgemental motivational human contact alongside online or digital interventions may support behaviour change prior to pregnancy through choice and autonomy, resulting in feelings of empowerment and self-efficacy.

Programme theories related to the intervention (content):

5.4.4 IF preconception care is considered as part of a broader sexual and reproductive health continuum in relation to peoples' health conditions THEN relevant aspects of sexual and reproductive health on the continuum of contraception / pregnancy planning are likely to be discussed and people are less likely to experience unplanned pregnancies.

Preconception care is just one element of a broader sexual and reproductive health continuum, which 13 studies identified as a gap in care for individuals with chronic health conditions (Charron-Prochownik *et al.*, 2001; Echenique *et al.*, 2017; Fischl *et al.*, 2010; Forde, Patelarou and Forbes, 2016; Frieder, 2010; Holmes *et al.*, 2017; Holmes *et al.*, 2012; Kazmerski *et al.*, 2017; Lopez *et al.*, 2015; McCorry *et al.*, 2012; Mittal, Dandekar and Hessler, 2014; Murphy *et al.*, 2010b; Simone *et al.*, 2018; Spence *et al.*, 2013). Taking a broader view of sexual and reproductive health (SRH), rather than just focusing on preconception care provides opportunities for a more personalized approach and may reduce unplanned pregnancies.

"Existing misconceptions around fertility and limited receipt of SRH care lead to sexual risk behaviors and unintended pregnancies..... young women want

improved SRH educational resources coupled with routine SRH discussions initiated by their [healthcare] providers." (Kazmerski et al., 2017 p822)

"... discussion of contraception to avoid unplanned pregnancies is limited ... health care for women with pre-existing diabetes should, therefore, strive to provide individualised care and advice, which is tailored to women's needs and relevant to their specific life circumstances ..." (McCorry et al., 2012 p401)

One study highlighted how preconception advice is sometimes given routinely, and

this may be perceived as irrelevant to many people:

"Delivering preconception counselling to younger women, in whom the prospect of pregnancy seems a long way off, is undoubtedly a challenge. Women in this study routinely questioned its effectiveness, suggesting it was often 'skimmed over' during annual reviews." (Murphy et al., 2010 p98)

Another study tested the use of a reproductive life plan for people with chronic health conditions. Both contraception and preconception were included in the brief counselling tool, with people demonstrating increased knowledge and feelings of empowerment as a result:

"...patients who benefited the most from the intervention were the women who started with lower baseline knowledge about childbearing and/or their chronic diseases, and that women without previous children may particularly benefit from reproductive life planning." (Mittal et al., 2014 p30)

This middle-range theory was partially supported by evidence identified in secondary searches, although it is unclear how long any beneficial effects might last as longer-term follow-up of study participants is required. Studies have shown that discussions should include both sexes, sexual and reproductive health services, contraception, personal life plans, and underlying social and community factors (Dean *et al.*, 2014; Liu, Parmerter and Straughn, 2016; Skogsdal *et al.*, 2019).

5.4.5 IF peer support networks are available THEN people are more likely to feel

emotionally / socially supported and will be more inclined to engage with the

medical advice and support they are offered

Seven studies included in the review identified peer support as beneficial to individuals

with health conditions (Doss, 2017; Grady and Geller, 2016; King et al., 2012; Lopez et

al., 2015; O'Higgins et al., 2014; Spence et al., 2010; Spence et al., 2013). Peer support

may be face to face or via other routes including social media:

"... women ... repeatedly acknowledged that a 'real life' approach was best ... with interview clips from 'real women' at the forefront ..." (Spence et al., 2013 p12)

"Several respondents indicated that they would prefer face-to-face meetings ... because they were concerned about discussing personal issues related to their conditions on publicly accessible social media groups." (Lopez et al., 2015 p565)

"Participants ... suggested that development of a social support group, a Facebook page, or an internet website with a blog, would improve this aspect ..." (Doss, 2017 p119)

Studies identified the value of people sharing experiences, demonstrating a deeper

understanding of common challenges, and creating social norms for people who might

otherwise feel that their experiences of pregnancy are "different":

"... Involvement in pre-pregnancy care enabled women to meet others, promoting an atmosphere of normality and reassurance that they could give birth to a healthy baby ... the comfort of knowing they are not alone in their struggle and frustration." (O'Higgins et al., 2014 p370 & 371)

"... participants were able to relate to their views and experiences, while hearing from someone who understood their daily challenges." (Spence et al., 2013 p11) This middle-range theory was supported by evidence from the secondary searches, which highlighted the value of peer support for individuals in a range of different circumstances. Common themes include an increased sense of hope, control, and ability to effect change, as well as a sense of community belonging (Davidson *et al.*, 2012; Gillard *et al.*, 2015; Naslund *et al.*, 2016). Some studies also showed that volunteer peer educators can influence effective physiological health changes (Gagliardino *et al.*, 2013; Piette *et al.*, 2013); a key element of peer support includes authentic presence, which provides effective support (Schmied *et al.*, 2011).

5.4.6 IF psychological counselling and support is available to address and reduce anxieties regarding pregnancy with a pre-existing health condition THEN people are more likely to be able to access preconception care and engage in appropriate behaviour change.

11 included studies acknowledged the impact of psychosocial factors in relation to preconception care (Earle *et al.*, 2017; Forde, Patelarou and Forbes, 2016; Kazmerski *et al.*, 2017; Komiti *et al.*, 2014; Lawther *et al.*, 2018; McCorry *et al.*, 2012; Murphy *et al.*, 2010b; O'Higgins *et al.*, 2014; Pashley and O'Donoghue, 2009; Steel, Lucke and Adams, 2015; Winterbottom, 2012):

"Women reported experiencing emotional stress whilst attempting to comply with preconception requirements unique to their diagnosed health condition ..." (Steel et al., 2015 p7)

"... the emotional complexities surrounding pregnancy ... can mean that women with pre-existing diabetes mellitus feel conflicted about pregnancy planning." (Earle et al., 2017) Some psychological issues may be severe, due to previous experience or poor

pregnancy outcome:

"... their experiences of guilt, loss and personal failure are extremely distressing and may not always be recognised during routine clinical care." (Murphy et al., 2010 p99)

One study suggested that psychological support may be an important element of successful preconception care:

"Changing health behaviour, without recognising and addressing the psychosocial and economic environment in which the behaviour takes place, is unlikely to be successful." (Pashley & O'Donoghue, 2009 p155)

Secondary searches supported this middle-range theory. Studies ranged from services implementing a very brief psychological intervention, to those that included a psychologist as part of the team; all demonstrated that implementing a psychological intervention resulted in some improvement in outcomes that were dependent on behaviour change (Armitage *et al.*, 2014; Harvey, 2015; Uchendu and Blake, 2017). Lunn, Restrick and Stern (2017) described a working model for service provision, using an adapted biopsychosocial model to illustrate the inextricable link between physical and psychosocial impacts of living with a chronic health condition.

Programme theories related to the people's beliefs (perceptions of pregnancy planning):

5.4.7 IF people perceive preconception care as normal THEN they are more likely to

seek / be receptive to preconception care and adopt appropriate behaviour

to optimise pregnancy.

Five studies included in the review (Earle et al., 2017; Forde, Patelarou and Forbes,

2016; Kazmerski et al., 2017; Murphy et al., 2010b; Poels et al., 2016) reported a desire

for normality among people with health conditions, which may be a barrier to

accessing preconception care since this does not align with social and cultural norms:

"... women just wanted their lives to be as normal as possible ... many women spoke about not just wanting a normal experience but wanting to feel the 'joy' of preparing for pregnancy." (Earle et al., 2017 p56)

"... the desire for a normal experience of ... pregnancy planning is cited ... as the reason why they would not attend for preconception care." (Earle et al., 2017 p56)

"... they wanted a normal pregnancy experience and PPC could mean that even prior to their pregnancy their diabetes would take precedence." (Forde, Patelarou and Forbes, 2016)

This links with the benefit of peer support providing a social group in which people

with similar health conditions feel normal as a result of shared experiences:

"Involvement in pre-pregnancy care enabled women to meet others, promoting an atmosphere of normality and reassurance ... 'been involved ... before and felt it was good'." (O'Higgins et al., 2014 p370)

Secondary searches showed that a 'normal' preconception experience does not involve

drastic lifestyle changes or information seeking. Consequently, when these are

required, it can lead to increased anxiety (Atkinson, Shaw and French, 2016). A desire

to be normal is well documented across patient groups, and perceptions of normality can be socially constructed (Genuis and Bronstein, 2017). New perceptions of reality can be established through shared experiences, which can help individuals with health challenges to accept the need for therapeutic interventions (Genuis and Bronstein, 2017).

5.4.8 IF people believe that their health condition reduces fertility and/or their use of contraception is suboptimal THEN they have a greater chance of unplanned pregnancies.

Three studies included in the review highlighted the impact of inaccurate health beliefs (Earle *et al.*, 2017; Forde, Patelarou and Forbes, 2016; Murphy *et al.*, 2010b); specifically, that inaccurate beliefs about contraception resulted in a higher risk of unplanned pregnancy due to suboptimal practises:

"There were beliefs that contraception was not necessary because the woman's diabetes meant they would not get pregnant or that contraception, particularly oral contraception, was inappropriate for people with diabetes." (Forde et al., 2016 p697)

In the secondary searches, studies supported this middle-range theory, showing that inaccurate health beliefs can have negative consequences. Two studies highlighted how inaccurate beliefs about the aetiology of a condition or efficacy of treatment can result in delays seeking medical advice and subsequent increased risk of morbidity and mortality (Jones *et al.*, 2014; Spencer, Carr and Doherty, 2012). Programme theories related to the process (guidelines and pathways):

5.4.9 IF individualised brief interventions about sexual and reproductive health issues, using the Health Belief Model, are a routine part of on-going care THEN people are more likely to seek / access preconception care, having considered key elements of the Health Belief Model and received 'cues to action'.

Six papers included in the review demonstrated that including preconception advice in routine medical appointments can act as 'cues to action', resulting in intentions to plan future pregnancies (Charron-Prochownik *et al.*, 2001; Charron-Prochownik *et al.*, 2013; Fischl *et al.*, 2010; Mittal, Dandekar and Hessler, 2014; Spence *et al.*, 2010; Spence *et al.*, 2013). What these studies had in common, however, was a broader focus on sexual and reproductive health, including contraception, as well as recognition of wider psychosocial and cognitive factors:

"READY-Girls can potentially empower young women with diabetes to make well-informed reproductive health choices for themselves and possible improve the future health of their children." (Fischl et al., 2010 p705)

"The DVD's message and framework were designed to alter cognitive factors... several major constructs of the Expanded Health Belief Model are reported to correlate with reproductive health behaviours in adolescents with type 1 diabetes: perceived susceptibility, knowledge, barriers, threats, intention, selfefficacy with using contraception and awareness of preconception care." (Spence et al., 2013 p8-9)

"Women felt empowered to make decisions about their reproductive future in the context of their chronic disease with the use of [a reproductive life plan] and a discussion with the clinician." (Mittal et al., 2014 p30)

When preconception advice was not focused on individual's needs, or repeated advice

was offered at times that were not relevant, however, this was found to be

counterproductive:

"Constant advice that is repetitive and untimely can actually be a disincentive to women in accessing preconception care." (Earle et al., 2017 p60)

Highlighting a high level of unplanned pregnancies and a limited discussion of contraception in routine medical consultations, (McCorry *et al.*, 2012) emphasised the importance of individualized care and advice:

"Healthcare for women with pre-existing diabetes should ... provide individualised care and advice, which is tailored to women's needs and relevant to their specific life circumstances, including women who are not actively considering pregnancy." (McCorry et al., 2012 p401)

The secondary searches identified studies reporting that a public health policy in the United Kingdom, 'making every contact count', aimed at encouraging health care professionals to support and facilitate behaviour change through opportunistic interventions, is closely aligned to and supports this middle-range theory (Nelson *et al.*, 2013). In order to effectively deliver this type of brief intervention, however, health care professionals need to identify appropriate recipients and have effective training for efficient delivery of interventions (Keyworth *et al.*, 2018). Studies in secondary searches also found that application of the health belief model has been shown to be effective in relation to contraceptive counselling for people with diabetes from a range of cultural and ethnic backgrounds (Johnson *et al.*, 2021).

5.4.10 IF provision is integrated across specialities and across both primary and secondary care THEN a shared vision for preconception care will result in consistently better provision of preconception care.

Twelve papers included in the review commented on the organisation of services in some way (Brennand *et al.*, 2016; Public Health England, 2018; Forde, Patelarou and Forbes, 2016; Frieder, 2010; King *et al.*, 2012; Knight *et al.*, 2017; Lawther *et al.*, 2018; Mortagy, Kielmann and Baldeweg, 2010; Murphy *et al.*, 2010b; Nguyen *et al.*, 2015; Simone *et al.*, 2018; Wiles *et al.*, 2015), many recommended an integrated approach, promoting a person-centred rather than a condition-centred approach:

"You're not dealing with diabetes you're dealing with a woman with diabetes." (Mortagy et al., 2010 p819)

The importance of giving a consistent message was highlighted:

"I don't think it matters who gives the message as long as we're all giving the same consistent message, GP's practice nurses, health visitors, community midwives, everyone." (Forde et al., 2016 p699)

Studies also recognised system-wide barriers, which may differ between countries in

view of the variation in healthcare systems:

"... lack of clarity in responsibilities was further attributed to the targets set up by the commissioning bodies regarded as 'mixed messages' and 'conflicting incentives' by some GPs." (Mortagy et al., 2010 p817)

"... division of responsibility between primary and secondary care, amounted to a source of tension. In some instances, the lack of a clear division of labour led to missed opportunities for patient care... " (Mortagy et al., 2010 p818) Despite these barriers, there was a clear need for a shared vision and guidelines between primary and secondary care, which would facilitate a consistent message to those seeking support:

"The secondary care team pointed out the need for a joint ... strategy as well as a clear shared vision with primary care, with GPs being active members of the team providing the preconception care service." (Mortagy et al., 2010 p818)

Studies identified in the secondary searches strongly supported this middle-range theory, identifying that an integrated approach to care for people with chronic health conditions was beneficial in terms of improved well-being and a reduced need for healthcare services (Kruis *et al.*, 2013; Nuño *et al.*, 2012). Whilst barriers to delivering integrated care exist, ways to overcome these have been identified and can be used to plan and implement integrated care (Ling *et al.*, 2012).

5.5 Summary of results

Figure 7 illustrates the subdivisions and connections between the three broad areas that were found to contribute significantly to both access and behaviour change in relation to preconception care. The intervention refers to the interaction during which preconception care, advice or support was offered. Provider characteristics that were identified as empowering and thus most likely to support behaviour change were those demonstrating a positive, non-judgemental, respectful attitude towards people, which promoted a partnership approach (Brener *et al.*, 2013; Lor, Crooks and Tluczek, 2016), and this was more likely when a trusting relationship was built through continuity of carer (Barker, Steventon and Deeny, 2017; Sandall *et al.*, 2016). Online delivery of information or support was found to complement face-to-face discussions with a health care professional and promote a partnership approach to care (Kelly, Jenkinson and Morley, 2018).

Three aspects of content were explored: the social and emotional benefits of peer support, the availability of psychological counselling and approaching preconception care as part of a broader sexual and reproductive health continuum. All three were identified as beneficial (Lunn, Restrick and Stern, 2017; Mittal, Dandekar and Hessler, 2014; O'Higgins *et al.*, 2014), although longer term follow-up studies are needed in relation to the broader sexual and reproductive health continuum for people with health conditions.

A desire to be normal was one of two theories relating to beliefs that people with health conditions shared (Forde, Patelarou and Forbes, 2016; Kazmerski *et al.*, 2017; Lopez *et al.*, 2015). With normality being socially constructed (Genuis and Bronstein, 2017), this highlights a mechanism by which peer support effects access and behaviour change in relation to preconception care. Accurate knowledge was also identified as important for this group, in view of the increased risk of unplanned pregnancy due to inaccurate health beliefs (Forde, Patelarou and Forbes, 2016).

Two theories relating to the process of preconception care were explored, including preconception advice in routine medical appointments. This was found to act as a "cue to action" and thus prompt people to access preconception care when planning pregnancy, but only if it was individualized, relevant and met appropriate sexual and reproductive health needs (McCorry *et al.*, 2012; Mittal, Dandekar and Hessler, 2014). This finding links to the need for an integrated approach across specialities and services (Kruis *et al.*, 2013), to achieve consistent messages. Whilst barriers to

achieving a clear shared vision may exist (Ling *et al.*, 2012), it is imperative to develop shared guidelines to achieve consistency and clarity (Mortagy, Kielmann and Baldeweg, 2010), which in turn will facilitate access and behaviour change in relation to preconception care.

5.6 Conclusion

In this chapter I have outlined the results of the realist review, providing a description of phase 1 searches and a document flow diagram to clearly illustrate how appropriate and relevant literature, was identified. I have presented tables showing document characteristics and the 35 initial programme theories that resulted from analysis and synthesis of this literature. The 10 selected theories were then examined further in phase 2 of the realist review, by testing for plausibility using existing literature not necessarily drawn from the same field; I have presented results of phase 2 searches here. I have also presented the data that contributed to analysis and synthesis in phase 2, resulting in the 10 outlined middle-range theories that will be discussed further in chapter six.

Chapter 6

Discussion and Conclusions from the Realist Review

In this chapter I will discuss and summarise the findings of the realist review that were presented in the previous chapter (five) and have been published in a peer-reviewed open access journal (Hopper *et al.*, 2023). This is the first realist review of preconception care for people living with health conditions to have been undertaken, providing novel and important theories explaining what works for whom, in what circumstances, and how. This chapter concludes part two of this thesis, and provides the starting point for part three, which will outline the realist evaluation that I undertook after the realist review.

6.1 Discussion of findings in relation to other published literature

As outlined in chapters one and two of this thesis, people living with pre-existing health conditions have an increased chance of morbidity and mortality during pregnancy, birth and immediately afterwards. Some health conditions have ongoing health implications for the person who has given birth and their offspring, but some risks can be reduced if preconception health is optimised. Preconception care for people living with health conditions is therefore recognised as an important area for improvement to optimise the health of future generations (Public Health England, 2018) (Public Health England, 2018) and there is a need to promote awareness of the importance of preconception health among people of reproductive age (Daly *et al.*, 2022b). This realist review has produced theories explaining how preconception care works, in relation to three broad areas: the intervention (including provider

characteristics, the content, and delivery mechanisms), people's beliefs (including perceptions of self, perceptions of support and perceptions of preconception care), and the process (including guidelines and pathways, and accessibility of services). These three areas were reported to contribute significantly to both access and behaviour change in relation to preconception care, for people living with health conditions.

Two studies have examined topics closely aligned with this area. One recent crosssectional survey of women of reproductive age in the Southwest of England (n=835) identified low knowledge of preconception health, alongside positive attitudes towards preconception health (Daly *et al.*, 2022b). Although this survey was not limited to people living with health conditions, Daly *et al.* (2022b) identified that participants reported recent contact with healthcare services and considered them to be acceptable sources of information regarding preconception care, alongside websites and printed materials. What this realist review adds is greater nuance, by providing an understanding of the mechanisms involved in effective access to preconception care and support for behaviour change among people living with preexisting health conditions, for whom preconception health has particular significance.

A second study identified that providing cues to action (using a reproductive life planning tool based on the health belief model), were effective at improving preconception knowledge among women accessing contraceptive counselling, chlamydia testing or cervical screening (n=338) in Sweden (Stern *et al.*, 2013). This study used a randomised controlled design and again, was not limited to people living with health conditions; results demonstrated the effectiveness of the reproductive life planning tool and highlights opportunities for increasing knowledge of preconception

care as part of routine health care interactions. The context in which the intervention was delivered, however, is a significant factor, and was not explored in any depth. In contrast, a realist approach offers researchers the opportunity to consider such complexities and explain to what extent the same intervention may or may not work in different contexts.

The findings of this realist review include themes that resonate with wider areas and experiences of health care, and are well supported by empirical evidence, such as personalisation (Lor, Crooks and Tluczek, 2016), continuity of carer (Sandall et al., 2016) and integration of services (Kruis *et al.*, 2013). People are more likely to seek and accept support from a healthcare professional that they trust, and trust can be built through respectful relationships and consistent advice (Earle *et al.*, 2017). People's behaviour is also affected by their values and beliefs (Jones et al., 2014), so their perceptions of self, support and preconception care are equally significant and contribute to whether or not they are able to access advice and support prior to pregnancy. Peer support can be beneficial for some people (O'Higgins et al., 2014), but this review has shown that preconception care and support can be, at times, both unavailable and unwelcomed (Earle et al., 2017; Kazmerski et al., 2017). Preconception care is, therefore, not a single intervention but part of a wider sexual and reproductive health continuum, and one that is an individualised pathway involving a complex series of interacting elements (including social systems and individual agency), which need consideration to answer the research question.

The realist review has identified that preconception care is offered at different times and settings, but there were insufficient data to conclude what may be particularly beneficial and appropriate for different groups of people in different contexts, or

stages of their preconception journey; this will therefore be considered in the realist evaluation (see part three of this thesis). Whilst undertaking this review, type 1 and type 2 diabetes were noted to have been the health conditions providing the focus of most published research regarding preconception care for people living with preexisting conditions; a wider range of health conditions need to be included in future research to reflect the diversity of preconception care experience among people living with health conditions.

6.2 Strengths and limitations of the realist review

A major strength of this review was the novel realist approach, which has provided a more nuanced causal explanation of how different approaches or aspects of preconception care might work for people living with health conditions, rather than generalised impacts. An additional strength was inclusion of a wide range of preexisting and chronic physical and mental health conditions, and the breadth of literature that was included. The involvement of people with lived experience, clinicians and researchers with international representation in the expert advisory group was also a strength; this stakeholder group played a key role in developing, testing and prioritising programme theories for more targeted searching, further synthesis and refinement. As with other realist reviews (Wong *et al.*, 2013b), these more targeted searches (phase 2) enabled refinement of programme theories based on empirical evidence outside the field of preconception care, resulting in middle-range theories.

The review had some limitations; firstly, the fact that the evidence from database searching regarding preconception care was mainly from studies focusing on diabetes 138

(both type 1 and type 2) (n = 22), with nine other health conditions covered in the other included papers (n = 15) (see Figure 6 in chapter 5). When data regarding the prevalence of diabetes compared with other health conditions is examined (see Table 1 in section 2.1 of this thesis), this is not justified, and demonstrates the lack of research regarding preconception care for people living with chronic health conditions other than diabetes, limiting the application of findings across all health conditions.

Secondly, availability of appropriate evidence was also limited by the lack of detailed descriptions in the literature of what was offered in terms of preconception care, and lack of detailed descriptions of the context in which preconception care was offered. Of note, none of the included papers used realist methodology. This may have contributed to the paucity of depth within the papers; most were conceptually thick (rather than rich), meaning that sufficient details of interventions were included to enable some underpinning theoretical concepts to be identified, but descriptions of context and mechanisms were not always clear. This, however, highlights the need for retroduction in realist research, to identify hidden causal forces behind observable patterns, using both inductive and deductive logic alongside insights and hunches to identify and refine initial programme theories (Rameses II Project, 2017a).

Thirdly, with limited time and resources, only 10 out of the 35 identified initial programme theories could be fully explored, so the process of prioritisation was used. With greater time and resources all 35 initial programme theories could have been explored.

Nonetheless, his realist review has identified how preconception care for people living with health conditions works, providing a description of reality, even if this is an incomplete "best reflection" of reality (Pawson and Tilley, 1997; Pawson, 2013).

Repeated patterns were evident in the realist review, often referred to by realists as "demi-regularities", which are acknowledged to be strongly dependent on context (Dalkin *et al.*, 2015) and therefore may not be an appropriate description of reality for everyone. A more detailed realist evaluation involving qualitative interviews was therefore subsequently undertaken and will be outlined in part 3 of this thesis; this allowed for testing of all 35 initial programme theories identified in the realist review.

6.3 Recommendations

This realist review has identified important approaches and principles that should be incorporated into the delivery of preconception care for people living with chronic health conditions. Healthcare professionals must demonstrate a positive, nonjudgemental, respectful attitude towards people living with health conditions, and adopt a partnership approach to care. Continuity of carer should be promoted to build trusting relationships between people and their healthcare professionals. Healthcare professionals should also encourage a partnership approach through access to accurate online information, which people can use to complement face-to-face discussions. Accurate information must be available to people at all stages along the sexual and reproductive health continuum. This must be relevant and personalised to promote healthy lives and planned pregnancies. Information should also be provided at routine medical appointments as part of a holistic approach to care. Peer support networks should be promoted so that people living with chronic health conditions can access social and emotional support from others with similar experiences, providing opportunities for preconception care to be normalised within these networks. Psychological counselling should be offered to everyone seeking preconception care,

recognising the additional anxiety people living with chronic conditions may face when planning a pregnancy. Shared preconception care guidelines providing consistency and clarity must be developed and an integrated approach across specialities and services is required to facilitate access to preconception care and support people to make appropriate behaviour changes where necessary. Finally, further longer-term follow-up studies are needed to evaluate preconception care, as part of the broader sexual and reproductive health continuum, for people living with chronic health conditions, and a realist evaluation to conclude what may be particularly beneficial and appropriate for different groups of people in different contexts has now been undertaken and will be outlined in part 3 of this thesis.

6.4 Conclusion

This chapter concludes part two of this thesis. In this realist review I have explored some of the complexities involved in providing preconception care for people living with health conditions and based on available literature identified specific mechanisms that contribute significantly to explanations of how, why, and in what circumstances people are able to access preconception care and support. The recommendations regarding the intervention, people's beliefs, and the process, in relation to preconception care should be considered by policy makers and health care providers to improve access to preconception care and support for behaviour change prior to pregnancy. Taking the programme theories identified in this realist review into the subsequent realist evaluation has led to further understanding of what works for whom, in what circumstances, and how, in terms of preconception care for people living with health conditions, which will be outlined in part 3 of this thesis. Using

realist methodology has been beneficial due to the complexity of preconception care for this group of individuals, which is dependent on both social structures and individual agency.

Part III

Realist Evaluation

Chapter 7

Methods used in the Realist Evaluation

In part three of this thesis, I will present the realist evaluation that I undertook following the realist review, using the 35 programme theories identified from published and grey literature as a starting point. In this chapter I will outline the methods used. Realist evaluation involves testing and refining programme theories through appropriate data collection (Wong *et al.*, 2016); in this study I undertook qualitative interviews (Manzano, 2016) with different stakeholder groups to provide a deeper and more detailed understanding of what works, for whom, in what circumstances, and how, in relation to preconception care for people with health conditions. I will discuss associated ethical issues and provide evidence of favourable ethical approval of this study, which involved of members of the public. Finally, in this chapter I will provide an outline of the methods used for data analysis and synthesis. I will present the results in chapters eight, nine, ten and eleven.

7.1 Study design

My original intention for the realist evaluation, following the realist review, was to evaluate three specific preconception care clinics in different locations across the Southwest of England, recruiting people with health conditions through posters advertising the study on clinic notice boards, flyers providing contact details, and clinicians signposting people to the study. I also planned to recruit clinicians involved in providing preconception care, to gain a deeper understanding of how the intervention worked. By evaluating clinics in different locations, aspects relating to 145 context could be explored as the same intervention may work better in one location compared with another (Pawson, 2013). The COVID-19 pandemic, however, occurred just as I was about to submit ethics applications, so I could no longer recruit via the NHS or visit NHS sites to undertake data collection of any kind. This offered both a challenge and an opportunity. The challenge related to study re-design and recruitment; the opportunity related to using alternative methods for recruitment and an online video communication platform (Zoom) for data collection. Conducting online interviews enabled me to interview people living in different areas, with experience of different circumstances and contexts. It reduced the need for travel and therefore also saved time and meant that people could be interviewed in their own homes, at their convenience.

The study was therefore re-designed in view of COVID-19 restrictions, with the following broad aims:

- To refine and consolidate theory generated in part two (the realist review) about how access to preconception care (including advice and support) for people with pre-existing health conditions works, and
- To refine and consolidate theory generated in part two about how implementing behaviour change prior to (in preparation for) pregnancy for people with pre-existing health conditions works.

The study was no longer restricted to locations in the Southwest of England, but incorporated a national reach, including anyone over the age of 18 assigned female at birth (the study information included the words woman / women) who had a preexisting physical or mental health condition, any partners or family members supporting a person with a health condition, and any healthcare professionals involved in providing preconception care to this group. The study included any type of preconception care and was not limited to preconception clinics in specific locations as was originally planned.

The study was called the PEAcH study; this acronym was taken from the full title: **P**reconception care; **E**xploration and **A**vailability of a**c**cess for women with **H**ealth conditions. A web page was established for information and recruitment purposes, along with an email address, Twitter (now X), Facebook and Instagram accounts.

Realist evaluations start with "if-then" propositions and follow a scientific logic to test these programme theories (Pawson, 2013). The programme theories developed from the realist review were therefore the starting point of this realist evaluation. The programmes included in the realist review were not identical, in fact no two programmes can ever be identical due to the context and circumstances (including location) in which they occur, but they had what Pawson (2013) describes as a family resemblance. These programme theories were therefore an appropriate starting point for a realist evaluation of any type of preconception care and prompted research questions that were addressed through empirical work. Pawson cautions, however, that evaluation can be a never-ending process (see Figure 8 illustrating the wheel of evaluation science), due to the endless complexities involved; the results are therefore only ever partial knowledge, but even so, to be able to partially improve preconception care would still be a significant achievement (Pawson, 2013).

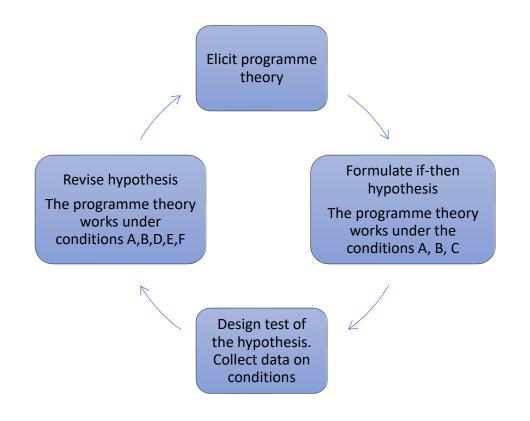


Figure 8. The wheel of evaluation science (Pawson, 2013)

Realist evaluations can involve a range of methods, including mixed and appropriate data to collect relevant evidence to answer questions arising from the initial programme theories (Pawson, 2013; Maxwell, 2012). These depend on both the questions and the situation (Maxwell, 2012). In this evaluation, the research questions arising from the 35 initial programme theories (see Table 6 in section 5.2) were not all listed, as that would constitute a very long and not especially helpful list. Instead, qualitative interviews were used to gather evidence from a range of stakeholders (people with health conditions, their partners or supporting family members, and healthcare professionals), about what, how, and in what context preconception care worked (or did not). A topic guide of open questions to allow free expression for each group was devised, based on work published by Manzano (2016), and this was used as a prompt for the researcher during interviews. This enabled relevant programme theories to be explored, starting with the interviewee recounting their experience of preconception care. It also provided the opportunity for new programme theories to emerge, acknowledging that the realist review could only ever provide a partial description of reality and therefore could not have uncovered all relevant programme theories. As principal researcher, the interviewer was familiar with the initial programme theories and their existing knowledge enabled a realist approach (Manzano, 2016). The data gathered from these interviews complemented and enriched the existing data regarding access to preconception care; in some cases they also contradicted, disputed and allowed for nuanced refinement of programme theories.

Interviews were conducted via Zoom, the use of which dramatically increased when the COVID-19 pandemic struck in 2020 due to the enforced global, national and local travel restrictions, bringing both advantages and disadvantages (Karl, Peluchette and Aghakhani, 2022; Lampa *et al.*, 2021). The opportunities that Zoom offered for this study included increased accessibility through flexibility of interview time, reduced travel time, wider geographical reach, and the ability to conduct interviews and still see people's faces, despite being geographically distant. The functions in Zoom allowing for audio recordings and transcription were also beneficial; these were stored securely on the researcher's password protected University laptop until they had been reviewed and transcribed verbatim onto separate word documents. Once the transcript was completed, the original recordings were securely destroyed.

The potential disadvantages of using Zoom included technical issues, especially when participants were less familiar with its use, and occasional poor sound quality. These situations, however, were infrequent due to people's familiarity with and use of Zoom,

and / or other digital communication platforms, which had greatly increased during the pandemic.

7.2 Recruitment of participants

Information about the PEAcH study was posted on social media (Facebook, twitter, Instagram) and by relevant charity groups (in newsletters), with their agreement; this method has become increasingly used by health researchers as part of recruitment strategies, especially among young adults (Darko, Kleib and Olson, 2022). The following charities were sent an email inviting them to promote the study: Diabetes UK, Epilepsy Action, Epilepsy Research UK, Epilepsy Society, British Heart Foundation, Versus Arthritis, National Rheumatoid Arthritis Society (NRAS), Lupus UK, Kidney Care UK, Asthma UK, Asthma and Allergy Foundation, Big Birthas, and Black Mamas Matter Alliance, (see appendix 4 for example emails and tweets). This enabled targeting of groups of people with specific health conditions, and was also targeted to include ethnically diverse and hard to reach groups (Darko, Kleib and Olson, 2022).

Anyone interested in participating in the study was asked to follow a link to the PEAcH study web page, which provided further information, including links to appropriate participant information sheets (one for women with health conditions, one for partners and supporting family members, and one for healthcare professionals (see appendix 5 for participant information sheets).

The information sheet included a link to a Jisc online survey (Jisc, 2023), where participants were invited to consent to take part, indicated likely availability (day and choice of morning, afternoon, and evening) and provided their email address for

contact (see appendix 6 for online consent form). This enabled the researcher to schedule an online interview via Zoom, which could be changed as required to suit the interviewee.

Eligible participants were from the three groups outlined above (healthcare professionals, women with pre-existing medical conditions and supporting partners or family members). Participants needed to be over the age of 18, be able to give informed consent and participate in online interviews (via Zoom) in English. People with any pre-existing physical or mental health condition were included and needed to be from OECD member countries (with similar approaches to healthcare and economic status). People specifically seeking fertility or genetic counselling were not included, as these topics were not the focus of the PEACH study, although it was acknowledged that these issues could arise. People did not have to have experienced pregnancy or have children; this was because the aim of the study was to look for causal explanations of how any type of preconception care (including opportunistic) worked, and why.

Sampling was purposive, in that three distinct groups of individuals were recruited. The initial aim was to recruit 10 healthcare professionals, 30 women with a range of medical conditions and 10 partners or family members. Numbers were an approximation due to the unpredictability of the realist process of theory-testing, the aim of relevance and rigour (as opposed to saturation) (Pawson, 2013) and timeframe for the study (as part of a PhD). Time was ultimately a limiting factor, and it was therefore acknowledged that some programme theories regarding particular groups or contexts could not be refined in as much depth as others. As mentioned above, there are endless complexities involved in preconception care for people with health

conditions that can be evaluated in a never-ending process, so knowledge of reality can only every be partial (Pawson, 2013), and a pragmatic approach is required (Gilmore *et al.*, 2019).

In line with realist methodology, which requires an iterative approach, participants were informed that they could be invited to a second interview, although by the end this was not necessary. Interviews with different groups provided triangulation of results, as each provided a different perspective and thus a different source of data from the others (Pawson and Manzano-Santaella, 2012).

7.3 Ethical approval

Since no recruitment was through NHS routes or using NHS resources, ethical approval to conduct the research was sought and obtained from the University of Plymouth Faculty Research Ethics and Integrity Committee on 13th April 2021 (reference number: 2594) (see appendix 7). The ethical principles of beneficence, non-maleficence, autonomy, and justice (Beauchamp and Childress, 2019) have been considered at every stage of this study, to protect both participants and researchers from any potential harm. Some key considerations are outlined below.

Openness and honesty were achieved through provision of participant information sheets (PIS; see appendix 5), which participants were required to read prior to giving informed consent. Each PIS included contact details of the researcher and director of studies, either of whom could have been contacted with any queries if required, with all questions answered in an open and honest way. The Faculty of Health research ethics and integrity committee email address was also provided on the PIS. All participants completed a consent form online, using a JISC online survey, which is GDPR compliant (Jisc, 2023). Being over 18 and having mental capacity was a requirement of the study. This was reviewed and consent confirmed by the researcher at the start of the interview. All consent forms were downloaded and stored securely according to the data management plan (see appendix 8).

Participants were informed, on the PIS, that they were free to withdraw from the study at any time without providing an explanation. They could also withdraw any data they had provided up to the point of data analysis (the point at which their data had been anonymised and incorporated with other data). Participants were provided with contact details of the researcher and director of studies for this purpose, and if they had any other questions or concerns.

Participants were informed (on the PIS) that they could request a debrief with the researcher if they wished. In the unlikely event that they became distressed in the process of recalling events or experiences they were advised to consider accessing counselling services via their General Practitioner.

Interviews were conducted online using Zoom. Zoom recordings included sound and transcription (often rather poor), but no video. After review and full transcription by the researcher, the Zoom recordings were securely deleted. Transcripts were given a unique number; a separate spreadsheet linked participant identities with the unique number on each transcript, maintaining anonymity of participants once data gathering was complete, and the researcher had confirmed that participants were not required for a second interview the spreadsheet linking participant identities with the unique number on each transcript will be securely destroyed in line with university processes and the Data Protection Act (*Data protection Act*, 2018). A Data Management Plan

outlined safe storage of all information in this study (see appendix 8). Data included in any thesis (university assessment) or publication, is anonymous, preventing any disclosure of participant identity. The names of any NHS Trusts mentioned during data collection is also anonymised to maintain NHS anonymity and confidentiality.

Use of websites and social media for information raises confidentiality issues since social media communications leave a permanent online trace and privacy settings within terms and conditions are difficult to comprehend (Hunter *et al.*, 2018). Whilst websites and social media were used to advertise and share information about the PEAcH study, however, no personal data was requested or taken from these. Providing a survey link to gain consent via a secure Jisc online survey after advertising on social media and charity websites maintained participant confidentiality at that stage (Darko, Kleib and Olson, 2022).

The confidentiality of participants and any NHS Trusts mentioned will continue to be maintained by the researcher and other investigators. As Nursing and Midwifery Council (NMC) registrants, both the main researcher and director of studies comply with the professional code of conduct (Nursing and Midwifery Council, 2018), which includes confidentiality. Processes are in place to restrict access to all sensitive personal information and destroy any such information as soon as possible (i.e. at the point that it is no longer required for the purposes of the study).

7.4 Qualitative interviews

All interviews were undertaken using a realist approach, in line with guiding principles outlined by Manzano (2016). There is a notable distinction between a constructivist

and a realist approach to interviews; qualitative interviews undertaken as part of realist evaluations seek to "inspire, validate, falsify, modify" (p295) programme theories using a "teacher-learner" (p305) approach (Pawson, 1996). The interviews undertaken in this study were therefore designed to firstly engage the interviewee and focus on preconception care, and subsequently to confirm, refute and/or refine the programme theories that were relevant to them. Listening to the interviewee's accounts of their experiences also provided opportunity for new programme theories to emerge or be "gleaned"; these were then further developed and refined through triangulation with data from other stakeholders (Pawson and Tilley, 1997).

Since the purpose of the interviews was to evaluate preconception care for people with health conditions, the interviewer needed to actively direct the questions and sometimes keep returning to questions when interviewees strayed off topic (Manzano, 2016). In this way, qualitative interviews used in realist evaluations differ from those used in ethnographic research, which require the interviewer to conceal their knowledge; conversely, the realist researcher is open about their knowledge of how a particular programme might work, asking exploratory questions of the interviewee to help make sense of it (Manzano, 2016).

Interview topic guides (see appendix 9) were therefore designed for each group of interviewees, and these were used as an aide memoire for the interviewer to ensure questions were appropriate to test hypotheses about how different programmes were thought to work, and why, identifying contexts, mechanisms and outcomes (both intended and unintended), at the same time as being able to explore previously unidentified hypotheses (Manzano, 2016; Pawson, 2013).

7.5 Data analysis and synthesis

Analysis pathways within realist evaluation have been described by various realist researchers (Mukumbang *et al.*, 2016; Cheyne, Abhyankar and McCourt, 2013; Pawson and Tilley, 1997; Gilmore *et al.*, 2019). Very few, however, provide detail of methods of analysis and synthesis actually used, with the exception of Gilmore *et al.* (2019), who provide practical and effective guidance, upon which the methods of analysis and synthesis used in our study were based (see Table 9 for a summary of steps 1 to 5).

Step)	Brief overview of process involved
1	Data preparation	Upload transcribed interviews to NVivo as files and add each initial programme theory as a node
2	Data extraction and CMOC elicitation	In NVivo, code relevant data to appropriate node and annotate a memo, linked to each node, demonstrating relevant context, mechanism, outcome configurations and decision making regarding whether the data (extract from interview) supports, refutes, or refines the initial programme theory.
3	Using CMOC's to refine programme theories	In NVivo, add child nodes with linked memos where programme theories are refined, and new nodes and linked memos where new programme theories emerge from the interviews. Use the memos as above.
4	Collating evidence and refinement verification	In a Word document, collate evidence in tables; one table for each programme theory, noting contexts, mechanisms, outcomes and CMO configurations. Add supporting quotes (data) and the refined programme theory to transparently demonstrate the process of analysis. Discuss and analyse with wider research team to tidy up and to identify new emerging groups of theories.
5	Synthesis resulting in middle-range theories	Identify demi-regularities and explore CMOCs to merge and abstract theories into middle-range programme theories with relevant broad context. Present these in diagrammatic and narrative form.

Table 9. Summary of steps involved in analysis and synthesis

Step 1: Data preparation

Transcription occurred as soon as possible after the interview had taken place, as this

contributed to the iterative process of realist data gathering and analysis through

familiarisation with the data (see appendix 10 for an example interview transcript: W4). Interview transcripts were then uploaded as files in NVivo (QSR International Pty Ltd., 2018) and the 35 initial programme theories taken from the realist review were each added as nodes in the same NVivo project.

Step 2: Data extracting and CMOC elicitation

Each interview was read again, and any data corresponding to one of the programme theories was highlighted and coded (extracted) to the relevant node (see appendix 11 for screenshot of coding stripes on interview W4 in NVivo). This process of coding alone was insufficient to enable retroductive theory refinement (Rameses II Project, 2017a), despite interview extracts being visible when each node (initial programme theory) was viewed in NVivo. When viewed in this way, each extract was taken out of the wider context of the interview, which may have included earlier or later information that was relevant (in terms of hidden causal forces), to either the intended or an unintended outcome.

The important element of this step was therefore, the addition of a memo, linked to each node (Gilmore *et al.*, 2019) (see appendix 12 for screenshot of NVivo showing memos). Each memo outlined the initial programme theory and provided a tool to demonstrate decision making in the process of theory refinement, using a template with the following headings: source, context, mechanism, outcome, CMOC, Supports/refutes/refines, how/why/decision making processes, links to other IPTs and additional notes.

This approach promoted retroductive analysis, with the initial programme theories became the starting point for analysis. Each interview was subjected to more in-depth exploration, using the memo template to document causal explanations and CMOC's,

leading to the conclusion that the interview either supported, refuted, or refined the programme theory. The memos linked to each node thus, showed the decision-making process and rationale for refinement of theory (see appendix 13 for example memo showing process of analysis).

Step 3: Using CMOC's to refine programme theories

Programme theories were refined throughout data analysis, with the researcher simultaneously undertaking steps 2 and 3, or returning to either step in an iterative fashion, as appropriate. When an initial programme theory was refined, often multiple novel causal explanations were identified, and child nodes, with associated memos, were added. In some cases, one initial programme theory was refined into 5 "child" theories, which each provided separate specific causal explanations for why or how a particular mechanism resulted on an outcome (so IPT1 became IPT1.1, IPT1.2, IPT1.3, IPT1.4, and IPT1.5). The number of programme theories thus expanded from 35 to more than 50 at this stage.

This process was repeated for each initial programme theory, resulting in numerous nodes, each with linked memos that documented the process of analysis. All interviews that contributed to supporting, refuting, or refining the programme theory were noted on the linked memo (one memo for each node), so these could be re-examined in the next iterative stage. Some memos therefore included data from multiple interviews (as in appendix 13). Any similar programme theories were then reviewed and combined as appropriate. This process was undertaken for all initial programme theories, using interviews with women, partners, and family members.

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Step 4: Collating evidence and refinement verification

To ensure analysis reflected all the data, a further set of tables (in a Word document, outside of NVivo), one for each programme theory, was developed, showing context, mechanism, outcome, configurations (CMOCs). This enabled evidence to be collated and programme theories could be further refined in view of evident demi-regularities (semipredictable patterns occurring in the data). Evidence from healthcare professionals was analysed and incorporated at this point, providing triangulation of results by adding evidence from more operational level data sources. The tables included all associated contexts, mechanisms, and outcomes, the resulting CMOCs, thought process relevant to the analysis, supporting quotes (data) providing evidence, list of each interview that contributed to refinement of the theory and finally the refined programme theory itself (see appendix 14 for example of a table with collated evidence).

The tables and theories were then examined by the wider research team, and discussion of programme theories resulted in further refinement due to similarities and overlaps, described aptly by Gilmore *et al.* (2019) as "tidying up". At this stage, the programme theories were still organised and numbered according to the three areas that were found to contribute significantly to access and behaviour change in relation to preconception care for people with health conditions from the realist review (see appendix 15 for an overview of all 69 programme theories). Discussion during the "tidying up" stage contributed to a review of these areas, resulting in the emergence of new groups of theories that linked together in a more appropriate and nuanced way (see appendix 16 for photos of paper versions of programme theories used in this discussion and analysis).

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Step 5: Synthesis resulting in middle-range theories

The final step involved a review of programme theories, with demi-regularities further identified between programme theories in the newly arranged groups. Following this, context, mechanism, outcome configurations (CMOC's) were explored in diagrammatic form, as this prompted helpful discussion and clarification of CMOC's, particularly the identification of resources and reasoning (Dalkin et al., 2015; Pawson and Tilley, 1997). Explanatory middle-range theories were thus identified, providing a level of abstraction that enabled the theories to be applied across all health conditions (broad context), whist still being relevant to specific cases (Westhorp, 2018; Rameses II Project, 2017b) (see appendix 17 for overview of programme theories and middle range theories following final stage of synthesis). The middle-range theories were therefore presented in both narrative and diagram form.

7.6 Conclusion

In this chapter I have outlined the methods used in the realist evaluation. I completed the planning and application for ethical approval during the COVID-19 pandemic, which impacted the study design. I started recruitment and data collection in May 2021 and completed it in March 2023, undertaking interviews online via Zoom. I commenced data extraction and analysis as soon as the first interview had taken place, using an iterative approach allowing me to apply learning from one interview to subsequent ones. The five-step process of data analysis and synthesis enabled me to test and refine the initial programme theories identified in the realist review and identify newly emerging theories. By analysing data from different sources, including people with a range of health conditions, people who supported them, and healthcare 160

professionals I was able to observe demi-regularities within the data and clearly document these to demonstrate trustworthiness and plausibility of results (Rameses II Project, 2019). I will present the results in subsequent chapters; chapter eight will provide an overview of the stakeholders who participated in interviews, and chapters nine to eleven will include results, with the refined middle-range programme theories available as diagrams alongside their narrative form.

Chapter 8

Stakeholders Participating in Interviews

In this chapter I will provide an overview of the participants (n=31); these individuals were stakeholders who engaged in interviews as part of our study. These participants provided conceptually rich data, contributing to the testing of initial programme theories, which led to the development of middle range theories relating to how access to preconception care and support for appropriate behaviour change to improve preconception health works, for whom, and how, when people have one or more health condition. Participants included women living with health conditions (n=20), their partners and supporting family members (n=2), and healthcare professionals providing preconception care in a variety of settings (n=9).

8.1 Recruiting participants using social media, charities, and other means

Recruitment and interviews took place between 1st May 2021 and 31st March 2023. Posting on social media and emailing relevant charities took time, so allocating time to undertaking this on a regular weekly (or two-weekly) basis was necessary. Agreement from participants mainly followed updated posts or information from charities, resulting in the receipt of consent forms via the Jisc survey. Interviews were then set up and calendar invitations sent out for mutually convenient times (for both participants and researcher). The UK was still experiencing waves of COVID-19 infections during this time, with tiered lockdowns until July 2021, many people working from home, and delays in accessing routine healthcare (Industrial Injuries Advisory Council, 2022); this added a layer of complexity to recruitment.

8.2 Participant characteristics

8.2.1 Women living with health conditions

Following recruitment via charities and social media, as outlined in the previous chapter, 21 women living with health conditions gave consent to be interviewed. Of these, one (W16) did not respond to the initial invitation to an interview, nor two subsequent polite reminders offering alternative times and dates for an interview. A total of 20 participating stakeholders, therefore, were included in this group. As shown in Figure 9, this included women living with a range of physical and mental health conditions, including depression, anxiety, epilepsy, cardiac, auto-immune, multiple sclerosis (MS), obesity, type 1 diabetes, marfans syndrome and systemic lupus erythematosus (SLE).

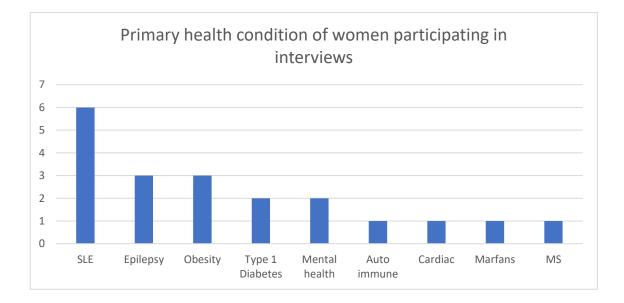
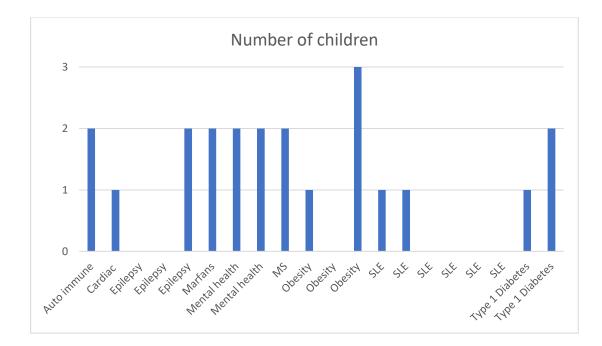


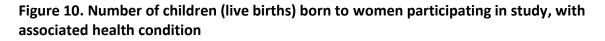
Figure 9. Number of women participating in the study experiencing each health condition

Where women were living with one or more health condition, their primary condition

is indicated.

At the time of the interview, seven women did not have any children (live births), five had one child, seven had two children and one had three children (see Figure 10 below).





Nine out of the 13 women who had children, had also experienced pregnancy loss at some point, and one woman who had no children was waiting for fertility treatment. All of these situations provide examples of some of the different and interacting contexts in which preconception care and support may be needed, offered, or accessed, and are therefore important factors that may contribute to causal explanations (expressed in programme theories).

