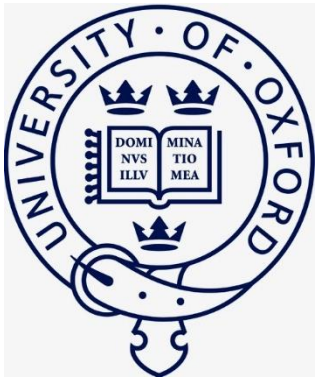

Lifestyle interventions among pregnant women living with pre-existing conditions

A THESIS PRESENTED FOR THE DEGREE OF *DOCTOR OF PHILOSOPHY*

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This thesis is dedicated to my parents.

For their unwavering and endless love, support, and belief in me.

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ABBREVIATIONS

APEC	Action on Pre-eclampsia
BCT	Behaviour Change Technique
BCW	Behaviour Change Wheel
BMI	Body Mass Index
BTT	Birth Territory Theory
C&C	Capability and Capacity
CH	Chronic Hypertension
COM-B	Capability, Opportunity, Motivation - Behaviour
DAPHNY	Diet and Activity for Pregnancy Hypertension
DASH	Dietary Approaches to Stop Hypertension
DM	Diabetes Mellitus
EPR	Electronic Patient Record
GP	General Practitioner
GWG	Gestational Weight Gain
HCP	Healthcare Professional
HRA	Health Research Authority
IOM	Institute of Medicine
IOM	Institute of Medicine
IPD	Individual Participant Data
I-WIP	International – Weight in Pregnancy collaboration
MFT	Manchester University Foundation Trust

MLU	Midwifery Led Unit
MoSCOW	Must have, Should have, Could have, Would like
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
OUH	Oxford University Hospitals
PBA	Person-Based Approach
PET	Pre-eclampsia
PPI	Patient and Public Involvement
PPT	Participant
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SGA	Small for Gestational Age
SMART	Specific, Measurable, Attainable, Responsible, Time-bound
T2DM	Type 2 diabetes
UX	User Experience

Abstract

Background: Little is known about the best way to support pregnant women with pre-existing conditions, such as chronic hypertension, to adopt evidence-based healthy behaviours that are proven to reduce blood pressure. Through quantitative and qualitative methods, this thesis aimed to contribute new evidence and understanding about how to optimise lifestyle support for pregnant women with chronic hypertension.

Methods: The thesis is comprised of three core work packages:

1. A systematic review collated evidence on the effect of lifestyle interventions on weight and blood pressure outcomes for those with existing conditions.
2. A qualitative evidence synthesis of local clinical guidelines was conducted to explore current practice recommendations for weight management during pregnancy.
3. A mixed methods intervention development study using the Person-Based Approach was undertaken involving an online survey, focus groups and early feasibility testing with healthcare professionals and women.

Results: A clear lack of interventional trials to support pregnant women with chronic hypertension was evident; exposing a key evidence gap subsequently addressed in this thesis. Interrogation of 28 diverse clinical practice guidelines revealed inconsistencies across local recommendations with limited practical information for clinicians to share with women about weight management strategies during pregnancy. A risk narrative prevailed which sat in opposition to maternity policy rhetoric that promotes partnership working with women.

An online survey of pregnant, or recently pregnant, women (*n*=85) provided a first step in understanding lifestyle behaviours in the context of pregnancy and chronic hypertension, that has not been undertaken before. Respondents were motivated and confident to engage in healthy behaviours despite less than half recalling being provided with lifestyle support at hypertension diagnosis or during pregnancy. Actual behaviours of participants did not meet

recommendations for some women indicating scope for improving the support women receive to optimise this area of their health.

A theoretically underpinned, evidence-based lifestyle App, named DAPHNY, was iteratively developed with women (*n*=21) and healthcare professionals (*n*=23). The DAPHNY App was viewed positively by participants as a beneficial, novel tool. Logic models demonstrated how key intervention features could lead to meaningful access and engagement and subsequent behaviour change. For example, goal setting, monitoring progress and a reward/ recognition system were implemented; increasing motivation for ongoing App use. Participants who tested the App at home mostly accessed pages to record blood pressure and step count but less accessed informational pages.

Thematic analysis exposed the complexity of the health lifestyle discourse within current maternity care pathways for women with hypertension, where lifestyle support is not embedded within routine antenatal conversations. The technical focus of appointments, underlying assumptions and biases, personal barriers and conflicting priorities were reasoned as significant challenges in the implementation of enduring and meaningful lifestyle support for women to better control their blood pressure. Embedding lifestyle information alongside existing self-monitoring Apps and within care pathways with ongoing, reciprocal conversations with a healthcare professional, were suggested strategies to increase engagement and support successful implementation.

Conclusion: This thesis exposes, and subsequently addresses, the lack of evidence to optimise lifestyle behaviours in a pregnant population living with chronic hypertension. The dominant risk narrative of clinical guidelines and antenatal appointments meant little space was given to lifestyle support as an adjunct to regular monitoring and medication administration; the current status quo for blood pressure management. Development of the DAPHNY App, underpinned by a distinguished behavioural framework for developing digital interventions and sociological theory, provides new and important data to support women

with chronic hypertension and healthcare professionals with this currently overlooked aspect of blood pressure management. Future research priorities include utilising mixed-methods to further modify, test and evaluate the implementation of a lifestyle component within a self-monitoring blood pressure App and explore the incorporation of this within antenatal consultations; continued work with stakeholders to understand and breakdown barriers and challenges to implementation; and exploration of alternative methods of antenatal care delivery that support professionals in their health promotion role that better meet the needs of women with chronic hypertension. Striving for a holistic and partnership approach that includes lifestyle support to manage blood pressure should be a priority to enhance women's overall experience of pregnancy alongside improved long-term cardiovascular health.

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Chapter 1 Introduction and background

1.1. Overview

Lifestyle factors including diet and physical activity play a vital role in the management of cardiovascular disease, and are well evidenced to provide sustained, clinically relevant, reductions in blood pressure.

Women who enter pregnancy with hypertension are at increased risk of pregnancy and birth complications. This is an additional concern for those who may also be living with additional co-morbidities such as a higher weight, which is of higher prevalence in this population. Supporting women with complicated pregnancies to adopt healthy behaviours could play an important role in blood pressure control during pregnancy and beyond. However, an understanding of how to best support women with existing hypertension with this aspect of their blood pressure management during pregnancy is unknown.

This thesis will explore existing lifestyle interventions during pregnancy and their effect on weight and blood pressure in a population with pre-existing conditions. It will also aim to examine and synthesise local 'weight management during pregnancy' clinical guidelines to gain an understanding of pathways related to lifestyle support during pregnancy. Building on gaps identified in the literature and knowledge obtained throughout preliminary studies, a digital lifestyle intervention will be designed, developed and tested. This will enhance our limited understanding of how to optimise healthy behaviours in a pregnant population living with chronic hypertension. Qualitative work will explore implications for implementation by exploring the narratives of women's lives, maternity system constraints experienced by professionals as well as societal structures that surround the complex discourse of lifestyle, hypertension risk management and pregnancy.

1.2. Objectives

In this opening chapter, I will state my research position before introducing the topic, population of interest and context for the different studies within my thesis. I finish with the overarching research questions to address the existing gaps in the literature. This thesis aims to develop a more comprehensive understanding of how women can be supported during a pregnancy complicated by hypertension to adopt healthy lifestyle behaviours to improve short and long term cardiovascular health.

1.3. Professional background, motivation and philosophical orientation

I trained as a Midwife at the University of Manchester and qualified with a First Class Honours degree. I worked in a large tertiary unit, with an annual birth rate of over 10,000 and subsequently worked in a maternity unit with around 3,500 births per year. I cared for many women experiencing complex pregnancies who went on to have various interventions that aimed to reduce risk and improve outcomes for mother and baby. My experience caring for women with complex pregnancies led to an interest in understanding the determinants of health and adverse outcomes specifically in relation to lifestyle, environmental and social contexts of women's lives. Completing an MSc in Nutrition and applying my knowledge and experience from midwifery, has driven the focus of this DPhil project. Though my clinical work as midwife is relatively short, it was impactful and collectively, with my journey through the DPhil, my position as a midwife and researcher has been shaped to emphasise the value of lifestyle and a public health approach to care for pregnant women with pregnancies complicated by pre-existing conditions.

I started my DPhil from a clinical midwifery perspective grounded in high-risk obstetric care. My chapters neatly reflect the journey I have travelled to become a critical mixed methods researcher. The first results chapter, Chapter 2, took a quantitative approach as a systematic review and narrative synthesis of randomised controlled trial data measuring the effect of lifestyle interventions on weight and blood pressure outcomes. This approach was valuable

because of the audience who place this method high in the traditional hierarchy of evidence which is important for policy making and translation to practice. As I started to engage with the realities of women's lives through interviews and focus groups, I approached the research questions more critically. I reached a realisation of the different methodologies, their strengths, and the importance of differing approaches to a question to give a holistic answer. I have maintained my woman-centred approach and feel this has been enhanced by my engagement with and critique of the multiple methodologies.

1.4. Terminology

The use of some of the terminology within this thesis is considered here. Firstly, I have used the term pregnant women, women and mothers throughout this thesis which includes all people who are pregnant or have given birth. An inclusivity statement is appropriate to ensure clarity that may be lost if there is inappropriate use of gender neutral language (1, 2).

The term 'high-risk' is a well-recognised term within the field to encompass pregnancies that have a higher risk of adverse outcomes (3). Where possible, I have avoided this classification as rigid risk categories can lead to stigmatisation and medicalisation of pregnancy; increasing anxiety, reducing choice, thereby disabling women's power and affecting pregnancy experiences (4). On the other hand, risk categorisation can ensure appropriate assessment and planning to ensure the safety of mother and baby. This falls into a wider debate around the language used within maternity to ensure respectful language that empowers all women that does not deny autonomy or informed decision making. Where possible, I have adopted phrases including 'pregnancy complicated by hypertension/ pre-existing conditions' or 'pregnant women with hypertension' and if I have used 'high-risk', I use inverted commas as a reminder to how this may be interpreted in different ways (3, 5).

The final term to address is where I have used 'high-BMI' and 'higher weight'. Though BMI, on its own, is sometimes preferable as it can be distanced from the person, as discussed with PPI contributors, I adopt the term 'higher weight' where possible as this has been considered less stigmatising (6). In Chapter 3 that examines clinical practice guidelines, I used the term BMI and high BMI frequently as this is the categorisation of weight used within guidelines. Throughout the rest of the thesis, where possible, descriptions include putting the person first, for example, 'a person living with overweight/ obesity/ higher weight'. I have taken the same approach when describing those living with hypertension to avoid labelling individuals living with chronic conditions (7, 8).

These language reflections and decisions were made during the write up stage of this thesis and therefore publications and appendices of earlier work, including the online survey, may not reflect this.

1.5. Population

1.5.1. Chronic hypertension during pregnancy definition, prevalence and importance

Chronic hypertension is high blood pressure (≥140/90mmHg) that predates pregnancy or is identified before 20-weeks gestation and complicates between 1% and 5% of pregnancies (9, 10). Women with chronic hypertension are at increased risk of poor pregnancy and birth outcomes including pre-eclampsia which occurs in a quarter of women with chronic hypertension (11). Superimposed pre-eclampsia is a multi-organ disorder characterised by severe high blood pressure and significant proteinuria.

The prevalence of chronic hypertension is increasing, indicating an important public health concern (12). This is likely due to increases in advanced maternal age at childbirth and obesity; both independent risk factors for chronic hypertension and pre-eclampsia (9, 10). Obesity is associated with a threefold increase in pre-eclampsia risk and women over the age of 35 are 1.5 times more likely to have pre-eclampsia than younger women (13, 14).

Women with chronic hypertension have a lifelong elevated risk of cardiovascular disease. Specifically, women with chronic hypertension have approximately 1.7 times increased risk of a major adverse cardiovascular event including a 1.8 times increased risk of a stroke compared to women who do not have any hypertension during pregnancy (15). Therefore, establishing optimum blood pressure management during pregnancy is vital to reduce the risks and poor outcomes for women and babies that are associated with elevated blood pressure (16).

1.5.2. Care management for women with chronic hypertension

Women with hypertension are likely to be cared for by multiple healthcare professionals before they are pregnant and during pregnancy. Appointment schedules vary depending on blood pressure control and the woman's needs but care is often consultant led with the aim of a achieving blood pressure reading of below 135/85mmHg, therefore regular blood pressure monitoring is recommended (15). Anti-hypertensive medication is reviewed for safety at the onset of pregnancy, or when receiving preconception advice. Induction of labour (before 37 weeks) is not routinely offered if blood pressure is below 160/110mmHg, unless there is another medical indication to do so. Closely monitoring blood pressure after birth is advised to ensure blood pressure remains below 140/90mmHg.

Optimising pharmacological treatment is essential in maintaining continued blood pressure control through pregnancy. Non-pharmacological approaches such as lifestyle modification have a vital role to play in both hypertension prevention and management, with proven blood pressure lowering effects (17, 18). Lifestyle, weight management, exercise and diet advice for women with chronic hypertension is the same as that provided for all pregnant women, with an additional recommendation on lowering salt in their diet in line with recommendations for hypertension in the general population (15). The benefits of healthy dietary patterns and adequate physical activity levels in the management of hypertension will be discussed in subsequent section 1.8.

In this thesis, blood pressure management encompasses all of the woman's care including medication, monitoring regimes and care pathways. Blood pressure control is the target blood pressure range or blood pressure readings below the target.

1.6. Context

1.6.1. Models of care

Midwives are highly skilled autonomous professionals who work in partnership with women to deliver care, support and provide information through pregnancy, labour and birth and throughout the early postnatal period (5, 19). There are two models of care within maternity and both have a role to play in optimising the care women receive.

The first is the midwifery model that aligns with the social model of care, holding the philosophy that pregnancy and birth are a natural physiological event where most women will have a normal and safe birth without intervention (20-22). Care is holistic and is orientated around the woman's social, spiritual and emotional journey to motherhood (23). UK maternity policy advocates a partnership approach to care where women and the healthcare professionals that they interact with during pregnancy share goals, and decisions are based on the woman's individual needs and preferences (5, 24, 25).

The medical model views pregnancy as only normal in retrospect and focuses on the interventions necessary to bring the pregnancy back to normal (21). Because of this, regular monitoring is promoted where treatment, surveillance and screening are all common features to ensure safety and reduce risk. The focus is on the woman's physiological progression through pregnancy, as opposed to the midwifery model that encompasses the woman's experience and recognises the embodied experience of pregnancy. The medical model has had a significant role in reducing maternal and neonatal morbidity and mortality through offering immediate access to medical expertise and rapid response to complications should they arise (26).

Those with chronic conditions such as hypertension or diabetes may experience both models because of the medical management required for ongoing disease management through pregnancy. Due to this, these women may experience fragmented care as they risk falling through the gaps between different models within maternity services (27). However, ensuring pregnant women with existing conditions experience woman-centred care within the complex web of models is vital to ensure the woman has good care, doesn't fall between gaps and has choice, and thus control, throughout their pregnancy journey (28, 29).

1.6.2. Clinical practice guidelines

Clinical practice guidelines, also known as policies or protocols, play an important role in providing evidence-based clinical care recommendations to assist healthcare professionals in making decisions about the most appropriate care pathways, treatment or intervention to promote safety and shared decision making (30, 31). National Institute of Health and Care Excellence (NICE) emphasises the importance of using clinical expertise and judgement alongside guidelines to ensure the individuals needs and circumstances are considered. Traditionally, clinical guidelines reflect the medical paradigm of diagnosis and treatment since decision making is based on quantitative medical research, mostly randomised controlled trials, that mirrors this. This can lead to guidelines that do not consider personal values, perspectives, social and environmental factors that all influence one's health (32).

Some maternity guidelines have been updated to reflect a more woman-centred, partnership approach to encompass these values (33). As well as this, guidelines have addressed the language used to ensure inclusivity to promote equity in care provision through effective communication that is essential for positive care experiences (4, 34). This move towards partnership relationships emphasises the reorientation of maternity care from the medical paradigm towards a midwifery model of holistic, woman-centred care. Chapter 3 will consider the ambition of UK maternity policy alongside maternity clinical guidelines, in relation to weight during pregnancy; a topic of public health relevance.

1.6.3. Health promotion during pregnancy

Public health *"is the science and art of preventing disease, prolonging life, and promoting health through the organised efforts of society"* (35). The public health role of maternity practitioners is well established as it is understood that midwives are in a unique position to deliver health promotional messages through their regular contact and interpersonal relationship with each woman (5, 36). This is recognised in several strategic level maternity and NHS reports including the Maternity Transformation Programme, the NHS long term plan and the Women's Health Strategy which commit to improve wellbeing by contributing towards prevention and tackling inequalities (25, 37, 38). Specific areas of focus include mental health, maternal weight and obesity and smoking.

One of the key drivers in mobilising the midwife's role in health promotion is because of the view that pregnancy is a teachable moment (36, 39). Women are seen to be receptive to health messages during this time because they are motivated to improve their health for the health of their baby. This isn't always supported in the literature. Atkinson et al., (2016) conducted interviews with women to investigate whether their experiences of pregnancy indicated their receptivity of behaviour change during pregnancy (40). They questioned the pregnancy period as a teachable moment as those who perceived themselves low-risk, made lifestyle choices that were described as "automatic" and "obvious" as opposed to enacting information provided by healthcare professionals during this time (40). Similarly, Lauridsen et al., (2018) found interventions during pregnancy had little impact on long-term behaviour change (41). These researchers challenged pregnancy as a window of opportunity as it assumed the woman holds all responsibility of her and her family's health which was not reflected by the women who were interviewed (42). Because of these findings and the differing individual accounts of the women in the study, authors concluded that interventions should be co-created with women to ensure women's experiences are considered and to avoid maternal blame.

1.7. Higher weight and hypertension during pregnancy – importance and relevance to this thesis

1.7.1. Gestational weight

Weight management during pregnancy is a complex phenomenon. Weight gain is a normal physiological process during pregnancy accounting for a growing fetus, increased blood volume, expansion of maternal tissue and amniotic fluid. Excessive gestational weight gain (GWG) is often classified as an increase from pre-pregnancy weight above what is required for a normal and healthy pregnancy to function and is associated with poor obstetric and fetal outcomes (43, 44).

Recommendations for appropriate weight to gain during pregnancy have been calculated based on observational studies, to reduce the risks associated with overweight, obesity and excessive gestational weight gain (45). These guidelines recommend different weight gain ranges depending on pre-pregnancy BMI, with those of a higher BMI having a lower weight gain threshold to achieve. This is of significance since more women are now entering pregnancy with overweight and obesity (less than half of women enter pregnancy within a normal BMI range) which can negatively impact health (46). Furthermore, when women gain extra weight during pregnancy, they may be more likely to enter subsequent pregnancies at a higher weight (47). Gestational weight gain, above or below what is recommended, regardless of pre-pregnancy weight, has recently been shown to have important implications for long term cardiovascular health (48).

Evidence has prompted national guidelines be implemented to support weight management during pregnancy. There is a lack of international consensus on weight management care during pregnancy, with varied recommendations in reviewed policies and guidelines (49, 50). Specifically, Scott et al., (2014) reviewed guidelines internationally and found 62% provided recommendations for healthy gestational weight gain, either based on the Institute of Medicine (IOM) guidelines or their own recommendations (49). However, NICE and

RCOG guidelines do not advocate regular weighing throughout pregnancy in the UK, and no weight gain threshold recommendations are given (51, 52). The rationale for this is because of the lack of non-observational evidence that regular weighing is an effective screening tool for poor outcomes, and there are variations in weight gain that leads to adverse pregnancy outcomes (53-55). This led to the removal of routine weighing for weight management as a screening tool within clinical guidelines in the UK (56).

1.7.2. Evidence in obesity and otherwise uncomplicated pregnancy

Evidence suggests that those with a higher weight and living with obesity are more likely to experience negative pregnancy and birth outcomes. These include gestational diabetes, pre-eclampsia, postpartum haemorrhage, prolonged labour, birth defects and fetal macrosomia (57-60). Intergenerational adverse health risks including obesity and cardiovascular disease in the offspring have also been reported (57, 61).

1.7.3. Evidence in obesity and pre-existing conditions including hypertension

The significance of weight and weight gain during pregnancy may be of greater relevance to those with existing conditions. This was evidenced by Yee et al., (2017) who found that the absolute frequency of adverse maternal and neonatal events was increased in a chronic hypertensive population with weight gain above recommendations compared with a normotensive population (62). The authors also note that weight gain below the recommended amount should also be cautioned against due to an observed increased risk of a small for gestational age (SGA) baby. However, Siegel and colleagues evaluated the IOM guidelines in women with chronic hypertension and determined that gaining less than the recommended amount was associated with a decreased risk of superimposed preeclampsia (AOR: 0.49, CI 95%: 0.26–0.93) without increasing the risk of SGA (AOR: 1.03, CI 95%: 0.57–1.86) (63). Neither of these authors took into account gestational age, an important metric in calculating appropriate gestational weight since they may suggest a stronger relationship may exist because a longer gestation would have a higher GWG

meaning poor outcomes associated with low GWG would be inflated. Despite this, there is an overall consensus that women living with existing chronic hypertension may need to pay closer attention to weight management during pregnancy to reduce the associated risks (64).

1.8. Lifestyle interventions

Due to the risks previously discussed in section 1.7, there has been much research to explore how lifestyle behaviours such as diet and physical activity can reduce these risks and improve long-term cardiovascular health. Therefore, the predominant focus of this thesis will be the modification of diet and physical activity behaviours.

1.8.1. Lifestyle interventions in non-pregnant populations and effect on blood pressure

The association between a healthy lifestyle and hypertension status is well established with poor dietary habits and minimal physical activity levels being associated with an increased risk of hypertension (18). Guidelines recommend patients diagnosed with hypertension are advised about a healthy diet, exercising, reducing alcohol intake, smoking and stress, as well as weight management (65). A NICE evidence review summarised interventions that address diet and physical activity finding these can reduce systolic and diastolic blood pressure, on average, by 5mmHg (66). However, the quality of studies was described as weak due to poor methodological rigour and would now be considered out of date.

American guidelines for hypertension offer more specific recommendations based on more up to date evidence (67). The Dietary Approaches to Stop Hypertension (DASH) diet is recommended which promotes the intake of fruits and vegetables, wholegrains, low-fat dairy products as well as reducing the intake of saturated fat (68, 69). This results in a low sodium intake and high potassium intake, important nutrients in the development of high blood pressure. The DASH dietary pattern has been the most effective diet in creating meaningful reductions in blood pressure (70). A 2020 systematic review and meta-analysis of RCTs

demonstrated that compared with a control diet, the DASH diet reduced both systolic and diastolic blood pressure (difference in means: −3.2 mm Hg; 95% CI: −4.2, −2.3 mm Hg; P < 0.001, and −2.5 mm Hg; 95% CI: −3.5, −1.5 mm Hg; P < 0.001, respectively) (71). Furthermore, Gay et al., (2016) found that the DASH diet is most effective compared with other diets where it caused reductions in blood pressure equal to that seen in some medication regimes (72). Authors conclude that dietary patterns may offer an alternative to medication administration in early hypertension diagnosis. Other meta-analyses have found clinically significant blood pressure reducing effects, when compared to baseline values, after following a DASH diet intervention and support its adoption in both hypertensive and non-hypertensive populations (72, 73).

1.8.2. Lifestyle interventions in pregnant populations and effect on blood pressure

Weight loss is a key recommendation for hypertension management outside of pregnancy but weight loss is not recommended during pregnancy (52). The focus on lifestyle during pregnancy is therefore attenuation of excessive GWG though it is not known whether this is used as a blood pressure management strategy as well. Lifestyle interventions tend to target diet and physical activity behaviours with appropriate weight gain being a proxy for improved maternal and neonatal outcomes.

There have been a plethora of trials examining lifestyle interventions in pregnancy subsequently followed by a number of systematic reviews (74-76). Studies have found a modest effect on attenuation of GWG, with more success usually seen in those in the “normal BMI” range.

The effect on maternal and fetal outcomes in syntheses of study level data have produced mixed results but there appears some, albeit low-quality, evidence that the interventions may have a protective effect on the incidence of pre-eclampsia, hypertension, gestational diabetes and preterm delivery (76, 77). An individual participant data meta-analysis of 36 RCTs including 12,526 women found rates of caesarean section were reduced in the

intervention group but no other significant effects were observed on complications (74). A small subgroup analysis of women with existing hypertension or diabetes found no differential effects for gestational weight gain or maternal composite outcomes as compared to when data was analysed as a whole. This is the only study that appears to have considered the differential effect of lifestyle interventions that may exist on this important subgroup however, the focus of the review and the included studies was not pregnant women with pre-existing conditions. Many unknowns still exist including what the most effective lifestyle intervention is that has a meaningful reduction in GWG that can improve outcomes including blood pressure control in a population with existing co-morbidities. I will address this research gap in Chapter 2.

1.8.3. Dietary interventions during pregnancy and effect on blood pressure

With strong evidence outside of pregnancy, there has been some consideration on the effect of the DASH diet in pregnant populations. A Cochrane review including six RCTs and 569 women found that the DASH diet during pregnancy decreased the incidence of pre-eclampsia (RR = 0.667; 95% CI: 0.451, 0.987, p = 0.043) and improved other outcomes including macrosomia and improved fasting plasma glucose levels (78). A recent observational study in Ireland found a diet that closely resembled the DASH diet was associated with lower mean blood pressure throughout pregnancy in low risk women and another, larger cohort study of women showed that maternal diets that closely resemble the DASH diet were associated with lower mid pregnancy diastolic blood pressure and improved fetal-placental vascular function in a low risk population (79, 80).

1.8.4. Challenges for healthcare professionals and women delivering and receiving advice about weight and lifestyle in practice

As previously discussed, healthcare professionals have an established health promotion role and they are recommended to provide information on healthy lifestyle behaviours to support progression of a healthy pregnancy. However, healthcare professionals report both

personal and contextual barriers in talking to women about health promoting behaviours relating to weight (81-83). Barriers such as a lack of knowledge and confidence is shadowed by a fear of stigmatising women who enter pregnancy with obesity. As a result, women report receiving inconsistent advice, confusion over the information they do receive and a lack of support, despite some women wanting to receive accurate and sensitive information about ways to manage weight and live a healthy lifestyle during pregnancy (84-89).

Creating further challenges in the delivery of lifestyle interventions is the multiple barriers recognised by pregnant women in enacting recommended behaviours. These include common pregnancy symptoms such as general discomfort, sickness or tiredness and work or family commitments, as well as safety concerns (90-92). A survey designed to identify the barriers and facilitators amongst women with risk factors for hypertension, found cost and time to be major barriers in consuming heart-healthy diets (93).

Given the breadth of research invested in understanding effective lifestyle interventions, there has been comparably minimal investigation in determining the factors influencing healthy behaviours in those pregnancies where women have existing chronic conditions, including hypertension. Though similar barriers may be identified, additional obstacles may exist given the complexities in managing a chronic condition outside and during pregnancy.

1.8.5. Conclusion about lifestyle interventions and relevance to the thesis

Despite the number of trials, no effective lifestyle interventions have been embedded into clinical practice for women with hypertension to manage their weight or help reduce blood pressure during pregnancy. Within the existing evidence, a consensus has been reached that doing something is better than doing nothing. Focusing on important subgroups rather than a ‘one-size fits all’ approach, and considering important psychological and psychosocial factors, may be a potential avenue for future enquiry to understand how best to support women through pregnancy (94). This thesis attempts to address this need by

focusing on women who enter pregnancy with a pre-existing condition who, as discussed, may benefit the most from lifestyle modification but where little attention has been paid.

1.9. Mobile Health (mHealth) and self-monitoring

As discussed there is not one effective lifestyle intervention that has been successfully embedded into existing maternity care pathways. Mobile Health (termed mHealth), which is the use of technology including mobile Apps, web-based programmes, text messaging servicing and self-tracking/ monitoring devices, is considered to have a growing and influential role in maternity care provision where high App usage amongst pregnant women may provide an opportunity to remodel pathways (95, 96). During pregnancy women use the internet and Apps to seek information, to increase their confidence when talking with their healthcare providers, to provide missing information between appointments and to make decisions (96-99). The NHS England Better Births report and NHS Long Term plan recognises the uptake and potential of digital technologies in healthcare settings and widespread App use amongst pregnant women (24, 37). These reports highlight the value that digital technology and the role digital tools may have in a move towards more personalised care, enabling informed choice through unbiased information provision and increasing women's engagement with services (24). The scalability of an intervention delivered via an App may be much better than a resource intensive intervention that requires specialists and multiple visits. Therefore, Apps must be considered when planning future care provision, especially in relation to lifestyle as alternative information from informal, and potentially less reputable, sources may be sought (95, 100-102).

The widespread use of Apps could increasingly replace information from healthcare professionals which is a concern when the majority of freely available pregnancy Apps that promote healthy behaviours are not based on robust scientific evidence or formally evaluated (103). There is also a lack of regulation of the Apps that go to market which raises further questions around the safety of their use for pregnant women as well as concerns on

the use and storage of data and privacy (96). Despite this, if developed robustly through quality research that involves healthcare professionals and women as the target user, reliability of information in these Apps would improve and they could have a function in empowering and informing women (103).

Increasingly, research has explored the role of Apps in the management of chronic conditions such as hypertension and diabetes. Successfully, remote monitoring of gestational diabetes via an App has been shown to be safe and acceptable to women (104, 105). An App to be used alongside self-monitoring blood pressure was developed and exponentially implemented during the Covid-19 pandemic where self-monitoring is increasingly being recognised as an adjunct to the management of hypertensive pregnancies (106-108). Women submitted blood pressure readings via an App which triggered a traffic light system to advise on the most appropriate action according to the reading taken. Researchers found self-monitoring to be safe, acceptable and feasible for women with some reporting feeling empowered and more aware of hypertension risks (109). Further work is exploring how self-monitoring could interlink with existing pathways since it is something that is increasingly happening in maternity settings but that its effectiveness or role in supplementing or replacing in-person care is unknown. Additional components alongside self-monitoring may be needed to bolster its effectiveness in the management of hypertension during pregnancy.

In summary, pregnancy Apps lack robust scientific input, lack regulation of content, screening for co-morbidities, healthcare professional involvement, and theoretical underpinning. Building on existing evidence for recently developed Apps to monitor hypertension and diabetes, this thesis (Chapter 5 and Chapter 6) will aim to directly address shortcomings in App development by producing a scientifically developed and theoretically underpinned lifestyle intervention for a hypertensive population during pregnancy.

1.10. Relevant theory and concepts

Several theories are drawn upon in this thesis. In developing the intervention (Chapter 5 and Chapter 6), the context of the healthcare system and women's lives into which this was being implemented was extremely complex. I have engaged with the literature of several sociological and psychological theories during the course of my DPhil and I have accessed these where appropriate, including weight stigma, accountability, identity, governmentality and the responsibilisation of health. However, the purpose of the thesis was not to do an in-depth critique of these, but I acknowledge and understand their impact in my research.

1.10.1. Behavioural science framework

The use of behavioural theories to develop interventions has been increasing since the publication of the UK Medical Research Council framework (110-112). They explain the importance of systematically exploring potential influences on behaviour during intervention development.

The Behaviour Change Wheel (BCW) is an implementation theory used by many healthcare researchers, incorporating 19 frameworks of behaviour change that can support intervention development through theoretical analysis of a particular target behaviour (113, 114). At the core of the behaviour change wheel is the COM-B model which stands for Capability, Opportunity, Motivation and Behaviour. All components influence behaviour directly or indirectly, while enacting a behaviour can influence capability, motivation and opportunity. Capability is subdivided into psychological and physical and these are the skills and knowledge needed to enact a behaviour. Opportunity is also subdivided into social and physical and is about how much the environment supports or prompts a particular behaviour. Motivation includes reflexive and automatic which are the brain processes that direct a behaviour for example, emotional responses, intentions and beliefs in the

consequences of a behaviour. It is posed that all three are required in order for the desired behaviour and is not a linear process (Figure 1).

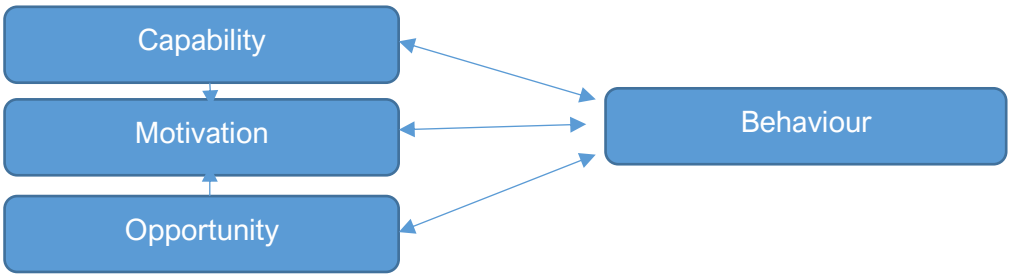


FIGURE 1 COM-B MODEL

Adapted from: Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6:42

This framework has been used to refine many health interventions including DAFNEplus, a programme for type 1 diabetes management as well as StayActive, an activity App for women with GDM (115, 116).

Behaviour change techniques are the operational functions such as goal setting, reinforcement and rewards that can be mapped against the COM-B components to theorise causal mechanisms that lead to behaviour change. A full list of 93 behaviour change techniques covering 16 domains were developed by the same researchers who developed the behaviour change wheel methodology. Attempts have been made to identify behaviour change techniques in existing lifestyle interventions to understand the effective 'ingredients' that lead to a desired behaviour (117, 118). These analyses are crucial for accurate replication and implementation into practice.

Despite the behaviour change wheel incorporating many different theories and frameworks, these psychological and cognitive theories have been criticised for having a narrow focus on behaviour that ignores the wider contextual and social issues and potentially oppressive structures at play both in maternity care and society that may also have a role in determining behaviour (119). I will discuss the limitations of the behaviour change wheel in Chapter 6

and how I have moved beyond the individual focus of the theory to apply a constructive sociological lens that emphasises the wider contextualisation of lifestyle change in pregnancy.

I will discuss here some further theories and concepts that I felt spoke throughout the thesis and are the lens used for interpretations of the datasets to help further our understanding of how pregnant women may be supported to engage in healthy behaviours and the impact of this on the women themselves.

1.10.2. Birth Territory Theory

Pregnancy is a social process and therefore cultural and social influences are fundamental in determining a woman's sense of control and power (120). The birth territory theory (BTT) is a framework for understanding how factors such as the birth environment, the equipment and people within this impact the experiences of birthing women. The theory proposes the locus of power will either inhibit or enhance a woman's capacity to experience her embodied self that enables her to feel safe, strong and empowered to achieve a pregnancy and birth experience she is satisfied with. It takes a post-structural feminist perspective and draws on Foucault's concepts of power (121, 122). The theory has a focus on the birth room but has been applied to other stages of the journey through motherhood including breastfeeding practices (123).

The BTT has two overarching concepts called 'jurisdiction' which relates to the power within the room and 'terrain' which refers to the features of the environment. 'Jurisdiction' is a concept drawn from Foucault's notion of power (121). Midwifery guardianship is a form of integrative power where the midwife is entrusted to protect the space and the power is shared so that the woman feels in control of her mind and body to respond intuitively and enable confidence for her to express her wishes and make her own choices about what happens. The opposite is midwifery domination which is a form of disintegrative power which is a "*subtle and manipulative form of power*" which is shown by resistance from the

woman or where she may give up on her own knowledge and intuition and responds to guidance from the professional (120). Clinical guidelines, derived from institutional risk and safety agendas, can off-balance power where the woman's embodied knowledge of her pregnancy can be devalued (124-126). The influence on the way guidelines are written on facilitating or disabling midwifery guardianship will be examined in Chapter 3.

The sub concepts of 'terrain' include 'sanctum' with the opposite being 'surveillance room' which draw on theories of surveillance, concepts of risk in maternity and Foucault's description of disciplinary power (127-129). Though this relates to the clinical environment, it can be amplified to antenatal care more widely. For example, 'sanctum' is described as a birth room that protects the woman's sense of wellbeing by having the necessary features that protect privacy and enhance comfort and feelings of calm. 'Surveillance' is a birth room where equipment is on display and facilitates the need of the professional as opposed to the woman. Most UK maternity units probably look like this. When we think of the concepts more widely in terms of antenatal care, surveillance can be illustrated by the categorisation of 'low or high-risk' pregnancies, regular check-ups to monitor the health of the baby and the mother via ultrasound and blood tests and continuous electronic fetal monitoring during labour.

I did not engage in the spiritual practices that construct some of the theory, just the functional part as this was more applicable to my work and was where I was personally comfortable using it. The birth territory theory was a useful lens in which to interrogate weight management guidelines during pregnancy in Chapter 3.

1.10.3. Risk discourse

In this thesis, I draw on the discourse of risk. As a society, we thrive to understand, manage and reduce risks associated with everyday life (130). It is within this context, that pregnancy has become a life event that is surrounded by a discourse of risk and the view that *"the pregnant body itself will inevitably deviate from the norm"* as it is *"susceptible to a range of*

ills and risks" (128). Whilst the desired outcome from this is good health for the mother and baby, it gives way to medical control where close surveillance is considered necessary to guarantee safety (129). Pregnant women show acts of self-surveillance where they seek opportunities, often from healthcare professionals, to provide reassurance that the pregnancy is normal and via self-monitoring behaviours to feel in control of their health during pregnancy (131, 132).

The risk discourse is relevant to this thesis because topics cross two co-morbidities: weight and hypertension, both of which are considered to be conditions in pregnancy that are at higher risk of adverse outcomes. The discourse around risk is often critiqued for leading pregnant women to be fearful of outcomes and guilty when things don't go as planned since women are often held responsible for upholding appropriate behaviours to maintain the health of the baby (128). This needs considering in the context of hypertensive pregnancies where a rapid and dangerous rise in blood pressure requires urgent medical attention; highlighting the role of appropriate monitoring and surveillance. What is more pertinent is how women interpret their own risk during pregnancy. Evans et al., (2005) used a hermeneutic phenomenological approach to understand women's experience of gestational diabetes (133). They found that a medicalised view of pregnancies affected by diabetes unsettled women's sense of control and negatively impacted her lived experience of pregnancy. In relation to weight and risk, the medicalisation of these pregnancies can lead to depersonalisation of care and feelings of shame (86, 134). This literature highlights the impact of the risk discourse that surrounds contemporary experiences of pregnancy. This thesis will grapple with the concept of risk given that healthy eating and physical activity behaviour modifications, especially in the realm of managing weight, can be considered reducing those "risk" behaviours to ensure the progression of a normal pregnancy.

1.11. Research gap and research questions this thesis aims to address

Given the background literature presented, this mixed methods thesis aims to address the following overarching research questions:

What evidence exists around lifestyle interventions in pregnancy for those with chronic hypertension and/ or pre-existing diabetes and what behaviour change techniques are utilised in these interventions? (Chapter 2)

Chapter 2 reports a systematic review undertaken to collate the existing evidence around lifestyle interventions specifically for pregnant women with pre-existing diabetes and/ or hypertension. The behaviour change techniques utilised within these interventions were identified.

How do NHS Trusts interpret national weight management guidelines to their local context to support weight management during pregnancy? (Chapter 3)

Chapter 3 reports a qualitative evidence synthesis undertaken to examine local interpretations of National weight management guidelines during pregnancy.

Are women with experience of chronic hypertension during pregnancy motivated and confident to lead a healthy lifestyle and what are their barriers and facilitators towards change? (Chapter 4)

Chapter 4 reports results of an online survey to find out current behaviour, motivation and confidence towards lifestyle change in relation to hypertension diagnosis and pregnancy.

How can we optimise a digital lifestyle intervention with healthcare professionals and with women who have experience of chronic hypertension during pregnancy? (Chapters 5 and 6)

A mixed methods intervention development study was conducted to design and develop a lifestyle App with women who have experience of chronic hypertension and have been pregnant.

Chapter 5 reports the iterative development of a digital lifestyle intervention.

Chapter 6 reports considerations for the context and implementation of a digital lifestyle intervention.

1.12. Statement of Contribution and Funding Acknowledgements

Table 1 lists colleagues who have supported the work carried out in this DPhil. This DPhil has been funded by the National Institute for Health and Care Research (NIHR) Applied Research Collaboration (ARC) studentship.

TABLE 1 STATEMENT OF CONTRIBUTION TO EACH CHAPTER

Chapter 2	The systematic review was conceptualised in discussion with the supervisory team following my initial scoping of the literature. The search strategy was devised by myself with the support a Nia Roberts, a specialist librarian. I ran the search and screened all articles with Dr Raj Patel who was the second reviewer on the systematic review. Discussions were regularly held with supervisors Dr Nerys Astbury and Dr Katherine Tucker to resolve any disagreements on articles and where needed, with Professor Richard McManus. I contacted authors as necessary and undertook the narrative synthesis and presentation of the data. I wrote the manuscript which was reviewed by the second reviewer and supervisors. I subsequently wrote up Chapter 2 of this thesis.
Chapter 3	I conceived the original idea for conducting the study to look at weight management clinical practice guidelines. I designed the study with guidance from supervisors. I collected the data and conducted the qualitative evidence synthesis with support on interpretations and analysis from supervisor Dr Jennifer MacLellan. I drafted the manuscript for publication with input from Dr Jennifer MacLellan and it was reviewed by all supervisors. The manuscript was written up in Chapter form for presentation at Confirmation of Status.
Chapter 4	I conceived the idea to undertake an online survey. I designed and wrote the survey with feedback from members of the research team, supervisors and PPI. I disseminated the survey online and in-person at study sites with advice from the Communications team. I collected the data and conducted the quantitative analysis of the online survey with support from supervisors Dr Nerys Astbury and Dr Katherine

	Tucker as well as statistical input from Dr Constantinos Koshiaris and Dr Ariel Wang.
Chapter 5	The App development team consisted of Professor Richard McManus, Dr Katherine Tucker, Layla Lavellee, Dr Cristian Roman and Dr Ethan (Yuan) Chi. I was the named Chief Investigator on the study and we collaborated with Professor Jenny Myers and Dr Lucy MacKillop who were site Principle Investigators. Professor Richard McManus and Dr Katherine Tucker provided regular supervision and oversight of study activity and Layla Lavellee in a Research Midwife role provided support at initial study set up. All provided feedback on the study protocol apart from Dr Yuan Chi who joined at a later stage. I advertised, recruited, enrolled and followed up participants for all of the studies. I carried out all interviews and focus groups and analysed the data. I designed, developed and adapted the DAPHNY prototypes and created and wrote the content on the DAPHNY App. I conducted the content analysis, developed logic models and regularly met with Dr Cristian Roman and Dr Ethan (Yuan) Chi provided technical support to design and develop the first version of the DAPHNY App ready for testing. They also provided App analytic data and analytical support on completion of the study.
Chapter 6	I conducted the qualitative analysis of the focus group and interview data with regular supervision and support from Dr Jennifer MacLellan.

1.13. Publications of Results

Chapters 2 and 3 have been published in peer reviewed academic journals:

- Goddard L, Patel R, Astbury NM, Tucker K, McManus RJ. Evidence of lifestyle interventions in a pregnant population with chronic hypertension and/or pre-existing diabetes: A systematic review and narrative synthesis. Pregnancy Hypertension. 2023;31:60-72. (Chapter 2)
- Goddard L, Astbury NM, McManus RJ, Tucker K, MacLellan J. Clinical guidelines for the management of weight during pregnancy: a qualitative evidence synthesis of practice recommendations across NHS Trusts in England. BMC Pregnancy and Childbirth. 2023;23(1):164. (Chapter 3)

Chapter 2 Evidence of lifestyle interventions in a pregnant population with chronic hypertension and/ or pre-existing diabetes: A systematic review and narrative synthesis

2.1. Overview

This chapter reports a systematic review and narrative synthesis of lifestyle interventions in a pregnant population with chronic hypertension and/or pre-existing diabetes.

The number of women entering pregnancy with chronic hypertension and diabetes is increasing due to increased maternal age and increasing obesity rates that often precede these conditions (9, 135-137). Beyond pregnancy, this population face a lifelong increased cardiovascular disease risk.

Weight loss or management through improved dietary intake and increased physical activity levels are key management strategies for disease management in non-pregnant populations (15, 138, 139) (see Chapter 1, Section 1.8.1). Since weight loss is not recommended during pregnancy, research has focused on ways to avoid excessive gestational weight gain to reduce pregnancy and birth complications (74-76, 140). However, little is known about the effect of lifestyle changes during pregnancy for those with existing conditions such as diabetes and hypertension and there has been little indication of the effect of these changes on blood pressure control (See Chapter 1, Section 1.8.5). Therefore, this review focused on effect of lifestyle interventions on a population who may benefit the most from additional lifestyle support during pregnancy.

This chapter, in paper form, is published in Pregnancy Hypertension Journal: Goddard, L., Patel, R., Astbury, N.M., Tucker, K. and McManus, R., 2022. Evidence of lifestyle interventions in a pregnant population with chronic hypertension and/or pre-existing diabetes: A systematic review and narrative synthesis. Pregnancy Hypertension (Appendix 1).

2.2. Aim and research questions

When developing the protocol for this review, I developed a logic model to provide a graphical representation of how the many different lifestyle interventions, reported in existing studies, may work (Figure 2). This helped to conceptualise, focus and structure the review. Through the process of theoretical modelling, three research questions were posed aiming to collate the evidence that existed around lifestyle interventions during pregnancies complicated by pre-existing diabetes and chronic hypertension:

- What evidence exists around lifestyle interventions in pregnancy for those with chronic hypertension and/ or pre-existing diabetes and what behaviour change techniques are utilised in these interventions?
- What effect do lifestyle interventions in pregnancy have on gestational weight in pregnant women with chronic hypertension and/ or pre-existing diabetes?
- What effect do lifestyle interventions in pregnancy have on blood pressure in pregnant women with chronic hypertension and/ or pre-existing diabetes?

As the logic model was developed a priori to refine the review questions, identify study eligibility criteria, guide the search strategy and explain the rationale behind the review population and outcomes, the model remained unchanged throughout the review process. Using a logic model in this way is a recognised method for systematic review authors (141). It was revisited and informed adaptations made when initiating the DAPHNY intervention development study, reported in Chapter 5 Section 5.4.4, to link the knowledge obtained from the current review and thus, the existing evidence base, to subsequent work carried out in the thesis.

Problem/ context – Women with pre-gestational diabetes or hypertension have a lifetime risk of poor cardiovascular health. In pregnancy, these women are also at high risk of adverse perinatal outcomes.

Evidence – Lifestyle interventions are the first line of treatment outside of pregnancy for hypertension and diabetes as they have been shown to have favourable effects on weight control, blood pressure management, blood glucose control and improve overall health. Evidence regarding the effect of lifestyle interventions, and their components, during a high risk pregnancy is yet to be determined.

Aim – To identify lifestyle interventions in pregnancy and their components including the behaviour change techniques that improve the management of hypertension and diabetes by supporting appropriate gestational weight control.

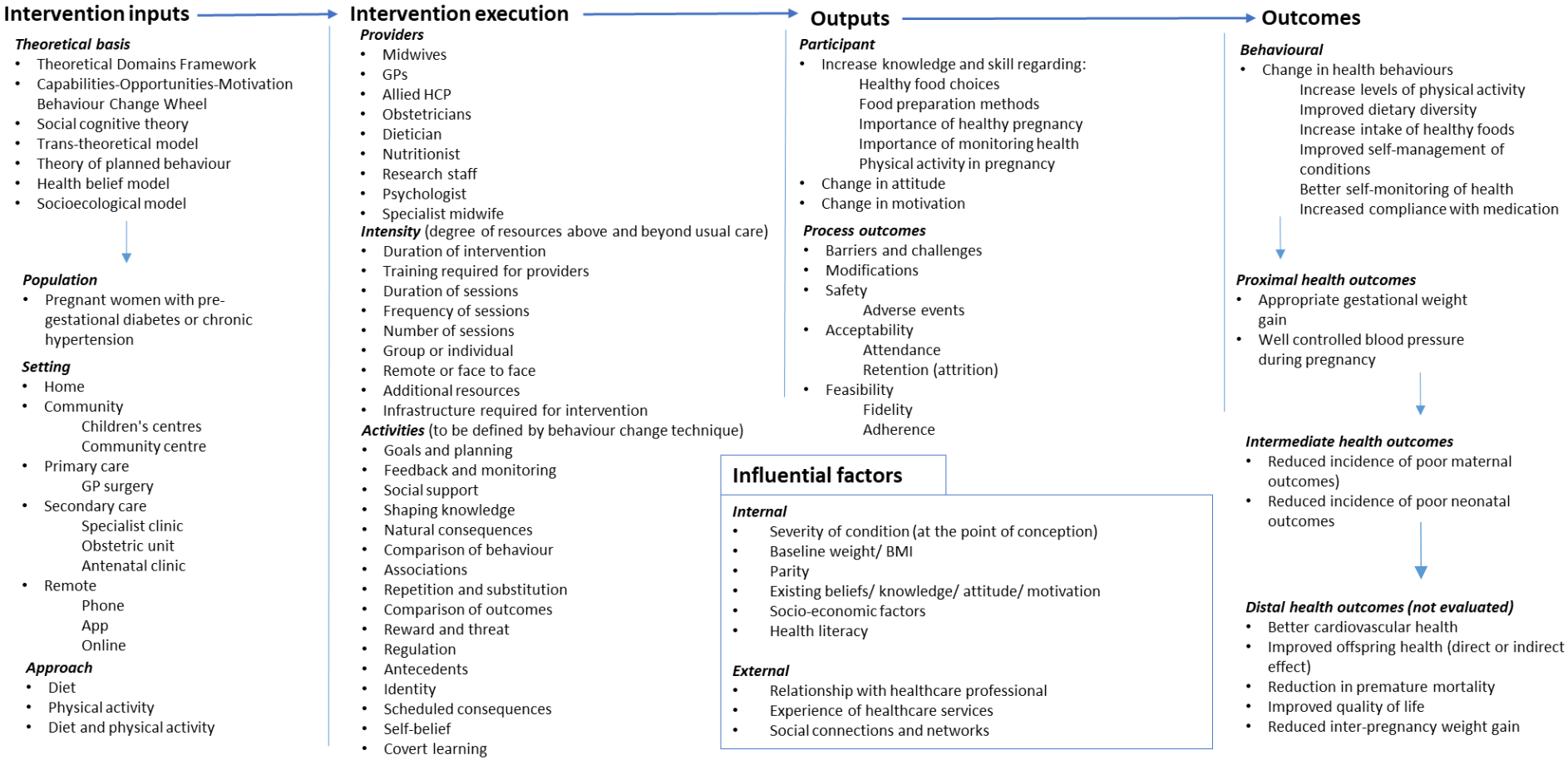


FIGURE 2 A LOGIC MODEL TO CAPTURE KEY ELEMENTS OF THE SYSTEMATIC REVIEW

2.3. Methods

The protocol was registered prospectively on PROSPERO (CRD42021244694) (Appendix 2). PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) (Appendix 3 and Appendix 4) and SWiM (Synthesis Without Meta-analysis) guidelines were used for reporting (142, 143) (Appendix 5).

2.3.1. Literature search

Medline, Embase, Web of Science, CINHAL, and PsycINFO were searched from inception to April 2021. The search strategy was devised with support from a specialist librarian (Appendix 6) and the search was conducted in April 2021. MeSH terms and keywords with all synonyms and spellings were used with Boolean operators. No language or time limits were applied. This was complemented by hand searching the reference lists of similar and recent systematic reviews identified through the databases. The references of individual participant data (IPD) meta-analysis were preferentially screened as well as recent, high quality systematic reviews (144). Grey literature, defined as documents such as academic papers, reports and ongoing research that are not controlled by commercial publishers but can be valuable sources of evidence, were screened and followed up if potentially eligible (145).

2.3.2. Study selection

Randomised controlled trials (including cluster RCTs), in any setting, that included pregnant women with chronic hypertension and/ or those with a pre-existing diagnosis of diabetes (DM or T2DM) were eligible for inclusion (15, 138, 139).

When it was not clear if the study included women with CH and/or pre-existing diabetes and the study included more than 200 participants, the authors were contacted for clarification. In a sample with less than 200 participants, authors were contacted if there was estimated to be, based on information available, at least 10 participants with either of these conditions

in the sample. A minimum of 200 participants was based on the prevalence of chronic hypertension during pregnancy which is 3-5% and less for pre-existing diabetes and therefore a larger study population would likely include those with pre-existing conditions, even if this data was not collected.

Lifestyle interventions were included if delivered during the antenatal period and aimed to change behaviour or knowledge about diet, physical activity, gestational weight or a combination of these. Interventions that included self-monitoring or self-management were only included if directly influencing a lifestyle behaviour (as opposed to titration of medication or to inform clinical management). Comparator interventions included routine antenatal care (as described by trialists), minimal intervention or an active comparator, for example, provision of a food diary or a visit from an interventionist that was additional to routine care.

2.3.3. Outcomes

Studies that reported gestational weight and/ or blood pressure change were included. Change during pregnancy was considered as the change in documented weight and blood pressure measurements closest to booking and closest to delivery as reported by authors. Where available, process outcomes including acceptability, feasibility and behavioural outcomes were collected. Important fetal, maternal and neonatal outcomes, as prioritised by an expert consensus, were collected when available (146). These included the development of preeclampsia and pregnancy induced hypertension (where applicable), gestational diabetes mellitus (where applicable), preterm delivery and caesarean section, intrauterine death, small or large for gestational age, and admission to the neonatal unit.

2.3.4. Data extraction and quality assessment

With the assistance of a colleague (RP), we independently screened studies using a decision aid to ensure consistency. Discrepancies were resolved through discussion with the supervisory team and reasons for exclusions documented.

Following identification of eligible studies, key study characteristics were collected and intervention characteristics were extracted independently by myself and a second reviewer (RP) and used the Template for Intervention Description and Replication (TIDieR) framework (147).

Behaviour change techniques, as described in detail (see Chapter 1 Section 1.10.1) were identified in the eligible interventions and the BCT taxonomy was used to code the interventions (113, 148, 149). The intensity of each intervention was determined according to classifications adopted from previous studies that have used a grading system for classifying self-monitoring blood pressure interventions (150, 151) (Table 2). The classification table was piloted with two colleagues.

TABLE 2 INTERVENTION INTENSITY CLASSIFICATIONS

Level	*Description*
1	A one off intervention such as a class, visit, counselling, leaflet, flyer but no further interaction with study personnel or HCP (above usual care)
	No continuous input from study personnel or healthcare professional
	Closely resembles usual care
2	May include components from level 1 in addition to*:
	Group classes that occurs more than once
	Access to an app
	Access to a website
	Ongoing support is likely but this is not tailored
	Does not demand one-to-one support
	Some regular input required by participant
3	May include components from level 1 and 2 in addition to*:
	Regular one to one support with input from intervention providers
	Likely to be personalised or offer tailored support
	Likely to require significant participant effort or interaction

Note: The intervention does not have to fulfil all descriptions within each level.

**In a multicomponent intervention, different components may fall into different levels. In this case, classify the intervention according to the highest level component included in the intervention.*

Protocols and supplementary materials were consulted when coding BCTs to provide more detail about the intervention (Appendix 7). Coding was completed independently by myself

and RP, interpretations were compared to ensure consistency, and this was followed by a discussion with the supervisory team.

Risk of bias of the included studies was judged to be at low, unclear or high-risk of bias independently by two reviewers using the Cochrane risk of bias assessment tool (152). This includes four domains assessing whether there was any selection bias arising from the randomisation process (random sequence generation, allocation concealment), any potential detection bias caused by approaches to measure the outcomes of interest (blinding of outcome assessment) and any risk of attrition bias (incomplete outcome data coded as low risk if overall numbers lost to follow up was not >50% or the difference between groups was not >20%) (153). A final domain to include other biases evaluated any suspected contamination from intervention to control arm, substantial baseline imbalances between groups and discrepancies in reported data. Performance bias was not assessed due to the nature of behavioural interventions.

2.3.5. Analysis

Moderate to high heterogeneity was anticipated, therefore a random effects meta-analysis for change in mean gestational weight and blood pressure was planned. A random effects meta-analysis is a useful form of statistical analysis to integrate the findings of a large collection of studies (154). However, a meta-analysis requires a common measure of effect size and consistency of outcome measures in the included studies. Due to the high clinical heterogeneity in the data retrieved and the lack of available data for the population of interest for this review, a meta-analysis would not have been appropriate and so a narrative synthesis was undertaken (155). This alternative approach to data analysis provides a transparent, textual presentation of existing studies.

2.4. Results

Following de-duplication, 1464 articles were screened for eligibility, 209 full text articles were screened and subsequently, nine studies were included (Figure 3). Grey literature and hand searching generated no further studies as there was complete overlap in the six studies identified from other sources to those already identified in the review.

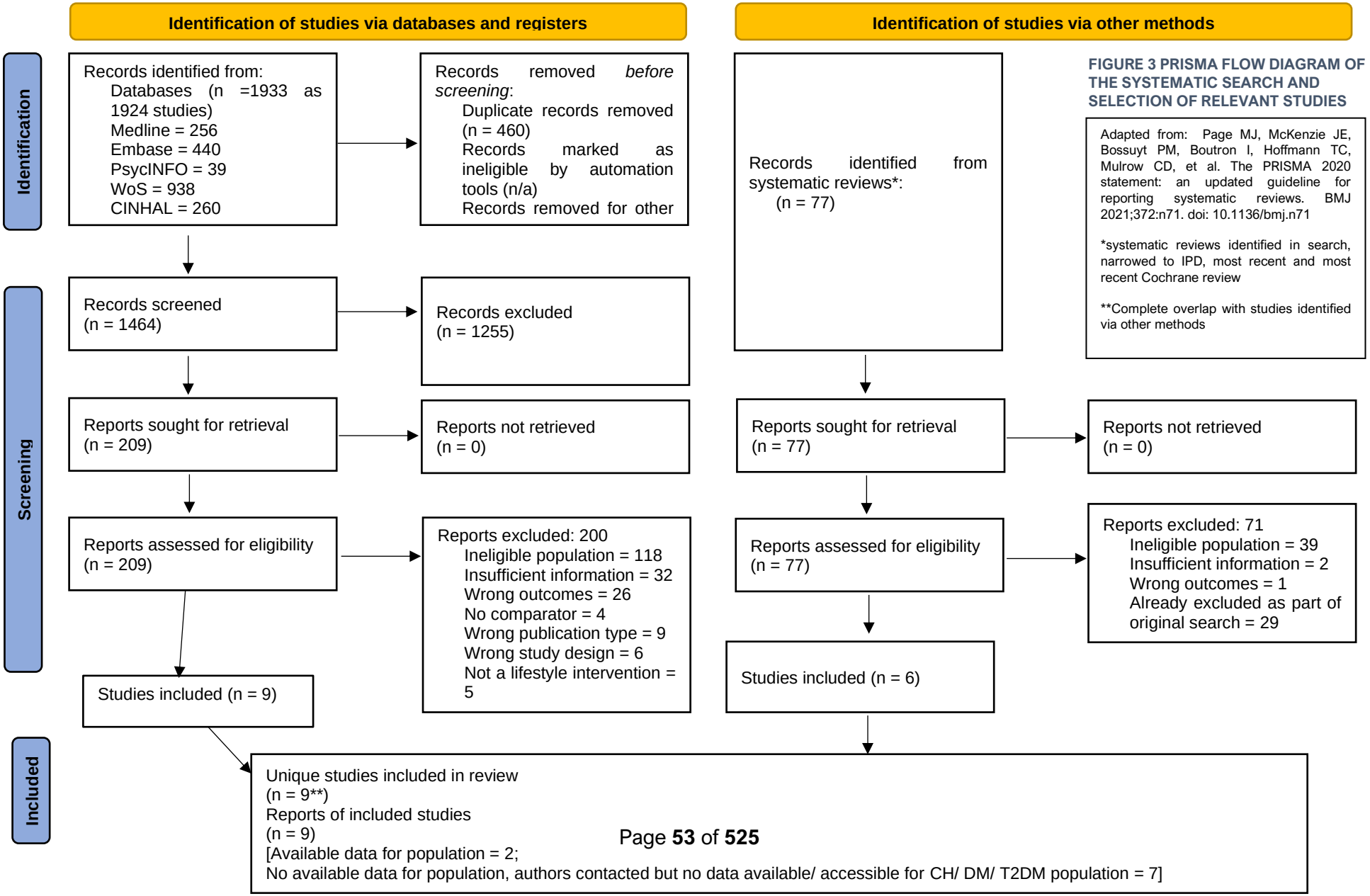


FIGURE 3 PRISMA FLOW DIAGRAM OF THE SYSTEMATIC SEARCH AND SELECTION OF RELEVANT STUDIES

Adapted from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

*systematic reviews identified in search, narrowed to IPD, most recent and most recent Cochrane review

**Complete overlap with studies identified via other methods

Studies were included where the authors confirmed inclusion of pregnant women with chronic hypertension and/ or pre-existing diabetes even if no subgroup data was available. This was a deviation from the protocol in order to incorporate all available evidence of interventions that included the population of interest for the review. This aimed to help build the knowledge base and guide and inform further research in this group. Where study authors were not able to clarify the inclusion of participants with chronic hypertension or pre-existing diabetes, the studies were excluded.

2.4.1. Study and participant characteristics

The nine included studies randomised a total of 7438 pregnant women with the sample size ranging from 20 to 2212 women (Table 3). Seven of the studies were standard RCTs (156-162) and two were cluster RCTs (163, 164). The studies were conducted in Australia, Finland, Brazil, the UK and the USA. One study was international and included nine European countries (Table 3).

Eight studies were mixed pregnant populations that included pregnant women with chronic hypertension and/ or pre-existing diabetes (156-160, 162-164). One study included a pregnant population with pre-existing diabetes (161). All but two studies (160, 161) excluded pregnant women with pre-existing diabetes.

TABLE 3 OVERVIEW OF RANDOMISED CONTROLLED TRIALS INCLUDED IN REVIEW

Study (Author, Year)	Country, year, design	Population	Study groups	Primary outcomes	Aim of trial and authors conclusion on weight and blood pressure (for total study population)
Studies that provide data on pregnant women with chronic hypertension and/ or pre-existing diabetes					
Simmons et al., (2017) (162)	9 European countries 2012 - 2015 RCT	436 pregnant women. 41 women with chronic hypertension. Women with pre-existing diabetes excluded.	Healthy eating and/ or physical activity (3 intervention arms) Usual care	GWG at 35 to 37 weeks, fasting glucose and HOMA-IR (Homeostatic Model Assessment for Insulin Resistance) at 24 to 28 weeks.	Test the effect of 3 lifestyle interventions in reducing GDM. Gestational weight change – Positive – the intervention (HE+PA) was effective compared to control in limiting GWG. See Table 6 for weight change in participants with chronic hypertension. Systolic and diastolic blood pressure change – Not an outcome.
Ney, 1982 (161)	USA Dates not stated. RCT.	20 pregnant women. 10 women with type 1 diabetes. 10 women with type 2 diabetes. No information on chronic hypertension.	HCF (High carb, high fibre diet) Control diet (Usual care for diabetes management)	Diabetic control.	Compared diets on various quantitative criteria of diabetic control. Gestational weight change - Positive – GWG was significantly lower in intervention arm compared to control. See Table 6 for weight change in participants with existing diabetes. Systolic and diastolic blood pressure change – Not an outcome.
Studies that provide data on the number of participants with chronic hypertension and/ or pre-existing diabetes but no outcome data available					
Watter et al., (2019) (158)	UK 2014 - 2016 RCT	1252 pregnant women. 58 women with chronic hypertension.	ESTEEM (Effect of Simple, Targeted Diet in Pregnant Women With Metabolic Risk Factors on Pregnancy Outcomes) intervention	A composite outcome combining gestational diabetes or preeclampsia and a composite outcome combining stillbirth, SGA	Assessed whether a Med diet reduces adverse outcomes in high-risk women. Gestational weight change – Positive – women allocated to the intervention gained less gestational weight. Systolic and diastolic blood pressure change – Not an outcome.

		Women with pre-existing diabetes excluded.	Usual care	or admission to neonatal unit.	
Nascimento et al., 2011 (160)	Brazil 2008 - 2010 RCT	82 women pregnant. ~23 women with pre-existing diabetes (Not exact number (only % given). ~37 women with chronic hypertension (Not exact number (only % given).	Study group Usual care	GWG during the programme and excessive maternal weight gain.	To evaluate the effectiveness and safety of physical exercise on outcomes and quality of life on maternal/ perinatal outcomes. Gestational weight change – Positive when stratified by BMI group – overweight women from the study group (*n*=9) gained less gestational weight than the control group (*n*=5). There was no significant difference in GWG between groups when data was analysed as a whole. Systolic and diastolic blood pressure change – No effect - The intervention did not affect systolic or diastolic arterial blood pressure.
Studies that include women with chronic hypertension but provide no further detail on these participants (pre-existing diabetes excluded from these studies)					
Dodd et al., (2014) (157)	Australia 2008 - 2011 RCT	2212 pregnant women. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Lifestyle advice Usual care	Incidence of infants born large for gestational age.	To assess whether dietary and lifestyle advice to limit GWG in overweight and obese women improves maternal, fetal and infant outcomes. Gestational weight change – No effect – There was no difference in total GWG between the groups. Systolic and diastolic blood pressure change – Not an outcome.
Dodd et al., (2019) (156)	Australia 2014 - 2017 RCT	641 pregnant women. Women with chronic hypertension included but no data collected.	Lifestyle advice Usual care	Proportion of infants with birth weight >4kg.	To evaluate the effect of dietary and exercise advice among pregnant women of normal BMI, on pregnancy and birth outcomes. Gestational weight change – No effect – There were no differences between the groups for total GWG.

		Women with pre-existing diabetes excluded.			Systolic and diastolic blood pressure change – Not an outcome.
Hedderson et al., (2018) (163)	USA 2011 - 2012 Cluster RCT	2014 pregnant women with gestational diabetes. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Tailored letter Usual care for gestational diabetes management	The proportion of women meeting the IOM guidelines for second and third trimester appropriate weekly rate of weight gain from gestational diabetes diagnosis to delivery. To note: this study evaluated one element of a larger trial that involved a postnatal intervention with a primary goal of reducing postpartum weight retention.	To evaluate if a tailored letter improves GWG among women with gestational diabetes. Gestational weight change (note: authors report % meeting IOM guidelines for appropriate weekly rate of GWG) – Positive - The intervention group had a statistically significant 8% increased likelihood of meeting the IOM guidelines for appropriate weekly rate of GWG. Systolic and diastolic blood pressure change – Not an outcome.
Luoto et al., (2011) (164)	Finland 2007 - 2009 Cluster RCT	399 pregnant women. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Intervention group Usual care	Proportion of women with gestational diabetes and new-borns birthweight.	To evaluate whether intensive lifestyle counselling could prevent the development of gestational diabetes and large for gestational age. Gestational weight change – No effect – Total GWG did not differ significantly between the groups. Systolic and diastolic blood pressure change – Not an outcome.

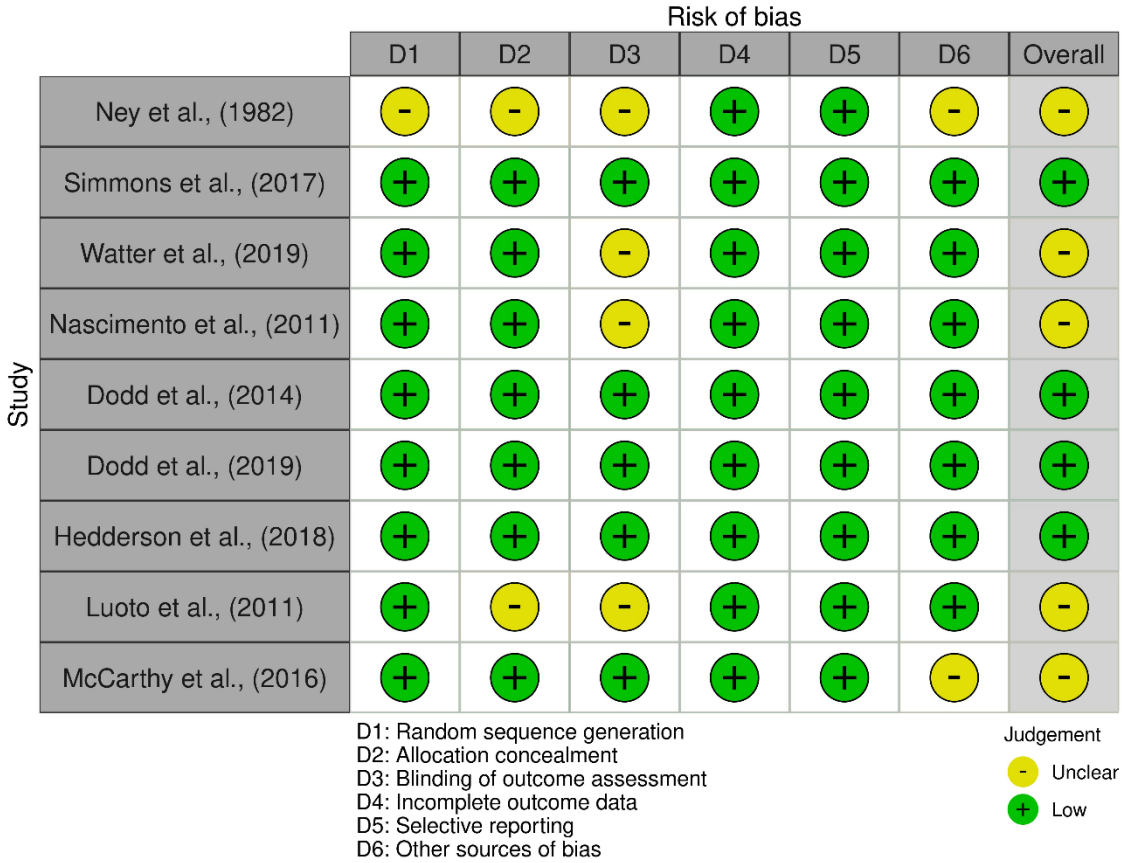
McCarthy et al., (2016) (159)	Australia 2011 - 2012 RCT	382 pregnant women. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Serial self-weighing and simple dietary advice Usual care	A composite of one or more obstetric complication (gestational diabetes, pregnancy induced hypertension, Mode of Delivery other than spontaneous vaginal delivery, postpartum haemorrhage, 3rd/ 4th degree tear, admission to intensive care unit, high dependency unit stay >6 hours, maternal death).	To determine the effect of the intervention on obstetric outcomes. Gestational weight change – No effect – Mean GWG was not significantly different between groups. Systolic and diastolic blood pressure change – Not an outcome

Abbreviations: HE, Healthy Eating; PA, Physical Activity; GWG, Gestational Weight Gain; BMI, Body Mass Index; IOM, Institute of Medicine

2.4.2. Risk of bias

Five studies were judged as unclear (158-161, 164) and four judged to have a low risk of bias (156, 157, 162, 163) (Table 4). Where unclear risk was evident, they were more likely to be low risk than high risk. The two reviewer's judgement for each domain is available in Appendix 8.

TABLE 4 RISK OF BIAS OF INCLUDED STUDIES



2.4.3. Intervention characteristics

Intervention procedures varied including the primary target behaviour or focus of the intervention (i.e. diet, physical activity, weight or a combination of these), delivery method, number, frequency and duration of intervention sessions, delivery personnel, intervention intensity and inclusion or absence of a theoretical underpinning (Table 5).

TABLE 5 INTERVENTION CHARACTERISTICS OF INCLUDED STUDIES USING TIDIER FRAMEWORK

Study	Groups	Interventions							Sessions		
	Comparator **Intervention**	**Underlying theory**	**Content**	**Provider (including any training)**	**Mode**	**Location**	**Duration/ Gestation at recruitment**	**Intensity**	**Number/ Frequency**	**When or at what gestation**	**Length per session**
Studies that provide data on pregnant women with chronic hypertension and/ or pre-existing diabetes											
Simmons et al., (2017) (139)	Usual care	N/A	Usual care	Midwife or obstetrician	N/A	N/A	Recruited <19+6/40	N/A	N/A	N/A	N/A
	Healthy eating (HE) Physical activity (PA) Healthy eating and physical activity (HE and PA)	Patient empowerment Cognitive behavioural technique Motivational interviewing	HE - lower carbohydrate, lower fat, higher protein diet. Focus on portion size to limit calories. GWG of 5kg. Handbook, educational materials and scales provided PA - aerobic and anaerobic PA promoted. GWG of 5kg. Materials as per HE plus pedometer/ Dyna-bands. HE and PA – above two interventions combined.	Health coach-training program included observed session. Standardisation sessions every 6 months. Selected on natural ability to be emphatic, background in either behavioural change, HE and/ or PA. Training on MI technique	F2F (individual) Telephone Mail	Hospital or maternity practice	Recruited <19+6/40 Intervention complete by 35/40	3	5 F2F sessions ≤4 phone calls Mail contacts (no. undefined)	Participants preference and availability of coach	30-45 minute sessions Calls ≤20 minutes

Ney, 1982 (138)	Control diet (usual care for women with diabetes)	N/A	Encouraged a diet commonly prescribed in pregnancy Caloric intake based on weight gain and activity levels and a GWG of 20-30lbs. Personal counselling and management according to lab and clinical data.	Usual diabetic team reviewed lab tests and clinical data.	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	High carb, high fibre diet	None described.	As above but nutrition counselling to encourage a daily intake of 60g-70g of dietary fibre and 65% calories from available carbohydrates. Unprocessed wheat bran and/ or muffins provided to have 3x a day.	Usual diabetic team reviewed lab tests and clinical data. Interventionist unclear.	F2F (individual) Telephone	Clinical research centre and High-risk obstetric clinic	Mean 16±2.3 weeks	3	Undefined	Weekly Regular phone contact	Undefined
Studies that provide data on the number of participants with chronic hypertension and/ or pre-existing diabetes but no outcome data available											
Watter et al., (2019) (135)	Current clinical practice	N/A	Dietary advice as per UK national recommendations for antenatal care and weight management	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

	Mediterranean-style diet	Social cognitive theory	Supported to follow the diet. Personalised SMART goals. Mixed nuts, extra virgin olive oil provided. Culturally adapted recipes and grocery list. Group sessions, partners involved. Educational materials.	Trial dietician and trained researchers/ allied health professionals.	F2F (1 individual and 2 group) Telephone	Unclear	From 18 weeks gestation Endpoint unclear	3	3 F2F 2 calls	18/40 20/40 28/40 32/40	Unclear
Nascimento et al., 2011 (137)	Control group	N/A	Routine prenatal advice (standardised nutritional counselling).	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Study group (Exercise counselling)	None described.	Counselling and education on recommended GWG and PA. Exercise journal and home exercises.	Trained physical therapist.	F2F (individual and group).	Unclear	Mean duration 12.3 weeks	2	Weekly Home exercise 5x/ week	Weekly	40 minute classes
Studies that include women with chronic hypertension but provide no further detail on these participants (pre-existing diabetes excluded from these studies)											
Dodd et al., (2014) (134)	Standard care	N/A	State wide perinatal practice (no routine provision of diet, exercise or GWG advice).	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

	Lifestyle advice	Stage theories of health decision making	Dietary advice consistent with Australian standard, individualised information on meal plans, healthy recipes, simple food substitutions, snacking, eating out, food preparation. Encouraged to increase walking and incidental activity. Workbook to monitor progress.	Trained research assistants and research dietician.	F2F (individual) Telephone	Unclear	Recruited between 10 – 20/40	3	3 F2F 3 phone calls	Initial session within 2 weeks of randomisation then 28, 36/40 sessions 22, 24, 32/ 40 phone calls	Unclear
Dodd et al., (2019) (133)	Standard care	N/A	Standard care (no routine provision of advice related to diet, exercise or GWG).	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Lifestyle advice	Stage theories of health decision making	Dietary advice consistent with Australian guidelines emphasising balance, reduce energy dense foods and increase fibre. SMART goals,	Trained research assistants and research dietician	F2F (individual) Telephone	Unclear	Recruited between 10 – 20/40	3	3 F2F 3 phone calls	Initial session shortly after trial entry then at 28, 36/40 20, 24, 32 weeks follow up phone calls.	Unclear

			significant other involved.								
Hedderson et al., (2018) (140)	Usual care for women with GDM	N/A	Health education materials as per usual care. Up to two calls/ week to review blood glucose and lifestyle advice. Nurses and dieticians available by phone. No advice on GWG.	Nurse	N/A	N/A		N/A	N/A	N/A	N/A
	Tailored letter	None described. (To note: this was one element of an intervention, the postnatal component involved counselling and has a theoretical basis)	A tailored letter with 6 messages: weight history, goal GWG specific to BMI, pregnancy weight goal, weight management recommendation, lifestyle tips, risk information on weight gain.	N/A	Postal letter	N/A	After GDM diagnosis	1	1 mailed letter	Shortly after GDM diagnosis	N/A
Luoto et al., (2011) (141)	Usual care group	N/A	Usual care (some dietary counselling and follow up of GW but little PA advice).	N/A	N/A	N/A		N/A	N/A	N/A	N/A

	Intensive counselling	PRECEDE-PROCEED and Stages of Change	Counselling on BMI-specific GWG to meet and to increase/ maintain/ adjust leisure time PA. Counselling to achieve a healthy diet based on Finnish guidelines and diabetes prevention research. Discussed barriers, opportunities for change. Notebooks to monitor behaviours objectives. Optional group exercise sessions.	Nurses and physiotherapists	F2F, messages, telephone	Maternity clinics of primary healthcare centres.	8-12/40 until 37-39/40.	3	5 counselling sessions. Monthly (optional) group sessions	8-12/40 16-18/40 22-24/40 32-34/40 36-37/40	First session = 20-30 minutes then 10-15 minutes 2 hours (optional) group sessions
McCarthy et al., (2016)	Standard care	N/A	Information card with booking BMI and advice on target GWG. No regular weighing.	N/A	N/A	N/A		N/A	N/A	N/A	N/A

	Serial self-weighing and simple dietary advice	None described.	Information card with booking BMI and advice on target GWG. Card included weight management advice based on the Australian Guide. Dietary advice given, encouraged serial self-weighing. Stickers on AN notes to encourage discussion about weight with care providers.	Research midwife.	F2F (individual).	Unclear	From 14/ 40 until delivery.	2	1	Unclear	30 minutes
		Underlying theory	**Focus/ content of intervention**	**Providers**	**Mode of delivery**	**Location**	**Duration**	**Intensity**			
Summary	-	5 with a theoretical basis	GWG only = 0 Diet only = 4 PA only = 0 GWG, diet, PA = 3 GWG, diet = 2 GWG, PA = 2 Diet, PA = 0	Research midwives nurses, research assistants, dieticians, physical therapists, trained health coaches	In-person and remote (calls, messages, mail) = 6 In-person only = 2 Remote only (via a posted letter) = 1	Where provided included: healthcare facilities (hospital or midwife clinic) and a clinical research centre.	Most recruited from 8 – 20/ 40 and sessions (if >1) often continued until around term.	Level 1 = 1 Level 2 = 2 Level 3 = 6	-	-	-

Abbreviations: HE, Healthy Eating; PA, Physical Activity; GW, Gestation Weight; GWG, Gestational Weight Gain; F2F, Face to face.

Comparators were usual or standard care that reflected current clinical practice and guidelines, but were minimally described by most authors. Generally, comparators either did not include dietary, physical activity, or GWG guidance or only minimal advice. Two studies included care for a diabetic population that included monitoring blood sugars and dietary advice (161, 163).

2.4.4. Gestational weight change

All studies reported gestational weight change as an outcome. One study presented this as the proportion of women meeting the Institute of Medicine (IOM) guidelines for weekly rate of GWG (163). Two studies provided subgroup data on the target population (161, 162). Simmons *et al.,* (2017) found women with chronic hypertension in the intervention groups gained less gestational weight overall than those in the control group (162). The least weight was gained in the intervention arm that included both the diet and physical activity component (Table 6**).** Ney *et al.,* (1982) found that the participants (pregnant women with pre-existing diabetes) gained less gestational weight in the dietary intervention group (161) (Table 6).

TABLE 6 GESTATIONAL WEIGHT CHANGE FOR INCLUDED STUDIES THAT INCLUDED ANALYSIS OF PARTICIPANTS WITH CHRONIC HYPERTENSION AND/OR PRE-EXISTING DIABETES

Study ID (Author, year)	No. participants	GWG end points	Control group (kg) Mean±SD	Intervention group(s) (kg) Mean±SD		
Ney *et al.*, (1982) (161)	20 participants type 1 or type 2 diabetes.	Maternal weight gain during pregnancy. End points not defined.	Control group (*n* = 9)	High carb, high fibre diet (*n* = 11)		
			15.9±NR	11.8±NR		
Simmons *et al.*, (2017) (162)	436 randomised in total 41 women randomised with chronic hypertension	Weight at baseline (study entry) and weight between 35 to 37 weeks.	Usual care (*n* = 9)	HE and PA (*n* = 12)	HE (*n* = 9)	PA (*n* = 11)
			11.2±5.4	4.9±3.9	8.4±5.0	7.7±4.7

Abbreviations: NR = Not reported; GWG = Gestational weight gain; HE = Healthy Eating; PA = Physical Activity

The remaining studies reported outcomes for the total, i.e. mixed populations, and are summarised as having 'no effect' (i.e. no difference between the groups) or a 'positive' effect (Table 3). Two studies (158, 163) reported a positive effect of the intervention on GWG and four studies (156, 157, 159, 164) found no effect of the intervention on attenuation of GWG. Nascimento *et al.,* (2011) found a positive effect for women who were overweight (*n* = 9) when data were stratified by BMI but when data was analysed as a whole, no effect was observed (160).

2.4.5. Blood pressure change

Nascimento *et al.,* (2011) reported systolic and diastolic blood pressure change, for the total population, from 16 weeks gestation to 40 weeks gestation. No analysable data were extractable or available upon request from authors (160). Authors stated that the

intervention did not affect systolic or diastolic arterial blood pressure. The remaining studies did not collect or report blood pressure data as a primary or secondary outcome.

2.4.6. Behaviour change techniques

Eight of the included studies gave sufficient information to code the BCTs in the interventions (156-160, 162-164). The 93 BCT's were collated into 14 domains to present more consolidated results (149). Studies included between five and eight different behaviour change categories (Table 7).

TABLE 7 BEHAVIOUR CHANGE CATEGORIES UTILISED WITHIN THE INTERVENTIONS OF INCLUDED STUDIES

Study	Code	Behaviour change category	Examples
Simmons et al., (2017)	*1*	Goals and Planning	Women encouraged to set personal goals and action plans.
	2	Feedback and Monitoring	They will have the possibility to measure their weight if they find this helpful.
	3	Social support	Behavioural strategies used to mobilise social support
	4	Shaping knowledge	Discussions about past successes
	5	Natural consequences	Education on risks and benefits supported with a manual
	9	Comparison of outcomes	Helping women to resolve feelings of ambivalence and a decisional balance sheet used as a tool.
	13	Identity	Making women aware that they can influence their weight even during pregnancy
	15	Self-belief	Discussion about past success
	Total no. behaviour change categories: 8		
Ney, (1982)		There is not enough information to appropriately code any behaviour change techniques.	Clinicians 'prescribed' a diet to follow. Dietary education was given to both groups. Although behaviour change techniques could be coded because, for example, a meal plan including caloric intake, was provided, they are not part of a behaviour change strategy from the interventionist that is

			directed at changing the participant's behaviour.
	Total no. behaviour change categories: 0		
Watter et al., (2019)	*1*	Goals and Planning	Personalised goals were based on the SMART model.
	3	Social support	Partners were involved as well as the whole family where possible.
	4	Shaping knowledge	A bespoke recipe book provided cooking advice.
	5	Natural consequences	The benefits of the diet on mother and baby were included in discussions.
	6	Comparison of behaviour	Participants were encouraged to share stories about their experiences including successes.
	9	Comparison of outcomes	Interventionists were considered credible sources of information.
	12	Antecedents	Cooking ingredients were provided to participants to use for the whole family.
	Total no. behaviour change categories: 7		
Nascimento et al., 2011	*1*	Goals and Planning	Encouraged to perform 5 home exercises per week.
	2	Feedback and Monitoring	Women recorded the type of exercise in a journal.
	4	Shaping knowledge	Participants provided with information about amount, intensity and duration of exercise and

			they attend an exercise class.
	5	Natural consequences	Counselled on important of physical activity during pregnancy and the effects.
	6	Comparison of behaviour	Attend an exercise class.
	7	Associations	Provided with a list of exercises to perform at home.
	8	Repetition and substitution	Attend an exercise class and encouraged to repeat these exercises when at home.
	9	Comparison of outcomes	Interventionists were considered credible sources of information.
	Total no. behaviour change categories: 8		
Dodd et al., (2014)	*1*	Goals and Planning	Women encouraged to make achievable goals and consider strategies to overcome barriers.
	2	Feedback and Monitoring	Participants provided with a workbook to self-monitor their progress.
	4	Shaping knowledge	Participants were given information about healthy snacking and eating out and current standards for diet and physical activity during pregnancy.
	9	Comparison of outcomes	Interventionists were considered credible sources of information.
	12	Antecedents	Participants were provided with advice on how to swap in healthier food choices and how to be healthier when eating out.
	Total no. behaviour change categories: 5		

Dodd et al., (2019)	*1*	Goals and Planning	Goals set using SMART model.
	2	Feedback and Monitoring	Participants encouraged to self-monitor.
	3	Social support	Women were encouraged to involve their partner.
	4	Shaping knowledge	Example menu plans and a recipe book were provided.
	9	Comparison of outcomes	Interventionists were considered credible sources of information.
	Total no. behaviour change categories: 5		
Hedderson et al., (2018)	*1*	Goals and Planning	Gestational weight gain goal based on current weight gain trends
	2	Feedback and Monitoring	Recommendations for weight are based on whether they have been gaining too quickly, are on track or too slowly relative to gestation.
	4	Shaping knowledge	Women provided with a list of specific lifestyle tips
	5	Natural consequences	The letter included a risk statement about the consequences of gaining too much weight during pregnancy
	9	Comparison of outcomes	The letter was printed on Perinatal Centre letterhead and personalised with the recipient's name
	Total no. behaviour change categories: 5		
Luoto et al., (2011)	*1*	Goals and Planning	Participants selected objectives to work on and they agreed and reviewed weekly action plans.

	2	Feedback and Monitoring	A follow up notebook was used to set plans.
	3	Social support*	Group exercise provided participants with social support.
	4	Shaping knowledge	Participants were provided with advice on various ways to be physically active.
	5	Natural consequences*	Advised on the benefits and effects of physical activity.
	6	Comparison of behaviour*	At the group exercise classes they were introduced to the ways in which to be physically active.
	8	Repetition and substitution	The participant's objectives were revised and set at a higher level or changed if needed.
	9	Comparison of outcomes	Interventionists were considered credible sources of information.
	Total no. behaviour change categories: 5 (+3)*		
McCarthy et al., (2016)	*1*	Goals and Planning	Gestational weight gain goal was based on BMI and participants were encouraged to discuss weight at appointment
	2	Feedback and Monitoring	Provided with a weight chart to record weights throughout pregnancy
	4	Shaping knowledge	Provided with information about weight management during pregnancy
	7	Associations	A sticker was planned on the antenatal notes to prompt discussion about weight at appointments

9	Comparison of outcomes	Interventionists were considered credible sources of information.
Total no. behaviour change categories: 5		

Note on Luoto et al., (2011) Many of the BCT were from the group exercises classes and most of this information was in the protocol. The group classes were offered during the primary visit, an opportunity to attend monthly 'thematic meetings on physical activity' which included group exercise.*

The most common techniques, used in all eight of the coded interventions, were ‘Goals and Planning’, ‘Shaping knowledge’ and ‘Comparison of outcomes’ (Figure 4). ‘Feedback and monitoring’ was coded in seven interventions. Four domains, ‘Reward and threat’, ‘Regulation’, ‘Scheduled consequences’ and ‘Covert learning’, were not identified in any of the coded studies.

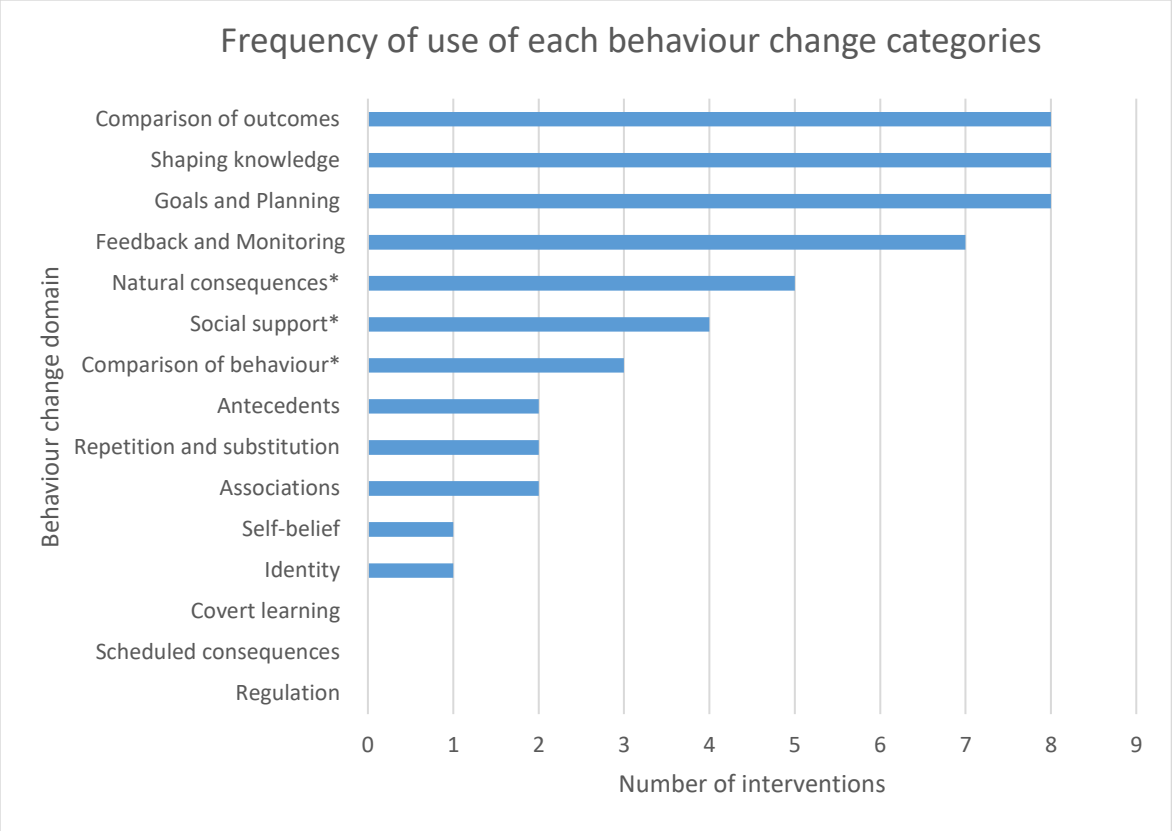


FIGURE 4 FREQUENCY OF USE OF EACH BEHAVIOUR CHANGE DOMAIN. *INCLUDES ONE STUDY WITH THE RELATED BCT OFFERED IN THE OPTIONAL SESSION

2.4.7. Process outcomes

Simmons *et al*., (2017) reported data on retention rates and found that 78 women withdrew before the final oral glucose tolerance test of which 21% had chronic hypertension (p = 0.02) (162). Process outcomes were reported in the remaining eight studies but no detail about the characteristics of women (i.e. whether they had hypertension or diabetes) were described and therefore are not reported here.

2.4.8. Behavioural outcomes

Whilst all studies targeted changes in diet or physical activity, none of the included studies reported the changes in dietary intake and physical activity levels for women with chronic hypertension and/ or pre-existing diabetes.

2.4.9. Clinical maternal and fetal outcomes

Watter et al., (2019) reported maternal and fetal outcomes for women with chronic hypertension including pre-eclampsia, gestational diabetes, small for gestational age and admission to neonatal unit (Table 8). No differences between the groups were found.

TABLE 8 MATERNAL OUTCOMES FOR THE WOMEN WITH CHRONIC HYPERTENSION (WATTER ET AL., 2019)

Pre-eclampsia	Intervention	Control
Number measured	36	30
Number with event	7	2
	aOR 3.62 (0.65 - 20.01), adjusted p-value 0.25	
GDM		
Number measured	27	27
Number with event	5	13
	aOR 0.28 (0.07 - 1.07), adjusted p-value 0.19	
SGA		
Number measured	35	29
Number with event	10	5
	aOR 2.02 (0.58 - 7.02), adjusted p-value 0.09	
Admission to neonatal unit		
Number measured	36	30
Number with event	6	2
	aOR 2.43 (0.43 - 13.79), adjusted p-value 0.22	

Abbreviations: GDM, Gestational diabetes; SGA, small for gestational age

The remaining included studies reported some or all of the pre-specified maternal and fetal outcomes to be collected in the review but data was available only for the total participant population and therefore not reported here.

2.5. Discussion

2.5.1. Key findings

Whilst there were many studies reporting interventions to promote lifestyle change during pregnancy, this review has found no studies that focused specifically on pregnant women with chronic hypertension and so very limited information on the impact of lifestyle change in this group on weight or blood pressure. One study focused on women with pre-existing diabetes and the remaining studies included mixed pregnant populations. Authors often did

not collect or report key baseline characteristics, including key chronic conditions, making it difficult to determine whether participants with these conditions were included. Where this information was present, women with chronic conditions were often excluded from trials, or in circumstances where they were included, no subgroup analysis was performed. Gestational weight change was frequently reported but blood pressure change was limited to one study. Therefore, there is a lack of evidence on the effect of lifestyle interventions on weight and blood pressure in pregnant women with chronic hypertension and/ or pre-existing diabetes, thereby exposing a key gap in the literature.

2.5.2. Comparison with literature

Key issues for women with chronic hypertension in pregnancy include their blood pressure and weight because of the higher risk of complications associated with uncontrolled hypertension and excessive gestational weight gain. Previous reviews have established that interventions that incorporate components of diet and physical activity have a modest effect on GWG in the general pregnant population or those who start pregnancy overweight or with obesity (74-76). A review conducted by the i-WIP collaboration also found few studies included or provided information on those with pre-existing conditions and the interventions were not specifically designed for this population. Perhaps due to their different inclusion criteria to this review or ability to access additional data, the i-WIP group conducted a sub-group analysis on women with pre-existing hypertension and diabetes. One-hundred and twenty eight women (2.9% of women in the sub-group analysis) were included in this analysis. The authors reported no differences in the results compared to when the data was analysed as a whole, i.e. those in the intervention group gained less gestational weight than the control. Combining the findings of both reviews, we can confidently say that there has been a lack of focus on pregnant women with these pre-existing conditions, who may benefit the most from lifestyle interventions.

The Mediterranean diet is known to reduce blood pressure in 'high-risk' groups outside of pregnancy (165). The ESTEEM trial, included in the review, investigated the effectiveness of a Mediterranean style dietary pattern in preventing maternal and fetal complications (158). In their sample of pregnant women with metabolic risk factors, authors found mothers in the intervention group gained less gestational weight than the control (MD -1.2kg, 95% CI -2.2 to -0.2) and it reduced the odds of gestational diabetes (aOR 0.65, 95% CI 0.47-0.91). The intervention had no significant effect on preeclampsia or any individual components of the composite offspring outcome. These data were not included in the current review as the published analysis included the total participant population (*n* = 1129), of whom 58 (5%) had hypertension. As well as the Mediterranean diet, authors are increasingly exploring the effect of other dietary patterns in both low and 'high-risk' pregnant populations on various clinical and metabolic outcomes (79, 80, 166-168). Studies indicate that diet during pregnancy has a role in promoting cardiovascular health where adherence to certain diets has the potential to improve maternal and offspring outcomes, support gestational weight management, glycaemic control and reduce blood pressure. As there continues to be evidence for the positive effect of specific dietary patterns that modify risk factors and support disease management, the current review now indicates that it is pertinent to test and understand the effect of these on important subgroups where there is potential to delay disease progression but where there remains little evidence.

Understanding and describing key behaviour change techniques used within interventions is an important step in developing future effective interventions. Two existing systematic reviews examined the effectiveness of BCT on GWG (118, 169). There is cross-over with the most frequently identified BCT found in the current review. Although, unlike these reviews, we were unable to determine the effectiveness of the techniques, we further the existing evidence-base by presenting the most frequently utilised techniques that should continue to be tested so that the core active components can be determined and, in turn,

ensure the implementation of effective interventions into practice. These will be revised when designing the initial intervention components reported in Chapter 5.

2.5.3. Strengths and limitations

This is the first systematic review to examine the effect of lifestyle interventions on weight and blood pressure outcomes in a pregnant population who have chronic hypertension and/ or pre-existing diabetes. Although studies of mixed populations were included, the focused review has helped identify significant gaps in this area of research. The review offers new insights and a new angle in which researchers should consider in future work in this area.

Robust methods were used including duplicate screening and data extraction with regular discussions on discrepancies to improve reliability. Authors were contacted, grey literature and the reference lists of recent and similar systematic reviews were searched. Risk of bias was assessed independently with none classified as high risk. Where bias was unclear, we decided that it was more likely to be low risk than high risk, therefore any bias present was unlikely to alter the conclusions made.

Insufficient reporting of inclusion and exclusion criteria in many studies created challenges during the review process and required us to make several assumptions based on the available data. Unlike women with pre-existing diabetes, it was not always clear if women with chronic hypertension were included or excluded in the sample despite contacting authors for clarification.

Pregnant women with chronic hypertension and/ or pre-existing diabetes were both included in the review. Although these populations share similar characteristics, differences exist. However, insights from diabetes research are often translated to hypertensive populations, perhaps because lifestyle modification is important in the management of both and is recommended first line treatment in general practice. This suggests that including populations with pre-existing conditions in one review, and acknowledging the relationship

between them, is a reasonable approach and has been noted in other studies (74, 170-172). Furthermore, transparency in reporting shows clearly the inclusion or exclusion of each of the two populations in each study and data has not been aggregated; reducing misinterpretation of the review findings.

There were insufficient data to perform a random effects meta-analysis and therefore I decided to conduct a narrative synthesis, which was more appropriate to address the review question. Transparency in reporting the findings helped avoid over-interpretation of included studies that had less directness in answering the review question (i.e. being explicit about studies that included mixed pregnant population). This narrative synthesis has provided a useful presentation of the evidence-base; vital in advancing the research field.

2.5.4. Implications for future research

Authors should attempt to collect and publish baseline data on important pre-pregnancy medical conditions, including hypertension and where they are excluded this should be clear in the eligibility criteria. If women with chronic medical conditions are included, authors should be encouraged to publish the necessary data required to perform additional subgroup analysis to support the collation of evidence on these small, but important, groups. Blood pressure is an important and routinely collected clinical parameter. Collecting this data could help in determining how improvements in diet and physical activity levels may affect blood pressure during pregnancy and into the postnatal period. Development of isolated interventions in pregnancy that consider individual conditions appears limited. Further consideration to conduct primary studies examining the effect of lifestyle interventions in important subgroups, by harnessing the knowledge from non-pregnant 'high-risk' populations, is warranted.

2.6. Conclusion

This Chapter has revealed a shortage of primary interventional studies examining the effect of lifestyle interventions in pregnant populations who enter pregnancy with chronic conditions. Regular exclusion of this important group, or omission of this detail in describing participant characteristics, hinders the ability to understand what is most effective for women who may benefit the most from lifestyle modification to reduce the risk of adverse pregnancy outcomes as well as improve long-term cardiovascular health.

Determining effective interventions is necessary to build evidence based recommendations for practice. To further our understanding of existing guidelines in relation to the care women receive about lifestyle during pregnancy, the following chapter will consider current clinical practice guidelines that inform weight management care during pregnancy within NHS maternity units. Subsequent chapters (Chapter 4, Chapter 5, Chapter 6) will address the gaps identified in this review to design and develop a lifestyle intervention with women who have chronic hypertension and have been pregnant.

Chapter 3 Clinical guidelines for the management of weight during pregnancy: a qualitative evidence synthesis of practice recommendations across NHS Trusts in England

3.1. Overview

This chapter provides a picture of existing weight management recommendations drawn from maternity units across England. Whilst the previous chapter specifically focused on pregnant women with pre-existing conditions participating in clinical trials, this chapter widens the lens to current NHS recommendations for care related to lifestyle.

Chronic hypertension in pregnancy may be accompanied by a higher weight which is associated with an increased risk of poor outcomes (See Chapter 1, Section 1.7). The National Institute for Health and Care Excellence (NICE) and Royal College of Obstetricians and Gynaecologists (RCOG) provide clinical guidelines for weight management during pregnancy (51, 52). These national guidelines are interpreted by NHS Trusts in England to fit the local context, population, resources and infrastructure. They turn best practice recommendations into policies and practical actions at the interface of maternity care delivery, supporting practitioners to support women in optimum weight management. An understanding of the weight management recommendations that exist within UK maternity units is currently missing.

This chapter has been published as a manuscript in BMC Pregnancy and Childbirth journal: Goddard, L., Astbury, N.M., McManus, R.J. et al. Clinical guidelines for the management of weight during pregnancy: a qualitative evidence synthesis of practice recommendations across NHS Trusts in England. BMC Pregnancy Childbirth 23, 164 (2023). https://doi.org/10.1186/s12884-023-05343-9 (Appendix 9).