Geographical location of women living with health conditions who participated in interviews was wide, facilitated by the use of Zoom. This included one participant living in Switzerland (originally from the UK), one in Northern Ireland, one in the Northeast of England, one in the North West of England, two in Yorkshire, one in the East Midlands, one in London, three in the South East of England, six in the South West of England, and three in Wales (see Figure 11 below).

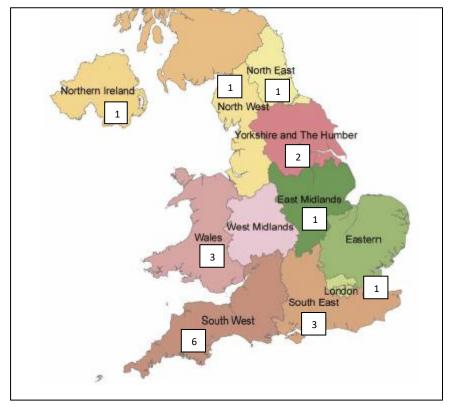


Figure 11. Geographical location of women participating in interviews

Location can also provide different contexts for preconception care and support due to variations in provision, distance, transport links and a range of other factors.

All participants described themselves as white British; there was therefore no ethnic variation within the group, despite advertising the study with charities supporting black mothers and highlighting the importance of including women from a range of ethnic backgrounds in social media posts. This context is important in relation to the findings. A different approach to recruitment may be required to reach specific cultural groups and identify what works for them and how, in relation to preconception care. Participants' highest educational achievements ranged from GSCE's (level 2) to PhD (level 8) (see Figure 12). Whilst most had achieved an undergraduate degree or higher, there was a range within the sample so context related to educational achievement could be considered.

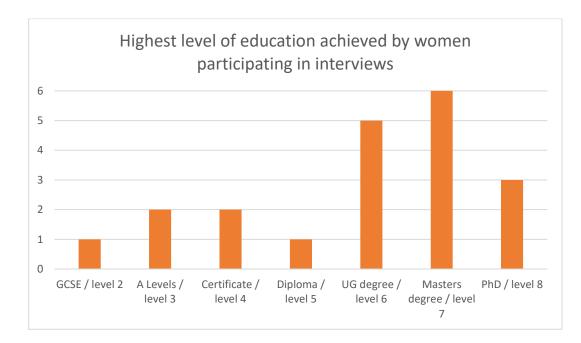


Figure 12. Highest level of education achieved by women participating in study at the time of their interview

8.2.2 Partners and supporting family members

Using recruitment via charities and social media resulted in no partners, or supporting family members, consenting to take part in this study. Despite discussing the importance of obtaining data from this group with all participating women living with health conditions, only one partner (of a woman living with type 1 diabetes) gave consent and participated in an interview. One supporting family member also gave consent and participated in an interview, having heard about the study via word of mouth. This person had a daughter living with cystic fibrosis (who did not participate herself). Two participants, therefore, contributed to this group; both lived in the

Southwest of England. Data from the one partner who was interviewed, suggests that difficulty recruiting this group may be because partners under-estimate the significance of their contribution, despite the importance (to women living with health conditions) of their support.

"I didn't go to any of the pre-pregnancy stuff, because that was just between her and her diabetes team ... I had no involvement with the medical staff before she was pregnant ... but obviously a lot of support with X herself. So, it was definitely emotional support and talking about it and listening, and everything." (P2)

8.2.3 Healthcare professionals

Following recruitment via social media and sharing information about the study at conferences and with colleagues, ten healthcare professionals consented to take part in this study. Sampling was purposive in that different healthcare professionals were sought through these recruitment sources, with a particular focus on general practitioners at a point where none had responded. This was successful, as the final sample included a wide range of healthcare professionals. Of these, one (HCP2) did not respond to the initial invitation to an interview, nor two subsequent polite reminders offering alternative times and dates for an interview. Nine healthcare professionals were therefore included in this group. All healthcare professionals provide preconception care in some form, and their professional roles included general practitioners (doctors) (n=3), practice nurses (n=2), a midwife, a dietician, a psychiatrist, and an epilepsy nurse (see Figure13 Below).

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The geographical location of healthcare professionals who participated in interviews was wide, facilitated by the use of Zoom for interviews.

This included one participant in the Northwest of England, one in Yorkshire, one in London, two in the Southeast of England, and four in the Southwest of England (see Figure 14 below).

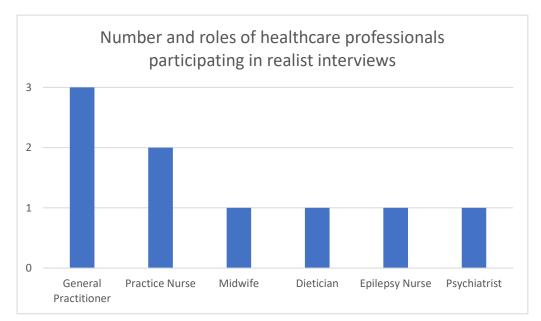


Figure 13. Number and roles of healthcare professionals participating in interviews

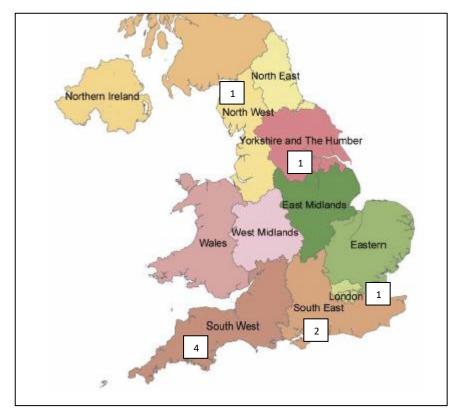


Figure 14. Geographical location of healthcare professionals participating in interviews

Most healthcare professionals participating in interviews described themselves as white British, with one from a country in the European Union; there was therefore very little ethnic variation within the group of healthcare professionals. Some participants, however, worked with people living in poverty and experiencing homelessness. This provided rich data from an operational perspective, regarding the impact of socio-economic contexts in relation to how and why preconception care works, or doesn't work, among different groups.

8.3 Conclusion

In this chapter I have provided an outline of results from recruitment, including key demographics of stakeholders who participated in interviews. The range of participating stakeholders was sufficient to provide information about contexts mechanisms and, or, outcomes needed for me to test and refine programme theories (Rameses II Project, 2019). Despite having sensitively targeted people from minority ethnic groups through appropriate charities, I was not successful in recruiting from these groups, and the timeframe of my PhD study did not permit me to pursue further sensitive and time-intensive recruitment strategies. This is, however, an important area for further research.

I was able to demonstrate rigorous recruitment, however, including targeting people living with specific types of health conditions and healthcare professionals with specific roles when required. I achieved this by regularly and iteratively reviewing participant characteristics as theories were tested and refined (Rameses II Project, 2019). One example includes consideration of people living with obesity; at one point there were no participants from this group, so I contacted the "Big Birthas" charity via email and they kindly agreed to post information about the PEAcH study on their website. This resulted in a response from three women living with obesity who agreed to participate in interviews.

Although participants gave consent to be contacted and re-interviewed to explore contexts and mechanisms more extensively, this was not required. I identified that data from interviews with all participating stakeholders were sufficient to demonstrate demi-regularities and triangulate the results. I was thus able to identify causal explanations that I could apply across different groups, resulting in novel and

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important middle-range theories about preconception care for people living with health conditions. I will present these programme theories in the subsequent results chapters (chapters nine, ten and eleven)

Chapter 9

Results, Focusing on Information, Knowledge, and Beliefs

In this chapter I will present the first group of refined programme theories from the realist evaluation. In the realist review, I grouped the programme theories into three areas that I found to contribute significantly to both access and behaviour change in relation to preconception care, based on the relevant available literature. Having used and tested those as initial programme theories, through analysis and synthesis of data gleaned from interviews in this realist evaluation, I re-grouped the refined theories into three more appropriate, nuanced, areas (step 4 of analysis and synthesis, outlined in chapter 7; also see appendix 11):

- Information, knowledge, and beliefs
- Therapeutic relationships, and
- Social structures and healthcare services.

The first of these areas relates to information, knowledge, and beliefs; this includes knowledge and beliefs of healthcare professionals, people with health conditions and the wider public (see Table 10).

Table 10. Refined programme theories and subsequently refined middle-rangeprogramme theories regarding information, knowledge, and beliefs

Refined programme theories regarding information, knowledge, and beliefs	Refined middle-range programme theories (information, knowledge, and beliefs)	
1.1.1 HCP knowledge of SRH and PCC	1. Healthcare professionals'	
2.3.3 Beliefs about pregnancy planning - accurate	knowledge and holistic approach to people with health conditions	
2.3.3.1 Beliefs about pregnancy planning - inaccurate		
1.1.1.2 Holistic approach to care facilitates PCC		
3.1.1 SRH and PCC as part of routine review		
3.1.1.1 (N) Consideration of SRH in condition usually affecting older people		
3.2.6 (N) Opportunistic PCC in primary care		
1.3.3 Ask a specific question about wanting a baby		
1.2.1 Alternatives to face to face	2. Using information available online	
1.2.2 App for ongoing monitoring	or via mobile apps to facilitate partnership working and a personalised approach	
1.3.1 Accurate information	3. The importance of accurate	
1.3.1.1 Accurate information helps a person feel in control and reduces less anxiety	information	
1.3.1.2 Impact of inaccurate information		
2.3.1.1 Inaccurate beliefs about contraception		
2.1.1 Self-belief or self-efficacy		
2.1.3 Anxiety or fear		
2.2.4.1 PCC NOT normal	4. Unhelpful social norms and	
2.3.1 Inaccurate beliefs about fertility	inaccurate beliefs	
2.3.5 (N) Pregnancy planning a taboo		
2.3.8 (N) Desire to have a baby		
2.4.2 (N) Negative messages about SRH from school		

The initial programme theories that I tested and refined, in this area, mainly originated from sub-groups related to both "the intervention" and "people's beliefs". The numbering of each programme theory in Table 10 above and the results below indicates the origins of the initial programme theories as demonstrated in the diagram below (Figure 15), with new theories emerging from the realist evaluation identified by the addition of the letter N: (N), providing transparency regarding this process.

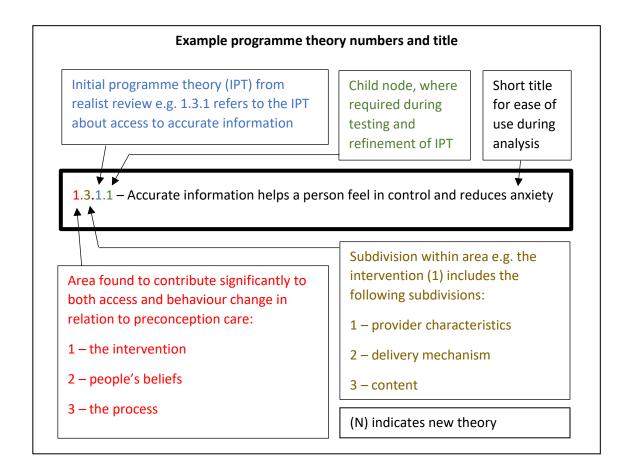


Figure 15. Explanation of numbering system for initial programme theories

I will present each refined middle-range programme theory below, in narrative form and as a diagram, with context, mechanisms (both resources and responses), and outcomes identified. Results from the interviews, providing evidence supporting each refined programme theory contributing to the refined middle-range programme theory will then be presented. The diagram clearly demonstrates the application of realist methodology and use of context, mechanism (resources and responses), and outcome configurations, in pursuit of programme theories that provide causal explanations of what works, for whom, and how. Evidence includes direct quotes from interviews, identified contexts (C), mechanisms (M) and outcomes (O), contextmechanism-outcome configurations (CMOC's), and brief thought processes contributing to analysis and synthesis leading to the refined programme theories.

9.1 Healthcare professionals' knowledge and holistic approach to people with health conditions

Each of the eight refined initial programme theories presented below operate within the context of people of reproductive age seeking care regarding their health conditions. These programme theories therefore relate to opportunistic preconception care, which can be accessed if healthcare professionals have appropriate knowledge and apply a holistic approach to people with health conditions. Combining and abstracting the eight programme theories resulted in one middle-range programme theory: When a person of reproductive age is newly diagnosed with a health condition or has a review of their health condition that may include a medication review (context) ...

If their healthcare professional has condition specific sexual and reproductive health, and preconception care knowledge, a clear understanding of what is meant by pregnancy planning, and asks the direct question "do you want to have a baby in the next 12 months" (mechanism; resources) ... and if they understand the importance of taking an holistic view of people of reproductive age, which includes sexual and reproductive health (mechanism; reasoning) ...

Then the healthcare professional can offer individualised preconception care and the person living with a health condition has the opportunity to improve their preconception health (outcome).

The theory is also presented as a diagram (Figure 16):

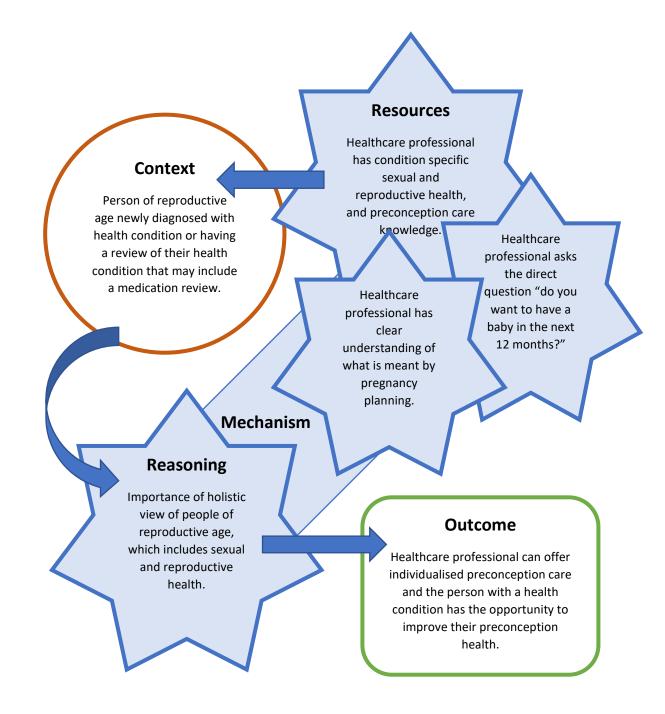


Figure 16. Programme theory 1: Healthcare professional's knowledge and holistic approach to people with health conditions

Evidence supporting the refined initial programme theories contributing to this refined

middle-range theory is presented below.

9.1.1 First programme theory contributing to refined middle-range theory

regarding healthcare professionals' knowledge and holistic approach to

people with health conditions

1.1.1 IF healthcare professionals (HCPs) have health condition-specific preconception knowledge and skills THEN they will be able to offer appropriate, individualised preconception care (PCC) including consideration of prescribing choices, to support people of childbearing potential improve their preconception health.

Contexts	Mechanisms	Outcome	Resulting context, mechanism, outcome, configuration (CMOC):
C1: Person newly diagnosed with epilepsy (at childbearing age), requiring medication	M1: HCP knowledge of medications recommended as safe in pregnancy	O1: HCP prescribes medication that is save during pregnancy (as first line)	People who have the potential to become pregnant can be newly diagnosed with a condition and / or require medication for their health condition. If
C2: Person (of childbearing age) with Marfans Syndrome requiring medication	M2: HCP knowledge of wider risks of health condition in pregnancy	O2: Person taking medication that is safe in pregnancy at point of discovering an "unplanned" pregnancy	the HCP prescribing first line medication has knowledge of drugs that are/are not safe during pregnancy, and knowledge of the wider risks of the health condition in pregnancy, then the HCP is able to prescribe pregnancy- safe medication (where possible) just in case of pregnancy despite the person not actively planning to become pregnant. If the person subsequently discovers an "unplanned" pregnancy, then they will be relieved that the medication they are taking to improve their health is also safe to take in the preconception (and pregnancy) period.
C3: Person with health condition not actively planning a pregnancy C4: Person with health condition (knowingly or un- knowingly) not using reliable contraception despite being sexually active	M3: HCP's (first line) prescribing choice safe in pregnancy "just in case" (despite the person not actively planning to become pregnant)	O3: Pregnant person relieved that they are on a medication that is safe in pregnancy, and that improves their health (in view of condition)	

The thought process involved in refining this programme theory includes issues around prescribing, and the fact that healthcare professionals may have prescribing choices when someone is either newly diagnosed with a condition or at a subsequent review. If the healthcare professional has knowledge of the wider risks of the health condition in pregnancy and knowledge of which drugs are (or are not) safe in pregnancy, then they may have the option to prescribe pregnancy-safe medication as a first-line treatment, as in the case of this person who was diagnosed with Epilepsy at the age of 14:

"I think if you're of childbearing age then the first medication to go to is this one." (W11; aged 34, living with epilepsy)

Even if people are not actively planning a pregnancy, they could (knowingly or unknowingly) not be using reliable contraception, despite being sexually active, and therefore have a chance of becoming pregnant. Therefore, prescribing pregnancy-safe medication for people with the potential to become pregnant can mitigate against unplanned pregnancy. More than one woman participating in interviews described discovering they were pregnant and being relieved that the medication they were taking to improve their health was also safe to take in the preconception (and pregnancy) period, this quote from a woman with cardiac problems due to Marfan's syndrome demonstrates this:

"I found myself pregnant, and it was a surprise it wasn't planned... it really wasn't planned ... I was so relieved, I felt like... Oh, my goodness! I cannot believe this. It cannot be true! But I just remember thinking, oh, thank goodness, she didn't try out this fancy-pants new drug, because then it would have been that awful decision ... maybe the baby, you know there's a there's a very real risk that they're going to be deformed or something, and then I think that would have been so traumatic!" (W21; aged 36 with Marfans syndrome)

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Evidence from several sources (W11; W15; W21; HCP4; HCP8, HCP9) contributed to the refinement of this programme theory, with one healthcare professional, a general practitioner, (GP) demonstrating that pharmacists can also contribute to providing preconception care whilst reviewing medication prescribed for various health conditions:

"We've got an in-house pharmacist doing a lot of our med reviews and she knows to ask the questions of women of reproductive age. And she will say, so if you are thinking about getting pregnant, then we probably need to optimize your asthma treatment. We probably need just to work a little bit more on your diabetes. We probably, you know, need to change this antipsychotic to this one, because it's probably safer for pregnancy. You know there are some clear opportunities to improve care, if your staff are thinking about them." (HCP9; GP working in Primary Care)

Additional thoughts regarding this programme theory include the fact that prescribing pregnancy-safe medication avoids the more time-consuming and potentially difficult conversation about contraception use, including either managing this within the medical specialty, or having timely and robust referral pathways for people to receive appropriate contraception and sexual health advice (see section 11.5 regarding programme theory about clear pathways and easy access to contraception). This programme theory also highlights the need for education of healthcare professionals.

9.1.2 Second programme theory contributing to refined middle-range theory

regarding healthcare professionals' knowledge and holistic approach to

people with health conditions

2.3.3 IF there is a shared understanding (between the person and clinician) of what is meant by "planning a pregnancy" THEN people have a greater chance of improving their preconception health in advance of trying to conceive. Contexts Mechanisms Outcome **Resulting CMOC:** M1: Accurate HCP 01: Informed choice C1: People with People with health epilepsy knowledge conditions, such as epilepsy, may take C2: People taking M2: HCP O2: Improved medications to control medication to experience of preconception their condition that are not control seizures health prior to women with recommended in that is not conception. complex pregnancy. Having open recommended in conditions that and honest conversations pregnancy have emotional with a HCP who has as well as physical accurate knowledge and impact experience of the condition, including the C3: Desire for M3: Open and O3: Person not purpose of preconception pregnancy honest taking teratogenic care, ensures they can conversations medication during offer appropriate support between HCP and pregnancy. and advice to improve person with preconception health. This condition facilitates informed choice and optimum health for both mother and baby.

This theory resulted from one interview (HCP1), with an epilepsy specialist nurse who

highlighted the importance of having a clear understanding of the purpose of

preconception care:

"The outcome is to know what the woman herself has as her own feelings and thoughts. One of the key things is around the amount of emotion that's connected to planning, and as well, some of the definitions about what planning's about.... The challenge is, are you someone who really feels that you are going to stop your medication, no matter what I'm going to tell you about what might be a safer medicine?" (HCP1; Epilepsy specialist nurse) Preconception care involves support to achieve stability of condition (improved preconception health) on appropriate medication (avoiding teratogenic medication) before conception; this may be very individualised (specific to the needs of that individual). This theory particularly relates to conditions involving medication, since some people might choose to stop medication as soon as they find they are pregnant; if they know this is what they will do, then they need to trial that before conception. Epilepsy is not the only condition which may involve teratogenic medication to achieve stability, but the condition carries a high risk to mothers, with the potential for sudden unexpected death due to epilepsy (SUDEP), that women and their families need to be aware of. One epilepsy specialist nurse highlighted the importance of having honest conversations with women to help them understand the purpose of preconception

care:

"Pregnancy is not a test zone ... so worst case would be that you have a bad seizure and it would kill you... we might lose you we might lose your baby; your partner and family are without you... that could be an outcome and it is an outcome for other women, so we talk about the SUDEP conversation." (HCP1; Epilepsy specialist nurse)

"I always ask the question "what would you do if you found yourself pregnant?" so the question there is to try and understand is this woman, no matter what I say, still in that view of "I will stop the medicine", because the challenge then is to say "let's do it now then!" Because whilst you're not pregnant I have not got you in pregnancy to be worried about, and if we are... you'll have to stop driving if you're driving... you need to approach that, you know it's not about you can just do it under the radar, there are ramifications in your life, and so there is a challenge there to the women ..." (HCP1; Epilepsy specialist nurse)

This particular interview also highlighted the role of a specialist nurse, and the time needed to effectively support someone with a complex health condition such as

epilepsy (see section 11.3 regarding multidisciplinary team approach to pregnancy

planning).

9.1.3 Third programme theory contributing to refined middle-range theory

regarding healthcare professionals' knowledge and holistic approach to

people with health conditions

2.3.3.1 If HCP's do not have a clear understanding of what is meant by "pregnancy planning" and do not provide accurate contraception advice THEN women requiring PCC from a specialist may be denied access to this (even if they know it is recommended) before becoming pregnant, reducing their opportunities to improve preconception health.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with heart condition	M1: HCP inaccurate knowledge regarding removal of contraceptive implant	O1: Reduced access to PCC (none from specialist)	People with health conditions are often advised to seek specialist advice prior to conception (PCC). If their general practitioner does not give clear advice about the
C2: Desire for pregnancy	M2: HCP lack of understanding of PCC	O2: no opportunity for behaviour change prior to pregnancy	purpose of this PCC and the need to continue contraception until any required improvements to
C3: Person aware of need to see specialist prior to conception	M3: HCP removed contraceptive before PCC appointment with specialist		preconception health are made, then this may prevent access to PCC due to pregnancy sooner than expected.

This theory resulted from one interview with a woman who had a cardiac condition from birth. She described how a GP took her contraceptive implant out at the same time as booking a consultant appointment for her. She knew that due to her cardiac condition she should seek specialist advice before becoming pregnant. The GP appeared to believe that the person would take a few months to conceive, but she became pregnant straight away, before the consultant appointment:

"I literally stopped it [contraception] had a period because I stopped taking it and then it was the week after that period that I then got pregnant, so it was within like the smallest amount of time. Like, I mean, that's not what the doctor told me!" (W12; aged 36, living with a cardiac condition) She was not given any advice about using alternative contraception, or waiting until

she had seen the cardiologist before she became pregnant; consequently she was

already pregnant when she saw the specialist:

"Actually no one really told me that I should be a bit more careful and wait another month or take precautions until I've actually seen the consultant. I wouldn't have been that blazee about it if I'd been told, you know. You know, you have to have this [cardiology] appointment before you start trying. I would have been careful and would have taken precautions, but they never did." (W12; aged 36, living with a cardiac condition)

"I kind of went in and she was like, Oh, OK, well, you're already pregnant now. So, you know, there's not really much we can do." (W12; aged 36, living with a cardiac condition)

Inaccurate beliefs on the part of the GP prevented this person from accessing

preconception care and achieving any required improvement in preconception health.

This was despite the person following advice to seek preconception care if they were

ever considering pregnancy.

9.1.4 Fourth programme theory contributing to refined middle-range theory

regarding healthcare professionals' knowledge and holistic approach to

people with health conditions

1.1.1.2 IF HCPs take a holistic view of people of reproductive age with health conditions, THEN they will be able to provide individualised care, including SRH and PCC advice, to support the people in their care make decisions regarding preconception health.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with Multiple Sclerosis (childbearing potential)	M1: HCP knowledge of SRH and PCC in relation to treatment of health condition	O1: Consideration of SRH and PCC impacts decision making regarding treatment of health condition eg appropriate medication choices	Whatever health condition a person has, their desire (all be it a future desire) to have / not have children may impact on decisions regarding treatment of the health condition, and vice
C2: Person with Epilepsy (childbearing potential)	M2: Knowledge and understanding of situation regarding health condition enables informed decision making (by the person) regarding SRH	O2: Treatment required for health condition impacts decisions regarding SRH and PCC	versa. A respectful, holistic approach by their HCP is therefore required, alongside knowledge of sexual and reproductive health in relation to the health condition and any recommended treatment. This ensures that there is consideration of SRH and PCC alongside decisions
C3: Person with Marfans Syndrome (childbearing potential)	M3: Respect for person – considers them in a holistic way	O3: Personalised care – in line with person's priorities / desires, including informed decision making.	made regarding treatment, and decisions regarding SRH and PCC can be made in view of the health condition. The overall outcome is personalised care, whereby the person's
C4: Person with Lupus (childbearing potential)	M4: Holistic view of people of reproductive age (similar to holistic	O4: Improved preconception health	priorities and desires are taken into consideration, and informed decisions can
C5: Desire to have children (at some point)	view of older people)		be made.
C6: People of childbearing age on medication			

This programme theory is not condition-specific, with contributing evidence from several interviews representing women with a range of health conditions as indicated above (W14; W15; W21; W4; HCP10); any health condition can have implications for sexual and reproductive health, including preconception care. People outlined how a holistic view enabled a more personalised approach and recognised that body systems are inextricably linked, as opposed to focusing just on the main part of the body or mind that the condition affects, which would generally exclude consideration of preconception care. One woman living with epilepsy expressed this eloquently:

"You're looked at holistically as opposed to just being someone with epilepsy, like being looked at as a person, who is dealing with epilepsy on the side ... So, what I see is the preconception ... like you, you get to the point where you're stable and healthy and also other factors are right, you know, because it's not just about epilepsy. Your life is more than that." (W15; aged 28 living with epilepsy)

As illustrated in these quotes from two women who expressed a desire to have

children, most participants had to ask about the implications for pregnancy, rather

than it being considered by their healthcare professional:

"... so that was at the forefront of my mind when I was having these consultations with the haematologist and the rheumatologist, so I mentioned it to them like will this affect like pregnancy and things because I'm really keen to try for a family. The rheumatologist took it on board but said, we need to get things under control first, so you can't start trying basically just hold off, and I think they did probably extra tests for me, because I was keen on the pregnancy." (W4; aged 32 with systemic lupus erythematosus (SLE))

"It was only when we started talking about treatment and chemotherapy and the MS nurses sort of saying, we don't know because it's so new, we can't tell you anything about what happens with having children ... that we seriously started then to think about it." (W14; aged 43 with multiple sclerosis (MS))

One healthcare professional, a GP working in primary care, however, highlighted that

people of reproductive age require a holistic approach to prescribing, in a similar way

to the need for a holistic approach when prescribing for older people; in this quote

they admitted to not putting as much thought into prescribing for younger people

compared with prescribing for older people:

"If you had, for example, a very elderly person sat in front of you, and you were talking about managing their blood pressure. It's sort of ingrained into us to think, actually, this is quite an elderly, frail person; they'll probably have, you know, high and low pressure. We don't want them to fall over, and so we think a lot more about the actual person sat in front of you; whereas, and I think this is sort of multi-faceted, but whereas for a younger person of reproductive age, firstly, generally, these appointments are on the phone, and so you're not actually seeing that person in front of you, which I think makes a bit of a difference; and secondly, because they are younger, we automatically think that therefore they're healthier, and so I don't think we put quite as much thought into the actual person at the end of the prescription; quite as much, probably. but that's wrong, we should do. But I think that's, I think probably we just don't think about it." (HCP10; GP working in primary care)

If it is possible to consider older people carefully and holistically when treating them,

then it is possible to do the same for people of reproductive age as well. When this

situation was explored a bit further, the GP highlighted that their training and

experience may contribute to this holistic approach to the care of older people,

whereas they do not think about preconception care for people of reproductive age in

the same way:

"It's probably ingrained from medical school and training that we, you know, consider that elderly person, probably in a bit more detail compared to a healthy, younger person of reproductive age. I think we have more contact with elderly people; generally, people who are young, we don't have much contact with, and if we do it's for, on the whole, quite an isolated issue. So, I think it's a combination of things really, but I think the primary issue is we don't think about it. I mean. That's just my opinion." (HCP10)

9.1.5 Fifth programme theory contributing to refined middle-range theory

regarding healthcare professionals' knowledge and holistic approach to

people with health conditions

3.1.1 IF individualised brief interventions about sexual and reproductive health issues, using the Health Belief Model (HBM), are a routine part of on-going care THEN people are more likely to be aware of the importance of preconception health, seek / access PCC, having considered key elements of the HBM and received 'cues to action'.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with	M1: making every	O1: raised	People with health
depression and	contact count (eg	awareness of	conditions need to be
anxiety	when discussing	importance of	aware of the
	contraception)	preconception	importance of
		health and	preconception health,
		availability of PCC	so that when they do
		when required	want to become
		(cues to action)	pregnant, they have
C2: Person with	M2: increased	O2: sought PCC	the opportunity to
Marfans	awareness of SRH	when needed later	access PCC and make
	/ PCC in view of		appropriate behaviour
	condition /		changes to improve
	medication		preconception health.
C3: Person with	M3: reality check	O3: improved	In some cases, this
T1 diabetes	(shock) for	preconception	awareness may lead to
C4: Person with	teenager by	health	improved health
Lupus (taking	highlighting		behaviours generally,
medication not	potential impact		and in other cases this
recommended in	on future		may act as a cue to
pregnancy)	reproductive		action that is not acted
C5 Person with	ability of not		on for a number of
cardiac condition	maintaining good		years.
	health		

Evidence to support this programme theory came from both women with health conditions (as indicated above) and healthcare professionals alike (W10, W12, W21, W2, W6, W7, HCP1, HCP10, HCP7, HCP9), with healthcare professionals providing triangulation and confirming that preconception care needs to be included as part of routine care. Knowing about the impact that a person's health condition may have on their sexual and reproductive health is important, so they can make informed choices regarding this area of their life. This relates to general health, medications, and

contraception, as well as pregnancy planning. Including preconception care in routine

appointments can provide "cues to action" for the future, even if the person is not

planning a pregnancy at the time, as demonstrated in these quotes:

"Yes, they always said to me if I was going to get pregnant to see the consultant before that happened. I think just to have like a general overall check. So, the plan was that was going to happen, and that appointment was all booked." (W12; aged 36 living with a cardiac condition)

"In every epilepsy review of a woman, you would want to make sure you had covered contraception, what drugs you're on, the implications for the choice of contraception, whether its on seizures (if it's lamotrigine) or the efficacy of the contraception (if you're on an enzyme inducer), or whatever, so just to put that in place." (HCP1; epilepsy specialist nurse)

"I was diagnosed when I was quite young. I was about 8, I think, and at some point it was on my radar that I knew that there was....There were things I should think about, were I to want to get pregnant, but it was kind of, you know, that was something that they'd said in a very appropriate age, appropriate way. It was kind of on my on my radar. I guess. I never felt like it was an inappropriate conversation, and they never pushed it. But it was that I I did know. Okay, I I should, I should be careful. And okay, I should, I should, you know, be aware of, like this condition is going to affect pregnancy in some way whatever." (W21; aged 36 living with Marfans Syndrome)

"When they were talking me through the medications that they were going to put me on, they said Okay, they took me through the side effects or you know, what they did, that kind of thing. And they said no, this drug you can't get, you shouldn't get pregnant on because of x,y,z... are you on any contraception, at the moment? Yeah, they were very thorough. Yeah, to be fair, I was at a private hospital, but I do still see the same rheumatologist now under the NHS. It was kind of, I don't know whether my experience, would have been the same had I gone straight into the NHS, I don't know. Obviously, you have a lot longer sessions, when you go private, and I used to go really regularly. I think the kind of you know, almost reassurance that this would be the plan, and it almost felt like, it wasn't going to be too complicated if that makes sense." (W7; aged 28 living with SLE)

The health belief module includes factors that contribute to choices regarding health

behaviour, including susceptibility to a condition, severity of condition, and self-

efficacy or belief in one's own ability to change a behaviour. For some people this is

effective, as described by this woman living with type 1 diabetes, who had been advised, as a teenager, that she may not be able to have children if she did not improve here blood glucose control (links with susceptibility and severity of condition in the health belief model):

"The thing that probably triggered me out of it [not maintaining good health as teenager] was that they said, if you carry on like this, you'll never going to be able to have children because you'll be you won't be controlled enough. To be able to have a safe pregnancy and even then, I knew that I would want children at some stage and I think just that it was it was a passing comment it wasn't like a big thing, it was a passing comment that really made me think okay I can't carry on like this, and that was probably when I was about 17. It was a reality check for me it, it was almost a bit of a snap to say right stop, you know, trying to pretend that it's not here; it is here and it's here for life." (W2; aged 29 living with type 1 diabetes)

Some healthcare professionals, however, highlighted the importance of self-efficacy.

Their experience of working with people from a range of socio-economic backgrounds

demonstrated that not everyone has self-efficacy, or the belief in their own ability to

change their behaviour; this also links with section 11.6 regarding preconception care

for people experiencing challenging socio-economic circumstances:

"you're still looking at that 50/50 probably or somewhere in that percentage of the women who really just don't engage, and we have people who don't come to clinic very often, you know, we don't really know where they're up to..." (HCP1; epilepsy specialist nurse) 9.1.6 Sixth programme theory contributing to refined middle-range theory

regarding healthcare professionals' knowledge and holistic approach to

people with health conditions

3.1.1.1 (N) IF HCPs are specialists in conditions that usually affect older people and do not take a holistic approach THEN they are unlikely to offer appropriate, individualised PCC, including SRH advice, to support the people of reproductive age prepare for pregnancy (improve preconception health), unless they are specifically asked for this.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with autoimmune disease	M1: lack of holistic approach to care	O1: PCC / SRH advice not routinely offered, reducing access to this	When a person has a condition that usually affects older people, the HCP may not be used to considering the impact of
C2: Person with MS	M2: HCP not used to seeing people of reproductive age	O2: Reduced ability to improve preconception health	this on potential pregnancy or sexual and reproductive health. If they do not apply a holistic approach, then PCC/SRH advice will not be offered, reducing the ability for the person to improve their preconception health.
C3: People with type 2 diabetes	M3: condition being seen in younger people now, but education package not "caught up"		

This theory is supported by evidence from people living with, or healthcare

professionals with experience caring for people living with conditions that may not be

common in younger people, as stated in the table above (W13, W14, HCP5). These

women felt that their healthcare professionals were not thinking about preconception

care for that reason:

"I think that's part of the problem because most people are diagnosed when they're in their 40s or 50s, so I think perhaps the target demographic isn't on their radar, and perhaps that's why they're not addressing it." (W13; aged 32 living with an auto-immune condition)

"Generally, a [typical] patient that has [specific issue], from what the nurses said weren't really in my demographic; they weren't really people that were going to be having children." (W14; aged 34, living with MS) Some conditions, such as type 2 diabetes, however, are becoming more prevalent within younger age groups, and this younger demographic requires consideration of preconception care. This was recognised by healthcare professionals during interviews, including a practice nurse working in primary care:

"You actually highlighted to me that there's a real gap in the education that we provide because we are diagnosing [type 2 diabetes], you know, I was diagnosing people that are in their early 20s. Historically all our patients were sort of 50 plus" (HCP5; practice nurse working in primary care) 9.1.7 Seventh programme theory contributing to refined middle-range theory

regarding healthcare professionals' knowledge and holistic approach to

people with health conditions

3.2.6 (N): If healthcare professionals working in primary care provide opportunistic preconception care when people with health conditions attend for any reason (eg contraception, smears, medication reviews) THEN people will receive accurate personalised information and holistic care, which they can use to improve their preconception health. This can be verbally, via printed information, or electronic links.

IITIKS.			
Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person	M1: Prescriber considers	O1: Access to	People with health
coming to GP	implications of	accurate,	conditions attend
for	medication in	evidence-based	primary care for a
medication /	preconception /	PCC	range of different
medication	pregnancy		reasons. If
review			preconception care is
C2: Person	M2: Holistic approach	O2: accurate	considered during
coming to GP		information /	these visits or
for		links that can be	appointments, then
contraception		sent to patients	opportunistic
C3:	M3: making every	for further	preconception advice
Opportunistic	content count	information	can be provided to
eg smear			ensure accurate
test.			information and
C4: People	M4: Ardens template		holistic care is offered
with obesity	provides an accurate		to people who need it
	evidence-based checklist		to improve their
	with links to NICE		preconception health.
	guidance		This can be verbally, via
	M4: Person can make		printed information, or
	informed choices about		electronic links.
	pregnancy planning		

This programme theory was supported by evidence from interviews with healthcare professionals (HCP10, HCP4, HCP5, HCP8, HCP9), all of whom worked in primary care and could see opportunities for the provision of preconception care as part of routine appointments:

"it's weaving it into all this stuff that goes on already … it's help with existing health conditions. Obesity, I think, is the biggest of them all, and medication,

which I guess comes under other health conditions." (HCP8; GP working in primary care)

"One of the things that we're counselling women on when they're starting medications is to talk to them about their plans for pregnancy and have that in the conversation from the beginning." (HCP8; GP working in primary care)

"I can't really think of anyone who has just sort of come to me and said, I want to talk about pre-conception care; it's often sort of been weaved in and integrated with a different presenting problem that they're coming to us with." (HCP10; GP working in primary care)

" the whole making every contact count, you know, just anything we could jump in at any opportunity really, so for diabetes, we would see patients for the annual review. Definitely, the minimum of once a year, but for patients, with sort of, worse control, it be sort of three to six monthly." (HCP5; Practice nurse working in primary care)

Healthcare professionals recognised that a holistic approach to people of reproductive

age could include preconception care. They also had innovative solutions to provide

information to people regarding preconception care, including sending text messages,

involving the whole team, and asking a direct question about pregnancy intention (see

section 9.1.8 below):

"I can very easily send an accurx message; a text message to a patient, and so if I'm dropping in some preconception comments and anyone wants more information I won't go into detail, but i'll say i'll just text you a couple of links to look at and let them sort it out." (HCP8; GP working in primary care)

"The way we've done it at our practice, is to work around the MECC [make every contact count] approach, so that everybody knows. So, the receptionists know, the nurses know, the pharmacist knows, the well-being centre team, because we've got social prescribers. And for me, the standard question, the easy question, well, the one we've been working on is, are you planning on a pregnancy within the next 12 months, and that we based off some; we did some co-production work with our patients, but also, I think it's what they use in Holland isn't it.... and women will go "oh, I really don't want to get pregnant!" Well, OK then, what are you doing about it? If they say well, we're thinking about it. Okay. So what are you doing about the fags? What are you doing about your weight? What do you think about your meds, what are you doing about whatever...? And it just triggers... here's your folic acid... do your rubella titre..." (HCP9; GP working in primary care) The healthcare professionals interviewed were, however, interested in preconception

care, and keen to make every contact count, recognising that additional training was

required to ensure that their colleagues were also considering preconception care:

"You know there are some clear opportunities to improve care if your staff are thinking about them. So, you start with the [make every contact count] approach, then you do some more focused education." (HCP9; GP working in primary care) 9.1.8 Eighth and final programme theory contributing to refined middle-range

theory regarding healthcare professionals' knowledge and holistic approach

to people with health conditions

1.3.3 IF people with health conditions are asked the direct question: "do you want a baby in the next 12 months?" at regular intervals, such as each annual check-up (could be written or verbal) THEN pregnancy intention is easier to assess, and THEN appropriate preconception support and advice (including regarding contraception) based on response (yes/no/don't know) can be given.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with lupus C2: Person with diabetes	M1: Makes the person think about their personal pregnancy intention – "reality check" M2: Identifies need	O1: Opportunity to improve health prior to conception and pregnancy O2: reduced	People with health conditions may be advised to take mediation that is teratogenic. In this case, their pregnancy intention and use of contraception should be
	for PCC and/or contraception	likelihood of unplanned pregnancy	accurately assessed. Direct questions
C3: Person with marfans syndrome	M3: Enables clear follow up regarding PCC including	pregnancy	regarding pregnancy intention and use of contraception is
C4: Person requiring teratogenic medication	access to and use of contraception		required by the HCP, and these must be
C5: Person requiring behaviour change to improve health prior to pregnancy			followed up with clear PCC, including access to and use of contraception if
C6: Person thinking their contraception was effective, but in reality, it was not			indicated. This will provide the opportunity to improve health prior
C7: People with physical and mental health conditions in general (primary and secondary care)			to conception and pregnancy, and reduce the likelihood of an unplanned pregnancy.

This theory highlights the effectiveness of direct questions about pregnancy intention,

but these are not always used. Both women and healthcare professionals provided

evidence that contributed to this theory (W5, W9, W21, HCP1, HCP5, HCP7, HCP8,

HCP9), and evidence from women living with a range of health conditions (see table

above) suggested that they didn't mind being asked:

"I wanted to have children, so anyway, it was just like yeah, I'm not there yet thanks for reminding me and but apart from that no, I didn't mind them mentioning it." (W5; aged 38 living with SLE)

"At the appointments we get asked very direct questions anyway. Uhm. Yeah. And if someone says that they aren't planning, that doesn't necessarily mean that they're not taking proactive steps. So, I don't know. Also, I don't know if this is just how my hospital used to do it, but while waiting to go into an appointment, we were always given a list; paper thing to fill in, where we had to go through it. For me, I would be happy with that, that very direct question; ... Are you planning to have a baby? Are you using contraception? Just again to have it as part of that very regular dialogue." (W9; aged 42, living with type 1 diabetes)

"That [question] could easily form part of their annual review, you know exactly for both males and females. And then you can be targeting your recommendations as well. When you think about what their goals are. So, what do we need to work on in order to get you there? So, it does make perfect sense. Really." (HCP7; dietician, working with people with cystic fibrosis)

Some interviews with healthcare professionals provided evidence that they did not

always use direct questions; this GP acknowledged that there can be emotion attached

to the question, and it may not be easy to ask some people:

"I think there's just so much kind of emotional, so much attached to that really simple question of; are you thinking of having a baby in the next year. It's not just a simple yes, no, for a lot of people, and I think that's and it's... I think that's what makes us a bit, not reluctant about asking it, but not just wanting to drop it in, because actually for a lot of people that is a very big thing that they think about. For some people it's not." (HCP10; GP working in primary care)

Most healthcare professionals, however, appreciated the value of asking this direct question about pregnancy intention, because it can lead to appropriate conversations including preconception advice and support, as demonstrated in these quotes from a GP and practice nurse: "So, the effect should be that women think, Oh, maybe this is important. That's what you're hoping. You know, how have we got people to get their podiatry checks if they're diabetic... because they realize it's in their best interest. Yeah, so that's the way you've got to sell it. I'm not just being nosy. I'm just asking this because actually, I can give you some advice if you want it." (HCP9; GP working in primary care)

"It's got to be a much more open conversation at earlier times ... and you've got a reason to ask it when you're doing pill repeats or when you're doing contraception reviews or discussions, you know, because it means you're not gonna give depot to someone who says, oh, we want to get pregnant in 6 months. So, I mean, you've got an excuse, and it's just a simple question. And if they say, oh, no, we're not thinking about it for another couple of years, then it gives you that opportunity well look, you do realise that when you want to get pregnant then your risk will be higher unless you do something about your weight now... you can give people a bit of a health warning." (HCP9; GP working in primary care)

"it's always there for me as a practice nurse ... something that I will touch base with people who come in for anything ... just while you're here.... something that just kind of you know, the whole making every contact count just anything we could jump in at any opportunity really." (HCP5; Practice nurse working in primary care)

One woman with a cardiac problem due to Marfan's syndrome provided evidence of

the impact (outcome) of not asking a direct question about pregnancy intention, and

not following that up with an open and honest question regarding contraception,

which was an unplanned pregnancy. If she had had the opportunity to discuss

pregnancy intention and options for contraception (also links to section 11.5 regarding

access to contraception), she would have had the opportunity to improve her

preconception health:

"I just must have been lucky for a very long time to be honest. I just didn't understand that, you know, no one had had that conversation. I guess that's quite interesting in that the doctors were kind of saying we don't want to give you this drug in case you get pregnant. But then I found it hard to have any discussions about contraception with anyone, because that's not ... it wasn't really the remit of my hospital team, I suppose." (W21)

9.2 Using information available online or via mobile apps to facilitate partnership working and a personalised approach

The two refined initial programme theories contributing to the second middle range programme theory concerning information, knowledge, and beliefs are presented below. Each of these operate within the context of people with health conditions at the stage of pregnancy planning. Combining and abstracting the two programme theories resulted in one middle-range programme theory:

When a person living with a health condition wants to improve their preconception health and is able to use digital technology to access information online (context) ...

If the person accesses condition related information online or via a mobile app and discuss the information with their healthcare professional (mechanism; resources) ... and if the healthcare professional works in partnership with the person and clarifies and applies the information to provide a personalised approach (mechanism; reasoning) ...

Then the person living with a health condition is empowered to improve their preconception health (outcome).

The theory is also presented as a diagram (Figure 17):

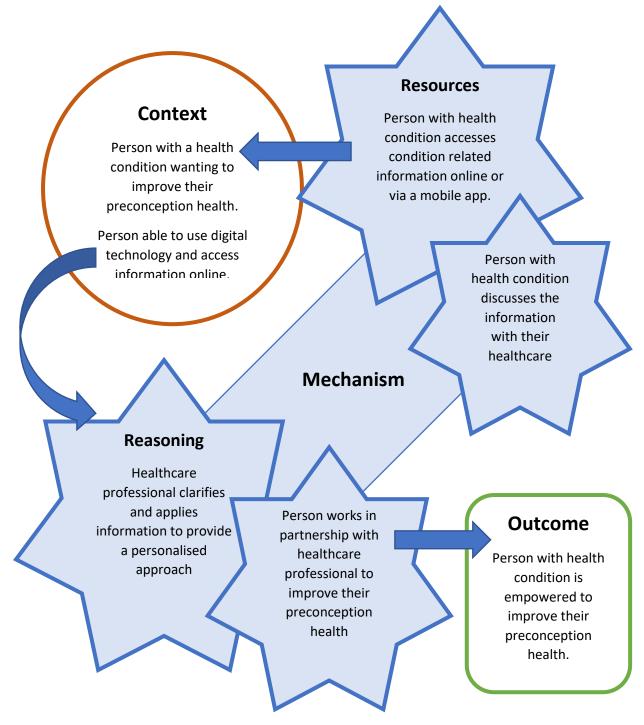


Figure 17. Programme theory 2: Using information available online or via mobile apps to facilitate partnership working and a personalised approach

Evidence supporting the refined initial programme theories contributing to this refined middle-range theory is presented below.

9.2.1 First programme theory contributing to refined middle-range theory regarding

using information available online or via mobile apps to facilitate partnership

working and a personalised approach

progress, which is both empowering and supports a personalised and partnership approach between the patient and their healthcare professional.				
Contexts	Mechanisms	Outcome	Resulting CMOC:	
C1: Person with depression	M1: Information seeking for increased knowledge	O1: Increased knowledge about condition (can take to HCP to apply to their situation)	People with health conditions often seek information from the internet (alternatives to face to face). If people are	
C2: Person with epilepsy	M2: Checking / clarifying / applying information to own situation through discussion with HCP	O2: cross- referencing information gained from internet and information provided by HCP	 well educated, this includes reading relevant research papers. By checking and clarifying the information through discussion with their healthcare professional, they are able to apply this to their own situation to increase their 	
C3: Person with diabetes	M3: Reading research papers	O3: Reassurance through using a range of sources of	knowledge, which can (in some cases) provide reassurance.	
C4: Person with MS C5: People educated in the UK with a Batchelors degree or higher		information		

Evidence contributing to the refinement of this initial programme theory came from

interviews with both women and healthcare professionals (W10, W11, W2, W14,

HCP10, HCP3, HCP8). The women with health conditions were eager for information

and identified that searching online can be beneficial, but also "terrifying", and

clarifying information with their healthcare professional was important to ensure it

was relevant and applied to them. This is demonstrated in the quotes below:

"I can sometimes find what I need through research online, but sometimes I want to have a conversation, because actually I might want to know... It could be anything, but I might want to double check, like, if I was taking any medication; I can read general advice, but it might not be relevant to me." (W10; aged 28 living with depression)

"I think rather than actually taking like a piece of paper and saying I found this, what do you think, I think it's more just like you know, just to understand what they're saying a bit more.... So, I know what that means, and I know the implications of that, but I can also clarify the implications with her." (W11; aged 34 living with epilepsy)

"Yeah, I found it really hard to do my own research, because I just couldn't find very much about it. So, it was really difficult. And then I'd sort of, you know, go on the old Google and terrified myself a little bit by looking at the people's stories and things, but then I would email her and be like, this happened to this lady in America; is it going to happen to me? And she'd say... I don't have a crystal ball. However, at present, it doesn't seem like that's going to happen to you." (W14; aged 34, living with MS)

Healthcare professionals mentioned resources that they might direct people with

health conditions to, offering a partnership approach and recognition that people have

agency but may find a recommendation or professional endorsement helpful:

"I think the Tommy's, you know, "get ready for pregnancy" is really good ... I think it's fantastic. It's just getting that to the people who need it" (HCP10; GP working in primary care)

"I might say, if you want to come back and talk about it some more than make an appointment with our practice, nurse. But I'm more likely to say, you know, get the Michael Mosely book, or you know; look into it, you know. Look on the NHS website about how to lose weight. I'm not trying to create more work for primary care, because people don't need a doctor to tell them how to lose weight, and as you say, lots of people try to lose weight and fail, but it's not necessarily ... We can't ... primary care can't solve the world, unfortunately, and I don't think we can... we haven't got the time to go through in detail for everybody. But there is ... it is available, you know. I would certainly say to people, yeah, you know, if you want to come back and talk about it some more, come back and see me, or make an appointment with the practice nurse, and we can talk about it some more." (HCP8; GP working in primary care) 9.2.2 Second programme theory contributing to refined middle-range theory

regarding using information available online or via mobile apps to facilitate

partnership working and a personalised approach

1.2.2: IF the intervention provides an application (app) for monitoring a condition / progress during the preconception period THEN women are able to discuss this with their HCP and make shared decisions about adjusting and monitor the effects of their behaviour change and also be encouraged or act on this information to improve preconception health.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with diabetes, higher than desired HbA1c levels C2: Aware of	M1: Discussion and partnership approach to care M2: Continuous	O1: Appropriate adjustment of medication O2: Improved stability	People with diabetes and a higher than recommended preconception HbA1c level may be aware of the need to improve their health prior to conception, but unsure how best to achieve this or find it
need to improve health prior to conception, but unsure of how best to achieve this / find it difficult to achieve this	glucose monitoring providing ability to automatically monitor and view of glucose levels on an App (seen by person)	in glucose levels (and lower HbA1c levels)	difficult to achieve this despite a desire for pregnancy. With a partnership approach between the person and their HCP, the ability to automatically monitor and view of glucose levels on an App (CGM - seen by person),
C3: Desire for pregnancy	M3: Ability to transfer data re glucose levels to specialist HCP (easy, without need to attend)	O3: Improved health prior to conception and subsequent pregnancy. i.e. facilitates effective behaviour change through increased knowledge.	and the ability to transfer data re glucose levels to specialist HCP (easily, without need to attend), appropriate adjustment of medication can be made. This facilitates effective behaviour change through increased knowledge, specifically, improved stability in glucose levels (and lower HbA1c levels), leading to improved health prior to conception (and pregnancy).