3.2. Aim and research questions

This chapter presents a theoretically underpinned qualitative analysis of how local NHS trusts interpret clinical guidelines for weight management during pregnancy and the postnatal period from the national guidance. I aimed to go beyond observing and documenting variations to synthesising the findings into analytical interpretations.

The research question posed was:

- How do NHS Trusts interpret national weight management guidelines to their local context to support weight management during pregnancy?

3.3. Theoretical framework

The Birth Territory Theory (BTT) and the risk discourse around pregnancy were introduced in Chapter 1, Section 1.10.2 and 1.10.3. The BTT and its key concepts critique the power imbalances in the woman/ professional relationship and encourages reflection, as advocated by UK maternity policy, to listen to, understand and work in partnership with each individual woman to ensure a positive pregnancy and birth experience whilst minimising poor outcomes. The BTT and the risk discourse in maternity were appropriate to provide an in-depth interpretation of the synthesis findings considering the purpose of guidelines within the context of current midwifery practice.

3.4. Methods

3.4.1. Design

This was a qualitative evidence synthesis of local NHS clinical practice guidelines and used the framework analysis approach of Gale et al., (2013) and synthesis methods of Thomas and Harden (2008) (173, 174). The framework approach was appropriate to systematically organise and provide clarity to the scope of the analysis and helped to provide a distinctive data summary (173). The Framework Method has become popular in applied health research that analyses textual data (175). It provides opportunity to compare across cases

(in this case, guidelines) as well as within cases. The Framework method is a flexible and adaptive approach, often used alongside a thematic analysis. Thematic synthesis as developed by Thomas and Harden (2008) was considered the best method for this study as it provides a flexible and transparent method for identifying, analysing and reporting patterns in a dataset (174, 176). The synthesis involved identifying, developing and interpreting themes across all of the guidelines, going beyond the individual documents, to construct analytical themes to help explain the findings in light of the research question.

3.4.2. Permissions

The University Clinical Trials and Research Governance group confirmed that no ethical approval was required to carry out this project. The Departments Information Governance officer was also consulted who confirmed that no action was required since no personal data were involved. All activities complied with clinical governance requirements at each NHS Trust. No patient outcome or process data was required.

3.4.3. Search method

A purposive sample of NHS Trusts across England was sought from the seven recognised NHS regional areas (www.england.nhs.uk/about/regional-area-teams, Accessed 08.04.2021). Purposive sampling was appropriate to ensure representation and adequate variation of the pre-specified attributes. These attributes were considered to potentially influence the results and included rural/ urban setting, catchment population size, number of births per year and university/ teaching status. Information was collected from provider websites and publicly available annual reports. If the University/teaching hospital status was unclear but there were established links with university institutions or teaching and education facilities, this was noted. The rurality of the Trust was judged as the top 10% of Trusts with the highest proportion of patients living in rural areas in 2018/19 and remoteness was judged as those with ‘unavoidably small hospitals’ as reported by Nuffield Trust (177, 178).

Guidelines were downloaded from Trust websites using disclosure logs or publication schemes. If guidelines were not available this way, an application through a Freedom of Information process (email or online form) between 1st April and 1st June 2021 was sent. One follow-up email was sent if there was no reply within 20 working days (179). In the case of non-responders, a Trust within the same region of similar size and university status was contacted. Upon receipt of each guideline, the associated Trust was assigned a unique sequential code to ensure anonymity.

3.4.4. Quality appraisal

Existing reviews of clinical guidelines have used the AGREE II tool to assess the quality of guidance including what and how information is reported to assess the rigour of its development (180). The purpose of this synthesis was not to judge the quality of the existing guidelines but rather to present what is currently recommended locally and examine the content of the guideline. Therefore, no quality appraisal was performed.

3.4.5. Data abstraction

Narrative sections of the localised guidelines were extracted and entered verbatim into NVivo for coding (QSR International Pty Ltd. (2020) NVivo (released in March 2020)).

3.4.6. Data Synthesis

Analysis began with familiarisation of the guidelines and involved reading and re-reading the guidelines; vital in developing an initial understanding, impression and interpretation of the data.

Narrative data were coded into a deductive framework of 18 pre-specified categories, constructed from the recommendations of the NICE Weight Management in Pregnancy guidelines and the RCOG Care of Women with Obesity in Pregnancy guideline (51, 52) (Table 9). Descriptive memos for each category supported consistency in coding. Each pre-specified category, and the coded text within it, was extracted and imported into Excel

(Microsoft Excel 2016) to generate a matrix, enhancing visualisation for data comparison and interpretation. Cells were tagged with direct quotes or important interpretations, in order to capture nuances and ambiguity between guidelines. This led to collapse and refinement of categories into broad descriptive themes.

Regular discussions were held with supervisors to discuss the emerging themes and to reflect on interpretations. Initial descriptive themes were further developed and refined through the critical lens of the BTT and the discourse of risk into three analytical themes that are presented in the results.

TABLE 9 FRAMEWORK BASED ON PRE-SPECIFIC CATEGORIES CONSTRUCTED FROM NICE AND RCOG GUIDELINES.

NICE/ RCOG recommendation (category)	Description and instruction
Address any concerns about physical activity in pregnancy	NICE: "Advise that moderate-intensity physical activity will not harm her or her unborn child." This includes reassuring women about the safety of physical activity in pregnancy.
Addressing a woman's concerns	NICE: Be "...sensitive to any concerns she may have about her weight." This includes any detail about the sensitivity of conversations about weight or the importance of communication between the woman and healthcare professional.
Advice on benefits of healthy diet and physical activity	NICE: "Advise that a healthy diet and being physically active will benefit both the woman and her unborn child during pregnancy and will also help her to achieve a healthy weight after giving birth." Discussions with the healthcare professional around healthy eating and being physically active that is not specific. Code as ‘Specific dietary or physical activity advice’ if specific advice is given.
Behaviour change advice	“Evidence-based behaviour change advice includes: understanding the short, medium and longer-term consequences of women's health-related behaviour helping women to feel positive about the benefits of health-enhancing behaviours

	and changing their behaviours recognising how women's social contexts and relationships may affect their behaviour helping plan women's changes in terms of easy steps over time identifying and planning situations that might undermine the changes women are trying to make" Only code this if it does not fit into any other code. For example, if they are provided with individualised advice, code only as 'Practical and tailored information'. This is because this code describes the way in which advice (within the other codes) may be provided.
Breastfeeding	NICE: "Midwives and other health professionals should encourage women to breastfeed. They should reassure them that a healthy diet and regular, moderate-intensity physical activity and gradual weight loss will not adversely affect the ability to breastfeed or the quantity or quality of breast milk." RCOG: "Obesity is associated with low breastfeeding initiation and maintenance rates. Women with a booking BMI 30 kg/m2 or greater should receive appropriate specialist advice and support."
Dieting or weight loss in pregnancy	NICE: "Dieting during pregnancy is not recommended as it may harm the health of the unborn child." RCOG: "Anti-obesity or weight loss drugs are not recommended for use in pregnancy."

	Any recommendation that refers to dietary programmes/ diets that promote weight loss.
Discuss her current eating habits and physical activity levels	NICE: "At the earliest opportunity, for example, during a pregnant woman's first visit to a health professional, discuss her eating habits and how physically active she is. Find out if she has any concerns about diet and the amount of physical activity she does and try to address them."
Dispelling myths	NICE: "Dispel any myths about what and how much to eat during pregnancy. For example, advise that there is no need to 'eat for two' or to drink full-fat milk. Explain that energy needs do not change in the first 6 months of pregnancy and increase only slightly in the last 3 months (and then only by around 200 calories per day)."
Explaining risks	NICE: "Explain to women with a BMI of 30 or more at the booking appointment how this poses a risk, both to their health and the health of the unborn child. Explain that they should not try to reduce this risk by dieting while pregnant and that the risk will be managed by the health professionals caring for them during their pregnancy." Do not code if risks are only stated at the beginning of the guideline (as part of the introduction). It should be clear whether risks are discussed with the woman.

Height and weight at the first contact	NICE: "Measure weight and height at the first contact with the pregnant woman" "Weight, height and BMI should be recorded in notes, the woman's hand-held record and the patient information system"
Not within NICE recommendations	Anything that is related to weight management that is not referred to by NICE or RCOG guidelines.
Practical and tailored information	NICE: "Offer practical and tailored information. This includes advice on how to use Healthy Start vouchers to increase the fruit and vegetable intake of those eligible for the Healthy Start scheme (women under 18 years and those who are receiving benefit payments)." Any guideline that indicates providing personalised or tailored advice based on the individual woman. If this is coded, check for code “Discuss her current eating habits and physical activity levels” If women are referred to a dietician or other programme it is likely they will receive personalised advice however for the purpose of examining the guideline only and therefore, first line of care, do not code if not explicitly described that advice is personalised or tailored.
Recommended weight gain ranges	NICE: "Many pregnant women ask health professionals for advice on what constitutes appropriate weight gain during pregnancy. However, there are no

	evidence-based UK guidelines on recommended weight-gain ranges during pregnancy.” RCOG: "There is a lack of consensus on optimal gestational weight gain. Until further evidence is available, a focus on a healthy diet may be more applicable than prescribed weight gain targets." Code if weight gain thresholds are given (and which ones, i.e. IOM) even if the lack of evidence on weight gain ranges is acknowledged.
Referrals	NICE "Offer women with a BMI of 30 or more at the booking appointment a referral to a dietitian or appropriately trained health professional for assessment and personalised advice on healthy eating and how to be physically active." Does not include obstetric or anaesthetic referrals for risk assessment or birth planning. Only referrals relating to weight management. Code even if guideline is not clear about who the referral is for or who/ where they are being referred. Code if weight management programmes are highlighted, for example, Slimming World, even if there isn’t a formal referral process described.
Signposting to reputable sources of information	NICE "Reputable sources of information and advice about diet and physical activity for women before, during and after pregnancy include: The Department

	of Health's 'The pregnancy book' and 'Birth to five' and the NHS eat well website." "Advise her to seek information and advice on diet and activity from a reputable source" Code if women are provided with a Trust leaflet/ signposted to Trust website to access content on weight management during pregnancy but do not code if these resources only detail obstetric or anaesthetic risks.
Specific dietary or physical activity advice	NICE: Specific dietary advice, e.g. eat fibre rich foods, eat at least 5 portions of fruit and vegetables each day, avoid increasing calorie intake. Specific physical activity advice e.g. 150 minutes of exercise per week.
Weighing women	NICE: "Do not weigh women repeatedly during pregnancy as a matter of routine. Only weigh again if clinical management can be influenced or if nutrition is a concern". RCOG: “For women with obesity in pregnancy, consideration should be given to reweighing women during the third trimester to allow appropriate plans to be made for equipment and personnel required during labour and birth” Code if women are weighed throughout pregnancy with information on recommended gestations.

	Code if recommendation is risk assessment weight in the third trimester as this is a weight that would influence clinical management. However, it is important to note, this is not for weight management purposes. For example, it is not for the purpose of starting a conversation with the woman about her diet and physical activity levels.
Weight management postpartum	NICE: "Encourage them to lose weight after pregnancy." RCOG: "Women should be supported to lose weight postpartum and offered referral to weight management services where these are available." Code both those that recommend providing healthy lifestyle advice and those that signpost women to other healthcare professionals/ weight management services.

3.4.7. Patient and Public Involvement

A plain English Summary was required on application to present a poster at the NIHR Academy Members Conference. Patient and Public Involvement (PPI) representatives who were involved in the DAPHNY study (reported in Chapter 5) shared their views on the plain English summary. Although not involved until after the research had been undertaken, this was useful as they had no prior knowledge of what the research involved and therefore their input was beneficial in identifying whether it was understandable by a lay audience. The PPI representatives were part of an ongoing discussion relating to the DAPHNY study which involved finding out their views on the intervention that aimed to support healthy behaviours. These conversations involved discussing weight management during pregnancy which helped orientate my thinking around this topic to develop more of an understanding of the woman's perspective.

3.5. Results

A total of 29 hospital NHS Trusts were contacted, and 28 guidelines received (Figure 5).



FIGURE 5 A MAP OF NHS TRUSTS CONTACTED FOR CLINICAL GUIDELINES. MAP CREATED WITH ZEEMAPS (HTTP://WWW.ZEEMAPS.COM)

Nine trusts were classified as rural or remote, 14 as university or teaching hospitals with five classified as both rural or remote with university or teaching status. The number of hospitals within individual Trusts ranged from one to eight, with number of births for the year 2019-2020 ranging from 955 to 14,270 (Table 10).

TABLE 10 CHARACTERISTICS OF NHS TRUSTS IN ENGLAND THAT PROVIDED GUIDELINES

*SOURCE: NHS Digital 2019/20

** Rural is classed as the top 10% of Trusts with the highest proportion of patients living in rural areas in 2018/19, calculated from Hospital Episode Statistics. Remote is classed as those with 'unavoidable small hospitals' (SOURCE: Nuffield Trust)

Code allocated to NHS Trust	Number of births per year*	Rural or remote**	Teaching/ University status	No. main hospital sites within Trust	Name of guideline
B	955	Remote	No	1	Standard Operational Procedure for the Management of Pregnancy Women whose Body Mass Index is ≥30kg/m^2
H	1295	Remote	No	1	Obesity in Pregnancy guideline
Y	1650	Remote	No	1	Guideline for the Management of obesity during pregnancy
AA	1925	No	No	1	Obesity in pregnancy birth and postnatal period
C	1960	Rural	No	1	Clinical guideline for the management of Obesity in Pregnancy
L	3775	No	Yes	1	Obesity in pregnancy, labour and puerperium
X	5840	No	No	1	The management of obesity in pregnancy

K	2580	No	Yes	2	Care of Pregnant Women with a Raised BMI ≥30kg/m^2
Q	3440	No	Yes	2	BMI Management in Pregnancy
E	4065	No	No	2	Raised Body Mass Index in Pregnancy
O	4270	Rural	Yes	2	Obesity: Management of Pregnant Women with a Raised BMI at Initial Consultation
BB	5125	Rural	Yes	2	Assessing and managing extremes of BMI in pregnancy
F	1495	No	No	3	Obesity in Maternity Care Guideline
A	2825	Remote	Yes	3	Obesity in Pregnancy
G	3805	No	No	3	Management of Obesity in Pregnancy Guideline
S	4010	Rural	Yes	3	Increased Body Mass Index (BMI) in Pregnancy, Labour and Post Delivery Clinical Guideline
J	4955	No	No	3	Management of obese women in pregnancy
U	5585	No	No	3	Obese Pregnant Women
W	5910	No	No	3	Management of Women with Obesity in Pregnancy

M	6310	No	No	3	Obesity in pregnancy
N	9030	No	No	3	Care of women with obesity in pregnancy
R	5230	No	Yes	4	BMI: Optimal weight for pregnancy and childbirth. Guidelines for women with BMI ≥30kg/m^2
Z	14270	No	Yes	4	Obesity in Pregnancy
T	8960	No	Yes	5	Obesity in Maternity
I	6007	No	Yes	6	Raised BMI during pregnancy
D	4820 4540 Figures from two merged Trusts.	No	Yes	7	Obesity in Pregnancy
P	4420	Remote	Yes	8	Obesity guidelines
V	7640	No	Yes	1	Management of a pregnancy for women with a BMI ≥30kg/m^2

Total = 28	N/a	9 rural/ remote	14 University/ teaching hospitals	N/a	N/a

All the guidelines received classified women with obesity as having a BMI≥30kg/m^2, except for one guideline (Guideline C) which classified women with obesity if they had BMI≥35kg/m^2. The synthesis of local clinical guideline interpretations of national guidance to deliver weight management care to people who are pregnant or in the postnatal period identified three core themes.

1. Recommendations at odds with a partnership approach to care
2. Advocating surveillance – to what end?
3. Discretionary and ambiguous pathways

Table 11 provides example quotes from the guidelines to exemplify my interpretations made throughout the analysis; providing some context to the themes that were developed. Quotes are divided into recommendations that may promote a supportive and collaborative approach to care and those that may hinder this. Although separating quotes into two broad categories risks ignoring the nuances of recommendations, this small sample provides a useful basis for guideline developers to reflect upon, alongside the findings of this study, to consider how the language used differs between guidelines and how this may influence the care provided by healthcare professionals and in turn, the experiences of pregnant women.

TABLE 11 QUOTES TO EXEMPLIFY INTERPRETATIONS OF THE DATA

Theme	Example quotes of recommendations that may promote supportive weight management care	Example quotes of recommendations that may hinder healthcare professionals ability to provide supportive weight management care
Theme 1: Recommendations at odds with a partnership approach to care	"The use of language in such conversations is an important factor that contributes to the holistic approach to care and the experience women will have of maternity care" *Guideline H*	"Women with BMI greater than 30 kg/m2 are at increased risk of mental health problems and should be screened at each visit" *Guideline J*
	"Sensitive and individualised care is important to avoid stigmatisation and promote a positive experience of pregnancy and birth" *Guideline L*	"Discuss and document risks of obesity in pregnancy – attach a sticky label explaining those risks in her hand-held maternity notes and provide patient information leaflet" *Guideline N*
		"General dietary advice in the antenatal clinic should be offered to all women with raised BMI" *Guideline N*
Theme 2: Advocating surveillance – to what end?	"support women to monitor weight […] reweigh woman to allow planning […] and establish further weight management support" *Guideline K*	"Consider reweighing at 36 weeks and recalculating BMI" *Guideline U*

	"There are currently no UK guidelines on weight gain, as further research is needed. The American Institute of Medicine produced recommendations in 2009, based on research with the American population, which many professionals from the UK have turned to. These should be discussed with women" *Guideline M*	"Encourage weight gain to be kept to 7–10 kg although there is a lack of consensus on optimal gestational weight gain" *Guideline J*
Theme 3: Discretionary and ambiguous pathways	“Eligible women should have an appointment with their named community midwife…following discussion and completion of the healthy lifestyle management checklist a decision should then be made for further support and ongoing care based on the woman’s choice” *Guideline G*	"Refer to dietetics if additional dietary advice is necessary and/ or community-based weight management programme subjected to availability of services in community" *Guideline X*
	“Consider measures to help with weight reduction, including writing to the GP for women with BMI over 30.” *Guideline I*	“Weight loss between pregnancies advised to reduce risks in subsequent pregnancies”. *Guideline M*

3.5.1. Theme 1: Recommendations at odds with a partnership approach to care

Healthcare professionals are advised in national guidance to discuss weight in a sensitive manner and allow opportunities for a woman to raise the concerns she may have about her

lifestyle and the ways to address these (51, 52). Providing a comfortable space for women to voice concerns relies upon a trusting partnership with the health professional. The local guidelines reflected this in varying degrees in their weight management recommendations. Ten emphasised the importance of sensitive and respectful conversations around weight where the language used was an important contributor to achieve a good relationship with the woman that laid the foundation for an equalised partnership (Guideline H, I, L, M, S, X, Y, Z, AA, BB). Seven guidelines further emphasised the importance of this to empower women (Guideline S, Z, AA, BB, H, M), to encourage active engagement in care (Guideline AA, BB, H, M, Z), and to promote a positive pregnancy and birth experience (Guidelines L, H). These examples demonstrate integrative power, protecting the emotional vulnerability that may be felt during sensitive conversations.

Three guidelines highlighted the sensitive nature of conversations around weight stigma and the lower self-esteem that may be experienced by women of a higher weight (Guideline L, M and I). This awareness may support the creation of a non-judgemental, safe environment for women to discuss concerns. An awareness of weight stigma and lower self-esteem was not addressed in twenty-five of the guidelines. A clinical approach was advocated in five guidelines where additional mental health screening was recommended (Guideline J, N, P, X, Z). This reflects RCOG recommendations that as women with a BMI above 30kg/m^2 are at an increased risk of mental health problems, they should be screened for these during pregnancy, without necessarily exploring the source of the mental distress (51).

National guidance advises professionals to inform women of how their weight poses a risk to their pregnancy and birth outcomes and advise that these risks will be managed throughout the pregnancy. Twenty-seven of the 28 guidelines recommended healthcare professionals discuss the risks associated with obesity during pregnancy with some recommending to explain *"the ways in which they [the risks] may be minimised"* or

management strategies to reduce the risks (Guidelines A, C, D, E, F, L, Q, U, Z). Guidelines mostly provided a list of risks for healthcare professionals to discuss, with one guideline (Guideline N) advising a sticky label, listing the risks, be placed in the women's hand-held notes. 5/28 guidelines provided risk calculations alongside at least one complication (Guidelines M, O, V, X, Y). No guideline offered a risk assessment framework to help healthcare professionals frame risk, or guidance on how risks may be minimised. Guideline H recommended that women should be advised of the risks but be reassured that most women with a raised BMI have straightforward pregnancies and healthy babies. This was unlike the general tone around risk observed in most guidelines, but paid attention to how risk information is translated by a woman who may already be feeling vulnerable. Conversely, it could cause confusion as to why risk is discussed if most women experience no complications or alternatively, provide false reassurance regarding their potential for poorer outcomes (181).

Advocating a healthy lifestyle and the provision of practical advice on how to improve dietary intake and activity levels are recommended in national guidelines (51, 52). Informing women of the benefits of adopting healthy behaviours during pregnancy was recommended in most local guidelines (26/28) but were limited in how they could work with women to achieve this. Seven guidelines offered brief recommendations on what a diet should consist of and recommendations for physical activity but overall information on how to translate this into the reality of women's lives was not evident (Guideline F, J, K, M, X, Y, Z). Women often seek their own information about diet and activity during pregnancy; demonstrating how women are often on a quest to be doing the 'right' thing. Their goal to achieve health during pregnancy aligns with the goal of the professionals and this shared outcome could be an anchor for conversations, led by the woman, about how she may implement the advice provided into her life.

According to national guidance, healthcare professionals should tailor weight management advice to the individual needs of each woman, enlisting behaviour change knowledge and techniques to provide an individualised approach to care (52). At a local level, three guidelines mirrored this more collaborative approach (Guideline E, F, G). They recommended healthcare professionals to initiate questions about the woman's own personal lifestyle, offering a woman an opportunity to frame their experience in a non-judgemental space; exemplifying midwifery guardianship. Three guidelines recommended addressing women's concerns around physical activity (Guideline F, I, M) or weight (Guideline F, M) but no guidelines made recommendations to address women's concerns specifically about her diet. Understanding the woman and providing an opportunity to listen to her concerns is central to ensuring equality in care. Guideline G described behavioural techniques such as goal setting to support women to make changes and expressed *that "every contact with women during pregnancy…is an opportunity for tailored health promotion".* Practical steps to identify barriers to behaviour change with women and make plans to overcome them were not clear in any guideline. Achieving individualised lifestyle counselling in current routine UK maternity pathways may be challenging due to time and knowledge constraints and this may explain the few numbers of guidelines that recommend this. The public health responsibility of maternity practitioners thus appears to sit in opposition to the system constraints on practice that may prioritise clinical assessments.

Twenty-two guidelines advised midwives to signpost women to reputable sources about healthy lifestyles during pregnancy. This was often in the form of a leaflet, the RCOG leaflet ("Why your weight matters in pregnancy" [source now archived] or "Being overweight in pregnancy and after birth") (8/28) or other externally sanctioned sources such as Tommy's or Trust resources (182, 183). Leaflets were either used as a tool to help guide discussion or to exemplify, as part of a checklist, that additional information had been given. As stated in national guidance, all women should be provided with accurate and accessible

information but only one guideline explicitly identified leaflets that were provided in different languages (Guideline S). It was not evident in other guidelines that there was leaflet provision for those whose first language was not English. If supported with good communication, providing leaflets can be useful in providing women with information and tools to engage in healthy behaviours during pregnancy. However, if it is not reinforced with a conversation and incorporated into the woman's individual context, it risks being discarded (184).

3.5.2. Theme 2: Advocating surveillance – to what end?

National guidance recommends that an accurate height and weight should be obtained at the first antenatal contact and a further weight in the third trimester should be considered to plan for appropriate equipment and personnel for birth (51, 52). Additional weight measurements should only be taken when "*clinical management can be influenced or if nutrition is of concern".* All 28 guidelines recommended a baseline BMI to be calculated at the booking (27/28) or first scan (1/28) appointment. An initial weight measurement is part of the risk assessment to determine the appropriate clinical pathway for the woman and her pregnancy as women with a higher BMI have poorer outcomes and therefore should have increased surveillance (51). Most guidelines (24/28) recommended further weight measurements with 13 aligning with national guidance to reweigh for risk assessment purposes or if nutrition was a concern (Guidelines E, F, G, J, M, N, O, Q, V, W, Z, AA, BB). Eleven recommended healthcare professionals to monitor weight throughout pregnancy (Guideline K, R, H, I, L, P, S, T, U, X, Y). The purpose of re-weighing was clear in only two guidelines to support weight management (Guideline K and R). Women need clear and consistent messaging to feel encouraged and supported. With no clear pathway following a measurement, communication between the woman and the healthcare professional may falter, disrupting the woman's sense of control and to no advantage to the healthcare professional.

National guidance does not provide weight gain thresholds for pregnancy because it concludes that there is no evidence or a lack of consensus on optimal gestational weight gain (51, 52). Whilst 15 guidelines acknowledged this, eight guidelines recommended weight gain thresholds (Guideline I, M, Q, AA, J, R, X, Y). These were based either on the Institute of Medicine guidelines or on recommendations of which the source was unclear (45). Current maternity care in the UK sits within a discourse of risk that explains the advocacy or attempts to adopt weight gain thresholds, but we do not have the evidence in which to determine what a healthy gain looks like. This paucity of evidence results in recommendations lacking information about what to do should a woman fall above or below thresholds. This challenges the healthcare professional's ability to support the woman effectively, thus, putting at risk the trusting relationship.

3.5.3. Theme 3: Discretionary and ambiguous pathways

National guidance recommends offering a referral to an appropriately trained health professional for women with a BMI of 30kg/m^2 or above at booking for assessment and personalised advice on a healthy lifestyle (51, 52). This was also recommended during the postnatal period. Referrals for additional weight management support were suggested (21/28) but clear eligibility criteria and how to initiate the referral were frequently missing or unclear. One guideline (Guideline G), although unclear in specifying the name of the support programme, highlighted the involvement of women in conversations about further support. This involvement was not evident across guidelines but demonstrated midwifery guardianship by advocating listening to women's own goals and wishes before decisions are made. Table 12 displays a breakdown of the suggested places for referral.

TABLE 12 TYPES OF REFERRALS SUGGESTED IN THE GUIDELINES

[a] Specified antenatal classes, workshops, specialist midwife follow-up or similar

[b] Community programmes including Slimming World (*n* = 3) or Weight Watchers (*n* = 1)

Referral type	Number of Trusts	NHS Trust Code
Dietician/ dietetic service	15	B, E, F, H, I, K, L, N, Q, R, X, Y, Z, AA, BB
Weight management programme (unspecified)	3	G, A, AA
Weight management programme offered within the Trust[a]	8	D, F, K, L, M, O, Q, R
Weight management programme offered in the community[b]	5	K, O, P, R, U

Referrals were sometimes at the healthcare professional's discretion to consider whether it was necessary and was dependent on resources or availability of services in the area. Referrals could have an important role in offering women more specialised or individualised care regarding her weight that may not be possible in routine appointments. Guideline R had a clear referral process where attendance at a specific workshop was requested via the midwife as early as possible. An additional referral was offered to women with a BMI above 25kg/m^2 to funded weight management services that included either one-to-one telephone support with a specialist midwife or support from a dietician via an App, depending on the area.

National guidance recommends that healthy lifestyle messages should be reinforced in the postnatal period and women should be advised to seek further support to manage weight or dietetic advice (51, 52). This was recommended in 23 guidelines but with few providing

clear, practical steps to support women to engage with this. Pregnancy is a life event for the woman and her family that continues beyond the remit of maternity service provision. The transition in services after birth is a tentative period as intervention, advice and information is often suspended or orientated toward the baby meaning women can feel a sudden loss of support and advice. Guideline I recommended that healthcare professionals write to the GP to consider measures to help with weight reduction. Sharing information with the woman's GP could provide a useful support link when women no longer fall within the scope of maternity services. Though subsequent guidance for GPs is limited, clear referral pathways after birth are essential in upholding the important health messaging established during pregnancy that are fundamental in determining the potential course of subsequent pregnancies. Breastfeeding was advocated, specifically in relation to supporting weight management, in four guidelines (Guideline A, D, G, R).

3.6. Discussion

3.6.1. Key findings

While local recommendations reflect the national guidance, this synthesis has exposed a disconnect between the partnership approach emphasised in national maternity policy, and the risk dominated discourse of local practice recommendations for weight management during pregnancy. The most consistent recommendations were to obtain a weight measurement at booking, inform women of the benefits of a healthy lifestyle and of the risks associated with being obese during pregnancy. Specific, practical advice about how to achieve a healthy lifestyle was lacking. This reflects National guidelines which raises questions about how to best equip professionals to help women during pregnancy to achieve this. There was variation in the adoption of routine weighing practices and referral pathways were ambiguous.

The BTT has exposed how the focus on surveillance and risk, as was observed in most guideline recommendations, is contrary to a partnership relationship with women where

women feel safe and empowered (120, 185, 186). In contrast but in alignment with the BTT, few guidelines promoted or facilitated an individualised or partnership approach; a characteristic of midwifery guardianship that displays an awareness of the sensitive and emotive nature of weight management conversations.

3.6.2. Existing literature

Healthcare professionals face significant personal and contextual barriers to having conversations about weight during pregnancy (81-83). Barriers include a lack of knowledge, skill, confidence, and a fear of stigmatising women who enter pregnancy with obesity. The focus on risk, absence of clear instruction on providing behaviour change advice, unclear pathways, and omission of practical lifestyle advice on how to work with women to manage weight that was observed in the local guidelines, though reflective of national guidance, offers explanation to why such barriers may exist. Weight management advice is often sought by women, but insensitive counselling around weight and in particular, risk, and the medicalisation of these pregnancies can result in depersonalisation of care and feelings of shame and guilt (86, 134, 187). Creating a non-judgemental space, where a woman feels safe to discuss her concerns with the healthcare professional is fundamental within conversations about weight that do not induce weight stigma. However, local guidelines fail healthcare professionals in advocating midwifery guardianship.

Local clinical guidelines derive from a medical perspective in which healthcare professionals dictate the course of clinical management, intervention and treatment based on the best available evidence. However, weight management is complex and incorporates biological, psychological, environmental, and social factors, and the guidelines examined often overlooked these factors and were orientated around risk and surveillance. Focus on risk disempowers women and elevates anxiety (184). During risk conversations, women can feel judged for their weight that can affect her decisions during pregnancy and if complications arise, made to feel they are to blame (181). Pregnant women understand risk in a context

specific way dependent on their previous experiences and socio-cultural factors emphasising the importance of individual assessment and framing of risk around the woman's cultural and social context to support her sense making (132). Previous research suggests women want constructive advice to follow new information about her risk and the omission of this detail creates challenges for healthcare professionals to ameliorate the anxieties created by risk counselling (188). Clinical guidelines can support the complex interplay between scientific evidence, healthcare provider's expertise and the woman's preferences by considering how each recommendation and the evaluated outcome may support, or inhibit, personalised and sensitive conversations that would instigate a partnership approach to care (32).

3.6.3. Implications for research and practice

Reconceptualising weight management care to align with the partnership approach that enacts midwifery guardianship, and reflects national maternity policy, is warranted. Whilst we work in a medical system that utilises clinical guidelines to inform practice, recommendations must consider how a woman's social, environmental, and psychological context can be considered to reduce weight stigmatisation, increase her choice, and empower her. To achieve the partnership approach that maternity care policy advocates, the way weight conversations in pregnancy are had, the subsequent communication of practical, individualised advice as well as the dominant risk-focus of the guidelines must be re-examined. Further to this, avoidance of stigmatising language or recommendations in the guidelines that may instil unconscious bias toward those of a higher weight for example when listing risks would be valuable for healthcare professionals using and enacting the recommendations in practice. Research in primary care settings has observed interactions that involve health behaviour change talk between patients and clinicians to support clinical guideline development (189). Learning from this could be translated to a pregnant population but examining best practice examples in antenatal consultations to inform

maternity guidelines should be considered. Consistent recommendations within a guideline, including clear referral pathways, may also facilitate the messaging that women receive about weight and how they interpret and engage with this.

Implementing evidence-based recommendations must be complemented by equipping professionals with specific training to increase skills, knowledge, and confidence, frequently identified as barriers to providing supportive weight management care. This includes offering professionals support in communicating risk about weight in a way that the woman can make sense of considering her values, beliefs, and preferences to dissipate feelings of anxiety or guilt. Co-designing clinical guidelines, or potentially alternative tools to support weight management care, including the provision of practical lifestyle information, with women who have experienced pregnancy with obesity or excessive gestational weight gain is fundamental in the design of tools we use to deliver weight management care. Continued evaluation of these tools to assess women's experience of care and healthcare professional's perspectives related to practice changes is important for continued improvements to women's care through pregnancy.

3.6.4. Strengths and limitations

To my knowledge, this is the first study to use a theoretical framework to understand weight management guidelines that are used across different NHS Trusts in England. Adding to existing evidence surrounding weight management care provision during pregnancy, this study helpfully adds a new perspective that challenges current practices by highlighting the disconnect between the ambition of maternity policy and guideline recommendations. It has also provided some context for the barriers faced by healthcare professionals as well as the experiences of pregnant women; providing momentum for ongoing inspection of national and local clinical guidelines that may hinder progression towards supportive, collaborative weight management care that empowers women.

A purposive sample generated a well-represented national picture of guidelines from all seven NHS regions in England. Maternity units in Scotland, Wales and Northern Ireland were not included due to the differences in NHS or non-NHS healthcare structures, which would have made comparability with NICE and RCOG guidelines difficult. Therefore, a study comparing local guidelines beyond England may be warranted.

Whilst these analyses have identified communication and language used as an indicator of the approach to care, it is not possible to elicit whether clear communication leads to better experiences for women, i.e. we cannot say that a guideline that did not describe the sensitive nature of weight as a topic led to suboptimal care provision, and vice versa. It can also be argued that the purpose of a clinical guideline is not to be explicit regarding these softer skills but rather it is there to serve as a constructive risk management tool to guide clinical decision making. However, reflecting on the language and the framing of recommendations could inform care by reinforcing stigma associated with weight and thus, the language, tone or approach that is used by healthcare professionals during consultations. Further research could explore the tools that support or hinder healthcare professionals to have conversations about weight that do not induce feelings of guilt or shame.

Using the NICE and RCOG guidelines as a deductive analysis framework was useful to ensure all aspects of weight management care were explored. However, I did not include associated guidelines such as ‘Maternal and child nutrition’, ‘Antenatal care’ or ‘Postnatal care’ (33, 190, 191). It is important to acknowledge that they may provide additional detail on the care women receive. However, the focus of this synthesis was weight management and therefore, to ensure a clear focus on this, other guidelines were not used in the framework for analysis.

3.6.5. Reflections

As discussed already, this study has exposed the variable approaches to the language used in guidelines and I have tentatively used this as a proxy to the communication women receive about weight. Further research is needed to explore whether this affects care, but I have reflected on my own practice and use of clinical guidelines whilst undertaking this research. From my experience, consistent, clearly structured, and accessible documents are more easily interpreted and used in practice to inform clinical tasks and management. This reflection alongside the findings of the study has made me consider whether having 'weight management guidelines', as we have collectively called them here, and using them in isolation is best practice for supporting women who enter pregnancy with a higher weight, considering the complex nature of the topic which is multifactorial and surrounded by stigma. Therefore, additional approaches or tools where professionals, supported by obtaining regular and up to date knowledge in the area, can have more autonomy in their approach to care for women to manage their weight that encourages midwifery guardianship to empower women.

Providing compassionate, holistic, person-centred care to ensure each individual woman has a physically and emotionally safe and life-enhancing experience through pregnancy to birth and beyond is a philosophy I maintain as a midwife. This chapter provided me with an opportunity to reflect on my midwifery training and my experiences as a qualified midwife that I have not confronted before. The obstetric led unit in which I worked may have shaped me as a midwife toward a more risk focused paradigm. However, this, in combination with my philosophy and passion to provide person-centred and quality care for women and their families, was integral in informing the analysis and interpretations made throughout interrogation of the practice guidelines. This tension between paradigms in which midwives may work has been noted by others where enacting women-centred care is challenging with organisational structures where a risk discourse prevails (28, 192). The combination of

examining the guidelines through the eyes of a midwife with the critical eyes of a researcher that mobilised a theoretical lens during analysis progresses the field both for those in practice and research. Midwifery researchers can provide a unique perspective on how the medical system in which we commonly work can coexist with the person-centred, partnership approach to care that we are taught and are passionate about providing for women and their families.

3.7. Conclusion

This chapter clearly shows that locally interpreted weight management guidelines are rooted in a risk discourse, rather than a partnership approach that is advocated in maternity policy. This new knowledge must be taken forward by clinical teams as this disconnect could explain the rifts in weight management care delivery that is evidenced in existing literature. There were differences in local interpretations of the national guidelines and ambiguous care pathways and unclear recommendations in both could hinder a healthcare professionals' ability to translate these into practice. Future research should address the tools in which maternity healthcare providers use to provide weight management care and a revaluation of the system in which they work to achieve the ambition for all pregnant and postnatal people to receive sensitive, personalised, and safe weight management care.

This thesis aims to take forward the issues raised in the current chapter. Firstly, as limited knowledge is known about lifestyle related behaviour in women with chronic hypertension (see Chapter 2), who may also enter pregnancy at a higher weight, the following chapter (Chapter 4) will provide an overview of the current behaviours, attitudes and needs towards lifestyle in a small sample of women. Subsequent Chapter 5 and Chapter 6 aim to design and develop a lifestyle intervention alongside women and healthcare professionals. The experiences, views, barriers and facilitators in receiving and providing weight management related care including lifestyle support will be further explored in these chapters. Together, this work will contribute to a more comprehensive understanding of how the guidelines

examined are translated in practice that I was not able to determine in the guideline synthesis.

Chapter 4 A survey to explore lifestyle behaviours and lifestyle change in women with experience of chronic hypertension during pregnancy

4.1. Overview

This chapter presents results of a survey conducted to explore and understand the lifestyle behaviours, motivation and confidence as well as the barriers and facilitators for lifestyle change, for women with experience of chronic hypertension during pregnancy. While Chapter 2 (systematic review) and Chapter 3 (clinical guidelines synthesis) reviewed the landscape of existing interventions designed for women with pre-existing conditions and existing clinical guidelines that are experienced by women during pregnancy, the current chapter aims to draw focus more closely on the population that is the focus of the DAPHNY intervention reported in subsequent Chapter 5 and Chapter 6. The aim of this chapter is to set the scene for the intervention development mixed-methods study that follows.

Identifying specific experiences and needs for health information is crucial in developing interventions and ways to support women. Though there have been a number of studies that have examined the barriers for pregnant women including those with obesity, a common risk factor for hypertension, the focus has not tended to be on women with existing hypertension (91, 92, 193) (See Chapter 1, Section 1.8.4). To my knowledge, one study exists examining the barriers and facilitators for women with hypertension in engaging in healthy eating behaviours but in their survey sample of 38 women, only 17.9% had chronic hypertension (93). Studies have identified the determinants of healthy behaviours including knowledge of healthy diets and support networks and barriers include common pregnancy symptoms, lack of access to healthy food including cost and also a lack of time that made it difficult to cook or invest both time and money in planning meals (91-93, 193).

As those with hypertension may have received advice about lifestyle upon diagnosis of hypertension, as per guidelines, existing behaviours and knowledge may differ to that of the

general pregnant population (65). The current knowledge and lifestyle behaviours and specific barriers and facilitators for women with chronic hypertension is currently unknown. An overview of this is needed to support the development of an appropriately targeted intervention that influences lifestyle factors that could optimise hypertension control and management. The survey reported here aimed to capture the existing knowledge, understanding and views of lifestyle change and current health behaviours in the context of those with hypertension who are and have been pregnant.

4.2. Aims and research questions

This survey aimed to explore women's knowledge of lifestyle factors and hypertension as well as current behaviours, levels of motivation and confidence towards lifestyle change. The survey set out to explore the following research question:

- Are women with experience of chronic hypertension during pregnancy motivated and confident to lead a healthy lifestyle and what are their barriers and facilitators towards change?

The survey also informed the iterative development of a lifestyle intervention, reported in subsequent Chapter 5 and Chapter 6 that report the study set up, iterative development of the intervention and consider important factors in the implementation of a lifestyle intervention.

4.3. Methods

4.3.1. Survey design

There are currently no validated tools to assess pregnant women's knowledge of lifestyle factors specifically associated with high blood pressure. Therefore, I explored the literature for surveys in the topic area that aimed to gain an understanding of women's lifestyle behaviours, motivation and confidence/ ability to change behaviour (93, 194-197) (BUMP Pilot survey, unpublished). The survey was drafted, piloted and refined by members of the

research group which included clinicians (GPs, midwives, obstetricians). The survey was then piloted with PPI representatives to test the comprehensibility and acceptability until a final version was agreed (Appendix 10).

The survey included seven sections and included quantitative and free-text responses (Table 13). The data for quantitative analysis included multiple choice and ranking questions. Questions accommodated for whether they were responding about a current pregnancy or previous pregnancy, for example “Did you/ do you weigh yourself during pregnancy”. Free text responses allowed participants to express any further thoughts on the topics raised; improving the richness of the data to support our understanding of the current behaviours and attitudes of the participants and ways to optimise a potential intervention. These free text responses provided insight to take forward in interviews and focus groups.

TABLE 13 SURVEY STRUCTURE

Survey section	Description
About You	Basic demographic information provided detail on the characteristics of the respondents and bookended the survey. Questions were categorical to reduce the sharing of personal identifiers with the hope that this would encourage people to participant. An "I prefer not to say" option was available.
Lifestyle	The first section of the survey gathered information about current knowledge around lifestyle factors and hypertension. Participants were asked about advice received from healthcare professionals at hypertension diagnosis and during pregnancy. Questions then asked about any engagement in health behaviour change during these two time points and any particular challenges related to this. Participants rated the degree to which they agreed, or disagreed, with statements relating to the importance they placed on being healthy, their motivation and their confidence in maintaining a healthy lifestyle.
Use of technology during pregnancy	Questions were asked around women's current use of lifestyle related pregnancy Apps or engagement with activity trackers to obtain an understanding of what women currently use or do not use.
Weighing practices during pregnancy	Frequency and views around weighing practices during pregnancy including both self-weighing and weight measurements undertaken at appointments was elicited to understand women's views on weighing and current practices.
Additional questions about lifestyle behaviours	Specific questions about consumption of fruits and vegetable based on national recommendations were asked as a measure of participants' health. Questions about physical activity levels outside and during pregnancy, based on government guidelines for physical activity, were included.
Support during pregnancy	During early PPI meetings, support for women with high blood pressure was identified as an area that women did not feel was

sufficient. To investigate this further, this final section asked respondents about where they usually sought information and what form of support they felt was needed.

4.3.2. Approval

The survey was approved as part of the DAPHNY intervention development mixed methods study protocol (Appendix 11). The protocol, study documents and other relevant material were given approval by The University of Oxford, as Sponsor, in April 2022 and favourable opinion by HRA and Health and Care Research Wales (REC ref: 22/WA/0130) in May 2022 (Appendix 12 and Appendix 13). Further details on the DAPHNY study set up and management are reported in Chapter 5, Section 5.5.

4.3.3. Study participants and recruitment

The sample was recruited using online platforms, community networks, and study sites. Eligible women were those who had experienced chronic hypertension during their current pregnancy or within the last three years and aged over 18 years old. Recruitment methods included convenience, snowball, and purposive. Response rate and response representation were monitored throughout to inform the sampling method.

Data were collected via a University approved online, survey platform (Jisc Online Surveys). A poster was displayed at participating maternity units and also on social media with a link or QR code for women to access and complete the survey. Online platforms included Facebook, Twitter, newsletters and other channels such as relevant charity groups, e.g. Action on Pre-eclampsia (APEC), promoted the survey. Only UK based Facebook groups were chosen because whilst non-UK respondents weren't screened out, the intervention was being developed in a UK setting and therefore, it held more relevance if participants were currently living in the UK. I worked with the department's Communications team to assist in dissemination via Department platforms and with contacts within the department

such as GPs to promote the survey within their practices and midwives in my network to promote to eligible women.

I attended participating sites and, along with healthcare professionals, signposted women to the survey at specialist clinics. Women attending clinics were given a choice to complete the survey on an iPad provided whilst they waited for their appointment or provided with an information postcard with a QR code so they could complete it at another time. Survey respondents that did not speak English as their first language or had specific accessibility requirements could contact the study team for further support to complete the survey. Where participants were approached in person, a translator service was available to use if needed.

Due to the low response rate during the first few months after the launch, a protocol amendment was submitted in November 2022 and approved in December 2022 to allow a postal invitation letter to be sent to eligible women at the participating sites (Appendix 14, Appendix 15). Continued Capacity and Capability at sites with consideration of the amendment was approved in January 2023 (Appendix 16).

After receiving the initial information about the survey, participants entered the survey tool which provided more information about the study with an expected time for completion. A tick box confirmed they understood the information, eligibility and that they agreed to take part. Responses were anonymous and each response was given a unique response ID.

4.3.4. Response rate and sample size calculation

As recruitment involved publicising via online sources, I did not know how many people it would reach and therefore did not calculate a response rate. However, using online platforms has been shown to give similar results to standard sample methods where the response rate is known (108, 198).

An estimated sample size was calculated based on previous surveys concerning women's motivation and ability to change lifestyle behaviours during pregnancy where they found that 75% of women were motivated for lifestyle change or had made lifestyle change during pregnancy (194, 195). I therefore aimed to reach 375 responses with a minimum of 96 responses to have a 95% confidence interval and a 5-10% margin of error around the estimate of the proportion of women prepared to make a lifestyle change during pregnancy.

4.3.5. Analysis

Data from the survey platform were exported to Excel for data cleaning and exported into STATA software for analysis. Free text responses were exported to Excel for further analysis and interpretation.

4.3.5.1. Quantitative analysis

Participant characteristics and demographic information are reported, and presented descriptively, in full, with continuous variables presented as mean (SD) and categorical data presented as *n* (%). The aim was to estimate the proportion of women prepared to make a lifestyle change, therefore the proportion, with 95% confidence intervals, were reported for women's knowledge, motivation, confidence and views towards making lifestyle changes as well as the behaviours undertaken to achieve this. To estimate the confidence intervals, I used a logit transformation meaning the confidence intervals may not be symmetrical.

Some participant characteristic groups had very low frequencies so, to make analysis more meaningful, ethnicity, age and BMI categories were regrouped into fewer categories so that the models I planned could be used. Comparison between different participant characteristics and answers selected were conducted using Fishers exact tests. Fisher's exact test was appropriate for the binary outcomes and categorical predictors collected in this survey. Furthermore, some responses were low frequency and therefore this test was appropriate for this data.

A logistic regression model, chosen due to its suitability for analysing binary outcomes, with missing indicator for missing BMI values was used to explore the potential association between participant characteristics including BMI, age, ethnicity and gravidity and specific behaviour changes. The reference group for the regression analysis were normal BMI, less than 35 years old, white ethnicity and primigravida women. I originally performed a logistic regression model for all variables of behaviour change. However, due to the small sample size it was not appropriate to use on all the variables. I have therefore only presented the two most frequently chosen behaviour to demonstrate the analysis but with recognition of the limitations in reporting this.

As reported in previous surveys, responses for 'strongly agree' and 'agree' were combined to indicate agreement and 'strongly disagree' and 'disagree' were combined, indicating disagreement (199). I decided it was important to keep neutral responses 'neither agree nor disagree' to reflect ambivalence towards the question.

4.3.5.2. Qualitative analysis

A qualitative directed (deductive) content analysis was conducted. This method of analysis uses existing theory or research findings to extend research about a phenomenon in different contexts, hence it was appropriate for the analysis of this survey (200).

Free text responses were exported into an Excel spreadsheet and were repeatedly read to familiarise myself with the data. A structured categorisation matrix was constructed to identify the barriers and facilitators of women engaging in a healthy lifestyle, using technology to support this and managing their weight and blood pressure (201). Barriers and facilitators were the categories used within the matrix as these are key to understanding behaviour change. As the matrix was structured, only responses that fitted the matrix were coded and unclear or unrelated content was not included into the analysis. No weighting was given to the frequency of identified barriers or facilitators as it was considered

important, no matter how many people had said it. An outline of the categorisation matrix is shown in Table 14. Where quantitative responses also indicated barriers and facilitators, these were also entered into the matrix to build an overall picture of key factors influencing behaviour change.

TABLE 14 OUTLINE OF STRUCTURED CATEGORISATION MATRIX

Behaviour	Barriers	Facilitators	Example of survey question eliciting this
Existing behaviours			
Blood pressure self-monitoring			
Engagement in physical activity			
Eating a healthy diet			
Weight management			
Self-weighing			
Using Apps			
Using technology			
Changing behaviours			
Physical activity level			
Eating a healthy diet			
Lifestyle behaviour change			
Blood pressure self-monitoring			

Each identified barrier and facilitator was then summarised into the theoretical domains of the COM-B model, introduced in Chapter 1, Section 1.10.1, including physical/ psychological capability, physical/ social opportunity and reflective/ automatic motivation. The matrix was then displayed graphically in a figure.

4.4. Results

4.4.1. Participant demographics

A total of 85 complete responses were collected between 30th August 2022 and 13th May 2023 when the survey closed. The survey did not reach the planned minimum response rate of 96, but 85/96 (89%) was felt to be sufficient due to the exploratory nature of the work.

There were three known respondents who required the use of a translator. The majority of participants (58%) were diagnosed with hypertension outside of pregnancy, 37% had a diagnosis of hypertension during pregnancy, before 20 weeks gestation, and 6% had hypertension during pregnancy that did not resolve following birth.

Demographic characteristics of the survey respondents are summarised in Table 15. Of the participants who provided weight (current or closest to booking) and height data (*n*=59), the mean BMI was 29.9kg/m^2 (SD 5.2). Over half (56%) of participants who provided weight and height information and were currently pregnant (*n* = 39), were obese or morbidly obese.

There were 53 participants currently pregnant with a mean gestational age of 26+7 weeks and gestation ranged from 6+6 and 38+2 weeks gestation.

The majority of respondents were of white ethnicity and over the age of 35 (Table 15).

TABLE 15 SURVEY PARTICIPANT CHARACTERISTICS (N = 85)

Variables	
BMI kg/m^2*mean (SD) (*n*=59)	29.9 (5.2)
BMI category *n* (%)	
Underweight	0 (0%)
Normal	13 (22%)
Overweight	15 (25%)
Obese	29 (49.2%)
Morbidly obese	2 (3.4%)
Pregnancy status *n* (%)	
Currently pregnant	53 (62.4%)
Not currently pregnant	32 (37.7%)
Gravidity n (%)	
Primigravida	26 (30.6%)
Multigravida	59 (69.4%)
Age n (%)	
18-24 years old	0 (0%)
25-34 years old	39 (45.9%)
35-49 years old	44 (51.8%)
>50 years old	2 (2.4%)

Location n (%)	
England	83 (97.7%)
Scotland	1 (1.9%)
Wales	0
Northern Ireland	0
Not in the UK	1 (1.9%)
Ethnicity n (%)	
White	61 (71.8%)
Mixed/ Multiple ethnic groups	1 (1.2%)
Asian/ Asian British	13 (15.3%)
Black/ African/ Caribbean/ Black British	5 (5.9%)
Other ethnic group	2 (2.4%)
I prefer not to say	3 (3.5%)
Highest education achieved n (%)	
No formal qualifications	2 (2.4%)
Vocational qualifications	4 (4.7%)
GCSE	15 (17.7%)
A-Level	7 (8.2%)
Professional qualifications	5 (5.9%)

First degree	20 (23.5%)
Post-graduate or above	26 (30.6%)
I prefer not to say	6 (7.1%)
Other conditions n (%)	
Type 1 diabetes	0
Type 2 diabetes	1 (1.9%)
Gestational diabetes	7 (8.2%)
No diabetes	76 (89.4%)
I prefer not to say	1 (1.2%)

*based on weight closest to booking, if pregnant, or current weight, if not pregnant

4.4.2. What is women's motivation, confidence and views toward the importance of a healthy lifestyle?

Overall, women reported feeling confident and motivated to have a healthy lifestyle and thought it was important for their own health as well as their babies' health; supporting the hypothesis that women during pregnancy are motivated to have healthy behaviours for both a desire for their own personal health and that of their offspring. As per the COM-B model, these are important mediators of behaviour change, linking to automatic motivation; the emotional reactions, wants and needs that can drive a behaviour (Figure 6).

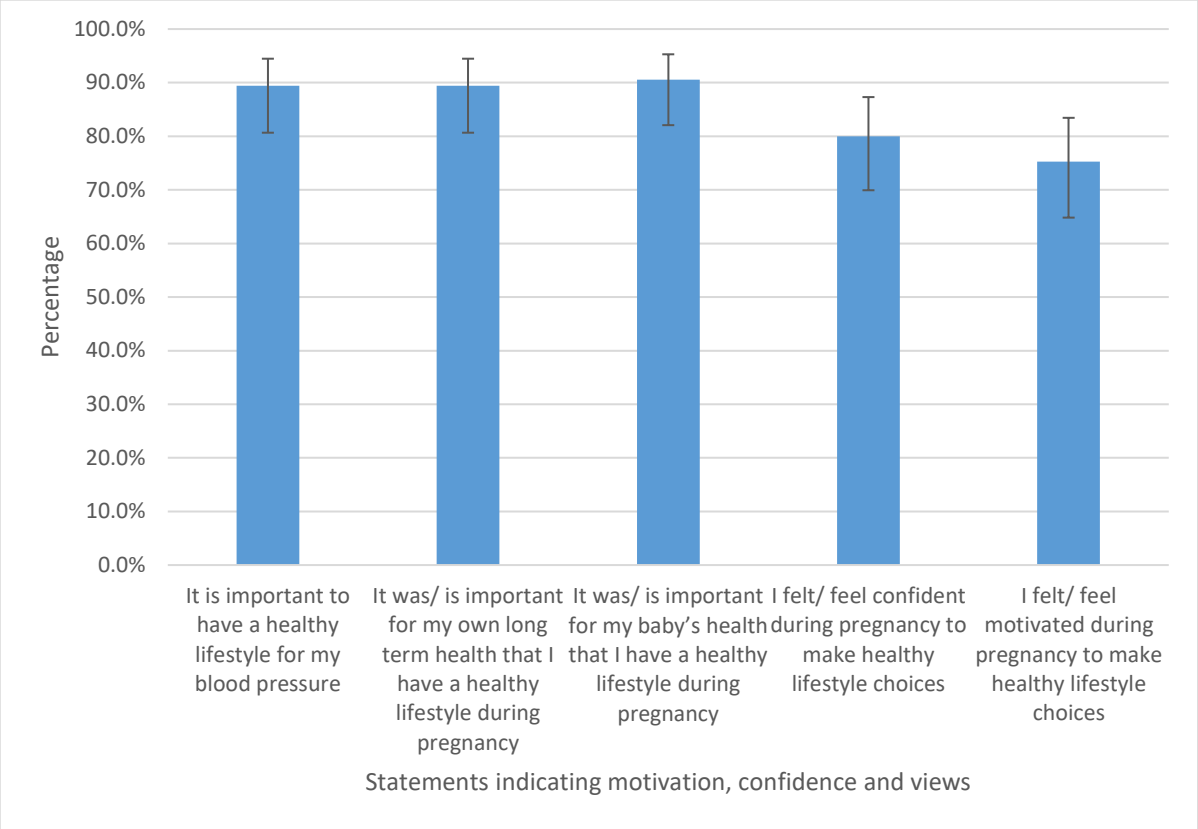


FIGURE 6 PROPORTION OF RESPONDANTS AGREEING TO EACH STATEMENT

4.4.3. What is women's knowledge about lifestyle in relation to hypertension and what sources of information are used?

Overall, the participants knew at least a little about how diet and physical activity affects blood pressure with only a few women (7%, 95% CI 3% to 15%) reporting that they did not know anything. There was no association between age, ethnicity, parity and knowledge (p=0.92, p=0.06, p=0.24, respectively). Most participants (88%, 95% CI 79% to 94%) understood the relationship between salt and blood pressure. Unsurprisingly, because it is not prominent within the UK guidance on hypertension or promoted in the UK, most participants (78%, 95% CI 67% to 85%) had never heard of the Dietary Approaches to Stop Hypertension (DASH) diet.

Most participants reported that they did not or do not currently use pregnancy Apps that focused on a healthy lifestyle (73%). There was no association between using Apps and if someone was pregnant for the first time or had been pregnant more than once (p=0.95).

Pregnancy Apps in general were less frequently cited as a place for this knowledge compared to online which was the most common source of information about what to eat during pregnancy and what exercise to do (Figure 7). Those who selected 'other' said they already knew this information (2/7), didn't look for this information (1/7), or cited pregnancy books (2/7), YouTube (1/7) or colleagues at their workplace (fertility clinic) (1/7) as sources of information.

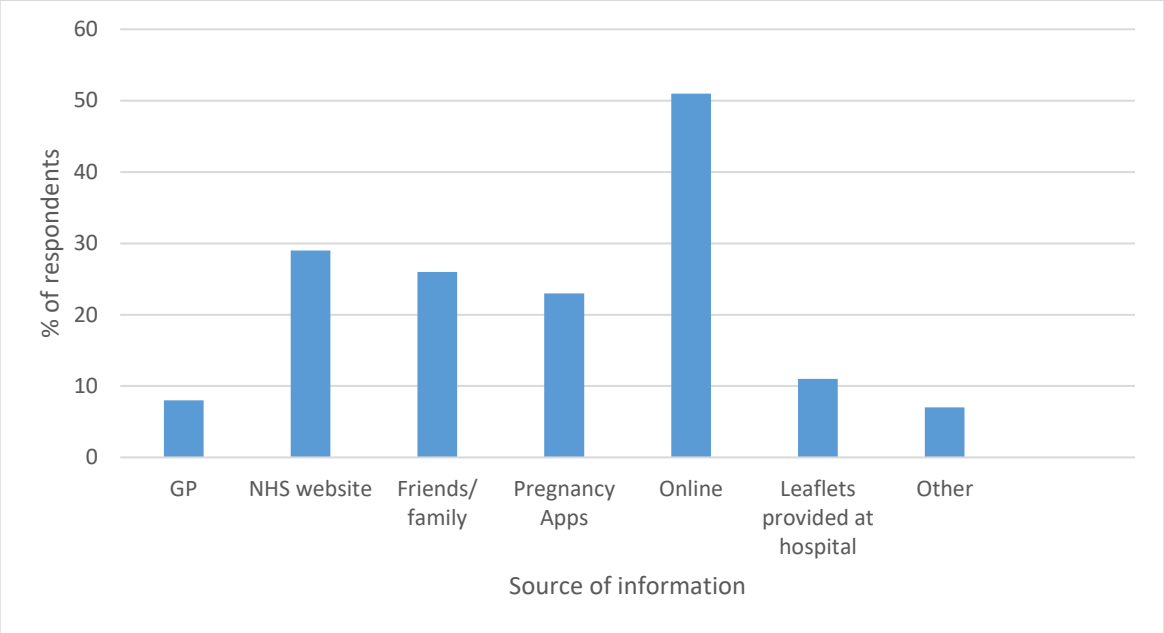


FIGURE 7 SOURCES OF INFORMATION

4.4.4. What are women's current behaviours and previous lifestyle change behaviours?

4.4.4.1. Snapshot of current health behaviours

Nearly half of women (45%, 95% CI 34% to 56%) reported that they currently lead a healthy lifestyle and there is nothing they would change (Figure 8). The remaining women either disagreed or they were ambivalent, suggesting there was a mix of views on participants perceived level of health.

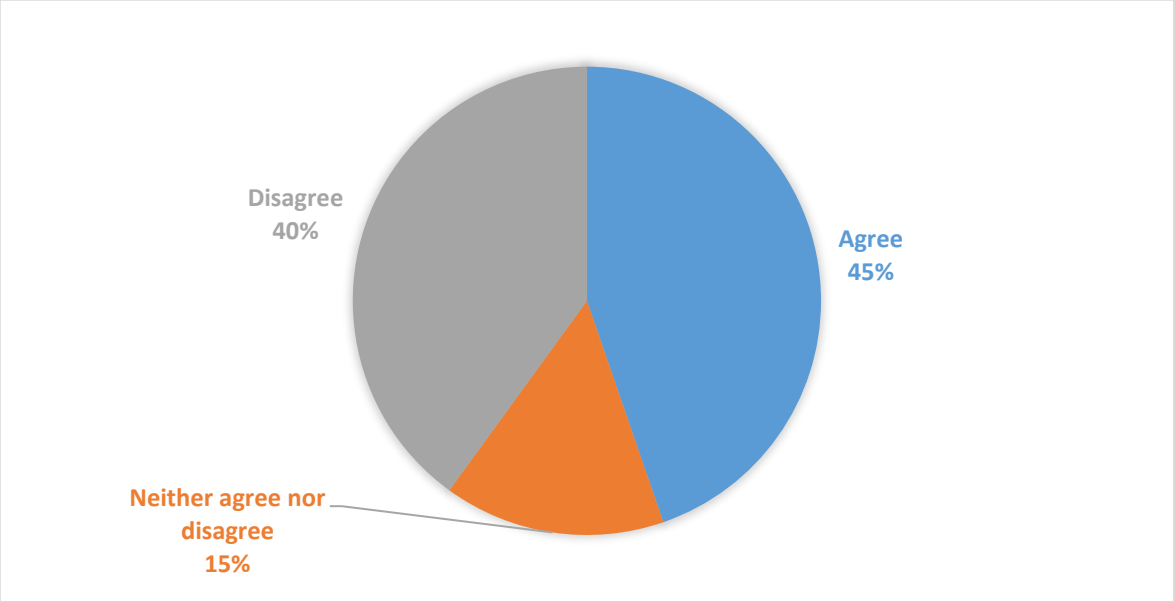


FIGURE 8 A GRAPH TO SHOW THE PROPORTION OF WOMEN AGREEING OR DISAGREEING THAT THEY LEAD A HEALTHY LIFESTYLE AND THERE IS NOTHING THEY WOULD CHANGE

Behaviours associated with a healthy lifestyle were explored including consumption of fruits and vegetables. The majority of the participants ate at least one serving of fruit and/or vegetables per day with one exception to this where one participant selected “Once a week or less/ never” for both fruit and vegetables (Figure 9). Most of the participants who selected “Once a week or less/ never” for either fruit or vegetables, selected “Once a day” for the other option. For example, someone who selected “Once a week or less/ never” for vegetables tended to select “Once a day” for fruit and vice versa. At least 23 of the 85 participants (27%) were predicted to meet the recommended government guidelines for consumption of at least 5 fruits and vegetables per day.

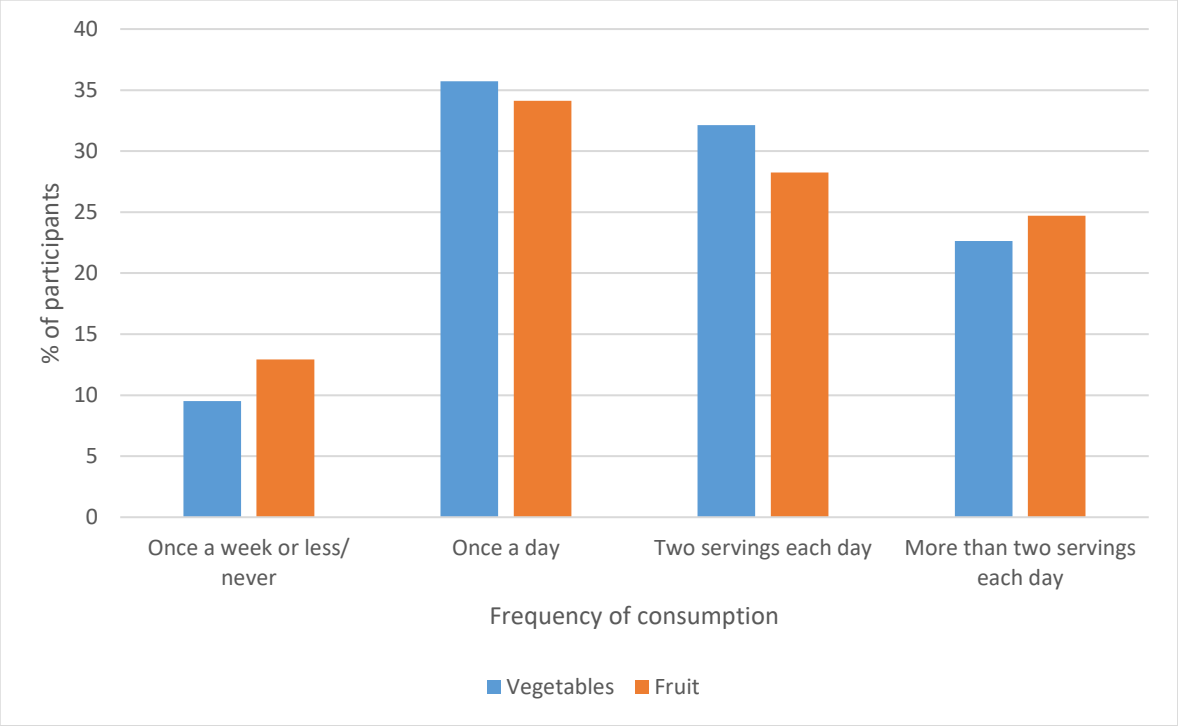


FIGURE 9 FREQUENCY OF FRUIT AND VEGETABLE CONSUMPTION

A higher proportion of women reported being active outside of pregnancy than during pregnancy (Figure 10). Generally, participants reduced their activity during pregnancy with 38 respondents reporting being less active during pregnancy than they were outside of pregnancy. Five reported increased activity during pregnancy than outside of pregnancy.

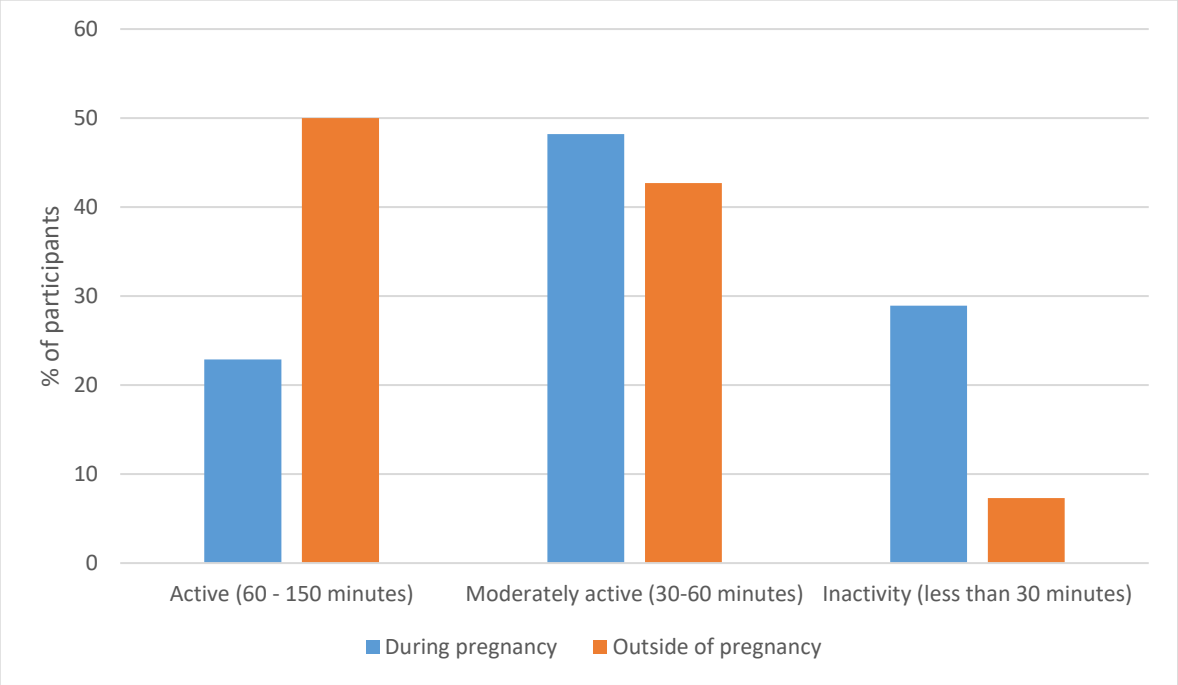


FIGURE 10 PHYSICAL ACTIVITY LEVELS DURING AND OUTSIDE OF PREGNANCY

4.4.4.2. Lifestyle change at hypertension diagnosis and pregnancy

Most participants actively engaged in changing lifestyle behaviours because they were diagnosed with hypertension (82%, 95% CI 73% to 89%) or because they were pregnant (82%, 95% CI 73% to 89%). The behaviours people engaged with varied and multiple answers could be selected. The most common lifestyle change because of hypertension diagnosis was eating less salt followed by making other healthy dietary choices (Figure 11). For the 29 respondents (34%, 95% CI 25% to 45%) who made healthy dietary choices because of hypertension diagnosis, there was a variety of actions undertaken to achieve

this with the most frequently selected action being eating more fruit and/ or vegetables (79%).

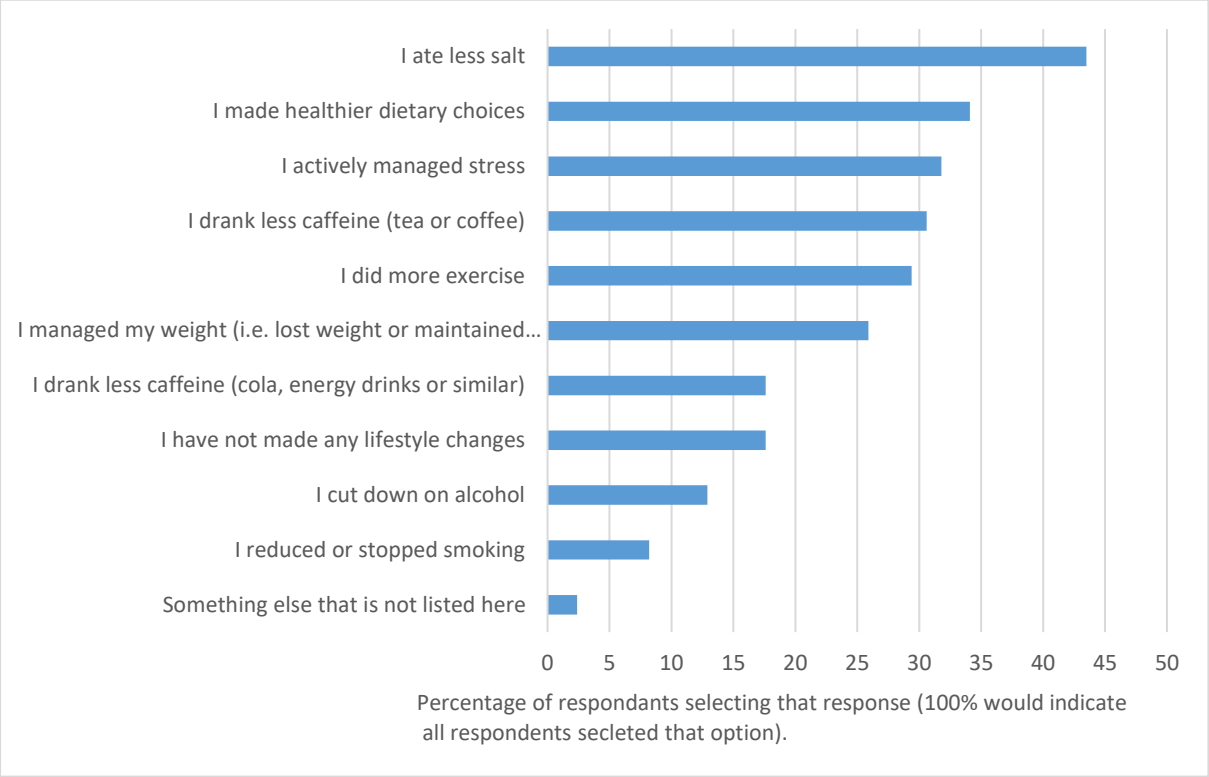


FIGURE 11 THE LIFESTYLE CHANGES PEOPLE MADE BECAUSE THEY WERE DIAGNOSED WITH HIGH BLOOD PRESSURE.

Logistic regression models were used to explore associations between participant characteristics and behaviours but this analysis was not progressed, acknowledging the multiple testing issue which would increase the likelihood of spurious findings. This decision was reinforced by the large confidence intervals that suggested the sample may be insufficient to reliably use the model and draw conclusions (Table 16).

TABLE 16 LOGISTIC REGRESSION MODELS EXPLORING ASSOCIATIONS BETWEEN CHARACTERISTICS AND BEHAVIOURS

Covariates	**"I made healthy dietary choices", OR (95% CI)**	**"I ate less salt", OR (95% CI)**
Age, 35 years or above	0.89 (0.33 to 2.38)	2.37 (0.85 to 6.61)
Parity, mulitgravida	1.19 (0.43 to 3.33)	2.39 (0.83 to 6.88)
BMI		
Normal	Reference	Reference
Overweight	0.59 (0.11 to 3.02)	0.68 (0.14 to 3.27)
Obese and above	1.01 (0.25 to 4.01)	0.38 (0.09 to 1.55)
Ethnicity		
White	Reference	Reference
Asian/ Asian British	0.82 (0.21 to 3.26)	3.93 (0.97 to 16.01)
Black/ African/ Caribbean/ Black British	1.35 (0.19 to 9.67)	0.98 (0.13 to 7.23)
Mixed & other ethnic groups	1.05 (0.16 to 6.92)	1.09 (0.18 to 6.55)
Note: Missing indicator for missing BMI values was used		

A variety of lifestyle changes was taken up because of pregnancy. The most common lifestyle change made because of pregnancy was drinking less caffeine (tea or coffee) and making healthier dietary choices (Figure 12).

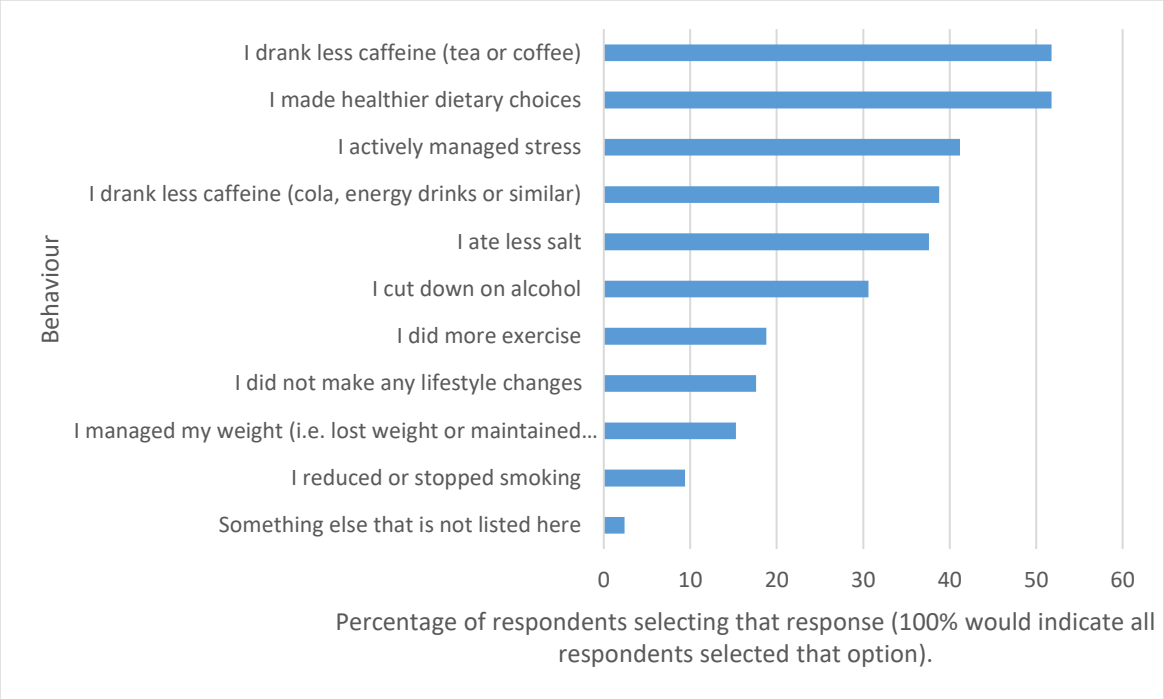


FIGURE 12 THE LIFESTYLE CHANGES PEOPLE MADE BECAUSE THEY WERE PREGNANT

4.4.4.3. Self-monitoring behaviours

Self-monitoring behaviours related to lifestyle were mixed. Although most did not use an activity tracker to inform health behaviours (59%, 95% CI 48 to 69%), more than half (70%, 95% CI 59% to 78%) took note of how many steps they did on at least some days. Participants were split in whether they weighed themselves during pregnancy with 52% (95% CI 41% to 62%) never having weighed themselves and 48% (95% CI 38% to 59%) reporting that they weighed themselves in varying degrees of frequency (from less than monthly to daily).

It was commonplace for women to self-monitor their blood pressure during pregnancy with most performing this daily (Figure 13). Prevalence of self-monitoring practices (of any frequency) was higher during pregnancy (98%) than outside of pregnancy (73%) and this appeared to be less frequently performed than daily.

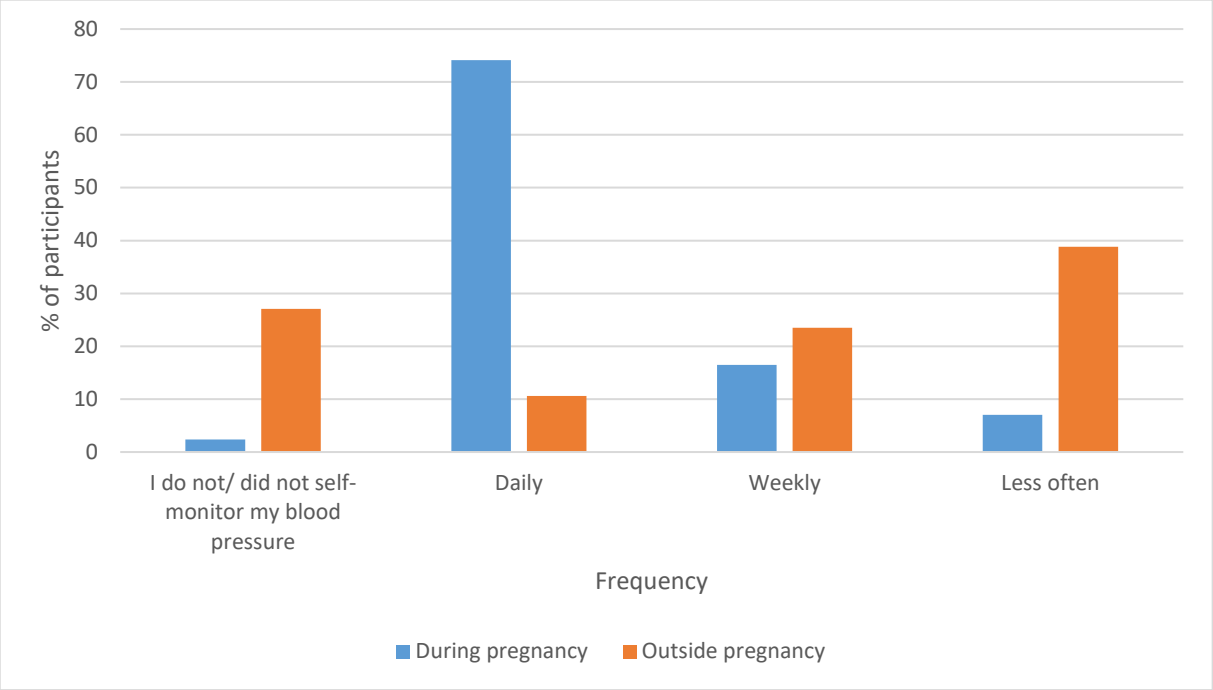


FIGURE 13 BLOOD PRESSURE SELF-MONITORING PRACTICES DURING PREGNANCY AND OUTSIDE OF PREGNANCY

During pregnancy, most participants (90%, 95% CI 82% to 95%) were advised to monitor their blood pressure by a healthcare professional and less respondants reported advice to self-monitor blood pressure by a healthcare professional outside of pregnancy (53%, 95% CI 41% to 66%). However, this may be skewed as it may be dependent on the time of hypertension diagnosis as those who completed the survey whilst they were pregnant and diagnosed before 20 weeks wouldn't have had hypertension outside of the pregnancy yet.

4.4.5. What are the barriers and facilitators?

4.4.5.1. Financial considerations

The cost of a healthy diet and physical activity was explored to identify potential environmental barriers. Most participants (77%, 95% CI 66% to 84%) stated that the cost of healthy food was not a problem for them and almost half (46%, 95% CI 35% to 57%) felt that they could afford to participate in physical activity. 22% (95% CI 15% to 33%) of participants didn't feel that they needed to spend more money to take part in exercise which left 20%

(95% CI 13% to 30%) of participants who felt that they couldn't afford to buy healthy food or couldn't afford to do exercise.

4.4.5.2. Interactions with healthcare professionals

Receiving information and support from healthcare professionals has been previously identified as a facilitator to having a healthy lifestyle. Less than half of respondents received advice about lifestyle factors from healthcare professionals both upon hypertension diagnosis and during pregnancy (42%, 95% CI 32% to 53% for both). Those who received advice during pregnancy, most often received this at one antenatal appointment (56%).

Twenty-six (31%, 95% CI 22% to 41%) participants reported having discussions about healthy weight gain with a healthcare professional during pregnancy. There was variation in the frequency of weight measurements taken with a healthcare professional. As this may have been due to the variation in the gestational age of respondents, results in Table 17 are separated for non-pregnant respondents in order to remove variation in gestation at the time of responding. Variation in frequency of weighing remained. For those who were not pregnant, there was no statistical difference between BMI groups on the number of weight measurements, though only 18 women were in this analysis (p=0.74).

TABLE 17 FREQUENCY OF WEIGHT MEASUREMENTS TAKEN WITH A HEALTHCARE PROFESSIONAL DURING PREGNANCY

	All responses (*n* = 85)	**Only non-pregnant participants (*n* = 32)**
Never	5%	3%
Once	22%	16%
Twice	24%	15%
3 to 5 times	21%	28%
More than 5 times	15%	25%
I'm not sure	3%	13%

Being weighed by a healthcare professional or self-weighing, did not appear to influence most of the participant's lifestyle habits (67% (95% CI 55% to 77%) and 51% (95% CI 36% to 67%), respectively). However, more participants would want to be weighed by a healthcare professional (57%, 95% CI 46% to 67%) than weigh themselves (37%, 95% CI 27% to 47%) during pregnancy, and there was no difference in preference by BMI group (p=0.59 and p=0.37, respectively). A proportion of women expressed ambivalence in respect to weighing practices by neither agreeing nor disagreeing and free text responses demonstrated mixed views on weight during pregnancy.

4.4.5.3. Support

Most participants were not part of any online support groups for women with high blood pressure (95%, 95% CI 88% to 98%) but almost half thought this would be valuable to them (47%, 95% CI 37% to 58%). Some were ambivalent about this (27%, 95% CI 19% to 38%) or did not think a support group would be valuable (26%, 95% CI 16% to 36%).

4.4.5.4. Identified barriers and facilitators mapped against the COM-B model

Table 18 and Figure 14 show the many barriers and facilitators women with chronic hypertension face when engaging in healthy behaviours. Although some were only observed by one participant, they highlight the unique needs of each individual woman navigating hypertension and pregnancy health.

TABLE 18 STRUCTURED CATEGORISATION MATRIX. BOLD TEXT INCORPORATES IDENTIFIED BARRIERS AND FACILITATORS FROM QUANTITATIVE QUESTIONS

Behaviour	Barriers	Facilitators		Example of survey question eliciting this
Existing behaviours				
Blood pressure self-monitoring	Size of device		**Perceived healthiness**	
Engagement in physical activity	Co-morbidities Hypertension diagnosis Cost/ **cost**		**Knowledge** **Online sources** **Support from others**	*Did you make any lifestyle changes because you were diagnosed with high blood pressure? Select all that apply. If you selected 'something else', please describe what this was.*
Eating a healthy diet	**Cost**			***Do you feel you can spend money on buying healthy food?***
Weight management	Pregnancy symptoms Hypertension diagnosis Lack of HCP support Co-morbidities	History of stable/ "normal" weight HCP advice and support		*Please use the space below if there anything else you would like to add relating to weighing during pregnancy.*

	HCP advice Lack of knowledge			
Self-weighing	Negative emotions	Pregnancy symptoms Fear of weight loss		*Please use the space below if there anything else you would like to add relating to weighing during pregnancy.*
Using Apps	Inclusivity Self-monitoring features Unrealistic advice	Information source Self-monitoring features Information all in one place		*Did you/ do you use pregnancy Apps which focus on a healthy lifestyle (diet and/ or exercise)? Please describe the features that you liked/ disliked or enjoyed/ disliked or would change.*
Using technology	Existing motivation	Self-monitoring features Motivational reminders Linked devices		*Is there any technology that would help you to have a healthy lifestyle during pregnancy? Note: 6 respondents said 'No' for this question, suggesting not everyone thought technology would help them to have a healthy lifestyle.*
Changing behaviours				
Physical activity level	Pregnancy symptoms Co-morbidities	Encouragement Blood pressure and pregnancy tailored classes	**Healthcare professional advice and support**	*In relation to any options listed in question 15 (making lifestyle change during pregnancy), was there anything that was particularly difficult or*

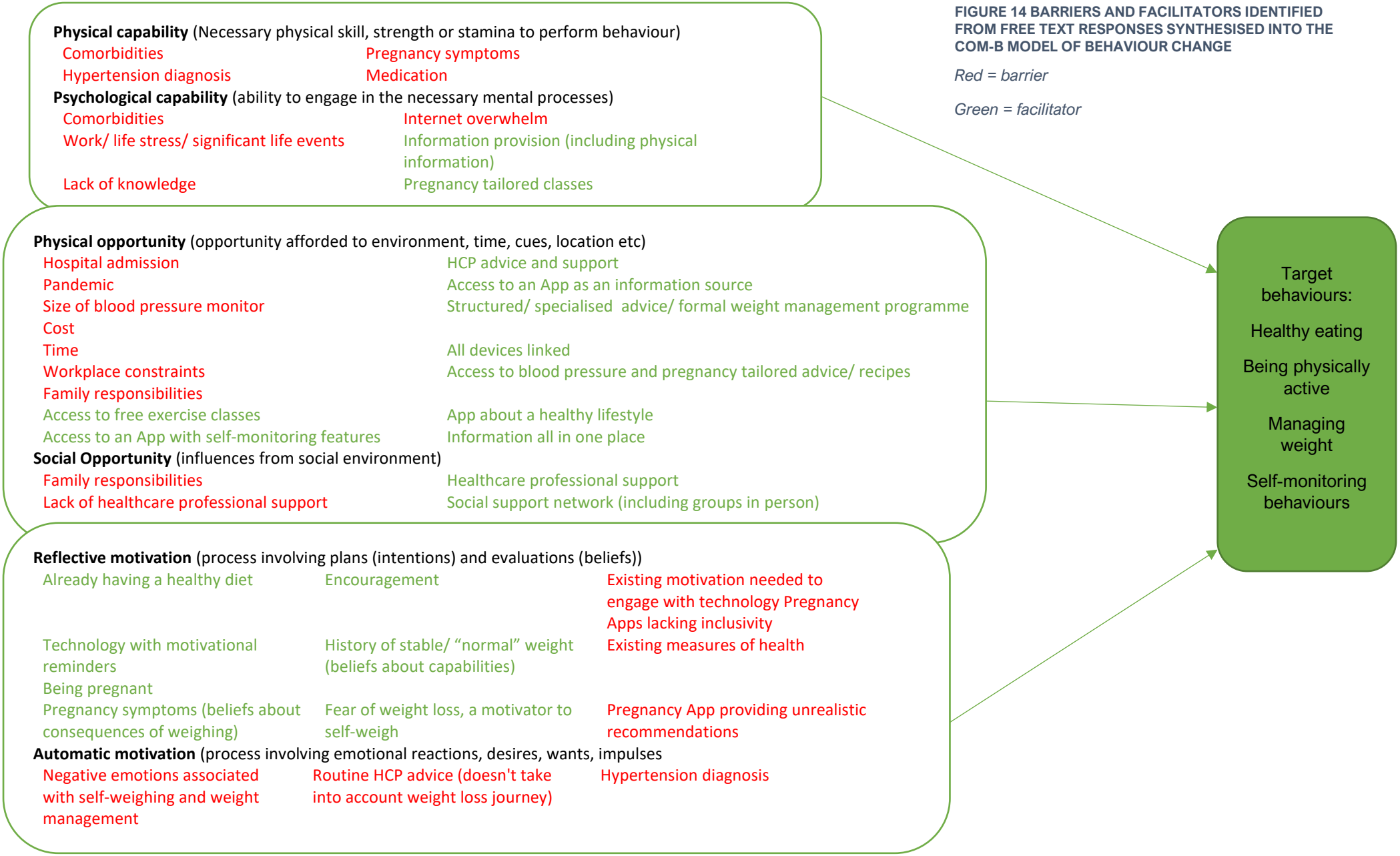
	Pandemic Hospital admission		*prevented you from making positive lifestyle choices? Please describe.*
Eating a healthy diet	Pregnancy symptoms	Formal weight management programme Existing healthy diet Blood pressure and pregnancy tailored recipes/ advice Specialised advice Structured advice	
Lifestyle behaviour change	Pregnancy symptoms Family responsibilities Workplace constraints Work/ life stress/ significant life events	Social support Physical information provision Motivational reminders Free classes App	*What would support you to have a healthy lifestyle during pregnancy? Please be as specific as possible.*

	Co-morbidities Lack of HCP support Social support Internet overwhelm Lack of knowledge Existing measures of health Hypertension diagnosis Medication	HCP support and advice Information provision Being pregnant **Hypertension diagnosis** **Being pregnant** **Overweight/ obesity/ missing BMI**	
Blood pressure self-monitoring		**Being pregnant**	***During pregnancy, did you/ do you self-monitor your own blood pressure at home?***

FIGURE 14 BARRIERS AND FACILITATORS IDENTIFIED FROM FREE TEXT RESPONSES SYNTHESISED INTO THE COM-B MODEL OF BEHAVIOUR CHANGE

Red = barrier

Green = facilitator



4.5. Discussion

4.5.1. Summary of findings

This survey set out to understand the current lifestyle behaviours, motivation, confidence and views towards lifestyle behaviours and explore the barriers and facilitators to lifestyle change for women with experience of chronic hypertension during pregnancy. This was the first step to help understand how an intervention may be designed to facilitate engagement in healthy behaviours to improve blood pressure control. The findings reveal that although many women with chronic hypertension know about the relationship between lifestyle factors and hypertension, this knowledge may not be translated into practice, with low levels of fruit and vegetable consumption and activity levels identified within the group. A lack of women receiving ongoing lifestyle advice for healthcare professionals was evident, perhaps exposing a missed opportunity to engage with these women during pregnancy as most reported feeling motivated and confident to have a healthy lifestyle for both their own health, in relation to their blood pressure, and also their baby. The COM-B model supported interpretation of free text responses which further informs our understanding of the barriers and facilitators and provides a starting block in how these may be overcome in an intervention and are further explored in qualitative interviews (reported in Chapter 5 and Chapter 6).

4.5.2. Existing literature and key implications for intervention development

Similar to others, I found that women were motivated, as well as confident, to lead a healthy lifestyle (194, 195). Women were also found to rate the importance of a healthy diet during pregnancy highly; aligning with previous studies around importance of healthy eating during pregnancy (202, 203). This also aligns with literature that describes pregnancy as an opportune moment to share public health messaging to improve health behaviour because women have a desire to do the best for the baby during this time (39). Women with chronic

hypertension may have an added layer of motivation where it was identified in this survey that having a healthy lifestyle was important for their hypertension. Having a positive attitude towards the positive effects of a healthy lifestyle and having existing motivation and confidence in one's own ability to engage in a behaviour, are key determinants of engagement in positive behaviour change. However, other factors such as physical and environmental constraints as well as social influences can disrupt the trajectory that leads to engagement in these behaviours.

Knowledge is described in multiple behavioural theories as a precursor for eventual behaviour change, for example the COM-B model and the theoretical domains framework (113, 204). The majority of survey respondents understood the relationship between lifestyle factors and high blood pressure including the link with a high salt intake but were not aware of a specific diet to reduce blood pressure (Dietary Approaches to Stop Hypertension). The few who had heard of it, may have been those participants who had taken part in other aspects of the DAPHNY study (reported in Chapter 5 and Chapter 6) and therefore had been made aware of it. As the DASH diet is not recommended to manage hypertension and there is little promotion of this dietary pattern in the UK, it is unsurprising that this particular diet was unknown to respondents (205, 206). If having knowledge is an enabler to making lifestyle changes, disseminating information about the positive benefits of a healthy diet such as DASH with supportive behaviour change strategies could facilitate women achieving recommendations.

Though half of respondents reported already leading a healthy lifestyle and had knowledge of the relationship between lifestyle and hypertension management, only 27% were predicted to meet the recommended government guidelines for consumption of fruits and vegetables. This is similar to the proportion of adults in the general population consuming 5 or more portions of fruit or vegetables a day (207). A fruit and vegetable intake above 3

servings per day has been associated with a reduced risk of cardiovascular disease progression and therefore particularly relevant and beneficial for this group (208).

A second indicator of a healthy lifestyle is physical activity levels where an active lifestyle is associated with improved health in a non-pregnant population as well as during pregnancy with evidence that leisure time activity and supervised activity can reduce the incidence of some pregnancy complications, such as the development of gestational diabetes and hypertension (209, 210). In 2019, 65% of women were considered active as classified by government guidelines which is higher than the 50% of women in my survey who were active outside of pregnancy (207); suggesting the women who responded to the survey may be generally less active than the general population. Twenty-three percent of participants reported being active during pregnancy which is lower than findings of others but similarly to other studies, demonstrates the decline in activity levels often observed during pregnancy (211-214).

No link can be made between those who felt they already led a healthy lifestyle and those who indicated higher healthy eating and physical activity levels but these data indicate that there may be some discrepancy between perceived and actual level of health. This could be determined by participant's valuation of what 'healthy' means for them. This was also noted when I spoke to a woman after she had completed the survey where she asked what was meant by a 'healthy diet' in the question relating to cost, asking if this was specifically organic foods. This is important because it indicates how people's knowledge and interpretation of a healthy diet is varied and may therefore influence their own perceived level of health, depending on what criteria they are assigning to these terms.

A high proportion of pregnant women use pregnancy Apps for providing information and monitoring babies growth and development (100, 215). However, in the current survey, pregnancy Apps were not a source of information for finding out what to eat or how active

to be during pregnancy suggesting they may serve a different purpose for women, even if Apps are available with this information. For example, multiple free text responses indicated that Apps were used to monitor babies' development. Understanding how lifestyle information may be presented within an App so that it is useful and practical is important to take forward in my line of enquiry as they are not currently the default source for this information, despite Apps being an attractive and convenient companion for pregnant women (95).

The prevalence of self-monitoring blood pressure both during and outside of pregnancy is higher than has been seen in previous surveys where it is estimated that 30% of hypertensive patients self-monitor their blood pressure at home, with around 40% owning a monitor and around 49% of women with hypertension self-monitoring their blood pressure at home during pregnancy (197, 216, 217). The Covid-19 pandemic and the publication of new guidance around self-monitoring blood pressure during pregnancy may explain the increased prevalence since the previous surveys were conducted (218). This may also explain the high proportion of participants who were advised to monitor their blood pressure during pregnancy, reflecting how obstetricians may be increasingly viewing self-monitoring as part of usual care for the management of hypertensive pregnancy, as has been identified by others (108).

The barriers identified in the survey are similar to findings by others exploring lifestyle behaviours in the general pregnant population (90, 91, 213). For example, common pregnancy symptoms such as general discomfort, sickness or tiredness and work or family commitments identified in free text responses in the current study have been identified by others as barriers to taking part in exercise (90, 91). Other existing co-morbidities or exercise-induced hypertension were additional barriers for some respondents, highlighting where individualised exercise advice may be required.

The survey identified some facilitators to making behaviour change including lifestyle advice that is individualised. Specialised advice is difficult to introduce in routine practice due to resource constraints and healthcare professional skills and knowledge. Currently personalised lifestyle advice via a referral is in theory offered to women based on booking BMI (52). The current survey suggests that women with hypertension, regardless of their weight, may want advice that is designed around their own individual needs and perhaps this is lacking in existing pathways. An intervention, specifically designed for women with hypertension, may be a small step towards a more personalised approach.

Unlike blood pressure monitoring where healthcare professionals have clear blood pressure thresholds and subsequent care pathways to follow, monitoring weight is different. This was exposed first in Chapter 3 which showed variation in recommendations for routine weighing practices across Trusts (219). Reflecting this, the survey showed there was a mix of experiences in routine weighing practices. The voices of the women in the free text responses mirrored the mix of experiences around weighing displayed in the quantitative questions showing varied and sometimes strong, opinions for wanting, or not wanting, to be weighed during pregnancy and the potential consequences to both mental and physical health in doing this. Knowledge of this variation was key to informing intervention components and discussions with women in subsequent intervention development methods and contributes to our understanding of how women are best supported in this area where weight management could carry benefits to blood pressure control.

4.5.3. Strengths, limitations and reflections

A strength of the survey was that it builds on only one existing survey that aims to understand the health behaviours in a population with chronic hypertension, specifically focused on behaviours associated with blood pressure control. Validity of survey responses may be reduced due to the use of non-validated assessment tools but the survey was piloted

and refined with researchers and clinicians within the group as well as patient representatives and was appropriate for the studies exploratory aims. I could have replicated a previous survey on women's knowledge and motivation towards lifestyle during pregnancy, for example, those used for the sample size calculation, but at the time I did not feel they would allow me the flexibility of asking specifically about changes related to hypertension diagnosis. Instead, I used these to ensure I included important questions such as those around degree of motivation and confidence using Likert scales.

The survey provided an opportunity to reach a wide and diverse group that was considered important as other methods to develop the DAPHNY intervention would be small and therefore less likely to be representative. However, I did not reach the minimum target sample size of 96. Despite this, the sample appeared representative of women with chronic hypertension during pregnancy in terms of BMI, ethnicity and age (106, 220-223). Specifically, there was a higher proportion of Asian and Black ethnicities than the general population of a similar age, and a higher proportion of women aged above 35 than the general pregnant population; both reflecting the higher prevalence of hypertension in these groups. A larger survey could be conducted which would allow further investigation about the influences of certain participant characteristics that I was not able to explore in my analysis due to limited sample size.

A low proportion of respondents identified cost as a barrier to engaging in health behaviours. This is in contrast to a survey of women at risk or with hypertension, where affordability of healthy food was found to be a major barrier to maintaining a healthy diet (93). This could suggest that the population who responded to the survey were financially equiped to choose healthy options and take part in physical activity; reducing the generalisability of the results as it may not have captured those with less resource to achieve these behaviours. Despite this, there remained a proportion who felt cost was a barrier and this was also highlighted

in free text responses, indicating that financial considerations are important barrier for some women. This must be considered in the design of future interventions, given that common recommendations may have limited enactability for some women.

There were some limitations to the survey questions themselves that may have skewed the results. For example, questions about specific changes to lifestyle did not include a baseline measurement to indicate whether there was a need for subsequent change. For example, people who do not drink alcohol or smoke would not select this behaviour to change and those who did not select reducing stress as a behaviour change may either not be stressed, so didn't select it, or highly stressed but don't manage it. If this survey is repeated, these questions should have a baseline in order to understand whether the behaviour change is relevant or needed to tease out these uncertainties.

The data collected as part of this survey were useful in providing an overview of lifestyle behaviours and views towards lifestyle in relation to hypertension and pregnancy. When conducting the analysis, I critiqued the design of some of the survey questions as I felt some were skewed towards the agenda for the intervention components. This may have been due to the nature of setting up the study where I was designing the survey alongside writing the study protocol and I had to provide preliminary components of the intervention to the ethics committee.

My own critique on this survey has identified where validity and reliability of results may be compromised but acknowledgement of this provides readers with an understanding of how these survey results should be viewed and carried forward in any future work. For the purpose of my work, the survey set the scene for subsequent intervention development activities reported in the following chapters.

Online promotion of the survey was difficult and I predict that few responses were generated from online sources. Despite working with the Communications team to promote the survey,

I found that attending clinics and posting the survey to eligible participants was the most effective method to increase responses. Facebook restrictions and being limited to wording that had been approved by the ethics committee made it difficult to adapt individual online posts so that it was engaging for potential participants. Every effort was made to increase responses further, but I had to be pragmatic about the time I spent increasing responses, to the output that the survey would generate as its purpose was to provide an overview that was further explored in interviews and focus groups.

4.6. Conclusion

This small but informative survey has shown that women with experience of hypertension during pregnancy do not always receive lifestyle advice from healthcare professionals but despite this, most reported having knowledge and made changes upon hypertension diagnosis and during pregnancy. Importantly, they were motivated and confident to lead a healthy lifestyle though there was evidence that dietary intake and exercise levels may be suboptimal for some women. This suggests that there is scope to explore how women may be best supported to improve behaviours that may in turn promote better blood pressure control.