Evidence from just one interview with a woman living with type 1 diabetes contributed

to this refined initial programme theory (W2). It was included, however, since there

will be other people in a similar situation, and this theory highlights how digital technology can contribute significantly to improved preconception health. This woman found a continuous glucose monitor and associated app invaluable for her, and her healthcare professional, to understand what was happening with her blood glucose levels over a 24 hour period and intervene to improve her preconception health:

"The continuous glucose monitor absolutely rescued my plans of being able to get pregnant, I would not have been able to get my HBA1C down low enough." (W2; aged 29 living with type 1 diabetes)

"I know that the CGM was a big part of my preconception care because that enabled me to understand ... basically what it showed was that, where the problems were lying was particularly overnight. it's a tool isn't it rather than the solution." (W2; aged 29 living with type 1 diabetes)

The monitoring app shows changes in blood glucose levels across 24 hours, so identifies specific periods of high and, or low blood sugar. Sharing this remotely with the healthcare professional facilitated a fast response, and discussion between the person and their healthcare professional, demonstrating how a partnership approach enabled effective changes in medication. The app also shows improvement, so provides positive feedback to effective change, which also provides a level of

motivation to the person:

"We look through it together and she said, you know, this might be this ...is there a reason for that or is that just how it is and it's very much it's a conversation, rather than a dictation. And, and I think that I appreciate massively that". (W2; aged 29 living with type 1 diabetes)

9.3 The importance of accurate information

The six refined initial programme theories contributing to the third middle range

programme theory concerning information, knowledge, and beliefs are presented

below. Each of these operate within the context of people living with health conditions at the stage of considering or pregnancy, which may cause them anxiety. Accurate information contributes to a causal explanation of how and why people living with health conditions are able to access preconception care and improve preconception health in each of these initial programme theories. Combining and abstracting the six refined initial programme theories resulted in one middle-range programme theory:

When a person living with a health condition has a desire for pregnancy (either first or subsequent) they may be anxious about pregnancy planning (context) ...

If the person can access accurate and personalised information about their condition and themselves (verbally and in writing), has knowledge of the potential health threats to themselves and their future baby, and has time to discuss and explore possible outcomes of different decisions with their healthcare professional (mechanism; resources) ... and if the person is motivated to optimise health of themselves and their future baby and has an Increased sense of control and feeling of self-efficacy (mechanism; reasoning) ...

Then the person living with a health condition will experience reduced anxiety, the ability to make informed decisions, and the potential to improve their preconception health (outcome). The theory is also presented as a diagram (Figure 18):

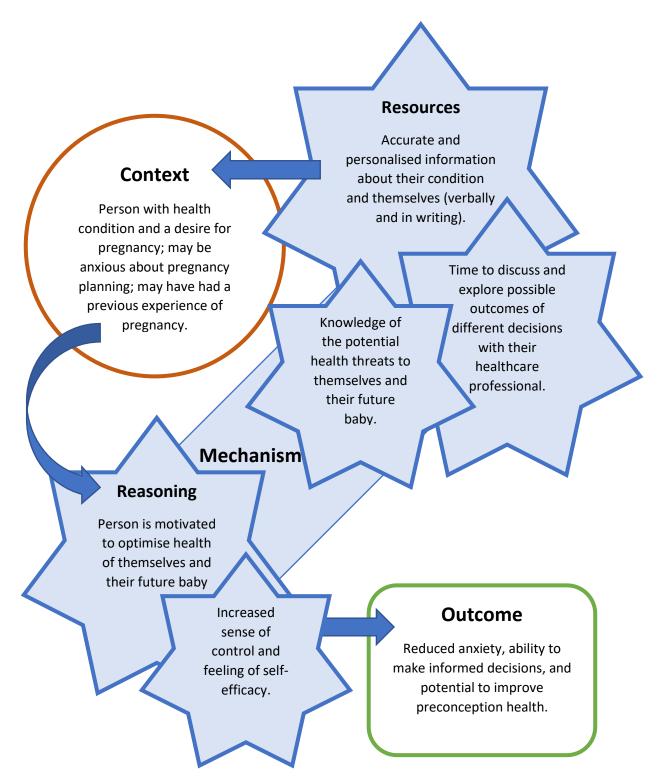


Figure 18. Programme theory 3: The importance of accurate information

Evidence supporting the refined initial programme theories contributing to this refined

middle-range theory is presented below.

9.3.1 First programme theory contributing to refined middle-range theory regarding

the importance of accurate information

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1.3.1 IF people have access to accurate information and therefore have good						
knowledge about pregnancy risks and benefits of improved preconception health,						
THEN they will have a more accurate perception of personal threat to themselves						
and their unborn child, and THEN they can make an informed decision about						
	appropriate behaviour changes to improve preconception health.					
Contexts	Mechanisms	Outcome	Resulting CMOC:			
C1: Person with depression	M1: Having accurate and personalised information about their condition and themselves	O1: Informed decision-making regarding behaviour change before becoming pregnant	People with a range of health conditions who are considering or have a desire for pregnancy want to know about their condition and the implications for pregnancy. Having			
C2: Person with epilepsy	M2: Exploring possible outcomes of different decisions, including potential threats to themselves and their future baby	O2: folic acid pre-conception (appropriate dose)	accurate and personalised information about their condition and themselves enables them to explore possible outcomes of different decisions, including potential threats to			
C3: Person with obesity C4: Person with diabetes C5: Person with lupus C6: Considering or desiring pregnancy C7: Desire for knowledge about their condition and potential implications for pregnancy	M3: Discussion with HCP		themselves and their future baby, through discussion with their HCP. This knowledge enables them to make informed decisions regarding behaviour change before becoming pregnant, including taking the recommended dose of folic acid, and/or continuing with contraception until improved preconception health.			

Evidence from women living with a range of health conditions (W10, W11, W17, W2, W3, W4, W6, W9) contributed to this programme theory, which links to the health belief model. One health care professional (HCP6) provided evidence triangulating this evidence. Accurate information may include difficult information about risk, but interviews with people living with health conditions demonstrated that wanted to

know, as this example shows:

"I think not knowing just how risky it was, I perhaps wouldn't have taken it as seriously. I don't know. I'm quite a stickler for rules and regulations anyway. But knowing that it could involve death, that's something that I think is it is crucial to know." (W9; aged 42, living with type 1 Diabetes)

Information about personal risks, or threats, formed part of both motivation and

decision making. Having agency and making informed decisions was also seen as an

important right by people contributing evidence to this programme theory:

"So, it was it was much, much better and I felt much more confident being under the care of those guys as well and hear directly from them about what my personal risks were overall, it was definitely a really good thing to help me kind of make the decision about definitely wanted to try for a baby really and the right way to do it kind of what to do and what not to do." (W4; aged 32, living with SLE)

"You know, what is the chance it's going to happen to you? Let us be the ones to decide if we want to put our own bodies through that ... Give us the knowledge, but don't try and influence our decision like, and like we said before, if you've decided that you want to become a parent, they could tell you that anything's going to happen to you. But if you've decided you're going to do it, you're going to do it regardless. It doesn't matter like. But it's better to have that information before, and go in open minded, or at least with your eyes open." (W17; aged 33, living with obesity and type 2 diabetes)

People spoke about their need to discuss the information and ask questions to gain

understanding and make informed decisions:

"I guess they had all the information they had like lots of my test results and things like that and I certainly was able to ask questions predominately they gave me a lot of information, and then I could ask questions if anything I wasn't sure about or what that meant, for me kind of thing." (W4; aged 32, living with SLE)

One healthcare professional, a midwife specialising in preconception care, provided

evidence of a general lack of knowledge amongst the women living with health

conditions that she had seen, as well as recognition of the value of information to

enable informed choice and improved preconception health:

"So, of the women I saw I think less than ten percent were already taking folic acid. Um! Ninety percent of them needed high dose folic acid, and they weren't even on a lower dose, so by the end of the appointment one hundred percent of them were prescribed, and when followed up, they were all compliant with taking the folic acid, so that worked um, and I was surprised by how many of them who, you know they're obviously planning a pregnancy, and they didn't know they needed to take it." (HCP6; midwife specialising in preconception care)

"In the appointment they have the information verbally discussed, which gives them an opportunity for you know that two-way conversation; we would ask those open questions to assess their understanding and confirm that they understand afterwards as well. So, they have it verbally. Then they are sent home with written documentation of all of that, plus a letter specific to them with any additional things. So, then they've got it visually that they can then refer back to you as well." (HCP6; midwife specialising in preconception care)

9.3.2 Second programme theory contributing to refined middle-range theory

regarding the importance of accurate information

1.3.1.1 IF people have access to accurate information and therefore have knowledge about pregnancy risks and benefits of behaviour change before pregnancy THEN they have an increase in feelings of control and THEN they are less anxious (about the unknown)

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with depression C2: Person with	M1: information / knowledge (resource) M2: Sense of	O1: reduced anxiety O2: Informed	People with a range of health conditions who are considering or have a desire for pregnancy may
epilepsy	control from greater awareness	decision-making regarding	be uncertain about the implications of their health condition on pregnancy
PCOS and obesity	-	behaviour change before becoming	(and vice versa). Where they only have anecdotal
C4: Person with Lupus		pregnant	information or opinion to go on, they will seek
C5: desire for a pregnancy			evidence-based information and this knowledge will facilitate a
C6: desire for evidence-based information			sense of control through greater awareness, which will reduce anxiety and
C7: Uncertainty and anecdotal information / opinion			enable informed decision- making regarding preconception behaviour change.
C8: people with mental health issues			

Evidence supporting this theory came from people living with a range of conditions (see table above) who were still seeking accurate information as well as those who had accessed support and information, which had helped reduce their anxiety (W3, W6, W7, W8, W10, W11, W20):

"For me, I think it's less stressful because I would much rather know what all of the options are and be prepared..." (W11; aged 34 living with epilepsy) "Well, I'd just feel a bit more comfortable about it all, and less anxious, I guess, and you know the anxiety 'n' stuff doesn't help getting pregnant so, yeah, I'd just feel a bit more supported really rather than just like well I don't know." (W6; aged 32 living with SLE)

"Yeah it's just understanding it a bit better, so you know what you're doing, and you don't need to worry as much ...and if, you know... I think if I had a bit more information it would help me make a decision about what I want to do." (W8; aged 31 living with SLE)

Evidence from a psychiatrist who provided preconception care to women with severe

mental health conditions (either current or historical) (HCP3) provided triangulation of

this evidence, demonstrating their understanding of the role of information,

understanding and planning in reducing people's anxiety:

"I think that the drivers that they can ease the anxieties in such cases. First of all, it's knowledge. All of this information that we give to people and all the resources that we ask them to research online. Also planning as well and they having this in writing that they can share with other professionals, with their GP, that they can sit down with their midwife in the future. OK. This is also something that I think that is very helpful." (HCP3; psychiatrist working in perinatal mental health)

9.3.3 Third programme theory contributing to refined middle-range theory

regarding the importance of accurate information

1.3.1.2 IF women are provided with inaccurate information resulting in unplanned pregnancy and/or fetal abnormality THEN they lose trust in their HCP, have feelings of guilt and anxiety, and are less likely to comply with future recommendations.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with epilepsy C2: Poor outcomes	M1: Daily reminder of impact as child affected by AED's M2: loss of trust	O1: feelings of guilt and anxiety, O2: poorly controlled	A person with a health condition (epilepsy) who has previously been given inaccurate information and false reassurance by a HCP,
due to being on Sodium Valproate and HCP giving false reassurance (child with long term health needs)	in HCP	Epilepsy	resulting in poor obstetric outcomes, will have to live with these outcomes for the rest of their life (this may include caring for a child with long term health needs due to the impact of
C3: Previous stillbirths (x2) due to being on AED's and HCP giving false reassurance		O3: not inclined to follow advice regarding taking AED's in preconception period/pregnancy	AED's). If they continue to feel that their HCP does not listen to them, then they will lose trust in their HCP and will have feelings of guilt and anxiety,
C4: Does not feel HCP listens to them			of guilt and anxiety, alongside a poorly controlled health condition (epilepsy). They will also be less inclined to follow HCP advice regarding taking AED's during any subsequent preconception period / pregnancy.

Evidence for this programme theory came from just one, very powerful interview with a woman living with epilepsy (W19), who had received inaccurate information that gave her false reassurance. She took Sodium Valproate throughout her first pregnancy and her son was affected. The outcome for her was guilt, and she had lost trust in healthcare professionals: "I live with the guilt constantly. Um, because I I done that, you know I wasn't given the information, but I almost feel like I should have known better. I should have done more research, and I live with a constant guilt that I chose to take those medications to control my seizures. But at the same time, I've done that to him. It is a really vicious cycle, living like that, you know. But you know. What can I do? But when you've got health professional saying to you?" (W19; aged 35 living with epilepsy)

"I was like I don't trust you. You know, you told me they were safe, you told me that they were the safer ones, you know. They don't know what they're talking about; you know, they've told me, you know, these are the safest and taking folic acid is going to make them even safer. And this is what's happened." (W19; aged 35 living with epilepsy)

"...so, I just decided no, I'm not taking medication at all. I'd rather risk having seizures through my pregnancy than having that happen again." (W19; aged 35 living with epilepsy)

This woman's story was heart-breaking, but I felt that it was important to include her

evidence to demonstrate the responsibility that healthcare professionals have to keep

up to date with evidence-based information, and use it in their every day clinical

practice.

9.3.4 Fourth programme theory contributing to refined middle-range theory

regarding the importance of accurate information

2.3.1.1 IF people with a health condition have not had the opportunity to discuss contraception with an appropriate HCP, and their use of contraception is suboptimal THEN they have a greater chance of unplanned pregnancies without behaviour change to improve preconception health.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with health condition	M1: Lack of contraception / family planning support from any HCP	O1: unplanned pregnancy	People with a health condition may have inaccurate beliefs about contraception, either because of a lack of support from a health care
C2: Person practicing natural family planning (in accurately, with no support from HCP)	M2: Uncertainty regarding where to go for contraception advice M3: Inaccurate knowledge / understanding of natural family planning method M4: SRH not the "remit" of HCP that is specialist in the health condition	O2: No behaviour change prior to pregnancy to improve preconception health	professional (SRH not being the "remit" of the HCP that is a specialist in the health condition), uncertainty where to go for contraception advice, or gaps in knowledge. This can result in a pregnancy without having implemented behaviour change to improve preconception health; a missed opportunity. This can also cause the person (and partner) anxiety.

Evidence for this programme theory also came from just one interview with a woman who had been aware that she was living with a health condition (Marfan's syndrome) since she was a child (W21). Inaccurate beliefs about contraception and fertility, and lack of access to contraception advice (for a number of reasons; also see section 11.5 for related programme theory regarding access to contraception) contributed to the outcome, which was an unplanned pregnancy:

"I thought I understood my cycles, and I thought that I understood when and when you couldn't get pregnant. But the reality is, I didn't understand this. I just

must have been lucky for a very long time to be honest. because it was just all; yeah, when I look back on it, I'm like No, no, like that was your most fertile window. I just didn't understand that, you know, no one had had that conversation ..." (W21; aged 36 living with Marfan's syndrome)

9.3.5 Fifth programme theory contributing to refined middle-range theory

regarding the importance of accurate information

2.1.1 IF people are resilient, motivated, resourceful, and able to implement evidence-based tools and techniques for behaviour change (low neuroticism) THEN this increases self-efficacy and THEN they will be likely to seek PCC when planning a pregnancy and THEN they are more likely to comply with PCC advice (behaviour change) even if they experience emotional stress in the process

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: person with anxiety and PTSD following first birth experience	M1: Motivated by first birth experience / wanted to get it right this time (self – belief that they can)	O1: improved preconception health through accessing support needed and coming off medication	A previous pregnancy or birth experience that was not as good as it could have been, can motivate people with a health condition to improve their health prior to a
C2: person with marfans syndrome	M2: resourceful individual (educated, able to do own research) (self- efficacy)		subsequent pregnancy. In order to improve preconception health they need to have self-belief, be resourceful (self-efficacy) and have sufficient self- awareness to know when
C3: desire for second pregnancy (and improved experience)	M3: able to ask for help (self- awareness)		to and be able to ask for help. Self-referral to PCC from a specialist HCP (example of midwife-led clinic), can facilitate access
C4: people with health conditions (any)	M4: self-referral to PCC support		to PCC.

The individuals I interviewed were mostly well educated and highly motivated. This programme theory, supported by evidence from both women and healthcare professionals (W1, W21, HCP1, HCP6, HCP9) demonstrates the need for self-belief and

self-efficacy, as well as self-awareness, which can lead to improved preconception

health through conscious decision making:

"I didn't want to become pregnant again before I had more of a handle on it and I was confident that I was kind of managing it well. It was very independently lead; it was about me working out what I felt I would need to be in place ahead of embarking on another pregnancy. I think that because I waited so long before I considered having another child, to make sure that I was a stronger person within myself before that happened." (W1; aged 39 living with anxiety)

The two women who contributed evidence supporting this programme theory were

both planning a second pregnancy, which may be an important context or factor that

provided them with more information and, or additional motivation:

"I did feel like I did receive pre-pregnancy care for my second child, but that was only because I actively sought it out and was organized and knew that was what I wanted..." (W21; aged 36 living with Marfan's syndrome)

Healthcare professionals were aware that some people did not have the same level of self-belief or self-efficacy, and therefore did not effectively plan pregnancy:

"The women who are harder to reach are the women who don't plan their babies. The women who have no.... their connection between what I do in my day-to-day living has no collection with what I bring to the epilepsy clinic, so I wouldn't think to tell you that I'm in a new relationship and we stopped our contraception 6 months ago and we could be pregnant right now." (HCP1; epilepsy specialist nurse)

Information, however, was still recognised as the important element (alongside self-

belief and self-efficacy):

"We found that self-referral was so important because they need to want to be change their behaviour." (HCP6; midwife specialising in preconception care)

"I think most people think oh, Well. I won't get pregnant, or it's too hard to get contraception, or ... there's a real push against hormones at the moment, which I really can't understand. I think people have forgotten how difficult it was, for, you know, my mum's era. So, yeah, there's a lot of myths. There needs to be a big Myth Busting thing." (HCP9; GP working in primary care) 9.3.6 Sixth and final programme theory contributing to refined middle-range theory

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with SLE	M1: ability to raise the question with HCP	O1: seeking further support and PCC	When a person with a health condition requires medication change prior to
C2: requiring medication change prior to pregnancy	M2: trust in HCP		pregnancy, they may be anxious about the efficacy of a different medication on their health condition.
C3: anxiety about the efficacy of new medication on health condition	M3: time for discussion with HCP		The desire for pregnancy, however will motivate them to seek support and PCC, although this require the ability to raise the
C4: desire for pregnancy			question with a HCP that they trust, and time to discuss PCC with their HCF

regarding the importance of accurate information

This initial programme theory started out with the idea that anxiety and fear would prevent people seeking preconception care, but there was no evidence from any interviews to support that. Instead, evidence from people living with health conditions, with one woman living with SLE (W7) providing a quote below, showed that anxiety drove a desire to know more:

"One of the challenges is that, you know, that is quite a scary thing to come off medication that's kept you stable for five years. I guess that adds an extra dimension of anxiety around it; and, obviously, on top of that there's all of the anxiety of you're more likely to have a miscarriage if you've got lupus... You know, all of that stuff as well ... I've kind of only had really initial conversations so, yeah probably don't feel like I've had as much advice or proper conversations about it... you kind of have to almost push it a little bit." (W7; aged 28 living with SLE) There are links with this theory and continuity of carer, which can help when people need to have difficult conversations (see section 10.2 regarding the significance of continuity of carer).

These data refute the original initial programme theory (that anxiety would prevent people seeking preconception care); the refined theory is not really a strong theory in itself, with only one interview contributing evidence. Also, anxiety is a context for many people with health conditions; the mechanism could be more about trusting the healthcare professional, continuity of carer, and resources available (time, specialist support etc). This theory has been included here, however, as it shows that anxiety and fear does not necessarily prevent people from seeking preconception care.

9.4 Unhelpful social norms and inaccurate beliefs

The five refined initial programme theories contributing to the fourth and final middle range programme theory concerning information, knowledge, and beliefs are presented below. Each of these operate within the context of people with health conditions at the stage of considering pregnancy; for some people this can arise from a very strong desire to have a baby. Unhelpful social norms and inaccurate beliefs contribute to a causal explanation of how and why people with health conditions do not access preconception care and therefore may not improve preconception health, which can result in anxiety and guilt. Combining and abstracting the five programme theories outlined below resulted in one middle-range programme theory. In this case the outcome in the diagram is outlined in red as it is negative:

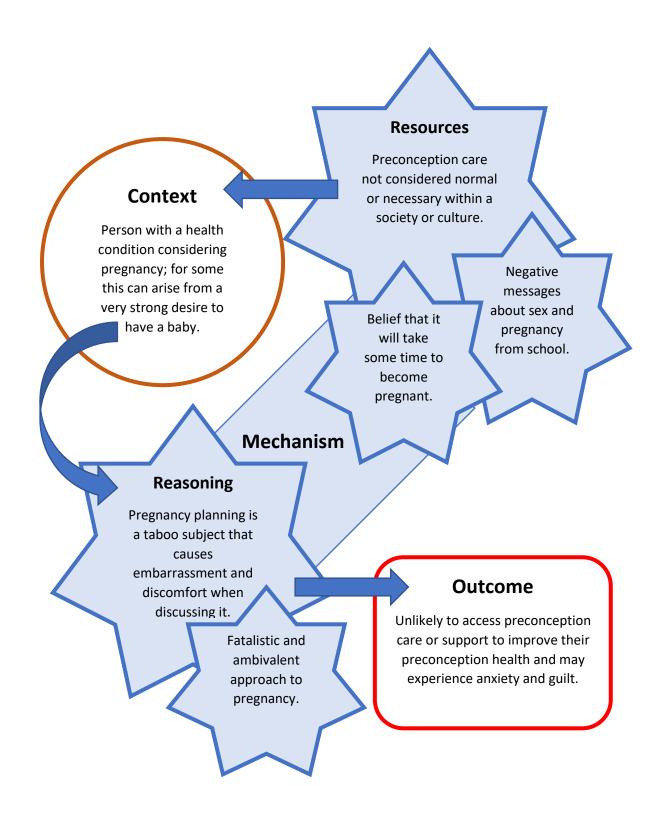
When a person living with a health condition is considering pregnancy, which for some can arise from a very strong desire to have a baby (context) ...

If preconception care is not considered normal or necessary within a society or culture, messages about sex and pregnancy are generally negative from school, and, or, the person believes that it will take some time to become pregnant (mechanism; resources) ... and if pregnancy planning is considered a taboo subject that causes embarrassment and discomfort when discussing it, and, or, the person has a fatalistic approach and ambivalence towards pregnancy (mechanism; reasoning)...

Then the person will be unlikely to access preconception care or support to improve their preconception health and may also experience anxiety and guilt (outcome).

The theory is also presented as a diagram (Figure 19):

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Evidence supporting the refined initial programme theories contributing to this refined

middle-range theory is presented below.

9.4.1 First programme theory contributing to refined middle-range theory regarding

unhelpful social norms and inaccurate beliefs

2.2.4.1 IF PCC is not perceived as normal (socially /culturally) THEN people will not consider PCC necessary; this includes HCP's as well as people considering pregnancy, and so THEN people will find it difficult to access appropriate PCC, support or advice and therefore may not improve preconception health.				
Contexts	Mechanisms	Outcome	Resulting CMOC:	
C1: Person with anxiety and PTSD following first birth experience	M1: PCC not considered normal or necessary by people in the UK (social / cultural norm)	O1: poor access to PCC	People with health conditions (and those without) will want to follow health advice when planning pregnancy. Since seeking PCC is not a cultural or	
C2: Person with PCOS and obesity	M2: PCC not considered normal or necessary by HCP	O2: reduced support to improve preconception health	social norm in the UK, people may not ask, and if they do, HCP's may not provide accurate preconception advice.	
C3: desire for pregnancy and to follow health advice	(along UK social / cultural norms)	O3: feelings of guilt	This results in poor access to PCC and reduced support to improve preconception health, which may also result in	
C4: some people with epilepsy			feelings of guilt.	
C5: everyone				

Evidence for this programme theory came from interviews with both women and healthcare professionals (W1, W20, HCP1, HCP10, HCP8). Evidence from healthcare professionals suggests that this theory, that preconception care is just not normal in the UK, relates to anyone not just those living with health conditions:

"The thing is, people don't come to the GP specifically for preconception care, and everyone working in preconception care knows that ... patients don't turn up and say, oh, hello, doctor, please can you give me some preconception care." (HCP8; GP working in primary care)

It may be normal to seek preconception care from GP's in other countries, but that is

not the case in the UK, so GP's may not consider it normal either:

"I don't think it's even known as a concept here. I remember a colleague arriving from Canada and she wanted to start a family and she went to a GP, and she said, oh I'd like to have a preconception appointment. And they were like, well what do you need to know, get on with it!" (W1; aged 39 living with anxiety)

"I think, in an ideal world what I really wanted before I started trying for a baby with Z... I booked a GP's appointment to talk to them about, you know essentially, well, what do we do? What do I need to do to get into shape for having this baby. She looked at me like a grown a second head and was like: "Have sex. I don't really understand what it is you are asking me for!" (W20; aged 35 living with obesity)

The fact that preconception care is not perceived as normal means that opportunities

to provide preconception care, and for people to improve their preconception health

are missed, resulting in guilt for some, as illustrated in these quotes:

"I remember I had so many sleepless nights about the fact that I wasn't on this high dose of folic acid, and obviously I'd damaged my baby's brain because I hadn't done it. Because when I saw the midwife at my booking appointment with Z, she was basically like, oh, you've not been prescribed the high dose folic acid. And I was like, that made me feel so bad, but I didn't know, nobody told me. And it was like, you know, it made me feel like, I remember I went home, and I cried and I cried. It was like, you know. I've already messed it up. I've been pregnant 5 min, and I've already got it wrong." (W20; aged 35 living with obesity)

"It's not the norm, in the population, for people to discuss these things, because I think they are really personal... I think, unfortunately, [the impact is that] people aren't as informed as we think, about preconception health, you know, when I speak to people about folic acid; Oh, do I need to take that before pregnancy? Well, yes, that's when, you know, you need to have it, you know, 3 months before; Oh, I had no idea!" (HCP10; GP working in primary care)

9.4.2 Second programme theory contributing to refined middle-range theory

regarding unhelpful social norms and inaccurate beliefs

2.3.1 IF people believe that they won't become pregnant straight away (reduced fertility either because of their health condition or because of the experience of their friends) THEN they may not make appropriate behaviour change prior to pregnancy.				
Contexts	Mechanisms	Outcome	Resulting CMOC:	
C1: Person with MS	M1: Belief that it can take a while to become pregnant	O1: No behaviour change prior to pregnancy to improve preconception health	People with health conditions may have a desire to become pregnant, and often believe (due to the experience of others, or themselves) that it will	
C2: Person with SLE	M2: Ambivalence towards pregnancy; neither planning nor not planning	O2: anxiety / uncertainty	 take some time to become pregnant. The combination of neither planning nor not planning (ambivalence), therefore not using contraception, but also not 	
C3: Desire to become pregnant at some point	M3: Not using contraception		having a frank discussion regarding pregnancy intention with their HCP, can result in a pregnancy	
C4: Expectation that it is likely to take a while to become pregnant (due to experience of friends)	M4: No frank discussion regarding pregnancy intention with HCP (either at appointment or due to long wait for appointment)		can result in a pregnancy without having implemented behaviour change to improve preconception health; a missed opportunity. This can also cause the person (and partner) anxiety.	

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There was no evidence from interviews that people thought their condition might reduce their fertility, but general belief, based on experience from friends, that it can be difficult, or at least take a while, to get pregnant. Two women, one with SLE and one with MS, both in their early 30's contributed evidence supporting this theory (W14, W6):

"I don't know, I think most people don't expect to get pregnant straight away... and it's really silly because I do know better, but at the same time, I really did

sort of think, well, we've got time for that, we don't need to start doing that just yet." (W14; aged 34 living with MS)

"I think a lot of my friends have been quite slow in getting pregnant ... and I think when you're surrounded by that, you almost feel like you're going to be like that as well." (W14; aged 34 living with MS)

"We've just said to just go ahead and try anyway, because it can take ages anyway can't it. Either way, it's not going to stop ... we both want children so it's not going to stop us, you know...." (W6; aged 32 living with SLE and waiting for an appointment with a specialist whilst also taking medication for condition)

Both these women described themselves as not planning a pregnancy, but also not not

planning; this involved not using contraception and therefore (from a medical

perspective), could be seen as planning a pregnancy. Neither of them, however,

considered themselves as planning a pregnancy due to their belief that it would take a

while to become pregnant. The outcome for one was a pregnancy before making

changes that could have improved their preconception health.

9.4.3 Third programme theory contributing to refined middle-range theory regarding

unhelpful social norms and inaccurate beliefs

2.3.5 (N) IF pregnancy planning and early pregnancy remain taboo subjects THEN women and HCP's will find it difficult to talk about it and THEN they will be less likely to access PCC and less likely to improve preconception health.				
Contexts	Mechanisms	Outcome	Resulting CMOC:	
C1: Person with SLE	M1: Social norms / taboo around discussing pregnancy planning, early pregnancy, and miscarriage	O1: Reduces access to PCC and the opportunity to improve preconception health	With the social norm in the UK generally being that talking about pregnancy planning, early pregnancy, and miscarriage is taboo, there is a general lack of knowledge about what is	
C2: Person with obesity	M2: Lack of knowledge about PCC	O2: increases anxiety	required for optimal preconception health and a reluctance to ask or raise the question about PCC	
C3: Person with autoimmune disease	M3: Embarrassment / discomfortable		due to embarrassment / discomfort. This reduces access to PCC and results in lost opportunities to	
C4: Person with Marfans	M4: Reluctance or not knowing how to ask / raise the question about pregnancy planning		improve preconception health, as well as causing anxiety for people with health conditions wanting to become pregnant. The taboo may arise from the	
C5: Desire for pregnancy C6: HCP in primary care	M5: negative messages about pregnancy and Sex from early age (school curriculum)		negative messages about pregnancy and sex within the school curriculum.	

This programme theory was not evident from the realist review but emerged from several interviews with both women and healthcare professionals in the realist evaluation (W13, W18, W7, W21, HCP10, HCP4, HCP6, HCP9). Evidence from interviews showed that pregnancy planning being a taboo subject caused discomfort or embarrassment for both women and healthcare professionals, as demonstrated in

these quotes:

"I was quite embarrassed at, you know, telling... having the conversation with my mum and me and my mum are so close.... And I said to [partner], people probably didn't know we were trying for a bit for about a good two years before we actually said we're actively trying because I felt a bit embarrassed about saying, you know, that we're trying to have a baby, and it's just not happening... and so it was kind of just like better to not say anything at all." (W18; aged 28 living with obesity)

"It feels not right to just drop in a conversation. Oh, are you thinking of having a baby in the next year, or if you are here's some folic acid. It is not sort of the social norm to talk about that in the middle of talking about something else, because obviously it's got a lot of emotion attached to it... it's quite an invasion of privacy to ask someone that question a bit out of the blue. I don't know. Yeah, I I think I think it is probably [about] the social norms." (HCP10; GP working in primary care)

One woman, who had an auto-immune condition, expanded on why preconception

care might be a taboo subject, identifying a link with early pregnancy and miscarriage,

as well as not talking about sex:

"I think I think it's partially about not talking about sex, but I think it's partially about the taboo of early pregnancy and, you know, having miscarriages is really common. And you know, the fact that people don't necessarily want to talk about it with someone that isn't their intimate partner. It's such a big taboo in general that, you know, people only announce it until they're at least 12 weeks pregnant. And even then, people are now leaving it later and later, because they.... They in case something happens." (W13; aged 32 living with an autoimmune condition)

This was expanded upon by healthcare professionals who identified that discussions

about pregnancy planning could upset people if they had chosen not to have children,

if they had experienced miscarriages, or if they were struggling to conceive. Whilst

healthcare professionals may know how to respond to someone who has experienced

loss, many people find it difficult, which contributes to the subject being taboo, as

illustrated in these quotes:

"I think sometimes society is uncomfortable asking that question because they don't want to be deemed as maybe insensitive or maybe it's nothing to do with them, and some people choose not to have children, so I think as a society, I think we're more um... considered, so maybe that's the reason why it's deemed as a taboo subject, you know ... people may not want to upset people." (HCP4; Practice nurse working in primary care)

"Women don't tend to talk about it. It's not a social norm to say we're trying because there's the fear around. What if it takes time? The judgment? And some people just don't want people constantly asking... um, it absolutely links in with miscarriage and loss, and also that's a really relevant time for preconception care um for somebody that's had a miscarriage..." (HCP6; Midwife specialising in preconception care)

"I think it's more taboo ... and people sort of not knowing how to talk about it, really. I think that's the thing of it. You know, people, if someone raises the question, a lot of people don't know how to answer it. You know, and people don't know how to respond. You know, it's quite difficult. You know, there's a lot of people who were asking me, you know, are you going to have another one. And I think I'd had a miscarriage about two weeks earlier and it was a missed miscarriage and I was supposed to be 14 weeks. You know, looking quite pregnant as you, which is your second time around. You know, and when you say I've just had a miscarriage, people are like. (PAUSE) I don't know what to say to, you know. So I think that's just it is a taboo." (W13; aged 32 living with an auto-immune condition)

Unfortunately, this situation is not helpful, in that it can prevent people from accessing

preconception care, as they may find it daunting to do so:

"Yeah, it was quite kind of a daunting thing to ask and, I guess also because of kind of anxiety of people saying Oh well, it won't work or something like that, and you know, I already know my head that it's gonna be a bit more tricky for me than it might be for anyone else so ...well there'll be definitely lots more admin, lots more planning and lots more risk." (W7; aged 28 living with SLE)

9.4.4 Fourth programme theory contributing to refined middle-range theory

regarding unhelpful social norms and inaccurate beliefs

2.3 8 (N) IF a person has a strong desire to have a baby THEN they won't want to wait too long before trying therefore will need timely access to supportive PCC regarding any health condition in order to improve their preconception health.

Contexts	Mechanisms	Outcome	Resulting CMOC:
Contexts C1: Person with obesity C2: Person with SLE C3: Person with strong desire for a baby C4: people with CF	Mechanisms M1: Strong desire to have a baby M2: View that "what will be will be", or that condition will not be a problem in pregnancy M3: Long wait to see specialist (for some)	Outcome O1: No access to PCC O2: No improvement in preconception health O3: Anxiety and uncertainty	Resulting CMOC: When a person with a health condition has a strong desire to have a baby, they will not want to wait too long to conceive. A number of things can contribute to preventing them from accessing preconception care and/or result in no improvement in their preconception health. These include: a "fatalistic" view that "what will be will be"; the belief that their condition will not be a
			problem in pregnancy; no support to improve preconception health; and /or a long waiting time to see a specialist.

This programme theory was not evident from the realist review but emerged initially from two interviews with women who lived with health conditions (W17, W6). Evidence from these interviews demonstrated that some people experience a strong desire to have a baby. In one case, the person was living with obesity and was told they needed to lose weight but was given no support; this person did not believe that their weight would cause a problem in pregnancy and they were otherwise healthy. Having a strong desire to have a baby meant that they did not want to wait before becoming pregnant: "Yeah, when you decide that you want to start family. You want to. You want to start straight away. You don't wanna potentially wait 2 years, or whatever to try and lose 2 stone ... we, you know, yeah, come hell or high water. We were gonna get there like, it doesn't matter what a doctor told me, you know. And even if you know, there had been issues with, you know, my fertility, like, I still don't think that would have stopped us. We would have found a way somehow." (W17; aged 33 living with obesity)

The person was on medication for their health condition, and had been waiting over a

year for an appointment with a specialist; this person had a fatalistic view that "what

will be will be", which meant that they were not using contraception:

"We've just said to just go ahead and try anyway, because it can take ages anyway can't it? Either way, it's not going to stop ... we both want children so it's not going to stop us, you know....I want a baby really like loads; that's you know, that it is what it is. But you know, I'm a big believer in everything happens for a reason so it's taken me four or five years to get over the last miscarriage so now." (W6)

Both people also thought it might take a while to become pregnant. Neither received

supportive preconception care and therefore they had no support to improve their

preconception health. Triangulation with evidence from healthcare professionals,

including a midwife and a dietician (HCP6, HCP7), confirmed that some people have a

strong desire to have a baby, even if it puts their own health at risk, as demonstrated

in this quote:

"We have people [with CF] who, their only objective; their only goal is around having a baby, and that's their ultimate motivation factor. So it's um. It's a really tricky thing, because you can see what their prognosis is going to be following that ... it's difficult, isn't it, because I guess a lot of what you advise patients, you're saying that based on the best of your clinical experience, and essentially, they are basing things on their lived experience, what their expectations are. So, I think that we are obliged professionally to tell patients what we expect to happen, but ultimately, it's up to them to make their own informed choice; yeah. It's down to providing information." (HCP7; dietician working with people with cystic fibrosis)

9.4.5 Fifth and final programme theory contributing to refined middle-range theory

regarding unhelpful social norms and inaccurate beliefs

2.4.2 (N) IF SRH messages at school continue to have a strong focus on STI's and preventing pregnancy THEN people will be poorly informed about the importance of preconception health and unlikely to openly seek SRH and/or PCC

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with PCOS and obesity C2: Person with Marfans syndrome	M1: negative discussions regarding pregnancy and sex at school M2: Focus on STI's and contraception at school	O1: lack of understanding about SRH and preconception health O2: Feeling of embarrassment / awkwardness re SRH O3: reduced access to PCC as a result	When messages from school about sex and pregnancy are negative, focusing on STI's and contraception, then this does not promote an understanding of SRH and/or preconception health, or a positive perception of the topic. This results on feelings of embarrassment and awkwardness regarding SRH, which can reduce access to PCC for people with health conditions.

The final programme theory contributing to the refined middle-range theory regarding unhelpful social norms and inaccurate beliefs also emerged from interviews with women who lived with health conditions (W18, W21). Evidence from these people shows that negative discussions about sexual and reproductive health in schools do not promote understanding, preconception care seeking behaviour or an open discussion. Instead, the strong emphasis on sexually transmitted infections and contraception promotes the underlying perception that sexual and reproductive health in general, and pregnancy planning, specifically, is a taboo subject, as illustrated in these quotes: "I think, you know, in school you get taught how not to get pregnant. It's never really spoke about how, what happens if you can't, and you know, there could be a chance, probably, you know, say in a in a group of girls in a classroom. They'll probably be two, three people who would struggle. so yeah, that's the other side of it. I guess. Isn't it?" (W18; aged 28 living with obesity)

"[re: the message from school] Do not have sex, you will get pregnant. It's awful, or you'll catch gonorrhoea and die! and that was probably it ... If there was actually a more, a more realistic kind of education, whereby, I don't know, you'd probably have to get someone in that wasn't your teacher to have these conversations about, you know, sex is great, and people have sex because ... it makes you feel good and yeah, you shouldn't feel awkward about it, and you know, and actually have a proper honest conversation about it. And did you know, girls, your periods are actually amazing, and your bodies are amazing. And this is what you should know about it. Because... you know.... you know, all of those kinds of conversations. But no, I think probably it was just awkward, awkward, awkward." (W21; aged 36 living with Marfan's syndrome)

9.5 Conclusion

In this chapter I have presented the data and refined programme theories focusing on information, knowledge, and beliefs, from the realist evaluation. In this group, 11 initial programme theories from the realist review were increased to 21 programme theories during analysis, with the addition of five new emergent programme theories and five child nodes as initial programme theories were refined. These were subsequently reduced, through step 5 of analysis (see chapter 7) to four middle rangeprogramme theories that I have presented here as both narrative and diagrams.

The four middle range theories in this group related to:

- Healthcare professionals' knowledge and holistic approach to people with health conditions
- Using information available online or via mobile apps to facilitate partnership working and a personalised approach
- 3. The importance of accurate information, and

4. Unhelpful social norms and inaccurate beliefs.

The first three theories focusing on information, knowledge, and beliefs provide causal explanations of positive outcomes, and the fourth theory provides causal explanations of negative outcomes in relation to preconception care for people with health conditions. I will provide further discussion of these theories in chapter 12 of this thesis.

Chapter 10

Results, Focusing on Therapeutic Relationships

In this chapter I will present the second group of refined programme theories from the realist evaluation. This group focuses on therapeutic relationships. Six of the initial programme theories that I tested and refined in this area, were originally grouped (from the realist review) into areas related to "the intervention", and one theory was originally grouped in the area related to "people's beliefs". Table 11 below shows the refined programme theories that contributed to the refined middle-range programme theories included in this chapter. As outlined in chapter 9, the numbering of initial programme theories in Table 11 below indicates the origins of the programme theories (see Figure15 on page 172).

Table 11. Refined programme theories and subsequently refined middle-rangeprogramme theories regarding therapeutic relationships

Refined programme theories regarding therapeutic relationships	Refined middle-range programme theories (therapeutic relationships)
1.1.3 Positive and respectful attitude to women	5. The difference that a positive and
2.2.2 Impact of feeling judged / not listened to	respectful attitude from a healthcare professional can make
1.1.4.1 CoC - trust - honesty - personalised care	6. The significance of continuity of
1.1.4.2 CoC facilitates difficult conversations	carer
1.1.4.3 CoC resulting in tailored approach by HCP	
1.1.4.4 CoC resulting in person understanding approach taken by HCP	
1.1.4.5 CoC Woman wanting to please the HCP	

The programme theories I will present in this chapter fall into two subgroups; the difference that a positive and respectful attitude from a healthcare professional can make, and the significance of continuity of carer. As in chapter 9, I will present each

refined middle-range programme theory below, in narrative form and as a diagram, with context, mechanisms (both resources and responses), and outcomes identified. Results from the interviews providing evidence supporting each refined programme theory contributing to the refined middle-range programme theory will then be presented.

10.1 The difference that a positive and respectful attitude from a healthcare professional can make

Two refined initial programme theories contributed to this refined middle-range programme theory. These both operate within the context of a person with any health condition considering pregnancy. They demonstrate the difference that a positive and respectful attitude from a healthcare professional can make, providing a causal explanation of how this can support the person to access preconception care and improve their preconception health. The opposite attitude can reduce access to preconception care and negatively impact the person's mental health. Combining and abstracting the two programme theories resulted in this middle-range programme theory:

When a person living with a health condition is considering pregnancy (context)...

If their healthcare professional listens to them, respects and acknowledges that they are an expert in their own condition, and if the healthcare professional focuses on the person rather than the condition and is accessible, providing factual, non-judgemental information whilst maintaining a positive approach (mechanism; resources) ... and if the healthcare professional

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supports the person regardless of their decisions, and the person trusts their healthcare professional and feels valued by them (mechanism; reasoning) ...

Then the person will access preconception care and support to improve preconception health, feel empowered to make informed decisions (having agency and autonomy), and will have a high level of satisfaction with their care (outcome).

If the opposite occurs, including a paternalistic, negative, and judgemental approach from the healthcare professional (mechanism; resources), leaving the person feeling judged and blamed, resulting in the person not feeling able to ask questions and not wanting to see the HCP again, and experiencing negative emotions including guilt and annoyance (mechanism; reasoning) ...

Then the person will be less inclined to seek PCC and will not get support to improve their preconception health; they may also experience low self-worth and self-belief, guilt, and poor mental health (outcome).

The theory is also presented as a diagram (Figure 20):

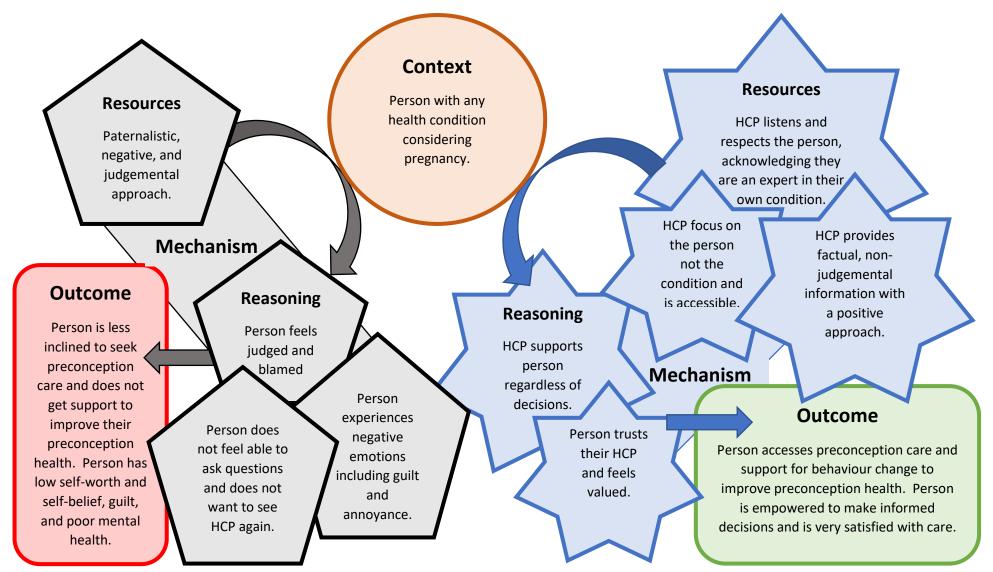


Figure 20. Programme theory 5: The difference that a positive and respectful attitude from a healthcare professional can make

Evidence supporting the refined initial programme theories contributing to this refined

middle-range theory is presented below.

10.1.1 First programme theory contributing to refined middle-range theory

regarding the difference that a positive and respectful attitude from a

healthcare professional can make

1.1.3 IF healthcare professionals have a positive, non-judgemental, respectful attitude towards people with the potential for pregnancy THEN they are more likely to listen to them and consider their feelings towards sexual and reproductive health / pregnancy and THEN people are likely to trust their healthcare professional, feel empowered and supported to make their own informed and appropriate choices resulting in behaviour change to promote preconception health and wellbeing. This approach also results in greater satisfaction with the care received.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with anxiety and PTSD after first experience of birth	M1: HCP provides factual information (without judgement), whilst maintaining a positive approach	O1: Behaviour change prior to pregnancy (reducing / coming off medication)	People with physical or mental health conditions, regardless of previous obstetric history, with a current or potential future desire for
C2: Person with depression	M2: HCP and person talk together (open and honest; adult to adult), rather than HCP talking "to" the person (i.e. not paternalistic)	O2: Person feels valued (self-worth / self-esteem) and empowered to make informed decisions (agency / autonomy)	pregnancy, feel empowered to make informed decisions, supported in the decision that is right for them, and able to make sustained behaviour change prior to
C3: Person with Epilepsy	M3: HCP is accessible to the person (waiting times not too long)	O3: Person supported in the decision that is right for them	pregnancy resulting in improved preconception health and wellbeing, when they receive positive and non- judgemental care that makes them feel valued and able to trust their healthcare professional. This involves the healthcare professional
C4: Person with Cystic Fibrosis	M4: HCP respects person, acknowledging they are often expert in own condition	O4: Improved physical and mental health prior to pregnancy	
C5: Person with diabetes	M4: Person feels valued and listened to	O5: Satisfaction with care received	

C6: Person	M5: HCP focus is on the	listening to them, having
with PCOS	person not the	open and honest (adult to
raised BMI	condition (personalised	adult) conversations
	approach)	together (not
C7: Person	M6: HCP supports	paternalistic), supporting their decisions, treating
with Lupus	persons decisions	them with respect and
C8: With or without previous history of miscarriage C9: Current	M7: Person trusts HCP M8: HCP listens	acknowledging they are often the expert in their own condition, focusing on the person not the condition, providing factual information
or potential future desire for pregnancy		(without judgement) whilst maintaining a positive approach, and being accessible (i.e. Waiting times not too
C10: People with mental health problems		long).

This programme theory is not condition specific, it probably is not even specific to preconception care, but decisions about pregnancy planning when living with a health condition can be challenging and are very personal, therefore a respectful and positive approach is required from healthcare professionals. Evidence supporting this programme theory came from women living with a range of health conditions (see table above), their partners and healthcare professionals (W1; W10; W11; W2; W20; W8; W9; P1; HCP1: HCP3); women talked about feeling supported and cared for in

these circumstances:

"It didn't feel like it was something that I wasn't going to be able to achieve. It was more of a this is what you need to be aiming for and when you can do this then it would be safe. It was all like it felt like we were a team, and we were going to work together, and, in the end, it was going to be successful." (W9; aged 42 living with type 1 diabetes)

"I felt that I was under the care of a team that really cared about me and were really invested from that preconception stage. They were really invested in me having a healthy baby at the end of it. So the whole experience with him was amazing; you know, from before it started up to when it finished." (W20; aged 35 living with obesity)

People do not just do what they are told, other factors are involved such as personal desires, values, feelings, and emotions; these things drive behaviour, so people need to be treated with consideration and respect. Interviews with women who were living with both physical and mental health conditions contributed to this theory, as illustrated in these quotes:

"My doctor is really great; she doesn't really talk at me, we kind of talk together, which is quite nice, so she listens to me while I say what I'm feeling, and she'll work with that rather than kind of saying no is what you should be doing but she'll obviously have a professional opinion." (W10; aged 28 living with depression)

"We look through it together and she said, you know, this might be this ... is there a reason for that or is that just how it is and it's very much it's a conversation, rather than a dictation, and I appreciate that massively." (W2; aged 29 living with type 1 diabetes)

People with both physical and mental health conditions talked about feeling

comfortable and how important this was as a contributing factor to being able to make

decisions:

"I felt like a respected intelligent human, and it was really, really nice it was really great It made me feel a lot more um, you know, a lot more comfortable ... she treated me with real respect; asked me proper questions ..." (W11; aged 34 living with epilepsy)

"She was really supportive of that [talking therapy] because we'd had so many conversations and because, obviously, the last time we'd spoken I was, you know, really pushing for trying other things other than medication so she knew I was already there ... it was helpful because I was able to make a quicker more informed decision." (W10; aged 28 living with depression)

The importance of respectful conversations between people and their healthcare

professionals was recognised by the supporting family member of a woman with a

health condition, as well as healthcare professionals themselves. This is illustrated in

these quotes, firstly from a supporting family member of a woman with cystic fibrosis,

and secondly from an epilepsy specialist nurse:

"I think it's been just very honest. I think it's about informed consent for me; if she wants to go down that road, then it's important she is aware, not deterred, if that's what she really wants to do." (P1; supporting family member of a woman with cystic fibrosis)

"I think what you're trying to do there, even if it's a woman who's never met us before, is talking about something that's really special; They're wanting a baby, and I think it's respecting, this is something that you are / we're working together, so we're in it together, this is a team approach." (HCP1; epilepsy specialist nurse)

When considering trust and feeling comfortable, these could be a mechanism or an

outcome, but in this programme theory it was considered a mechanism, leading to the

outcome of improved access to preconception care and ultimately better

preconception health, as identified in the table above.