Chapter 5 Intervention Development: Content, design and iterative development (optimising the intervention)

5.1. Overview

Chapter 1 outlined why healthy lifestyle behaviours are beneficial to blood pressure control and management, especially for those with chronic hypertension during pregnancy where high blood pressure can lead to poor outcomes for mother and baby. However, the systematic review, reported in Chapter 2, identified no studies that had been specifically developed and tested interventions to support healthy lifestyle behaviours for women who have chronic hypertension who may benefit the most from lifestyle modification. Chapter 3 exposed the risk-orientation of clinical weight-management guidelines during pregnancy that lacked clear, specific and practical recommendations for lifestyle modification to pass to women. Survey responses detailed in Chapter 4 revealed few women with chronic hypertension receive lifestyle advice from their healthcare providers despite national guidance to do so. Importantly, most respondents were motivated and confident in how to be healthy but current healthy behaviours were sub-optimal for some, revealing an important need to develop interventions to support optimal lifestyle behaviours in this group.

This Chapter introduces the DAPHNY (Diet and Activity for Pregnancy Hypertension) study which was a mixed methods intervention development study involving three linked studies:

- Study 1: An online cross-sectional survey for women (reported in Chapter 4)
- Study 2: Focus groups with healthcare professionals (reported in Chapter 5 and Chapter 6)
- Study 3: Early feasibility testing with women involving think-aloud interviews (Component 1) and individual semi-structured interviews (Component 2) (reported in Chapter 5 and Chapter 6)

The aim of the DAPHNY study was to design and develop an optimal digital lifestyle intervention for pregnant women with chronic hypertension. Iterative intervention development through studies 2 and 3 are detailed in this chapter including the methods, tools and analysis to design and develop the DAPHNY App prototypes and Version 0.0.4 for testing. Chapter 6 will present the qualitative thematic analysis of focus groups and interview data that contextualises the implementation of the intervention.

5.2. Aims and research questions

The aim of the intervention development mixed methods study was to work with pregnant women who have experience of hypertension during pregnancy and antenatal healthcare providers to answer the following overarching research question:

- How can we optimise a digital lifestyle intervention with healthcare professionals and with women who have experience of chronic hypertension during pregnancy?

Four sub research questions to meet several study objectives were determined and will be addressed in the current chapter and Chapter 6 (Table 19).

TABLE 19 INTERVENTION DEVELOPMENT RESEARCH QUESTIONS AND OBJECTIVES

Research questions to address what is currently unknown	**Objectives set out to answer the research questions**
What are the current health behaviours and barriers and facilitators towards lifestyle change in those who have chronic hypertension and been pregnant?	To explore current knowledge, understanding, behaviours, as well as potential barriers and facilitators, towards making lifestyle changes in pregnancy. To develop a theoretical framework that captures the processes and mechanisms that lead to positive health behaviour change. To explore how a digital lifestyle intervention can be optimised for pregnant women with chronic hypertension. To explore the healthcare professionals role in supporting a lifestyle intervention in pregnancy. To explore the views and experiences of women who use the intervention. To provide an indication of the Apps accessibility and acceptability to inform whether to proceed to a feasibility study.
What are the key intervention features and components required to support women's overall understanding, use and engagement with the digital intervention?	
What are the potential barriers and facilitators for women and healthcare professionals to support the use of the intervention?	
What are the views and experiences of women who use and engage with the intervention and do they engage with it as intended?	

The current chapter reports the findings directly addressing the intervention design and development. An in-depth thematic analysis of the interviews and focus groups is reported in Chapter 6.

5.3. MRC Framework and the Person-based Approach

The UK Medical Research Council (MRC) offers guidance on developing complex interventions (110-112). The framework promotes a thorough evaluation of current research

evidence, identifying an appropriate theoretical underpinning, incorporating target user input and early piloting. Together these aim to maximise intervention success which is defined by positive changes in healthcare via widespread implementation in practice. Of particular relevance to the development of digital interventions is the person-based approach (PBA) that offers practical methods for carrying out recommendations of the MRC guidance (224).

I chose to use the person-based method, developed by Yardley and colleagues, because it has been used for digital intervention development and advocates a systematic approach, incorporating user design methods and evidence-based behaviour change methods (225, 226). The person-based method is a non-linear iterative process comprised of three core elements: 'Planning', 'Optimisation' and 'Implementation and Evaluation'. Research can move back and forth between the stages reflecting an iterative process that responds to the research findings and development of the intervention. This flexible approach has been widely applied to develop interventions for promoting healthy behaviours, supporting patients to manage weight and long-term conditions including hypertension, as well as interventions designed for healthcare professionals (227-229). Gaining in-depth insight from the people who will use the intervention is fundamental to the person-based approach. This insight is combined with evidence and relevant behavioural theory to guide the specific components and behavioural techniques embedded in an intervention. Ultimately, this leads to interventions that prioritise the needs and perspectives of the end users which will lead to more relevant, engaging and effective interventions. Expertise in the research group who were familiar with this approach as well as my own motivation to work closely with pregnant women to listen to their views and experiences, meant the person-based approach was appropriate to use as a flexible framework for the conduct of the DAPHNY study.

5.3.1. DAPHNY study outline and set-up

The DAPHNY study incorporates elements of the planning and optimisation stage of the person-based approach. This involved reviewing relevant literature, carrying out preliminary PPI groups, developing intervention guiding principles and developing a working logic model. Figure 15 provides a visual representation of the development process through planning and optimisation which is described in subsequent sub-sections.

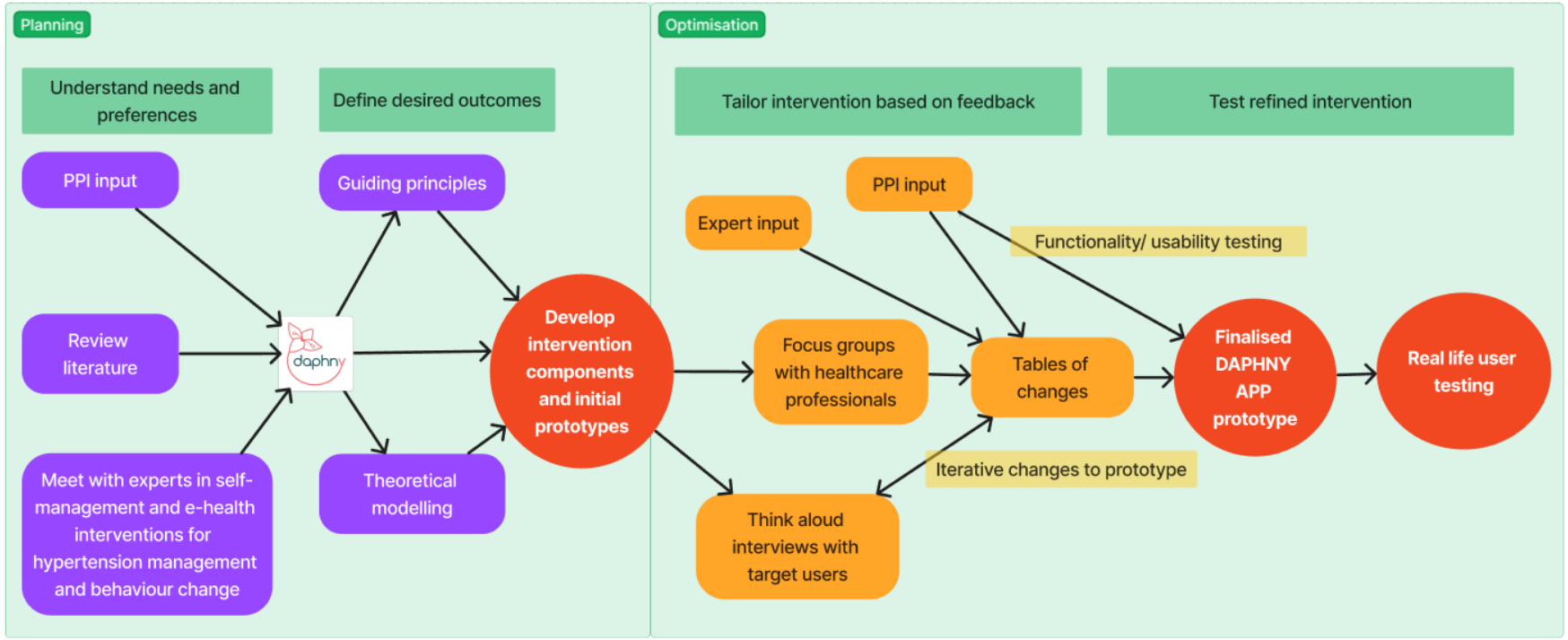


FIGURE 15 PLANNING AND OPTIMISATION PROCESS BASED ON THE PERSON-BASED APPROACH

5.4. DAPHNY protocol development

In the planning phase, I spoke to pregnant, or recently pregnant women with chronic hypertension, reviewed the evidence base and regularly met with supervisors, and a team with experience and expertise in self-management for hypertension and developing digital technologies. The outcome of these contacts are reported in the following section and led to a set of guiding principles, a preliminary logic model, and the first iteration of the DAPHNY App along with the DAPHNY study protocol.

5.4.1. Participant and Patient Involvement

In summer 2021, I held two group sessions each with four women, a session with three women and one individual meeting with women who had chronic hypertension and had recent experience of this during pregnancy. I wanted to gain insight into women's experiences and provide an informal space for them to discuss what a good intervention would look like that would help them have a healthy lifestyle during pregnancy, if this was something they were seeking to do. I had questions as a prompt but mainly followed the direction of the conversation, ensuring a comfortable platform for women to express ideas and needs in this area.

The women provided valuable insight into lifestyle advice received from healthcare professionals during pregnancy. They expressed that they did not receive lifestyle advice in relation to their hypertension during pregnancy and few reported being given advice at hypertension diagnosis; echoing findings of the online survey (reported in Chapter 4). Women reported that advice was generic, without practical tips of how to be healthy and that this was rarely in relation to blood pressure management.

Medication was a point of discussion where some were not aware that lifestyle measures could help blood pressure control. The potential side effects of medication including drowsiness was cited as a barrier to being more active. Despite this, a reduction in

medication dose or avoiding having to take medication was a strong motivating factor for enacting healthy lifestyle change. Support within the community of women with long-term hypertension was discussed as lacking and suggestions were put forward as to how an intervention may provide this missing, but important, social contact and support.

Discussions around a potential intervention were linked to some of the women's own experiences of using self-monitoring blood pressure Apps including the BUMP App if they had been a participant in the trials or the BPm-Health App that was rolled out following the trial, during the Covid-19 pandemic (106, 218). Overall, providing specific lifestyle advice with prompts and gentle reminders of encouragement alongside an App where they entered home BP readings was suggested as an obvious improvement in the information they currently received. Considerations for this included culturally sensitive dietary advice, sensitivity around raising the issue of weight and concern in overloading people with information.

Following interviews, two patient representatives continued to have involvement following these preliminary group sessions. They were involved in setting up the DAPHNY study by reviewing all study documents including the protocol, posters, and participant information sheets before submission to the ethical review boards. As well as this, PPI contributors provided valuable perspectives on the intervention as it developed. I discussed emerging findings from the interviews with them and kept them informed throughout where practical considerations for conducting the study were discussed regularly.

All those who took part and the two patient representatives were reimbursed as per NIHR guidance (230).

5.4.2. Scoping the literature

Previous evidence informed the development of the content and initial prototypes since it was important that before the study started, I had something to show to participants on

which to orientate questions. This is common in the person-based approach. By drawing on evidence of interventions that were reported as successful outside of pregnancy, I was able to create initial intervention prototypes that were further refined and iteratively developed through incorporating findings of the online survey (see Chapter 4) and subsequently, DAPHNY studies 2 and 3.

5.4.2.1. What evidence exists around lifestyle interventions for this population and why is it important?

Blood pressure management is of long-term importance to those with chronic hypertension and the motivation to maintain good blood pressure control (as evidenced in the online survey, Chapter 4) and potentially reduce medication administration (as discussed with PPI) during pregnancy could provide a unique opportunity to promote healthy lifestyle behaviours. However, there is a lack of interventions that specifically focus on lifestyle changes for a pregnant population with long term hypertension (Chapter 2) (231). Knowledge of behaviour change techniques used in existing interventions were used to inform specific features of the DAPHNY App (see Section 5.4.4).

5.4.2.2. What is the role of lifestyle in hypertension?

Chapter 1, Section 1.8, laid out the established role of diet and physical activity in the development and management of hypertension to slow disease progression and the potential to improve the quality of life in hypertensive populations (17, 232). A recent large systematic review including 105 trials and 6805 participants found statistically significant reductions in systolic blood pressure following improved dietary intake (-5.0mmHg; 95% CI: 3.1–7.0) and increased physical activity levels (-4.6mmHg; 95% CI: 2.0–7.1), where a decrease of at least 1-5mmHg is considered clinically relevant (17, 233). This emphasises the rationale for developing a lifestyle intervention with a specific focus on diet and physical activity in this group.

5.4.2.3. What lifestyle advice is given to pregnant women who have hypertension?

Hypertension management during pregnancy largely focuses on pharmaceutical treatment, often due to the acute nature of pregnancy where a sudden, rapid, and dangerous, rise in blood pressure may occur. Broad recommendations of care suggest that healthcare professionals should advise women with hypertension in pregnancy about weight management, exercise, healthy eating, and lowering salt intake (15). Specific and practical guidance on the best ways in which to go about this is lacking.

Similarly vague guidance was noted in Chapter 3 where I concluded that evidence of vague, ambiguous and contradictory guidelines would hinder healthcare professionals providing advice that would support women. Whilst the focus was weight management, lifestyle factors are inherently interlinked with this and often overweight coexists with hypertension meaning these women may also experience the recommendations of care in these guidelines. The survey provides evidence for this, where the mean BMI was 29.9kg/m^2. In Chapter 3, I posited that different tools could be used to support healthcare professionals deliver lifestyle advice to enable them to collaborate with women because guidelines examined may not be able to enable this in practice. Furthermore, less than half the women in the survey reported receiving lifestyle advice, suggesting current delivery formats for lifestyle advice may not achieve wide-spread engagement. Whether the App could be the appropriate tool to do this, is to be tested, but the information and contents of the App aim to provide more specific and practical detail on lifestyle that is lacking in this sphere of practice. Furthermore, the App will be developed with pregnant women to ensure it is acceptable, supportive, relevant and useful for those it serves.

5.4.2.4. What components would be important to address the lack of specific advice for pregnancy complicated by hypertension?

As discussed, hypertension and weight management guidelines lack clear advice that can be recommended in a meaningful way to pregnant women. Chapter 1, Section 1.8, introduced the American guidelines for hypertension, given the more specific recommendations that are based on more up to date literature (67). To summarise briefly, the Dietary Approaches to Stop Hypertension (DASH) dietary pattern has been shown to be the most effective in reducing hypertension as recommended in the American guidelines (70, 71). This diet promotes the intake of blood pressure lowering nutrients such as potassium, calcium and magnesium and a reduced intake of sodium, which is known to have a negative impact on blood pressure (68). Popular diets that include convenience foods have high salt to potassium ratio, therefore, cooking from scratch is a recommended part of the diet to ensure the right proportions of different food groups. Importantly in relevance to pregnancy, the DASH diet is not a weight loss diet but rather a sustainable approach to eating, though depending on the individual's current diet, weight loss may be a side effect (234-236).

Examination of the DASH diet during pregnancy is limited (see Chapter 1, section 1.8). Small trials and observational studies have not yet been able to provide conclusive evidence on the beneficial effects of the DASH diet on pregnancy outcomes but they point towards the diet having a role in modifying risk factors and promoting cardiovascular health (78-80, 237). Importantly, no adverse events have occurred due to adoption of the diet.

Due to the strong evidence outside of pregnancy, the DASH diet was a proposed initial component of the App. Given the limited evidence during pregnancy as well as complete adherence to the diet that includes calculations for calorie intake and physical activity levels, only the principles of the diet were introduced in the App.

More than half of respondents to the online survey, reported in Chapter 4, took note of how many steps they performed each day, indicating an interest in engaging in this behaviour. Increasing one's step count led to a reduction in blood pressure, as opposed to a specific target of 10,000 steps in a study of adults with or without lifestyle related diseases, including hypertension (238). This knowledge led to the implementation of a movement area of the App prototype that was focused around walking, since this is accessible for those living a sedentary lifestyle and may be a preferred form of activity, considering barriers in pregnancy such as pelvic pain and tiredness, identified in the survey, early PPI groups and the literature (see Chapter 1, Section 1.8.4). Exploring the accessibility of this and usefulness of this component was to be explored in the DAPHNY studies.

Weight management is also seen as an important strategy for hypertension management outside of pregnancy. During pregnancy, evidence suggests that gaining within the IOM guidelines may mitigate risks associated with gaining excessive gestational weight. As evidenced in Chapter 3, guidelines were very varied in recommendations about weight gain and weighing routines. It was posed that this was not beneficial to either professionals or women as guidance on how to act on measurements was not clear. Though NICE guidance cautions against regular weighing in case of psychological harm, it is welcomed by women, especially if complemented with appropriate guidance (56, 196, 239, 240). Authors generally conclude that more empirical evidence needs to be collated to understand the views of pregnant women and healthcare professionals in respect to weighing, whilst understanding if it has a role in attenuating weight during pregnancy or mitigating risks associated with this. As discussed previously, weight management forms part of hypertension management, highlighting the relevance of exploring weighing practices in this population which will take place in the DAPHNY studies.

5.4.2.5. Why a digital intervention during pregnancy?

Monitoring health via mobile technologies is increasingly popular and, meeting this demand, there are many freely available pregnancy Apps (95). However, few are based on robust scientific evidence and they often lack incorporation of behaviour change techniques and regulation of content as well as lacking screening for co-morbidities (241-243). In addition, exploration of how these Apps interact with current care practices is limited, highlighting the importance of conducting this study which poses research questions that aim to explore this important interaction within women's journey through maternity care.

Previous and ongoing work within the wider research group includes the development of a blood pressure self-monitoring App for pregnant women, self-monitoring blood glucose for pregnant women at risk of or with diabetes and an App that is currently being tested to increase physical activity amongst women with gestational diabetes (104, 227, 244) (StayActive, unpublished). These similar interventions have incorporated user feedback to ensure a theoretical understanding of the mechanism of action of the intervention that result in behaviour change and to ensure user acceptability and satisfaction. Knowledge gained from this work and working with colleagues involved in this work, which includes experts in intervention development, engineering as well as healthcare professionals, supported the development of the initial prototypes of the lifestyle App.

Given the expertise in the group with experience working with a hypertensive population, this research was well positioned to take forward my line of enquiry to further explore how a digital intervention, specifically about lifestyle, can be optimised for this group to support healthy behaviours and blood pressure management.

5.4.3. Guiding principles

Brief guiding principles were created to summarise the intervention objectives and were referred to throughout when making development decisions. There were three key design objectives and the ways the intervention could address these are displayed in Table 20.

TABLE 20 INTERVENTION GUIDING PRINCIPLES

Design objective	Key intervention features
Design objective 1: To increase awareness of the association between lifestyle and high blood pressure	Provide evidence for the association between diet and activity patterns and blood pressure Provide education on nutrients that support good blood pressure management
Design objective 2: To motivate women and increase confidence to undertake positive and sustainable lifestyle changes during pregnancy	Emphasis on how to make small changes to build on overtime as a way to protect their own health in the short and long term health and a way to support their baby's growth and development Create a platform that provides feedback to increase confidence and motivation Motivational messages to prompt movement Notifications to prompt uptake of healthy dietary habits Repetition of information to enable understanding Opportunity to self-monitor behaviour Acknowledgment of the barriers to behaviour change and ways to overcome these
Design objective 3: Intervention content is simple, clear and appropriate for lower health literacy	Short sentences, avoiding complex language, terminology, abbreviations, and jargon Create a platform that is visual, attractive and easy to navigate Wording and content of platform supportive and encouraging Content and messages piloted with diverse group of women including those whose first language is not English

5.4.4. Theoretical modelling

The PBA underpins interventions with evidence and relevant behavioural theory. The COM-B model of behaviour change and the behaviour change techniques utilised in existing lifestyle interventions were identified in Chapter 2 (Systematic review). The most common were: Goals and Planning, Shaping knowledge, Comparison of outcome and Feedback and monitoring. The COM-B model was appropriate to underpin the DAPHNY intervention development given its incorporation of other theories and practical application through identifying barriers and facilitators that need to be addressed to enable behaviour change. Using knowledge gained through the systematic review, PPI groups and evidence reviews, an introductory logic model for the DAPHNY study was built; forming a hypothesis of how the intervention may work (Figure 16). This formed the basis and was adapted to build subsequent logic models that were a result of the content analysis.

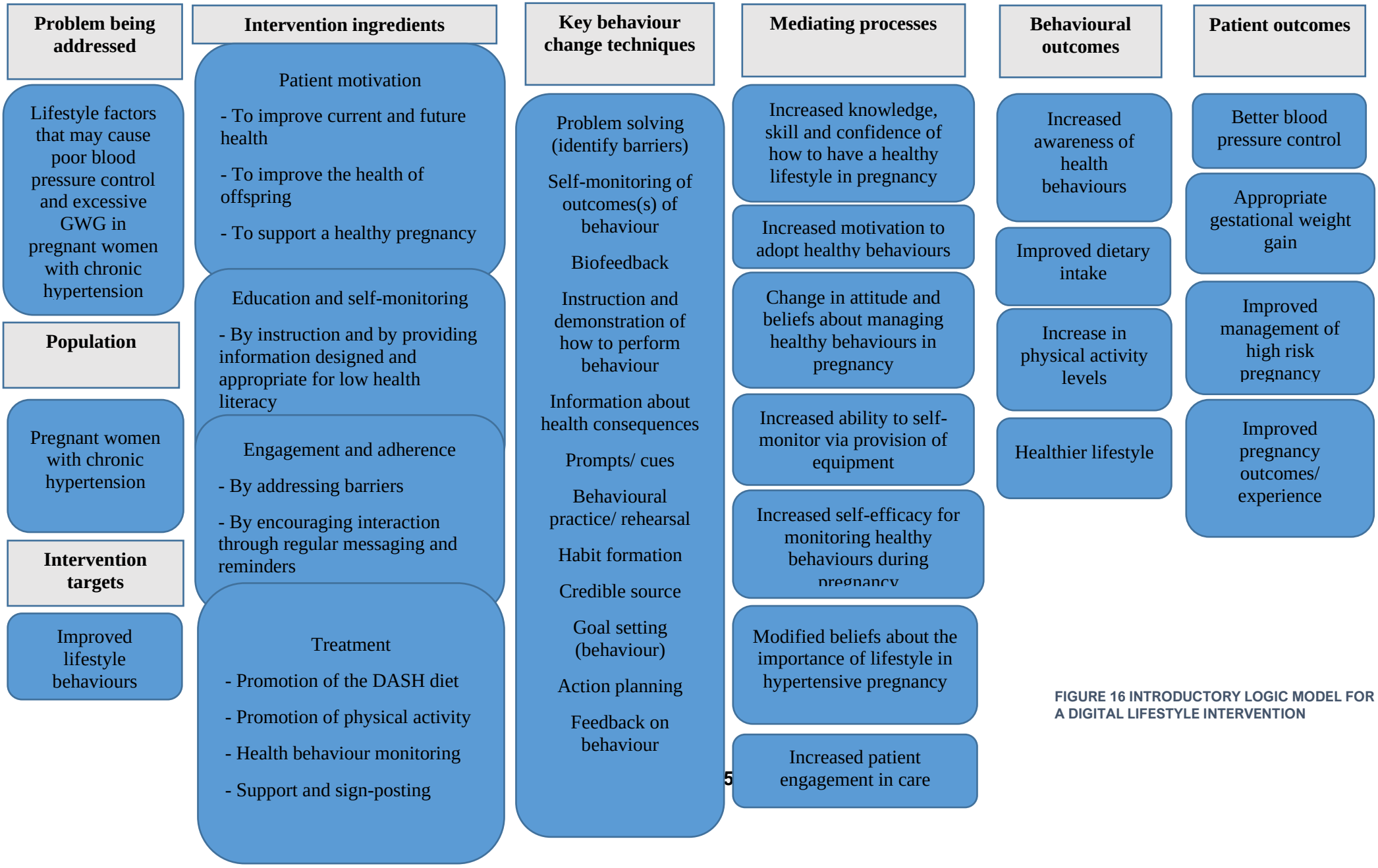


FIGURE 16 INTRODUCTORY LOGIC MODEL FOR A DIGITAL LIFESTYLE INTERVENTION

5.5. The DAPHNY Study

5.5.1. Protocol

A protocol was developed including detail of the three primary data collection studies to develop the intervention (Appendix 11):

- Study 1: Online survey for women (Reported in Chapter 4)
- Study 2: Focus groups with healthcare professionals
- Study 3: Early feasibility testing with women

5.5.1.1. Study documents

Posters were tacked up in the lifts and wards in the maternity unit at the John Radcliffe Hospital, Oxford University Trust, and Saint Mary's, Manchester Foundation Trust to encourage participation (Appendix 18). Participant information sheets to describe the study to potential participants were developed so that they had enough information to decide to take part (Appendix 19). Two informed consent forms were created in alignment with University of Oxford regulations to allow for remote and in-person consent to take place (Appendix 20).

Two enrolment questionnaires were created to ensure I captured important and relevant details about participant characteristics (Appendix 21).

5.5.1.2. Ethical approval

All study documents and other relevant documents were submitted to the University of Oxford, as Sponsor. This was approved in April 2022 (Appendix 12).

Subsequently, all documents were submitted for NHS HRA approval. This was given favourable opinion by HRA and Health and Care Research Wales (REC ref: 22/WA/0130) in May 2022 (Appendix 13).

An amendment to the protocol was submitted in November 2022 and approved by REC (December 2022) and sites confirmed continued Capability and Capacity in January 2023

(Appendix 14, Appendix 15 and Appendix 16). This provided screenshots of the content and design of the intervention prototypes as requested by the REC sub-committee at the initial review (Appendix 23). A letter of invitation was also included in the amendment to increase responses to the online survey (reported in Chapter 4) (Appendix 16) and a change to the advertisement postcard (Appendix 22).

The women who took part in the study, received a £10 shopping voucher to thank them for their time and participation.

5.5.1.3. Trust R&D approvals

Capability and Capacity for Oxford University Hospitals Foundation Trust was confirmed in August 2022 and for Manchester Foundation Trust in October 2022. The delay between REC approval and Trust approval were due to a convoluted process of having the correct contracts signed by the necessary parties and a new EPR system being introduced at one of the Trusts meaning capacity for the review process was reduced.

5.5.1.4. Study management

The study was part of the NIHR portfolio. I submitted recruitment numbers via the Central Portfolio Management System each month and to Trust clinical managers for their local reporting systems.

5.5.1.5. Challenges in governance

The DAPHNY App was reviewed for safety by the University department via a Third Party Security Assessment and Oxford University Foundation Trust via a Data Protection Impact Assessment. Information Management and Technology (IM&T), providers of the server platform that the DAPHNY App was located, was also assessed for security. From initiating initial enquiries to approval for the study to commence, these processes took over 3 months to carry out.

The growing use of technology for health and within the NHS has led to increased regulation of digital technologies. Even over the course of my DPhil, tighter restrictions on data access and security of Apps became evident. This caused significant delays and lengthy administrative tasks to resolve and comply with new policies and procedures that were not necessarily straightforward or transparent to follow. This is an important consideration for the implementation of new Apps within the healthcare system as complying with Information Governance could halt, or at least slow, the roll out of new interventions.

5.5.2. Methods: Study 2 - Focus groups with healthcare professionals

I conducted focus groups with healthcare professionals to gain an understanding of their views on the DAPHNY intervention. As healthcare professionals have a role in health promotion, it is vital to seek their views on a lifestyle intervention where they have frequent contact with women who have hypertension throughout pregnancy.

Focus groups are a frequently used methodology within healthcare research as they encourage participants to explore issues in their own terms which can draw out nuances in care delivery that could otherwise be overlooked (245). This is relevant for intervention development as interventions cannot be delivered within their own silo and must navigate the dynamics of multidisciplinary teams that work together and with women to support them through their pregnancy journey.

This chapter reports the results of the content analysis to inform the iterative development of the DAPHNY intervention. This will follow with a thematic analysis, providing an in-depth analysis of the role and perspectives of healthcare professionals supporting women with hypertension in the wider context of maternity care provision and this is reported in Chapter 6.

5.5.2.1. Study 2: Participants, sampling and recruitment

Eligible participants were any healthcare professionals who provided care for pregnant women with hypertension and were willing and able to give informed consent for

participation in the study. I aimed to speak to different health professionals to elicit differing perspectives. Therefore, I purposively sampled midwives and obstetricians with varying levels of experience from different areas of the maternity unit. I had intended to speak to staff at Manchester Foundation Trust but due to delays in study set up at this site, I was not able to. However, when attending this site for other parts of the study, I was able to speak to staff on an informal basis about the study and the intervention being developed, adding insight that could inform my analysis and thus the development of the intervention.

Through collaboration with staff at the participating sites, I approached potential participants and provided a participant information sheet (Appendix 19). They could decide to take part at that point or later by contacting me by email to arrange an interview time. Focus groups took place in a pre-booked room in the hospital, any available room on the ward, a break room or the ward manager's office. All focus groups took place in-person. Individual interviews were carried out if we were unable to co-ordinate timings between participants for a focus group or if this was more convenient for the professional. Participants were given an opportunity to ask any questions and provided written consent (Appendix 20) prior to commencing the focus group or interview.

5.5.2.2. Study 2: Topic guides

Topic guides were oriented around the DAPHNY App but were revised throughout the data collection period, depending on feedback from preceding focus groups (Appendix 24). Discussions began with talk about usual care pathways for pregnant women with chronic hypertension and participants' experience of providing lifestyle advice for this group. Potential components of the intervention were introduced to the group to stimulate discussion. Questions were orientated around these features and discussions were fluid between directly relating to the intervention, to the wider challenges experienced by health professionals and views in providing care for these women.

5.5.3. Methods: Study 3 - Early feasibility testing with women

Early feasibility testing involved qualitative and quantitative methods which analysed App usage and engagement data. Component 1 involved, think-aloud interviews, an evidenced based qualitative interview technique commonly adopted in the PBA to gather important insights from target users about how the intervention can be adapted to meet their needs and overcome barriers (246, 247). Mock-ups of the intervention were created using a prototyping tool called FIGMA which is a web application for user interface design (https://www.figma.com). Participants could freely explore the prototype, navigating into the different intervention components as they wished. Whilst doing this, they were encouraged to share immediate reactions and verbalise their thoughts throughout to establish user acceptability and inform changes.

For the second component of the early feasibility testing, participants were invited to use the DAPHNY intervention at home for a minimum of two weeks and then I interviewed them about their views and experiences of using the intervention. I also explored any lifestyle changes that were made as a result of engaging with the intervention.

This Chapter reports on the content analysis of the think-aloud interviews and the quantitative analysis of the App usage data generated from the second component of the early feasibility testing. The following chapter, Chapter 6, will report the thematic analysis of both think-aloud and individual interviews following the short testing period.

5.5.3.1. Study 3: Participants, sampling and recruitment

Participants were pregnant, or recently pregnant (for component 1), women with chronic hypertension. For component 2, participants were required to be currently pregnant and have a smartphone that was compatible with the App, either an Apple or Android device.

I purposefully sampled, aiming to reach a diverse sample in terms of parity, gestation, ethnicity, age, experience of self-monitoring and attitudes to technology. This ensured that I spoke to women with different perspectives who could provide insight into optimising the

intervention, taking in the needs of different groups. Women from both Oxford University Hospital and Manchester Foundation Trust were approached via email for those had had their baby in the last year), at specialist antenatal clinics or on the maternity wards. Posters were also used to advertise the study with my contact details so women could get in contact if interested to take part.

If women were interested, I provided details about the study with the participant information sheet, allowing time for them to decide whether to take part and ask questions (Appendix 19). Arrangements were then made to conduct the think-aloud interview or to download and introduce the DAPHNY App for testing. Obtaining consent (Appendix 20), enrolling participants to the study and the interviews could take place in-person or online via Teams or, in the case of the component 2 interviews, via a phone. In-person interviews took place in an available room on the ward, if the participant was an inpatient, or in an available room at the clinic.

5.5.3.2. Study 3 (Component 1): Think-aloud interview topic guides and procedure

Topic guides were designed around the participant's interaction with the intervention prototype (Appendix 25). I explained to participants the difference between think-aloud interviews and qualitative interviews as this was often a new concept and thinking out loud can feel unnatural. To ease participants into the think-aloud interview, I started with more general questions about advice they had received from healthcare professionals about health behaviours in relation to their blood pressure. Before showing them the intervention, questions also explored current blood pressure management and any technology use that supports this or supports engagement in healthy behaviours.

I showed participants the DAPHNY prototype either on my laptop, if interviews were in-person or via the shared screen function, if sessions took place online. Participants began on the welcome pages and then were free to navigate around the different components.

The prompts on my topic guide were flexible to respond to women's interaction with the prototype. I drew on the recommended think-aloud topic guide of the person-based approach to ensure I elicited the most useful information for intervention development and optimisation. As well as this, my questions were informed by the COM-B model, the theoretical model that underpinned this study from the outset, so that I could determine the key barriers and facilitators to behaviour change. For example, I asked questions around motivating factors for engagement and long-term positive behaviour change.

More directed questions were asked if changes had been made to the intervention that needed exploring with new participants to ensure understanding or acceptability. As well as this, as the intervention was large, it was not always possible to explore the whole of the intervention with each participant, therefore I took a flexible approach where I was informed by previous interviews about the most pertinent section to explore. This was sometimes led by a participant's particular interest or insight in an area of the App. In these cases, I wanted to maximise insight into specific components rather than attempting to look at all areas but gaining less insightful answers.

The topic guides were piloted with the two PPI collaborators before being used with the participants. The benefit of this was twofold, firstly they offered insight into the intervention which was taken forward into the analysis and secondly, they helped ensure the procedure and questions asked were understandable and acceptable before starting the study.

5.5.3.3. Study 3 (Component 2): Individual interviews following testing period and procedure

The development of the topic guide for the second component of the early feasibility testing, is reported in Chapter 6, Section 6.3.3, where the analysis of these interviews is reported.

Participants were approached in the same way as for the think-aloud interviews but for this part of the study, an enrolment session was either booked with me or I enrolled participants to using the App when I recruited them. Following consent, the enrolment session involved

completing the basic demographic questionnaire (Appendix 21) and registering participants on the DAPHNY online dashboard that enabled use of the App. I orientated participants to the App, providing information about key components and areas of the App that could be explored and used. Written instructions provided a brief overview of the App for participants to refer to if required over the course of the testing period (Appendix 26).

During the study set up, conversations were had regarding the provision of pedometers for participants in order for them to track their step count. Early on in the development of the DAPHNY study, I trialled a FitBit watch for one week to assess whether this could work alongside the DAPHNY App. However, the FitBit device has to be associated with a separate App and it uses several behavioural techniques including motivational messages, reward badges sent via email and movement prompts. This meant it would be very difficult to isolate the participants use and interactions with the features of the DAPHNY App for behaviour change. In the think-aloud interviews I explored women's views around pedometers with many identifying their own watches that track their steps or they used their phone to track this, since this was on them most of the time. Discussions were held with the App development team on the use of a pedometer given my experience using the FitBit and being realistic about whether providing an additional device for people to use would be needed given that many already have their own way of recording this. A decision was made to provide a simple pedometer with limited features with the DAPHNY App where participants could enter their step count manually. As this wasn't a trial measuring the accuracy or comparing participants step count, we decided that I would provide a pedometer to those who had no existing way of measuring the steps (either using an activity tracker/ watch or their phone). The purpose of the DAPHNY App was to explore whether there was motivation to engaged with the App features, as opposed to whether the App resulted in an increase in step count from start to finish, and therefore was appropriate for this study.

I provided the study contact number for participants to contact me if they had any immediate technical issues with the App or comments that they wanted to share whilst they were using the App. They were aware not to use the study phone number for any concerns relating to the pregnancy or if they felt unwell and the relevant triage numbers were highlighted.

After the first few participants were recruited, from the interviews and analysing the App usage data, it became apparent that there was minimal engagement with the App for some. This prompted me to provide more thorough orientation around the DAPHNY App, including setting a step goal and food focus with the participant, during the enrolment session and to send a text half way through the testing period to check in with how they were finding using the App. This was discussed with supervisors and PPI contributors and agreed to be an appropriate strategy.

At the end of the enrolment session, we chose a time and date that suited the participant, to conduct the interview. This ranged from approximately 2 weeks to 4 weeks.

5.5.4. Methods: Study 2 and 3 (Components 1 and 2) - Data collection

All focus groups and interviews were audio-recorded, de-identified and transcribed by myself or an independent transcriber. Transcriptions were cut and transferred into an Excel workbook which was used to organise and manage the dataset for the content analysis.

Data collection continued until I felt that no new, major information was appearing with additional interviews, i.e. comments related more to personal preferences than key intervention functions that influenced user engagement or behaviour change, as recommended in the PBA.

5.5.4.1. Usability testing

After the content analysis was complete, I worked with engineers in the Biomedical engineering department who were part of the intervention development team to build the first version of the DAPHNY intervention. Initial usability testing was carried out by myself,

two supervisors and two PPI representatives. This revealed any functional or visual changes needed or any points of confusion prior to conducting the second component of the early feasibility testing where women would use the App.

5.5.5. Analysis

5.5.5.1. Study 2 and 3 (component 1): Content analysis

For the content analysis and using the guidance from the PBA, I performed a content analysis of the interview and focus group data using a coding framework and the MoSCOW framework (248). Analysis was conducted throughout data collection so that modifications could be made to the intervention and then shown to subsequent participants.

I familiarised myself with the data by reading and re-reading each transcript. I extracted and tabulated all quotes relating directly to the intervention design, content, component, and features. This included both positive and negative comments as well as any suggested changes, all of which gave insight into factors that will affect engagement with the App and behaviour change (i.e. increasing healthy eating/ physical activity).

Each comment was considered against a coding framework (Table 21) used in the PBA, to support decision making about potential intervention modification. These were then given a priority using the MoSCOW framework (Table 22), a commonly used prioritisation model for developing digital interventions (248).

TABLE 21 CODING FRAMEWORK FOR MAKING DECISIONS ABOUT MODIFICATIONS

Code	Stands for	Means
IMP	Important for behaviour change	Likely to impact behaviour change or a precursor to behaviour change (e.g. acceptability, feasibility, persuasiveness, motivation, engagement)
		Or is in line with the Logic Model
		Or is in line with the Guiding Principles
EAS	Easy and uncontroversial	Easy change that doesn't involve major design changes
REP	Repeatedly	Said repeatedly, by more than one participant
EXP	Experience	Something supported by the experience from Patient and Public Involvement
		Evidence from the literature
NCON	Does not contradict	Does not contradict experience, Logic Model, or Guiding Principles
NC	Not changed	e.g. Not feasible
		Or only one person said this

TABLE 22 MOSCOW FRAMEWORK (AS PER BRADBURY ET AL., 2014)

Must have this for the intervention to be effective in changing participants behaviour
Should have (if possible) for the intervention to be a success, but may be able to be delivered in a different way, or is in some way less critical than a Must have
Could have this as it would be useful, but only if time and resources are available
Would like but is not essential for behaviour change and can be put on hold

Data analysis and data collection was cyclical and happened rapidly. Increasing the integrity of this process, I had regular discussions with the wider team to seek expert opinion, as well as regularly drawing on evidence, theory, and incorporated PPI input throughout. These discussions informed decision making to ultimately improve the intervention, overcoming important barriers to make the intervention more acceptable and accessible to women. A large 'table of changes' documented the decisions and actions throughout the process, to provide an audit trail of how the intervention developed over the course of the study.

As explained, the table of changes was the tool used for discussions and to detail the changes made to the intervention. Using the behaviour change wheel as a theoretical basis for this intervention, the 'table of changes' was then summarised into draft logic models to present how each identified target behaviour was addressed by the intervention. Within the logic model, the data was mapped against the COM-B model; Capability, Opportunity, and Motivation to clearly define what participant felt the barriers and facilitators were to its use and engagement. The modifications to the intervention to address these are detailed in the logic model with the associated behaviour change technique; successfully linking the data to core elements of the behaviour change wheel that ultimately underpin the intervention.

A thematic analysis of the data, extending interpretations of the data beyond behavioural theory described above is reported in Chapter 6.

5.5.5.2. Usability testing

I used a basic usability testing worksheet and fed back any issues to the App development team. Firstly, I developed a functionality testing instruction sheet that included all possible actions that a participant could do on the App (Appendix 27). Along with this I created a set of questions to ask during my conversations with my PPI reps to find out whether the App was working as intended and to discover if it was user friendly (Appendix 28). I used guidance from the general UX field, specifically for the development of mobile Apps, to focus the questions around functionality, as opposed to its actual implementation in women's lives that was explored in the individual interviews with the women who had used the App.

5.5.5.3. Study 3 (component 2): App usage analysis

The raw data collected from participants using the App was collected on the DAPHNY website dashboard. App usage logbooks detailed the pages accessed, data entered by participants and duration of interactions. These were exported into Excel a week following enrolment and repeated the day before the interview. This informed the interview guide so that their actual usage could be explored more meaningfully in interviews.

I worked closely with YC to analyse the app's usage logbooks, specifically tracking user interactions with 'in' and 'out' pages. I obtained the following insights: the total duration of app usage (including number of days and minutes), the duration and number of individual sessions (presented as mean (SD), median and range), and the pages that were most frequently accessed. Due to unforeseen circumstances, certain information was missing from the app's usage logs. In response, we used an automated tool and compared this to manual outputs, which addressed the issue. Duration of total App usage, duration and number of sessions, pages most frequently accessed are presented in a summary graph and tables to provide a big picture view of how the App was used. Data entered by the participants, including step count and blood pressure, are reported descriptively.

Data extracted included sessions 20 minutes after initial installation of the App (to exclude the initial orientation session) to 5pm on the date of the participant interview. A session was defined when a participant exited the App or if the App was not exited but it was running in the background but the participant did not return to it again within half an hour. Sessions that were less than 5 seconds long were removed from the analysis to exclude any unintentional interactions that were too short to be meaningful (249). This would possibly remove interactions such as looking at notifications but it removed interactions such as navigating through pages which would result in the higher-level pages appearing most popular.

5.5.6. Results

5.5.6.1. Study 2: Participant characteristics

A total of 23 healthcare professionals took part in a focus group (*n* = 7, consisting of between 2 to 4 participants) or an individual interview (*n* = 4). These included an interdisciplinary mix of midwives (community and hospital based), student midwives, maternity support workers, junior doctors, and obstetric consultants (Table 23). Focus groups lasted between 22 and 45 minutes.

TABLE 23 CHARACTERISTICS OF FOCUS GROUP/ INTERVIEW PARTICIPANTS (N=23)

Profession	
Midwife	14
Doctor	5
Student Midwife	1
Support/ assistant practitioner	3
Main orientation	
Rotational (more than one area of maternity)	13
Antenatal ward	2
Community and/ or MLU	6
Research	1
Other	1
No. years' experience	
0-5	7
6-10	4
11-15	6
16-20	4
20+	2

5.5.6.2. Study 3 (component 1): Think-aloud interview participant characteristics

Eleven women took part in think-aloud interviews and viewed the App prototypes (Table 24). Seven participants were patients at the John Radcliffe hospital in Oxford and four were booked at Saint Mary's Hospital in Manchester. Interviews lasted between 32 and 60 minutes.

TABLE 24 PARTICIPANT CHARACTERISTICS OF THE WOMEN WHO TOOK PART IN THINK-ALOUD INTERVIEWS (STUDY 3: COMPONENT 1) (N=11)

Age category	
25-34	6
35-49	5
Current pregnancy status	
Currently pregnant	8 (Gestational age range 22+5/40 – 37+4/40)
Pregnant within last 12 months	3
Gravidity	
1	6
≥2	5
Hypertension diagnosis	
During pregnancy (<20/40)	5
Pre-pregnancy	6
Ethnicity	
White British	8
White European	2
Asian	1
Highest education attainment	
Other	4

Degree or above	7

5.5.6.3. Content analysis of study 2 and study 3 (component 1)

Eleven women and 23 healthcare professionals informed the iterative development of the DAPHNY App. From participant feedback and content analysis, three logic models were generated, summarising the key barriers and facilitators of each target behaviour and the intervention features aimed to overcome these. The logic models are a visual and testable representation to hypothesise how the intervention may work. The preliminary logic model (see Section 5.4.4) provided a broad overview of the intervention but through detailed work on the content analysis to gain a thorough understanding of the key intervention targets, it was important to develop more refined logic models that provide fine-grain detail on the barriers and facilitators and the implemented features used to address these. Within these, key behaviour change techniques in the intervention were identified using the 93 BCT taxonomy and these are highlighted in the logic model (149).

Logic model 1 (Figure 17) acts as a mediating process that is necessary to lead to logic model 2 (Figure 18) and 3 (Figure 19) i.e. accessing and engaging with the App (Logic model 1) is required to increase knowledge and capability to increase healthy eating (Logic model 2) and physical activity levels (Logic model 3) during pregnancy. Subsequent changes in blood pressure are outcomes associated with logic model 2 and 3 but was not a testable part of the intervention, or within the scope of this study. Screenshots of the key components in the App and the features identified in the logic models follow.

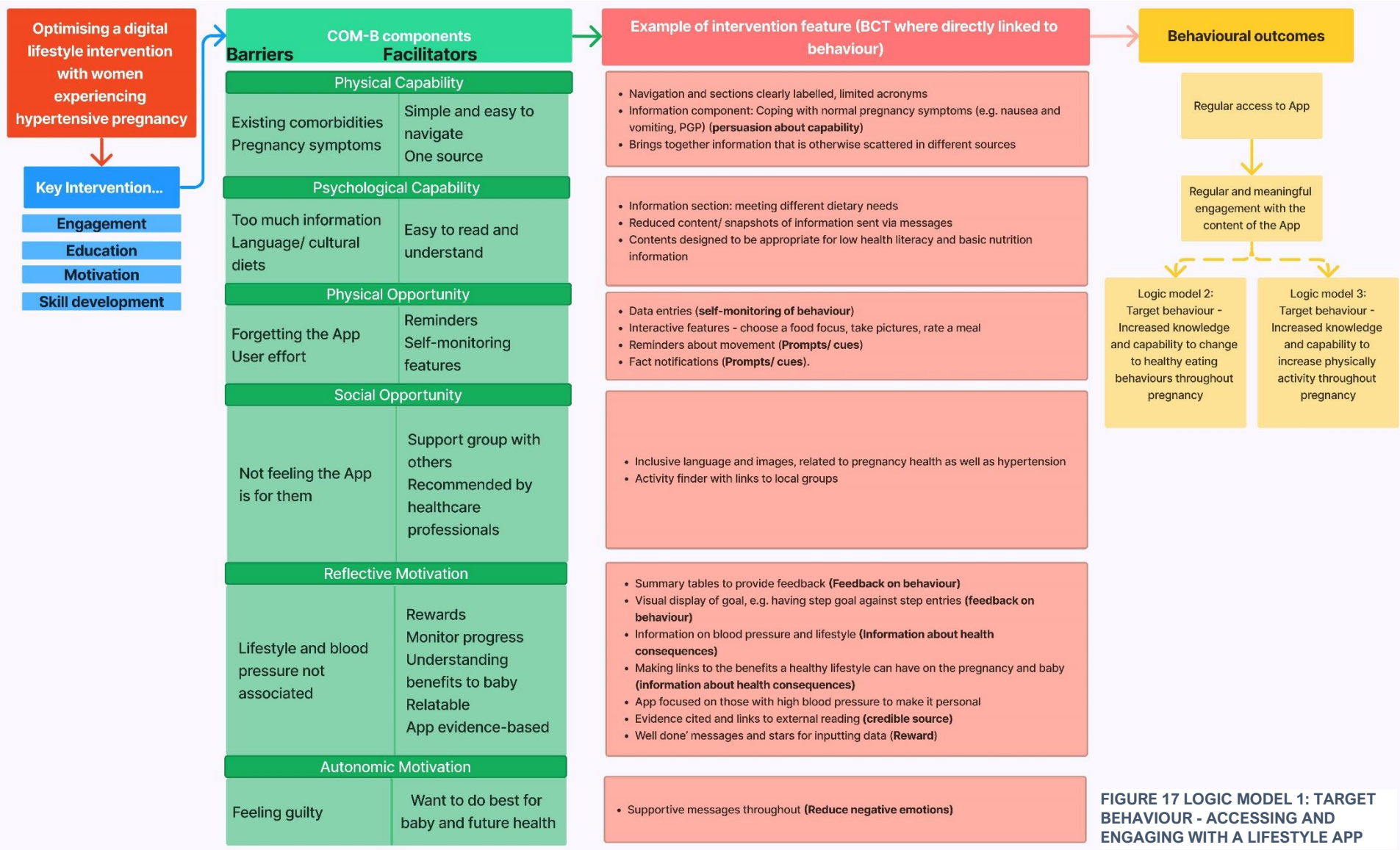


FIGURE 17 LOGIC MODEL 1: TARGET BEHAVIOUR - ACCESSING AND ENGAGING WITH A LIFESTYLE APP



FIGURE 18 LOGIC MODEL 2: TARGET BEHAVIOUR - INCREASED KNOWLEDGE AND CAPABILITY TO CHANGE TO HEALTHY EATING BEHAVIOURS THROUGHOUT PREGNANCY

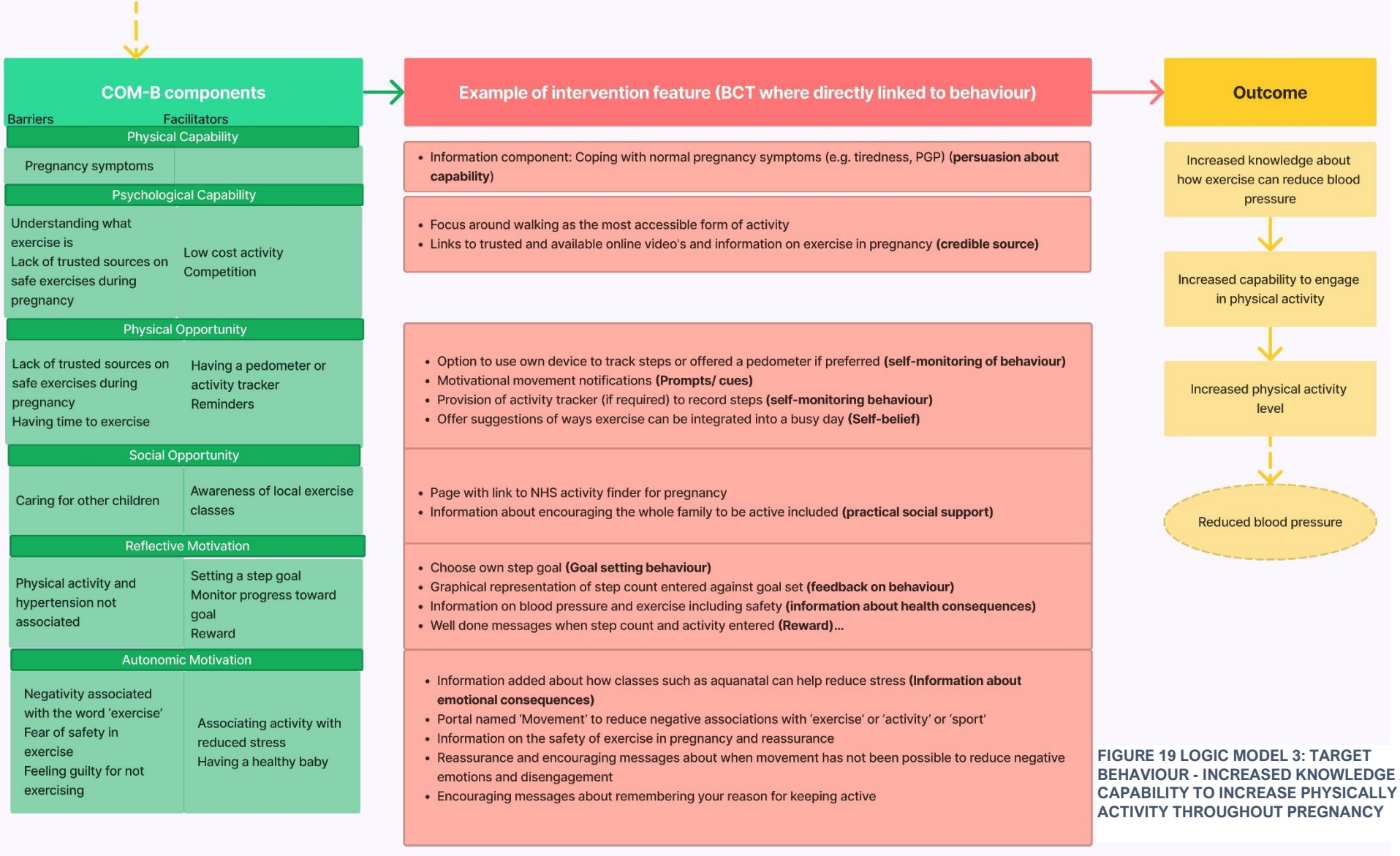


FIGURE 19 LOGIC MODEL 3: TARGET BEHAVIOUR - INCREASED KNOWLEDGE AND CAPABILITY TO INCREASE PHYSICALLY ACTIVITY THROUGHOUT PREGNANCY

As displayed in the logic models, key features included: supportive messaging, acknowledging the challenges of being pregnant, goal setting, rewards and recognition that effort has been made, feedback on behaviour including self-monitoring data, prompts via push notifications, shaping knowledge around how to have healthy behaviours, providing information about health consequences such as pregnancy outcomes associated with poor blood pressure control and the information on the App being from a credible source and therefore sources used clearly referenced. The screenshots from each section of the App show where and how these have been implemented in the first version of the DAPHNY App (Figure 20, Figure 21, Figure 22 and Figure 23).