10.1.2 Second programme theory contributing to refined middle-range theory

regarding the difference that a positive and respectful attitude from a

healthcare professional can make

2.2.2 IF the person feels judged, stigmatised, looked down on, criticised, and not listened to, by their healthcare professional, THEN this will impact negatively on their mental health and reduce their ability to access preconception care.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with MS and Graves disease	M1: feeling judged by HCP	O1: feels unable to seek PCC / unsupported in efforts to improve preconception health.	People with health conditions can have strong desires to become a parent, and thus desire pregnancy (like anyone else). If they encounter a paternalistic, negative
C2: Person with obesity	M2: paternalistic approach from HCP	O2: did not want to see the HCP again	approach from their HCP, they can feel judged and blamed by the HCP. This
C3: Person with obesity and PCOS	M3: feeling blamed for condition by HCP	O3: negative emotions including low self-worth / self- belief, guilt, annoyance, upset.	results in negative emotions including low self-worth / self-belief, guilt, annoyance and being upset. It can also cause poor mental health and the
C4: Person with diabetes	M4: negative attitude from HCP	O4: poor mental health	person will not want to see the HCP again and/or feel
C5: Person with epilepsy; aware of need to stabilise condition prior to pregnancy			unable to ask them questions, including questions about PCC.
C6: desire for pregnancy	M5: person feels HCP is not listening to them	O5: loss of trust in HCP	

This programme theory considers the outcome of the opposite of the previous programme theory, when a healthcare professional does not display a respectful attitude towards the person living with a health condition. This involves the person feeling judged, stigmatised, and criticised. Evidence from several women, with a range of health conditions (see above), and one healthcare professional (a midwife specialising in preconception care) supported this programme theory (W14, W15, W17, W18, W9, HCP6). This highlights the importance of how information is delivered and discussed, linking to the nature of informed consent. The quote below, from a woman with MS, illustrates the impact of such an attitude, which left her feeling judged, and like the prospect of having children was not something she could consider or even discuss with her healthcare professional:

"I don't feel like I could have said, Oh, well, I'd like to have a baby in the next year because like, I felt like I'd be judged. You've got a condition, you need to sort that out. I guess the medication I was being put on and the condition I had, it was just like, No, you can't have children on this. And that wasn't a discussion. No, it was just like, you can't have children on this. It wasn't discussed. I was just told and that was that, and it was quite a quick appointment anyway." (W14; aged 34 living with MS)

Several people talked about how their healthcare professional's attitude could make them feel. The strength of these feelings was very apparent in the interviews, so it was important to include these as both mechanisms (responses) and outcomes, where applicable, in the programme theory. Feeling judged, blamed or guilty were mechanisms in the form of responses, that resulted in the outcome of reduced access to preconception care, as illustrated in these quotes from women with various health

conditions:

"Yeah, it was, it was quite insensitive, and it was just: "This is what you need to do to have a baby", and I kind of felt guilt, almost, you know. Okay, this is my fault now, you know ... This because I'm overweight, and it did affect my mental health." (W18; aged 28 living with obesity)

"You do feel rubbish, and you feel really horrid for wanting to have a baby. And you think God, am I going to be a terrible parent? Because I'm in a bigger body like. I don't think people appreciate that sometimes bigger people have like eating disorders and stuff, and all of that stuff. They assume it's just skinny people. But, you know, large people may have binge eating disorders, you know, and it's the mental aspect of it, um, somebody saying, oh, no, you're too fat to be a parent like you're not worthy to be a parent because you're fat. It's just rubbish." (W17; aged 33 living with obesity)

"She's [HCP] going straight to the "let's try and get you a healthy baby without killing you or the baby"! Which was not a constructive conversation, and it was all it was delivered in quite an aggressive way, as if I was a problem. I came out of the appointment feeling that I was a problem. And then if I didn't do it right then it was going to be my own fault essentially... It was a horrible experience and I hated her for a long time 'cause she was rude to me... so I just was angry with her and just ignored what she had said... I said I don't want to see her again. She was rude. She was awful. She was offensive, and I never did." (W9; aged 42 living with type 1 diabetes)

The fact that some people did not feel valued, or felt blamed for their condition,

suggested that some healthcare professionals' values were not in line with their

professional codes of conduct. The quotes below show the impact that this can have

on people; the first is from a woman living with epilepsy who felt that her neurologist

did not care whether she lived or died, and the second is from a woman living with

obesity who felt that her healthcare professional blamed her, implying that she was a

bad person:

"I think what I need is I need the neurologist to listen to me. Because this is the issue I have with my neurologist; he doesn't listen to me ... [that makes me feel] inadequate, worthless; that, like he couldn't actually care ... he couldn't care less whether I have a good quality of life or not ... I think they just see it as sort of seeing someone with epilepsy as a formality, and couldn't really care less whether I live or I die at the end of the day." (W15; aged 28 living with epilepsy)

You've learned that fat is self-inflicted, and therefore, yeah, fat is bad; you are fat; you are bad, because you've done it to yourself! Like, all these people that are like, oh, well just lose weight... oh, sure, if it was that easy, everybody would be skinny." (W17; aged 33 living with obesity)

It was encouraging to hear from healthcare professionals who were respectful, and

aware of the importance of feelings and emotions in relation to preconception care.

This quote from a midwife specialising in preconception care demonstrated this:

"Lots of women say they don't want to be labelled high risk. I don't want to be high risk. I don't want a label. I don't want to be judged there's a lot of feeling of being judged. Especially for women with raised BMI or women with diabetes, if they find it hard to control, because they haven't found maybe a medication that works well for them yet, and they're still juggling that...and because there's guilt involved, if they're high risk, am I, should I ...a) not be having a pregnancy, or b) am I putting my baby at risk unnecessarily, so that feeling of guilt is really apparent. So, it's supported, and to take ownership, to have that knowledge that they've done everything they can to optimize that, and that they're not wrong for wanting a pregnancy... we'll work together in collaboration to support [them]." (HCP6; midwife specialising in preconception care)

10.2 The significance of continuity of carer

Five refined initial programme theories contributed to this refined middle-range programme theory about continuity of carer. These were all developed as child nodes from the initial programme theory about continuity of carer, as it was refined during interviews. They operate within the context of a person with any health condition considering pregnancy. They explain why continuity of carer is significant, and how it can improve the therapeutic relationship between healthcare professionals and people with health conditions, due to the impact of continuity on both parties, which can lead to more time-efficient, personalised care, promoting access to preconception care and support to improve preconception health. Combining and abstracting the five programme theories resulted in one middle-range programme theory:

When a person living with a health condition is considering pregnancy (context) ...

If they have continuity of carer: the same healthcare professional seeing the person over a period of time, who has a respectful and positive attitude (mechanism; resources), ... and if that HCP knows the person's medical history, situation and personal goals, and is able to personalise their approach accordingly (mechanism; reasoning – HCP) ... and if this means the person does not need to repeat their story at each visit, develops trust in their HCP and is therefore able to be open, honest, and have difficult conversations, is aware of the HCP's approach so can prepare for appointments, and may also be keen to "please" the HCP (mechanism reasoning – person with health condition) ...

Then the person will receive time-efficient, personalised care, providing access to preconception care and support to improve preconception health, with an increased sense of empowerment, self-worth, and satisfaction with care (outcome).

The theory is also presented as a diagram (Figure 21):

Context

Person with any health condition considering pregnancy.

Resources

Continuity of carer: the same healthcare professional seeing the person over a period of time, who has a respectful and positive attitude.

Reasoning (HCP)

Knowledge of the person's medical history, situation and personal goals, and ability to personalise their approach accordingly.

Mechanism

Person aware of

HCP's approach so

can prepare for

appointments; may

also be keen to

"please" the HCP.

Outcome

Time-efficient,

personalised care, providing access to preconception care and support to improve preconception health.

Increased sense of empowerment, selfworth, and satisfaction with care.

Reasoning (person)

No need to repeat story at each visit; develops trust therefore able to be open and honest and have difficult conversations.

Figure 21. Programme theory 6: The significance of continuity of carer

Evidence supporting the refined initial programme theories contributing to this refined

middle-range theory is presented below.

10.2.1 First programme theory contributing to refined middle-range theory

regarding the significance of continuity of carer

1.1.4.1 IF there is continuity of carer, and the person and healthcare professional have established a positive, trusting therapeutic relationship THEN people are more likely to share information and be honest with their healthcare professional and THEN the healthcare professional is able to provide a more personalised, realistic and effective approach to preconception care and the person is more likely to feel safe, empowered and supported to achieve their goals.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with epilepsy	M1: Relational continuity	O1: HCP has the ability to provide personalised care	People with health conditions often have increased anxiety (for a range of reasons), whilst planning, considering or desiring a pregnancy. Relational
C2: Person with depression	M2: Trust	O2: Realistic and effective approach to PCC	continuity with a healthcare professional increases trust, honesty and openness, and results in the healthcare
C3: Person with PCOS and raised BMI	M3: Honesty and openness	O3: Satisfaction and self-worth (person)	professional knowing the person's story, situation, personal goals etc so that the person does not need to repeat
C4: Person with anxiety and PTSD after first birth experience	M4: HCP knowing the person's story, situation, personal goals etc	O4: Person feels empowered and supported	things (i.e. no need for repeated "coming out" about their condition/s). In this way, relational continuity promotes a
C5: People with anxiety about pregnancy (for whatever reason, but related to health condition) C6: People	M5: Person not needing to repeat things (no need for repeated "coming out" about condition etc) M6: Respectful,	O5: Person feels safe	respectful, caring, holistic approach, whereby the healthcare professional sees the person before the condition and is able to provide personalised care, with a realistic and effective approach to preconception care. This results in greater satisfaction with care, empowerment, self-worth and
considering or	caring, holistic approach		

desiring	M7: HCP seeing the	feelings of being safe and
pregnancy	person before the	supported.
	condition	Beneficial for HCP as well – enables personalised and appropriate advice and support.

Several women with a range of health conditions (see above) provided data contributing to this theory (W1; W2; W10; W11; W14; W20;), with healthcare professionals also providing data triangulating this theory (HCP1; HCP10). Health conditions generally increase people's stress and anxiety (due to impact on many aspects of life), and people get tired of repeatedly explaining their situation ("coming out"), so continuity of carer reduces the need to do this, as illustrated by this quote from a person living with epilepsy:

"I know this might sound a bit silly ... sometimes it can actually be quite almost like... traumatic is too strong a word, but you didn't want to have to keep on talking about the fact that you're trying to have a baby ... and, you know, you don't want to have to keep on explaining that to people all the time. Because, after a while it just is like I don't want to talk about it anymore, so it was nice that somebody knew the situation, and I didn't have to explain ..." (W11; aged 34 living with epilepsy)

A trusting therapeutic relationship encourages openness and honesty about personal hopes, desires, fears and anxieties, which then enables a more personalised approach. Several women provided evidence supporting this benefit of having continuity of the person providing care, which made them feel safe and supported, as illustrated below:

"I think just trust and acceptance and understanding I felt supported by her and I felt like she was able to look after me, that she understood, and that I felt safe with her, for some reason." (W1; aged 39 living with anxiety)

"It definitely helped; the fact that she already knew that as well ... So, I didn't feel like I had to explain myself or justify my actions; I knew that she'd be supportive." (W10; aged 28 living with depression) Feeling empowered and supported to achieve goals may or may not mean improved physical health, but does mean improved mental health and wellbeing. Healthcare professionals who participated in interviews that contributed evidence supporting this theory highlighted the importance of honesty (from the person living with a health condition) to know how to support and advise people:

"I just want you to be honest with me so I can help you through this, I will, you know, even... if you say that that is your thought, in your heart of hearts you know that you would not want to be taking your medicine, that's OK to tell me that, but I need to know it now, because it might be that we want to try it out." (HCP1; epilepsy specialist nurse)

"I think it's incredibly important ... we see an awful lot of. women of reproductive age who are struggling with low mood, mental health, anxiety. So, keeping that trusting relationship and that rapport going is really key." (HCP10; GP working in primary care)

Evidence showed that people genuinely felt supported by a healthcare professional

that knew them. These quotes from women with both physical and mental health

conditions demonstrate that:

"It was just easier to have those conversations, because I had that relationship with her." (W10; aged 28 living with depression)

"Because it's always Dr X, it's just....I don't have to explain myself, if I'm saying I feel awful, he understands... he knows me as well, so he knows if I say my pain's a "six" then he knows that it really is, it's not me making it out to be worse than it is it." (W2; aged 29 living with type 1 diabetes)

"It was really helpful [knowing the HCP due to continuity of carer] because ... I think just knowing the person and knowing that they know you, they know your sort of condition and you've asked them all your questions before, so they're building on what they already know about you. So yeah, I think it was really helpful that it was the same person." (W14; aged 34 living with MS)

10.2.2 Second programme theory contributing to refined middle-range theory

regarding the significance of continuity of carer

1.1.4.2 IF there is continuity of carer, and the healthcare professional has developed a knowledge of the persons medical, family, and social history, THEN people are more likely to be comfortable with their healthcare professional and have quicker, more honest conversations that they may otherwise find difficult.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with mental health issues	M1: Established therapeutic relationship	O1: Easier to have difficult conversations	People with health conditions often have increased anxiety (for a range of reasons), whilst
C2: Person with Epilepsy	M2: no need to keep repeating medical / family / social history	O2: Saves time	planning, considering or desiring a pregnancy. Relational continuity with a healthcare professional
C3: Person with SLE	M3: HCP builds on information they already know about a person	O3: Facilitates personalised care / support	results in the healthcare professional knowing the person's medical, family and social history so that the person does not need to
C4: Person with autoimmune disease C5: Person with MS	M4: Quicker consultations / conversations		repeat things, the healthcare professional can build on what they already know, and consultations /
C6: People with anxiety about pregnancy (for whatever reason, but related to health condition)			conversations can be quicker. In this way, relational continuity facilitates conversations that people might otherwise find difficult to have (due to time,
C7: People considering or desiring pregnancy			lack of trust etc).

This programme theory was supported by several women with health conditions (W10; W11; W2; W13; W14; W8) who provided evidence about how much quicker they found appointments when they knew the healthcare professional. This was because they had already established a relationship and they did not need to repeat their medical, family or social history, and was evident in the quotes from two women

(one with SLE and one with an auto-immune condition) included below:

"When it's the same doctor you don't have to explain yourself every time; it's a lot easier. It's quicker as well; you spend like 15 minutes explaining what's going on, especially when you've got like long term stuff." (W8; aged 31 living with SLE)

"Well, I think it would make a difference if I was designated a particular nurse or a, you know, a couple of nurses; I think it probably would make a difference because then you don't have to tell your life story to the same person when you ring. Yeah. You know, I do have a very complex medical background and I have neurological issues as well that they haven't got to the bottom of. So it's quite it's quite difficult for me to explain to someone what's happening in order for them to appreciate the situation that I'm currently in to know how best to help me because quite often what they advise is things that have already happened or even done.... Oh, it would make a big difference and it would actually save time as well as the frustration of having to explain it several times; yes... it would probably save some consultant appointments, I imagine, as well." (W13; aged 32 living with an auto-immune condition)

10.2.3 Third programme theory contributing to refined middle-range theory

regarding the significance of continuity of carer

1.1.4.3 IF there is continuity of carer, and the person and their healthcare professional have established a positive, trusting therapeutic relationship THEN healthcare professionals can build up knowledge about different individuals, and can tailor their approach to provide more personalised, timely, realistic and effective support to individual people, without them having to keep repeating themselves / their history.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with type 1	M1: Established therapeutic relationship	O1: Personalised	People with health conditions can have complex health
diabetes C2: Person with SLE	over time M2: HCP knows history	care O2: Improved preconception health	issues and require support to improve health or adjust medication prior to pregnancy. If they have
C3: Complex health conditions that have implications for pregnancy	M3: HCP knows "how person works" and how to get the best out of them		established a therapeutic relationship over time with a healthcare professional who knows their history and "knows how that person works", then they are able to adapt their approach to get
C4: Desire for pregnancy	M4: HCP adapts approach to individuals M5: Person trusts HCP M6: HCP trusts person		the best out of them. This promotes trust between the person and the health care professional, and vice versa, which promotes personalised care and improved preconception health.

Several women also contributed evidence to support and refine this theory (W2; W3; W4; W5; W6). Continuity of carer enables the healthcare professional to get to know the person; this is a therapeutic relationship, not a friendship, so the nature of the knowledge relates to their medical history, personality, social situation, and approach to challenges. This helps the healthcare professional to provide person-centred, or personalised care, as illustrated in the quote below from a woman living with type 1 diabetes who participated in an interview:

"A clinic appointment with X, now she knows all the background, she knows how I work, you know we saw each other every few weeks for the whole of the pregnancy so she knows how my mind works, she knows how ... You know, it is that that relationship thing isn't it, the more you know someone, the more you can understand how best to get something out to them and that's where she's an incredible clinician. She knows how to phrase things for me that will work for me and I'm sure she does it differently for different people." (W2; aged 29 living with type 1 diabetes)

10.2.4 Fourth programme theory contributing to refined middle-range theory

regarding the significance of continuity of carer

1.1.4.4 IF there is continuity of carer, and the person and healthcare professional have established a positive, trusting therapeutic relationship THEN people can build up knowledge about the way their healthcare professional works, and can tailor their approach and expectations to maximise each appointment and gain the information and support they need.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with Lupus C2: Desire for a pregnancy C3: Person has resources to seek emotional support elsewhere, also does own research and is able to discuss / raise questions with healthcare professional	Mechanisms M1: Person prepares ahead of the appointment (questions / expectations) M2: Person knows the HCP's "style" / approach to care M3: HCP style focused on facts / information rather than emotional support	O1: Person tailor's expectations to maximise appointments O2: Person knows to seek information from condition specialist, but emotional support from elsewhere (e.g. partner / family) – saves any disappointment	People with health conditions may need to improve their preconception health prior to conception; if they have continuity of carer providing PCC, then they will know the healthcare professional's style / approach to care and can therefore prepare ahead of appointments to maximise these opportunities. This includes seeking emotional support elsewhere (e.g. from partner / supporting family) if the specialist is more information
			focused, to save disappointment.

This programme theory was refined based on just one interview (W4), but it provides an additional causal explanation regarding how continuity of carer works in terms of support to improve preconception health. This involves the person getting to know their healthcare professional; their manner, approach, and thus what to expect from appointments. It highlights that continuity of carer is not just about the healthcare professional getting to know the person; the opposite is also helpful, as outlined in the quote below. This person was living with SLE and was aware that their healthcare professional, whilst extremely knowledgeable, tended to deliver a direct message. The person living with SLE therefore sought emotional support elsewhere, and knew to expect a factual approach at each appointment:

"He comes across as kind of an expert in things, what he's doing, but also, he's like efficient, so he doesn't kind of, take extra time; he doesn't kind of, take into account the emotional aspect of kind of making a diagnosis or things like that; not saying that that he's cruel or anything, but he's just straight to the point, kind of matter of fact, really. But I'm confident that he knows what he's doing and he takes into account what I'm saying I feel kind of even in the way that I feel able to say look, this is really what I want in terms of moving towards having a baby, so we need to tailor the medication in that way, and things like that, and he always listens to me and that, he's not kind of saying we can't do this, it's like a choice. So, I guess, I feel like I make the most out of the appointments, because I know his way of working and I don't have other expectations and I'm not let down, so I get kind of the emotional support and things elsewhere if that makes sense." (W4; aged 32 living with SLE)

10.2.5 Fifth and final programme theory contributing to refined middle-range theory

regarding the significance of continuity of carer

1.1.4.5 IF there is continuity of carer, and the person and healthcare professional have established a positive, trusting therapeutic relationship THEN people will endeavour to make the appropriate behaviour change prior to pregnancy because they feel more empowered to achieve agreed goals, and want to please their healthcare professional.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with diabetes	M1: Desire to please / succeed	O1: Improved preconception health through	Some people with health conditions will find that the desire to please other people
C2: Desire for pregnancy	M2: Person is told what they need to do	achieving more stable blood	will help them to improve their preconception health by
C3: Desire to keep others happy		glucose levels	following the instructions given by the healthcare professional. For others it may be more about accountability and agreed goals.

This programme theory was identified through an interview with a woman with diabetes (W9), and triangulation was achieved during an interview with a healthcare professional who provided preconception care to women with a range of health conditions (HCP6). Both suggested that women may be motivated to maintain behaviour change by wanting to please their healthcare professional; this may be similar to students wanting to please their teachers; wanting to succeed and maybe get top grades. People can be motivated by making others happy, as illustrated in these quotes:

"This is gonna sound very silly. I kind of wanted to please them because they'd told me what I needed to do. I'm that kind of person that likes to make other people happy. I like to be helpful, and they told me to do something, so I felt like I should do it for them as well." (W9; aged 42 living with type 1 diabetes)

"I think I think there's an element of people wanting to prove themselves. and being empowered to do that, and with midwifery it's very much about ... And I think a little bit of us all is a people pleaser." (HCP6; midwife specialising in preconception care) There may also be an element of accountability within this programme theory; the

person may keep to the agreed plan because they know they will be seeing the

healthcare professional again soon, as demonstrated in this quote:

"... she came back repeatedly for that sort of support. And check-ins and for her she wanted regular check-ins to encourage that. You know [specialist pcc midwife]'s going to check in and ask how I've been doing and she said that helped with when she would want to just binge; she'd say, No, I'm going to speak to [specialist pcc midwife] soon, you know we've got plan in place. We've got a plan. We're, you know we're working towards something." (HCP6; midwife specialising in preconception care)

10.3 Conclusion

In this chapter I have presented the data and refined programme theories focusing on therapeutic relationships. In this group, three initial programme theories from the realist review were increased to eight programme theories during analysis, with the addition of five child nodes. Two initial programme theories were then combined, as they were refined, leaving seven refined initial programme theories. These were subsequently reduced, through step 5 of analysis (see chapter 7) to two middle rangeprogramme theories that I have presented here as both narrative and diagrams.

The two middle range theories in this group related to:

- The difference that a positive and respectful attitude from a healthcare professional can make, and
- The significance of continuity of carer

The first theory provides a causal explanation of positive outcomes that result from a positive and respectful attitude from a healthcare professional, whilst also explaining how a judgemental attitude from a healthcare professional can result in negative

outcomes. The second theory provides a causal explanation of the significance of continuity of carer in relation to preconception care for people with health conditions. I will provide further discussion of these theories in chapter 12 of this thesis.

Chapter 11

Results, Focusing on Social Structures and Healthcare Services

In this chapter I will present the third group of refined programme theories from the realist evaluation. This group focuses on social structures and healthcare services. The initial programme theories that I tested and refined in this area, were originally grouped into areas related to "the intervention" and "the process". Table 12 below shows the refined programme theories that contributed to the refined middle-range programme theories included in this chapter. As outlined in chapter nine, the numbering of initial programme theories in Table 12 below indicates the origins of the programme theories (see Figure 15 on page 172). I will conclude this chapter with a summary of results from chapters nine, ten and eleven, in relation to different stages of a person's journey, from the point of diagnosis of their health condition(s), up to and including the point of pregnancy planning.

Table 12. Refined programme theories and subsequently refined middle-rangeprogramme theories regarding social structures and healthcare services

Refined programme theories regarding social structures and healthcare services	Refined middle-range programme theories (social structures and healthcare services)	
1.3.5.1 Family support reduces anxiety and helps decision making	7. Family support	
1.3.5.2 Support from family attending appointments with lots of information		
1.3.6 Peer support	8. Peer support	
1.3.6.2 (N) Peer support negative online		
1.3.7 Psychological support	9. Multidisciplinary team approach to	
1.3.9 PCC clinic with follow-up support	pregnancy planning	
3.1.2 Integrated across primary and secondary care		
3.1.3 Multi-disciplinary PCC clinics for complex conditions		
3.1.4 Role of specialist nurses or midwives		
3.2.5 Waiting time for appointments		
2.3.7 (N) Treat obesity as a health condition	10. Treat obesity as a health condition	
3.1.5 Clear pathways and easy access to contraception	11. Clear pathways and easy access to contraception	
3.2.2 Socioeconomic factors	12. Preconception care for people experiencing challenging socio- economic circumstances	
3.1.7 Incentives to provide or refer for PCC	13. How to increase preconception care in primary care settings	

The programme theories I will present in this chapter fall into seven subgroups. As in chapters 9 and 10, I will present each refined middle-range programme theory below, in narrative form and as a diagram, with context, mechanisms (both resources and responses), and outcomes identified. Results from the interviews, providing evidence supporting each refined programme theory contributing to the refined middle-range programme theory will then be presented.

11.1 Family support

Two refined initial programme theories contributed to this refined middle-range programme theory. These both operate within the context of a person with any health condition with a partner and, or family available to provide support. This may include psychological, social, and, or physical support. They demonstrate the importance of the social structure of family and provide a causal explanation of how this can facilitate improved preconception health. This also provides a causal explanation of how people without support from a partner or family may find it difficult to improve their preconception health. Combining and abstracting the two programme theories resulted in this middle-range programme theory:

When a person living with a health condition is considering pregnancy has a partner and, or family available to provide support (may include psychological, social, and physical) (context) ...

If they are offered preconception care and advice, including the opportunity for the person to attend an appointment with their partner or family member (mechanism; resources), they will be able to talk about desires, options and difficult decisions with a person that is known and trusted, be able to express their emotions freely, and feel listened to and validated. They will also be able to review what was said at appointments together (mechanism; reasoning) ...

Then the person will be supported to improve their preconception health through reduced anxiety, ability to make informed choices, and sense of shared responsibility (outcome).

The theory is also presented as a diagram (Figure 22):

Context

Person living with health condition has family (including partner) available to provide support (may include psychological, social, and physical).

Resources

Preconception care and advice, including the opportunity for the person to attend an appointment with their partner or family member.

Mechanism

Ability to

review what

was said at

appointments

together.

Reasoning

Ability to talk about desires, options and difficult decisions with people that are known and trusted. Ability to express emotions freely; feel listened to and validated.

Outcome

Support to improve preconception health through reduced anxiety, ability to make informed choices, and sense of shared responsibility.

Figure 22. Programme theory 7: Family support

Evidence supporting the refined initial programme theories contributing to this refined middle-range theory is presented below.

11.1.1 First programme theory contributing to refined middle-range theory

regarding family support

1.3.5.1 IF the person with a health condition is able to talk about the situation and how they feel about it (challenges / fears / hopes / options etc) with their partner, and, or family, and has their support, THEN that person will feel validated, emotionally supported, less anxious, socially (including practically) supported, and more able to make decisions regarding pregnancy planning / sustained behaviour change to improve health.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with cystic	M1: Talking	O1: Reduced	People with health
fibrosis	about desires /	anxiety	conditions sometimes
	options /		have difficult
	difficult		reproductive choices to
	decisions with		make due to treatment
	family –		options / health
	people you		concerns. Family can
	know and trust		provide physical, social
C2: Person with type 1	M2: feeling	O2: ability to	and psychological
diabetes	validated /	make own	support. This may
	listened to	informed	include talking about
		choices	desires, options and
C3: Person with MS	M3: physical /	O3: shared	difficult decisions with
	social /	responsibility	family (people you know
	psychological	for health	and trust), the ability to
	support		cry and express
C4: Person with obesity	M4: being able		emotions openly, being
C5: Person with difficult	to cry /		listened to and feeling
decisions in view of	express		validated. This helps reduce anxiety and
treatment options	emotions		facilitate the ability to
C6: Family could improve	openly		make informed choices.
health too			In some cases, especially
C7: Challenging			where family members
reproductive decisions			could also improve their
C8: People with a partner			health through
and, or family who can provide support.			behaviour change, this
provide support.			results in a shared
			responsibility for health
			improvements.

Evidence contributing to this theory came from both women living with a range of health conditions (see above), and their partners or supporting family members (P1, P2, W9, W14, W18). People living with health conditions have more challenging reproductive decisions than those without; people spoke of the need for medication change, achieving stability of condition, or other behaviour change to improve preconception health. For some, including people with cystic fibrosis, a pregnancy may have implications for their own future health. People living with health conditions who participated in interviews spoke of a range of reproductive choices due to their condition, including opting for pregnancy earlier than previously planned, delaying pregnancy, or even deciding not to become pregnant. People therefore spoke of the importance and value of emotional, psychological, and social support from their partners and, or close family during the preconception period, which contributed to reduced anxiety and the ability to make informed decisions:

"I think I have family members that I value their opinion and you just want approval and I have other family members that would be like, no, that's a stupid idea or that's a good idea. And they would go away and look at it and help me like, make a more informed decision." (W14; aged 34 living with MS)

"My husband.... so, I think he might have come with me for the first [appointment]. And yeah, I I had a bit of a cry about it later ... yeah, 'cause it's it was such a terrifying list of things that could happen. And again, coming back to just being generally in a rage about having diabetes and it ruining everything." (W9; aged 42 living with type 1 diabetes)

Practical or physical support was also provided; even small things like the timing of meals were identified as something that could make a difference. The impact of having support from partners or supporting family members was described as contributing to a feeling of being part of a team and less isolated or alone. This was reflected in interviews with partners and supporting family members: "You're there, both as psychological support, but also social support, and in many ways physical as well, I suppose." (P1; supporting family member of a person living with cystic fibrosis)

"So, it was definitely emotional support and talking about it and listening, and everything. We also, we timed things, so we didn't eat late, for example, because eating late kind of played havoc with her blood sugar. I think she felt that it was a joint project, and that we were in it together, rather than it was her thing, which I think is something that we do for most things. So, I hope that it meant that she felt that she was supported, and that had anything going wrong, then we'd have been in it together." (P2; partner of person living with type 1 diabetes)

11.1.2 Second programme theory contributing to refined middle-range theory

regarding family support

1.3.5.2 IF a supporting partner or family member attends a specialist appointment with a person with a health condition THEN they can listen to the information offered, advocate for the person, and support them by reviewing the appointment with them afterwards.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1:	M1: Family member	01: Maximise	A person with a health condition
Person	listens to	benefits of	and desire for pregnancy is often
with lupus	information at	appointment	able to take a partner or family
	appointment (helps	with specialist	member with them to an
	particularly if lots of	HCP and	appointment with a specialist HCP.
	information)	promote	This is beneficial because they can
C2: Desire	M2: Family member	preconception	both listen to information provided
for	may have different	health	at the appointment (helps
pregnancy	perspective of what		particularly if lots of information),
	was said		and the family member may have
	M3: Person and		different perspective of what was
	family member can		said (perhaps focusing on the more
	review and reflect		positive aspects). They can ten
	on the appointment		review and reflect on the
	afterwards		appointment afterwards,
			maximising the benefits of the
			appointment to promote
			preconception health.

This programme theory was refined based on just one interview (W4), but it provides

an additional causal explanation of how and why support from a partner or close

family member can contribute to improved preconception health, through joint

attendance at appointments. People often struggle to remember everything said at an appointment. This may be due to anxiety, other concerns, or the volume of information. Having support in appointments helps with recall of information provided as well as remembering questions to ask, and in this way being able to advocate for the person living with a health condition:

"It's a lot of information to take in and kind of they would sometimes ask the questions that I maybe wouldn't be thinking of ... I was really upset, and I cried in that appointment. And then they were able to kind of maybe take in a bit more, maybe ask a couple of questions of what that meant ... I think getting a lot of information and weighing up things, kind of afterwards with someone is helpful." (W4; aged 32 living with SLE)

Close family members can advocate for a person in different ways and having been at an appointment can review what was said and discuss it with them afterwards. The person living with SLE who contributed to this programme theory described how this was helpful, especially when she came away from an appointment with a different perspective on the same information. She described how her mum would attend appointments with her and remind her of the positive things that were said. Her contrasting experience during the COVID-19 pandemic highlights the importance of being able to attend appointments with a supportive person:

"... they're giving me a much more of the positives balanced view that maybe I wouldn't see myself if I'm just feeling really upset about the potential risks ... yeah, the times when I've come out and I've said oh they've said this and this and they would point out, like the other side, they said this is possible ... and yeah it's quite funny. I think I've missed that during COVID actually, having someone with me in the appointments; I've been kind of maybe focusing on more of the negative side of things really. Yeah, that would have been good to have someone there." (W4; aged 32 living with SLE)

11.2 Peer support

Two refined initial programme theories contributed to this refined middle-range programme theory about peer support. One was from the realist review and the other emerged from interviews with women living with health conditions. Both theories operate within the context of a person with any health condition considering or planning a pregnancy. They demonstrate the potential positive outcomes of face-toface peer support and provide a causal explanation of how this can facilitate improved preconception health through shared experiences and emotional support. This also provides a causal explanation of how online forums providing "peer support", from people who they generally do not know, can be detrimental, due to more negative content. One exception is that people with cystic fibrosis always meet through virtual (online) peer support groups, never face-to-face, to reduce the risk of passing on lifethreatening infections (Conway, 2008). These two theories have therefore been combined into one middle-range theory:

When a person living with a health condition is considering or planning a pregnancy (context) ...

If they access face to face peer support (virtually for people with cystic fibrosis) (mechanism; resources), and if there is a sense of normality and mutual support through shared experience, an ability to laugh about things and people see others' success, which provides a sense of hope and reassurance (mechanism; reasoning) ...

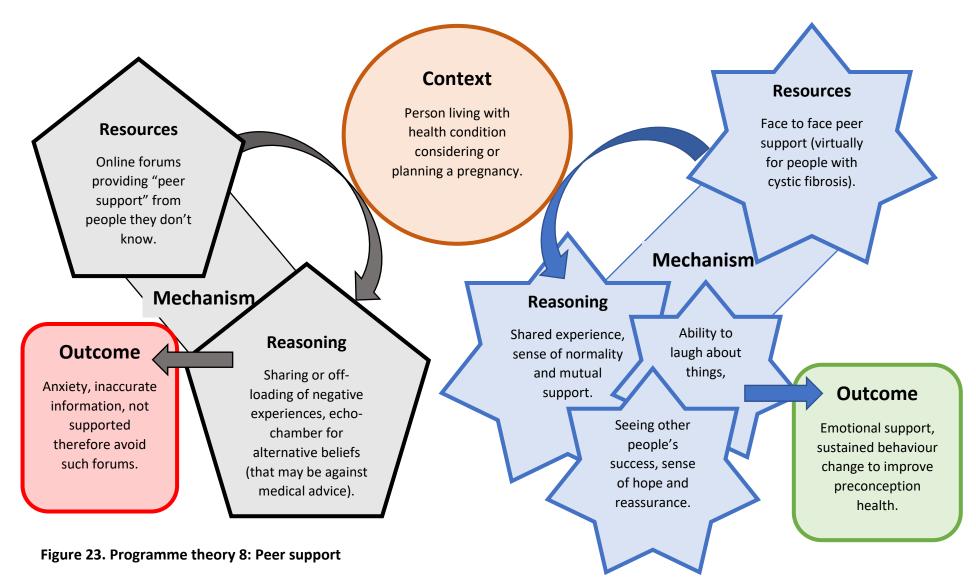
Then they will experience emotional support to sustain behaviour change required to improve preconception health (outcome).

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If they seek peer support from people they don't know via online forums (mechanism; resources), and if these involve sharing or off-loading of negative experiences, and, or become echo-chambers for alternative beliefs (that may be against medical advice) (mechanism; reasoning) ...

Then they will experience anxiety, inaccurate information, will not feel supported and therefore avoid such forums in the future (outcome).

The theory is also presented as a diagram (Figure 23):



Evidence supporting the refined initial programme theories contributing to this refined middle-range theory is presented below.

11.2.1 First programme theory contributing to refined middle-range theory

regarding peer support

1.3.6 IF people experience positive peer support (more usually face to face - NB exception of Cystic Fibrosis) THEN they are able to identify with each other through shared experiences, promoting a sense of normality, hope, emotional and social support. This can help sustain behaviour change to improve preconception health.

Contexts	Mechanisms	Outcome	Resulting CMOC:
			·
C1: Person with	M1: Shared	01: emotional	People with health conditions often
epilepsy	experience	support	have greater anxiety regarding the
C2: Person with	M2: Sense of	O2: sustained	challenges associated with
obesity	normality	behaviour	conception / pregnancy. Face to face
C3: Person with	M3: ability to	change to	peer support provides the
SLE	laugh about it	improve	opportunity to share experiences
C4: desire for	M4: mutual	preconception	and even laugh about them, which
children	support	health	provides a sense of normality and
C5: anxiety	M5: seeing other		mutual support. Seeing other
regarding the	people's success		people's success also adds to this
challenges	M6: sense of hope		and the overall effect is emotional
associated with	/ reassurance		support, which can encourage
conception /			sustained behaviour change to
pregnancy			improve preconception health.

Evidence supporting the benefits of peer support came from several women living with different health conditions, as outlined above (W11, W15, W18, W4, W5). They found that genuine support included emotional and psychological support, and that their shared experience made them feel more normal. This is demonstrated in the quote below:

"It makes it makes you feel more normal, I think that you're not the only one that's having these weird things that are happening, and you know she's a normal functioning human so it makes me feel better that I can be a normal function human as well." (W11; aged 34 living with epilepsy) People living with different health conditions (including epilepsy, obesity and SLE)

found support from a group of peers provided encouragement and reduced feelings of

isolation. During the preconception period this emotional support also provided a

sense of hope, especially when they were concerned about the potential impact of

their condition or medication on any future child, as in the case of women living with

SLE:

"It did give me kind of hope that she was able to go through it and everything was fine, and her little boy wasn't kind of harmed by the lupus or any medication. So, you've got people that you know, she's been through it with relatively few complications then it gives you hope that that you can do the same, I guess." (W4; aged 38 living with SLE)

"It's not nice for anyone to go through it, but to know there are people out there as well who have been through it or are going through it, just lets you know that you're not alone..." (W5; aged 38 living with SLE)

These women spoke about face-to-face peer support, although one healthcare

professional who worked with people living with cystic fibrosis (CF) (HCP7) highlighted

that similar support could be gained virtually. Virtual peer support is well established

for people with CF, for whom meeting face-to-face increases their risk of contracting

life-threatening infections.

11.2.2 Second programme theory contributing to refined middle-range theory

regarding peer support

1.3.6.2 IF peer support groups are available online THEN they can result in mainly negative					
stories and /or inacc	stories and /or inaccurate information and THEN women seeking preconception care will				
not find them emotion	onally supportive o	or helpful sources of a	ccurate preconception advice.		
Contexts	Mechanisms	Outcome	Resulting CMOC:		
C1: People with	M1: Other	O1: Anxiety and	People with a desire to have a		
autoimmune	"peers" online	negative feelings	baby, and a health		
disease	mainly older	(in general)	condition(s) that is linked with		
C2: People with SLE	M2: Online	O2: Inaccurate PCC	complex pregnancy, seek		
	posts involve	information shared	information from a range of		
	sharing negative	by individuals	sources including online.		
	experiences	online	Information posted by peers		
C3: People with	M3: Echo	O3: Avoidance of	mainly involves sharing		
obesity and PCOS –	chamber for	online "peer	negative experiences and the		
condition known to	alternative	support" platforms	online site can become an		
cause fertility	beliefs		echo chamber for alternative		
issues			beliefs. This causes anxiety		
C4: Desire to have			and negative feelings (for the		
a baby			person seeking information),		
C5: Seeking			may include inaccurate PCC		
information from a			advice, and results in people		
range of sources,			avoiding online peer support		
including online			platforms. Negative feelings		
			are enhanced when the health		
			condition is more prevalent		
			among older people.		

Several women contributed to this theory, which emerged from interviews (W13; W20; W3; W4; W7). They identified that people seek information inline, as this is a readily available source that can be searched easily using a mobile phone. Women living with SLE, auto-immune conditions and obesity described using online forums that were condition-specific to seek information, since their health condition could give them an increased chance of complex pregnancy, poor outcome, or infertility. They had a desire for information that was based on other people's experiences, especially if their condition was rare and they did not know anyone else with a similar condition. Without exception, however, their experiences were negative; they did not find these online forums helpful, and so they tended not to engage with them:

"I find [online forums and groups] quite depressing to be honest with you; there's a lot of.... doom and gloom and I try not to ... obviously it's a big part of my life, but I try not to kind of define myself with it ..." (W7; aged 28 living with SLE)

"I think online groups are a bit... [pause] I avoid them because I thought it was almost like a competition to see who was worse." (W3; aged 34 living with SLE)

"...there's an air of, like a "woe is me" kind of air around it and I'm not that kind of person. And I find it really difficult to relate to that sort of attitude, I feel like it brings you down a little bit, so I don't engage." (W13; aged 32 living with an auto-immune condition)

One woman living with obesity felt that the reason why online forums are negative and

do not provide effective support include the fact that people who post tend to be

those with big problems, those having a terrible time, and some become an echo

chamber of views that can be against medical advice. She described this as providing a

skewed sample, leaving people who had good experiences of pregnancy or pregnancy

planning not contributing to the online discussion:

"Oh, there's all this horrible, terrible stuff; well, that's because nobody comes on there to say, "oh, I'm just having a wonderful pregnancy gals; nothing ever goes wrong for me," because that's called putting the boot in." (W20; aged 35 living with obesity)

"You end up with this real echo chamber of everybody reinforces everybody else's, you know, stance on things. And then you suddenly end up with this group of women who have all decided that wild pregnancies where you have no medical check-ups, no preconception care, you don't go into your scans, and then you free birth ... So I think you have to be really careful..." (W20; aged 35 living with obesity)

11.3 Multidisciplinary team approach to pregnancy planning

Six refined initial programme theories contributed to this refined middle-range programme theory regarding a multidisciplinary team approach to pregnancy planning. These theories operate within the context of a person with a complex health condition, or conditions planning a pregnancy. They explain why, and how, a multidisciplinary team approach to pregnancy planning provides access to appropriate preconception care and support to improve preconception health. This is achieved through excellent communication between health professionals and the person concerned, which is facilitated by one point of contact (a specialist nurse or midwife), and results in personalised care that makes the person feel valued and validated, resulting in reduced anxiety and timely access to support. Combining and abstracting the five programme theories resulted in one middle-range programme theory:

When a person living with a complex health condition, or conditions, is considering or planning a pregnancy (context) ...

If appropriate specialist health professionals are involved in providing preconception care and they communicate with each other, and if one point of contact (a specialist nurse or midwife) is easily accessible via phone or email between any required specialist follow up appointments, with psychological counselling and support also available (mechanism; resources). And if there is shared vision and agreement for personalised preconception care between appropriate specialists, timely access to support when needed urgently, in addition to support for change that may take longer, making the person feel valued and validated (mechanism; reasoning) ...

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Then they will experience reduced anxiety, access to personalised preconception care and timely support to improve preconception health (outcome).

The theory is also presented as a diagram (Figure 24):

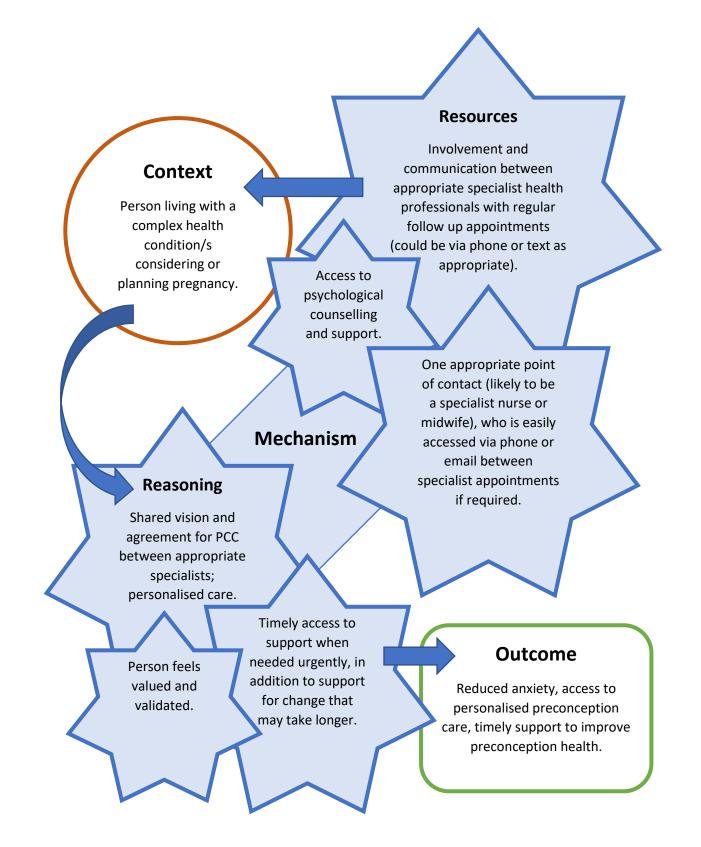


Figure 24. Programme theory 9: Multidisciplinary team approach to pregnancy planning

11.3.1 First programme theory contributing to refined middle-range theory

regarding multidisciplinary team approach to pregnancy planning

1.3.7 IF psychological counselling and support is available to people with health conditions in the preconception period THEN people will be able to discuss their situation, which will help reduce anxiety and assist with behaviour change aimed at improving preconception health.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with SLE	M1: discussion of	01:	People with health conditions often
	difficult decisions	reduced	have anxiety regarding the challenges
C2: Desire for	M2: verbalise	anxiety in	associated with conception and/or
pregnancy	anxiety	PCC period	pregnancy. Being able to discuss
C3: anxiety regarding	M3: feel listened		decisions and verbalise anxiety (with a
the challenges	to - validated		psychologist rather than medical
associated with			professional linked with condition)
conception /			helps the person by them feeling
pregnancy			listened to and validated, which
C4: People with			reduces anxiety in the preconception
epilepsy			period.

One woman living with SLE provided the majority of data that contributed to the refinement of this initial programme theory (W5), with two healthcare professionals providing triangulation of evidence (HCP1; HCP6) based on their experiences of working with people living with other conditions, including epilepsy, type 1 and type 2 diabetes. In addition to data from these interviews, most people thought that psychological support would be helpful even if they had not experienced it themselves. People highlighted that there was lots more to think and worry about with a health condition when planning a pregnancy. This included putting their own health at risk, which highlighted the relevance of psychological counselling, where they could verbalise concerns and feel validated, which helped to reduce anxiety:

"You're making that decision to try for a baby knowing it could put your health at risk and you do like ... you go through all the scenarios like. If I did have a flare up would I have to choose between the pregnancy and ... all these sorts of things are kind of there in the back of your head. There is a lot that goes around in your head ..." (W5; aged 38 living with SLE) "We will refer on to counselling if someone is very anxious or struggling. But we do that for epilepsy as well. Worry is big... yes." (HCP1; specialist epilepsy nurse)

"The impact, I think, I think it's being heard. I think it's being listened to, and being acknowledged, and that feeling of validation of having these fears and concerns, and that they're normal, and that they are not in the wrong for having any of these thoughts and feelings and worries." (HCP6; midwife specialising in preconception care)

11.3.2 Second programme theory contributing to refined middle-range theory

regarding multidisciplinary team approach to pregnancy planning

1.3.9 IF people receive ongoing follow up support from a preconception care clinic, via appointments, phone calls, texts or other means, THEN the healthcare professional can provide regular assessment, reassurance and support, THEN people will feel valued and cared for and are more likely to adopt appropriate behaviour change (eg. glycaemic / seizure control) to improve preconception health.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with	M1: regular	O1: improved	People with a health
diabetes	appointments for 12-	health prior to	condition who wish to
	18 months until	conception –	become pregnant, may
	achieved goal HbA1c	sustained	need to improve their
		behaviour change	health prior to
C2: Desire for	M2: specialist support,	O2: HCP has	conception, through
pregnancy	reassurance, guidance	overview of	sustained behaviour
C3: Person aware	M3: Specific PCC clinic	treatment and	change (this may include
they need to	(can be with	changes in	medication change /
achieve improved	pregnancy as well) to	preconception	adjustment. Regular
glycaemic (or	maintain monitoring /	health	appointments until
seizure) control.	support		desired goals are
i.e. improve			achieved provide the
preconception			specialist support,
health.			reassurance and guidance
C4: People with	M4: ability to refer to		needed to improve
epilepsy	other support,		preconception health,
C5: People with	including reduced cost		which may take over a
obesity	exercise class /gym		year. Having a clinic for
C6: People with			PCC enables the HCP to
health conditions -			maintain monitoring and
any			support this specific
			group.

This programme theory was supported by a woman living with type 1 diabetes (W9) and healthcare professionals with experience of supporting people living with a range of health conditions that may require sustained behaviour change to achieve improved preconception health (HCP1, HCP6). They found that regular follow-up appointments helped people living with health conditions to achieve their goals, whether that was more stable blood glucose and HbA1c levels for people living with diabetes, seizure control on appropriate medication for people living with epilepsy, or weight loss for women living with obesity. This theory also links with the theory about continuity of carer, since this was provided in cases where follow-up appointments were discussed:

"I think [it took] a year, year and a half to get everything to a safe enough level to start [trying to conceive]. So, I was seeing them every few months through that time. So, reasonably often 'cause it took me quite a while to get to a level that I was happy with." (W9; aged 42 living with type 1 diabetes)

"The focus is on getting them started at the beginning of the journey and then supporting them through, so we don't lose sight of them ... So that's really how the clinic has started and my role within it is obviously to support women, look at their treatment, their seizure control..." (HCP1; epilepsy specialist nurse)

The need for follow up appointments was identified as dependant on the individual. One midwife specialising in preconception care and offering a clinic for people with health conditions identified that very few people needed to return for a face-to-face visit, having gained information and support initially. She was able, however, to offer email contact if people had further questions, and arrange a phone call if that was required. She found that the option of just having a "check in" was beneficial for some people. This was the case particularly for people who needed to sustain behaviour change to improve their preconception health:

"It was very much about optimizing their health, and women would report back and say that actually having a check in ... was an added incentive to stick to their behaviour change ... [providing an example] she said that helped with when she would want to just binge; she'd say, No, I'm going to speak to [the midwife] soon, you know we've got plan in place. We've got a plan. We're, you know we're working towards something." (HCP6; midwife specialising in preconception care)

11.3.3 Third programme theory contributing to refined middle-range theory

regarding multidisciplinary team approach to pregnancy planning

3.1.2 IF provision is i	3.1.2 IF provision is integrated care between appropriate health professionals, across primary			
and secondary care systems as required THEN a shared vision for preconception care will result				
in a consistently better provision of preconception care, reduced anxiety for the person, and				
support to improve	preconception health			
Contexts	Mechanisms	Outcome	Resulting CMOC:	
C1: Person with	M1:	O1: Access to	People with health	
epilepsy	communication	appropriate PCC and	conditions who are	
	between HCPs	support	considering or planning a	
C2: Person with SLE	M2: HCP's in	O2: Support to	pregnancy may need input	
	different settings /	improve	from more than one	
	specialities are all	preconception	healthcare professional.	
	aware of the	health	Specialists need to maintain	
	situation		effective communication, so	
C3: People with	M3: specialist	O3: Reassurance and	they are all aware of the	
mental health	midwife acts as	reduced anxiety	situation, and having one	
conditions	point of contact /		providing a point of contact	
C4: People with	resource /		and co-ordinating care will	
any health	connector		ensure that access to	
condition			appropriate preconception	
C5: considering or		O4: shared vision for	care and support is available.	
planning a		PCC between HCP's	Having input from relevant	
pregnancy			healthcare specialists will	
			provide reassurance and	
C6: need input			reduce anxiety and therefore	
from more than			contribute to support to	
one healthcare			improve preconception	
professional			health.	

This initial programme theory was supported by evidence from both women living with a range of health conditions (see above), and healthcare professionals (W11, W7, HCP3, HCP6). This theory highlights the importance of shared knowledge and communication between appropriate healthcare professionals in different settings, which results in a shared vision and the opportunity for improved preconception health. People identified that good communication made sure that everyone involved was aware of any decisions, plans, or medication changes, especially when a person living with a health condition is mainly supported in primary care, with occasional specialist input, as in the case of some mental health conditions. One consultant psychiatrist working in the area of perinatal mental health welcomed communication from GP's working in primary care, and was particularly aware of the importance of preconception care to maintain good mental health when women had a history of previous serious perinatal mental health problems:

"These [letters] act as an aide memoire, OK, because when people are stressed, sometimes they miss information. So, these letters are important for them because they are an account of our discussion. This is why I write the letters and I also send them to the GP ... The GP or the other professional that works with this lady would be able to get advice from me at any point in time. They can email me, or they can contact me and tell me what's happening, and I would be happy to offer my advice." (HCP3; consultant perinatal psychiatrist)

11.3.4 Fourth programme theory contributing to refined middle-range theory

regarding multidisciplinary team approach to pregnancy planning

3.1.3 IF a multidisciplinary model of preconception care is used (where specialists in the health condition as well as specialists in maternity care are involved in the consultation and ongoing communication) THEN this enables expert input and collaboration (regarding planning for complex pregnancy), promoting support to improve preconception health, personalised care, reassurance, autonomy, and informed decision making.

personalised care, reassurance, autonomy, and informed decision making.			
Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with SLE	M1: HCP's in	O1: Access to	For people with complex
(x3)	different settings /	appropriate, person-	health conditions
	specialities have	centred PCC and	involving multiple body
	relevant	support	systems and potentially
	information		teratogenic medication,
C2: Person with	M2:	O2: Support to	multi-disciplinary PCC
diabetes	communication /	improve	provide the opportunity
	discussion between	preconception	for information sharing
	HCPs	health	and joint decision
C3: people with CF	M3: person with	O3: Reassurance,	making. This level of
	health condition	reduced anxiety &	communication and
	also involved in /	greater feelings of	personalised care
	aware of discussion	control	promotes access to
C4: people		O4: increased	appropriate support to
planning pregnancy		information	improve preconception
with complex		promoted informed	health and also provides
health conditions		decision making	reassurance, reduced
involving multiple			anxiety and greater
body systems and			feelings of control. This in
potentially			turn, promotes informed
teratogenic			decision making.
medication.			

Evidence supporting this programme theory came from interviews with women living with complex health conditions that might affect more than one body system, including SLE and CF, as well as healthcare professionals (W3, W4, W5, W9, HCP6, HCP7). This theory is relevant for people with complex health conditions, who benefit from the input of more than one specialist. Women with SLE described attending a face-to-face preconception care clinic when they were considering and or planning a pregnancy. They identified that conversations between appropriate specialists and themselves promoted person-centred discussion, decision making and reduced anxiety. This was followed up by ongoing email communication, as required, behind

the scenes where results from blood tests might inform ongoing treatment:

"It was a joint pre pregnancy counselling clinic ... So, I had a consultant nephrologist, obstetric physician a consultant obstetrician and then there were quite a few students in the room, as well ... it was really reassuring that they were taking my health seriously and discussing the various issues potentially with a pregnancy. It really did put my mind at ease, although going [there] was a pain, but at the same time, I was like, I'm seeing the best people. I think it made me feel like there was a plan, if I did get pregnant." (W5; aged 38 living with SLE)

"There was four of them really that were kind of emailing and communicate and about the results and what this meant and what's the best kind of treatment for me. They communicated behind the scenes really. So, I did feel that kind of I was on the best medication that I could have to balance the risks really, and they were all in agreement about that." (W4; aged 32, living with SLE)

Communication between specialists and the person with the condition promotes

planning, support, and provides the opportunity to consider complex situations,

including medication issues. The person knowing that specialists are having

considered conversations to promote their wellbeing also provides reassurance,

knowledge of what to expect, and promotes self-worth:

"I felt much more confident being under the care of those guys as well and hear directly from them about what my personal risks were as well ... so, overall, it was definitely a really good thing to help me kind of make the decision about definitely wanting to try for a baby really." (W4; aged 32 living with SLE)

"I felt reassured, I think that knowing that ... everyone that I've seen was copied into the letter and I got a copy as well so, it felt like it wasn't done in isolation, they were having conversations, but they were sharing their findings as well to help, so say if anything was missing, I don't think it was, someone might go oh, have you thought of this. So, by having these people involved I feel they're having the whole spectrum of potential issues ... my GP and my renal consultant at my local hospital as well." (W5; aged 38 living with SLE)

In this theory, it was noted that follow up appointments with a multidisciplinary team

were not necessarily needed; these were generally one-off appointments, and the

person living with a health condition would continue with routine appointments after

that.

"[People with CF] are attending [the PCC] in order to get a bit of sign off and reassurance, that this is an OK thing to want and to desire. and to see whether there are particular things they should be targeting from their CF perspective, to improve or to optimize before actually getting pregnant. Yeah, to my knowledge, I think most patients have just attended as a one off, because then they would essentially have these targets set that would be fed back into their routine clinical care, and then with the view to hopefully improving everything and being seen in the pregnancy clinic in the future." (HCP7; dietician working with people living with CF)

11.3.5 Fifth programme theory contributing to refined middle-range theory

3.1.4. IF people have access to a specialist nurse or midwife (in relation to their health condition) THEN they can access support and advice in a timely manner, including condition specific preconception care and, or access to a consultant if required. THEN this will reduce their anxiety due to reduced waiting times, uncertainty, and promote access to preconception care to improve preconception health.			
Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: person with autoimmune condition	M1: specialist nurses accessible (via phone or email)	O1: timely access to PCC to maintain / improve preconception health	People with health conditions benefit from easy and timely access to a knowledgeable health care professional between consultant appointments. A
C2: person with MS	M2: specialist nurses knowledgeable, so able to provide relevant support or refer to consultant if required	O2: reduced anxiety	specialist nurse with condition-specific knowledge can be trusted to provide this, with email or telephone access. This can also facilitate prompt referral to a
C3: person with SLE C4: person with diabetes	M3: trust in specialist nurse/s		consultant if necessary and reduces anxiety for the person. Timely access promotes preconception health by preventing unnecessary delay.

regarding multidisciplinary team approach to pregnancy planning

This programme theory was supported by women living with a range of health

conditions (see above) (W13, W14, W4, W7, W9), who provided evidence regarding

the benefit of specialist nurses, some of whom may have been advanced nurse (or clinical) practitioners. One midwife specialising in preconception care also contributed evidence (HCP6). An important aspect described by people living with health conditions was ease of access to a specialist nurse or midwife, either via email or phone, which they did not experience from a consultant; this provided reassurance and reduced delays to accessing urgent advice. The specialist nurses were also described as very knowledgeable and compassionate. The quotes included below demonstrate support for this theory from women living with a range of health conditions:

"It's very reassuring. It's nice to know that if I have a change in circumstances or I need advice, I can pick up the phone any day of the week; generally, other than the weekend and they will contact me, they will get back to me and I know that then I don't have to wait for weeks for an appointment with a consultant. ... The GP's, you know, are very good, but they don't understand your condition the way the specialist nurses do." (W13; aged 32 living with an auto-immune condition)

"I think, knowing that you can reach out to somebody when you need to and you're not waiting for like six monthly or yearly appointment, just being able to reach out when needed [is helpful]. Yeah." (W14; aged 34 living with MS)

"I think like it gives you maybe some autonomy that you can kind of contact them yourselves, rather than kind of having to go around the houses, I don't know, like a general number and it taking a while to get back, like a direct contact is it feels more personal and supportive really." (W4; aged 32 living with SLE)

"Having that point of contact, which is difficult [for me] at the moment, there isn't really that. Yes, that would be good I would like that ... a point of contact that you don't have to wait four months for and that is actually useful; where you can actually speak to anyone about it. And if i'm calling the number is because I want to speak to someone. I'm not doing it for a laugh; yeah, it's because there's a problem it's, not because I want to chat. If I wanted to chat, I'd call my friend." (W7; aged 28 living with SLE)

"Yeah. The, the, the nurse that I had, she was amazing, very knowledgeable, very compassionate. Yeah, I think seeing just her would have been fine." (W9; aged 42, living with type 1 diabetes)

The specialist midwife worked in a slightly different way; rather than being a specialist

in one health condition, she was able to communicate regarding preconception care

and advice with a range of appropriate consultants. She provided a similar service to

women with a range of health conditions, however, in terms of access and

compassion:

"You know you're the person that's coordinating information from all different places, but they know where to come. And also, I think an important thing is that they've also got that open access, almost like you know they can come back to you. They do know who to call, and they're not just left in the dark." (HCP6; midwife specialising in preconception care)

11.3.6 Sixth and final programme theory contributing to refined middle-range

theory regarding multidisciplinary team approach to pregnancy planning

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: person with depression	M1: long wait for PCC	O1: no improvement in preconception health prior to	People with health conditions and a desire for pregnancy may not have the opportunity to improve their preconception health if
C2: person with lupus C3: person with epilepsy C4: desire for pregnancy	M2: awareness of "biological clock"	O2: anxiety	there are long waiting times for PCC appointments. An awareness of the "biological clock" or limited window of fertility increases anxiety around this and may lead to people becoming pregnant before accessing PCC and having the opportunity to improve preconception health.

Three women with health conditions contributed evidence supporting this programme theory (W10, W6, W11). They had experienced increased waiting times for appointments due to the COVID-19 pandemic and other pressures on the NHS. There are also regional variations in waiting times for appointments. Delayed appointments for preconception care can result in people not accessing support to improve their

preconception health, as they will become pregnant before their appointment:

"At the moment [during COVID pandemic] my doctors won't even see people at the moment they're not doing any general appointments, it's just emergencies." (W10; aged 28 living with depression)

"I've got my first [specialist] appointment on Tuesday; that's taken almost a year, and it's a phone call ... We've just we've just said to just go ahead and try anyway, because it can take ages anyway can't it? Either way, it's not going to stop ... we both want children so it's not going to stop us, you know...." (W6; aged 32 living with SLE)

One woman living with epilepsy was aware of reducing fertility with age; she described

how excessive waiting times for appointments could cause additional anxiety:

"I'm now in my mid 30's and it's a finite amount of time left. And so, there's more of an impetus I think it's important to speak to somebody, a specialist about it so I must admit that I got an appointment within, it was definitely within a month, to see the [specialist] and that was actually really, really quite good because it, you know calmed my anxiety about everything. Yeah, um but I mean if I had to wait, more than three months, that would just be really stress inducing." (W11; aged 34 living with epilepsy)

11.4 Treat obesity as a health condition

One programme theory contributed to this refined middle-range programme theory, which operates within the context of a person living with obesity. It provides a causal explanation of how preconception health could be improved by treating obesity as a health condition and emphasises the importance of treating people with kindness and respect:

For people living with obesity (context) ...

If they are treated with kindness and respect, and obesity is treated as a health condition, including maintaining records of people's height and weight and making treatment options available (mechanism; resources). And if the person and their healthcare professional can discuss this condition, without feelings of guilt or blame, including changes in body mass index (BMI) over time and effectiveness of treatment (mechanism; reasoning) ...

Then they will have support to improve their preconception health (outcome).

The theory is also presented as a diagram (Figure 25):

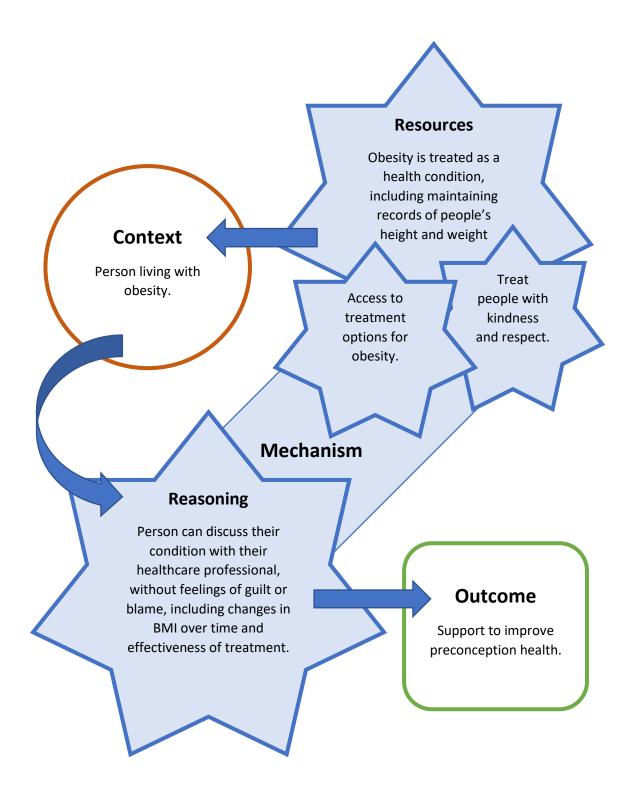


Figure 25. Programme theory 10: Treat obesity as a health condition

Evidence supporting the refined initial programme theory contributing to this refined

middle-range theory is presented below.

11.4.1 Programme theory contributing to refined middle-range theory: treat obesity

as a health condition.

2.3.7 IF women living with obesity are just told to lose weight, despite having tried many times before THEN they will not be supported to improve their preconception health BUT IF obesity is treated as a health condition, women are treated with kindness and respect, and appropriate treatment options and support are offered THEN they will have the opportunity to improve their preconception health.

		1	
Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person living with obesity C2: History of	Negative M1: Repeated messages to lose weight, which feels like they are being blamed. Negative M2: Lack of clear	Negative O1: No support to improve preconception health Negative O2:	Women living with obesity often have a history of attempted weight loss. When they are contemplating or planning a pregnancy,
attempted weight loss	solution to reduce weight from GP (tried before and not succeeded)	Reduced self - esteem and poor mental health	if they feel blamed due to repeated messages to lose weight, with no clear
C3: Desire for pregnancy	Positive M3: Treat obesity as a health condition, including maintaining records. Positive M4: Treat people living with obesity with kindness and respect. Positive M4: Offer treatment options such as referral to weight management service (specialist support), with regular meetings and accountability for actions Positive M5: peer support from others in weight management group (seeing successes / sharing)	Positive O3: Support to improve preconception health	solution of how to do so offered by their GP, then they will experience reduced self-esteem, poor mental health and will not be supported to improve their preconception health. If women living with obesity are treated with kindness and respect, and obesity is treated as a health condition with treatment options, such as referral to weight management services, then women are more likely to be supported to improve their preconception health.

This programme theory emerged from interviews with women living with obesity (W17, W18), and healthcare professionals working in primary care (HCP8, HCP9). Both women had poor experiences of repeatedly being told to lose weight and exercise more, despite struggling with their weight but not being offered any effective support. This resulted in them feeling blamed and even shamed, for their condition, resulting in poor mental health, reduced self-esteem and no preconception support:

"You've learned that fat is self-inflicted, and therefore, yeah, fat is bad; you are fat; you are bad, because you've done it to yourself! Like all these people that are like, oh, well just lose weight... Oh, sure, if it was that easy, everybody would be skinny ... Yeah, because they think you can just stop being fat. That's the thing. They know that you can't just stop being epileptic, but they think that you can just stop being fat, like, Yeah, I I could work at it, and all of this stuff, or I could go for surgery, or I could do this, blah blah blah! But I am fat right now, and it's not... You know, there's no miracle cure. There's no quick fix. It's. It is what it is. So I think that's what they, Yeah, that's where it comes from, that that oh, just lose weight, like that's such a flippant remark. And they say that oh, it's obvious; eat less and exercise more." (W17; aged 33 living with obesity and also type 2 diabetes)

Whilst one of the women had experienced similar feelings, having been referred to a weight loss management service she described feeling more supported. She attributed this to being part of a group of like-minded individuals, receiving relevant support around nutrition and exercise, seeing other people progress, hearing their stories, and

being accountable on a regular basis for your own achievements:

"So, it's all about accountability ... I think it's [how it works], having other people there as well. So, I think it's like being in a group, because everybody, you know puts in how they're feeling and how they've done. um have you tried this? But for my nutrition sessions there's people in there who have been in the service for over a year, you know, and they can say, well, I lost like five stone, which is amazing, but they can tell you, you know, tips and tricks on how they did it." (W18; aged 28 living with obesity and also polycystic ovary syndrome) Healthcare professionals contributing to this theory compared obesity to diabetes and highlighted the need to monitor weight in a similar way to blood glucose or blood pressure. Currently, obesity is not treated as a health condition, so weight is not monitored regularly. Obesity may then not be addressed until it is identified through its impact on another area of health, such as type 2 diabetes or joint pain. The healthcare professionals participating in interviews providing evidence supporting this programme theory both worked as GPs in primary care and expressed concern regarding rising obesity levels in view of the impact this has on other areas of health, including the impact of obesity on pregnancy. They felt that treating obesity as a health condition could result in people being supported earlier, including the provision of preconception care.

"If you had someone who was diagnosed as diabetic, they would get their HbA1c measured annually. I think, in my practice it would be by the nurse. [But] for someone who is obese; a non-diabetic obese person; no [there is no annual follow-up], because we would have no record that she's obese in the first place, because the registers aren't up to date and no one measures it ... if someone's obese, you wouldn't necessarily even do a blood test to see if they're diabetic; that wouldn't automatically follow, so obesity is neglected. Obesity needs to be measured, addressed, and managed; that will have a positive effect on other health conditions on you know... risk of everything, on preconception health, on everything. It's not about the preconception health, it's about the obesity." (HCP8; GP working in primary care)

One healthcare professional recognised that people living with obesity may carry feelings of guilt due to a previous problem, such as a miscarriage. Healthcare professionals thus acknowledged that people living with obesity, as with any health condition need to be treated with respect and should not be blamed for their condition.

"You don't want to scare them ... You've just got to be careful about weight management advice, because if somebody's had a miscarriage or a problem, a

stillbirth. And you imply it was because of their weight they've already got enough guilt.... So, it's about how you give the message isn't it." (HCP9; GP working in primary care)

11.5 Clear pathways and easy access to contraception

One programme theory contributed to this refined middle-range programme theory, which operates within the context of a person with a health condition not wanting to, or advised not to, become pregnant before improved preconception health. It provides a causal explanation of how unplanned pregnancy could be avoided and preconception health could be improved by ensuring contraception is clearly discussed and easily available. The theory has therefore been further refined into one middlerange theory:

When a person living with a health condition does not want to or is advised not to become pregnant before improved preconception health (context) ... If there are clear guidelines, pathways, and services available to access contraception easily, and if healthcare professionals communicate clearly about contraception (mechanism; resources). People will know the importance of using contraception and be able to access it easily (mechanism; reasoning) ...

Then they will have access to effective contraception reducing anxiety, unplanned pregnancy and enabling improvement in preconception health (outcome).

The theory is also presented as a diagram (Figure 26):

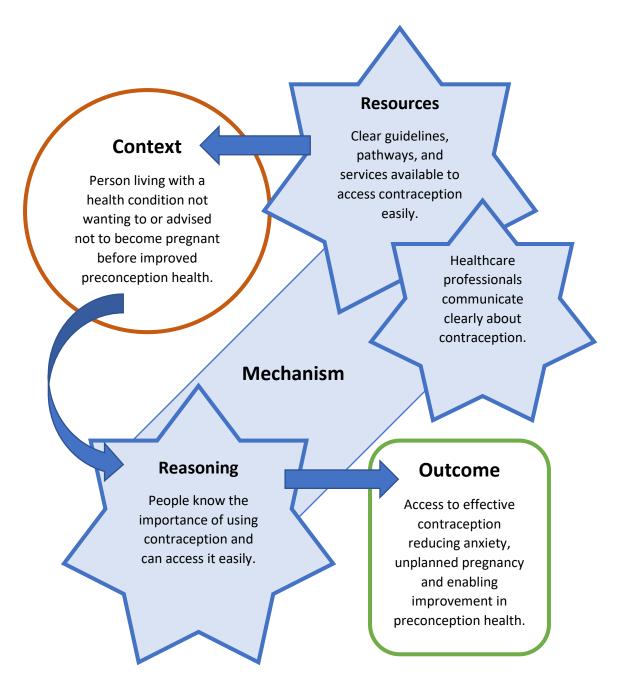


Figure 26. Programme theory 11: Clear pathways and easy access to contraception

Evidence supporting the refined initial programme theory contributing to this refined

middle-range theory is presented below.

11.5.1 Programme theory contributing to refined middle-range theory regarding

clear pathways and easy access to contraception

3.1.5 IF clear guidelines and pathways are available to access contraception easily, and healthcare professionals have open and honest conversations about this THEN people with health conditions are more likely to access appropriate contraception, prevent unplanned pregnancies, and have reduced anxiety.

pregnancies, and	pregnancies, and have reduced anxiety.				
Contexts	Mechanisms	Outcome	Resulting CMOC:		
C1: Person with	Negative M1: No real	Negative O1:	People with health conditions		
health	conversation with	poor	are sometimes advised not to		
condition,	HCP – closed	contraception	become pregnant, due to		
advised not to	questions used	therefore	medication or other treatment		
become	regarding	unplanned	that is required to improve		
pregnant before	contraception	pregnancy prior	preconception health. When		
improvement in		to	this advice is not followed by		
preconception		improvement in	supportive conversations		
health		preconception	regarding effective		
		health	contraception, and there are no		
C2: person with	Negative M2: No	Negative O2:	clear pathways to access		
busy lifestyle	clear pathway to	uncertainty and	contraception, this can result in		
	access contraception	anxiety	uncertainty, anxiety, poor		
	Negative M3: feeling		contraception use and		
	awkward talking		unplanned pregnancy prior to		
	about contraception		improvement in preconception		
	/ SRH		health or when a person is		
			taking teratogenic medication.		
			Clear pathways and easy access		
			to contraception is therefore		
			required to reverse this.		

This programme theory was refined using evidence provided by two women with different health conditions and a healthcare professional (W21, W3, HCP9), all of whom lived in different regions of the UK. The theory was developed from people's experiences of a lack of clear pathways to access contraception, including the impression that the GP receptionist would turn them away, which led to uncertainty, anxiety, and in some cases unplanned pregnancy prior to optimisation of

preconception health.

"Well essentially yeah, I think the gist of [the conversation] was "Do not get pregnant before you have this heart operation", because, you know it was very high risk at that point. But again. I didn't take any contraception ... I don't even know now, if I wanted ... I probably should start taking contraception again, because I really don't want to have another child, but I don't even know where I'd start. Would I just call up the GP? And try and like get through their receptionist, that I need to have a conversation, like I don't even know. Did there used to be like family planning clinics or something that you're meant to go to. But I don't think there's one near us. I feel like I'd be wasting the GP's time..." (W21; aged 36 living with Marfan's syndrome)

"[The specialist HCP] just said, "don't get pregnant" and that was it. No discussions with the GP... because I tried to make an appointment my GP at the time. Because I had other concerns with [specific medication] because it's horrible. The receptionist... I tried a couple times ... the receptionist said, no you don't need one. I was completely fearful [about becoming pregnant]." (W3; aged 34 living with SLE)

The GPs that contributed to evidence supporting this theory were aware of the

challenges for women seeking access to contraceptive advice and care, acknowledging

the impact of this. They highlighted pressures in primary and secondary care, and

difficulties identifying where to access contraception. One GP working with women

experiencing socio-economic deprivation described offering opportunistic long-acting

reversable contraception (LARC) and also having a mobile unit that will provide care,

including contraception, where it is needed. This, however, is not usual practice across

the UK.

"In our clinic we do opportunistic coil fitting and implants. You know, if I'm the middle of clinic and they've got [someone] in and she's finally agreed to have an implant, you know, we will do it there and then. And we've got a mobile unit that will go out ... you know, but yes, it's been a common complaint over the last few years, particularly that it's harder and harder [to access contraception] so, you've got to be able to know where your pathways are." (HCP9; GP working in primary care in area of high deprivation) 11.6 Preconception care for people experiencing challenging socio-economic circumstances

One programme theory contributed to this refined middle-range programme theory, which operates within the context of people with health conditions experiencing challenging socio-economic circumstances, including chaotic lifestyles. Data to inform this programme theory came from healthcare professionals, not the people themselves, so provides an organisational perspective and would benefit from further refinement, which would require more evidence. This theory, however, provides a causal explanation of how relevant preconception information and appropriate accessible services to improve preconception health can be provided for people with health conditions experiencing challenging socio-economic circumstances. The theory has therefore been further refined into one middle-range theory:

People living with health conditions experiencing challenging socio-economic circumstances, including those with chaotic lifestyles, are often excluded from healthcare services that are offered to the majority (context) ...

If people's needs are identified, information about preconception care is coproduced, and people's psychosocial needs are considered, and if innovative services are provided to meet people's needs (mechanism; resources), by offering healthcare services that are relevant and accessible (mechanism; reasoning) ...

Then access to preconception care and support to improve preconception health will be available (outcome).

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The theory is also presented as a diagram:

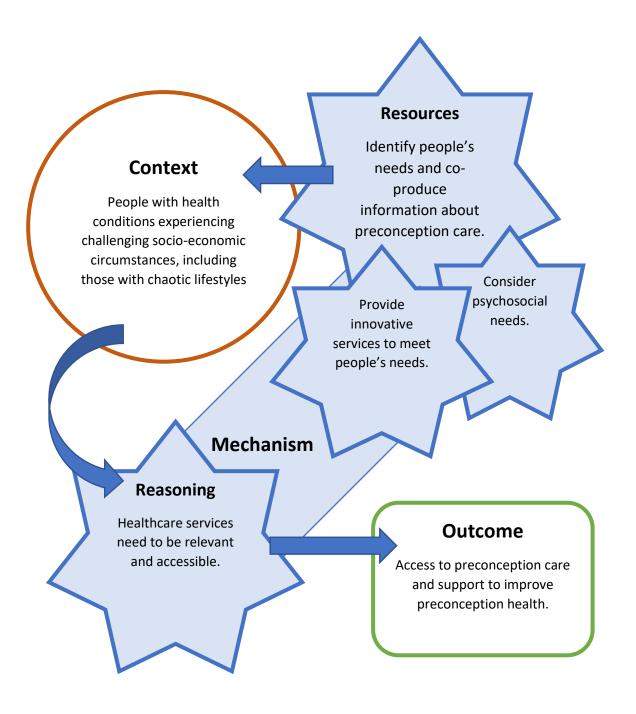


Figure 27. Programme theory 12: Preconception care for people experiencing challenging socio-economic circumstances

Evidence supporting the refined initial programme theory contributing to this refined

middle-range theory is presented below.

11.6.1 Programme theory contributing to refined middle-range theory regarding

preconception care for people experiencing challenging socio-economic

circumstances

3.2.2. If a person experiences challenging socio-economic circumstances and has a chaotic lifestyle THEN they will not find it easy to engage with healthcare services (offered to the majority of the population). IF healthcare providers identify people's needs, work with them to co-produce information, and design innovative services to meet their needs, including psychosocial needs THEN preconception care messages and services will be relevant to them, and access to preconception care will improve resulting in improved preconception health.

		. .	
Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: People	M1: Identify	O1: relevant	CMOC from HCP data (not women /
with health	people's needs	services and	partners)
conditions and		messages	
"chaotic			Healthcare services are not designed
lifestyles"			to meet the needs of people with
C2: sex	M2: Co-production	O2: Improved	chaotic lifestyles.
workers who	of preconception	access to PCC	
have	information		To provide PCC to people with
experienced	M3: innovative	O3: Improved	chronic conditions in these contexts
previous loss	services to meet	preconception	it is important to identify their
(children	the needs of	health	needs, work with them to co-
taken into	people with chaotic		produce information, and design
care)	lifestyles		innovative services to meet their
	M4: consider		needs, including psychosocial needs.
	psychosocial needs		This will ensure that PCC messages
			and services are relevant and access
			to PCC is improved, resulting in
			improved preconception health.

The healthcare professionals providing evidence supporting this theory had experience providing care to people with challenging socioeconomic circumstances and, or chaotic lifestyles (HCP1, HCP9). They acknowledged that individuals in these circumstances (or contexts) do not find it easy to access healthcare services, which may require transport, planning, organisation, and motivation to attend. This results in lack of access to preconception care and contributes to poor preconception health in this group.

"She's got a very chaotic life, and I think you bring chaos into anyone's life... and I think as well, it's almost like... I don't think her epilepsy is always in her mind ... In between babies we reach out to her, she just doesn't attend her appointments, she just doesn't come. And it's not for the want of talking her through it." (HCP1; specialist epilepsy nurse)

The healthcare professionals acknowledged that a different approach is needed for different populations. Women who have experienced adverse childhood events (ACEs) may have very low levels of self-esteem and self-efficacy; sex workers will have trauma from a history of perinatal loss and repeatedly having any baby taken away. These examples highlight the need to identify people's needs before co-production of innovative services to increase preconception care for people within those groups living with health conditions. Evidence from one GP working in an area of high deprivation, who participated in an interview, demonstrated that innovative approaches were possible.

"The population we deal with, you know, lots of women have got ACE's [adverse childhood events]. So, one of the lessons we learnt early on was that you can't deliver the same preconception messaging to everybody ... you couldn't give the same message to the sex workers ... we work very closely with a local voluntary sector organization, and since they've been running, maybe 10 years, every pregnant sex worker has had the baby taken off them. So, if you talk to the sex workers about, you know, planning your pregnancy; for them, it just re-lives their trauma, so we had to be very careful about making those messages much more around unpicking, well we had a psychologist working with us, a family and social psychotherapist, and she did some very in-depth work trying to pick the ACE's and then empowerment and choices." (HCP9; GP working in primary care in area of high deprivation)

11.7 How to increase preconception care in primary care settings

One programme theory contributed to this refined middle-range programme theory, which operates within the context of people with health conditions accessing primary care. Data to inform this programme theory came from healthcare professionals, providing a relevant organisational perspective and would benefit from further refinement, which would require more evidence. This theory, however, provides causal explanations of how access to timely, accurate, evidence-based preconception care could be increased, through either a "push" or "pull" effect. The theory has therefore been further refined into one middle-range theory:

When people living with health conditions access primary care (context) ...

If financial incentives, reminders on patient record systems, electronic checklists with links to appropriate guidelines, or a government mandate was in place to provide preconception care; or if there was celebrity endorsement of preconception care (mechanism; resources), these would either "push" provision of preconception care or provide a patient driven "pull" for preconception care (mechanism; reasoning) ...

Then people would be able to access timely, accurate and evidence-based preconception care in primary care settings (outcome).

The theory is also presented as a diagram (Figure 28):

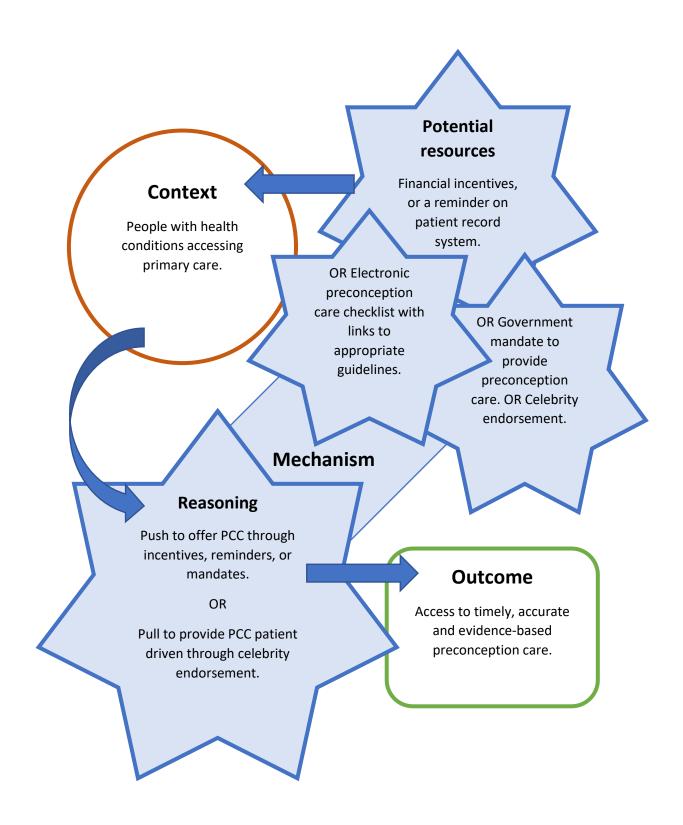


Figure 28. Programme theory 13: How to increase preconception care in primary care settings

Evidence supporting the refined initial programme theory contributing to this refined

middle-range theory is presented below.

11.7.1 Programme theory contributing to refined middle-range theory regarding

how to increase preconception care in primary care settings

3.1.7. IF incentives, reminders, or government mandates were used to encourage healthcare professionals in primary care to provide preconception care, and, or if preconception care was patient driven through celebrity endorsement, THEN people with health conditions would be more likely to access timely, accurate and evidence-based preconception care in primary care settings.

Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Providing PCC	M1: incentivised	O1: Access to	Based on data from HCP's;
in primary care	through QOF or	accurate and	no data from interviews with
	similar scheme	evidence-based PCC	W or P's to support this
C2: People with	M2: Reminder on	for people with	theory (possibly as
long term	patient record	health conditions	expected).
conditions	system with "flag"		
	M3: Electronic PCC		
	checklist – with links		
	to relevant NICE		
	guidelies (easily		
	available to HCP's in		
	primary care)		
	M4: government		
	mandate to provide		
	PCC		
	M5: patient driven		
	through celebrity		
	endorsement		

Four healthcare professionals provided data that contributed to this theory (HCP10, HCP5, HP8, HCP9). They acknowledged that the provision of preconception care in primary care settings needed to increase, providing a variety of suggestions that may help, with conflicting opinions on whether these would work or not. These included reminders on patient record systems, templates that can be used with primary care IT systems and, or financial incentives (such as the quality outcomes framework, referred to as QOF); the aim being to provide a trigger for preconception care to become "normal" for people with health conditions. The quotes below demonstrate that

opinion is divided regarding the effectiveness of QOF:

"You know, we try and get QOF all the time, and unfortunately, we don't want to be driven by money and incentives. But generally, that's how things are done ... So maybe that's the way to get people to do it." (HCP10; GP in primary care)

"It's about patient safety and about good quality care [QOF]. But you do get payment for those things, so if it's on the list, you definitely are going to do it." (HCP5; Practice nurse working in primary care)

"The only way, probably, you'll get people to do an annual follow up [for someone with obesity] is, if it was, if it was linked to QOF ... GP's hate QOF and don't like being financially incentivized for things, on the whole.... that's not... It's not why we do our job. That's not what it's about." (HCP8; GP in primary care)

Using templates or reminders that link with patient records in primary care IT systems

is another option that has been suggested to increase access to preconception care for

people living with health conditions accessing primary care, as these can assist

healthcare professionals by pre-populating information and prompting a healthcare

professional to consider a person's preconception health. By linking to NICE guidelines,

they also provide current guidelines regarding appropriate preconception care, such as

high dose folic acid for people living with conditions such as diabetes, obesity and

epilepsy:

"Ardens [a health information organisation] do it [provides checklists] ... They're kept really up to date, They're evidence based. They've got links to the NICE guidelines, and so on. There's one for preconception care; it's a brilliant template. It's got everything. It's got all the domains. It's an electronic checklist and the way these work is they pre-populate with the last recording of that domain.

You don't even have to remember this stuff, guys. You just have to remember to ... click on the template ... it's an aide memoir. It's a prompt. ... I think these are the game changers, the Ardens teamplate, it's what everybody's called for, like I say, is an electronic checklist. It exists." (HCP8; GP working in primary care)

Another suggestion to improve the uptake of preconception care in primary care settings was celebrity endorsement, with healthcare professionals citing the "Jade Goody effect" leading to increased uptake of cervical screening around the time of her death; she became well known due to featuring on the television programme "Big Brother". More recently there have been an increase in requests for hormone replacement therapy (HRT) following endorsement and television programmes featuring Davina McCall. The final suggestion was for a government mandate, making

preconception care a requirement.

"Why is menopause done so well? Right now... you may still say it's not done well. But what's the difference ... it's because Davina McCall has said that all women will look fantastic, like her, if they take HRT, so all women come in and say I want HRT... Why did cervical smears go up so much when Jade Goody died? And, you know 3 years later there was another surge, because people signed into the programme, so, you know, if you want you, you need [a celebrity] to [promote preconception care] you know, that's what we need." (HCP9; GP working in primary care)

"It's got to be mandated. So, look at the work that's going on in Holland, you know, we've got to be mandated because I think health care professionals there are obliged to ask. So, there's some lovely work going on in Holland. So, they've got the government mandating something about primary care... you know, you've either got to have a mandate, or be reimbursed, or have patient driven, to make a difference." (HCP9; GP working in primary care)

11.8 Conclusion

In this chapter I have presented the data and refined programme theories focusing on social structures and healthcare services. In this group, 11 initial programme theories from the realist review were increased to 13 programme theories during analysis, with the development of two child nodes from one initial programme theory and the addition of two new programme theories. The resulting 14 programme theories were subsequently reduced, through step 5 of analysis (see chapter 7) to seven middle range-programme theories that I have presented here as both narrative and diagrams.

The seven middle range theories in this group related to:

- Family support
- Peer support
- Multidisciplinary team approach to pregnancy planning
- Treat obesity as a health condition
- Clear pathways and easy access to contraception
- Preconception care for people experiencing challenging socio-economic circumstances, and
- How to increase preconception care in primary care settings

The first two theories relate largely to social structures, providing causal explanations of positive outcomes that result from family and peer support. The other theories provide causal explanations regarding healthcare services in relation to preconception care for people with health conditions. I will provide further discussion of these theories in chapter 12 of this thesis.

11.9 Summary of results presented in chapters 9, 10 and 11

The results of the realist evaluation have been presented in the three groups that were identified through analysis and synthesis of data leading to refinement of programme theories:

- Information, knowledge, and beliefs
- Therapeutic relationships, and
- Social structures and healthcare services.

The thirteen middle range programme theories can also be considered in relation to different stages of a person's journey, from the point of diagnosis of their health condition(s), up to and including the point of pregnancy planning. I acknowledge that this journey is not always linear, and a health condition may be diagnosed before, during, or after, a pregnancy, but the principles of this approach still apply. This categorisation of programme theories was based on the programme theories themselves, and thus from evidence provided by stakeholders during interviews. This approach aims to demonstrate how and why people living with health conditions can access preconception care and be supported to improve their preconception health. This approach also aims to identify areas where change could lead to improved access to preconception care and support to achieve improved preconception health for people living with health conditions, aided by the identified causal explanations from this realist evaluation (see chapter 13; implications for practice).

Table 13. Relevant programme theories regarding preconception care at differentstages for people living with health conditions

At point of diagnosis of health condition AND At routine appointments	When considering or planning a pregnancy	
1.1 Healthcare professionals' health conditions (presen	knowledge and holistic approach to people living with ted in section 9.1)	
1.2 Clear pathways and easy a	access to contraception (presented in section 11.5)	
1.3 Treat obesity as a health o	condition (presented in section 11.4)	
1.4 How to increase provision (presented in section 11.7	o of preconception care in primary care settings)	
1.5 Preconception care for pectic circumstances (presented	ople experiencing challenging socio-economic in section 11.6)	
	2.1 Using information available online or via mobile apps to facilitate partnership working and a personalised approach (presented in section 9.2)	
	2.2 The importance of accurate information (presented in section 9.3)	
	2.3 Unhelpful social norms and inaccurate beliefs (presented in section 9.4)	
	2.4 The difference that a positive and respectful attitude from a healthcare professional can make (presented in section 10.1)	
	2.5 The significance of continuity of carer (presented in section 10.2)	
	2.6 Family support (presented in section 11.1)	
	2.7 Peer support (presented in section 11.2)	
	2.8 Multidisciplinary team approach to pregnancy planning (presented in section 11.3)	

Table 13 summarises the programme theories relevant at different stages for people living with health conditions. There are two groups of theories; those that apply at all stages of a person's preconception journey and are thus described as overarching programme theories, and those that apply when a person is considering or planning a pregnancy. I will discuss these refined middle-range theories in chapter 12, using this approach, based on a person's journey, from the point of diagnosis of their health condition(s), up to and including the point of pregnancy planning.

Chapter 12

Discussion of Results from the Realist Evaluation

In this chapter I will discuss the results from the realist evaluation and consider these in the light of supporting and relevant literature. I will also present a conception framework of what works for whom and in what circumstances, regarding preconception care for people living with health conditions, based on the results of this realist evaluation.

I will consider the results in relation to different stages of a person's journey, from the point of diagnosis of their health condition(s), up to and including the point of pregnancy planning, as outlined in section 11.9 and outlined in Table 13. In the first section of this chapter, I will explore the identified overarching programme theories applicable at any stage of a person's journey; these include:

- Healthcare professionals' knowledge and holistic approach to people living with health conditions (presented in section 9.1)
- Treat obesity as a health condition (presented in section 11.4)
- Clear pathways and easy access to contraception (presented in section 11.5)
- Preconception care for people experiencing challenging socio-economic circumstances (presented in section 11.6), and
- How to increase provision of preconception care in primary care settings (presented in section 11.7)

In the second section of this chapter, I will explore the identified programme theories that apply when a person is planning a pregnancy; these include:

- Using information available online or via mobile apps to facilitate partnership working and a personalised approach (presented in section 9.2)
- The importance of accurate information (presented in section 9.3)
- Unhelpful social norms and inaccurate beliefs (presented in section 9.4)
- The difference that a positive and respectful attitude from a healthcare professional can make (presented in section 10.1)
- The significance of continuity of carer (presented in section 10.2)
- Family support (presented in section 11.1)
- Peer support (presented in section 11.2)
- Multidisciplinary team approach to pregnancy planning (presented in section 11.3)

There are an additional four programme theories that emerged from interviews with participating stakeholders that were not included in this thesis due to limited evidence. I will discuss these briefly in the third section of this chapter before concluding the chapter with a summary and conceptual framework of what works for whom and in what circumstances, regarding preconception care for people living with health conditions. 12.1 Overarching programme theories applicable at any stage of a person living with health conditions' journey

12.1.1 Healthcare professionals' knowledge and holistic approach to people living with health conditions

The first overarching programme theory applicable at any stage of a person's preconception journey was presented in section 9.1, and highlights the importance of a healthcare professional's knowledge and holistic approach to people living with health conditions. The significance of the programme theory identified in this study is the causal explanation, which relies on both resources and reasoning, within the context of a new diagnosis or review where treatment, including medication, may be considered. It identifies that asking a direct question about pregnancy intention, with appropriate knowledge, are resources that provide a mechanism, alongside the reasoning of taking a holistic view of people of reproductive age, that can increase access to preconception care for people living with health conditions.

Whilst asking "do you want to have a baby in the next 12 months" has been demonstrated to be beneficial in providing contraceptive advice to all women of reproductive age in a primary care setting (Stulberg *et al.*, 2019), it is also important for condition-specific specialists, as well as general practitioners, to ask as this question since many people feel embarrassed and thus avoid asking their healthcare professional questions about sexual and reproductive health (Kingsberg *et al.*, 2019). Studies suggest that specialists in some health conditions do not routinely discuss sexual and reproductive health issues, which may be due to lack of knowledge or experience having the conversation, despite recognition of its importance by both clinicians and affected young adults alike (Farrell *et al.*, 2021; Frederick *et al.*, 2018;

Parry *et al.*, 2020; Kazmerski *et al.*, 2019). It may also be due to embarrassment, lack of training, lack of privacy or lack of time (O'Connor *et al.*, 2019). Many people are thus prevented from accessing preconception care at the point of diagnosis and, or at routine health reviews, whether or not they are planning a pregnancy.

This programme theory aligns to the public health approach known in the UK as "make every contact count" (Nelson *et al.*, 2013; Public Health England, 2016), which involves healthcare professionals offering brief interventions to enable positive change. One way of achieving this is to increase a person's motivation; pregnancy intention could enable that for some, since pregnancy itself has been identified as a teachable moment for behaviour change (Rockliffe *et al.*, 2022).

Healthcare professionals need to have appropriate knowledge, understanding, and be able to ask a direct question to ascertain pregnancy intention, but they also need to apply the reasoning that holistic care (considering the person as a whole) is important for people of reproductive age, just as much as it is for older people (Zazzara *et al.*, 2021), so that their sexual and preconception health needs are considered as well as the area predominantly affected by the health condition. This aligns with values that are part of the NHS constitution, which highlights the importance of respecting people's aspirations in life (Department of Health and Social Care, 2023); this may include wanting to have children.

A quote from a young woman with cystic fibrosis poignantly illustrates that not all healthcare professionals take a holistic view of their patients: *"I don't think [CF providers] think about vaginas. I think they just think about lungs."* (Kazmerski *et al.,* 2017, p. 820). This is despite research demonstrating the importance of considering a broader view of an individual (what else is going on in their life, and how might their

condition impact on that, or that impact on their condition), since this facilitates the provision of personalised care, which has been shown to improve patient outcomes and improve health status (Stewart *et al.*, 2020; Zazzara *et al.*, 2021; Lor, Crooks and Tluczek, 2016).

With sexual and reproductive health issues being important to people of reproductive age, this novel theory is therefore relevant and helpful, by providing a causal explanation, to ensure people have access to individualised preconception care and the opportunity to improve their preconception health. The theory identifies that healthcare professionals need to ask direct questions about pregnancy intention and have the appropriate sexual and reproductive health knowledge; this, in addition to maintaining a holistic view of people of reproductive age, can result in increased access to preconception care for people living with health conditions.

12.1.2 Clear pathways and easy access to contraception

The next overarching programme theory applicable at any stage of a person's preconception journey concerns access to contraception. This theory was presented in section 11.5, and highlights the importance of clear guidelines, pathways, and services to enable easy access to contraception. The significance of this programme theory is the causal explanation of how easy access to contraception, within the context of a person living with a health condition, can enable improved preconception health. The mechanisms involved include the resources of clear guidelines, pathways, and contraception services, and the reasoning about the importance of effective contraception to prevent pregnancy until the person is ready and has taken steps to optimise their preconception health. The outcome includes reduced levels of anxiety

and unplanned pregnancies, in addition to the opportunity to improve preconception health.

Contraception is an important element of preconception care for people with health conditions, since it may take time for them to improve their preconception health, thus pregnancy may be intentionally delayed. This realist evaluation, however, showed that people did not always have clear conversations about, or easy access to contraception, which caused anxiety and unplanned pregnancy for some people. Difficulty or uncertainty accessing contraception is not unusual in the UK currently (Ayorinde et al., 2021; Balachandren et al., 2022), and convenient access to contraception has been highlighted as a requirement in the recent Women's Health Strategy for England, based on over 110,000 responses from members of the public (Department of Health and Social Care, 2022). What our study adds is the link between contraception and preconception care, providing a causal explanation for how clear pathways and easy access to contraception can contribute to improved preconception health. This demonstrating the need for improvements in this area so healthcare professionals can provide accurate advice and guidance, and people living with health conditions can easily access contraception services. Implications for practice are outlined in chapter 13.

12.1.3 Treat obesity as a health condition

The third overarching programme theory applicable at any stage of a person's preconception journey was presented in section 11.4, and concerns obesity. Evidence from both women and healthcare professionals in our study contributed to this novel programme theory, which demonstrates that treating obesity as a health condition (or

disease), enables support to improve preconception health. The mechanisms contributing to a causal explanation for this involve resources that include monitoring and treatment, and reasoning that reduces feelings of guilt or blame, and facilitates effective communication between the person living with obesity, and their healthcare professional.

This is supported by evidence in published literature, which demonstrates that weight stigma is evident among healthcare professionals (Phelan *et al.*, 2015; Ward-Smith and Peterson, 2016), it can lead to reduced quality of care during pregnancy (Hill and Incollingo Rodriguez, 2020), and that not classifying obesity as a non-communicable disease (NCD) contributes to stigma, shame and the lack of a cohesive approach (Arora *et al.*, 2019). Arora *et al.* (2019) also state that this neglect and stigma is unethical and violates peoples' human rights, reminding readers that healthcare professionals should treat people living with obesity with dignity and professionalism, removing any discrimination and so viewing them in the same way as other people living with a NCD.

The view that obesity should be treated just like any other NCD, is not new (Aronne, Nelinson and Lillo, 2009). It is, however, gathering global support (Ramos Salas *et al.*, 2023), including from the World Health Organisation, which calls for accurate diagnosis and defined treatment of obesity (World Health Organisation, 2022). This approach would align obesity with substance addition: the classification of which as a disease, has contributed to improved access to healthcare and treatment for people living with this condition (Heilig *et al.*, 2021).

What this realist evaluation adds is the link with preconception health, demonstrating that obesity needs to be treated as a health condition, such as epilepsy, diabetes, or

cardiac disease. Our study also provides a causal explanation for this, by exploring the mechanism involved that includes resources and reasoning.

This scenario also demonstrates that most programme theories identified in this realist evaluation apply across all health conditions, and there is very little variation between these groups, in terms of causal explanations for access to preconception care. Since obesity is not currently considered a NCD, it is somewhat of an outlier and people living with obesity report difficulty accessing preconception care, as illustrated by this quote from a woman living with obesity, regarding her experience of asking for preconception advice:

"[The GP] looked at me like a grown a second head and was like: "Have sex. I don't really understand what it is you are asking me for!" (W20; aged 35 living with obesity and polycystic ovary syndrome)

Obesity should therefore be treated as a health condition, so that healthcare professionals can offer people living with obesity regular monitoring, effective treatment, and people living with obesity should be treated with kindness and respect.