FIGURE 20 DAPHNY APP SCREENSHOTS AND IMPLEMENTED CHANGES FOLLOWING CONTENT ANALYSIS (WELCOME PAGES, NOTIFICATIONS AND ADDITIONAL INFORMATION)

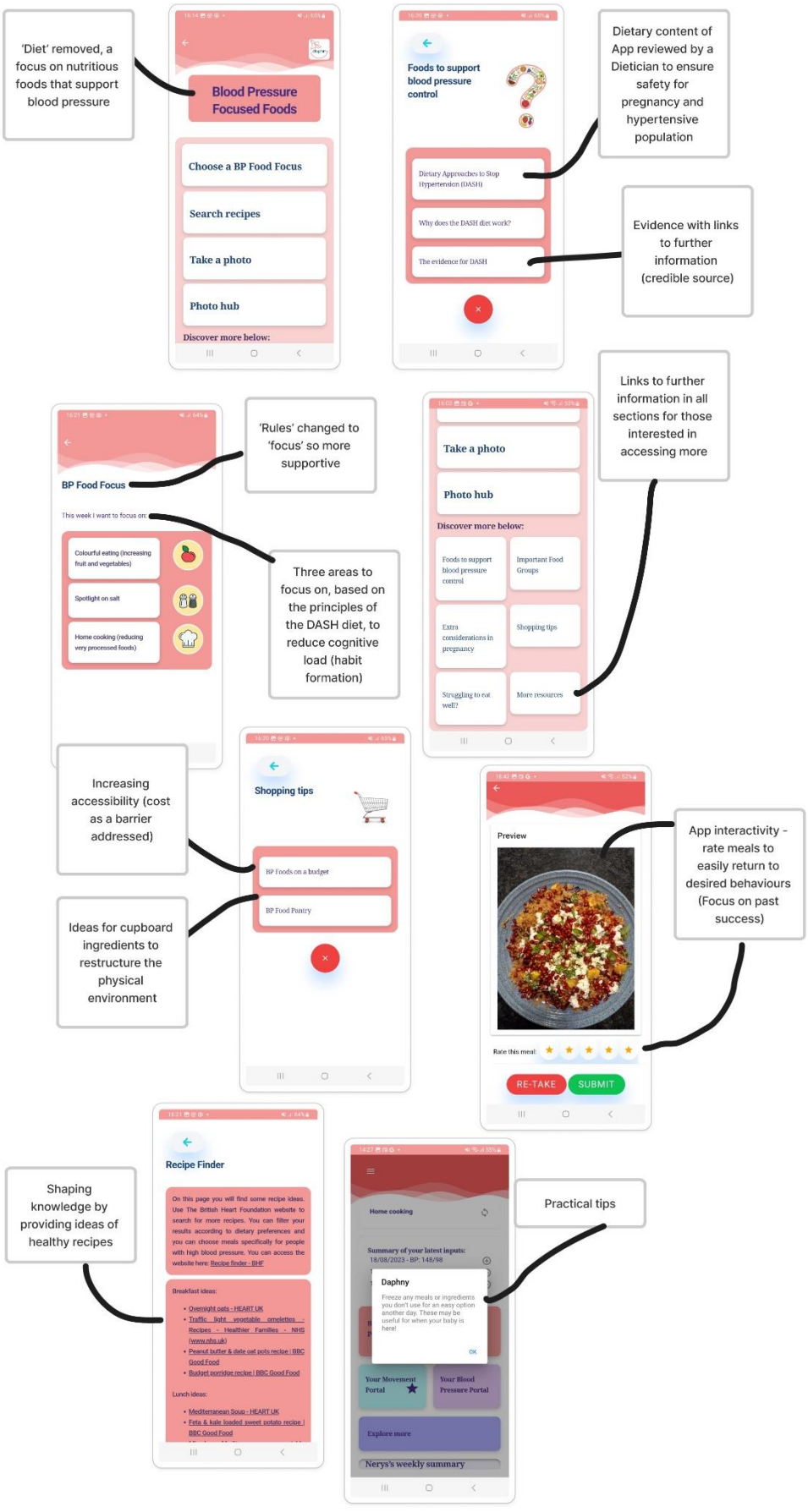


FIGURE 21 DAPHNY APP SCREENSHOTS AND IMPLEMENTED CHANGES FOLLOWING CONTENT ANALYSIS (BLOOD PRESSURE FOCUSED FOODS PORTAL)

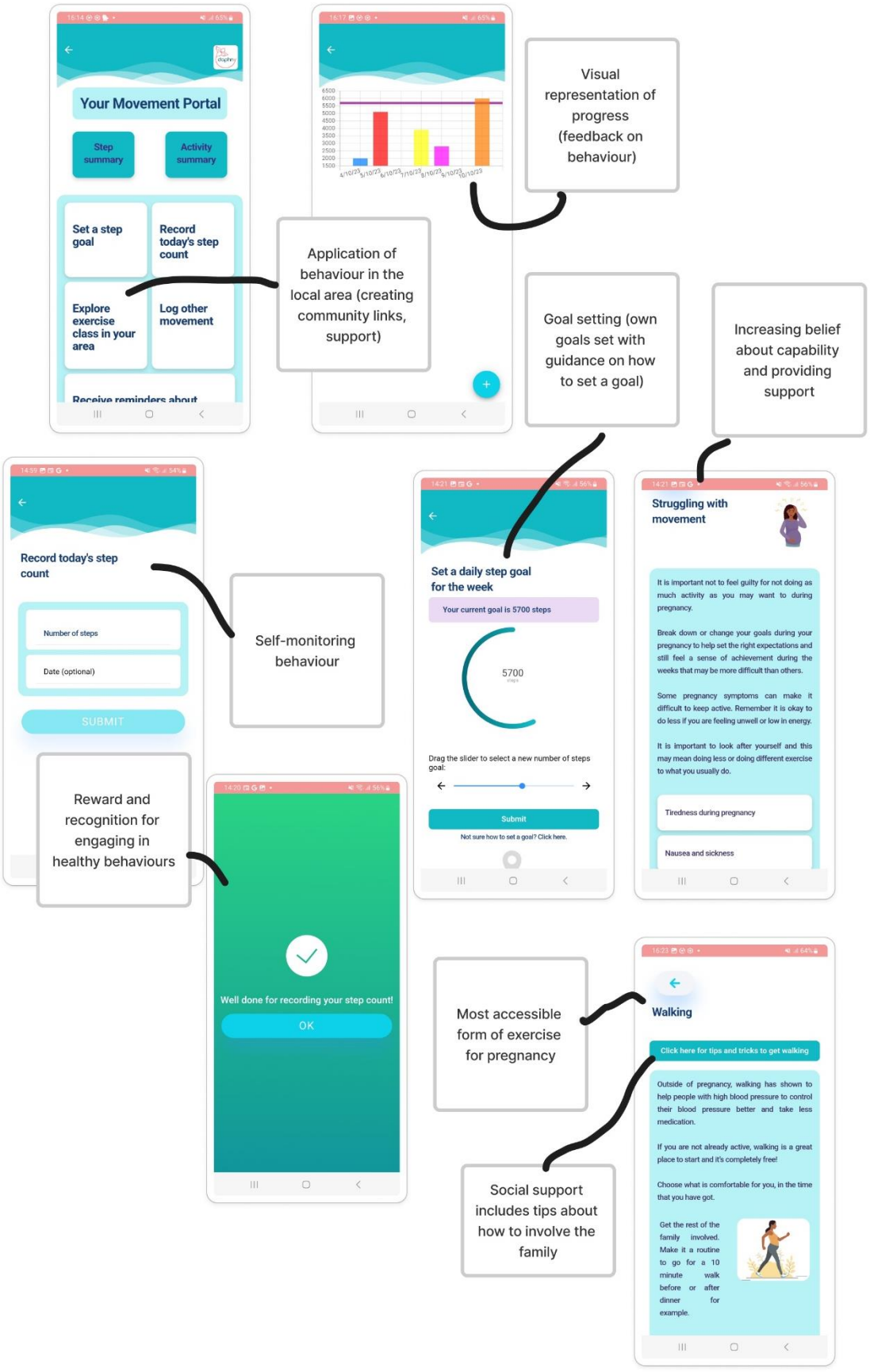


FIGURE 22 DAPHNY APP SCREENSHOTS AND IMPLEMENTED CHANGES FOLLOWING CONTENT ANALYSIS (MOVEMENT PORTAL)

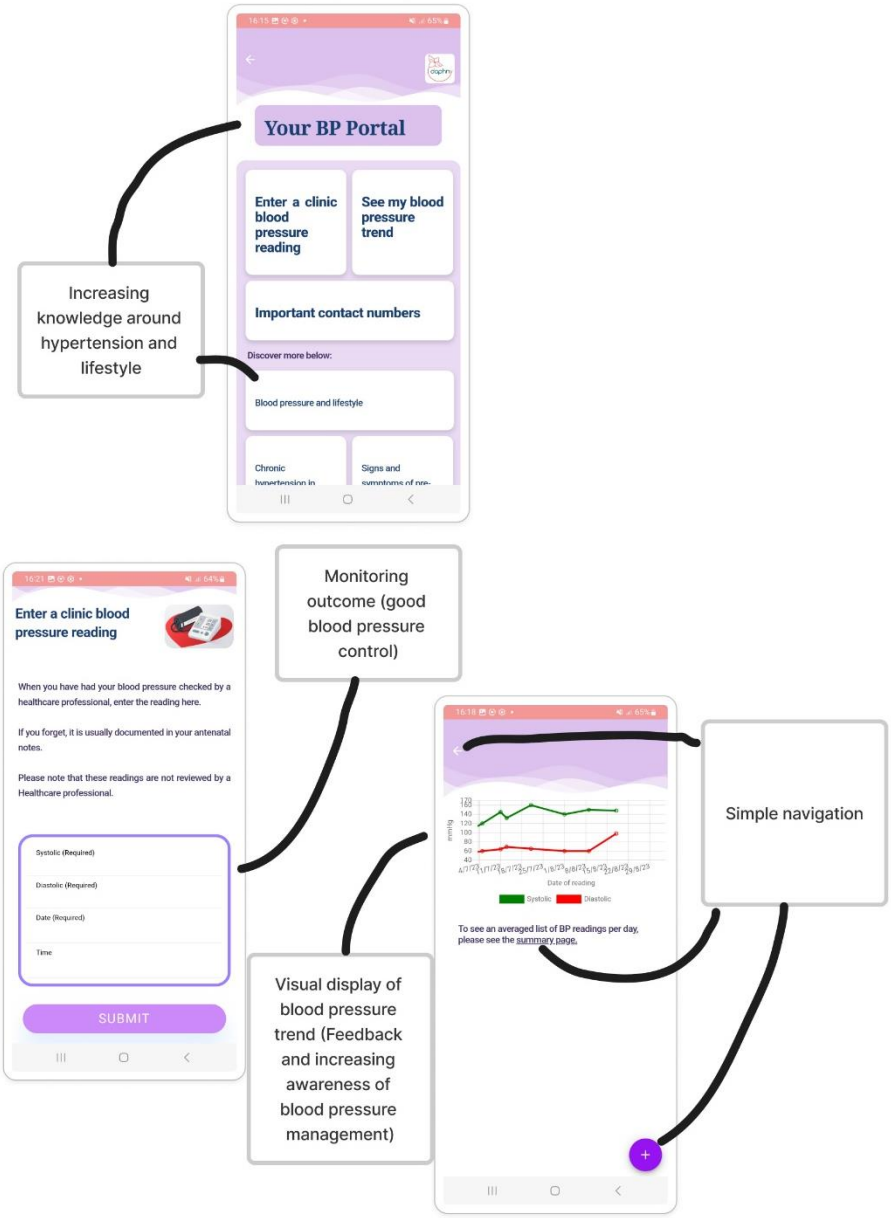


FIGURE 23 DAPHNY APP SCREENSHOTS AND IMPLEMENTED CHANGES FOLLOWING CONTENT ANALYSIS (BLOOD PRESSURE PORTAL)

5.5.6.4. Considerations for future iterations

The logic models encapsulate all the implemented features based on participant's feedback, to optimise the intervention. It does not display the feedback received that we were not able to achieve in this version of the DAPHNY App due to time and resources and to keep within the scope of the study. Future features that were desirable amongst participants and would support them accessing and engaging with the intervention are displayed in Table 25.

TABLE 25 FEATURES TO CONSIDER FOR FUTURE ITERATIONS

COM-B component	Future features to consider
Physical capability • Not all women have smartphones or use Apps • Downloadable on different devices • Clear meal plans	• Printable and web version • Generate weekly meal plans with shopping list
Psychological capability • Only available in English	• Available in different languages
Physical opportunity • Healthcare professionals do not have training on lifestyle factors and hypertension • Tool to help facilitate healthcare professionals talk about the App • Linked devices • Entering food intake to learn about intake • Being able to measure portions sizes	• Specific training for healthcare professionals about lifestyle factors and hypertension • Implement a prompt for consultations to remind professionals to introduce the App • Link to other devices and Apps (relevant to self-monitoring features) • Optional food tracking feature • Specific lifestyle related training • Provision of food scales
Social opportunity • Recommended by a healthcare professional • Support community • Seeing other people's stories • Competition with others (steps)	• Chat forum with other users or similar • Success stories about making lifestyle changes • Gamification with other users

Reflective motivation • Using the App in the postnatal or preconception period	• Talk to GPs and other healthcare professionals about the App • Consider application across the life-course
Autonomic motivation • None identified	

5.5.6.5. Specification document

Alongside the iterative development process, I built a specification document to detail technical information about the app features, key user interactions and also detail the content of App pages (Appendix 29). This was a live document that was used alongside the FIGMA prototypes by the engineers to build Version 0.0.1 of the App. I had regular meetings with CR, a member of the App development team with expertise in App development to support home monitoring, to implement features that were realistic in terms of the scope for this study and time frame.

5.5.6.6. Usability testing

Once version 0.0.1 was built, the App was ready for usability testing. These changes were focused on the technical detail such as connections between pages working. Appendix 28 provides the detail of this feedback from one of my PPI representatives. An example of an additional change that was made, was having links to the summary page of each portal from the homepage. Technical issues with the App not going back to the correct pages were resolved. Appendix 27 exemplifies how the functions and visuals of the App were thoroughly tested prior to the final study. I worked closely with CR and YC to implement these changes.

This feedback generated 3 further iterations of the App leading to a Version 0.0.4 that was used for participant testing.

5.5.6.7. Study 3 (Component 2): Individual interview participant characteristics

Ten pregnant participants were recruited and consented to using the App for at least 2 weeks (Table 26). Interviews lasted between 21 and 44 minutes. All participants were pregnant and gestational age ranged from 15+2/40 to 34+6/40. I provided a pedometer to 3 participants (Realalt 3DTriSport 3D Pedometer), and others used their own activity trackers including an Apple watch (3), Fitbit watch (2), Garmin watch (1) and one was unknown.

TABLE 26 PARTICIPANT CHARACTERISTICS OF WOMEN WHO USED THE DAPHNY APP AT HOME (N=10) (STUDY 3: COMPONENT 2) *TWO DID NOT COMPLETE INTERVIEWS BUT PARTICIPANT CHARACTERISTICS AND USAGE DATA IS PRESENTED

Age category	
18-24	2
25-34	4
35-49	4
Gravidity	
1	2
≥2	8
Hypertension diagnosis	
During pregnancy (<20/40)	5
Pre-pregnancy	5
Ethnicity	
White British	4
White European and South African	1
South African	1
Asian	1
Black African	2
Arab	1
Highest education attainment	
Other	6

Degree or above	4

5.5.6.8. Summary of total App usage

Participants had access to the App for between 16 days and 27 days. The proportion of days participants accessed the DAPHNY App within this time varied from 14% and 90%, with none of the participants accessing the App every day. Figure 24 displays the variation in App usage between participants. The total number of minutes a participant accessed the App over the course of their participation ranged from as little as 5 minutes 57 seconds (PPT19) to 51 minutes 8 seconds (PPT18) (Figure 24). A session by PPT18 was 21 minutes 40 seconds long and was removed from the analysis because 8 seconds were spent on the homepage and the remaining time was spent on one other page (Step summary graph), suggesting the App was left open but the participant was not interacting with it for all of that time. Despite removing this session, PPT18 remained the most engaged, spending the most time, had the most number of sessions (23) on the App and accessed it on the majority of days during participation (90%).

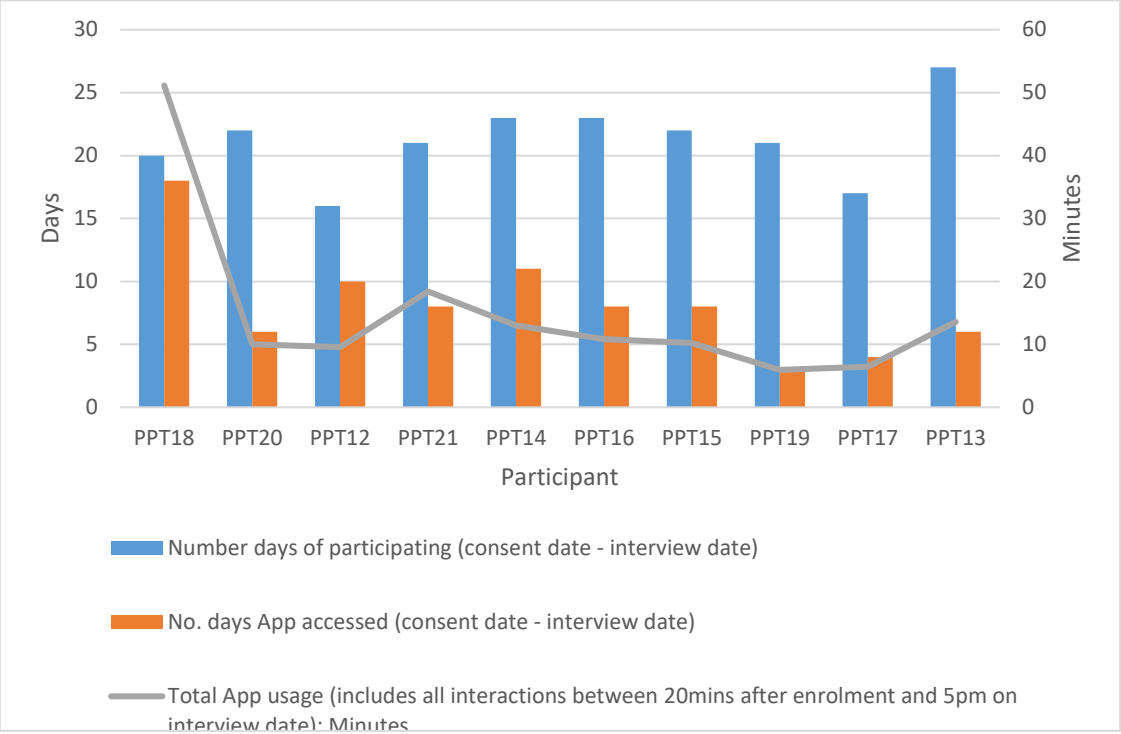


FIGURE 24 TOTAL APP USAGE BY EACH PARTICIPANT (ORDERED BY NO. SESSIONS, HIGH TO LOW)

Spending fewer days on the App did not necessarily equate to less time on the App. For example, PPT20 and PPT12 spent a similar amount of time on the App (10 minutes 1 second and 9 minutes 34 seconds, respectively), yet for PPT12 this was spread over 4 more days than PPT20, indicating more frequent access to the App but shorter sessions.

There were 116 sessions in total and the number and duration of sessions is displayed in Table 27. The majority of the sessions had durations that were more akin to the minimum duration, with a median length of 36 seconds.

TABLE 27 SUMMARY OF SESSIONS

	Mean (SD)	Median	Range (min-max)
Number of sessions per participant	13 (6.84)	13	3-23
Duration of sessions (mm:ss)	01:19 (02:27)	00:36	00:05-05:20*

*21:40 session has been removed. Mean and Median are calculated from inclusion of 21:40

5.5.6.9. Individual App pages accessed

The number of individual pages that the participants accessed ranged from 7 to 23 pages. Figure 25 displays the 14 pages accessed by more than 3 participants. The pages requiring the user to make an action, such as blood pressure readings and choosing a Food Focus were accessed by more participants than the pages with written information which required a deeper level of engagement through multiple layers of the App. The four information pages that were accessed by more than 3 participants included, 'Chronic hypertension during pregnancy' 'Signs and Symptoms of pre-eclampsia', 'Walking' and 'Weight gain during pregnancy'.

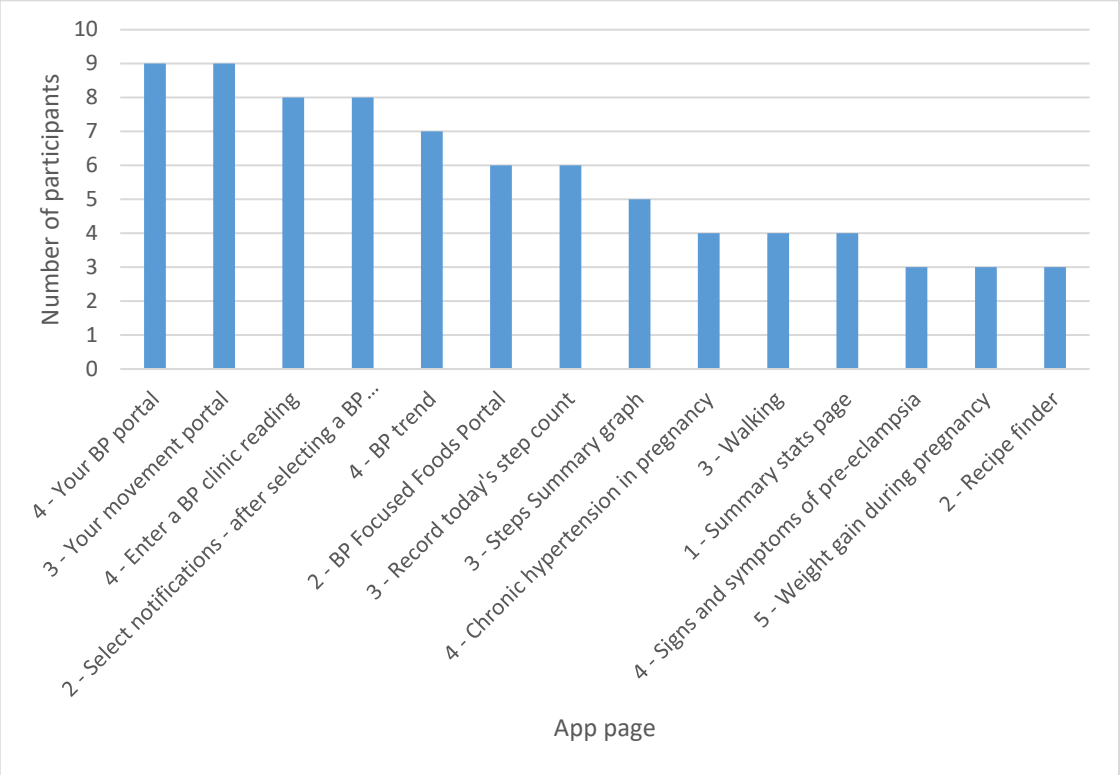


FIGURE 25 APP PAGES ACCESSED BY MORE THAN 3 PARTICIPANTS (HOMEPAGE REMOVED)

The least explored area of the App was the food portal, which can be seen in the list of pages that no participant accessed for more than 5 seconds where none of the food group pages were accessed (Table 28). Even though these pages were not accessed, participants spoke about how it was useful having this information in one place where they could find out more if they needed it. Furthermore, information about food was received in notifications which may have led to reduced interaction with this section. In some cases, participants felt they could have explored more of the App if they had had a longer amount of time between enrolment and the interview, and this was seen following their interview, where some participants engaged more with the App. These data are not captured here but could suggest that the interview prompted them to engage, highlighting how regular instruction and prompts with the women about the App may be needed for ongoing engagement.

TABLE 28 APP PAGES NOT ACCESSED

App page name *(Associated Portal/ section of App)*	
About DAPHNY *(Welcome pages)*	Wholegrains (6-8 per day) *(BP Focused Foods)*
Add contact *(Blood Pressure)*	Fruits and vegetables (4-5 servings of each per day) *(BP Focused Foods)*
Sleep *(Explore More)*	Dairy (3 servings each day) *(BP Focused Foods)*
Smoking *(Explore More)*	Lean proteins (up to 6 servings each day) *(BP Focused Foods)*
Alcohol *(Explore More)*	Nuts and seeds (4-5 servings per week) *(BP Focused Foods)*
Enter a weight page *(Explore More)*	Fats and oils (2-3 servings per day) *(BP Focused Foods)*
Weight trend *(Explore More)*	Sweets and added sugars (up to 5 servings per week) *(BP Focused Foods)*
More resources *(Explore More)*	Shopping tips *(BP Focused Foods)*
Page after entering a weight *(Explore More)*	BP foods on a budget *(BP Focused Foods)*
Struggling to eat well? *(BP Focused Foods)*	BP food pantry *(BP Focused Foods)*
Feeling overwhelmed *(BP Focused Foods)*	More resources *(BP Focused Foods)*
Nausea and sickness *(BP Focused Foods)*	Help *(Welcome pages)*
Different dietary preferences *(BP Focused Foods)*	Staying active, high blood pressure and pregnancy *(Movement)*
DASH *(BP Focused Foods)*	Walking tips and tricks *(BP Focused Foods)*
The evidence for DASH *(BP Focused Foods)*	Photo hub *(BP Focused Foods)*

Important food groups *(BP Focused Foods)*	Take a photo page *(BP Focused Foods)*

Figure 26 shows the App pages which had more than 5 sessions, i.e. were the most frequently accessed. Ignoring the Homepage, the data entry pages 'Enter a clinic blood pressure reading' (40 sessions) and 'Record today's step count' (39 sessions) had the most number of sessions, indicating again that participants use of the App was predominantly the interactive elements as opposed to reading information. This aligns with findings of the survey (Chapter 4) where monitoring features were desirable in an intervention. The blood pressure portal (24 sessions that were over 5 seconds) was the most frequently accessed portal. The 'Explore more' portal had only 3 sessions of over 5 seconds. This portal included information on weight, healthy living after giving birth as well as stress, sleep, alcohol and smoking information, indicating few participants accessed these additional subsections.

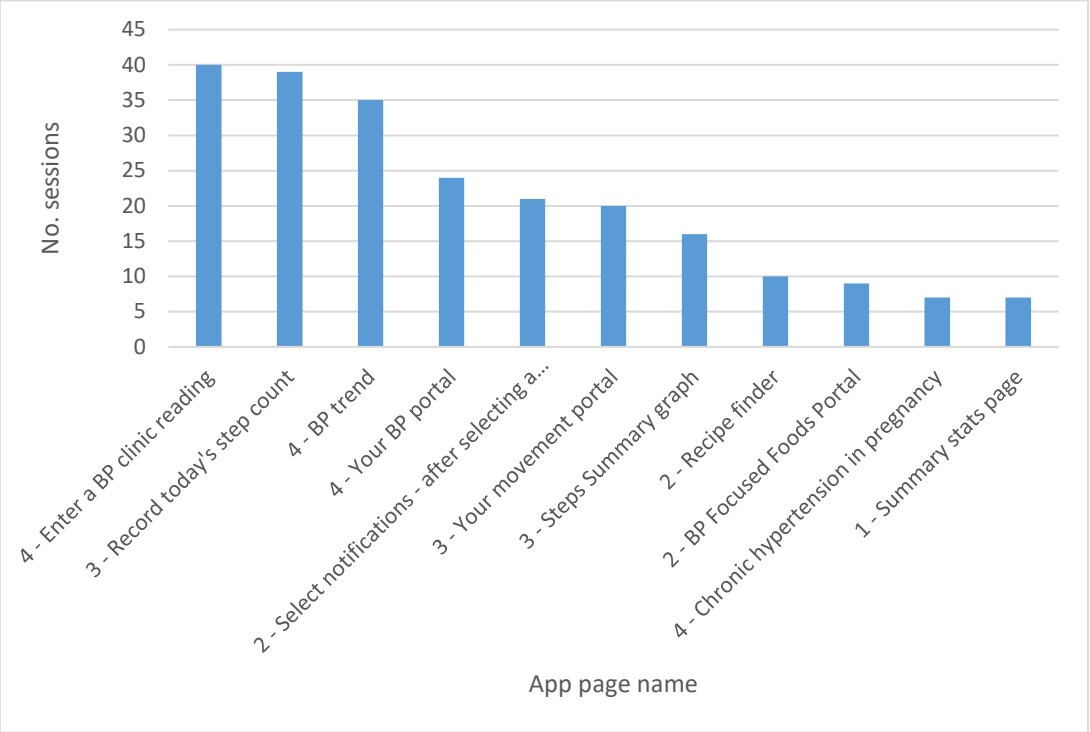


FIGURE 26 APP PAGES ACCESSED FOR MORE THAN 5 SESSIONS

5.5.6.10. Entering data

Nine participants entered blood pressure readings. Instruction was given at enrolment that these should be readings from the clinic since the DAPHNY App was not connected to a healthcare professional. This was agreed during the early development phase where there were concerns that participants would use the App to self-monitor but this wouldn't then be reviewed by a healthcare professional, as they may have been used to, so it reduced any potential risk of using the DAPHNY App. Despite this, four participants entered blood pressure readings between 4 and 19 times, suggesting some were using it to record their self-monitoring readings. Five participants entered one reading and during interviews these participants indicated that they were reporting self-monitored blood pressure readings elsewhere. There was a keenness to have some of the information available on the DAPHNY App in the same place as they were entering their self-monitoring blood pressure reading.

Setting goals was an important feature implemented based on feedback from the think-aloud interviews during the iterative development phase of the study. Five participants set a step goal, 3 of whom did this with myself during the enrolment session. Six participants

entered a step count between 2 and 12 times, of whom two of these six did not set a step goal. Some participants did not enter a step count because they reported in interviews that this was recorded elsewhere on Apps linked to existing activity trackers or their phone. This was a feature that was recommended to improve the functionality and ease of use of the DAPHNY App. Two participants who entered their steps, commented that these were on days where they had done more than their normal number of steps, indicating how reporting may be skewed towards days that were more active.

Participants could enter additional activities since it was recognised that some people will do more than walking to be active during pregnancy. Only one participant entered an additional activity which was housework (that increased your heartrate), an activity added during development because it was frequently mentioned in interviews as requiring physical exertion but was not often recognised as such.

As seen above, the 'Weight gain during pregnancy' page was accessed by 3 participants. One participant entered a weight and at interviews some participants had not seen this available feature but because there was already enough on the App to engage with, that it did not feel like it was missing. During the think-aloud interviews, a decision was made to remove the weight section from the main homepage (which was on the original prototypes). However, few participants engaged with this section, perhaps because it wasn't an obvious key component and because they had to navigate through multiple pages to reach it. When participants were asked if they thought there was any missing elements from the App, weighing was not a feature that was highlighted as missing. Participants felt there was enough already in the movement, diet and blood pressure sections to explore.

Participants could choose to focus on three key areas of their diet to improve their dietary habits and nutritional intake including 'Home cooking', 'Colourful eating' and 'Spotlight on Salt'. They could choose to receive regular notifications with top tips relating to each focus. Nine participants chose a food focus and five changed the focus in the duration of

participation. The participant who did not choose a food focus said that she felt she already had a lot of knowledge around what to eat so did not feel a need to engage with this part of the App. The notifications were felt to be helpful but one participant commented that she would like them to be more tailored towards her diet. More than one participant was prompted to engage in healthy dietary habits such as choosing a new fruit in the supermarket, being more aware of how much salt was in foods and trying new recipes. These short bursts of information appeared to be taken on board by participants more so than the information on the food portal which was infrequently accessed or not accessed at all by participants (see above).

5.5.6.11. Recommendations based on App use and interviews

There were several recommendations suggested during the interviews that participants felt would have increased their overall use and engagement with the App. Here, I briefly describe recommendations relating to the functional changes that could be taken forward, should this App be further developed, which could impact App usage.

When asked what participants felt was missing from the App, more than one spoke about the need for a chat or community forum that could function as a support network to encourage others and share experiences of hypertensive pregnancy. In the PPI groups that I held with women whilst conceptualising the DAPHNY study, the women spoke about how they were pleased to meet others who had experienced hypertension during pregnancy as support groups with other mums with similar risk factors was lacking. Feeding through the think-aloud interviews and then the final feasibility period, participants spoke of how a chat function to discuss matters with other mums would be beneficial and would encourage them to use the App and provide additional motivation to engage in healthy behaviours. This was not implemented in the DAPHNY App due to governance requirements for a chat forum that would need continued monitoring but demonstrates that women with chronic hypertension are seeking more support and a community in which they can share experiences. As an

alternative, the App could link out to relevant support groups such as charities related to hypertension (e.g. APEC) or general support forums (e.g. Mumset). However, women in the survey reported few groups exist specifically for those existing hypertension, highlighting where an embedded support group within the DAPHNY App may fill this gap and be of additional benefit.

As seen in the App usage data, not all areas of the App were accessed. In interviews, when I spoke to participants about areas that they didn't access, some were not aware that they had missed these despite the App being designed, and reported, to be easy to use and navigate. Having an in-built introductory walk-through of the App to highlight all its available portals may have helped orientate participants in how they could use the App and reinforce discussions with me at the enrolment interview.

Participants spoke about self-monitoring their blood pressure which was a feature that they were keen to have connected to some of the information available on the DAPHNY App. Within this discussion, adding the time and dose of medication administration was suggested as a useful feature where their blood pressure readings could be directly related to whether they had taken this at the right time or not. As well as this, the position of the reading, including the arm the blood pressure reading was taken on, would be helpful to similarly provide information on influential factors on their readings.

Overall, the App was a passive form of information giving which may have led to its low engagement. Increasing the interactive features to potentially include gamification was highlighted in the think-aloud interviews and reinforced by those who used the App. For example, competition with others and receiving rewards for achievements were noted as desirable features that would lead the participant to return to the App. Although the DAPHNY App sent regular notifications to participants, suggestions to engage in different areas within notifications, could work well, as well as having these directly linked to the data that the participant was entering, and were suggested as ways to improve the App.

5.6. Discussion

5.6.1. Summary of the study

The DAPHNY study aimed to optimise a digital lifestyle intervention for pregnant women with chronic hypertension. Through the methods of the Person-based approach, the DAPHNY App intervention development followed an evidence-based and iterative process, prioritising the needs and perspectives of the target population. Multiple iterations of the App were made, leading to a first version (0.0.4) that was tested by a group of women. A content analysis informed three logic models that identify the key intervention features implemented, hypothesised to increase access to the App that could result in subsequent health behaviour change and thus detailing how to optimise the intervention. App usage data revealed that despite designing and developing the App with participants, engagement patterns were low overall. Chapter 6 will report the thematic analysis of the think-aloud interviews with women, focus groups with healthcare professionals and the individual interviews of those who tested and used the intervention in their own lives.

5.6.2. Relating the intervention development to the wider literature

Participants were generally positive about the concept of an App that linked their high blood pressure with their lifestyle. They described the prototypes as something that they had not seen before but would be beneficial, and a way that they could link their blood pressure readings with daily activities. As many used an App already to monitor their blood pressure readings, the information on the DAPHNY App was viewed as an obvious, but lacking resource that could support management beyond clinical consultations.

Based on the content analysis, features that the participants wanted to be included in the App were 1) credible information that they could trust 2) behaviour change techniques such as goal setting, prompts, rewards, feedback and self-monitoring 3) Links to more information for those interested 4) Practical information they could easily enact.

Perhaps because of the motivation women appeared to have to be healthy, the participants in the study spoke of navigating through multiple sources of information. This was often in a quest to find one they trusted, and this took place at hypertension diagnosis and during pregnancy. This information seeking behaviour through pregnancy is recognised by others where women report using Apps as a source of information during pregnancy (95). However, the reliability of the sources commonly accessed has been questioned as well as the user's ability to assess the quality of the information (250). Therefore, if the App provided one place to access trusted information, this was viewed as an improvement on their current information seeking activities.

Women view healthcare professionals as a credible source of information and therefore if the App was endorsed by them or it had an NHS logo it increased their confidence in the information and thus, their likelihood to engage. The lack of healthcare professional involvement in App development may not only affect engagement, it also raises concerns on their safety or efficacy if used to support health and wellbeing (251). Additionally, many Apps available in pregnancy, lack screening for co-morbidities and, in the case of physical activity Apps, do not align with evidence-based guidelines which may lead to inappropriate use (252). The DAPHNY App was specifically designed with experts, including healthcare professionals, thereby ensuring appropriate and tailored information provision according to existing conditions.

Goal setting is a common feature in behavioural interventions and has been shown to have a role in supporting weight management in pregnancy (253). Though goal setting was an important feature for participants in the think-aloud interviews, not all participants decided to use this feature. This is in conflict to the evidence that suggests effective interventions derive from the use of well-defined behaviour change techniques (117). However, goal setting could be enhanced if set publicly or created with others, suggesting future avenues to explore to increase engagement (254). It may be plausible to pose that too many

behaviour change techniques, or target behaviours may reduce engagement. The complexity of each individual technique is highlighted here such that a BCT including goal setting may need examining for each related behaviour to avoid a multitude of techniques and target behaviours that overwhelm users.

Adding a blood pressure reading was the most accessed section of the App. Though participants were encouraged to enter blood pressure readings from clinic, some participants used the portal to report home readings, with some stating that this was the feature that led them back to the App. Pregnant women with hypertension are increasingly self-monitoring blood pressure and this may explain why this was a commonly used and acceptable feature of the App (Chapter 4)(197). Conversely, incorporating self-weighing was met with contention where they were a mix of views on its inclusion in an App that was focused on hypertension. Similarly, to Ferrey et al., (2021) some of the anxiety around weight gain was that women didn't know what was expected during pregnancy (196). Therefore, including information around the norms of this practice in the UK were included in the App. This was also added due to concerns from healthcare professionals who were apprehensive about including this if it would prompt women to ask them questions, since this was not routine practice. This is similar to findings of two qualitative studies with healthcare professionals investigating routine weighing and midwives role in antenatal weight management (255, 256). Participants expressed concerns around weighing as it could induce anxiety for women, especially as they were not sure of subsequent advice should a woman gain too much or too little.

Even though information was added to support women and healthcare professionals with trusted information on gestational weight, most participants did not use this feature. Some participants did not see this as an important or relevant modifiable factor for high blood pressure but viewed the nutrition focus more favourably. This may be because focusing on weight during pregnancy raises concerns about promoting weight loss which is not

recommended during pregnancy (52). Minimal engagement may also be because weighing was removed as a core component of the App following initial feedback. Therefore, though self-monitoring features were identified as important (weight, step count and blood pressure), not all behaviours may be self-monitored by participants and may depend on a participants health goals in relation to their hypertension as well as how in-depth the user explores the App.

Participants in think-aloud interviews were keen for more information on the App, with many suggesting other areas that would be useful (e.g. sleep and stress) but at the same time did not want to be overloaded with information. Most of the participants chose to receive notifications with top tips about dietary behaviours that could improve blood pressure control. The short snippets of information about diet may have been preferable to reading the content within the food portal, hence, no one accessed this. A study that developed an intervention for hypertensive patients found the lifestyle component had little interaction, especially if medication sufficiently controlled blood pressure, suggesting the lack of overall engagement in this part of blood pressure management (225). The App provided a convenient resource that can be dipped in and out of as needed over the course of a pregnancy. One participant was keen to explore more on the App after I had an interview with her, potentially indicating how the limit of 2-4 weeks that participants had with the App was not enough the capture how they may use the resources, and information sections, across a longer period of time.

In previous chapters I have spoken about how both National and Local guidelines for hypertension, and weight management, lack specific and practical advice for women to enact healthy behaviours in the context of their lives (Chapter 1 and Chapter 3). Women in the study reflect this by commenting that the guidance they received was often generic and did not consider potential cultural or dietary differences. Dietary recommendations need to be culturally adapted whilst preserving the core components that promote health which is

posed to increase adherence and thus, health outcomes (257). This has been seen in adaptations of the Eatwell guide (258, 259). Since the App was based on the principles of the DASH diet, as opposed to strict rules, this allowed for some flexibility and adaptations to be made and this was discussed with participants. Based on findings that few were aware of the associations between hypertension and specific nutrients that could lower blood pressure, the introduction of these principles with women indicates a need to explore how such information could be further adapted to meet their specific needs.

Interest in the DASH diet was shown by both women and healthcare professionals, as this diet was unknown to many. Having a more specific diet that was focused on nutrients to lower blood pressure was realised as a way to provide more specific advice and a step towards personalisation that meant women felt the App was for them. The DAPHNY App did not achieve complete personalisation which has been described as a desired App feature for pregnant women by other authors (260). This study conducted a survey and interviews to create a hypothetical ideal pregnancy App. Whilst there are concerns that these technologies may disrupt or replace in-person care, the DAPHNY App could advance existing lifestyle guidance that women feel is generic and does not meet their needs.

The notorious challenge of integrating systems was brought to light in the DAPHNY studies. For example, some women did not use the App to monitor their steps, because this was recorded elsewhere, and automatically. Healthcare professionals expressed an enthusiasm for the App to be linked to other existing Apps as well as electronic health records. Though there is a significant preference across all participants for embedding and linking existing technologies, the complex landscape of both the digital field and large healthcare systems continues to be a barrier to the implementation of Apps (261). Adjoining what has been learnt through the DAPHNY studies with existing Apps that are used within current care would be appropriate to investigate, prior to proceeding to a feasibility trial, owing to the importance placed on this by women and healthcare professionals.

5.6.3. Strengths and limitations

The study used the person-based approach and I worked closely with both PPI representatives as well as the participants to ensure that the voices of those who would use the App were heard. There were many perspectives even in the small sample of women that I interviewed but consolidating the needs or addressing the conflicting opinions on content or features must be further explored with a different group of participants. Despite this, the unique challenges, and perspectives of those with long-term hypertension was elicited, something that, to my knowledge, has not been done before.

I spoke to pregnant women whose first language was not English, and speaking to those who followed their own cultural diets was useful when discussing the food related sections of the App. There was limited diversity of sample of the women in the think-aloud interviews but I recruited women from 6 different ethnic backgrounds for the final testing period. Furthermore, there was a range of educational attainment which is a strength of the study as those with lower education levels are generally considered underrepresented in research (262). By incorporating the views of people with varying educational levels, we were more likely to achieve content that was accessible to different groups; increasing the potential reach of the intervention.

During the initial stages of the DAPHNY study, when the guiding principles were developed, accessing the App, as a key target behaviour that would lead to engagement, was overlooked. In retrospect, I can acknowledge this shortcoming in that none of the guiding principles focussed on access or the motivation needed to engage with the App. However, the guiding principles were used when making decisions about the App content and accessing the App has been identified as a key behavioural target resulting from a robust content analysis and thus can be added to the guiding principles in any further work.

The structure of the think-aloud interviews created unique challenges and potential limitations, and this echoes methodological challenges with the technique reported by

others (263). Firstly, participants may give socially desirable answers, especially since I had developed the intervention that they were reviewing. However, critical comments about the intervention from participants, suggested that they felt they could express what they genuinely thought. Think-aloud interviews are also a very unnatural method, and this led to me having to give quite a lot of prompts meaning they appeared less inclined to think aloud as they became more reactive to what I was asking. The method worked well for visual content and testing the logic of connections between App pages, but was less effective for the written content where participants answered with their thoughts on this so quickly it was doubtful that they had read it all. Though this was the case, it provided a good impression of whether a particular section was relevant to include or not. As well as this, I was able to ask my PPI reps to read the content, including the messages that participants would receive so I could address any content that was not reviewed during interviews with participants.

I was only able to recruit healthcare professionals from one site because there was a delay setting up the study at the Manchester site. I had discussed with my supervisors about conducting further focus groups after an initial analysis but due to time restrictions and competing tasks at the time, I was not able to achieve this. It would have also been good to speak to GPs as other healthcare professionals cited them as having a role in supporting blood pressure management outside of pregnancy. However, recent organisational changes in the NHS have reduced GPs input in antenatal care and therefore may not have been within the remit for the DAPHNY study. Exploring GPs insight into a digital lifestyle intervention would be valuable given the increasingly recognised life-course approach to women's health and the importance of good and effective connectivity between care services and pathways that women with complications may experience before, during and after pregnancy.

5.6.4. Reflections

Some of the desired features discussed exist in many commercially available and popular health Apps. In addition to this, though participants commented that they liked the look of the App, more animation and visuals throughout would have improved the App and made it more visually appealing. This is something that was a challenge to compete with during the design and iterative process to develop the first version of the DAPHNY App. Few commercially available Apps are developed through robust research that involves healthcare professionals or experts in developing Apps to support chronic disease and behaviour change theory (243, 251). Furthermore, content lacks evidence-based guidance and they are not always designed with the target population which is essential for user acceptability and relevance (224, 264). Through the DAPHNY studies, using the person-based approach, I have addressed these shortcomings. Aligning knowledge gained from the DAPHNY studies with the expertise of those working in User Experience design and gamification could be a potential next step in developing the App into something that is accessed more regularly with the more complex functionalities that participants were seeking.

The above led me to think about the continual competing challenge I found between achieving good science that is grounded by behaviour change theory whilst ensuring good user experience that is vital to whether someone will use an App or not. Creating prototypes that worked and reflected the potential interface of an App was just as important as ensuring the App was evidence-based and safe for a pregnant population with high blood pressure. Integrating these two approaches, though difficult, is essential and hence, a cross-disciplinary industry team would enhance App development in healthcare settings.

Although the think-aloud interviews and the processes of prioritising changes was based on the evidence, behavioural theory, and discussions with the App development team, I found it a challenge not to try and meet everyone's needs when developing and creating content

for the App. For example, deciding the preference of one participant over another required careful decision making. This revealed a challenge in co-production where, even in a small sub-group of women, needs and preferences differed.

5.7. Conclusion and next steps

I used the person-based approach to build a theoretically underpinned, evidence-based lifestyle App that addressed the needs and perspectives of women who had experience of chronic hypertension during pregnancy. I applied knowledge of existing literature with expert knowledge, including PPI, to design the first iteration of the DAPHNY App. Study 2 and 3 (component 1) used evidence-based qualitative methods to listen to women's and healthcare professionals' views on the App, informing multiple iterations to address barriers and facilitators. These were conceptualised in three logic models that detail intervention components and their associated BCTs targeting access, engagement, and behaviour change. Study 3 (component 2) found that despite optimising the intervention, the hypothesised mechanism was not achieved as there was overall low engagement. Logic models may be too linear and miss contextual influences on behaviour that could explain the low engagement. Therefore, the following chapter will explore the role of the intervention in the reality of women's lives and current care pathways to understand the peripheral influences on the interventions use and potential implementation. The implications for research and practice of the DAPHNY study will be discussed in subsequent Chapter 6.

Chapter 6 Intervention development: Exploring the intervention in context

6.1. Overview

This chapter aims to explore the engagement and implementation of the DAPHNY (Diet and Activity for Pregnancy Hypertension) App intervention in practice and in women's lives. This chapter reports the thematic analysis of:

- Focus groups held with healthcare professionals,
- Think-aloud interviews held with pregnant, or recently pregnant, women with chronic hypertension and;
- Semi-structured individual interviews held with pregnant women with chronic hypertension.

The focus groups explored healthcare professional's perspectives of supporting healthy lifestyle behaviours within current care pathways for women with chronic hypertension and how an App may integrate, or not, within this. The think-aloud interviews explored women's experiences of hypertension and lifestyle information and behaviour in the antenatal period and focused on women's impressions of the mock-up version of the App to inform design and content refinement (see Chapter 5). Further individual interviews were held with a different sample of women who had trialled using the developed Version 1 of the DAPHNY App in real life, to gather insight about their views and engagement with the App and consequent experiences of making lifestyle changes.

6.2. Aims and research questions

The study aimed to explore the intervention (the DAPHNY App) in context to further refine the content and design of the piloted DAPHNY App. In doing this I aimed to understand how the intervention might be adapted to fit within current care pathways. This Chapter reports the perspectives, views and experiences of healthcare professionals and women and

informs future implementation strategies for the App to support women to have healthier lifestyle behaviours.

The research questions and objectives for the intervention development studies are restated in Table 29. The current chapter provides further evidence to address these.

TABLE 29 INTERVENTION DEVELOPMENT RESEARCH QUESTIONS AND OBJECTIVES

Research questions To address what is currently unknown	**Objectives** Set to answer the research questions
Overarching research question: How can we optimise a digital lifestyle intervention with healthcare professionals and with women who have experience of chronic hypertension during pregnancy?	To explore current knowledge, understanding, behaviours, as well as potential barriers and facilitators, towards making lifestyle changes in pregnancy. To develop a theoretical framework that captures the processes and mechanisms that lead to positive health behaviour change. To explore how a digital lifestyle intervention can be optimised for pregnant women with chronic hypertension. To explore the healthcare professionals' role in supporting a lifestyle intervention in pregnancy. To explore the views and experiences of women who use the intervention. To provide an indication of the Apps accessibility and acceptability to inform whether to proceed to a feasibility study.
What are the current health behaviours and barriers and facilitators towards lifestyle change in those who have chronic hypertension and been pregnant?	
What are the key intervention features and components required to support women's overall understanding, use and engagement with the digital intervention?	
What are the potential barriers and facilitators for women and healthcare professionals to support the use of the intervention?	
What are the views and experiences of women who use and engage with the intervention and do they engage with it as intended?	

6.3. Methods

6.3.1. Theoretical approach

As reported in Chapter 5, the theoretical framework guiding intervention development was the COM-B model of behaviour change. Though this framed the content analysis of the data, the current chapter goes beyond behavioural theory to provide a more complete picture of

how the intervention sat in current maternity care and the landscape through which women who are currently pregnant navigate. I have still used the COM-B concepts to inform interpretations in this analysis as this lens remained useful but over-reliance on individual behavioural theory to develop behaviour change interventions has been critiqued for ignoring social and contextual factors (119). Although the Behaviour Change Wheel that I have utilised includes key environmental and social determinants of behaviours, it remains focused on the individual and I felt this constrained my analysis, given the wider contextualisation of lifestyle change in pregnancy that was offered by participants. I think this approach benefits our understanding of how the intervention can be successfully developed to support women. A constructive sociological lens was adopted through the emergence of themes that emphasised the role of the institution, the embodied experience of pregnancy, inter-personal interactions between the professional and the woman and the agency one has in the control and motivation relating to their lifestyle.

6.3.2. Data collection

Healthcare professionals who provided care for pregnant women with hypertension and were able and willing to give informed consent were eligible for participation in the focus groups. Women with experience of chronic hypertension during pregnancy, within the last year, were eligible to take part in the think-aloud interviews. For the testing period, women were also required to be currently pregnant and have a Smartphone that was compatible with the App (Full details in Chapter 5, Section 5.5.4).

Potential participants were approached at the John Radcliffe Hospital in Oxford and Saint Marys Hospital in Manchester. I provided information about the study to interested participants and arrangements were made for enrolment and consent prior to commencing the study.

6.3.3. Topic guides development for the final interviews

The development of the focus group and think-aloud topic guide is reported in Chapter 5, Section 5.5.2.2 and Section 5.5.3.2 (Appendix 24 and Appendix 25).

The topic guide for the individual interviews conducted following testing were revised upon completion of the think-aloud analysis and iterative development of the App to ensure that questions generated deeper insight into any emerging findings (Appendix 30). The focus of the think-aloud interviews was on the intervention prototypes. Navigating the features of the App during these interviews opened up conversations about the wider context of a healthy lifestyle in pregnancy. These conversations formed the basis of the individual interview topic guide. This was piloted with one of my PPI reps who provided a suggested change to one of the questions so that it was clearer and prompted me to think about the questions that would be important to ask, to help answer the key questions or concerns raised in previous interviews. For example, it was not clear how this intervention could complement existing care pathways, though healthcare professionals indicated in the focus groups that they thought the intervention would be beneficial for the women in their care. Further to this, women thought that promotion of the App from a healthcare professional would promote its use. But in apparent contradiction, women thought the App was good because it was separate from consultations and was something they were in control of in their own lives, rather than within the medical setting. I wanted to explore this contradiction further to understand if the App could help both the professionals provide advice and support women's engagement with the App and health behaviours. Therefore, a key question I took forward in the final interviews asked women's thoughts on if and how they could envisage the App working alongside the care that they currently receive from midwives and obstetricians.

All focus groups and interviews were audio-recorded, de-identified and transcribed by me or an independent transcriber. NVivo software package was used to organise and manage the dataset.

Data collection continued until data saturation was reached (265).

6.4. Analysis

6.4.1. Data analysis

The focus groups ran alongside the think-aloud interviews with women and were first analysed following the principles of content analysis for the iterative App development (reported in Chapter 5). Subsequently, thematic analysis was undertaken for all interview and focus group data as 'a method for identifying, analysing, and reporting patterns' in the dataset (176). These themes inform our theoretical understanding of the context of the DAPHNY App implementation.

Data analysis began with familiarisation of the transcripts, reading and coding line-by-line. Broad descriptive themes were developed and then the 'one sheet of paper' technique was used to visualise relationships and patterns between these which informed the construction of interpretive themes (266). The research questions guided the interrogation of the data in discussion with supervisors. They offer an explanatory framework for the optimisation of the digital intervention for women with chronic hypertension.

6.5. Results

Focus group results are presented first, followed by analysis of the think-aloud interviews and the analysis of individual interviews following the testing period.

6.5.1. Study 2: Focus groups with healthcare professionals

6.5.1.1. Participant characteristics

The characteristics of the 23 healthcare professionals who took part in the focus groups are reported in Chapter 5, section 5.5.6.1. Focus groups were between 22 and 45 minutes long and analysis constructed 4 themes:

1. Technical tasks direct care interactions;
2. The professional's knowledge and assumptions guide lifestyle conversations;
3. (Dis)/ engaging with the subjective;
4. The task of giving lifestyle advice could be shifted to the App

6.5.1.2. Theme 1: Technical tasks direct care interactions

Structures and routines of the clinical environment were described by participants as guiding their practice. Technical, or clinical tasks in antenatal consultations comprised of objective measures that determined subsequent care management and risk assignment. These objective measures appeared to direct the care interaction during appointments for women with hypertension.

> *"a lot of the time it's been sort of managed by medication and it's been more sort of checking the blood pressure readings have been okay. [erm] And as long as they're fine and the medication, they're on medication that's working sort of lifestyle thing sort of goes a bit, unspoken really actually".* ***HCP18, Midwife***

Participants described feeling tied to a risk management agenda illustrated by the completion of templates, tools or proformas that allowed little space to talk meaningfully about a woman's lifestyle.

> *"…particularly probably when you see them acutely when you get very focused on medication and that sort of thing. But actually, we probably should be taking every opportunity to, to discuss lifestyle advice and make sure they do that".* ***HCP24, ST2***

A comparison to diabetes was drawn by one participant who expressed that dietary advice was easier to give because of the direct, specific quantifiable outcome resulting from food intake. As blood pressure readings do not act in this same way, conversations did not appear to extend further than to adjust medication or to inform care management. When discussing weight measurements, women's expectation of this technical approach was assumed.

> *"I think a lot of women see it as when I'm weighing them it's a medical, a clinical, completely "oh well I'm pregnant they just need to know", rather than "this is my weight" that you normally do in private".* ***HCP08, Midwife***

This emphasises the role of institutional norms that can influence women's expectations of care and reflects a shift in ownership of their body to a system that has limited discursive space during consultations to discuss diet and physical activity as the healthcare professional is directed by the technical tasks.

Time constraints especially during the booking appointment, were frequently cited as a significant barrier to lifestyle discussions. This was further compounded by the fact that women classified as 'high-risk' were more likely to need referrals (such as to specialist clinics), which were prioritised and took up time in appointments.

> *"It's really difficult because I feel like it's all, you don't really, there's so many things that we are expected to talk about…"* ***HCP04, Midwife***

Although participants expressed time constraints as a limiting factor, when lifestyle was discussed, it was brief and physical activity appeared to be more preferably discussed than diet. Discussions happened at the booking appointment but were not frequently discussed again during the pregnancy.

Unless specific questions or concerns were raised by women, health promotion was described as "tick boxy" leading to parrot messaging of public health related topics.

"I feel it's a bit of a tick boxing exercise when you are perhaps somebody at booking…Talked about that, tick". ***HCP12, Maternity assistant practitioner***

Participants expressed how they felt that lifestyle advice was suboptimal to help women understand and enact positive health behaviours. Providing enough information to tick a box demonstrates compliance to auditable paperwork, but it is unclear, if and how this is translated to being understood, in a meaningful way, by women.

6.5.1.3. Theme 2: The Healthcare professional's knowledge and assumptions guides lifestyle conversations

Participants described their role in health promotion but how their limited knowledge, specifically around diet and physical activity, affected their ability to provide appropriate and tailored advice to women. Most participants described giving generic advice about how to achieve a healthy lifestyle, regardless of hypertension status, at the booking appointment. Commonly, participants had received little training and felt they had minimal knowledge on specialised lifestyle advice for women experiencing hypertension in pregnancy.

Despite this, participants felt that they were in an advantageous position to give advice because they could work with the women's intuitive desire to connect with her pregnant body to do what is best.

"Plus we get them at a really good point 'cos most people when they are pregnant they are open to change because they want, most people want what's best for the baby, even if it means stop smoking, stop drinking [erm] starting exercising a bit more. So, we are in a good position to give them advice". ***HCP16, Midwife***

"…I think that a lot of women are more susceptible to make those changes when they are pregnant. So, benefit them and not just themselves, but their baby [erm] in the long-term". ***HCP17, Midwife***

This unique period of transition in women's lives was viewed by participants as an opportunity to engage with women. An increased automatic motivation, described as the emotional processes involving desires and inhibitions that drive behaviour, was observed by the participants to be present in those pregnant with their first baby or those living with a chronic condition.

> *"But I feel like if you've been diagnosed with hypertension, you probably are very interested in finding out more, rather than just thinking medication".* ***HCP13, Student Midwife***

> *"Whereas a, you know, a new [erm] pregnant mother that's not had babies before, I feel that they are more susceptible to that advice".* ***HCP17, Midwife***

Women's transition through pregnancy to motherhood opens them up to new information and learning that some professionals may perceive as maternal motivation. Conversely, others thought hypertension may result in complacency around lifestyle behaviours, especially if the blood pressure was well controlled and they didn't feel unwell with it.

> *"you might get some people because they don't feel unwell and not necessarily [noise] wanting to engage and [erm] change".* ***HCP24, ST2***

One participant recognised how it would be important to work with the woman to identify her priorities for health before imparting advice, thus providing advice in a way that would enable constructive conversations.

> *"I think it's important yeah to recognise that not everybody is going to want to be as active all the time"* ***HCP17, Midwife***

This recognises how different women will have varying interpretations of what being healthy is as well as different ideas of what they want to do to achieve this. This informed the intervention design including the tone of messaging to avoid the woman achieving or

failing healthy behaviours by recognising and accepting the impact of women's own life priorities.

Aligning the professional opportunity that participants expressed that they have in health promotion with the motivation of the woman could contribute to individualised discussions about diet and physical activity.

Formal training was limited for the participants I spoke to and some relied on their own self-informed knowledge to provide lifestyle advice. Some participants were only made aware of the link between hypertension and lifestyle because of participation in the study.

> "*I don't think…I've linked the two together in terms of hypertension and lifestyle, I think it's just been general fit for pregnancy sort of diet, lifestyle advice."* ***HCP03, Midwife***

National guidelines recommend that pregnant women with chronic hypertension are offered advice on weight management, exercise, healthy eating and lowering the amount of salt in their diet. Despite this, participants did not describe this as part of routine care for these women, indicating a lack of health education resources or awareness specifically for this group. Participants recognised more readily the relationship between a higher or lower than normal BMI and lifestyle factors. This acted as a flag for the delivery of lifestyle advice and monitoring of weight, more so than hypertension alone.

> *"I've seen BMI as more of a reason to perhaps keep a closer eye on people's weight, but not hypertension".* **HCP06, Midwife**

> *"I'd say the targeted diet and exercise advice is for everybody but I'd be more inclined to give it to raised BMI say, than women essential hypertension with no raised BMI"* ***HCP03, Midwife***

The fact that a higher weight acted as a trigger, when hypertension did not, despite similar clinical guideline recommendations for these groups suggests this knowledge may be

socially informed rather than from professional expertise. However, participants described how framing lifestyle advice around hypertension would be preferable because it meant conversations were kept within the medical domain of the 'condition' where professionals are expected to hold the expertise.

> *"When it's something directly related to something they've been diagnosed with, I feel that would be a much easier way in because you're not just generalised saying, it's good to be healthy. You're saying, you know, you've got specific problems that could impact your pregnancy and possibly your labour. We've got some really specific ways in which to help you and to deal with it."* ***HCP13, Student midwife***

A multitude of factors including economic, political, structural, inter-personal and social were frequently brought to the fore when talking about women taking on the lifestyle advice provided and engaging with the intervention. The most dominant were the economic and social factors.

Some commented that in general people, including pregnant women, were aware of health messaging about what eating healthily means and the role of physical activity, but factors outside of their control affected how and whether they would enact the recommendations.

> *"I do firmly believe that a lot of women know what they should and shouldn't be doing but for whatever reasons often out of their control, they can't achieve that"* ***HCP04, Midwife***

Participants felt that these "reasons" made conversations about lifestyle difficult perhaps because they were not gifted the time or skills to adapt information with the woman. Acknowledging that lifestyle choices are, by in large, socially determined, created hesitancy in providing advice that might deem the individual responsible for, but in which they were unable to act on.

> *"Yes… well it's the social determinants that we now know, kind of, what that is and you're asking, you're putting all of that onus on this individual without accounting for any of the things that trickle down to them from kind of where they live, what they do for work, what they can afford, what their education levels are, all this sort of stuff and it seems a bit counterintuitive".* ***HCP04, Midwife***

It was evident that the participants felt unequipped to adapt the information to the woman's personal circumstance. The potential challenges and complexities of the women's lives impacted participant assumptions about who would be receptive to advice and engage in the recommended healthy behaviours.

> *"I was just thinking lots of people haven't got time have they? I'm thinking very specifically about, you know, potentially a lady, you know, this might be her fourth baby. You know, she gets by—.* ***HCP10, Midwife***

> *With long shifts in the factory or they're in shared accommodation and they don't know how—They don't have the facilities or something like that. Or a single mum".* ***HCP12, Midwife***

This was pertinent with the community midwives I spoke to who had a lot of emotional insight into just how difficult it may be for some women to change behaviours. These participants expressed that different cohorts of women between community groups had varying levels of engagement which influenced the amount of time given to lifestyle advice. The variation in the provision of advice matters in the context of the lifestyle intervention as healthcare professionals may act as gatekeepers of App provision which may widen inequalities in access to health information.

> *"Obviously, depending on what they say. If she comes with a sheet that tells us every day then that's good and do it a bit more. I find my women I see are pretty clued up."* ***HCP09, Midwife***

Women with perceived high-levels of health literacy, as above, were given the space to discuss lifestyle behaviours. However, there was evidence that more focus on lifestyle was also given to those who participants thought would discard the information.

> *"…Whereas, you can say it to other women and you know they are just gonna discard the information and not do it. So, you know, they're the women you need to spend a bit more time with".* ***HCP14, Midwife***

Whilst this showed that both those with high and low health literacy were in receipt of lifestyle advice, a couple of participants overtly identified specific groups, based on weight and education levels, as particularly unreceptive to advice about diet and physical activity.

> *"[…] But people who [erm] are less well educated or people with a more raised BMI I think are less inclined to want to hear it […]".* ***HCP19, Midwife***

The discrimination that women of a higher weight often experience may cause them to disengage with care and hence perceived to be unreceptive to lifestyle advice, as expressed by this participant. The reflective motivation which involves the participant's conscious decisions to act in a certain way, may be influenced by existing structural stigma that could in turn determine the role they take in providing lifestyle support.

Despite the existence of, and acknowledgement by some, of organisational stigma associated with being a higher weight or having a lower educational status, the challenges of some women's lives and the specific needs of different populations were empathetically expressed by most participants. In discussing how the intervention may work for the groups that were specifically identified by participants, the importance of ease of access (both to receive the intervention and the content), language, burden of user input and cost were identified as key considerations for a system that may facilitate practitioners in supporting women who wish to engage with the intervention.

Incorporating health promotion into their professional role was determined by the participant's knowledge, competence, cultural awareness, and motivation afforded to understand the woman's own context and wishes. A scattered and subjective approach, exemplifying the complex nature of the topic, was evident throughout this theme. This ad hoc approach may mean not all women may receive optimal lifestyle support during pregnancy.

6.5.1.4. Theme 3: (Dis) engaging with the subjective

Participants frequently described conversations about lifestyle and weight as important but difficult or tricky especially if the woman was overweight or had a history of an eating disorder.

> *"I know lots of people dodge it because it's a hard conversation to have for some people. I think sometimes the weight of the healthcare professional also impacts on whether they're going to discuss it as well".* ***HCP01, Midwife***

Two participants reflected on their own body size and how this might be interpreted by the woman when giving lifestyle advice. One participant who identified as overweight felt hypocritical giving advice on what to eat and promoting increased physical activity. Another was concerned that her slim physique may make the woman feel targeted.

> *"I think there's that little bit of defence as well like taking on that advice, especially you know, if they sit there and think well, you're a larger size and so are you not taking on the advice you're giving me. But, of course, this is specifically for pregnancy. So, this, this is different, isn't it."* ***HCP06, Midwife***

Tasks such as taking a blood pressure measurement may not be subject to the self-embodiment that was evident here during lifestyle conversations. Participants showed awareness of the societal pressures to adopt behaviours to maintain a healthy weight and the stigma associated with being overweight. This made them concerned about being

judged by the woman which could have a role in gatekeeping information, even if unintentionally, due to this awareness.

Most participants were aware of the challenges to adopt healthy habits and taking a woman-centred approach was necessary to engage with the woman and meet her where she was at in her pregnancy journey, putting their own personal challenges aside.

> *"it's just assessing who you're with at the time and, and being sort of understanding to them and as I say […] just understanding their wishes".* ***HCP14, Midwife***

When discussing weight, some participants were concerned that lifestyle advice may make the woman feel guilty and focusing on weight could cause distress.

> *"If someone asks us to weigh them then we will weigh them but we don't want to focus on that because obviously some women can be quite upset"* ***HCP02, Midwife***

Participants were therefore careful about how they framed advice, especially when it came to weight measurements by disengaging with the subjective domain of the woman and framing the dialogue around a medical narrative.

> *"I think so. I think 'cos it's, 'cos it's a number. You know, we've done your blood pressure. You know, or we've done your obs and next thing is your weight. It's less of a social thing".* ***HCP13, Student Midwife***

Medical reasons for weighing women, such as for drug calculations, and classifying obesity as a medical condition were suggested as easier ways to approach conversations. Pathologising obesity perhaps exempted the woman of responsibility, taking away the blame that participants expressed concern about. It became something that is fixable, like prescribing medication to control hypertension, where professionals determine treatment; thus, making for a less messy conversation that could negatively affect relationships.

> *"I think it's really important and I think healthcare in general sometimes people ignore obesity and are scared to mention it [erm] but it is a medical condition. [erm]*

But it's trying to, to approach it without putting people off and making them disengage." ***HCP24, Doctor***

Focusing on improving nutrition and physical activity levels as opposed to weight, was seen by some participants as a strategy that could have positive effects on wellbeing with improved weight management as a beneficial side effect. This was viewed as a way to avoid weight stigma and providing women with information about weight on the App, but without being a principal component, was put forward as a way for women to get the information themselves without having to address the topic directly. This would then give the woman an opportunity to ask questions about it at subsequent appointments, should she wish to, which made for an easier conversation.

"They can sort of read the information at their leisure and not feel like they're sat there with a doctor or a midwife saying, you shouldn't be gaining weight and maybe might be less judged […] Whereas if someone's read the information, weighed themselves and wants to know the information and they're asking you, I think that's probably an easier conversation and say, oh you know, it's really good that you, that you've mentioned this" **HCP24, Doctor**

Allowing the woman a platform to bring questions and concerns to the appointment complements the subjective nature of lifestyle discussions as well as aligning with a woman-centred approach. However, this analysis has exposed the difficulty of enacting this in existing care pathways.

6.5.1.5. Theme 4: The task of giving lifestyle advice could be shifted to the App

Although technical tasks informed the format of appointments, participants, both midwives and doctors, reflected that public health promotion was part of their role. Signposting to resources was a way to get through the list of health promotion topics and encourage

responsibility of the woman for her health but these were not routinely followed up at subsequent appointments.

> *"And I say to my women are you happy to have a look at the official guidance online, it's really important".* ***HCP10, Midwife***

> *"It's up to them then, isn't it".* ***HCP09, Midwife***

> *"Yeah. And we don't formally follow it up later".* ***HCP10, Midwife***

The intervention was viewed as a potential facilitator in fulfilling this public health component of their role by reminding them, or informing them, about the link between hypertension and lifestyle and the App filled a gap in current practice.

> *"if we've got this App it's going to remind us that we talk about it because they've got the information there, we can just direct them to it, we don't have to have the big long specific conversation"* ***HCP02, Midwife***

Participants agreed that most women were open to Apps and technology suggesting that these are more engaging than leaflets, a view that was shared by the women that I spoke to.

Participants discussed other Apps that women used with some expressing that they should all be on the same platform or linked to each other to avoid unnecessary burden. This was particularly relevant for women with hypertension who often already used an App to monitor their blood pressure, and women with diabetes who often used an App to monitor blood sugars.

The participants viewed the App as an opportunity to provide more information to women and if the App was linked to a healthcare professional women may be more likely to engage, facilitating an ongoing reciprocal conversation.

> *"I think if it went to the healthcare professionals and if this was their means of communicating their readings to their healthcare professionals they'd be more inclined to go on the app".* ***HCP19, Midwife***

> *"I think community midwives would be thankful to be like, if you go on this App and then we can talk about at our next appointment. […] And then they can pick up questions that they want to bring to you, rather than you having to be like… which is time consuming and also can be quite ignorant to the person's individual experience".* ***HCP08, Midwife***

This participant reflected the notion that the App would not shift the task of giving lifestyle advice but would facilitate a care relationship where the professional and woman can work together toward a shared goal, to mobilise the woman's beliefs in her own capabilities to enable behaviour change. Consequently, meeting the needs of those who may not be able to access the information on the App, was important for participants.

> *" …Well I guess if we had the App and women didn't have access to it for whatever reason, we could be that resource where you could just call me and I can translate this information to you, however you need it".* ***HCP04, Midwife***

Specific education around the information in the App would help guide professionals in how they could translate and apply information to the woman's individual social and environmental context. Some participants specifically spoke of the App being an educational resource for themselves, emphasising how the App may be an informational resource for both the professional and the woman.

> *"You don't really get taught about what to say and that sort of thing. Actually, if we all had a look at this it's quite useful. It's like looking through a patient's information. I know actually this might be a useful resource to a clinician who don't necessarily*

have that much experience. If we look through that and see the sort of advice you should be giving is quite useful as well for us". ***HCP24, ST2***

Participants have discussed the challenges of tailoring their advice to a woman's personal context and how this can impact the woman's motivation and ability to change their lifestyle behaviour. The App was acknowledged as a potentially useful tool to collaborate with women to bridge this gap.

6.5.2. Study 3 (Component 1): Think-aloud interview with women

The interviews with women aimed to elicit their views on the intervention prototypes and how it could be optimised given the barriers women may face during a pregnancy complicated by hypertension. The think-aloud interviews were structured around the participant's interaction with the prototype as these informed the App iterations. The thematic analysis reported here explores the interface between care experiences, and lifestyle behaviour and the App through three themes.

6.5.2.1. Participant characteristics

The characteristics of the 11 women who took part in the think-aloud interviews and viewed the developing App prototypes are reported in Chapter 5, Section 5.5.6.2. Interviews lasted between 32 and 60 minutes. Three themes were constructed from the data, with associated subthemes:

1. **Existing experiences of lifestyle advice in care pathways**
    - Conversations about lifestyle as a trigger for engagement
    - Fitting the profile
2. **Determining factors of App acceptability**
    - Existing motivations for health
    - Familiarity with the use of Apps in health
    - Psychological burden that could impact engagement with an App
    - Uniqueness and relatability of the DAPHNY App

3. **Tension between the value placed on the intervention and external factors that influence behaviour**

    Social and personal contexts

    Introducing the DAPHNY App

6.5.2.2. Theme 1: Existing experiences of lifestyle advice in care pathways

To complement the healthcare professional experience and perspectives on the delivery of lifestyle advice in the care of women with hypertension in pregnancy, I asked women about their experience to further contextualise current care practices and expose ways the App could integrate with existing pathways.

Conversations about lifestyle as a trigger for engagement

Participants described a mixture of experiences when talking about the discussions they had had about their lifestyle with healthcare professionals. Most described having received no or minimal information about diet and exercise that they found useful. Aligning with the advice that the healthcare professional participants in the focus group gave, participants commented that this advice was often not related to their hypertension.

> *"Whenever I've had my blood pressure taken, you know, they kind of skip over the fact, you know, lose a bit of weight, do a bit of more exercise, eat healthy. But there's never like direct guidance […] you know, should, this is what would help to reduce your risks or reduce your blood pressure."* ***Amelia, 25***[+1]

Other existing or arising medical complications as well as fragmented appointments or pathways were given as reasons that these conversations weren't had, because this wasn't the priority for the woman or the healthcare professional.

> *"…then they just referred me through to the high risk pregnancy team. Again, I just got a letter saying I've been referred through. I didn't like particularly know why [...] Umm, so I was a little bit confused and I got that contact but then I didn't get anything*

from the high risk team around it at all either, but that's probably because I was a little bit complicated. […]. So I don't think that was their priority then." ***Olivia, postnatal***

Although advice about lifestyle may have been minimal for most participants, it triggered some to seek more information on the topic. The App was viewed as a reliable resource that could fulfil this source of information that wasn't always received from professionals.

"I wish I'd've had something like this maybe three months ago to, to have the guidance there 'cos it's so, as I said, it's, to find out all the information that's maybe on this app, I'd ask you three, you know, a book, some google and I've had to go to multiple places and you can't be bothered always to do that. [erm]" ***Amelia, 25+1***

Fitting the profile

More than one participant reported being described by healthcare professionals as not being a "prime candidate" or not "fitting the profile" for a hypertensive patient. These labels appeared to be accepted by the women, but one participant speculated that she received minimal advice about diet because she was presumed to be healthy already due to having a normal weight. This led to blood pressure management being solely around medication.

"I think it was much more on the medication side of things because I didn't fit the profile from what they were saying […] I think they were surprised I had high blood pressure. I wasn't overweight, didn't have diabetes and had an active lifestyle […] The conversation was much more focused on the management of the high blood pressure through medication". ***Charlotte, 31+5***

Some participants expressed that the weight section of the App may be more relevant and useful for those who were overweight and obese.

"Yeah, I think it's definitely good to just have it as an option. I just don't really know what you'd do with the information unless you felt you were overweight" ***Lottie, 22+5***

> *"I certainly have friends who are overweight and not aware of things who are trying for children and stuff and I think that they have no awareness so I can see a benefit for people like them".* ***Emma, 27+4***

There is a parallel here with the healthcare professionals I spoke to who commented that a higher weight acted as a flag to discuss lifestyle advice, more so than hypertension alone. This exposed how socially informed knowledge informed both advice given and the expectations participants had in receiving advice about weight and lifestyle.

One participant who identified as slim, expressed that she was disappointed she did not receive more advice, commenting that her midwife may have assumed she was well informed on the topic. A different participant who also identified as slim shared this same view that professionals may assume she does a lot of exercise but explained she did little activity and could do more. Healthcare professionals described how they would tailor advice according to the woman's health literacy but if this is judged solely on the weight of the woman, as seen here, it may mean advice does not meet the woman's needs.

Taken together, these findings suggested that participants felt that if lifestyle was identified as the cause of hypertension, or presumed to be the cause, i.e. if the woman was overweight and therefore assumed to be less healthy, more directed lifestyle advice may be given. Counteracting this assumption, one participant who identified as overweight did not receive any specific advice.

> *"There's not been a conversation about that in terms of making like lifestyle changes diet, that kind of thing."* ***Imogen, 29+2***

The healthcare professionals that I spoke to, expressed difficulty in having conversations about lifestyle with women of higher weight, and that this was impacted by perceptions of their own body size. This may explain the experience described by Imogen. Though the professionals alluded to hypertension being an easier approach to instigating lifestyle

conversations, potentially because there is less stigma attached to it, it appears that in this case, neither hypertension or weight status prompted a conversation to happen. This illustrates the inconsistency in messaging that is filtered through assumptions and subconscious bias, both from the women and healthcare professionals that I spoke to. Navigating this complex landscape is a challenge but the App could cut across weight assumptions by providing equal information to all women with hypertension regardless of their weight.

6.5.2.3. Theme 2: Determining factors of App acceptability

There were four key factors that were important for the acceptability of the App as an intervention. These included the participants existing motivations for health, familiarity with the use of Apps in health, the psychological burden that could impact engagement with an App and the uniqueness and relatability of the DAPHNY App.

Existing motivations for health

Having a healthy lifestyle was viewed as important during pregnancy by the participants, even if it was not the cause of their high blood pressure and this meant an App was seen as an obvious resource to be offered to pregnant women.

It is commonly understood that women are motivated to be healthy during pregnancy and this was seen in my dataset with some expressing this was because of the responsibility they felt not to put their baby at risk.

> *"I start to feel more responsible because it's the two lives. Yes, my life and my baby's life. Yeah, I feel like a more, much more responsible about that to take care of more careful."* ***Elena, postnatal***

This aligns with contemporary discourses around maternal responsibility for fetal health. For one mother, her age of becoming a mother was her motivation to be healthier.

"Yeah, my motivation has just completely changed, you know, not only do I want to obviously look after her, I also want to look after myself". ***Jo, 37+4***

For others, having hypertension meant they were fearful of potential poor outcomes or did not want to have to take medication and therefore were motivated to engage in healthy behaviours to try and reduce the likelihood of these scenarios.

"now it's much more thinking about the, the baby inside me like that's gonna be affecting him […] So, like, you know, having like medical issue and then be worried because I were in the hospital or something". ***Karolina, 30+6***

"I think it's very quick to assume that you've got high blood pressure and therefore you need medication and for me, I'm not, medication is like a last resort for me. If there's methods to try and reduce it myself I'll absolutely take what I can but I think for as well I also, when I did have to introduce medication I struggled to accept it" ***Emma, 27+4***

Those who expressed worry or concern over their high blood pressure, were particularly keen to engage with the information on the App to see if there was anything that they could do to improve their health.

On the other hand, participants who had controlled high blood pressure or did not feel unwell with the high blood pressure, were less concerned about monitoring their health. For example, when discussing an App to enter blood pressure readings, one participant said that now that their blood pressure was stable, they were not as bothered to do this.

"it's not that I don't wanna use the app. I think it's probably me being a bit lazy and because they've been like stable, I've not maybe worried about it as much." ***Tabitha, 34+6***

This is exactly what healthcare professionals said and indicates a challenge in incorporating lifestyle advice in the overall management of hypertension. This participant and the view of

healthcare professionals offers a case of potential disengagement with the DAPHNY App if the determining factor for someone's motivation is feeling healthy.

Most participants had existing motivations that meant the App was viewed as acceptable as there was a willingness to be supported with this aspect of their life. However, even in cases with clear motivations to be healthy, some felt that they should do more, knew what to do but they did not know how to achieve it or they signposted to future plans to engage in healthy behaviours. For some women, the App was welcomed as a way to build on this intrinsic motivation, evidenced by women, to achieve the behaviours they wanted to.

Familiarity with the use of Apps in health

Most participants had previously engaged with or currently used Apps and related technology to engage in healthy behaviours.

Even if participants did not actively engage in Apps, the plethora of Apps available for both lifestyle related behaviours outside of pregnancy as well as general pregnancy was indicated by the participants; reflecting the growing landscape of digital health.

Participants frequently expressed that having specific and relevant information for those with hypertension, would be an improvement on existing Apps that felt generic and less personal. As most participants were using Apps, in their own personal arena, or aware of their existence, they were open to using the DAPHNY App as it was offering something that didn't currently exist.

> *"… actually that's been quite a good resource to dip in and out of, but it's not specific to high blood pressure".* ***Charlotte, 31+5***

> *"So, this is why, it's [the DAPHNY App] really nice feeling because when you feel like yeah, you want to stay in this application because you have like some common things what is like say related to you."* ***Karolina, 30+6***

Not all participants regularly used Apps during pregnancy. One participant spoke about her limited general phone use so was ambivalent about her use of the intervention if it was available. Despite this, she stated that Apps can be a suitable alternative to leaflets for finding out information quickly.

Because most women already used Apps, including blood pressure self-monitoring Apps, the participants repeatedly highlighted the need for all this information to be available on one platform. This view was shared by the healthcare professionals I spoke to.

> *"There's so many apps, they all kind of are slightly different, yeah. So, it'll be good to have like something that's just one place you know to go [laughs]. […] which one's telling the truth? Like which one do I go with?"* ***Amelia, 25+1***

In this quote we can see that although Apps are frequently used, they are not necessarily viewed as a trustworthy source of information. An App that had a clear evidence base with the option to read more about the scientific research was for some, an important feature to trust the information on the App and this would be motivating.

> *"even if I wouldn't actually read all of the like academic studies or something, if they're referenced, it just feels like it's got more legitimacy."* ***Charlotte, 31+5***

<u>Psychological burden impacting engagement with an App</u>

Participants felt that a risk of the App was that it added psychological burden. A way to overcome this was for the App to offer small, clear and manageable information and recommendations and this gave women a sense of control to focus on what they felt capable of.

> *"I don't know whether people would like the idea or not of like a tip for the day type thing where it's just like one little thing to think about or concentrate on".* ***Olivia, postnatal***

Participants expressed that the App needed to require little effort for the user.

> *"I just want something that is really easy and doesn't require too much kind of thought/ power on my part".* ***Imogen, 29+2***

Differentiating between what efforts may be required of engaging with an App and the efforts that may be needed to engage in healthy behaviour was not always made clear by participants. However, the psychological burden of pregnancy came across from the women I spoke to. The participants may be offering a point of resistance in that the pressure and expectations of their life meant introduction of a new intervention would need to align closely with existing habits and behaviours or be easy for them to engage with to reduce the potential psychological burden.

Along similar lines, there was a strong sense that women did not want the App to be strict and dictate a prescriptive list of behaviours to engage with or not.

> *"If it's presented in a way that's supporting rather than telling me off then I'd definitely take that on board."* ***Emma, 27+4***

The participants who read the content of the intervention suggested how the language and tone were important in ensuring it was supportive and therefore acceptable to take on board.

> *"perhaps a tab that's kind of like "feeling overwhelmed by the targets and breaking it down". For those people who can't quite get to where they should be, building up to it in small steps".* ***Olivia, postnatal***

> *"And then the practical changes like, you know, reducing the intake of salt seem something I could actually do. I'm sort of in my head, had the changes I was willing to make and those that I was thinking, oh, I don't think that's gonna make enough of a difference. And it would make me, you know, I wouldn't be very happy about to give up all my bacon sandwiches".* ***Charlotte, 31+5***

Charlotte felt that reducing salt would make a difference but would still want to be able to eat the food she wishes to. The App may provide an opportunity for women to obtain information but not diminish their ability to make decisions autonomously.

To overcome the potential psychological burden, there was a keenness to ensure that information on the App did not overwhelm users. This was linked to people's current knowledge of lifestyle factors in relation to hypertension, pregnancy and more generally too. Participants suggested that the key information should be easy to find and read with an option to read more should they want to or feel ready to.

> *"And people that are ready to find more can access the bigger pages and do it for themselves and do a chunk of bullet points at once. But if you kind of not really ready for that, then you're feeling like, Oh my God, I'm juggling all of these different things".*
>
> ***Olivia, postnatal***

Uniqueness and relatability of the DAPHNY App

The participants made comments usually at first look of the prototype or at the end of the interview to express their overall thoughts on the intervention. It was clear that for some that they would want to engage with the DAPHNY App if it was offered to them during a consultation.

> *"I would certainly use something like that over a more generic one because I know that that's what I need to focus on for my health whereas I'm not so interested in some of the aspects of the more generalised ones."* ***Emma, 27+4***

Participants who expressed enthusiasm to use the App explained that the App contained the information they have either tried to seek themselves, expected to receive on existing blood pressure Apps or they were keen to engage because they had gained new knowledge about their blood pressure and lifestyle through participation in the study that they felt could be a useful addition to existing self-management practices.

It was understood that the "personalised" aspect of the App, in that it was specifically for pregnant women with high blood pressure, was desirable and something that did not currently exist.

> *"So, this is why, it's really nice feeling because when you feel like yeah, you want to stay in this application because you have like some common things what is like say related to you."* ***Karolina, 30+6***

Whilst there was positivity on its use, it was commented that the App was likely to be used by health-conscious individuals or some pages may be less relevant if lifestyle is not the given cause for hypertension.

> *"I guess it might feel less relevant in a way to me because I've not been told that that's [lifestyle factors] why I have it. But not irrelevant to me like".* ***Tabitha, 34^{+6}***

Tabitha went on to say that the information was still relevant for pregnancy, and it was important to highlight this in the content of the App, so women still felt that it was specific for them even if lifestyle was not the obvious cause of the hypertension. This same notion was shared by other participants.

> *"I like that it says like to help your baby. It's personal."* ***Amelia, 25^{+1}***

Overall, the App was felt to complement the intrinsic motivation that the participants often had to be healthy during pregnancy and this meant it was easily accepted as a resource that they would use. However, the acceptability of the App was further determined by the psychological burden that it could create if it gave unsupportive and prescriptive advice. Although resistance to the App was evident, the uniqueness and relatability increased the acceptability of the intervention, even if lifestyle factors were not the cause of the hypertension, as a good source of information that was often sought in pregnancy.

6.5.2.4. Theme 3: Tension between the value placed on the intervention and external factors that influence behaviour

Although there was much agreement that the App was a good idea, participants spoke frequently about the things that would affect their engagement with making lifestyle changes; creating tension between the value placed on the concept of engaging with the intervention with the factors that affected the participants actual ability to enact healthy behaviours. Solutions to overcome these factors were discussed and were instrumental in the iterative development of the prototypes and are discussed within the theme.

Social and personal contexts

It was interesting listening to women's narratives as we wove in and out of talking directly about the intervention and its content to participants indicating the things in their own life that would make it difficult to use the App or enact healthy behaviours.

Firstly, environmental factors such as having a long commute to work and economic factors such as the perceived expense of healthy foods. Although work was identified as a barrier for some, a career change from restaurant manager to police officer for one participant had led to a significant shift in lifestyle that led to reduced smoking and alcohol consumption, less junk food and better sleeping habits.

> *"I sort of changed over lockdown, I changed my [er] job. Got myself a new career. To some degree that [drinking, smoking, late nights] all changed a little bit."* ***Jo, 37+4***

This highlights the role of the social environment on influencing behaviours. Emphasising this, one participant spoke about the fact she worked in an office and sometimes from home with back-to-back meetings which both led to a sedentary lifestyle.

Women often spoke about other people in their social network including partners, children and other relatives that influenced behaviours; suggesting how lifestyle change cannot be viewed in an individualistic silo but must consider interpersonal processes. Prioritising the

family was frequently commented on by participants. The multiple roles participants adopted was evident with some finding little time to prioritise themselves.

> *"I didn't know that I needed to take care of myself. I was looking after my husband and doing household affairs. I didn't take time to realise that these factors were not good for me. I was too busy to think about them".* ***Nadia, postnatal***

As well as personal context and environmental factors, a key challenge that women spoke about was being pregnant.

> *"with life, with, with work, with, with kids and with kind of. Just the tiredness and all of the stuff that comes along with pregnancy"* ***Imogen, 29+2***

The embodied experience of pregnancy was a determining factor in women's experience and perceived ability of achieving healthy behaviours. For example, participants frequently spoke of sickness, tiredness, pain or feeling uncomfortable as common pregnancy experiences that were, in some cases, disabling.

> *"first three months for me was really tough like, you know, being sick, feeling like so sleepy. Then absolutely you do not have the energy for the exercises. And even if someone says to me like, okay, you should walk thirty minutes, I was like, no, no, I should be like sleeping thirty minutes and I was so tired."* ***Karolina, 30+6***

This participant clearly expressed their realities of being pregnant. This led to concern for some that despite having all the information on the App, they would not be able to achieve it and this would make them feel guilty.

> *"My barrier would have been, I read it all and found it very interesting and thought, yeah, this is all great and then add I've tried to eat something and throwing it all up and then I would have felt even more guilty about the fact that I wasn't doing all of these things."* ***Olivia, postnatal***

Despite this, the participant felt that maybe if she had an App that gave support for those struggling, she may have felt encouraged to do more.

Most participants reported that they wanted to have a healthy diet and be active. However, environmental factors, social influences, the physical constraints of pregnancy and the personal predispositions to engage or not in certain behaviours reduced their capability to achieve this. Participants offered ways that the App may bridge the gap between acceptability and capability. These were thoroughly considered in the iterative development of the App, and fully reported in Chapter 5, to ensure the App supported women in the most appropriate way. Features such as creating personal, achievable goals and monitoring progress towards these was important for both reflective motivation, via self-conscious intentions and evaluations, and autonomic motivation, via reinforcement of success. Encouragement, recognition of achievements and practical support to enact behaviours were key features implemented to address the concerns raised by participants around guilt and increase beliefs around their own capability. These filled a gap that was not being met during routine consultations.

Introducing the DAPHNY App

Interviews ended with discussions around a hypothetical situation in which they were advised to use the DAPHNY App by their midwife or obstetrician. This further revealed ways that the App may be a tool to bridge the gap between acceptability and capability summarised above and detailed in Chapter 5.

More than one participant explained that they would be more inclined to go to the App and enter blood pressure readings if these were shared with a healthcare professional with the instance given that this would prompt them to look at other sections of the App. An example from Olivia (below) displayed how the App could form part of a conversation with their midwife, suggesting it could have a role in routine care. This is something that was offered by the healthcare professionals that I spoke to as way to support women with hypertension

management by using the App as a tool for useful and practical conversations about lifestyle factors.

> *"…And actually when you went kind of the midwife appointments or something, they were like, right. So we have a look at your blood pressure readings on your app. So you knew that somebody else was gonna actually be using the information…That always makes me more inclined to do something. While I know that it's got a useful purpose".* ***Olivia, postnatal***

This displayed how participant's view of healthcare professionals can influence behaviour in relation to blood pressure management with the App providing an opportunity for their efforts to be recognised. This could be the key driver in engaging women with information around lifestyle that, as discussed, falls outside the medical domain but one which women would be willing to engage with in their own time.

Some participants offered other opportunities for engagements, in particular the postnatal period which was frequently cited as a time when they would benefit most from advice on the App.

> *"two days after I gave birth to her, I felt the best I'd felt in months […] I felt better and would have had more energy and focus to do these things then"* ***Olivia, postnatal***

As well as having relief from the challenges of pregnancy, participants felt that the postnatal period was a time when the focus could turn back to the mother. A description from one participant conformed to contemporary dialogues for women to always appear the best version of themselves by describing the expectation to spring back to a pre-pregnancy body after birth.

> *"You're kind of more concerned with you know "springing back" in quotes. Not that I would expect to spring back, but kind of losing any weight that you do gain, I think you're more focused or in pregnancy less with kind of your own health but making*

sure that that the baby that you're growing Is growing in the right way. You're kind of more concerned with them than with you as the as the vessel, I suppose". ***Imogen, 29+2***

Whilst this challenged the introduction of an App that promotes health that may be interpreted by some as bringing women to conform to social norms, the DAPHNY App was not described by participants as adding to the undue pressures to look a certain way but was favoured in its approach to provide supportive information. It did expose the field in which the DAPHNY App would be implemented in, which would need close consideration given the popularity of commercial health Apps and normative expectations commonly placed on women.

The pre-conception period was also identified as a time to introduce the DAPHNY App where promotion by GPs and midwives would encourage its use.

"I think you could almost do it when, I mean, I'd probably even download it if I was, you know, you went to the GP and you said you were trying to conceive, I think it'd even be mentioned at that point." ***Lottie, 22+5***

These highlighted the potential for the intervention to span across all women with hypertension of reproductive age; recognising that for some, especially those with challenging or complications during pregnancies, it is not always possible to achieve optimal diet and physical activity habits. A more flexible and fluid approach by offering an intervention throughout the life course may be more forgiving in relieving the pressures placed on women during pregnancy and could support sustainable adjustments in lifestyle that would benefit long-term health.

6.5.3. Study 3 (Component 2): Individual interviews with women who trialled the App

6.5.3.1. Participant characteristics

Participant characteristics of the eight participants who took part in an individual interview after they had used the App for a short period are reported in Chapter 5, Section 5.5.6.7. Interviews lasted between 21 and 44 minutes and thematic analysis constructed 3 themes:

1. The App was easy to use and aligns with health priorities but does not necessarily mean engagement or behaviour change
2. The App as a facilitator for a holistic approach to hypertension management
3. Integrating the App with routine life and maternity care pathways

6.5.3.2. Theme 1: The App was easy to use and aligns with health priorities but does not necessarily mean engagement or behaviour change

The App was easy to use and liked by participants and it aligned with their existing health priorities. Similarly to the women that took part in the think-aloud interviews, these priorities were often generated from a personal desire to have a healthy pregnancy, to avoid pregnancy weight gain or be healthy to secure the health of the rest of their family; recognising the strong connection between their own health and that of their children.

> *"a healthy pregnancy I'm directly linking to a healthy baby because ultimately that's what it's about. It's making sure that your baby is healthy at the end."* ***Eleanor, 15^{+6}***

> *"health is important for me and the baby I'm carrying. It will have an impact on my lifestyle, the kids' lifestyle. The family. Everything really"* ***Hana, 15^{+5}***

Having long term high blood pressure during pregnancy led to fear and demonstrates the emotional journey of a hypertensive pregnancy where healthy outcomes were not always guaranteed.

> *"…being pregnant really did scare me a little bit because obviously I thought I wasn't gonna have [erm] a safe pregnancy because of the blood pressure and all the complications that come with [erm] hypertension in pregnancy".* ***Zahra, 18***$^{+3}$

Because of this, pregnancy could be viewed as a precarious time for health but meant they wanted to do what they could to reduce the risk of poor outcomes, and this included accessing information about lifestyle factors available in the App.

Since many described how their health was a priority during pregnancy, they were motivated to use the App. For one participant, using the DAPHNY App had coincided with a diagnosis of pre-diabetes which was more of an incentive to use the information on the App than hypertension; which she had not associated with lifestyle change, a theme that was brought to light in the think-aloud interviews and focus groups.

For some, who already felt that they knew the information about living healthily, it was described as a reminder but saw the App as an opportunity to reengage.

> *"the rest of it, I've probably read or heard at some point and it was again a good reminder".* ***Hana, 15***$^{+5}$

> *"A lot of it I already knew, but it was, it was like to have that reminder on the app [erm] every day. So, it found me looking through the app and I'm just, you know, click on it just to remind myself [erm] and then I'm making a conscious decision [clears throat] you know, whether or not to add the extra salt for my, to my meat or just to cut it down a little bit as well."* ***Zahra, 18***$^{+3}$

A criticism of health Apps is that the population who use these are probably the ones who least need the support and advice and the DAPHNY App, as a standalone intervention, is not immune to this. Though there was evidence that participants may be health-conscious individuals, information about salt was highlighted to be new by some and of relevance given the relationship with high blood pressure.

The DAPHNY App mobilised the existing intrinsic motivation they had to be healthy that was predicted from the think-aloud interviews with women.

> *"So [erm] I realise that I have been more active and tracking my steps a lot more than I would have, even with my [er] my Fitbit watch. So, I just find myself checking that on the, on the watch and then inputting it into my, into my app. So, possibly that's the biggest [erm] positive for me with this app."* ***Zahra, 18+3***

However, even those with motivation, the DAPHNY App wasn't enough to change behaviour. Some App features that were taken forward from the participants in the think-aloud interviews, such as goal setting and practical information and tips to prompt movement and healthy eating were not enough to actually change behaviours and more help to incorporate these behaviours around their own life was needed. This confirmed the proposed point of disengagement identified in think-aloud interviews.

> *"[a step] target wouldn't necessarily force me to, you know, to, to leave the house. It's more like, you know, the circumstances and the reality rather than, you know, a set [er] number, yeah."* ***Natalia, 30+4***

The environmental and structural barriers were again, as first described in theme 3 of the think-aloud interviews, significant barriers to enacting the information they received through the App. For example, a sit-down job or a job on the road where the only available food outlet was KFC, described by another participant, gave little choice but to choose an unhealthy meal and this would not be overcome by receiving a notification about cooking from home, for example.

Information within the App such a shopping on a budget and ideas for healthy food cupboard ingredients were other nuggets of information that participants suggested during the think-aloud interviews that would be valuable in overcoming the barriers to being healthy.

However, deep engagement in the App was limited and these pages were not accessed by participants who used the App.