12.1.4 How to increase provision of preconception care in primary care settings

The fourth overarching programme theory applicable at any stage of a person's preconception journey addresses the challenge of how to increase provision of preconception care in primary care settings. This was presented in section 11.7. The theory identifies that there are opportunities for people living with health conditions to access preconception care in primary care settings, but mechanisms to enable this are required. Evidence for this theory comes from healthcare professionals with

experience of providing preconception care in primary care settings, and this demonstrates that opinions are divided; the topic therefore requires on-going evaluation to further refine the theory. Nonetheless, by exploring the mechanism that works within the context of people accessing primary care, to identify how this leads to the intended outcome of timely, accurate and evidence-based preconception care, some clear reasoning has been identified, along with potential resources.

As part of a mechanism in realist methodology, reasoning is described as a stakeholder's response to the resources provided (Pawson and Tilley, 1997; Dalkin *et al.*, 2015). The options presented in this programme theory either encourage healthcare providers to "push" preconception care out to their patients (through financial incentives, reminders, guidelines and checklists, or legal requirement), or a "pull" to people with health conditions encouraging them to seek preconception care (through celebrity endorsement). These terms are more often used in marketing (Keeling *et al.*, 2019), and are therefore helpful in this situation, where preconception care to provide preconception care, however, also needs to be marketed to healthcare providers, and on this level, an incentive could be seen as a "pull" to primary care providers. Alternatively, this could be viewed as a programme strategy, as opposed to part of a mechanism. This, therefore, requires further exploration.

The resources that are mentioned in our study have been used with some effect in other areas. These include the Quality Outcomes Framework (QOF), which resulted in an increased uptake of long-acting reversable contraception (LARC) (Arrowsmith *et al.*, 2014), although a systematic review by Forbes *et al.* (2017) found no evidence of improvement in co-ordination of care, holistic care or patient experience as a result of

QOF. Reminders on IT systems guidelines and checklists can also be helpful, although a small qualitative study found that 70% of reminders were ignored by GP's and practice nurses, therefore this system may need further development to ensure that reminders are appropriate (Cecil et al., 2021). The Dutch Solid Start programme is an example of a government mandate, which includes preconception care, with seven indicators for local monitoring of this national project to reduce perinatal health inequalities and improve health outcomes for parents and children (Molenaar et al., 2022); this has yet to be evaluated fully. Finally, celebrity endorsement or influence has been shown to improve health seeking behaviours; notably the increased uptake of cervical screening, following Jade Goody's diagnosis and death (Lancucki et al., 2012). Whilst this evidence supports the programme theory and provides causal explanation of a positive outcome, this requires further testing in the area of preconception care, where there is currently no QOF or government mandate, reminders, guidelines and checklists are not routinely used, and there are no celebrities providing visible and widespread influence in the area of preconception care. What this theory does identify, however, is the need to enable and encourage the provision of preconception care in primary care settings, as this will increase access to preconception care for people living with health conditions.

12.1.5 Preconception care for people experiencing challenging socio-economic circumstances

The fifth and final overarching programme theory applicable at any stage of a person's preconception journey relates to the contexts of challenging socio-economic circumstances; this was presented in section 11.6. This theory identifies that people

living with health conditions in these contexts are often excluded from healthcare services and therefore particular resources and reasoning are required to enable access to preconception care and thus provide support to improve preconception health.

Evidence from interviews with healthcare professionals who had experience of working with women living in more deprived circumstances, identified this context as one that may not enable mechanisms to "fire" that usually would for people experiencing less deprivation. Whilst this programme theory requires on-going evaluation and further refinement, it does provide broad overarching mechanisms that need to be considered.

The reasoning identified in this programme theory is important; preconception care services need to be relevant and accessible. To achieve that, this realist evaluation has identified important resources that contribute to a causal explanation of how access to preconception care can be provided for these groups, which are supported by other studies in published literature. Firstly, the needs of the community must be assessed, and this assessment must include psychosocial needs, not just physical needs (Ravaghi *et al.*, 2023). Secondly, any information or intervention must be co-produced; this process can ensure that appropriate people influence the design of any improvements (Chauhan *et al.*, 2021), and also creates a sense of urgency to act on issues raised and legitimise improvements in discussion with management (Vennik *et al.*, 2016). As a result, innovative services are required, such as the Street Health Bus (in Bradford), that provides outreach sessions to people who are homeless or in temporary accommodation (NHS England, 2023).

This realist evaluation raises awareness that preconception health is part of health services that are needed by people experiencing challenging socio-economic circumstances. Evidence shows that the impact of chronic health conditions is greater among people living in low socio-economic groups when compared with those in higher socio-economic groups (Van Wilder *et al.*, 2021). Living with a health condition, as a young adult, shapes a person's identity (Steinberg, 2020), and can be associated with anxiety, fear for the future, and feeling abnormal (Wilson and Stock, 2019). Low socio-economic circumstances may therefore compound the anxiety of having a chronic health condition; demonstrating the importance of ensuring that people in this context have access to preconception care.

This programme theory thus provides a causal explanation of how people living in these contexts can access preconception care, demonstrating that needs first need to be assessed, information and interventions need to be co-produced, and innovative services may be required. Ongoing evaluation, however, is required to refine this programme theory further and explore what works for who and how, in specific locations and circumstances.

12.2 Programme theories that apply when a person living with a health condition is planning a pregnancy

The programme theories in this section apply when a person living with a health condition is considering or planning a pregnancy. This highlights the importance of pregnancy planning, which, as outlined in chapter 1 (section 1.1), varies between countries, and was most recently reported in the UK by Stephenson *et al.* (2014) at

around 73%. This figure was based on a fairly small sample (n=1173) in one region of the UK (London), therefore a larger and more up to date study would be beneficial. For people living with a health condition, the nature of pregnancy planning may involve behaviour or treatment change, supported by a healthcare professional. With fewer than 50% of people with type 1 diabetes attending preconception care appointments in a recent scoping review by Ferry *et al.* (2023) (outlined in chapter 1; section 1.3), this is an area that requires further attention. Programme theories that demonstrate factors that provide a causal explanation for how and why pregnancy planning is enabled, for people living with health conditions, are therefore important. In addition to all five overarching programme theories above, which apply when a people living with health conditions are first diagnosed and receiving routine healthcare appointments, the programme theory outlined below in section 12.2.3 regarding unhelpful social norms and inaccurate beliefs, is significant in this regard.

12.2.1 Using information available online or via mobile apps to facilitate partnership working and a personalised approach

The first programme theory relevant at the point when a person is planning a pregnancy, whether this is a consideration or more active planning, was presented in section 9.2. It highlights the importance of a partnership approach between a person living with a health condition and their healthcare professional, since people often seek information or advice online or via mobile apps and a partnership approach enables clarification of such information and a personalised approach by identifying what may be applicable or relevant to them.

A recent systematic review regarding online health seeking behaviour also identified that internet and smartphone users tended to seek health information online, often regarding diet, nutrition, exercise, mental health, certain diseases, and this included sexual and reproductive health information (Jia, Pang and Liu, 2021). They identified that people used this source due to convenience, time-efficiency, and confidentiality, and that young people, women, and those with higher education levels were most likely to seek health information online (Jia, Pang and Liu, 2021); this equates to the demographic of women interviewed in this realist evaluation.

In this realist evaluation, however, people reported seeking preconception information regarding their health condition online and considering this alongside a discussion with their healthcare professional, since this enabled them to identify what was relevant to them, providing personalised advice. This provided a causal explanation that involved a partnership approach, which again, is known to be beneficial at many levels (individual, organisational, community) (Seale, 2016; Lor, Crooks and Tluczek, 2016).

A further example of using an app, in collaboration with a healthcare professional, in this realist evaluation, involved the sharing of 24-hour glucose monitoring data; discussion of results and partnership working between the person living with diabetes and their healthcare professional resulted in improved preconception health. What this realist evaluation adds to current knowledge, is the causal explanation of how digital information technology, a partnership approach, and personalised (or personcentred) care can empower someone to improve their preconception health, when considering or planning a pregnancy. Healthcare professionals should therefore support the use of digital information technology and use it to enhance care and empower people to improve their preconception health.

12.2.2 The importance of accurate information

The second programme theory relevant at the point when a person is planning a pregnancy, whether this is a consideration or more active planning, highlights the importance of accurate information; this was presented in section 9.3. It highlights the importance of accurate information, providing the causal explanation that such information, along with the opportunity to discuss and explore possible outcomes of different decisions, can lead to reduced anxiety, and promotes informed decision making, leading to improved preconception health in the presence of motivation and self-efficacy on behalf of the person living with a health condition.

People living with health conditions, including pregnant women, are known to experience increased levels of anxiety (Vancampfort *et al.*, 2017; Prescott, Mackie and Rathbone, 2018); this also applies during pregnancy planning, as identified by women in our study. This should not be confused with health anxiety, a disorder characterised by excessive worries about health, hypervigilance, fear of developing a serious illness and constant need for reassurance, although this can be comorbid with other health conditions, and has increased over recent years possibly due to increased use of the internet (Tyrer and Tyrer, 2018). Indeed, other studies have identified an association, although not causality, between increased anxiety and increased knowledge (Selinger *et al.*, 2013) and links between people who are prone to health anxiety and frequent information seeking online (Lagoe and Atkin, 2015; Prescott, Mackie and Rathbone, 2018).

Other studies have shown that access to health information reduces anxiety among people with health conditions (Kugbey, Meyer-Weitz and Oppong Asante, 2019), and improved health literacy (which includes engaging with and understanding health

information) can lead to changes in health behaviours (Walters *et al.*, 2020). This realist evaluation has shown that people want accurate information that is relevant to them, when planning a pregnancy, and this is an important part of the mechanism identified in this programme theory.

The obligation for healthcare professionals to provide information that will enable them to make informed choices is also a legal requirement, in view of what has become known as the "Montgomery ruling" (Montgomery v Lanarkshire Health Board, 2015). The outcome of the case involving a woman living with type 1 diabetes whose son suffered brain damage and now lives with cerebral palsy due to significant hypoxic injury sustained during birth (involving a 12-minute delay between birth of his head and shoulders; shoulder dystocia), was that the doctor should have provided her with all the information to allow her to make her own choice between options (vaginal vs caesarean birth). The law on consent therefore clearly recognises that people are autonomous and require adequate information to make their own decisions about their health and care.

There are some similarities between this programme theory and the health belief model, which includes perceived threat of condition, perceived benefit of action and cues to action (such as information and advice from others) as modifying factors (Jones, Smith and Llewellyn, 2014). Behavioural intentions, however, which do not feature in the health belief model, were found to be an important mediator of health behaviour change in studies included in a systematic review evaluating the effectiveness of health belief model interventions by Jones, Smith and Llewellyn (2014). The intention to become pregnant appears to be an important element of this programme theory, since that is the context in which the mechanisms (both resources

and reasoning) "fire" to achieve the outcome of improved preconception health. Thus, when a person with a health condition has a desire for pregnancy, they are motivated to make behaviour changes to improve their preconception health but require accurate and personalised information to achieve this. This programme theory, therefore, identifies that healthcare professionals need to provide people living with health conditions accurate verbal and written information, along with the opportunity to discuss and explore possible outcomes of different decisions when planning a pregnancy.

12.2.3 Unhelpful social norms and inaccurate beliefs

The third programme theory relevant at the point when a person is considering pregnancy, concerns the unhelpful social norms and inaccurate beliefs regarding pregnancy planning, and was presented in section 9.4.

This realist evaluation has identified that preconception care is not generally considered normal healthcare practice in the UK, and as a social norm; this applies to healthcare professionals as well as the public. If healthcare professionals do not consider preconception care as normal healthcare practice, this reduces access to preconception care even when people ask for advice. What our study has identified, are factors that may contribute to reduced access to preconception care due to social and cultural norms; these include generally negative messages regarding sex and pregnancy from school, the inaccurate belief that most people will not become pregnant for several months despite having unprotected sexual intercourse, discomfort or embarrassment when discussing pregnancy planning, and a fatalistic approach or ambivalence towards pregnancy planning.

This is supported by a study showing that social perceptions influence healthcare professionals' perspectives and can prevent discussions regarding sexual and reproductive health (O'Connor *et al.*, 2019).

This realist evaluation identified that messages about sex and pregnancy from school (in the UK) were generally viewed as negative, with the secondary school curriculum on sexual relationships and sexual health focusing on sexually transmitted infections and contraception (alongside issues such as consent) as opposed to any positive aspects of pregnancy planning and preconception health (Department for Education, 2020). These resources, alongside poor fertility knowledge (Grace, Shawe and Stephenson, 2023), and resulting embarrassment about discussing pregnancy planning, or fatalistic approach, provide a causal explanation for why people with heath conditions are unlikely to access preconception care and then later may experience anxiety and guilt for having not done so.

Together with other women's sexual and reproductive health issues, pregnancy planning has been identified as a taboo subject (French, 2023), with women feeling unheard, even by healthcare professionals. There is, however, a desire to reverse this through the Women's Reproductive Health Survey and Women's Health Strategy for England (Department of Health and Social Care, 2022) and what this programme theory adds is a causal explanation of how doing so may improve access to preconception care and thus enable people to improve their preconception health. Specific recommendations based on this and other programme theories will be included in chapter 13.

12.2.4 The difference that a positive and respectful attitude from a healthcare professional can make

The fourth programme theory relevant at the point when a person is planning a pregnancy, whether this is a consideration or more active planning, highlights the difference that a positive and respectful attitude from a healthcare professional can make. This programme theory highlights the outcomes of both a positive respectful approach and a negative judgemental approach, and was presented in section 10.1.

This programme theory was identified in the realist review (Hopper *et al.*, 2023) and developed further in the realist evaluation. What our study provides is a causal explanation of why a positive and respectful attitude from a healthcare professional is important in relation to preconception care, adding to the evidence from other aspects of healthcare (Brener *et al.*, 2013; Holt *et al.*, 2018; Lor, Crooks and Tluczek, 2016; McCormack and McCance, 2006; Stenner, Courtenay and Carey, 2011; Sword *et al.*, 2012).

This programme theory highlights that healthcare professionals will promote access to preconception care, for a person living with a health condition who is considering pregnancy, by listening and respecting them, focusing on them as a person rather than just their condition, and facilitating a trusting professional relationship through which the person feels valued.

12.2.5 The significance of continuity of carer

The fifth programme theory relevant at the point when a person is planning a pregnancy, whether this is a consideration or more active planning, highlights the

significance of continuity of carer; this was presented in section 10.2. What this realist evaluation provides is a causal explanation of how continuity of carer leads to improved access to preconception care. Mechanisms in this theory focus on reasonings, based on the resource of continuity of a respectful healthcare professional over a period of time. These reasonings include:

- The knowledge that a healthcare professional accumulates about the person's medical history, situation, and personal goals
- The fact that the person does not have to keep repeating their story
- The person's awareness of their healthcare professional's approach, and
- The person's desire to please their healthcare professional.

These elements of the mechanism identified in this programme theory enable access to personalised and time-efficient preconception care when a person living with a health condition is considering pregnancy.

Continuity of carer has been identified in previous published studies as a factor leading to better health outcomes in both general practice and maternity care (Barker, Steventon and Deeny, 2017; McLachlan *et al.*, 2012; Parker, Corden and Heaton, 2011; Sandall *et al.*, 2016; Van Walraven *et al.*, 2010). What this programme theory about continuity of carer in relation to preconception care identifies is the relevance of the "dimmer switch" analogy of a mechanism (Dalkin *et al.*, 2015), rather than the "gunpowder" analogy (Pawson and Tilley, 1997), since the reasoning outlined accumulates over time as the person living with a health condition and their healthcare professional develop and maintain a therapeutic relationship over a number of months or years.

This programme theory therefore supports the proposal that the healthcare professional who provides routine care in relation to the person's health condition should be able to provide preconception care, and thus links with the programme theory outlined in section 12.1.1 regarding healthcare professionals' knowledge and holistic approach to people with health conditions. It highlights that where possible, continuity of the healthcare professional providing care for people living with health conditions should be offered.

12.2.6 Family support

The sixth programme theory relevant at the point when a person is planning a pregnancy demonstrates the contribution that a supportive partner and, or family can have to preconception health; this was presented in section 11.1. The programme theory identifies that people living with health conditions who have a supportive partner or family member are able to talk to them about their desires, express their emotions freely, and feel listened to and validated by them. If they are able to attend appointments with a supportive partner or family member then they can review what was said at that appointment together, which provides a supportive environment and shared responsibility for any behaviour change required to improve preconception health.

This theory is supported by published literature, which shows that pregnant women with support from family and friends experience lower levels of anxiety (Wang *et al.*, 2021; Bedaso *et al.*, 2021; Yu *et al.*, 2020) and the positive influence of social support on health is well established (Reblin and Uchino, 2008; Castarlenas *et al.*, 2023; Zhou and Kulick, 2023). This programme theory adds to this literature by providing a causal

explanation for how this support can lead to improved preconception health. People living with health conditions should therefore be encouraged to attend appointments with a supportive partner or family member, so they can benefit from this form of support. This programme theory also suggests that people without family support, and those who experience domestic abuse, may feel isolated, more anxious, and not be supported to improve their preconception health.

12.2.7 Peer support

The seventh programme theory relevant at the point when a person is planning a pregnancy concerns peer support and is presented in section 11.2. This programme theory has two parts, identifying both positive and negative examples of peer support. Face to face peer support has been identified in this and other studies as beneficial (Davidson *et al.*, 2012; Gillard *et al.*, 2015; Naslund *et al.*, 2016; Gagliardino *et al.*, 2013; Piette *et al.*, 2013). In this programme theory the mechanism identified involves shared experience, mutual support, and a sense of hope; this aligns with work by Schmied *et al.* (2011), who identified that peer support provides "authentic presence".

The negative experiences of peer support described by participants in our study all involved online forums, which suggests that these may not provide the same authentic presence as face-to-face groups, possibly due to the more impersonal nature of interactions, with people off-loading negative experiences and some forums becoming echo-chambers for alternative beliefs that may be against medical advice.

Anonymity can be beneficial, however, and one example of an online support service, the Big White Wall, provides effective online peer support to many people living with

mental health conditions (Dosani, Harding and Wilson, 2014). An important distinction, however, is that the Big White Wall has professional moderators, guided support, live therapists, and wall guides, who monitor the wall and aim to remove trolls (people who post abuse or hateful remarks) and flames (contemptuous or horrible arguments) as well as providing support to anyone in crisis (Dosani, Harding and Wilson, 2014). The fact that people living with cystic fibrosis routinely access peer support online, due to the risks of them contracting life-threatening infections from meeting face-to-face (Conway, 2008), also suggests that it is not the medium itself (the internet) that causes negative experiences.

A qualitative study by Prescott and Mackie (2017) identified that pregnant women search the internet for information and support, noting that they found reassurance from the experiences of others. They also identified that there can be an overrepresentation of people who have had problems, which aligns to the findings of our study that contributed to the negative side of this programme theory regarding peer support. Prescott and Mackie (2017) note that whilst some women felt they knew when to stop (including when the information was no longer helpful), others found it harder to stop, which aligns with other research showing that people living with health anxiety are more likely to seek health information via online forums, and that seeking health information online may increase health anxiety (Lagoe and Atkin, 2015).

What this programme theory adds is a causal explanation of how beneficial peer support can contribute to improved preconception health and should therefore be encouraged among people living with health conditions. However, it also provides a causal explanation of how online forums can be detrimental for women living with health conditions when they are considering or planning a pregnancy. Other research

in this area, along with programme theory 2.1, highlights the role of healthcare professionals who can provide a personalised approach to balance online information that may cause anxiety by over-representation of negative stories.

12.2.8 Multidisciplinary team approach to pregnancy planning

The final programme theory relevant at the point when a person is planning a pregnancy highlights the importance of a multidisciplinary team approach to pregnancy planning for those living with complex health conditions, and was presented in section 11.3. This theory is supported by evidence from other areas of health care, such as cancer care and mental health, where multidisciplinary teams are well established (Social Care Institute For Execellence, 2023) and have been identified as beneficial for people living with chronic health conditions (Poot et al., 2021). This programme theory provides a causal explanation for how a multidisciplinary team approach can enable improved preconception health for people living with complex health conditions or multiple health conditions. Based on data from interviews, people who had received this type of preconception care experienced reduced anxiety and access to the support they needed to improve their preconception health as a result of a shared vision and agreement regarding personalised preconception care, with timely access and support for change making the person feel valued and validated. Resources identified as significant mechanisms to achieve the required outcome in this realist evaluation were: ensuring all appropriate professionals were involved, excellent communication between professionals, one easily accessible point of contact for the person living with the condition(s), follow up appointments as required, and the opportunity to receive psychological counselling, in view of

increased anxiety levels among people living with health conditions (Vancampfort *et al.*, 2017).

How this was achieved varied between programmes, with some people attending appointments with members of the multidisciplinary team, and others seeing one health professional who then communicated with others. When people required time to improve their preconception health, however, having one easily accessible point of contact was important, and this was often a specialist nurse who could respond and refer on, as appropriate. The effectiveness of advanced clinical (or nurse) practitioners has been demonstrated in a range of specialities, compared with physician-led or usual care (Htay and Whitehead, 2021), and this programme theory demonstrates their potential contribution to preconception care as part of a multidisciplinary approach. Preconception care for people living with complex health conditions should therefore involve an appropriate multidisciplinary team who communicate clearly with an identified point of contact who is easily accessible via phone or email between any required specialist follow-up appointments, with psychological counselling and support also available.

12.3 Programme theories with limited evidence

Four further programme theories; one initial programme theory from the realist review and three new theories that emerged from interviews, were not included in this thesis due to limited evidence. The first related to the availability of interpreters for people who may experience language barriers when accessing healthcare. This theory was identified in the realist review, but only one participant in the realist evaluation

experienced problems accessing preconception care due to language barriers, so the theory could not be adequately explored or refined. This person was living overseas and found that she did not fully understand healthcare providers when they spoke a language in which she was not fluent. One outcome for her was that she felt guilty for not being able to understand; this is an area that would benefit from further research. The initial programme theory regarding language barriers related to people in the UK for whom English was not their first language. This highlights that limited evidence was obtained in the realist evaluation from minority ethnic groups; this theory therefore requires further research.

The second programme theory that was not included concerned transitions that disrupted access to preconception care, including moving location to attend University, or for a new job. The third theory not included concerned people who decided not to have children. These theories emerged from interviews, but with limited evidence they were not adequately explored or refined. Again, these theories would benefit from further research.

The final programme theory that emerged from interviews with limited evidence concerned same sex couples who may have limited access to preconception care due to their requirement for assisted conception to become pregnant. When access to assisted conception is restricted due to health conditions (including obesity), this appears to discriminate against women who are in established same sex partnerships, including marriage. Again, this theory requires further research.

12.4 Summary and conceptual framework

The refined programme theories identified in our study (see Table 13) can be traced from initial programme theories identified in the realist review, through testing, analysis, and synthesis as part of the realist evaluation, with some emerging from interviews during the realist evaluation. They provide causal explanations of how, and why, people living with health conditions can gain access to preconception care, and also how, and why, certain approaches or elements of care can contribute to improved preconception health in certain circumstances. Using a realist approach has resulted in thirteen programme theories that fall into three distinct and significant areas: knowledge information and beliefs, therapeutic relationships, and social structures and healthcare services.

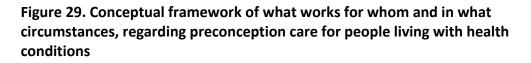
Five programme theories apply at all stages of the person's journey, from the point of diagnosis of their health condition(s), to the point of pregnancy planning, and eight programme theories apply at the point of pregnancy planning. Whilst it could be argued that some of these eight apply at all stages, the evidence contributing to these theories from interviews demonstrated their significance at the point of pregnancy planning or consideration. This highlights the importance of pregnancy intention, or reproductive life planning, for people living with health conditions, and aligns with the first programme theory discussed above; healthcare professionals' knowledge and holistic approach to people living with health conditions, which includes consideration of pregnancy intention as part of a holistic approach to caring for people of reproductive age. It also highlights the significance of the theory regarding unhelpful social norms and inaccurate beliefs, which shows how these can prevent access to preconception care on a social or cultural level. Finally, it shows how

recommendations from our study apply at a range of levels (individual to organisational) and in a range of areas (health, education, research, and society).

To illustrate the findings, a conceptual framework of what works for whom and in what circumstances, regarding preconception care for people living with health conditions, has been provided (see Figure 29 below). The outer arc includes the five overarching programme theories regarding access to preconception care for people living with health conditions at all stages of their preconception journey, and the inner semicircle includes the eight programme theories within the context of pregnancy planning. The theories are colour coded according to the identified areas of significance







12.5 Strengths and limitations of the realist evaluation

12.5.1 Strengths of this study

An important strength of this study was the use of a realist approach. This enabled the generation of refined and robust programme theories providing credible causal explanations for outcomes regarding access to preconception care and support for improved preconception health. Whilst this has been time consuming, the theories provide insights that inform practice in a very practical and realistic way. This was the first realist evaluation of preconception care for people living with health conditions, so the results were novel and contribute new knowledge to this area of healthcare.

The broad scope of the study, considering preconception care for people living with any physical and mental health condition was also a strength. Rather than just limiting the study to one health condition or a specific intervention, maintaining a broad scope enabled the similarities that existed between health conditions to be recognised. This also allowed for identification of contexts or circumstances where different approaches are required, such as challenging socio-economic circumstances, and obesity. It also allowed for identification of contexts or circumstances where further work is required to identify what works, for whom, and how, such as improved access to preconception care in primary care settings.

The use of qualitative interviews provided conceptually thick data, which contributed to refinement of programme theories; this was a strength of the study, along with the inclusion of different stakeholder groups that provided different perspectives of the situation. Women and partners or supporting family members were able to share their lived experiences of accessing preconception care and both contribute to and explore programme theories through interviews, and healthcare professionals were 338

able to share their lived experiences of providing preconception care, exploring programme theories from an organisational perspective. This provided both triangulation of results, and learning, as some healthcare professionals identified and discussed limitations within healthcare services during their interviews.

The use of Zoom for interviews also proved to be a strength of this study; these enabled participants living further away to contribute, reducing travel time and cost for both interviewer and interviewee alike.

12.5.2 Limitations of this study

Despite trying to recruit a broad range of stakeholders to participate in interviews, they were mainly white, well-educated and most were employed. The context of most refined programme theories was therefore limited to this demographic. This may possibly be due to chosen recruitment strategy via social media, due to limitations during COVID-19 pandemic, and future research in this area needs to be more inclusive to reflect the diverse society in which we live. Whilst evidence provided by healthcare professionals with experience of working with people living in challenging socioeconomic circumstances provided some evidence in this context, limited evidence regarding access to preconception care and support to improve preconception health for people in minority ethnic or cultural groups was obtained, and therefore further research is required to explore this context.

Very few partners or supporting family members contributed to stakeholder interviews, limiting exploration of programme theories from this perspective. Men are

under-represented in this and other research regarding preconception health, which needs to be addressed in future research.

Another limitation was that some theories, particularly those that emerged during interviews, were only supported by one or two stakeholders. Whilst it would have been possible to invite additional stakeholders to participate in a second interview to explore these programme theories, there was limited time to do so within this study and a pragmatic approach is required when deciding where to stop with any realist evaluation. Where programme theories require further evaluation and refinement this has been clearly identified. For instance, further evaluation of interventions to improve access to preconception care is required for people experiencing challenging socio-economic circumstances. Further evaluation of interventions to improve preconception care in primary care are also required.

Finally, some new emerging programme theories were not fully explored, and so not presented in this thesis. They have been included in section 12.3 above but will require further evaluation and exploration to identify credible causal explanations that can be used to inform practice.

12.6 Conclusion

In this chapter I have discussed the results of the realist evaluation and considered these in the light of supporting and relevant literature. I have also presented a conception framework of what works for whom and in what circumstances, regarding preconception care for people living with health conditions. In chapter 13 I will present the implications for practice and recommendations for future research.

Chapter 13

Implications for Practice and Recommendations for Future Research

In this chapter I will outline implications for practice that have been identified from our study. These include recommendations for healthcare professionals working with people living with health conditions, recommendations regarding public health messaging, and recommendations regarding the organisation of healthcare services for people living with health conditions. I will then highlight areas that would benefit from future research, based on the results and my experience during our study.

13.1 Implications for practice

The following recommendations have been directly identified from the 13 middlerange programme theories outlined in the results chapters (9-11) and discussed in chapter 12.

13.1.1 Recommendations for healthcare professionals working with people living with health conditions:

- Healthcare professionals require access to condition specific sexual and reproductive health and preconception care knowledge, and a clear understanding of what is meant by pregnancy planning.
 - This has implications for education and training of healthcare professionals, including doctors, nurses and others who support people living with health conditions. This could be pre- or post-registration, but must include appropriate knowledge, and the principles that pregnancy

planning involves achieving stable, optimal preconception health, which may require medication and, or behaviour change, during which people should be using effective contraception, before they have unprotected sex or seek assisted conception with the intention to conceive and thus become pregnant.

- Healthcare professionals need to understand the importance of taking a holistic view of people of reproductive age, which includes sexual and reproductive health, and be able to ask and respond to the direct question "do you want to have a baby in the next 12 months".
 - This also has implications for education and training of healthcare professionals, including doctors, nurses and others who support people living with health conditions. The value of a holistic approach should be embedded in pre-registration education, since respecting people and their aspirations is one of the NHS values that underpins the delivery of care.
 - Healthcare professionals will require training in relation to asking direct questions about pregnancy intention, in view of the concern expressed by some healthcare professionals who participated in interviews, and the need to provide appropriate sexual and reproductive health advice depending on people's responses.
- Healthcare professionals need to support the use of digital information technology and use it to provide a personalised approach when working in partnership with people living with health conditions.

- The principle of working together with and for people living with health conditions should already be embedded in pre-registration education, since this is one of the NHS values that underpins the delivery of care.
- Healthcare professionals, including doctors, nurses and others who support people living with health conditions need to be aware of digital information technology, signpost people to appropriate information online, use technology that is beneficial to improve preconception health, and discuss this with people to provide personalised information that can inform their choices.
- Healthcare professionals need to provide people living with health conditions
 with personalised information about their condition and themselves (verbally
 and in writing), along with preconception information about potential health
 threats to themselves and their future baby. They also need time to discuss and
 explore possible outcomes of different decisions with people living with health
 conditions.
 - Alongside implications for education and training, healthcare professionals working with people living with health conditions need to participate in continued professional development (CPD) regarding preconception care.
 - Healthcare professionals must be aware of their legal obligation to provide all information required to allow people living with health conditions to make informed choices, including regarding preconception care.

- Healthcare professionals need to provide person-centred care, and listen to, respect, and acknowledge that people living with health conditions are often experts in their own condition.
 - The principles underpinning person-centred care, including respect and dignity, and working together with and for people living with health conditions should already be embedded in pre-registration education, since these are core NHS values that underpins the delivery of care.

13.1.2 Recommendations related to public health messaging:

- Positive and accurate public health messages about preconception health and fertility are needed. These topics should be included in the school curriculum, and more widely shared via public health marketing platforms.
 - The school curriculum should be reviewed, and age-appropriate positive public health messages about reproductive life planning should be added.
 - Other ways of promoting positive and accurate public health messages about preconception health and fertility should be identified and implemented.

13.1.3 Recommendations related to organisation of healthcare:

• People living with health conditions should have continuity of carer, which involves, where possible, the same healthcare professional seeing the person over a period of time.

- Continuity of carer for people living with health conditions should apply in both primary and secondary care.
- People living with health conditions should be able to attend healthcare appointments with a partner, family member, or other person of their choice. When people living with health conditions do not have family support, this should be acknowledged as a point of concern.
 - Appointment letters, emails and, or messages should encourage people living with health conditions to bring a person of their choice to provide support if they wish.
 - Healthcare professionals should enquire about partner and or family support and recommend other opportunities for support, such as peer support, if it is lacking.
- People living with health conditions should be encouraged to access peer support that provides authentic emotional support. They should be made aware that not all online forums will offer this.
 - Peer support groups should be encouraged and information about these provided to people living with health conditions.
 - Healthcare professionals should caution people living with health conditions about advice that may be offered via online forums that do not involve professional moderation.
- People living with complex health conditions should be able to access multidisciplinary preconception care, which involves excellent communication between all parties, one point of contact with easy access between appointments, and the offer of psychological counselling.

- Multidisciplinary preconception care clinics should be available and accessible to people living with complex health conditions in all areas of the country.
- Healthcare professionals working together to support people living with complex health conditions should have effective channels of communication and ensure that the people themselves are also included in this communication
- Multidisciplinary preconception care clinics should identify and offer one point of contact, who should be available via email or a phone number to respond to urgent questions and refer to specialists as required.
- Psychological counselling should be offered to all people living with health conditions who seek preconception care.
- Obesity should be treated as a health condition, and people living with obesity must be treated with kindness and respect.
 - A national policy that involves the consideration of obesity as a health condition should be expedited, agreed, and implemented.
 - Health monitoring in primary care should include an accurate height measurement annual measurement of weight, with BMI calculation for all.
 - Guidance regarding weight management should include appropriate recommendations and treatment options for people identified as struggling to maintain a healthy weight, as well as those living with obesity.

- Education and training needs of healthcare professionals must be identified, to ensure they treat people living with obesity with respect and are aware of recommendations and treatment options available for people identified as struggling to maintain a healthy weight, as well as those living with obesity.
- Clear guidelines, pathways and services should be available for people living with health conditions to access contraception advice and care.
 - Clear guidelines and pathways must be identified in all areas so
 healthcare professionals can provide appropriate and accurate advice
 and signpost people to easily accessible contraception services.
 - Contraception services must be available in all areas so people living with health conditions can easily access contraception in a location that is accessible and acceptable to them.
- Preconception care for people living with health conditions experiencing challenging socio-economic circumstances needs to be relevant and accessible; this requires identification of needs and co-production of information and services.
 - Providers of healthcare services must assess the preconception health and care needs of people living with health conditions in their area.
 They need to identify the needs of people experiencing challenging socio-economic circumstances.
 - Providers of healthcare services need to work with people in these groups to co-produce information and appropriate services to meet these needs.

- Preconception care for people living with health conditions needs to be offered in primary care.
 - Effective and acceptable strategies need to be identified to ensure that preconception care for people living with health conditions is offered in primary care settings.

13.2 Recommendations for future research

Based on the results and discussion of these in chapters 9-12, the following areas require further research:

- Further exploration of what works, for whom, and how, in relation to access to preconception care for people living with health conditions when they are experiencing challenging socio-economic circumstances.
 - This needs local research as needs and solutions may vary between specific locations.
- Further exploration of what works, for whom, and how, in relation to access to preconception care for people living with health conditions when they are part of minority groups.
 - This includes circumstances when English is not the first or preferred language for people living with health conditions.
 - This needs local research as needs and solutions may vary between specific locations and groups.
- Further exploration of what works and how, in relation to increasing the provision of preconception care in primary care settings.

- Strategies need to be both effective and acceptable to healthcare professionals working in primary care settings; multiple strategies may be required.
- Further exploration of what works and how, in relation to access to
 preconception care and support to improve preconception health when people
 living with health conditions transition from one healthcare professional /
 healthcare provider to another. This should include the following
 circumstances:
 - Transitions from paediatric services to adult services, including exploration of when is an appropriate age to introduce the concept of preconception care for people who are diagnosed with a health condition either from birth or during childhood, and how this message should be developed through transition to adult services.
 - Temporary transitions when people move location to attend university or training to ensure they do not lose contact with supportive healthcare professionals and services.
 - More permanent transitions when people move location for other reasons, to ensure they connect easily with healthcare professionals and services in their new location.
- Further exploration of what works and how, in relation to access to preconception care and support to improve preconception health for women living with health conditions who are part of same-sex couples.
 - This includes access to assisted conception for people living with health conditions, which may usually be required due to fertility issues (for

heterosexual couples), but in these circumstances may not be associated with infertility.

13.3 Conclusion

In this chapter I have outlined implications and recommendations for practice and future research that have been identified from the refined middle-range programme theories developed in our study. These programme theories provide credible causal explanations of what works, for whom, and how, for people living with health conditions in relation to access to preconception care and support to improve preconception health. Implementation of these recommendations will lead to increased access to preconception care for people living with health conditions and is strongly advised to achieve improved health for people living with health conditions, their children, and future generations.

Conclusion

This PhD study involved two phases: a realist review and a realist evaluation. The realist review identified, through analysis and synthesis of data extracted from included published and grey literature, causal explanations regarding how, why, for whom, and in what circumstances, approaches to preconception care work, for people living with health conditions. These causal explanations were presented as programme theories, which were explored and refined further through interviews with appropriate stakeholders in the realist evaluation. Key aspects promoting access to preconception care and support to improve preconception health identified in the realist review were personalised care, a partnership approach, continuity of carer, and integration of healthcare services. The realist review highlighted the importance of providing accurate, relevant information regarding preconception health in routine appointments, so this could be acted on when needed. The realist review also identified that both peer support and psychological counselling can provide beneficial emotional support for people living with health conditions who are considering or planning pregnancy.

The realist evaluation undertaken as phase two of this study further explored, refined, and tested the programme theories identified in the realist review, which was limited by the paucity of detailed descriptions regarding preconception care in the available literature. Interviews with appropriate stakeholders provided conceptually rich data that enabled theories to be robustly tested, leading to 13 middle-range theories relating to contexts and mechanisms (both resources and responses) that provide credible causal explanations of how, why, and in what circumstances, people living

with health conditions both access preconception care and are supported to improve their preconception health.

The realist evaluation has highlighted the importance of pregnancy planning for people living with health conditions, and therefore the five programme theories that provide a causal explanation of how pregnancy planning can be enabled, from the point of diagnosis of a health condition to the point of planning or considering a pregnancy, are significant. These five programme theories highlight the need for healthcare professionals to maintain a holistic approach, ask direct questions about pregnancy intention, and have accurate knowledge and skills to respond appropriately. Contraception has been identified as an important aspect of preconception care, and obesity needs to be treated as a health condition. Opportunities to offer preconception care for people living with health conditions need to be promoted in primary care settings, and accessible, relevant preconception care needs to be offered to people experiencing challenging socio-economic circumstances.

Eight further programme theories have been identified as significant when people living with health conditions are considering or planning a pregnancy, as these provide causal explanations for effective access to preconception care and support for improved preconception health prior to conception and pregnancy itself. These programme theories highlight the importance of continuity of carer and a personalised partnership approach to support for people living with health conditions, involving the use of digital information technology where appropriate. Healthcare professionals need to have condition-specific sexual, reproductive, and preconception health knowledge so they can provide accurate information to people living with health conditions. Positive and accurate public health messages about preconception health

are needed to enable conversations about pregnancy planning, and people living with health conditions should be able to attend healthcare appointments with a person of their choice. They should also be encouraged to access peer support that provides authentic emotional support. Finally, people living with complex health conditions should be able to access multidisciplinary preconception care, which involves excellent communication between all parties, one point of contact with easy access between appointments, and the offer of psychological counselling.

This is the first study using a realist approach to explore preconception care for people living with health conditions. The results have identified new knowledge about causality; what works for whom, and how. Knowing how identified mechanisms (both resources and responses) work, within specific contexts, will enable targeted interventions that lead to improved access to preconception care and support for people living with health conditions to optimise their preconception health. This will lead to improved health of future generations. By including any physical or mental health condition the study shows that there are many important similarities between groups (people living with different conditions) and therefore principles, of why and how preconception care can be effectively provided, can be shared between healthcare professionals (and providers) working in different specialities.

Further work is now needed to enable healthcare professionals and providers of care for people living with health conditions to implement the recommendations from this study. That will involve further evaluation of current practice in different specialities, identification of need, and updating of clinical guidelines. It will require a review of education and training, identification of required content, timing, and mode of delivery of key preconception care messages, followed by implementation across all relevant

specialities, including primary care and public health. In view of the range of specialities, areas, and health professionals involved, it may be helpful to identify and appoint preconception care champions to drive this work forward across all specialities, among all relevant health professions, and in all areas of healthcare. Further research is also required to evaluate any changes, and ensure they lead to improvements in access to preconception care and support for people living with health conditions to optimise their preconception health.

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Appendices

Appendix 1

Realist Review Phase 1 Search Strategy

Summary	
Database	Hits
MEDLINE	1503
Embase	2421
PsycINFO	259
Cochrane Library	192
British Nursing Database	372
CINAHL	853
Total	5600
Duplicates	2727
Total to screen at title/abstract stage	2873

MEDLINE

Database: MEDLINE Host: Ovid Data parameters: **Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily, and Versions(R)** 1946 to August 1, 2018 Date searched: Aug 2, 2018 Searcher: AW Hits: 1503 Strategy:

#	Searches	Results	
	((preconception or pre-conception or periconception or peri-conception or		
1	pregestational or pre-gestational or prepregnancy or pre-pregnancy or	1603	
1	pregestational or pre-gestational or prepregnancy or pre-pregnancy or interconception or inter-conception) adj4 (counsel?ing or advice or care or	1003	
	planning or clinic? or program*)).ti,ab,kw.		
2	limit 1 to english language	1503	

Embase

Database: Embase Host: Ovid Data parameters: **Embase** 1974 to 2018 August 01 Date searched: Aug 2, 2018 Searcher: AW Hits: 2421 Strategy:

#	Searches	Results
1	((preconception or pre-conception or periconception or peri-conception or	2597
1	pregestational or pre-gestational or prepregnancy or pre-pregnancy or	2397

	interconception or inter-conception) adj4 (counsel?ing or advice or care or		
	planning or clinic? or program*)).ti,ab,kw.		
2	limit 1 to english language	2421	

PsycINFO

Database: PsycINFO Host: Ovid Data parameters: **PsycINFO** 1806 to July Week 4 2018 Date searched: Aug 2, 2018 Searcher: AW Hits: 259 Strategy:

#	Searches	Results
1	((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,id.	272
2	limit 1 to english language	259

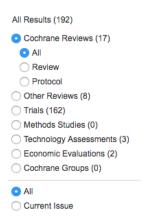
Cochrane Library

Database: Cochrane Library Host: Wiley Data parameters: n/a Date searched: Aug 2, 2018 Searcher: AW Hits: 192 Strategy:

ID Search Hits

#1 ((preconception or pre-conception or periconception or peri-conception or pregestational or pre-gestational or prepregnancy or pre-pregnancy or interconception or inter-conception) near/4 (counsel?ing or advice or care or planning or clinic? or program*)):ti,ab,kw 192

(preconception or pre-conception or periconception or periconception or periconception or pregestational or pre-gestational or pre-pregnancy or pre-pregnancy or inter-conception) near/4 (counsel?ing or advice or care or planning or clinic? or program*)):ti,ab,kw	TH	<u>192</u>
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N.B. No language filter used (not available in Cochrane Library)

British Nursing Database

Database: British Nursing Database Host: ProQuest Data parameters: n/a Date searched: Aug 2, 2018 Searcher: AW Hits: 372 Strategy:

(TI((preconception or pre-conception or periconception or peri-conception or pregestational or pre-gestational or prepregnancy or pre-pregnancy or interconception or inter-conception) NEAR/3 (counsel*ing or advice or care or planning or clinic* or program*)) OR AB((preconception or pre-conception or periconception or peri-conception or pregestational or pre-gestational or prepregnancy or pre-pregnancy or interconception or inter-conception) NEAR/3 (counsel*ing or advice or care or planning or clinic* or program*)) AND LA(english)

British Nursing Database	
Basic Search Advanced Search Publications Change databases	
(TI((preconception or pre-conception or periconception or peri-conception or pre- pre-pregnancy or interconception or inter-conception) NEAR/3 (counsel*ing or a OR AB((preconception or pre-conception or periconception or peri- prepregnancy or pre-pregnancy or interconception or inter-conception) NEAR/3 clinic* or program*))) AND LA(english)	dvice or care or planning or clinic* or program*)) r pregestational or pre-gestational or
□ Full text □ Peer reviewed	
372 results	Modify search Recent searches Save search/alert ▼

N.B. Proximity operators differ between Ovid and ProQuest. Ovid's adj4 and ProQuest's NEAR/3 are functionally the same.

CINAHL Database: CINAHL Host: Ebsco Data parameters: n/a Date searched: Aug 2, 2018 Searcher: AW Hits: 853 Strategy:

#	Query	Limiters/Expanders	Last Run Via	Results
	TI((preconception or pre-conception or			
	periconception or peri-conception or			
	pregestational or pre-gestational or		Interface -	
	prepregnancy or pre-pregnancy or		EBSCOhost	
	interconception or inter-conception) N3		Research	
	(counsel#ing or advice or care or planning or		Databases	
	clinic# or program*)) OR AB((preconception or		Search	
	pre-conception or periconception or peri-		Screen -	
	conception or pregestational or pre-gestational		Advanced	
	or prepregnancy or pre-pregnancy or	Narrow by	Search	
	interconception or inter-conception) N3	Language: - english	Database -	
	(counsel#ing or advice or care or planning or	Search modes -	CINAHL Plus	
S2	clinic# or program*))	Boolean/Phrase	with Full Text	853
	TI((preconception or pre-conception or			
	periconception or peri-conception or			
	pregestational or pre-gestational or		Interface -	
	prepregnancy or pre-pregnancy or		EBSCOhost	
	interconception or inter-conception) N3		Research	
	(counsel#ing or advice or care or planning or		Databases	
	clinic# or program*)) OR AB((preconception or		Search	
	pre-conception or periconception or peri-		Screen -	
	conception or pregestational or pre-gestational		Advanced	
	or prepregnancy or pre-pregnancy or		Search	
	interconception or inter-conception) N3		Database -	
	(counsel#ing or advice or care or planning or	Search modes -	CINAHL Plus	
S1	clinic# or program*))	Boolean/Phrase	with Full Text	864

N.B. Proximity operators differ between Ovid and Ebsco. Ovid's adj4 and Ebsco's N3 are functionally the same.

Appendix 2

Extract from online survey use to prioritise 35 initial programme theories for further investigation (using nominal group technique)

Preconception care theories for prioritisation (copy)

0% complete

Page 1: Welcome

Thank you for agreeing to complete this survey. There are only 4 questions but they each require you to rank up to 10 theories about preconception care (in the form of "if / then" statements) in order of priority.

Thus 1 = the statement that you think should be prioritised for further investigation (this may be because you think it is most relevant or interesting in relation to preconception care); 2 = the statement that you would consider (or rank) next... through to 10 = the least important or relevant and would be at the bottom of your list for further investigation.

No personal information will be collected in this survey.

This survey may take up to 30 minutes to complete.

Next >

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Page 2: Statements about the provider characteristics / delivery mechanism of the intervention

This part of the survey uses a table of questions, view as separate questions instead?

Please rank the 6 statements below in order, starting with the statement that you think should be prioritised fo further investigation (1) and finishing with the statement that you would rank lowest on a priority list for further investigation (6). You may find it easier to view the statements as separate questions instead of a table. HCP = Healthcare professional SRH = Sexual and reproductive health PCC = Preconception care

Please don't select more than 1 answer(s) per row.

Please select exactly 6 answer(s).

Please don't select more than 1 answer(s) in any single column.

	1	2	3	4	5	6
IF HCP's have appropriate knowledge and skills regarding SRH / PCC in relation to medical conditions THEN they will include appropriate SRH advice and recommend PCC to the women in their care						
IF HCPs have a positive, non-judgemental, respectful attitude towards women THEN women are more likely to trust HCPs and feel empowered and supported to make informed and appropriate choices / behaviour change						
IF there is continuity of carer, and this experience is positive THEN women are more likely to trust their HCP feel empowered and supported to make appropriate choices / behaviour change						

N.B. Question 1 relates to statements 1 - 6 inclusive; only 3 of the 6 statements are shown here as an illustration. Question 2 relates to statements 7 - 15. Question 3 relates to statements 16 - 25. Question 4 relates to statements 26 - 35.

Appendix 3

Realist Review Phase 2 search strategy

The following targeted searches were undertaken in Scopus, during January 2021. Results were ordered according to citations (highest first) to enable identification of most frequently cited empirical evidence.

Topic area	Search terms	Hits	Included in review
Continuity of carer	TITLE (continuity W/3 care*) AND (LIMIT-TO (PUBYEAR , 2020) OR LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2018) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR , 2016) OR LIMIT-TO (PUBYEAR , 2015) OR LIMIT-TO (PUBYEAR , 2014) OR LIMIT-TO (PUBYEAR , 2013) OR LIMIT-TO (PUBYEAR , 2012) OR LIMIT-TO (PUBYEAR , 2011) OR LIMIT-TO (PUBYEAR , 2010)) AND (LIMIT-TO (DOCTYPE , "ar") OR LIMIT-TO (DOCTYPE , "re")) AND (LIMIT-TO (SRCTYPE , "j"))	731	5
Respectful and non- judgemental care and trust	TITLE-ABS-KEY ((respect* OR non- judgement*) W/3 care AND "trust") AND (LIMIT TO (SRCTYPE , "j")) AND (LIMIT- TO (SUBJAREA , "MEDI") OR LIMIT- TO (SUBJAREA , "NURS") OR LIMIT- TO (SUBJAREA , "PSYC")) AND (LIMIT- TO (DOCTYPE , "ar")) AND (LIMIT- TO (PUBYEAR , 2020) OR LIMIT- TO (PUBYEAR , 2019) OR LIMIT- TO (PUBYEAR , 2019) OR LIMIT- TO (PUBYEAR , 2018) OR LIMIT- TO (PUBYEAR , 2018) OR LIMIT- TO (PUBYEAR , 2016) OR LIMIT- TO (PUBYEAR , 2016) OR LIMIT- TO (PUBYEAR , 2015) OR LIMIT- TO (PUBYEAR , 2013) OR LIMIT- TO (PUBYEAR , 2013) OR LIMIT- TO (PUBYEAR , 2012) OR LIMIT- TO (PUBYEAR , 2011) OR LIMIT- TO (PUBYEAR , 2011) OR LIMIT- TO (PUBYEAR , 2009)) AND (LIMIT- TO (LANGUAGE , "English"))	77	5
Health information via Mobile app / smart phone / web based	TITLE-ABS-KEY ("mobile app" OR "smart phone" OR "web based" AND health W/3 information) AND DOCTYPE (a r OR re) AND PUBYEAR > 2009 AND (LIMIT- TO (EXACTKEYWORD , "Education") OR LIMIT- TO (EXACTKEYWORD , "Information Seeking	220	4

	Behavior") OR LIMIT-TO (EXACTKEYWORD, "Qualitative Research") OR LIMIT-TO (EXACTKEYWORD, "Access To Information") OR LIMIT- TO (EXACTKEYWORD, "Perception")) AND (LIMIT- TO (LANGUAGE, "English")) AND (LIMIT- TO (SRCTYPE, "j")) (N.B. Limits using key words to reduce to manageable numbers and find more qualitative analysis. Sorted by most recent date, in view of technology advances)		
PCC as part of sexual and reproductive health continuum in relation to	TITLE-ABS-KEY (preconception AND "sexual and reproductive health") AND DOCTYPE (ar OR re) AND PUBYEAR > 20 09	13	4
health condition	And: TITLE-ABS-KEY ("reproductive life plan") AND DOCTYPE (ar OR re) AND PUBYEAR > 200 9	+ 48	
Peer support	TITLE-ABS-KEY ("peer support" AND health) AND PUBYEAR > 2009 AND (LI MIT-TO (SRCTYPE , "j")) AND (LIMIT- TO (DOCTYPE , "ar") OR LIMIT- TO (DOCTYPE , "re")) AND (LIMIT- TO (LANGUAGE , "English")) AND (LIMIT- TO (EXACTKEYWORD , "Peer Support"))	661	6
Psychological counselling and support to promote behaviour change	TITLE-ABS-KEY ((psychol* W/3 support*) AND "behaviour change") AND (LIMIT-TO (SRCTYPE, "j")) AND (LIMIT-TO (PUBYEAR, 2020) OR LIMIT-TO (PUBYEAR, 2019) OR LIMIT-TO (PUBYEAR, 2018) OR LIMIT-TO (PUBYEAR, 2017) OR LIMIT-TO (PUBYEAR, 2015) OR LIMIT-TO (PUBYEAR, 2014) OR LIMIT-TO (PUBYEAR, 2012) OR LIMIT-TO (PUBYEAR, 2011) OR LIMIT-TO (PUBYEAR, 2010)) AND (LIMIT-TO (LANGUAGE, "English")) AND (LIMIT-TO (SUBJAREA, "MEDI") OR LIMIT-TO (SUBJAREA, "PSYC") OR LIMIT- TO (SUBJAREA, "NURS") OR LIMIT-TO (SUBJAREA,	62	4

	"HEAL") OR LIMIT-TO (SUBJAREA , "SOCI")) AND (LIMIT-TO (DOCTYPE , "ar")) And:	+	
	TITLE-ABS-KEY ((psychol* W/3 intervent*) AND "behaviour change") AND (LIMIT-TO (SRCTYPE, "j")) AND (LIMIT- TO (SUBJAREA, "MEDI") OR LIMIT-TO (SUBJAREA , "PSYC") OR LIMIT-TO (SUBJAREA, "NURS") OR LIMIT- TO (SUBJAREA, "HEAL") OR LIMIT-TO (SUBJAREA , "SOCI")) AND (LIMIT-TO (DOCTYPE, "ar")) AND (LIMIT-TO (PUBYEAR, 2020) OR LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR, 2018) OR LIMIT-TO (PUBYEAR, 2017) OR LIMIT-TO (PUBYEAR , 2015) OR LIMIT-TO (PUBYEAR, 2014) OR LIMIT-TO (PUBYEAR, 2012) OR LIMIT-TO (PUBYEAR , 2011) OR LIMIT-TO (PUBYEAR, 2010)) AND (LIMIT- TO (LANGUAGE, "English"))	145	
	And:	+	
	TITLE-ABS-KEY ((psychol* W/3 intervent*) AND diabetes) AND (LIMIT-TO (SRCTYPE, "j")) AND (LIMIT-TO (SUBJAREA , "MEDI") OR LIMIT-TO (SUBJAREA, "PSYC") OR LIMIT- TO (SUBJAREA, "NURS") OR LIMIT-TO (SUBJAREA , "HEAL") OR LIMIT-TO (SUBJAREA, "SOCI")) AND (LIMIT-TO (DOCTYPE, "ar")) AND (LIMIT-TO (PUBYEAR , 2020) OR LIMIT-TO (PUBYEAR, 2019) OR LIMIT-TO (PUBYEAR, 2018) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR, 2015) OR LIMIT-TO (PUBYEAR, 2014) OR LIMIT-TO (PUBYEAR , 2012) OR LIMIT-TO (PUBYEAR, 2011) OR LIMIT-TO (PUBYEAR, 2010)) AND (LIMIT-TO (LANGUAGE , "English"))	154	
Perceptions of PCC as normal	TITLE-ABS- KEY (normal* W/3 perception AND "behaviour") AND PUBYEAR > 2009 AND (LIMIT- TO (SRCTYPE , "j")) AND (LIMIT- TO (DOCTYPE , "ar") OR LIMIT-	83	2

	TO (DOCTYPE , "re")) AND (LIMIT- TO (SUBJAREA , "MEDI") OR LIMIT- TO (SUBJAREA , "NURS") OR LIMIT- TO (SUBJAREA , "PSYC") OR LIMIT- TO (SUBJAREA , "HEAL") OR LIMIT- TO (SUBJAREA , "SOCI")) AND (LIMIT- TO (LANGUAGE , "English"))		
Health beliefs / attitudes being a barrier to accessing care	TITLE-ABS-KEY ("health beliefs" AND barriers AND access* W/3 care) AND DOCTYPE (ar OR re) AND PUBYEAR > 2009 AND (LIMIT- TO (LANGUAGE , "English")) AND (LIMIT- TO (SRCTYPE , "j"))	212	2
Make every contact count – PCC as routine part of medical care	TITLE-ABS-KEY (making W/3 contact W/3 count) AND (LIMIT-TO (DOCTYPE , "ar")) AND (LIMIT-TO (LANGUAGE , "English")) AND (LIMIT-TO (SRCTYPE , "j")) And:	+	3
	TITLE-ABS-KEY ("cues to action" AND diabetes) AND (LIMIT-TO (PUBYEAR, 2020) OR LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR, 2017) OR LIMIT-TO (PUBYEAR, 2016) OR LIMIT-TO (PUBYEAR , 2015) OR LIMIT-TO (PUBYEAR, 2014) OR LIMIT-TO (PUBYEAR, 2013) OR LIMIT-TO (PUBYEAR, 2010)) AND (LIMIT-TO (DOCTYPE, "ar")) AND (LIMIT-TO (LANGUAGE, "English")) AND (LIMIT-TO (SRCTYPE, "j"))	21	
Integrated health care	TITLE-ABS-KEY ("integrated care" AND quality OR effective*) AND PUBYEAR > 200 9 AND (LIMIT-TO (SRCTYPE, "j")) AND (LIMIT- TO (DOCTYPE, "ar") OR LIMIT- TO (DOCTYPE, "re")) AND (LIMIT- TO (LANGUAGE, "English"))	1,779	3

Appendix 4

Example emails and tweets used for recruitment



Dear,

I am writing to you as a midwife and student studying for my PhD at the University of Plymouth.

I would like you to consider supporting my proposal for research in principal by helping me to recruit potential participants to the study after the necessary approvals are in place from the research integrity and ethics committee.

You will be aware that women with both physical and mental health conditions can benefit from advice and support before pregnancy; this is what is referred to as preconception care. Effective preconception care can improve health outcomes for both mothers and babies, and in some case even prevent death or stillbirth. Not all pregnancies are planned, however, and even if they are, many women find it very difficult to optimise their health prior to pregnancy. This study will explore preconception care to find out what works, for whom and in what circumstances. I am looking to recruit and interview health care professionals, women with pre-existing medical conditions and their partners or supporting family members. The aim is to improve services for women with a range of pre-existing medical conditions, with a view to improving health and wellbeing.

Please would you consider including a short paragraph about this study on your website or in a newsletter? This would include a link to the study website so potential participants can find out more information and take part if they wish.

Thank you for taking the time to read this email and consider supporting this study in principal. If you decide you would like to support this study or would like any additional information about this request, please contact me directly.

Kind regards,

Heather Hopper (Registered Midwife, BSc(Hons), MSc, PGCE, PhD Student) <u>Heather.hopper@plymouthac.uk</u>

Director of Studies: Professor Jill Shawe (Registered Nurse and Midwife, PhD)

Jill.shawe@plymouth.ac.uk

Example tweet:

Do you have a pre-existing physical or mental health condition? Have you ever received prepregnancy (preconception) care or advice? Whether or not you have ever considered, planned or been pregnant, we'd like to hear you about your experiences. The PEAcH Study is now recruiting women, partners/supporting family members, and health care professionals. We want to find out what works for who, and how, in terms of preconception care, with the aim to optimise services and improve health and wellbeing during pregnancy and beyond. Find out more here: <u>https://www.plymouth.ac.uk/research/maternal-and-family-health-research-</u> <u>group/peach-study</u>

97 words

"physical or mental health conditions" above will be substituted for specific conditions for advertising through condition-specific charity newsletters or websites. For example: Diabetes Type 1 diabetes Type 2 diabetes Epilepsy Rheumatoid arthritis Lupus Fibromyalgia Congenital heart disease Kidney disease High blood pressure Chronic pain Irritable bowel syndrome (IBS)

Text sent to Big Birthas Charity for advertising on their web site:

PEAcH Study is recruiting women with +30 BMI to learn from their experiences of prepregnancy care.

Do you have a BMI over 30 or have ever been told you are "obese"? Have you ever received pre-pregnancy (preconception) care or advice? Whether or not you have ever considered, planned or been pregnant, we'd like to hear you about your experiences. The PEAcH Study is now recruiting women with health conditions (including +30 BMI). We want to find out what works for who, and how, in terms of preconception care, with the aim to optimise services and improve health and wellbeing during pregnancy and beyond.

Find out more here:

https://www.plymouth.ac.uk/uploads/production/document/path/19/19703/PEAcHStudyWo men_PIS220421.pdf

If you would like to take part, please follow the instructions about how to provide initial information, confirm consent and give your contact details at the bottom of the information sheet accessed via the link above.

Thank you Heather (Midwife and Researcher)

Appendix 5

Participant information sheets

For women living with health conditions:



Participant information sheet – PEAcH Study Group: women with pre-existing medical conditions (Version 1, April 2021)

Preconception care; Exploration of Availability and access for women with Health Conditions PEAcH Study.

A realist evaluation of availability and access to preconception care for women with preexisting medical conditions; what approaches work, for whom and in what circumstances?

Invitation

You are invited to take part in a research study on preconception (pre-pregnancy) care for women with pre-existing medical conditions. You may or may not have ever been pregnant. If you wish to take part, you must be 18 or over, have an on-going medical condition (affecting your physical or mental health), be able to give informed consent, and participate in an online interview in English.

What is the purpose of the study?

Women with both physical and mental health conditions can benefit from advice and support before pregnancy (preconception care). Effective preconception care can improve maternal, fetal and infant health and well-being during and after pregnancy. Not all pregnancies are planned, and even if they are, many women find it very difficult to optimise their health prior to pregnancy.

This study will explore preconception care to find out what works, for whom, and in what circumstances. The aim is to identify how to optimise services that provide preconception care to women with pre-existing medical conditions, with a view to improving health and wellbeing during pregnancy and beyond.

The study is being conducted as part of a PhD for Heather Hopper, under the supervision of Professor Jill Shawe. Heather is a midwife and associate professor in midwifery; both Heather and Jill are employed by the University of Plymouth and work in the School of Nursing and Midwifery, in the Faculty of Health.

What will you be asked to do?

If you decide to take part, please click on the link at the bottom of this information leaflet to give your consent and provide your contact details so an online interview (via Zoom) can be arranged. Heather will be conducting the interviews and will ask you about your experiences of preconception care (if any). Please be aware that this may include sensitive topics, particularly if you have had previous difficult experiences, including pregnancy or baby loss. The interview will focus on what aspects or approaches to preconception care you feel would or have worked well for you. The interview is likely to take between half an hour and an hour.

The interview will be recorded for analysis; you will have the option to turn the camera off during the recording if you wish. Heather may invite you to a second interview; this may help to clarify a point that she is interested in. As soon as your interview(s) have been transcribed (written down), all Zoom recordings will be destroyed. All data from interviews will be anonymised, so you will not be identifiable in any report or publication.

Are there any possible benefits from participation in this study?

The findings from the study will influence preconception care in the future, and taking part may not directly benefit you, but will help to develop and improve preconception care in the future.

Are there any possible risks from participation in this study?

No, there are no anticipated risks from participation in this study. If, however, you become distressed in the process of recalling particular events or experiences, you may wish to access counselling services via your GP or request a "de-brief" (giving you an opportunity to review what has been discussed during the interview) with Heather; this could be at the end of the interview or in a follow-up telephone or zoom call.

What if I change my mind during or after the study?

You are free to withdraw from the study (including the interview) at any time, without providing an explanation. You may also withdraw any data you have provided up to the point of data analysis; after that it will not be possible to remove data, as they will have been anonymised and incorporated with other data.

What will happen to the information when this study is over?

All data will be treated in a confidential manner by the research team.

Any personal data will be stored securely, on a password protected database that only the research team have access to, in accordance with the Data Protection Act (2018) for 6 years before being destroyed. Any anonymised research data will be stored securely, in accordance with the University of Plymouth Research Policy, for 10 years.

How will the results of the study be published?

A summary report will be produced and available on request once the study is completed. The findings will also be disseminated to local service providers, written up for publication in a suitable peer reviewed scientific journal, shared with Public Health England and disseminated at relevant conferences nationally and internationally. You will not be identifiable in any reports or publications.

What if I have questions about this study?

If you have any questions or concerns about this study, or need to change or cancel an interview, please contact either Heather Hopper (the researcher) or Professor Jill Shawe (academic supervisor) via the following email addresses:

Heather.hopper@plymouth.ac.uk jill.shawe@plymouth.ac.uk Peachstudy@plymouth.ac.uk

This study has been approved by the University of Plymouth Ethics Committee. If you would like to contact someone independent, please contact the Research Administrator to the Faculty Research and Ethics Integrity Committee <u>hhsethics@plymouth.ac.uk.</u>

How do I confirm that I am interested in taking part?

If you are interested in participating in this study, please click on the link to provide your contact details. Heather will then contact you (via email), to organise an online interview via Zoom.

Link (to online survey) to provide initial information, confirm consent and give contact details: <u>https://plymouth.onlinesurveys.ac.uk/peachstudy-consent-and-contact</u>

Thank you for reading this information sheet and considering participating in the PEAcH Study.

Heather Hopper (PhD student and Midwife)



For healthcare professionals:



Participant information sheet – PEAcH Study Group: Health Care Professionals (Version 1, April 2021)

Preconception care; Exploration of Availability and access for women with Health Conditions PEAcH Study.

A realist evaluation of availability and access to preconception care for women with preexisting medical conditions; what approaches work, for whom and in what circumstances?

Invitation

As a healthcare professional providing care to women with a pre-existing medical condition(s), you are invited to take part in a research study on preconception (pre-pregnancy) care.

What is the purpose of the study?

Women with both physical and mental health conditions can benefit from advice and support before pregnancy (preconception care). Effective preconception care can improve health outcomes for both mothers and babies, and in some cases even prevent death or stillbirth. Not all pregnancies are planned, and even if they are, many women find it very difficult to optimise their health prior to pregnancy.

This study will explore preconception care to find out what works, for whom, and in what circumstances. The aim is to identify how to optimise services that provide preconception care to women with pre-existing medical conditions, with a view to improving health and wellbeing during pregnancy and beyond.

The study is being conducted as part of a PhD for Heather Hopper, under the supervision of Professor Jill Shawe. Heather is a midwife and associate professor in midwifery; both Heather and Jill are employed by the University of Plymouth and work in the School of Nursing and Midwifery, in the Faculty of Health.

What will you be asked to do?

If you wish to take part, you must be a health care professional who provides care to women with pre-existing medical conditions. This may be as part of routine on-going medical care, and may, or may not specifically involve preconception (pregnancy planning) care. You will be asked to give informed consent and participate in an online interview in English. The interview is likely to take between half an hour and an hour. You will be expected to participate in your own time. If you decide to participate, please click on the link at the bottom of this information leaflet to give your consent to take part and provide your contact details so an online interview (via Zoom) can be arranged. Heather will be conducting the interviews and will ask you about your experiences of providing preconception care (if any). The interview will focus on what aspects or approaches to preconception care you feel work well.

The interview will be recorded for analysis; you will have the option to turn the camera off during the recording if you wish. Heather may invite you to a second interview; this may help to clarify a point that she is interested in. As soon as your interview(s) have been transcribed (written down), all Zoom recordings will be destroyed. All data from interviews will be anonymised, so you will not be identifiable in any report or publication.

Are there any possible benefits from participation in this study?

The findings from the study will influence preconception care in the future, and taking part may not directly benefit you, but will help to develop and improve preconception care in the future.

Are there any possible risks from participation in this study?

No, there are no anticipated risks from participation in this study. If, however, you become distressed in the process of recalling particular events or experiences, you may wish to access counselling services via your GP or request a "de-brief" (giving you an opportunity to review what has been discussed during the interview) with Heather; this could be at the end of the interview or in a follow-up telephone or zoom call.

What if I change my mind during or after the study?

You are free to withdraw from the study (including the interview) at any time, without providing an explanation. You may also withdraw any data you have provided up to the point of data analysis; after that it will not be possible to remove data, as they will have been anonymised and incorporated with other data.

What will happen to the information when this study is over?

All data will be treated in a confidential manner by the research team. Any personal data will be stored securely, on a password protected database that only the research team have access to, in accordance with the Data Protection Act (2018) for 6 years before being destroyed. Any anonymised research data will be stored securely, in accordance with the University of Plymouth Research Policy, for 10 years.

How will the results of the study be published?

A summary report will be produced and available on request once the study is completed. The findings will also be disseminated to local service providers, written up for publication in a suitable peer reviewed scientific journal, shared with Public Health England and disseminated at relevant conferences nationally and internationally. You will not be identifiable in any reports or publications.

What if I have questions about this study?

If you have any questions or concerns about this study, or need to change or cancel an interview, please contact either Heather Hopper (the researcher) or Professor Jill Shawe (academic supervisor) via the following email addresses: Heather.hopper@plymouth.ac.uk jill.shawe@plymouth.ac.uk Peachstudy@plymouth.ac.uk This study has been approved by the University of Plymouth Ethics Committee. If you would like to contact someone independent, please contact the Research Administrator to the Faculty Research and Ethics Integrity Committee hhsethics@plymouth.ac.uk.

How do I confirm that I am interested in taking part?

If you are interested in participating in this study, please click on the link to provide your contact details. Heather will then contact you (via email), to arrange an online interview via Zoom.

Link (to online survey) to provide initial information, confirm consent and give contact details: <u>https://plymouth.onlinesurveys.ac.uk/peachstudy-consent-and-contact</u>

Thank you for reading this information sheet and considering participating in the PEAcH Study.

Heather Hopper (PhD student and Midwife)



For partners or supporting family members:



Participant information sheet – PEAcH Study Group: Supporting partners or family members (Version 1, April 2021)

Preconception care; Exploration of Availability and access for women with Health Conditions PEAcH Study.

A realist evaluation of availability and access to preconception care for women with preexisting medical conditions; what approaches work, for whom and in what circumstances?

Invitation

As a partner or family member who provides support to a woman with a pre-existing medical condition (physical or mental health), you are invited to take part in this research study on preconception (pre-pregnancy) care. Your partner or family member may or may not have ever been pregnant. If you wish to take part, you must be 18 or over, have a partner or family member (who you support) with an on-going medical condition (affecting their physical or mental health), be able to give informed consent, and participate in an online interview in English.

What is the purpose of the study?

Women with both physical and mental health conditions can benefit from advice and support before pregnancy (preconception care). Effective preconception care can improve maternal, fetal and infant health and well-being during and after pregnancy. Not all pregnancies are planned, and even if they are, many women find it very difficult to optimise their health prior to pregnancy.

This study will explore preconception care to find out what works, for whom, and in what circumstances. The aim is to identify how to optimise services that provide preconception care to women with pre-existing medical conditions, with a view to improving health and wellbeing during pregnancy and beyond.

The study is being conducted as part of a PhD for Heather Hopper, under the supervision of Professor Jill Shawe. Heather is a midwife and associate professor in midwifery; both Heather and Jill are employed by the University of Plymouth and work in the School of Nursing and Midwifery, in the Faculty of Health.

What will you be asked to do?

If you decide to take part, please click on the link at the bottom of this information leaflet to give your consent and provide your contact details so an online interview (via Zoom) can be arranged. Heather will be conducting the interviews and will ask you about your experiences. Please be aware that this may include sensitive topics, particularly if you have had previous difficult experiences, including pregnancy or baby loss. The interview will focus on what aspects or approaches to preconception care you feel would or have worked work well for you and your partner or family member. The interview is likely to take between half an hour and an hour.

The interview will be recorded for analysis; you will have the option to turn the camera off during the recording if you wish. Heather may invite you to a second interview; this may help to clarify a point that she is interested in. As soon as your interview(s) have been transcribed (written down), all Zoom recordings will be destroyed. All data from interviews will be anonymised, so you will not be identifiable in any report or publication.

Are there any possible benefits from participation in this study?

The findings from the study will influence preconception care in the future. Taking part may not directly benefit you or your partner or family member but will help to develop and improve preconception care in the future.

Are there any possible risks from participation in this study?

No, there are no anticipated risks from participation in this study. If, however, you become distressed in the process of recalling particular events or experiences, you may wish to access counselling services via your GP or request a "de-brief" (giving you an opportunity to review what has been discussed during the interview) with Heather; this could be at the end of the interview or in a follow-up telephone or zoom call.

What if I change my mind during or after the study?

You are free to withdraw from the study (including the interview) at any time, without providing an explanation. You may also withdraw any data you have provided up to the point of data analysis; after that it will not be possible to remove data, as they will have been anonymised and incorporated with other data.

What will happen to the information when this study is over?

All data will be treated in a confidential manner by the research team. Any personal data will be stored securely, on a password protected database that only the research team have access to, in accordance with the Data Protection Act (2018) for 6 years before being destroyed. Any anonymised research data will be stored securely, in accordance with the University of Plymouth Research Policy, for 10 years.

How will the results of the study be published?

A summary report will be produced and available on request once the study is completed. The findings will also be disseminated to local service providers, written up for publication in a suitable peer reviewed scientific journal, shared with Public Health England and disseminated at relevant conferences nationally and internationally. You will not be identifiable in any reports or publications.

What if I have questions about this study?

If you have any questions or concerns about this study, or need to change or cancel an interview, please contact either Heather Hopper (the researcher) or Professor Jill Shawe (academic supervisor) via the following email addresses: <u>Heather.hopper@plymouth.ac.uk</u>

jill.shawe@plymouth.ac.uk Peachstudy@plymouth.ac.uk

This study has been approved by the University of Plymouth Ethics Committee. If you would like to contact someone independent, please contact the Research Administrator to the Faculty Research and Ethics Integrity Committee <u>hhsethics@plymouth.ac.uk.</u>

How do I confirm that I am interested in taking part?

If you are interested in participating in this study, please click on the link to provide your contact details. Heather will then contact you (via email), to organise an online interview via Zoom.

Link (to online survey) to provide initial information, confirm consent and give contact details: <u>https://plymouth.onlinesurveys.ac.uk/peachstudy-consent-and-contact</u>

Thank you for reading this information sheet and considering participating in the PEAcH Study.

Heather Hopper (PhD student and Midwife)



Appendix 6

Online consent form

This information will be collected via an online survey (GDPR Compliant)

Consent form

PEAcH Study

FREIC ID Number:

Research conducted by Heather Hopper as part of PhD study.

Director of studies – Professor Jill Shawe

Additional supervisors – Dr Kerryn Husk and Dr Kate Maslin

Please initial the boxes provided if you agree with the accompanying statements:

Statement:	Verify:
I have read and understand the study participant information sheet.	
I have had the opportunity to ask questions.	
I have had sufficient time to consider my participation ahead of providing consent.	
I understand that I am free to withdraw my participation and data from the study up until the point it is incorporated in data analysis (at which point it will be anonymised).	
I understand that my data will be held in accordance with the University of Plymouth's 'Research Participant Privacy Notice' and 'Data Protection Policy' and GDPR (2018).	
I understand that my data will be held in confidence to those named in the research team (above) as well as the data asset owners, as per the University's 'Research Data Policy'.	
I understand that my data will be securely destroyed after 10 years of secure storage at the University of Plymouth in accordance with the 'Data Retention and Erasure Policy'.	
I understand that my data will be used in the dissertation (research project submitted to the University for PhD examination) of the above named student.	
I understand that my data may be published externally (in presentations, magazine or journal articles) and that in this instance my data would be anonymous and I would not be identifiable either directly or indirectly.	
I hereby give consent to participate.	

Please provide the additional following information:

Please indicate which apply to you (may be more than one of the following):		
I am a Health Care Professional		
I am a woman with a pre-existing medical (affecting physical or mental health) condition (please state what condition)		
I am a partner or supporting family member (please state what medical condition your partner has)		
Availability:		
I am likely to be available for an online interview at the following times (select one or more from Monday to Sunday, morning, afternoon or evening – total of 21 options)		
My availability may vary from week to week, so please contact me to confirm.		
I agree to being contacted by the researcher via the following:		
Email address: invitation)		
Telephone no: but may be helpful)		

Participant Name:

Date:

Ethics approval letter



13/04/2021

Confidential

Mrs Heather Hopper

Dear Mrs Heather Hopper

Research Ethics Application Approval - Faculty Research Ethics and Integrity Committee:

2594

A realist evaluation of availability and access to preconception care for women with pre-existing medical conditions: what approaches work, for whom and in what circumstances.

The committee has considered your application and has granted ethical approval to conduct this research.

Approval is for the duration of the project. If you wish to continue beyond this date, you will need to seek an extension.

Please note that if you wish to make any minor changes to your research, you must complete an amendment form or major changes you will need to resubmit an application.

Yours sincerely

Dr Daniela Oehring

Chair, Faculty of Health Staff Research Ethics and Integrity Committee

Data management plan

Student name: Heather Hopper Director of Studies name: Prof Jill Shawe Project title: PEAcH Study – Preconception care; Exploration of Availability and access for women with Health Conditions. Project start date: 1/03/21 Project end date: 28/02/23 *Funder (if appropriate):* No external funding Research Ethics & Integrity Committee (chair=data asset owner): Faculty taught PhD Data storage duration: 10 years Any data storage offsite: NO The overall (highest of all components) security classification level for this research study is (refer to Table 1 if needed): 1: Restricted

Description of dataset:	Level :	Storage details: Please add start date, end date and destruction method	Justification:	Storage location:	Named persons with access to the data:
Digital consent forms (includes confirmation of a persons medical condition)	1	Start date: 1/3/21 – 28/2/23 plus secure storage for 10 years. Electronic file erasure under data asset, steward and IT personnel supervision.	Signed consent is required- This involves data defined under the Data Protection Act (1998) as 'personal data' Additional data related to medical condition is defined as 'sensitive personal data'	Online Surveys under University license- closed upon study end date. Excel document exported from Online Surveys held onward. Held in password protected	Excel export in OneDrive: Heather Hopper (PhD Student) Prof. Jill Shawe (Director of Studies) Dr Kerryn Husk (supervisor) Dr Kate Maslin (supervisor

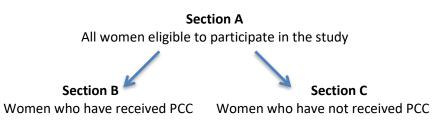
				OneDrive account under the University of Plymouth license.	Plus, as per University policy: Prof. Sarah Neil (FREIC chair name) Prof. Jerry Roberts DVC research)
Temporary zoom recordings (video) of interviews about a medical condition and experience of preconception care	1	Recording date to 3 months following recording. Secure destruction as soon as transcriptio n and analysis allows. Electronic file erasure under data asset, steward and IT personnel supervision.	This involves data defined under the Data Protection Act (1998) as 'sensitive personal data'.	Zoom meeting recording to take place on University of Plymouth password protected laptop. Immediat e storage of Zoom recording to password protected computer (secure access by HH only – UoP password protected.	OneDrive: Heather Hopper (PhD Student) Prof. Jill Shawe (Director of Studies) Kerryn Husk (supervisor) Kate Maslin (supervisor) Kate Maslin (supervisor) Plus, as per University policy: Prof. Sarah Neil (FREIC chair name) Prof. Jerry Roberts DVC research)
Excel spread sheet of participants providing a "key code" linking participants to data.	1	1/3/21 – 28/2/23 so that participants can be invited to be interviewed a second time, during the duration	This involves data defined under the Data Protection Act (1998) as 'sensitive personal data'.	OneDrive account under the University of Plymouth license.	OneDrive: Heather Hopper (PhD Student) Prof. Jill Shawe (Director of Studies)

		of the study, if required. Secure destruction as soon as analysis allows. Electronic file erasure under data asset, steward and IT personnel supervision.			Kerryn Husk (supervisor) Kate Maslin (supervisor) Plus, as per University policy: Prof. Sarah Neil (FREIC chair name) Prof. Jerry Roberts DVC research)
Pseudoanonymise d transcriptions of interviews about a medical condition and experience of preconception care	4	Start date: 1/3/21 – 28/2/23 plus secure storage for 10 years (NB data becomes anonlymised after destruction of "key code" spread sheet identified above. Electronic file erasure under data asset, steward and IT personnel supervision.	This involves data defined under the Data Protection Act (1998) as 'sensitive personal data'. However, personal data has been anonymised (after descrtuction of "key code" spreadsheet) and participants have given explicit consent for publication.	OneDrive account under the University of Plymouth license.	OneDrive: Heather Hopper (PhD Student) Prof. Jill Shawe (Director of Studies) Kerryn Husk (supervisor) Kate Maslin (supervisor) Rate Maslin (supervisor) Plus, as per University policy: Prof. Sarah Neil (FREIC chair name) Prof. Jerry Roberts DVC research)

Topic guides for interviews

Topic guide for Interviews - Women V2 PEAcH Study H. Hopper March 2021

FLOW DIAGRAM



Section A:

The interviewer will first:

- Introduce the study and clarify the medical condition/s (to be explained as any medical condition, for which a participant has required on-going input from a health care professional – such as doctor or nurse – prior to pregnancy). This does not require confirmation from the participant's HCP.
- 2. Clarify what is meant by preconception care; to be explained as care and advice that is given, in relation to the medical condition, in preparation for, or in relation to, pregnancy. This includes advice that may be offered to all women / girls "in case they ever consider pregnancy", and advice that is sought out specifically because a woman is planning a pregnancy.

Can you tell me what your experience of preconception care has been? (The answer will confirm condition and dictate the direction of future questions. Looking for different examples of PCC, different experiences etc)

What do you consider the outcomes of preconception care (or NOT having had any PCC) to have been for you?

(May need to explain what is meant by outcomes – impact / result / effect, for example, by way of prompting. May need to ask for greater description if outcomes are unexpected or meaning unclear)

Can you give me an example (of stated outcome)? (Prompt for evidence / clarity)

Do you think that this/these outcome/s (state specifically) would be the same for all women with this condition (state specifically)... what about sub-groups – eg older/younger women or women from different groups in terms of social disadvantage?

(Seeking to identify to what extend and for whom the programme might achieve this/these outcome/s)

What we are very curious about is how preconception care causes these outcomes (if NO PCC, still explore stated outcomes). How do you think the care/support/advice you received has caused or helped to cause the outcome/s (specify the outcome/s identified earlier by the participant)?

(Starting to ask about mechanisms – further probing needed – if "education" given as response, ask how this may have helped... did it provide necessary skills, different attitudes, change beliefs etc?)

At this point either:

- a. If the woman reports having received PCC, continue with section B questions below, and do not ask questions in section C, or
- b. If the woman reports having NOT received any PCC, skip section B and continue with section C questions below.

Section B (questions for women who report having received PCC):

Do you think preconception care (or element of PCC) changed the way you think or feel about preparation for pregnancy (or planning for a pregnancy)?

(Looking for reasons why PCC might work – or not. This may be from past experience – if the woman has been pregnant, or in terms of future experiences)

There are lots of ideas about how preconception care actually works, and we think it probably works differently in different situations for different people. One of these ideas is (give mechanism from one of the 10 identified programme theories). Has it worked at all like that for you? Can you give an example?

(testing / refining / consolidating programme theory – try with 2 or 3 relevant theories, depending on participant responses and time available)

What is it about the way this particular preconception care/advice/service was implemented that made a difference to how it worked?

(exploring contest - may need further probing or exploring)

We've seen different examples of how preconception care is delivered in different places. What do you think makes it work well / less well here? (exploring context in relation to culture, resources, relationships, communication etc)

If you could change something about this service to make it work more effectively, what would you change and why?

(exploring why a programme might not have worked as well as it might – related to context and mechanism)

What else do you think we need to know, to really understand how preconception care has worked here?

(adjust question accordingly, but seek further comments about how PCC works in a particular context)

Non-identifiable demographics questions: Age: Ethnicity: Highest qualification: Location (eg county or city):

Section C (questions for women who report having NOT received any PCC):

Do you think that having preconception care (or an element of PCC) would change the way you think or feel about preparation for pregnancy (or planning for a pregnancy)? (Looking for reasons why PCC might work – or not. This may be from past experience – if the woman has been pregnant, or in terms of future experiences)

If you could change something about the care/support you have received, to make it work more effectively, what would you change and why? (exploring why a programme might not have worked as well as it might – related to context and mechanism)

What else do you think we need to know, to really understand how preconception care could worked for you? (adjust question accordingly, but seek further comments about how PCC could work in a particular context)

Non-identifiable demographics questions: Age: Ethnicity: Highest qualification: Location (eg county or city):

(**Reference**: Westhorp G. & Manzano A. Realist Evaluation Interviewing – A "Starter Set" of Questions. The RAMESES II Project. Available at:

https://www.ramesesproject.org/media/RAMESES II_Realist_interviewing_starter_questions. pdf_Accessed 8/2/21)

Interview guide for Interviews – HCP's V2 PEAcH Study

H. Hopper March 2021

The interviewer will first:

- 1. Introduce the study and clarify that, for the purposes of this study, medical condition/s means any medical condition, for which an individual has required on-going input from a health care professional prior to pregnancy.
- 2. Clarify what is meant by preconception care; to be explained as care and advice that is given, in relation to the medical condition, in preparation for, or in relation to, pregnancy. This includes advice that may be offered to all individuals "in case they ever consider pregnancy", and advice that is sought out specifically because an individual is planning a pregnancy.

Can you tell me what your involvement in preconception care has been? (The answer will clarify experience/speciality and dictate the direction of future questions. Looking for different examples of PCC, different medical conditions, different stakeholder viewpoints etc)

What do you consider the outcomes of preconception care to have been for the women you see?

(May need to explain what is meant by outcomes – impact / result / effect, for example, by way of prompting. May need to ask for greater description if outcomes are unexpected or meaning unclear)

Can you give me an example (of stated outcome)? (Prompt for evidence / clarity)

Do you think that this/these outcome/s (state specifically) would be the same for all women with this condition (state specifically)... what about sub-groups – eg older/younger women or women from different groups in terms of social disadvantage?

(Seeking to identify to what extend and for whom the programme might achieve this/these outcome/s)

What we are very curious about is how preconception care causes these outcomes. How do you think the care/support/advice you give/have given has caused or helped to cause the outcome/s (specify the outcome/s identified earlier by the participant)? (Starting to ask about mechanisms – further probing needed – if "education" given as response, ask how this may have helped... did it provide necessary skills, different attitudes, change beliefs etc?)

Do you think preconception care (or element of PCC) changed the way women with (specify) condition think/s or feel/s about preparation for pregnancy (or planning for a pregnancy)? (Looking for reasons why PCC might work – or not)

There are lots of ideas about how preconception care actually works, and we think it probably works differently in different situations for different people. One of these ideas is (give mechanism from one of the 10 identified programme theories). Has it worked at all like that in your experience? Can you give an example?

(testing / refining / consolidating programme theory – try with 2 or 3 relevant theories, depending on participant responses and time available)

What is it about the way this particular preconception care/advice/service was implemented that made a difference to how it worked? (exploring contest – may need further probing or exploring)

We've seen different examples of how preconception care is delivered in different places. What do you think makes it work well / less well here? (exploring context in relation to culture, resources, relationships, communication etc)

If you could change something about this service to make it work more effectively, what would you change and why?

(exploring why a programme might not have worked as well as it might – related to context and mechanism)

What else do you think we need to know, to really understand how preconception care has worked here?

(adjust question accordingly, but seek further comments about how PCC works in a particular context)

Non-identifiable demographics questions: Age: Sex : Ethnicity: Highest qualification: Location (eg county or city):

(**Reference**: Westhorp G. & Manzano A. Realist Evaluation Interviewing – A "Starter Set" of Questions. The RAMESES II Project. Available at:

https://www.ramesesproject.org/media/RAMESES II Realist interviewing starter questions. pdf Accessed 8/2/21)

Interview Guide for Interviews – Partners / Supporting family members V2 PEAcH Study

H. Hopper March 2021

The interviewer will first:

- 1. Introduce the study and clarify that, for the purposes of this study, medical condition/s means any medical condition, for which an individual has required on-going input from a healthcare professional prior to pregnancy
- 2. Clarify what is meant by preconception care: to be explained as care and advice that is given, in relation to the medical condition, in preparation for, or in relation to, pregnancy. This includes advice that may be offered to all individuals "in case they ever consider pregnancy, and advice that is sought out specifically because an individual is planning a pregnancy.

Can you tell me what your involvement in preconception care has been? (The answer will clarify relationship and type of condition, and also dictate the direction of future questions. Looking for different examples of PCC, different medical conditions, different stakeholder viewpoints etc)

What do you consider the outcomes of preconception care to have been for your partner/family member?

(May need to explain what is meant by outcomes – impact / result / effect, for example, by way of prompting. May need to ask for greater description if outcomes are unexpected or meaning unclear)

Can you give me an example (of stated outcome)? (Prompt for evidence / clarity)

Do you think that this/these outcome/s (state specifically) would be the same for all women with this condition (state specifically)... what about sub-groups – eg older/younger women or women from different groups in terms of social disadvantage?

(Seeking to identify to what extend and for whom the programme might achieve this/these outcome/s)

What we are very curious about is how preconception care causes these outcomes. How do you think the care/support/advice you observed has caused or helped to cause the outcome/s (specify the outcome/s identified earlier by the participant)?

(Starting to ask about mechanisms – further probing needed – if "education" given as response, ask how this may have helped... did it provide necessary skills, different attitudes, change beliefs etc?)

Do you think preconception care (or element of PCC) changed the way your partner/family member with (specify) condition think/s or feel/s about preparation for pregnancy (or planning for a pregnancy)?

(Looking for reasons why PCC might work – or not)

There are lots of ideas about how preconception care actually works, and we think it probably works differently in different situations for different people. One of these ideas is (give mechanism from one of the 10 identified programme theories). Has it worked at all lake that in your experience for your partner (or family member)? Can you give an example? (testing / refining / consolidating programme theory – try with 2 or 3 relevant theories, depending on participant responses and time available)

What is it about the way this particular preconception care/advice/service was implemented that made a difference to how it worked? (exploring contest – may need further probing or exploring)

We've seen different examples of how preconception care is delivered in different places. What do you think makes it work well / less well here? (exploring context in relation to culture, resources, relationships, communication etc)

If you could change something about this service to make it work more effectively, what would you change and why?

(exploring why a programme might not have worked as well as it might – related to context and mechanism)

What else do you think we need to know, to really understand how preconception care has worked here?

(adjust question accordingly, but seek further comments about how PCC works in a particular context)

Non-identifiable demographics questions: Age: Sex: Ethnicity: Highest qualification: Location (eg county or city):

(**Reference**: Westhorp G. & Manzano A. Realist Evaluation Interviewing – A "Starter Set" of Questions. The RAMESES II Project. Available at:

https://www.ramesesproject.org/media/RAMESES_II_Realist_interviewing_starter_questions. pdf_Accessed 8/2/21)

Example interview in full

Interview W4 (woman living with SLE) – 25/6/21

Heather Hopper: Okay brilliant Thank you obviously after I've done the transcribing, I ju delete it and then it's then it's gone and also it doesn't record your picture it just record the sound	
Heather Hopper: yeah	0:19
Heather Hopper: So Okay, so you were beginning to tell me that you were quite	0:32
Heather Hopper: Medicated before you got pregnant so tell me about your experience preconception care so that's before pregnancy that's that's what i'm interested in basica	of
W4: Well, I guess i'll just start briefly with my diagnosis of lupus that wasn't too long age	
W4: That was November 2019 and.	1:00
W4: I got married in December 2019 so kind of it was just a few months, just a few brief months of tests	:
Heather Hopper: wow.	1:03
W4: and seeing a heamatologist and he referred me to rheumatology and	1:12
Heather Hopper: so had you been having problems, a long time before that.	1:13 1:18
W4: No, no, not hugely at all reallyI know the average diagnosis for Lupus is about six years, but for me it was a few months i'd only been having joint pain.	
And swelling.	1:22
W4: From kind of the summertime 2019 and it only got bad in September, October, so i was only waiting a couple of months, fortunately, before I started medication.	1:32 it
W4: I did have to pay private, for the first consultation with the rheumatologist because even for agent cases it was three or four months.	1:33
W4: And I was I just couldn't have gone that long with me getting married and things and my fingers my knuckles were like the elephant man, it was it was awful.	1:45 nd
Heather Hopper: mmm	1:52
	2:00
W4: so it was sudden, but like quite like severe really.	2:02
W4: Not horrendous I was still able to go to work and things, but I was in a lot of pain	2:07

yeah. 2:11 W4: So. 2:12 W4: So, because we'd obviously booked our wedding and things in the December and me and T have been together like 10 years before that and I always wanted a baby so, I thought as soon as we get married, we'll start trying. 2.14 W4: so that was at the forefront of my mind when I was having these consultations with the haematologist and the rheumatologist, so I mentioned it to them like will this affect like pregnancy and things because i'm really keen to try for a family. 2:25 Heather Hopper: So that was right at the when you were first diagnosed. 2:38 Heather Hopper: Okay, so you brought it up, they didn't bring it up you brought up. 2:41 W4: Exactly so whether it would have been different if I was at kind of a different stage or I didn't mention it, I don't know but. 2:44 W4: The rheumatologist took it on board but said, we need to get things under control first. 2:52 W4: so you can't start trying basically just hold off, and I think they did probably extra tests for me, because I was keen on the pregnancy. 2:56 W4: So, from the beginning, they tailored my medication to give me ones that would be suitable during pregnancy. 3:06 Heather Hopper: that's good. 3:12 W4: I'm on immunosuppressants but some of them are kind of like chemotherapy drugs which wouldn't have been suitable for trying for a baby, so I wasn't on them. 3:12 Heather Hopper: So you never started any of the kind of the worst medications i'd say. 3:21 W4: No so i'm on steroids and the main immunosuppressant is azathioprine and although that's an old one and it's not as effective it's kind of the safest in pregnancy really in terms of immunosuppressant so that's what i'm on. 3:27 Heather Hopper: that's good that's that's really good that they right from the beginning, because they knew you wanted to get pregnant they kind of got you on the right medication, from the start. 3:46 yeah. 3:57 W4: In terms of the extra tests that they did they gave me a kidney biopsy. 3:59 W4: and even though I didn't have huge symptoms of the nephritis, there was a couple of things like blood in my urine.

4:03

W4: So they said we'll refer you to like the nephrology the kidney team, and they can k of see if you need the kidney biopsy, but it was more an exploratory one rather than a confirmatory one.	ind
W4: but they did find that the antibodies were there around the kidneys, which is why i Stage one, but there was no damage, my kidneys were so good.	4:11 it was
W4: so they did that kind of preemptively because.	4:21
I wanted to get pregnant.	4:28 4:32
W4: Because obviously kidneys are hugely important in pregnancy, if they were damag might have been different	ed it
W4: In terms of how they manage the pregnancy and things.	4:37
Heather Hopper: But you know.	4:40 4:43
Heather Hopper: Sorry, so you don't know whether that would be standard practice for know women being.	r you
Heather Hopper: diagnosed with lupus.	4:44
W4: No, I don't think a bit kidney biopsy would be done straight way, I think you'd nee more symptoms for that.	
W4: Because actually the kidney specialist who I saw with the results said he'd never ac seen my results before in terms of the antibodies were all there the full House, I think is called sticking to the kidneys but without having damaged them.	2
W4: So it was kind of like it's probably going to go this way but we've caught it so early there's.	5:00 y that
W4: No damage already if that makes sense.	5:15
Heather Hopper: it mean it does make sense and that's fantastic but i'm just thinking if you 're if you didn't say that you wanted to get pregnant and they havdn't done.	5:19
Heather Hopper: That I suppose you still would have gone on to the immunosuppressative treatment So hopefully.	5:22 ant
Heather Hopper: That would have controlled it.	5:30
W4: Yes, yeah.	5:39
Heather Hopper: don't know.	5:41
W4: I think so because it didn't really change the treatment plan.	5:42
Heather Hopper: No okay.	5:44
	5:48

W4: it gave them a better idea of what they were playing with I guess.	
Heather Hopper: yeah	5:49
Heather Hopper: Did they do a test for the antiphospholipid syndrome then because a pregnancy issue isn't it.	
W4: Yes, So they tested me for that, I think that would have been standard because th a lot of different antibody tests and I had lots of them come back positive so they wou have tested that .	-
W4: anyway, but that was the thing that made my rheumatologist say you can't try for baby that was in January, so I was really upset at that point.	
W4: Because obviously, we'd just got married and I was ready to have a baby and the were like no you can't start yet and I was like This is awful	-
W4: like all the potential risk of miscarriage and things I was like, is this never going to under control, really, but obviously.	-
W4: Fortunately, it was, it was OK, so he, my rheumatologist basically said wait six more that you've got to get the lupus, especially the nephritis under control.	
W4: The six months without like a flair for you can start trying because that's associate with kind of the best outcomes of lupus not flaring during pregnancy.	
W4: hmm and so how I got to the preconception planning was due to the kidney biop	6:42 osy. 6:51
W4: So, because I went over to X hospital which is a specialist hospital.	7:00
W4: under the specialist over there, he said, oh we've got this brilliant clinic with, it wa consultant obstetrician.	is a
W4: And then, it was an obstetrician who specializes in kidney disorders, so he said i'll you in with them two for a preconception planning meeting or whatever it was so	7:04 get
W4: That was in the March	7.00
Heather Hopper: mm hmm.	7:22
W4: So they basically took all the history, the results, all my medical conditions, the medication that I was on and they all kind of came together with the plan.	7:23
W4: Of the immunosuppressant medication.	7:26
HH: Okay, so when you first went to the rheumatologist That was a bit more, although was Rheumatologists, but it was more general I suppose.	
Heather Hopper: He or she sent you for tests.	7:38
Heather Hopper: Sorry.	7:49

	7:52
W4: you mean generally not in terms of the pregnancy thing?	
Heather Hopper: yeah yeah.	7:53
W4: Yeah, he was much more focused just on me and the Lupus, he didn't want to add complication of.	7:56 the
W4: kind of a baby,	7:58
	8:02
W4: Which is understandable, because it was very early to know, because lupus can aff all your different organs,	
W4: I had a whole range of tests from like the lungs and an X Ray on my chest, and this like that so he got a baseline of everything and and he started me on hydroxychloroqu and steroids, and not the immunosuppressants because it seemed like.	0
	8:09
W4: let's see how the hydroxychloroquine does things and steroids kind of work quickle reduce the inflammation.	y to
	8:28
Heather Hopper: yeah.	0.24
W4: And then it wasn't till the further tests came back ; antiphospholipid and the kidne thing that they all agreed kind of the kidney specialist and the obstetricians.	8:34 Y
	8:35
W4: That aothioprine would be safest for pregnancy .	
Heather Hopper: Okay, so, then he so the rheumatologist sent you to this specialist clir X hospital.	8:45 nic at
	8:50
Heather Hopper: And you said.	
Heather Hopper: There was an obstetrician a specialist renal obstetrician who else do y think was involved.	8:56 ou
W4: That was it so it was kind of the rheumatologist, then the kidney specialist that kid specialist referred me to two others, which was kind of the obstetric team that specializ kidneys.	
W4: kind of.	9:05
W4: I don't know kidney difficulties in pregnancy I guess.	9:16
where a don't know Kuney annealdes in pregnancy i guess.	9:17
yeah.	9:21
W4: There was four of them really that will kind of emailing and communicate and abo the results and what this meant and what's the best kind of treatment for me.	
the results and what this meant and what's the best kind of treatment for me.	9:23
Heather Hopper: yeah so were they all present when you went for an appointment, or more that it was all they communicated	
	9:31

W4: they communicated behind the scenes really, yeah	
Heather Hopper: Okay, so they communicated behind the scenes who did you actuall	9:39 ly see ? 9:41
W4: I saw my rheumatologist fairly regularly and.	
W4: saw the kidney specialist a couple of times and then I just had a one off meeting the obstetrician team basically.	9:59 with
W4: so they give their advice and kind of wrote it down.	10:03
W4: you need to start on the azathioprine, they said.	10:11
W4: They said they wouldn't wait that long if it were me, so kind of rheumatology was hold off when you get Lupus under control and the obstetricians and the kidney spec himself, as well, was like.	
M(4) there is need to kind of weit that lang was make sure you've not kind of herein	10:18
W4: there's no need to kind of wait that long, yes, make sure you're not kind of havin flare but sooner rather than later, is better because the condition is progressive.	-
W4: you're not going to get any better, and you're getting older so the risks are going increase like.	10:31 g to
W4: do it sooner rather than later, especially if you want a couple of children I guess	10:40
Heather Hopper: so what effect did that have on you, you know and did you feel that conflicting advice or not really because obviously it's coming from different viewpoin	ts.
W4: yeah it was a bit conflicting, not totally, like it's not like there's any definitely to g you won't have a chance and he said you definitely can.	
W4: obviously they can't tell you what to do, it's just an informed choice isn't it.	11:02
W4: but I was swaying towards wanting to try	11:11
W4: but equailly not wanting to have the negative outcomes if	11:15
W4: my Rheumatologists was saying, look, if you do try, you might not get pregnant,	11:20 it
might be more difficult.	11:25
W4: Or you might have a miscarriage or the lupus might flare up, then you in a much situation than if you waited a few more months.	
W4:, so we did wait	11:29
W4: but I kind of asked him the question each appointment like when can we start try really.	11:35 /ing
W4: Things seem under control i've taken all my meds and i've kind of been looking a	11:38 after
myself so.	11:45

Heather Hopper: So you felt that they gave advice, you understood the reason behind	l the
advice and then very much it was still your decision.	11:51
W4: Oh certainly yeah.	12:03
Heather Hopper: yeah yeah that's good that's good so um.	12:05
Heather Hopper: So, having had um so having had that experience like of the preconception care.	
Heather Hopper: How, did that help, what was the effect of all that input that you had you think.	12:11 do
W4: I guess, the first thing was kind of getting on the right medication.	12:21
	12:29
Heather Hopper: yeah.	12:33
W4: it's obviously balancing the risks of kind of potential medication being harmful bu keeping the lupus under control because that would potentially be more harmful	ut also
W4: So I did feel that kind of I was on the best medication that I could have to balance	12:34 e. 12:44
W4: The risks really and they were all in agreement about that and the obstetrician kind of so I was consultant lead throughout and she kind of.	she
W4: saw me regularly she saw me every month when I got pregnant so basically the a was, this is the medication.	
W4: and start trying when when things are settled, and let us know soon as you get pregnant basically.	12:59
W4: So literally when I got the positive test I rang her Secretary was booked in the new	13:06
with her, which was fantastic like absolutely amazing, and they started me on a couple different things and did all baseline stuff whatever they need to do.	2
	13:11
Heather Hopper: Okay, so you saw sorry just going back to the preconception you saw consultant obstetrician just once.	w the
W4: Yes, in March.	13:26
	13:34
Heather Hopper: before got pregnant in terms of preconception care, it was one appointment to.	
	13:35
Heather Hopper: sort of.	13:39
Heather Hopper: confirm medication, give you a plan and you knew at that point th could contact her because the the being able to contact the secretary, obviously, is key	
key.	13:41

W4: yeah so they basically just did a summary letter of all my history, and what that m the kind of implications for pregnancy, so they outlined all the risks and things like the with all my different conditions in different antibodies that I had.	
W4: This meant I had an increased.	
W4: risk of stillbirth and miscarriage but also like low birth weight premature, the kidn flare up, with potential pre-eclampsia or eclampsia	
W4: but also the lupus, the kidneys flaring up because of the lupus basically.	14:10
W4: And then also these anti bodies that I had can cause congenital heart defects like block and things like that.	14:20 heart
W4: so basically that i'd be very closely monitored and and yeah we'd recommend that	14:24 at you
start this medication and then start trying	-
W4: When you're ready, in agreement with your rheumatologist, as soon as you get pregnant contact us, and that was that.	14:33
	14:41
W4: for kind of six months, or something so that went to the rheumatologist, I continu with him, when things were settled, we started trying, got pregnant straight away, the cycle contacted her, and that was it so.	
	14:47
W4: for all the awful kind of forecasting it worked out really well.	15:00
Heather Hopper: yeah okay so i'm picking out.	
Heather Hopper: The some of the things that you gained and from the preconception was about information because you had quite a lot of information, some of it was about the.	
	15:09
Heather Hopper: medication getting on the right medication, but underlying that you got.	
Heather Hopper: I don't know, did you find all that information scary or you know what your response to that was it that was scary was it was it was reassuring or you know h did you feel about because you just told me that you were told you could have had stillbirth or.	OW
Heather Hopper: You know how did that come.	15:31
	15:45
Heather Hopper: How did you find that are just kind of react to that, as it were.	15:47
W4: it was tough, it was upsetting.	
W4: I kind of seek a lot of information, I mean the amount of journals and things that read on all my various kinds of.	15:51 i've
	15:54

W4: conditions and kind of the nuances of my condition and things like that, and the risks like i've read and read and read so to be able to kind of meet with the people in the know who've done it and kind of you've.

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W4: worked with hundreds of women who've been on certain medications and have got through things fine and been okay was really reassuring at the same time.

W4: and I think my rheumatologist was obviously by no means an expert in pregnancy and things like that he's focused on the lupus and me basically.

W4: So it was it was much, much better and I felt much more confident being under the care of those guys as well and hear directly from them about what my personal risks were as well because the information on the Internet isn't tailored to your own circumstances is it so....

16:33 W4: overall, it was definitely a really good thing to help me.

W4: kind of make the

W4: decision about definitely wanted to try for a baby really and the right way to do it kind of what to do and what not to do.

Heather Hopper: So did you do obviously you did a lot of your background reading before the appointment, so at the appointment.

Heather Hopper: You kind of you had stuff to bring but obviously they have their expert knowledge and experience so did you feel it was very much a sort of equal kind of maybe equal's, not the right word but.

Heather Hopper: Like a two way conversation, they were respecting you and you know.

Heather Hopper: what you bought.

W4: yeah I think so, but I guess they had all the information they had like lots of my test results and things like that and I certainly was able to ask questions and things but they kind of just outlined a lot of it anyway, so it was....

W4: predominately they gave me a lot of information, and then I could ask questions if anything I wasn't sure about or what that meant, for me kind of thing.

Heather Hopper: so they had information about you and your tests and your specific condition before you turned up they had done their homework, as it were.

W4: yeah yeah when I was with referred, yeah.

W4: yeah they.

18:04

W4: kind of knew everything that was going on.

Heather Hopper: It sounds like you were really able to trust that team would you, would you agree.

W4: yeah definitely i'd say I trust all my kind of all the consultants that were involved f	18:08
the kidneys rheumatology hematology they've all been brilliant yeah really good.	
Heather Hopper: yeah no, it does sound like you've had a really good experience.	18:18
W/4: It halps that I'm from a scientific background and I trust the modical research and	18:28
W4: It helps that I'm from a scientific background and I trust the medical research and things and I can do my own research, I guess, to kind of backup what they're saying a	
W4: I guess that means I'll present the information in a certain way as well, rather than getting fixated on other things that because you do have short appointments, kind of need to focus the information on what's important and what you want to get out of the guess.	,you hem l
Heather Hopper: yeah yeah So do you think that might not be quite as good for.	18:44
	18:57
Heather Hopper: You know other women in in different situations.	19:02
W4: yeah possibly not, I guess it's hard to say, but I think.	
W4: Because part of the forums and things about lupus and things like that, and there there is kind of themes around not being listened to, maybe not being believed about certain symptoms and things like that, and I think for me it's important for me to.	t
W4: I don't know use the appointments to the best of their ability and what I know i'm going to get out of them so I know from my rheumatologist personality and the way delivers news and things like that.	
W4: That i'm not going to get kind of a sympathetic ear from him, so I don't go lookir that, kind of talking about my symptoms, in a certain way, does that make sense.	
	19:39
Heather Hopper: yeah okay so so one of the things that has come out in sort of doing interviews and reading up some background on this is about how.	
Heather Hopper: Having continuity of care really helps and actually what's interesting	19:48 that a
lot of it is about because the.	19:58
Heather Hopper: Healthcare professional then knows you and you don't have to repeat stuff but what you're saying is actually it's because you know them as well, so tell me bit about that, because you said that you know.	at a little
Heather Hopper: I don't know I don't put words into your mouth, what is it that helps fact that you're used to him, and you know his way of doing things do you think?	20:07 in the
	20:22
W4: I think, maybe just the way the way he delivers news and the way he talks to me things is really factual and it's kind of.	
W4: Efficient because he's he's really busy his clinics are always crazy over-subscribed,	20:34 , the
fact that we had to pay private to kind of get in.	20:43

W4: like three or four months earlier and some people whose conditions are under contended know kind of wait one to two years for a follow up, so it's absolutely crazy.	ontrol I
W4: so I know that kind of.	20:52
W4: He knows what he's doing he comes across as kind of an expert in things, what h doing, but also he's like efficient, so he doesn't kind of.	21:01 ne's
W4: Take extra time he's not.	21:05
W4: kind of I don't know how to explain it but.	21:14
W4: he doesn't kind of take into account the emotional aspect of kind of making diag or things like that, not saying that that he's cruel or anything but he's just straight to point kind of matter of fact, really.	-
W4: But i'm confident that he knows what he's doing and he takes into account what saying I feel kind of even in that way that I feel able to say look, this is really what I w terms of.	
W4: moving towards having a baby, so we need to tailor the medication in that way, things like that, and he always listens to me and that, he's not kind of saying we can't this, it's like a choice.	
Heather Hopper: yeah	21:46
W4: So guess, I feel like I make the most out of the appointments, because I know kir his way of working and I don't have other expectations and i'm not let down so I get the emotional support and things elsewhere if that makes sense.	kind of
Heather Hopper: Yes, it does make sense and so Where would you go for the emotio support, do you think.	21:59 onal
W4: family and friends, mostly.	22:12
yeah.	22:20
W4: So before COVID I was able to take.	22:22 22:23
W4: kinda family members along which has been nice so occasionally mom or dad w come, my sister would come.	ould
W4: Because it's a lot of information to take in and kind of they would sometimes as questions that I maybe wouldn't be thinking of when he's just said, oh this the antiphospholipid, for example, I was really upset and I cried in that appointment.	
W4: And then they were able to kind of maybe take in a bit more maybe ask a couple questions of what that meant, and what we could do.	22:30 e of
W4: Just reflecting on it afterwards, with them.	22:43
	22:50

Heather Hopper: yeah.	
Heather Hopper: And I say.	22:53
W4: I think getting a lot of information and weighing up things, kind of afterwards.	22:54
W4: with someone is helpful, and talking to my husband he hasn't been able to co any of the appointments because he was working up in Edinburgh at the time.	22:55 me to
W4: And then since COVID he hasn't been able to come to that many with.	23:01 23:09
With the baby and things.	23:12
W4: Just afterwards talking through with him about it, a lot has been helpful and o friends has actually got lupus and so sharing experience with her has been good as	ne of my
Heather Hopper: And she had children or trying for them or.	23:26
W4: she's got two, yeah she had one before she was diagnosed and I think that po triggered it, so she had her second one whilst hers was under remission as well, so of made me feel better, although we didn't have.	tentially
The same issues,	23:30
W4: it did give me kind of hope that she was able to go through it and everything and her little boy wasn't kind of harmed by the lupus or any medication.	23:42 was fine
W4: and I actually went to like em.	23:44
W4: kind of like a forum like support group of people with lupus and I met a nice la and she's she was pregnant, at the same time as me, she got pregnant before me a little girl just before me as well, so that's been nice to kind of go.	
W4: Through that together.	23:59
Heather Hopper: Okay well that's really interesting because, so you talked about d things you talked about support from family and friends, and you've talked about what I would call peer support so someone who's got the same condition, other pe	more
Heather Hopper: That i've interviewed have said they haven't found well, I suppose lupus isn't that common they've been looking on the Internet at kind of Internet fo and they found that probably not terribly helpful because it's been quite negative.	e, because prums
Heather Hopper: So talk me through the peer support; what is it about that that's l and would you say you found the same with online stuff compared with maybe mo to face.	ore face
W4: yeah, I think, so I guess it's two different things, so one of them, because my fi from school had lupus it's it's much more personal and I know her and things.	
Okay.	24:57

	25:07
W4: So that's different from just kind of finding it on a forum I guess.	25:08
W4: although she had a really, really difficult time and in terms of diagnosis, it took her long time, and she was really poorly and she was a teacher and she had to quit her job which was horrendous.	
W4: And she was in in bed basically for like days at a time with with the fatigue and thir	25:13 ngs. 25:25
W4: And rashes and she was always kind of going up to Newcastle A&E when different things were flaring up and it gave her like meningitis, and like affected her eyes and thi like that.	
W4: but she's got a couple of other autoimmune kind of really rare ones, something cal "behcet's", I think.	25:31 lled
W4: So hers was potentially more complicated because she didn't get kind of the antibe that say it's definitely lupus whereas, for me it was.	25:42 odies
W4: Kind of full blown quite classical Lupus with all the antibodies and stuff.	25:49 25:57
Heather Hopper: yeah yeah.	26:01
Heather Hopper: So she was it was she what they call seronegative.	
W4: Yes, I think so, for like the dsDNA one that's the one that they all talk ahout about, guess, so obviously I didn't know that that was like a thing that meant you've definitely lupus because, it was the hematologist, the blood doctor who I saw first, because I had platelets.	got
W4: My platelets were.	26:07
	26:25
	26:25
	26:29
	26:32
W4: Well, I mean I didn't know anything about that, my best friend's actually a GP and I texted her being like what does this mean, and she was like what the hell are you sure t not wrong	
W4: He's just sent you home	26:37
W4: So they repeated them and they dropped to 21 I was like oh God	26:49
W4: But anyway	26:50
	26:59
	27:02

	27:07
Heather Hopper: yeah.	27:11
W4: got me thinking oh God, I could have this, what my friend's got, what the hell doe mean for like my career for like.	
W4: My future like.	27:12
W4: relationship with T like because her husband was, or her partner, he's great, and has lot of stuff looking after the babies and things like that, and her mom.	
W4: really helped her get through it so I was like it's going to be a huge role change of because I guess i'm kind of the person who does lots of the caring and lots of things.	
W4: T's like focused on work and stuff like that, so that was a potential big change in relationship, so that was scary in a lot of ways, but equally knowing her, I could be tot honest about like my fears and worries and what that meant, and you can just ask any questions, can't you.	tally
W4: face to face with a friend.	27:38
	27:55
W4: like informally, so it had positive and negative I guess.	27:57
Heather Hopper: yeah.	28:02
W4: And my other friend was actually through a forum so.	28:03
W4: it was the Facebook group, Lupus UK I think , they do locality meetings.	28:07
W4: I went to one, I was quite nervous but T came with me and I went to one which w in the May I think.	vas like
W4: Like before COVID really took hold over here.	28:16
W4: Or it might have been earlier than May because it was face to face anyway and I r this woman.	28:23 met
W4: she was lovely and.	28:27
	28:31
W4: She wasn't negative she was really positive about.	28:35
W4: she'd been diagnosed a long time, and she really struggled at the beginning and thought she couldn't have children and things like that, because some of the treatment she was on and but actually she's kind of.	
W4: I Think for about seven years it was really bad she said, but then she she got into remission came off all medication things like that, and she was able to be kind of a low risk pregnancy didn't need consultant led or anyting.	
	28:50
W4: So she was like a really nice. Example even though	29:04

W4: we did meet through the Internet we met face to face and then we've spoke on Facebook and things.	
Heather Hopper: yeah.	29:07
W4: arranged to meet up with our babies as well, which will be really nice	29:13
Heather Hopper: So, you met her before you got pregnant.	29:13
W4: Yes, a	29:16
HH: and you talked to your other friend with lupus before you got pregnant.	29:21
Heather Hopper: and so.	29:25
Heather Hopper: What did that, what did those conversations and what did that supp kind of give you.	
W4: hope that it could be okay really.	29:28
W4: I mean, you can read all the statistics online and kind of it could be quite doom a gloom, or you can think the risks are relatively low either though.	29:35 and
W4: it's a risk, it's still like 25% or something so you like well well, then you can hit the jackpot with lupus because it's so so rare, especially in Caucasians it's like well if you all those things, then potentially it's going to go wrong , you kind of think that minds don't you.	can get
W4: So you've got people that you know he's been through it with with relatively few complications then it gives you hope that that you can do the same, I guess.	,
W4: yeah yeah.	30:03
Heather Hopper: But that's partly because they have been positive, so if you had a pe support group that was very negative.	30:12 er
Heather Hopper: That might not have the same impact really.	30:16
W4: no, and I think so, I'm on the is it health unlocked, the online forum.	30:29
W4: And you can.	30:32
	30:38
W4: Get daily emails and people post questions and things like that. W4: So I don't engage with it a lot but I have sought information from there, in terms	30:38 of
medication, people's experiences, side effects and things like that. W4: and slightly about pregnancy, but not so much about pregnancy and I think if the was negative information about that I would quite quickly turn that off, to be honest, because.	
	30:50

30:50

W4: i'd find that really unhelpful and I wouldn't kind of seek out negative stories and because.	things
W4: That will just terrify me even more I guess and because I knew that I wanted to hab baby, it wasn't ever	31:00 ave a
buby, it wasn't even	31:06
W4: It was slightly should I shouldn't I, but it was much more we've we've got to try a what happens basically and try everything we can to do that.	
W4: So I would have turned away from that negative information, but the negative sto otherwise about like the doctors, or how long it takes or the complications and things able to kind of filter through that quite well, I think, with my psychology background, have.	s i'm
W4: More of like a positive mindset, because I know.	31:21
W4: The power of the mind and kind of being optimistic and kind of glass half full and	31:38 d
thinking.	24.44
W4: You are still in control of a lot of the things you can control kind of things that you enter in terms of like.	
W4: exercise and controlling your stress and listening to the doctors and taking all the medication, doing everything possible.	31:47 e
	31:53
W4: To kind of give yourself more of a chance of a positive outcome, I guess.	32:01
Heather Hopper: So, do you post stuff on the forum, so you know if there was some s negative stuff would you sort of, say, well, actually, this is my experience and it's not a negative.	
	32:06
W4: yeah so I have only when it's kind of really within my experiences my specific.	32:15
W4: meds that i've used my journey of like pregnancy or something like that I don't p lot but occasionally i've replied to some people, who've asked and have maybe been struggling, so I can give like a positive light on it.	
	32:22
Heather Hopper: yeah.	32:33
W4: I definitely do, I think that's important.	32:34
Heather Hopper: yeah that's good yeah.	
Heather Hopper: Okay, so thinking about your the support you get from family and fr	
Heather Hopper: what's that compared with like the peer support and again try to thi about the pre pregnancy stuff what you talked about the fact that you got more emo support from family and friends, and it was really helpful them coming to appointmen	tional
yeah.	JC.41
	33.01

Heather Hopper: Why, why was that what what does that help with how does it help?	33:03
W4: I guess them knowing me.	33:09
W4: They kind of know how much I want a baby and things like that, and them knowi personality and knowing that I want to follow medical advice to a TEE and things like and kind of besides the lupus being healthy before that and not really.	ng my that
W4: abusing my body with kind of substances and things.	33:12
They could kind of.	33:27
	33:30
W4: know me and know that I would have a really good chance, even though the doc are saying potentially these risks and i'm thinking about those risks, but they're giving much more of the.	
	33:31
W4: The positives balanced view that maybe I wouldn't see myself if i'm just feeling re upset about the potential risks, does that make sense.	ally
Heather Hopper: yeah yeah so having them at the appointment	33:40
heather hopper, year year year so having them at the appointment	33:48
Heather Hopper: Are you saying it's because they because you've given so much information so partly they can sort of, say, well, this is what I heard you know you mig have heard something quite negative, but they might have heard a slightly different a or something.	
W4: yeah that's true actually yeah.	33:55
v. year that's true actually year.	34:06
W4: yeah the times when i've come out and i've said oh they've said this and this and	
W4: And they would find out, like the other side, they said well, this is possible and it's quite funny.	34:09 yeah
it's quite fullity.	34:13
Heather Hopper: Well, you know, especially if you say yes, there are risks, you know th a 25% risk of this so you might be hanging on to the risk of this, but actually they said yeah but so that means there's a there's a 75% risk that you won't have it.	
	34:22
W4: yeah yeah.	34:35
Heather Hopper: yeah.	34:37
W4: I think i've missed that during COVID actually, having someone with me in the appointments	54.57
WA: I've been kind of maybe focusing on more of the negative	34:38
W4: I've been kind of maybe focusing on more of the negative.	34:42
W4: side of things really.	34:45
W4: And I think my consultant obstetrician.	34:47
	JH.47

W4: Was was brilliant but also maybe slightly kind of I do this all day, every day, so it's really she's not thinking about house the certain things, maybe impact on me and my worries about it, if that makes sense.	
W4: yeah that would have been good to have someone there.	34:49
	35:03
Heather Hopper: But that sounds a bit like the way you were talking about the the rheumatologist as well you know it's quite factual they know their job they just	35:07
W4: yeah expert and confident that they can get you through it and they know how to you, but not totally thinking about kind of the emotional side of things really.	o help
yeah.	35:15
W4: Thinking about when I did get pregnant, so the day after hours booked in and sa and she outlined kind of all these risk and things so it's one thing having it written do	
W4: Potential complications in a letter, for future thinking, but then another thing who you're actually like two weeks pregnant and then all these different things, because I the obese category as well.	en
W4: So that added extra complications, and.	35:35
	35:46
W4: I needed.	35:49
W4: kind of blood thinners and things, so I had to have an injection every day.	35:50
W4: yeah.	35:54
W4: And then there was.	
W4: Risks personally for me kind of coming towards the third trimester extra things and I ended up with loads of different complications.	35:55 and
: I ended up with.	35:56
W4: gestational diabetes as well.	36:05
	36:06
W4: which meant more injecting every day	36:08
Heather Hopper: did you need insulin.	36:11
W4: Not insulin just the blood sugar injections, I was at diet controlled and then.	36:13
Metformin as well	36:18
	36:18
W4: yeah and then I ended up with obstetric cholestasis	36:20
W4: My liver was inflamed and I was crazy itching just in the last couple of weeks, thankfully.	

	36:24
W4: And then I also ended up with severe pre-eclampsia in the end, and the swelling v just crazy honestly, they ended up getting her out by an emergency section at 37 wee	vas
Heather Hopper: Okay yeah.	
W4: She was measuring big all the way along.	36:44
Heather Hopper: yeah so they didn't introduce you or anything you just went straight	36:45 for
section.	36:47
W4: Yes, yeah and that was more me than the consultants, they thought induction wor okay, but I guess we had that conversation before the cholestasis or the preeclampsia	uld be
Heather Hopper: Yes, yeah.	37:04
Heather Hopper: yeah okay yeah oh i'm so pleased i'm so pleased you've got her after incredible journey.	
W4: Absolutely the relief was just crazy overwhelming.	37:07
	37:15
Heather Hopper: yeah yeah sounds it so it sounds like you need both the facts and the of.	e kind 37:19
Heather Hopper: You know the sort of hard line, maybe that's a bit harsh but actually also need the other support.	
	37:30
Heather Hopper: that emotional support.	37:35
yeah.	37:38
Heather Hopper: Because these things are quite difficult to take.	
Heather Hopper: So you, you would you say that you didn't get any emotional suppor the NHS you've got that more from friends family and maybe other peers with lupus o I, making an assumption there.	
M4. I think it would depend on the destars kind of personalities and things the kide	37:45
W4: I think it really depends on the doctors kind of personalities and things, the kidner specialist who are saw was was brilliant in terms of the emotional support thing.	У
W4: He came at it from kind of a holistic point of view of him, being a father and thing	38:00 JS
which was really nice.	38:11
W4: So he kind of explained all about like the biopsy and then nephritis and what that meant for babies and how he'd work with moms with kidney transplants and been abl have babies, so he.	
	38:19
W4: he supported me for the preconception planning, because he knew how importar was to me, and he was more like we don't need to totally listen to the Rheumatologist hold off for however long it's about you and your decision, and things and he was	
	38:29

W4: Emotionally quite warm, I guess, which was nice.	
yeah.	38:43
W4: I have had some emotional support from the NHS.	38:46
Heather Hopper: Oh yeah.	38:49
W4: But I think it should be more readily available in terms of counselling and th that, because there was never anything offered to me, I didn't ask for it, but I thi have been offered really.	nk it should
W4: I mean that first appointment was awful and I felt awful after that that first of was pregnant. Umm you weren't really asked like how you felt about that, and because it was a lot to take in, and I was on my own really.	like
W4: So obviously I processed it with T afterwards, like on the journey home and got home and things like that, but it's a huge amount of information to take in w kind of in your emotional brain aren't you	vhen you're
W4: especially just found out you're pregnant then you've got all these things be you like I probably wasn't taking in everything that she was saying, if that makes	-
W4: it's some kind of counseling reflection on that in the process to help me thre pregnancy might have been good, even though myself, I could I could get those elsewhere.	ough
W4: But other people potentially couldn't, and may have struggled with that mo know.	
Heather Hopper: So do you think he do you think that would help in terms of preconception as well, the more an offer	39:53
Heather Hopper: At least have some psychological counselling.	40:01
W4: yeah.	40:09
Heather Hopper: Someone to talk to you about how you're feeling and work it t	-
W4: Yeah definitely ,even just a one off session, kind of weighing up the risks an	40:14 d benefits
really of trying and kind of the emotional impact of what that might be, I guess, going through such a journey.	kind of
really of trying and kind of the emotional impact of what that might be, I guess,	kind of 40:17
really of trying and kind of the emotional impact of what that might be, I guess, going through such a journey.	40:17 40:29 ds and

40:43 Heather Hopper: No... that sounds yeah it's definitely something that i've picked up from you know from the literature, is actually ... and also to be fair, from a friend of mine who set up a preconception clinic. 40:55 Heather Hopper: locally. 41:09 Heather Hopper: She she basically said, people need that level of emotional support. 41:10 Heather Hopper: As well as the factual stuff that was her opinion i'd say. 41:17 Heather Hopper: Okay, so is there anything else that you think could have made it better. 41:22 Heather Hopper: In terms of preconception, we're thinking preconception here. 41:31 W4: It was it was enough for me, I think. 41:37 W4: kind of them having all the information meeting with me discussing it individually, giving me the chance to ask questions my Mum came along to that one which was good and. 41:40 W4: And I felt like I could have contacted them for more information if I'd needed it, if something had come up afterwards and they helped me kind of. 41:52 W4: With with the medication treatment as well, so I don't think anything else other than potentially an offer of like a counselling session to reflect on kind of things like that. 42:00 Heather Hopper: So just coming back to the thing about having the contact and being able to ... did you say you could email them or or phone up the secretary or something what what, why is that important. 42:11 Heather Hopper: What does that give you. 42.23 W4: I think like it gives you maybe some autonomy that you can kind of contact them yourselves, rather than kind of having to go around the houses, I don't know, like a general number and it taking a while to get back, like a direct contact is it feels more personal and supportive really. 42:27 Heather Hopper: yeah 43.17 Heather Hopper: My husband got quite dark hair, so I guess, they were bound to be dark but yeah. 43:23 Heather Hopper: So are you thinking of having another one. 43:36 W4: i'm not sure ... 43:38 W4: My Mum has literally forbidden it because she's been a nervous wreck the whole time. 43:42 Really. 43:45

W4: Especially the end she had a tough year,	44:25
Heather Hopper: And I guess the thing the difference is with you because of the lupu can't just make a rash "oh go on let's do it again" decision.	-
Heather Hopper: you do have to plan.	44:33
W4: yeah.	44:43
	44:45
W4: that's it the consultant I just had to follow up with the six week follow up and she when you're thinking of trying for the next one will have another preconception plan and get the medication sorted and things like that, and she was like basically when ra than if	ning
W4: I was like I'm not sure if I wanted a second one, but she just kind of assumes tha	44:46 +
everyone does I guess, and so she was like so i'll see you again in the future, but.	L
W4: Wait a year, for my uterus to heal from the caesarean.	45:03
	45:13
Heather Hopper: you absolutely need time you know to.	45:17
Heather Hopper: you know you forget you forget how how horrible it was.	45.22
Heather Hopper: you honestly do and I wouldn't have believed that.	45:23
Heather Hopper: but you do.	45:28
neather hopper. but you do.	45:31
W4: It's faded a lot already, like I said like a couple of days after to one of the nurses.	45:33
W4: This is like this is horrendous Why do people will ever do this?	
W4: Like even like a week or two later I was oh, it so lovely and, like all the oxytocin is flowing.	45:37 5
Heather Hopper: yeah yeah and I think it's that.	45:48
neather hoppen, year year and r think it's that.	45:55
Heather Hopper: I suppose it's nature's way of making sure you do have another one you do.	, and
	45:58
Heather Hopper: reproduce so like you say the oxytocin and the endorphins, though like make you feel great.	just
	46:03
W4: yeah.	46:10
Heather Hopper: And then, like I say they're so cute.	46.10
Heather Hopper: yeah even, even though they keep you up at night and the you kno	
yeah.	46:14
	46:18
Heather Hopper: I do think.	

46:20

Heather Hopper: I do think the other thing I mean after having children you have that you have real extremes of emotion don't you, you know I don't know whether you found that.

46:21 W4: yeah definitely someone said it to me before I had her, It's not the normal kind of highs and lows of everyday life it's.

46:29 W4: like you're really happy or really sad.

46:38

Heather Hopper: yeah yeah the really happy is great, but the really sad is just like dreadful. 46:43

W4: yeah. 46:51 W4: It's true. 46:56 Heather Hopper: well. 47:10 Heather Hopper: Did you say it was your mom who kind of accompanied you to . 47:12 Heather Hopper: To the preconception stuff. 47:16 W4: That was just the one off appointment with the Kidney consultant and the obstetrician, my mom came to that one yeah. 47:19

Heather Hopper: yeah yeah yeah okay.

W4: My Mum came to The one where I was diagnosed with lupus as well, she got all the difficult ones

47:26

47:25

Heather Hopper: i'm wondering whether she would be willing to have a chat with me about that experience as well because i'm wanting to interview, I wanted to interview some healthcare professionals and but also.

47:32 Heather Hopper: i've put partners or supporting family members and i'm just wondering in your case rather than it being your husband it being actually your mom because she seems to have come along to appointments. 47:44

Heather Hopper: And I don't know I mean I could email you the link again.

Heather Hopper: yeah. 47:59

Heather Hopper: And if you think.

Heather Hopper: She would be willing, it will be really interesting to talk to her, because she.

Heather Hopper: You know, it sounds like she has supported you and she's had a rough time as well, and actually she might have found it really hard so.

48:06

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Heather Hopper: You know to be able to ask her as someone who's supporting you, well what would help you.

	48:15
You know.	48:21
Heather Hopper: could be guite interesting.	40.21
	48:23
W4: yeah yeah I'll certainly ask her, she just might not be a fan of the zoom but she mi	ight
kind of speak to on the phone.	



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Screenshot of memos in NVivo

Appendix 12

Example memo from NVivo showing process of theory refinement based on evidence from interviews

Peer support 1.3.6

Initial Programme Theory:

IF peer support networks are available THEN people are more likely to feel emotionally and socially supported and will be more inclined to engage with the medical advice and support they are offered.

Source: W11 C: Woman with epilepsy M: shared experience - promotes sense of normality M2: able to laugh about it O: emotional support - "makes me feel better" CMOC, (what does this CMOC do in relation to the IPT?):

Support/refute/refine, (narrative about how you got there):Refines How/Decision-making / evidence:

Heather Hopper: And again about the kind of support you know what is it about that well actually you know we all need that kind of emotional support and we all need to feel well I think there's some almost like a feeling of normality isn't there so if you know someone else with epilepsy, you're not the only one.

W11: yeah absolutely you're not the only one and I think it also I mean it definitely helps me to sort of like joke about things. It's just a better way of dealing with things and she's also like a quite a similar sort of person so it's quite Nice that and we can sort of yeah it's like nice to have the support, but also that you can laugh at this like not nice thing that's happened to both of you.

W11: And it makes it makes you feel more normal, I think that you're not the only one that's having these weird things that are happening, and you know she's a normal functioning human so it makes me feel better that I can be a normal function human as well. This weird condition, because it really is a strange condition.

Result/refined: IF people experience positive peer support THEN they are able to identify with each other through shared experiences, promoting a sense of normality, emotional and social support.

Links/ripple effects: links with sense of normality Notes: Unclear from data if this increases access to PCC or behaviour change - more about emotional support.

Other codes: PCC perceived as normal (2.2.4)	
Source: W15 C: Woman with epilepsy M: shared experience (taking medication) - promotes sense of normality M2: mutual support O: adherence to treatment (medication) and emotional support CMOC, (what does this CMOC do in relation to the IPT?):	
Supports:	
Heather Hopper: you know, friends, and even others around who are taking medicatio you know. Does that? Does that help in any way to make? I don't know. Is it help you take your medication, or is it more help to go?	
	32:02
W15: I feel quite normal in this household, you know, It's not. I'm not unusual to take medication. It's just what we do.	
	32:17
W15: It does. It does feel like that here. It is very much this is normal. I was in like my in student houses. It was always take my medication before I go downstairs because everybody was always like	n the
	32:23
W15: a comment would always be made about my medication, or, like i'm a drug addi	ct.
	32:38
W15: No, not very helpful at all because then you're like, well, do I really need them?	
	32:46
W15: It's like, Yeah, you do. Because if I stop taking the klobazan, I my anxiety medicat I'll go into withdrawal.	tion.
5	32:51
W15: So it's	
	33:01
Heather Hopper: Yeah, yeah.	
	33:03
W15: But here	
	33:05
W15: I do feel normal.	

Links with - support from family and friends (1.3.5) 449

450

Source: W18

- C: woman with high BMI attending weight management programme
- M: seeing other people's success
- M2: sense of hope
- O: sustained behaviour change to improve preconception health

Supports:

HH: I'm just sort of thinking about the, you know again, the sort of why does it work? How does it work? What's the kind of mechanism for that weight management program? Is it information? Is it almost competition with other people? Is it an emotional support with other people? What do you think it is about it that helps you?

W18: I think it's having other people there as well. So I think it's like being in a group, because everybody, you know puts in how they're feeling and how they've done. um have you tried this? But for my nutrition sessions there's people in there who have been in the service for over a year,

W18: you know, a year and a half, and they can say, Well, I lost like five stone, say,

W18: which is amazing, but they can tell you, you know, tips and tricks on how they did it. There's an informal Facebook group for the service, which the people who run the service aren't in it. But obviously the members are. If you want to be,

HH: does that help?

W18: Yeah, It does help, but for me, because I don't want, you know, like the gastric band or the gastric surgery,

W18: it sometimes I've found it to be a bit unrealistic in terms of how quick. They've dropped the weight, because i'll say I won't be

W18: having. You know what I don't want to have the surgery, so it's going to be more of a longer thing for me, but it's amazing to see the results that people have, and they've had You know a couple of babies through the service as well. They've said, from people who have lost weight, where it has helped them.

34:41

34:52

35:11

35:16

35:34

35:48

Links with treating Obesity as a health condition (2.3.7)	
Source: W4	
C: woman with lupus	
M: seeing other people who have gone / are going through similar experiences	
M2: sense of hope	
O: emotional support - sense of hope	
Refines:	
W4: she's got two, yeah she had one before she was diagnosed and I think that potentially triggered it, so she had her second one whilst hers was under remission as well, so that kind of made me feel better, although we didn't have.	k
23:30	С
The same issues,	
23:4	2
W4: it did give me kind of hope that she was able to go through it and everything was fine and her little boy wasn't kind of harmed by the lupus or any medication.	
23:4-	4
W4: and I actually went to like em.	
23:54	4
W4: kind of like a forum like support group of people with lupus and I met a nice lady there and she's she was pregnant, at the same time as me, she got pregnant before me and had a little girl just before me as well, so that's been nice to kind of go.	
23:5	9
W4: Through that together.	
Heather Hopper: What did that, what did those conversations and what did that support kind of give you.	
29:20	8
W4: hope that it could be okay really.	
29:3	5
W4: I mean, you can read all the statistics online and kind of it could be quite doom and gloom, or you can think the risks are relatively low either though.	

W4: it's a risk, it's still like 25% or something so you like well well, then you can hit the jackpot with lupus because it's so so rare, especially in Caucasians it's like well if you can get all those things, then potentially it's going to go wrong, you kind of think that mindset don't vou.

29:46

29:37

W4: So you've got people that you know he's been through it with with relatively few complications then it gives you hope that that you can do the same, I guess.

Result/refined: IF people experience positive peer support (more usually face to face -NB exception of CF) THEN they are able to identify with each other through shared experiences, promoting a sense of normality, hope, emotional and social support. This can help sustain behaviour change to improve preconception health.

Links/ripple effects: links with sense of normality Notes: Unclear from data if this increases access to PCC or behaviour change - more about emotional support.(added hope)

Other codes: PCC perceived as normal (2.2.4)

Source: W5

C: woman with lupus

M: seeing other people who have gone / are going through similar experiences

M2: sense of hope/reassurance

O: emotional support - sense of hope / reassurance

Supports

Heather Hopper: yeah Okay, and what about, do you know any other people with lupus or have you kind of got any networks of peer support I just wonder whether that helps at all.

	23:55
W5: um one woman, I work with has lupus.	
	24:07
W5:, and it affects her heart, in her case.	
	24:10
W5: it's been helpful, especially in the last year as well with.	
	24:17

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W5: COVID and.

W5: So, because of the different medications we 're on, I had to shield she didn't, and so it was it was interesting talking to each other and going oh, have you had a shielding letter, a vaccine and....

W5: yeah and yet and.

W5: And she's a bit older me older than me, but she she had a daughter I mean she must be about 20 now... so that's reassuring in a way she did have some complications but it's still been reassuring to know that she did have a daughter successfully

Heather Hopper: What does the peer support what does that give you know what's, why is that helpful.

W5: um just to have someone who kind of knows what you're going through as well and I don't I don't think she had troubles like i'm having to conceive and I don't think i've actually really asked her about what it was like.

	25:35
W5: 20 years ago.	
	25:52
W5: In terms of the preparation, she had to take.	25.52
W5: become pregnant and.	25:53
	25:57
W5: but it's still reassuring to know that there is that person there that.	
	26:00
W5: can share their experience.	26.04
Heather Hopper: yeah.	26:04
	26:06
W5: I mean there's forums and other things that i've looked on as well, but I think h real person.	aving a
	26:07
That you know.	

24:35

24:24

25:27

25.25

	26:12
W5: is a bit easier sometimes	
	26:14
Heather Hopper: yeah, how do you find the forums, is that helpful at all or.	
	26:15
W5: It's the same as anything online sometimes I'll read it and it's fine I'll take it in an then other times it's just it hits home a bit too close if that makes sense.	nd
	26:24
W5: I think I've had enough of that todayI'll come back to that another time.	
	26:33
Heather Hopper: yeah.	
	26:37
W5: yeah it's it's not nice for anyone to go through it, but to know there are people of there as well who have been through it or are going through it	ut
	26:39
W5: just lets you know that you're not alone	
	26:47
Heather Hopper: yeah yeah absolutely not being alone,	

Linked Item

Nodes\\1.3.6 Peer support (RR)

Example of table of collated evidence for one programme theory (peer support)

1.3.6 Peer support			
Contexts	Mechanisms	Outcome	Resulting CMOC:
C1: Person with	M1: Shared	01: emotional	People with health
epilepsy	experience	support	conditions often have
C2: Person with	M2: Sense of	O2: sustained	greater anxiety regarding
high BMI	normality	behaviour change	the challenges associated
C3: Person with	M3: ability to	to improve	with conception /
lupus	laugh about it	preconception	pregnancy. Face to face
C4: desire for	M4: mutual	health	peer support provides the
children	support		opportunity to share
C5: anxiety	M5: seeing		experiences and even laugh
regarding the	other people's		about them, which provides
challenges	success		a sense of normality and
associated with			mutual support. Seeing
conception /			other people's success also
pregnancy			adds to this and the overall
	M6: sense of		effect is emotional support,
	hope /		which can encourage
	reassurance		sustained behaviour change
			to improve preconception
			health.
Thought process:	. /		Evidence:
Relates to face to f		•	W11, W15, W18, W4, W5,
unable to meet wit			HCP7 (CF exception)
has a strong online	•		
be because time is			
share experiences	• •		
vulnerable). Suppo	-		
•	nai / psychological	element important	
(also social).			
Supporting Quotes		also that you are low	ah at this like not nice thing

"It's like nice to have the support, but also that you can laugh at this like not nice thing that's happened to both of you. And it makes it makes you feel more normal, I think that you're not the only one that's having these weird things that are happening, and you know she's a normal functioning human so it makes me feel better that I can be a normal function human as well." (W11)

"I feel quite normal in this household, you know, It's not. I'm not unusual to take medication. It's just what we do. It does feel like that here. It is very much this is normal. I was in like, in the student houses. I would always take my medication before I go

downstairs because everybody was always like, a comment would always be made about my medication, or, like I'm a drug addict." (W15)

"I think it's having other people there as well. So, I think it's like being in a group, because everybody, you know puts in how they're feeling and how they've done. um have you tried this? But for my nutrition sessions there's people in there who have been in the service for over a year, you know, a year and a half, and they can say, well, I lost like five stone, say, which is amazing, but they can tell you, you know, tips and tricks on how they did it. it's amazing to see the results that people have, and they've had You know a couple of babies through the service as well. They've said, from people who have lost weight, where it has helped them." (W18)

"It did give me kind of hope that she was able to go through it and everything was fine, and her little boy wasn't kind of harmed by the lupus or any medication. So, you've got people that you know he's been through it with relatively few complications then it gives you hope that that you can do the same, I guess." (W4)

"It's not nice for anyone to go through it, but to know there are people out there as well who have been through it or are going through it, just lets you know that you're not alone..." (W5)

"There's no, um, mixing of [CF] patients face to face from an infection control perspective; It has always been the case. But there, because of that, there is actually quite an active online community I would say, and like kind of social media before social media was even a thing. Um, so patients would be, or many patients would be, very active online with other people or their friends with CF. That they communicate with virtually." (HCP7)

Refined Programme theory 1.3.6:

IF people experience positive peer support (more usually face to face - NB exception of CF) THEN they are able to identify with each other through shared experiences, promoting a sense of normality, hope, emotional and social support. This can help sustain behaviour change to improve preconception health.

Links with:		
1.3.5.1	Family support reduces anxiety	
1.3.7	Psychological support	
2.2.4	PCC viewed as normal	

Overview of Programme Theories in Realist Evaluation

69 theories in total, from the realist review and data from interviews – indicates some theories removed, some refined (child nodes added in some cases), and some demi-regularities (commonly occurring – semi-predictable patterns) prior to final analysis and synthesis.

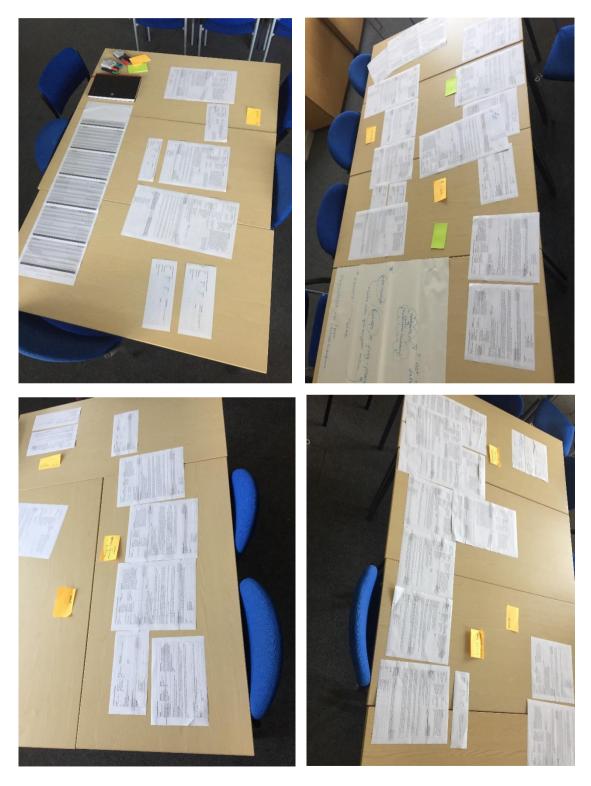
Number and Name of Programme Theories	Notes
1.1.1 HCP knowledge of SRH and PCC	
1.1.1.1 Knowledge of condition and individual	Updated 14/5/23 – this PT removed as data relates to multi-disciplinary clinic
1.1.1.2 Holistic approach to care facilitates PCC	
1.1.2 Positive approach to PCC	Removed – merged with 2.4 2 – messages re SRH from school
1.1.3 Positive and respectful attitude to women	
1.1.4 Continuity of carer positive (RR)	Updated 20/5/23 – this PT removed as expanded on in child nodes below. Sub- nodes may be re-merged with further development
1.1.4.1 CoC - trust - honesty - personalised care	
1.1.4.2 CoC facilitates difficult conversations	
1.1.4.3 CoC resulting in tailored approach by HCP	
1.1.4.4 CoC resulting in person understanding approach taken by HCP	
1.1.4.5 CoC Woman wanting to please the HCP	
1.1.5 Continuity of carer negative	
1.2.1 Alternatives to face to face (RR)	
1.2.2 App for ongoing monitoring	
1.3.1 Accurate information	
1.3.1.1 Accurate information - feeling in control - less anxious	

Number and Name of Programme Theories	Notes
1.3.1.2 Inaccurate information	
1.3.2 Utilising an individualised SRH continuum approach	No data added here, but links with 1.1.1 – HCP Knowledge of SRH and PCC, and 1.1.1.2 Holistic care
1.3.3 Ask a specific question about wanting a baby	
1.3.4 Positive message	Same as 1.1.3 – positive and respectful approach
1.3.5 Support from family and friends	General (related to health condition) rather than PCC specific
1.3.5.1 Family support reduces anxiety and helps decision making	
1.3.5.2 Support from family attending appointments with lots of information	
1.3.6 Peer support (RR)	
1.3.6.1 Peer support negative as feeling judged	Removed as related to postnatal experience not PCC
1.3.6.2 Peer support negative online	New IPT emerging from interview data
1.3.7 Psychological support (RR)	? find more data to support this
1.3.8 Ongoing follow-up support in difficult circumstances	This IPT not used in analysis - ? check with 3.1.4 – role of specialist nurses, as relevant data may be there; follow up also included in 1.3.9
1.3.9 Ongoing follow-up support valuing women	
2.1.1 Perceptions of self-belief or self-efficacy	
2.1.2 Being labelled as high-risk	No data to support
2.1.3 Feelings of anxiety or fear	? collapse this as closely linked with other theories such as 1.1.4.1 and 1.1.4.2 (continuity)
2.2.1 Individualised and non-judgemental support	Data added to 1.1.3 – respect (very similar IPT), although this one includes cultural beliefs (data did not identify this specifically)
2.2.2 Feeling judged	
450	

Number and Name of Programme Theories	Notes
2.2.3 Percepions of HCPs being trustworthy	Data added to 1.1.4.1 – only from one interview, and this also fitted with theory about CoC, trust and personalised care.
2.2.3.1 Trust HPC - confidence in likely response - seek PCC	Merged with 1.1.3 – positive and respectful attitude – data already included there.
2.2.4 PCC perceived as normal (RR)	No data to support
2.2.4.1 PCC NOT normal	Reverse of 2.2.4 – shows that PCC is not normal socially / culturally in the UK – links with pregnancy panning a taboo subject (2.3.5)
2.3.1 Beliefs about fertility (RR)	
2.3.1.1 Inaccurate beliefs about contraception	
2.3.2 Beliefs about reproductive autonomy	No data to support
2.3.3 Beliefs about pregnancy planning - accurate	
2.3.3.1 Beliefs about pregnancy planning - inaccurate	
2.3.4 Cultural and religious beliefs relating to pregnancy	No data to support, although links with 2.3.5 – Taboo subject ?
2.3.5 Pregnancy planning a taboo subject	New IPT emerging from interview data (similar to PCC NOT normal?)
2.3.6 Deciding not to have children	
2.3.7 Treat obesity as a health condition	New IPT emerging from interview data
2.3.7.1 Reasons to weigh people	Linked with 2.3.7 – NOT analysed – general rather than PCC specific
2.3.8 Desire to have a baby	New IPT emerging from interview data
2.4.1 Stigma associated with a condition	New IPT emerging from interview data
2.4.2 Messages about SRH from school	New IPT emerging from interview data
3.1.1 SRH and PCC as part of routine review (RR)	
3.1.1.1 Consideration of SRH in condition usually affecting older people	New IPT emerging from interview data

Number and Name of Programme Theories	Notes
3.1.1.2 Clear guidelines regarding treatment for women and girls	
3.1.2 Integrated across primary and secondary care (RR)	
3.1.3 Multi-disciplinary PCC clinics	
3.1.4 Role of specialist nurses or midwives	
3.1.5 Clear pathways for referral	
3.1.6 IT System prompts for referral	No data to support this from interview with women
3.1.7 Incentives to provide or refer for PCC	No data to support this from interview with women
3.1.8 Transitions disrupting access to care	New IPT emerging from interview data
3.2.1 Choice of location for PCC	No data to support this
3.2.2 Socioeconomic factors	
3.2.3 Choice of appointments	No data to support this from interview with women
3.2.4 Availability of interpreters	
3.2.5 Waiting time for appointments	
3.2.5.1 Waiting increases anxiety	
3.2.6 Consideration of preconception health in primary care	Added in view of discussions with GPs
3.2.7 Same sex couples denied access to PCC	New IPT emerging from interview data

Photos of printed out programme theories used in step 4 of analysis; discussion with wider research team to tidy up and identifying new emerging groups of theories



Overview of re-grouped programme theories and refined middle range theories following final stage of synthesis

New groups:

- Information, knowledge, and beliefs (table highlighted in blue)
- Therapeutic relationships (table highlighted in orange)
- Social structures and healthcare services (table highlighted in green)
- Programme theories with limited evidence so not developed further (table highlighted in grey)
- Key: (I) initial PT from RR; (C) child node identified in analysis; (N) new node identified in analysis

Information / knowledge / beliefs	Middle-range theories
1.1.1 HCP knowledge of SRH and PCC (I)	1. Healthcare professionals' knowledge and holistic approach to people with health conditions
2.3.3 Beliefs about pregnancy planning - accurate (I)	
2.3.3.1 Beliefs about pregnancy planning - inaccurate (C)	
1.1.1.2 Holistic approach to care facilitates PCC (C)	
3.1.1 SRH and PCC as part of routine review (I)	
3.1.1.1 Consideration of SRH in condition usually affecting older people (N)	
3.2.6 Opportunistic PCC in primary care (N)	
1.3.3 Ask a specific question about wanting a baby (I)	
1.2.1 Alternatives to face to face (I)	2. Using information available online or via mobile apps to facilitate partnership working and a personalised approach
1.2.2 App for ongoing monitoring (I)	

Information / knowledge / beliefs	Middle-range theories
1.3.1 Accurate information (I)	3. The importance of accurate information
1.3.1.1 Accurate information helps a person feel in control and reduces less anxiety (C)	
1.3.1.2 Impact of inaccurate information (C)	
2.3.1.1 Inaccurate beliefs about contraception (C)	
2.1.1 Self-belief or self-efficacy (I)	
2.1.3 Anxiety or fear (I)	
2.2.4.1 PCC NOT normal (C)	4. Unhelpful social norms and inaccurate beliefs
2.3.1 Inaccurate beliefs about fertility (I)	
2.3.5 Pregnancy planning a taboo subject – (N)	
2.3.8 Desire to have a baby – (N)	
2.4.2 Negative messages about SRH from school – (N)	

Therapeutic Relationships with HCP's	Middle-range theories
1.1.3 Positive and respectful attitude to women (I)	5. The difference that a positive and respectful attitude from a healthcare professional can make
2.2.2 Impact of feeling judged / not listened to (I)	
1.1.4.1 CoC - trust - honesty - personalised care (C)	6. The significance of continuity of carer
1.1.4.2 CoC facilitates difficult conversations (C)	
1.1.4.3 CoC resulting in tailored approach by HCP (C)	
1.1.4.4 CoC resulting in person understanding approach taken by HCP (C)	
1.1.4.5 CoC Woman wanting to please the HCP (C)	

Social structures and healthcare services	Middle-range theories
1.3.5.1 Family support reduces anxiety and helps decision making (C)	7. Family support
1.3.5.2 Support from family attending appointments with lots of information (C)	
1.3.6 Peer support (I)	8. Peer support
1.3.6.2 Peer support negative online (N)	
1.3.7 Psychological support (I)	9. Multidisciplinary team approach to pregnancy planning
1.3.9 PCC clinic with follow-up support (I)	
3.1.2 Integrated across primary and secondary care (I)	
3.1.3 Multi-disciplinary PCC clinics for complex conditions (I)	
3.1.4 Role of specialist nurses or midwives (I)	
3.2.5 Waiting time for appointments (I)	
2.3.7 Treat obesity as a health condition (N)	10. Treat obesity as a health condition
3.1.5 Clear pathways and easy access to contraception (I)	11. Clear pathways and easy access to contraception
3.2.2 Socioeconomic factors (I)	12. Preconception care for people experiencing challenging socio-economic circumstances
3.1.7 Incentives to provide or refer for PCC (I)	13. How to increase preconception care in primary care settings

Programme theories with limited evidence so not developed further

3.1.8 Transitions disrupting access to care - New IPT emerging from interview data

3.2.4 Availability of interpreters (I) – language barriers

3.2.7 Same sex couples denied access to PCC - New IPT emerging from interview data

2.3.6 Deciding not to have children - New IPT emerging from interview data