This demonstrates how the vision of the App that was thoroughly thought through in the think-aloud interviews contradicts the reality of its use. Theme 3 that emerged in the think-aloud interviews identified that there may be a gap between the value placed on the intervention with external factors that would inhibit its use. The current analysis has revealed that the suggested ways to overcome these barriers, cannot solely be achieved through the App; indicating that even where someone has the motivation, behaviour change techniques

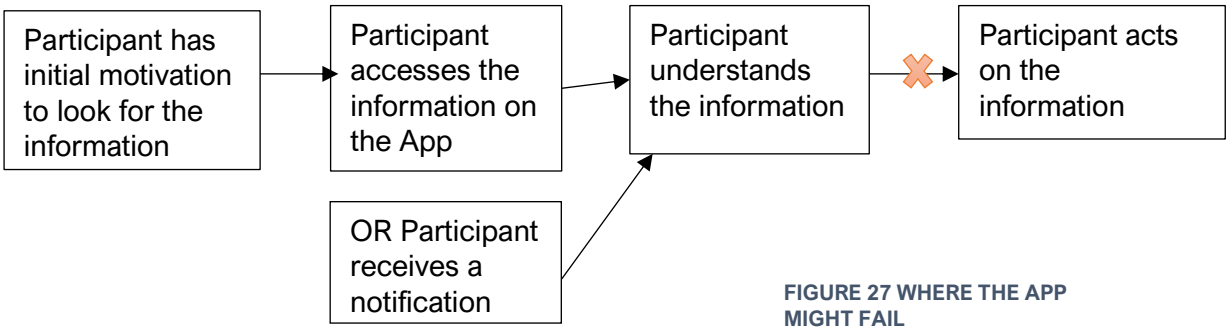


FIGURE 27 WHERE THE APP MIGHT FAIL

(goal setting and information provision) are not enough to impact someone's lifestyle behaviours; disproving the conceptualised logic models presented in Chapter 5, section 5.5.6.3. This idea is displayed in Figure 27 and is important in our understanding of why and where the App may face challenges in its aim to change behaviour through engaging with the information.

6.5.3.3. Theme 2: The App as a facilitator for a holistic approach to hypertension management

As was seen in the think-aloud interviews and focus groups, participants described a 'medication first' approach to their hypertension management. The following quote articulates the status quo for blood pressure management, and this was seen across the dataset.

> *"The way it is now, currently, its advice to read and it's up to the patient how much they access it and follow it. But it's not actually linked to the conversations that*

happen in the clinic because it's more about have, have you seen spots, do you have headaches and, you know, those sort of typical things that are linked with pre-eclampsia I guess rather than preventative. So the default seems to be medication, which I get because they don't wanna risk the blood pressure [er] increasing. But there hasn't been discussion around the possibility of decreasing medication in pregnancy once the blood pressure is sort of under control and that is a real possibility, isn't it, if you follow all the steps in the app well that's the point of it is that you can be healthier." ***Eleanor, 15^{+6}***

The DAPHNY App introduced a different approach to hypertension management and since treatment was described by participants as the focus of care, it is unclear whether there is space for a more preventative outlook for hypertension care. It is therefore challenging to optimise a lifestyle App when the fundamentals of hypertension care do not include lifestyle advice. However, the participants felt that it could, and should, become part of the package of care.

The participants who used the App enjoyed being able to view their blood pressure trend overtime because it provided a more complete picture of their blood pressure control. This was not a feature some had seen before, and this helped the participants to understand their blood pressure which was especially important for those who had a recent diagnosis. They were able to link it to other things they were doing in their life, via the other data inputted in the App (e.g. step count), and the information they read, that made them think about what may be influencing blood pressure readings.

"I love the fact that there's a graph at the end and then visually it's very nice to see. [...] if I saw a certain peak on a certain day, it would prompt me to think, what did I do on that day. Was I stressed on that day you know, I am kind of looking for things like that on the app." ***Hana, 15+5***

Blood pressure control for Hana was more than medication and along with others she demonstrated a desire to understand and have knowledge about their blood pressure control. The DAPHNY App presented a way that this more rounded approach to blood pressure management could be met that was not always met during consultations.

The importance of attending appointments was highlighted by the participants, signifying why pregnancy is often cited as an appropriate time to deliver lifestyle information.

> *"I think it definitely should because midwife is the one that no one misses. Everyone goes to their midwife appointments. So, actually that's the vehicle for communication I think from healthcare professionals is, is through the midwife and I think it, it's an important part of, especially if you've got blood pressure issues in pregnancy there should be an additional set of [er] questions or things that midwives talk to you about."* ***Eleanor, 15+6***

The relationship women have with midwives is unique and this was described by participants where they placed emphasis on the role that they have in their hypertension management. The DAPHNY App was disconnected from this relationship and their overall care management which may have influenced use since participants emphasised the importance of having a conversation about the App with their healthcare providers.

> *"But in general, for it to work you would have to be actively looking rather than have it as a notification, while, if it comes [er] as a conversation with your [er] [er] healthcare provider, I think it's got more chances of, you know, yeah."* ***Natalia, 30+4***

> *"if those two things came together, it'll be more of a [erm] a positive experience because, you know, I, I, I'm, I'm you know, doing what I have to do to keep my blood pressure under, under control and you know, tracking everything through the app but also, I can get some advice from healthcare professionals, if I need to"* ***Zahra, 18+3***

The App could act as a bridge between personal care and medical care. Having the App disturbed the routinely technical focus of consultations that was also reported in focus groups, to a more holistic approach where the woman and her efforts in engaging with the App were noticed and spoken about, whilst she navigated the challenges of being pregnant; a topic that frequently emerged during interviews.

6.5.3.4. Theme 3: Integrating the App with routine life and maternity care pathways

A thread that emerged through all participant interviews and focus groups is that people's live are busy. Despite incorporation of information in the App suggesting ways to overcome barriers and tips to enact healthy behaviours, it was common that the participants felt they had little time for themselves and therefore to use the App and access the information, especially those working or with other children.

> *"It's like I haven't got a lot of time just to sit. Whereas if I think it was like for someone let's say a first time mum, I think, obviously then have a lot more time to sit and read, whereas obviously having a little one that you are like, if you're on the phone it's like, what you doing. What you doing. It's like okay, I'll just put this away."* ***Danielle, 15+2***

When giving examples about how they had used the App in their daily life, a couple of participants explained how they sat down and looked at the information when they had time and they enjoyed being able to focus on themselves.

> *"I will only do it sort of when I've got time. And then, you know, try and do a blood pressure when I'm relaxed. For me, it's a relaxing thing. You know, that, the time I opened the app used to be me time."* ***Hana, 15+5***

The App did not align with the business of women's lives where it was perhaps a privilege to have time to access all of the information. There was no additional space for the DAPHNY

App with suggestions that it needed to be linked to what you were already doing for it to be used and be effective.

> *"if it links more directly to what's happening for you because at the moment, I'm having to go into the app to be and if you're busy, if you've really like I've got a toddler and work full-time. I'm having to find time to go into the app rather than the app coming, the information coming to me."* ***Eleanor, 15+6***

Further to this, the vastness of the digital field was recognised with some eluding to the fact that Apps are downloaded and quickly forgotten.

> *"especially with me and I know a few people like it's like you get an app and it's not like you get bored of it, but you forget you have it a lot of the time".* ***Danielle, 15+2***

Emphasising this further, when I asked one participant about the notifications, she showed me a screen of notifications on a phone, scrolling through a long list to see that she had received the DAPHNY notifications.

> *"Yeah, I do have some [erm] some messages, but [er] I am horrible when it comes to these notifications, if I'm honest, yeah. I have to find them now to [laughs] to remember"* ***Natalia, 30+4***

The participants who used the App have again shown that engagement with the DAPHNY App faces significant challenges, both because of the limited time people have as well as the plethora of Apps and other notifications that are now embedded into routine life within modern society.

Both blood pressure self-monitoring and healthcare professional contact acted as anchors for accessing the App; reaffirming what was found in the think-aloud interviews. Self-monitoring blood pressure is becoming increasingly common amongst this group and this group of participants were regularly using an existing blood pressure monitoring App. For

some, having the App prompted them to take a home blood pressure reading and then this triggered exploration into the rest of the contents.

> *"If I don't use the app, I won't monitor my blood pressure. I will only monitor when I got headache, when I've got the feeling something isn't right but once I've got the app, I do it every day."* ***Nia, 33+3***

> *"cos I'm logging in to do the blood pressure readings that it reminded me to do the steps, I guess. And to focus on it more and perhaps getting it through the day."* ***Hana, 15+5***

> *"Because you have to go into [NAME OF APP USED IN CLINICAL CARE] every day and put your blood pressure in, you're then gonna be going into DAPHNY every day. You put your blood pressure in and because you're in the app, putting that in, it could directly link you to certain things to go and have a look at or you could see your progress on it".* ***Eleanor, 15+6***

The self-monitoring Apps that the participants spoke about were connected to a healthcare professional who would view the readings, which participants described as comforting and reassuring.

> "…*that's comforting also that you know that someone will, you know, look into to that [er] at some point."* ***Natalia, 30+4***

Seeking reassurance may be due to fear of the potential poor outcomes described by participants previously. Participants care what healthcare professionals say to them and participants demonstrated the instrumental role in their journey through pregnancy. Since the DAPHNY App was not connected to a healthcare professional interaction, this could be the missing link to increase use and engagement.

Furthermore, some described how if the App was supported by healthcare professionals, the advice about lifestyle would be taken more seriously than if it was something they had

chosen to do off their own agenda, further emphasising the integral role of the healthcare professional.

> *"I would actually take it way more seriously as well. [erm] Because if I, if, you know, you were just have in your personal life, sometimes you, you might forget about it. You might not use it as much as [er] well, I might not use it as much as I should. But, if it's something that, you know, healthcare professionals saying, okay, we want you to do this and to do this just for this long, I think I would definitely be on board."* ***Zahra, 18+3***

The importance of incorporating the App within existing methods of blood pressure management as well as promotion from a health professional was highlighted by participants, especially as the App, in its current form, may not be any better than the current delivery format of a leaflet.

> *"being given a flyer or equivalent of a flyer in the app, that's not necessarily going to make, you know, revolutionise your, your life".* ***Natalia, 30+4***

It was clear that not everyone wanted all of the information on the App and for some, the focus on food in the App led to disengagement because of the close association with weight loss dieting. This led the participant to feel the App was stigmatising and categorising her into a higher weight group. In the think-aloud interviews, the participants offered a way the App could cut across weight assumptions. However, providing dietary advice in a non-stigmatising way appears to be a challenge in the delivery of lifestyle advice due to this close association. The participant who felt stigmatised suggested an opt-in/out system where you could choose the components most relevant for you; asserting control to the user according to what was felt most relevant and highlighting a desire for further personalisation of the App.

> *"Kind of running two different systems. You know like referring patients to one or the other, rather than it being one app that has got everything on it and you kind of a bit lost about which bit applies to you and which bit doesn't".* ***Ashley, 25+5***

The App was not viewed in this way by most participants and in contrast, another participant suggested that the App could reduce stigma by providing a platform on which to instigate an informed conversation by taking into account a woman's valuation of her health and needs and then tailor the App use accordingly.

Significant changes to the current version of the App that were suggested by participants were to reduce the contents, or to have a selection of what content you wanted to explore, making the App more personalised, reduce the user effort required and combining it with existing self-monitoring Apps. Optimising the App in this way could be a step in a direction that could help facilitate a more holistic approach to blood pressure management that women wanted. However, the recurrent themes of environmental and structural barriers may act as long-term challenges in the effectiveness of such an intervention that could be mitigated by healthcare professional monitoring of progress and partnership working if feasible within exiting care pathways.

6.6. Discussion

6.6.1. Key findings

This study found that women who enter pregnancy with high blood pressure often do not receive regular lifestyle advice to specifically support blood pressure control, and this is subsequent to minimal lifestyle advice given at hypertension diagnosis. The healthcare professionals and the women I spoke to, shared challenges in delivering and enacting lifestyle advice provided such as the existing delivery formats and appointment structure, preconceived assumptions and conflicting clinical and personal priorities and barriers. However, the women I spoke to were enthusiastic to supplement current care and practices such as blood pressure self-monitoring with more information about key lifestyle behaviours

that influence blood pressure and importantly, demonstrated motivation to engage in an App that could help them to achieve this. Alongside this, healthcare professionals described the App as a useful tool to initiate a more informed conversation with women about their lifestyle as a management strategy beyond medication administration, which is the current status quo. Although participants described the App as valuable and were motivated, the women's narratives sometimes contradicted their proposed engagement in health behaviours. Women's actual use of the App played out this contradiction where there remained enthusiasm for a lifestyle App, yet engagement was minimal. The themes developed offered ways this disconnect could be mitigated, where the App could contribute to a missing component of holistic blood pressure care management. Interpretations of these findings in relation to the wider field are discussed.

6.6.2. Relating to the existing literature

System constraints meant that participants prioritised activities other than health promotion in the care interaction, despite professional's belief in their role in health promotion. Within this context, this was a barrier to supporting the use of a lifestyle App. The task focused narrative of appointments is one that has been identified in other antenatal care settings including consultations with those living with pre-existing conditions (267, 268). Parallels can be drawn from this exploratory study where authors concluded that the medical focus of appointments could mean that women with pre-existing conditions may be more likely to receive assessment and monitoring focused appointments. Due to these system constraints, information about lifestyle was passed to the woman without scheduled follow up or progress checking. A long-term commitment based on a partnership of mutual respect and a trusted relationship between hypertensive patients and their care providers is important for sustainable change and important to patients (269). Providing advice, or signposting to an App as could potentially happen, leaves space for the professional to perform acute clinical tasks during appointments, of which professionals may feel more accountable for, as opposed to lifestyle support that appears to be hidden work during consultations in the

data. This hidden work of healthcare professionals, described by others as invisible tasks, unseen work or "nonquantifiable" practices fall outside the discrete, concrete checklists or charts that can be ticked off, audited, monitored or assessed (270-274). However, Patanwala (2012) notes the importance of hidden work in their ethnographic study of pharmacists finding that most medication errors were identified during informal consultative activities with staff, as opposed to formal, documented medication reviews (275). These unstructured and informal activities provided a contextual understanding when prescribing medication that were important for patient safety. The task focused nature of appointments coupled with the lack of a clear directive, or perhaps inappropriate use of a tick-boxing exercise for giving lifestyle advice, could prove insufficient in supporting women. Given the social, cultural, and psychological discourses that surround the personal matter of lifestyle, discussions cannot be constricted and quantified, as other tasks can, into the narrow focus of antenatal consultations. The practical and clinical application of lifestyle health promotion is challenged within my dataset and understanding how a lifestyle App can facilitate this hidden work, within the routine surveillance of managing a pregnancy complicated by hypertension, is important for women to feel supported and for healthcare professionals to fulfil their health promotion role.

There was an undercurrent of preconceived assumptions that guided practice and interactions between women and professionals. These could potentially influence who would receive the intervention, demonstrating the healthcare professionals gatekeeping role which, although sometimes in an effort to protect the pregnant woman, in this case the relationship, can contradict the partnership approach to care that promotes choice (276, 277). Diet and physical activity were closely associated with weight which can be highly stigmatised within healthcare and other settings (278-280). This stigma can result in dissatisfaction with care, affect shared decision making and negatively impact outcomes (281). Whilst weight is a visible condition, blood pressure is invisible and stigma manifests differently however there is little research exploring this stigma. Contributing to our

knowledge, and similarly to one study exploring the effect on stigma and adherence to high blood pressure treatment, I found stigma surrounding hypertension was often closely linked to diet, weight, and exercise (282). Therefore, midwives must be aware of their own biases and respond appropriately to signals from the woman about the importance the woman places on a particular topic (277). This was seen in the data where the participating women wanted a conversation alongside the App so that it could be personalised according to the woman's valuation of her health; reducing the preconceived assumptions surrounding provision of lifestyle advice and enabling choice about what to engage with.

It was important that the App was not strict and offered flexibility considering practical issues, such as personal budgets and dietary preferences, as well as consider the varying emotional experiences of the distinct phases of pregnancy. Participants wanted to have choice on what they could eat, reflecting how pregnant women may seek, successfully or not, to retain control of their changing bodies through paying attention to diet and exercise habits (283). In particularly, women with complications are more likely to report this lack of control and choice, suggesting why having control was important to the population in my study (29). The socially, and perhaps institutionally, constructed expectations of being a good mother through behavioural correction to control their pregnant bodies may contribute to why strict messaging was disliked (131, 284). In an interview study eliciting women's experiences of GDM care, some women reported feeling distressed by the externally imposed self-discipline placed upon them to avoid harm to the baby (285). In my study, it was evident that for some this self-discipline was internally generated perhaps due to the often unwavering acceptance that they were ultimately responsible for their own health and that of their babies (283). Though they may accept this pressure of themselves or from others, this burden of responsibility meant they were resistant to an App adding to this. Women with hypertension and gestational diabetes may have additional pressure compared to the general pregnant population due to the higher risk of poor outcomes which intensifies this responsibility. Whether pressure is internally or externally imposed, the moral

imperative to do the right thing to avoid feelings of guilt or self-blame, terms used by the participants in my study, remains omnipresent during the pregnancy experience (131). The desire for supportive and non-prescriptive content in the App could show pregnant women's opposition to the plethora of, sometimes unsolicited, advice they receive regarding their everyday habits and a desire to make their own choices and thus, retain feelings of control through the childbearing continuum.

It is argued that pregnancy has moved from a social event towards a medical event, owing to intense surveillance and monitoring (129, 286). This has also been evidenced in the DAPHNY study. Incorporating the social, environmental, economic, and emotional factors that intertwine with diet and physical activity behaviours is an important part of that social dialogue that may only be considered when institutional constraints allow. Pregnancy crosses the margin between illness and health and more so for those with hypertension due to the presence of potential risk that is recommended to be monitored (27, 287). However, remembering pregnancy is inherently embedded within the social and cultural contexts is important and highlighted by women in the study who spoke of wanting authentic conversations with healthcare professionals about their changing body, where it was important that efforts made toward lifestyle changes were acknowledged. Similarly, the wider literature shows that people want to be "seen and heard" during consultations through meaningful relationships, to meet their psycho-social and emotional needs; highlighting the desire to be recognised as an individual which requires time, creativity and authenticity by healthcare professionals (268, 288, 289). Bringing women back in the conversation about their own bodies including ways she may manage blood pressure in her personal domain, beyond the maternity care setting, could contribute toward opening up the dialogue. The DAPHNY App could give women a tool to become part of that conversation by providing content that is woman-centred, the underlying philosophy of the App, to facilitate productive conversations; enhancing the partnership approach that women seek.

6.6.3. Strengths, limitations, and reflections

I gained in-depth insight from interviews with 21 women who have experience of chronic hypertension during pregnancy. To my knowledge, this is the first study to reveal such insight into this population for them to talk about their experience of pregnancy in relation to their hypertension and their lifestyle and understand their motivations to use a lifestyle App and to change behaviours. Furthermore, by talking to women initially about the intervention and then asking a different group of women to use the intervention, as per the Person-Based Approach, we have a more complete picture of how this intervention could work or not work in any future implementation by confirming what was arising in the initial interviews (226). Also, by only asking a few people to test the App, as opposed to rolling it out in a full feasibility trial, we have exposed important considerations needed before this next step, which would require more resources.

There was congruence between what the healthcare professionals said and what the women in the study said. For example, healthcare professionals expressed that the advice they provided about diet and physical activity may not meet the needs of the women and the women felt that advice was generic and not practical. This provides evidence of what is happening in practice and also affirms the findings of Chapter 3 that concluded that guidelines may not support healthcare professionals in providing effective lifestyle support, highlighting the need to address this further by, for example, involving women in guideline development.

I would have liked to have started the thematic analysis of the focus group data before all the focus groups were completed so that I could conduct subsequent focus groups with an initial impression of emerging patterns to explore. However, this was not possible as I was conducting the content analysis and implementing the changes to the DAPHNY App prototype so that new iterations could be shown to subsequent participants. Despite this, conducting the content analysis gave me a fuller understanding of the transcripts so when I

began the thematic analysis, I had an initial impression of themes. Furthermore, if I had more time, I would have followed up the focus groups with the healthcare professionals in Manchester, but I was not able to achieve this within the time constraints of the studies.

When conducting this study, I felt conscious of the potential digital exclusion that could amount through the development of an App based intervention. Given my work as a midwife, I understand well the communication and access barriers experienced by women travelling through maternity pathways. Furthermore, the MBRRACE-UK report starkly highlights the poorer outcomes that some groups experience (16). I fully acknowledge that the DAPHNY App may achieve support for only a small group of women, and it may not be the best way to support all women with hypertension during pregnancy. The group of women who I spoke to may be more likely to already be healthy, and they report shortcomings in their support with this aspect of their life, it could therefore be presumed that those with existing barriers to care, are likely to receive worse care and support relating to lifestyle behaviours. The learnings from this work that women want personal and practical information that is part of an ongoing discussion with healthcare professionals can be applied to other delivery methods to ensure inclusivity. Therefore, this research has indicated a need to work with specific groups to understand differing perspectives from those who may be underserved, but face significant barriers.

6.6.4. Recommendations and implications for practice and research

If a lifestyle App is to be successfully embedded within maternity pathways so that collaborative conversations can be had to support its use, a system level intervention is needed to address the underlying biases, knowledge deficits and resource constraints that were evident. This system level change was also brought to the fore in Chapter 3 where it was posited that guidelines may promote unconscious bias and may make it difficult for supportive and productive lifestyle conversations to happen in practice. Therefore, work must be done from an implementation point of view to embed change in practice. For

example, working with key stakeholders involved at a strategic level with ongoing evaluation and action planning. Apps should be developed within this multi-disciplinary team including healthcare professionals and importantly, alongside women. These collaborations need to lead to a shared understanding of delivery methods to support all women in ways that are meaningful for her and do not impact negatively on relationships.

Though the intervention being developed cannot directly tackle the change that is needed, this work has identified contention in the lifestyle support being provided for women with hypertension that requires further exploration since it is an important recommended part of care that could improve outcomes. This could be achieved by analysing the care interactions between the midwife or obstetrician and women with hypertension to explore how conversations actually play out. This could help shape the progression of understanding how women with hypertension can be supported to achieve healthy lifestyle behaviours and how an App like DAPHNY could be built into and facilitate this collaborative conversation.

6.7. Conclusion

The concept of the DAPHNY App as a lifestyle intervention specifically for pregnant women with long-term high blood pressure was viewed positively as something that did not currently exist but could potentially be beneficial for both women and healthcare professionals. Despite iteratively developing this with women, key behaviour change techniques and incorporated content were not enough to support women given the multitude of personal and societal factors that play into one's ability to have a healthy lifestyle. Healthcare professionals have an integral role in supporting the ongoing use of an App like this particularly when it is related to blood pressure management. This is ultimately a big challenge because healthcare professionals find it difficult to prioritise lifestyle advice and therefore it is not embedded in routine antenatal care. Signposting to an App that delivers advice will not necessarily be a better option than existing delivery formats of lifestyle

information unless it becomes part of the package of care for blood pressure management. Therefore, integration with existing care pathways for women with hypertension, for example, adding some information to a self-monitoring blood pressure App and working closely with healthcare professionals in how they talk about the contents of the App with women is a potential avenue to consider before proceeding to a feasibility trial, to further optimise a lifestyle intervention for pregnant women with chronic hypertension.

Chapter 7 Final discussion, reflections and conclusions

7.1. Overview

In this chapter, I will discuss the main findings of this thesis, which has contributed new evidence through qualitative and quantitative methods that led to the development of a unique lifestyle App for pregnant women who enter pregnancy with existing hypertension. I will discuss the findings in the context of existing literature, highlight the key strengths and limitations, reflect on my journey and comment on the clinical and research implications of this body of work.

7.2. Summary of Results

The systematic review reported in Chapter 2 found that randomised controlled trials conducted during pregnancy to improve health behaviours often exclude pregnant women with chronic conditions, such as long-term hypertension, and where they were included, no sub-group analysis was carried out, despite potential variations in treatment effect. The lack of primary interventional trials means there was no understanding of how to support positive lifestyle behaviours in this group, which may improve disease management.

Those with chronic hypertension may also be of a higher weight since these often co-occur (106, 137). Chapter 3, a qualitative synthesis of local guidelines for the management of weight during pregnancy, showed varying and limited, practical information for healthcare professionals to support women in the best way. Due to the risk orientation of recommendations, current guidelines were in opposition to the rhetoric within maternity care which promotes women-centred and partnership working where women are confident to express their views and share their goals with professionals.

Due to the paucity of evidence to understand lifestyle behaviour change in a pregnant population with chronic hypertension, an online survey (Chapter 4) provided a snapshot of existing behaviours, motivation and confidence toward lifestyle change in this population.

This was the first study to reveal this insight, finding that less than half of women receive or remember receiving lifestyle advice at hypertension diagnosis or pregnancy, despite guidelines recommending this. Though women reported motivation and confidence to be healthy, some behaviours such as consumption of fruit and vegetables and activity levels were suboptimal for some. This gave a first impression of where there may be a mismatch in achieving healthy behaviours during pregnancy despite motivation to do this. This was described by participants where barriers and facilitators were identified which were taken forward to inform intervention components and topics explored in subsequent qualitative methods.

A theoretically informed, evidence-based lifestyle App was developed with women who have experience of chronic hypertension and been pregnant, along with healthcare professionals. Logic models conceptualised the mechanism of intervention components needed for behaviour change by identifying key behaviour change techniques to optimise the intervention. However, this did not achieve high rates of engagement when tested despite positivity about the novelty and benefit of an App that focused on blood pressure and lifestyle, since this was described as something that didn't exist but was seen as beneficial by both women and healthcare professionals. Further modifications to the intervention and changes required within clinical pathways for any future implementation were indicated and further explored in subsequent Chapter 6.

In Chapter 6, the lifestyle App was explored in the context of current maternity care pathways and women's lives. This exposed the complexity of discussing lifestyle within consultations that would ultimately create challenges in the implementation of such an intervention. Lifestyle advice was not necessarily prioritised by either the women or healthcare professionals which may explain the low levels of advice reported in the online survey. This was due to structural, societal and personal barriers as well as pre-conceived assumptions that affected who firstly received lifestyle advice and secondly, enacted

recommendations. Though behaviour change techniques were implemented in the App, these did not overcome the deeply ingrained barriers reported which affected women's access and overall engagement with the lifestyle App, which was low. Linking the App with existing care pathways such an existing self-monitoring App may boost its use as this was an accepted practice for women with chronic hypertension. Importantly, women wanted the App to be part of the package of care and linked to an ongoing conversation with a healthcare professional to ensure they were recognised for their efforts and could work together to achieve their own health goals during pregnancy. Progression to a feasibility trial would require significant changes to the intervention but this thesis has identified that there is a need, and a want, for lifestyle behaviours to be optimally supported during pregnancy with some preliminary ideas of how this could be achieved going forward.

This thesis has gathered evidence of lifestyle in the context of pregnancies complicated by existing hypertension, which has not been seen before. I found enthusiasm from pregnant women to be supported in achieving health behaviours that could support blood pressure control, however there were significant entrenched institutional constraints and societal barriers to overcome. This thesis has grappled with these challenges given the dominant narratives that run in existing maternity care together with the subjective nature and personal domain of lifestyle that meant there was little space for lifestyle support and thus, a lifestyle App-based intervention.

7.3. Relating findings to the wider literature

A theme that was brought to the fore in the intervention development studies was that quality lifestyle support is not currently embedded in routine antenatal care pathways. This was despite the fact that pregnant women with hypertension should be provided with support to enable health behaviour change, according to National guidelines (15). In the introduction of this thesis (Chapter 1), I provided a strong case for the important role that lifestyle modification including optimal dietary patterns and physical activity levels can have to

support blood pressure control. There appeared to be an implementation gap between the plethora of interventions being developed to support healthy behaviours in pregnancy and current practice which is further amplified in the case of hypertensive pregnancy, where there has been limited trials examining the effect of lifestyle interventions in this population (Chapter 2).

The reason that there is a gap from intervention to practice can be predicted to be due to the nature of lifestyle conversations which are viewed as an invisible task that get lost within consultations which prioritise clinical assessment, especially for those experiencing more complex pregnancies (267). The subjective nature of lifestyle, as a conversation, requires time (at more than one appointment), skill and knowledge to understand a woman's biological, psychological, environmental, and social factors that influence behaviours (113, 290). These have been identified as significant barriers in supporting women with lifestyle during pregnancy (81, 291). In my study, lifestyle advice was not seen as an auditable task, like blood pressure that is dictated by a set of coherent guidelines, therefore it did not appear to be prioritised. This suggested that the public health responsibility of maternity practitioners sits in opposition to the system constraints and structural norms that dictate the format of appointments. Many others have reported the challenges in condensing public health messaging into short antenatal appointments (292-294). Bolstering the efforts of midwives by referring to specialist support has been suggested as a way to share the public health agenda across services, though caution has been drawn due to the risk of fragmenting care provision and disrupting continuity which can already be a challenge for those with complications (292). An additional challenge shared by participants in my study and others is the struggle to deliver public health messages at an individual level, finding they often ignore personal factors that dictate one's agency to engage in certain "desired" behaviours (294). Despite these challenges, the participants I spoke to unanimously agreed that they were ideally placed to promote public health and would like to be able to deliver messaging more effectively if resources allowed. The specific hypertension focus of the App

was seen as a practical and informational tool professionals could use to prompt them to raise the topic, adapting as necessary, which potentially also met their own educational needs. However, this vision needs to be substantiated in a feasibility trial that is embedded within pathways to assess how it may resurface lifestyle as an important component of the consultation.

Women were motivated and recognised lifestyle as something they were responsible for in their own personal arena but since motivation didn't lead to engagement with the intervention, sharing responsibility with a practitioner may mobilise their evidenced motivation with actual behaviour change. Having self-motivation alone is not enough to lead to behaviour change (113) but having a personal discussion with a trusted professional could be more effective (295, 296). Demonstrating this concept, a shared decision-making tool for structuring brief lifestyle change conversations was developed by researchers who found the tool promoted patient autonomy in those with cardiovascular disease risk factors (297). This personal interaction that was facilitated by the tool was viewed favourably by patients. Similarly to the DAPHNY intervention, the challenge of incorporating these conversations within the current format of consultations was a barrier to its use, though authors suggested making the tool digital would support implementation in a GP context as digital tools have been associated with improvements in health without replacing the important healthcare provider and patient relationship (298).

Although the COM-B model was a systematic framework through which to map intervention components to barriers and facilitators, within the unique context of pregnancy, some of the constructs did not translate neatly into behaviour change techniques and subsequent behaviour change. Challenges in using the COM-B model have been identified by others which usually relate to the subjectivity required to categorise intervention features which appears to diminish the robust scientific method of utilising an established theory (299-301). Extending beyond one framework is vital in the development of lifestyle interventions during

pregnancy since understanding the significant psychological and physiological changes that happen cannot be necessarily addressed via specific behaviour change techniques. A wider perspective is needed to incorporate intervention components beyond the provision of an App sitting in its own silo.

The moral responsibility of being pregnant was a burden that was evidenced throughout the research studies and reflected the self-embodiment of pregnancy that differs to that of, for example, a hypertension diagnosis. The obligation to be a responsible reproductive citizen has been critiqued by Lupton who wrote that this results in constant surveillance and monitoring (131). Within this critique, Lupton drew on Foucaldian ideas around self-governing in order to conform to healthy ideals, thus determining the pregnant woman a prime candidate for neoliberal government strategies (127, 302). The App crossed boundaries between medical care and the personal domain of one's lifestyle choices and arguably conformed to this top down neoliberal approach by tapping into the societal drive for people to govern their health via technology (303). Furthermore, the App was a form of surveillance that may add to the burden of responsibility, already carried during pregnancy. Counteracting this critique is that the intervention was built with women and meaningfully incorporated their perspectives, where it was viewed positively if it was discussed with professionals, where this responsibility could be shared (224). Where there was some resistance through concerns around additional burden, this co-development method considered these burdens and ensured supportive language and messaging that aimed to orientate users from feeling guilty to providing acceptable information to access if and when they feel ready.

The midwifery discourse is grounded in holistic, woman-centred care, built on trusting relationships, and is vital for women to feel safe, listened to, in control and able to make decisions (5, 24, 25, 289, 304). It was evident in the data that within pregnancies complicated by hypertension, a biomedical risk narrative could prevail. Mechanistic processes, task

orientated and time restricted appointments, create challenges for midwives to truly work in partnership with women (27, 129, 268, 305). Specifically, Naughton et al., (2021) found that organisational and professional barriers constrained midwives ability to deliver woman-centred care to women with complicated pregnancies (27). This can disrupt women's confidence in their bodies and loss of control. The intervention development studies exposed that women are seeking a holistic, woman-centred approach, perhaps due to their experiences of services that do not align with this, heightened by their hypertension status. Given the subjective nature of lifestyle as a topic, the intervention, if implemented with a conversation about the woman's individual context and needs could disrupt the predominantly technical focus of consultations where the woman and her efforts are noticed and spoken about.

A holistic approach to blood pressure management through the inclusion of lifestyle factors could be further achieved as participants spoke of the potential for the App to deliver messages that could translate across the life course, not solely the 9 month window of pregnancy. This demonstrates the potential value of the App. Pre-conception and the postnatal period are being increasingly recognised as a critical time period to deliver health promotion messages, highlighting a move toward a life course approach for women's health (148). Recognition of this life course approach is also seen in the government strategy for women's health; highlighting the relevance of this work in the broader context (38). Women with existing hypertension may engage in the health service, prior to pregnancy, due to their hypertension and thus this opportunity could be used to introduce other pillars of health (i.e. diet and physical activity) that may contribute to good blood pressure management. Furthermore, the postnatal period is a time when women report less satisfaction with the care they receive but where they feel they can achieve healthy behaviours (306, 307) (Chapter 6, Section 6.5.2.4). These two periods could be unique anchors for contributing to women's cardiovascular health across the life course.

Self-monitoring blood pressure is being increasingly recognised as playing a role in the long-term management of hypertension, with an increasingly recognised and embedded role within pregnancy and maternity pathways (108, 197, 308). Women in the study were accustomed to self-monitoring their blood pressure and this led to the App being an acceptable addition to this existing practice. The additional information about lifestyle on the App was not available on current self-monitoring Apps the participants used to monitor their blood pressure. In one way, the information on the App was therefore viewed as novel and a desirable feature, given this existing gap. On the other hand, it was evident that because this wasn't the norm and incorporated into current practices, it was not accessed by some participants. The management of hypertension through lifestyle behaviours was less frequently recognised as a component of care compared to weight and lifestyle which were readily associated. The challenge of promoting positive lifestyle behaviours within hypertensive populations has been recognised by others where there is a lack of willingness even where there is knowledge of the benefits (225, 309). Specifically, authors found that where hypertension was well controlled with medication, there was little interaction with the lifestyle component of a blood pressure home monitoring App (225). This disconnect between the role of lifestyle within hypertension management is a significant challenge in the field. In non-pregnant populations, there appears to be a lack of momentum to change lifestyle for the benefit of blood pressure control and it appears to face similar challenges during pregnancy. Though tacking lifestyle advice onto a self-monitoring blood pressure App could be a step in the right direction toward increasing uptake and engagement, ensuring all components are meaningfully accessed is needed.

7.4. Strengths and limitations

The biggest strength of the thesis is that prior to commencing this work, little was known about how healthy lifestyle behaviours can be supported in women who are living with long-term hypertension. Through a mixed methods approach, this thesis has begun to unpick this complex field, discovering how pregnant women with chronic hypertension view and

experience their pregnancies and in this context, how they can be supported to adopt healthier behaviours to achieve short and long term good health. Although the research questions were broad and exploratory, this was necessary given the lack of evidence. This thesis has contributed one piece of the healthy lifestyle discourse puzzle specifically relating to women with chronic hypertension during pregnancy. However, due to limitations, sometimes due to the lack of existing data, tighter research questions are needed in future research to extend the observations that I have seen.

A plethora of lifestyle interventions have been developed for the general pregnant population, but few have focused on a chronic hypertensive population who may benefit the most from lifestyle modification (see Chapter 2) (74). This thesis addressed the call for lifestyle interventions that focus on specific subgroups as opposed to a one-size fits all intervention (94). The unique experience of a pregnancy complicated by hypertension and the needs of these women in relation to lifestyle support has, until now, been unknown.

A strength of this thesis is that I have involved women with experience of chronic hypertension during pregnancy as well as healthcare professionals. Therefore, perspectives on the developed intervention was gathered from both care providers as well as end users of care and the intervention. I also regularly spoke to those with expertise in the field of self-management of chronic conditions and digital interventions. PPI involvement throughout my DPhil strengthens this work considerably since I ensured the methods of data collection, the tools I used and my interpretations of the data were reasonable for the group it was intended for. However, two PPI contributors does not represent the whole population and therefore, taking this work forward, a wider, more diverse patient advisory board would be beneficial. The methods adopted stemming from the person-based approach, contributes to meeting the needs of different groups and I was enthusiastic in my efforts to ensure that participants were from a range of backgrounds. However, the views of the women in this study may not be transferable. Especially since they were from two NHS Trusts that have high research

activity, as well as having an App used in routine care for women to self-monitor their blood pressure. The overall acceptability of a digital intervention that I found may not be seen by women attending Trusts that do not currently have these resources. Though the findings may not be transferable, the credibility and trustworthiness of the findings for this particular group of participants is increased as regular discussions with academic supervisors and those involved in developing complex interventions were held through data analysis.

A limitation of the methods adopted is that preliminary components of the intervention to show participants needed to have been developed whilst writing the protocol. Whilst it is recommended in the development phase of the person-based approach that participants are shown prototypes, it may be difficult for participants to explore ideas outside of what they are shown (224). Ideally, I would have held more PPI groups or focus groups with women and healthcare professionals prior to this work, with a broader scope about an intervention to support lifestyle behaviours. I think this is of particular importance given the little evidence in the area, bringing into question whether jumping straight to the development of an App is appropriate given how little is known on the topic. Despite this, in developing an App and through the multiple methods of analysis adopted, I have managed to expose the complexity of the phenomenon which can be taken forward.

7.5. Reflections

In each chapter, I have offered some reflections on each of the studies carried out and how this has influenced my work. Reflexivity is not something I practiced from the outset of my DPhil as the value of it was unknown to me. Initially, it felt very exposing since it meant being confronted with what felt like the methodological inadequacies of my research. However, I now appreciate its role in providing transparency by exposing my personal biases and perspective that influence my construction of new knowledge and to demonstrate an audit trail of my journey from a clinical midwife and research assistant, to an independent researcher with a much more grounded but flexible philosophy that appreciates the multiple

realities of truth. As I began to practice reflexivity, I felt uneasy about my earlier work but as I navigated my own standpoint, I now appreciate that the construction of new knowledge to address a problem requires multiple methodologies and this is appropriate to answer the research questions posed.

Being a registered midwife, I could identify closely with the views of the healthcare professionals when discussing the topic of lifestyles within consultations. One of my motivations for conducting this thesis was because of my experience of providing antenatal care to women where health promotion felt like a tick box exercise and there was little time for discussion with the woman about her views on these topics. I set aside my own views during the focus groups to ensure I didn't become involved in the discussion but rather facilitated it which was a challenge when I could resonate with the significant challenges of a resource constrained system. During analysis, I felt quite uncomfortable incorporating some of the views of professionals which came across as quite paternalistic. It was confronting to realise that institutional norms may subconsciously influence and filter into our care practices. It is only through conducting the research in this DPhil that I am more aware of these preconceived assumptions and how my personal perspectives influence my midwifery practice.

Being a midwife also affected my interaction with the participants. I had discussions prior to conducting interviews about whether I should present myself as a midwife and researcher to the women that I approached as professional roles can influence the data gathered through qualitative methods (310). I chose to introduce myself as a PhD researcher who was also a registered midwife but made it clear that I was solely conducting research studies. I gave no midwifery advice or support though it is likely that some comments made during interviews may be influenced by my midwifery knowledge and experience. I think this was appropriate as I do not think the fact that I was a midwife affected the participant's responses. I hope the qualities and attributes I have as a midwife, enabled women to feel

they were in a comfortable space and able to answer honestly. Whilst I have focused on my professional background, it is also relevant to these studies that I have not been pregnant, I am a normal weight, exercise regularly and wear an activity watch; suggestive of an active and healthy individual if based on potential assumptions. If I had a personal experience of pregnancy and had been overweight or had a weight loss journey through adopting healthy behaviours, I may have had different insights into the research. Engaging with the literature on topics surrounding the pregnant body as well as obesity has contributed to a new self-awareness of my own perspectives that I kept in my mind throughout my interactions with participants and analysis. Conducting this research as a midwife is a strength of this work since I maintained a woman-centred philosophy that I believe has filtered through into the contents and implementation considerations of the intervention which is influential in where this work takes us next.

The wider societal context is also important to reflect on in relation to this topic of research. Firstly, it is hard not to discuss the scrutiny that our maternity services are under at this time. Inadequate staffing levels, lack of time and highly stressful environments, that I have personally experienced, were prevailing topics that arose from the interviews and focus groups. I grappled with where my work sat within this, given that it was evident that women and midwives wanted and needed more time in appointments to provide a holistic approach to care. However, being overtly aware of these challenges is instrumental in contextualising an intervention and, though it does not solve these issues, it contributes to the evidence about what needs to change in practice that is essential in optimising women's experiences during pregnancy.

Secondly, I was not able to thoroughly unpick some key issues brought to light during interviews and focus groups, due to the scope and time I had for these studies. This included the cost of living crisis that was particular prominent in the media during the think-aloud interviews and focus groups. Though I tried to address these in the intervention by providing

recommendations around shopping on a budget, ultimately the issues that surround the topic of having a healthy lifestyle are much larger than the intervention can tackle.

7.6. Research and clinical implications

This thesis has shown that the research evidence around lifestyle and pregnancies complicated by hypertension is limited with few studies examining how women in this population can be supported to adopt healthy behaviours and whether these have an impact on outcomes is unknown. Whilst much research is ongoing to develop lifestyle interventions for the general pregnant population, there needs to be a continued effort to work with women who have chronic hypertension, potentially across the life-course, to develop interventions that address the specific needs for this group, considering they may benefit the most from this support.

A disconnect lies between the dominant medical narrative of clinical guidelines and the structure of appointments, and the ambition of maternity services to provide woman-centred care to promote health behaviours during pregnancy. First and foremost, the way in which conversations are had, as well as the tools used to talk to women about their lifestyle when they have hypertension needs to be addressed. Understanding how conversations about weight and lifestyle play out in practice and co-designing new tools and strategies is suggested as a good first step in addressing the shortcomings in the health promotion aspect of midwifery care for women with hypertension.

Women in the study wanted a lifestyle App to be supported by regular discussion and follow up with a professional but the realities of existing clinical practice present a challenge to implementing this with success. From the data, there is a risk that the task of giving lifestyle advice shifts to the App thus creating responsibility for the woman to enact recommendations, without creating a partnership where there is a shared goal. The responsibility felt by the women in the study to achieve health behaviours without additional support was highlighted as a potential point of resistance to engagement as it could induce

feelings of guilt. From a healthcare professional viewpoint, if they are not given the time or resources to understand and be educated on the content of the App and how to deliver this information sensitively, it may become another health promotion task they feel unable to deliver on, despite recognition of their public health role. This moral distress in achieving their professional role could negatively impact relationships with the women and thus, care. Therefore, the institutional structures that led to limited time and skill to discuss lifestyle needs to be further interrogated and addressed to comprehensively gather evidence to how the intervention could support, as opposed to hinder, healthcare professionals in their health promotion role for pregnancies complicated by hypertension.

There was definitely an appetite for a lifestyle intervention in the form of an App by both healthcare professionals and women. The enthusiasm for some of the lifestyle information on the App must be explored within the context of existing self-monitoring practices that was evident across participants in the studies. There is a risk that this may result in medicalising lifestyle advice by adding additional self-surveillance and monitoring in already highly medically orientated pregnancies. However, a counter-argument presents a lifestyle component as inviting a more holistic approach to blood pressure management, by extending observations of each woman beyond the quantitative measure of blood pressure readings alone. Therefore, a feasibility trial with embedded implementation theory and use of qualitative methods is needed to determine whether the lifestyle component is utilised to its full potential to facilitate holistic blood pressure management that women in the study described was lacking, but was wanted.

Successful implementation of an App requires significant consideration of existing healthcare systems. Synchronising a digital intervention across different Trusts and professionals would require a host organisation to manage, update and provide governance to oversee safety and ongoing usability of an intervention. This would require significant funding and national level stakeholder involvement, for example NHS England, who could

facilitate this. Looking forward to implementation strategies, ongoing communication with existing collaborations and with those driving the digital agenda within maternity care pathways is essential to bolster the development of a lifestyle intervention beyond its own silo.

The intervention development work in this thesis focused on the planning and optimisation stage of the person-based approach. Further work is needed to build on this addressing the recommended changes to the intervention with a view to move towards the implementation and evaluation stage so it can be formally piloted and evaluated to determine its potential effectiveness that I was not able to do in these preliminary studies. In consideration of this, there are five key research priorities arising from this thesis:

1. Observations of antenatal consultations for women with hypertension around weight and lifestyle to gain new insight into how guideline recommendations play out in practice. Use this knowledge to develop training for professionals that successfully challenge bias's and underlying assumptions to breakdown their potential gatekeeping role in lifestyle advice provision.
2. A feasibility trial to test a lifestyle component in addition to a self-monitoring blood pressure App measuring feasibility, acceptability and behaviour change. This will inform progression to a future full trial.
3. In depth qualitative interviews to explore women and healthcare professionals experience and views of incorporating a lifestyle component of an App within care pathways and consultations, as well as women's lives.
4. To develop clear, practical and actionable recommendations that work alongside an intervention for healthcare professionals that facilitate a partnership to talk with women about weight and any relevant lifestyle behaviours.

5. Explore different models or methods of antenatal care delivery that support healthcare professionals in their health promotion role and better meet the needs of women with chronic hypertension.

7.7. Final conclusion

Lifestyle factors such as diet and physical activity can slow cardiovascular disease progression in a hypertensive population. These factors are also important for a healthy pregnancy. Women who enter pregnancy with high blood pressure may also be of a higher weight and thus, supporting healthy behaviours in this group should be given full attention. The thesis has exposed and addressed significant gaps in the literature on how best to support women, drawing initially on research from non-pregnant and the general population about lifestyle factors to support blood pressure control. This work demonstrated that the care of women with hypertension is not focused on prevention that incorporates holistic management with embedded lifestyle support that could influence blood pressure control beyond medication. Development of a digital lifestyle intervention for these women is viewed positively by women and healthcare professionals as something that does not currently exist but would be beneficial. Implementing the lifestyle intervention in the current context of maternity services and the complexities of women's lives is complex and likely requires significant resource. This needs careful and ongoing evaluation to ensure it does not increase health inequalities and facilitates a partnership to enable holistic conversations that could impact a woman's experiences during a pregnancy complicated by hypertension, as well as her cardiovascular health during this time and beyond.

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Appendices: Chapter 2

Appendix 1 Manuscript Goddard et al., 2023

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Evidence of lifestyle interventions in a pregnant population with chronic hypertension and/or pre-existing diabetes: A systematic review and narrative synthesis

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ABSTRACT

Background: Pregnant people with chronic hypertension, pre-existing diabetes or both are at high risk of developing cardiovascular disease. Lifestyle interventions play an important role in disease management in non-pregnant populations.

Aim: To review the existing evidence of randomised controlled trials (RCTs) that examine lifestyle interventions in pregnant people with chronic hypertension and/or pre-existing diabetes.

Methods: A systematic review and narrative synthesis was conducted. Five electronic databases were searched from inception to April 2021 for RCTs evaluating antenatal lifestyle interventions in people with chronic hypertension and/or pre-existing diabetes with outcomes to include weight or blood pressure change.

Results: Nine randomised controlled trials including 7438 pregnant women were eligible. Eight studies were mixed pregnant populations that included women with chronic hypertension and/or pre-existing diabetes. One study included only pregnant women with pre-existing diabetes. Intervention characteristics and procedures varied and targeted diet, physical activity and/or gestational weight. All studies reported weight and one study reported blood pressure change. Outcome data were frequently unavailable for the subset of women of interest, including subgroup data on important pregnancy and birth complications. Eligibility criteria were often ambiguous and baseline data on chronic hypertension was often omitted.

Conclusion: A lack of primary interventional trials examining the effect of lifestyle interventions on weight and blood pressure outcomes in pregnant populations with chronic hypertension and/or pre-existing diabetes was evident. Lifestyle modification has the potential to alter disease progression. Future trials should address the ambiguity and frequent exclusion of these important populations.

1. Introduction

Chronic hypertension (CH) complicates ≤5 % of pregnancies and those entering pregnancy with a pre-existing diagnosis of type 1 diabetes mellitus (DM) or type 2 diabetes mellitus (T2DM) has a global prevalence of between 0.5 % and 2.6 % [1–3]. Prevalence of these conditions has increased substantially over recent decades and both continue to rise; influenced by advances in maternal age and increasing rates of obesity that often precede these conditions [1,2,4]. Women with CH are nearlyeight times more likely to develop superimposed pre-eclampsia than those in the general population are to develop pre-eclampsia [5]. Additionally, they are at least twice as likely to experience an adverse neonatal outcome compared with the general pregnant population [5]. Those with pre-existing diabetes are four times more likely than those who do not have diabetes to experience a fetal death and as well as these obstetric and neonatal complications, both groups have a lifelong cardiovascular disease (CVD) risk [1,5–7]. These data spotlight the importance of examining these populations to improve disease management during pregnancy and to reduce the associated short and long-term risks.

Weight management and more specifically, weight loss is recommended to hypertensive and diabetic populations for disease

Abbreviations: BCT, Behaviour Change Technique; BMI, Body Mass Index; BP, Blood Pressure; CH, Chronic hypertension; CVD, Cardiovascular disease; DM, Type 1 diabetes mellitus; GWG, Gestational Weight Gain; IPD, Individual Participant Data; RCT, Randomised Controlled Trial; T2DM, Type 2 diabetes mellitus.

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management [8–10]. Whilst weight loss is not advocated in pregnancy, avoiding excessive gestational weight gain (GWG) is important for all pregnant women, irrespective of body mass index (BMI), as this can lead to an increased risk of adverse pregnancy outcomes [11,12]. Evidence suggests that for pregnant women with existing risk factors such as hypertension or diabetes additional support may be needed to help reduce excessive weight gain during pregnancy [13–15]. This is to address both the health of the pregnancy and their CVD risk where weight is a modifiable risk factor.

Lifestyle interventions in non-pregnant populations improve blood pressure control and the quality of life in hypertensive populations [16–18]. A review of 105 trials including 6805 participants found statistically and clinically significant reductions in systolic blood pressure following improved dietary intake [17]. Avoiding elevated blood pressure is of utmost importance for the health of the pregnancy but to our knowledge, the effect of lifestyle interventions on blood pressure in a pregnant population with chronic hypertension or pre-existing diabetes is unclear.

Pregnancy is often cited as a powerful 'teachable moment' where women are motivated to adopt risk-reducing health behaviours [19]. Systematic reviews of interventions designed to exploit this have examined the effect of lifestyle interventions in the general pregnant population [20–22] or those with overweight or obesity [23] rather than those with pre-existing conditions. An individual participant data (IPD) meta-analysis that included 12,526 women from 36 randomised controlled trials (RCT), found diet and physical activity interventions successfully reduced GWG but found no convincing evidence that interventions improve maternal and fetal outcomes. This was also observed in a subgroup analysis of 128 women with existing hypertension or diabetes. However, the focus of the review, and thus the included studies, was not pregnant women with existing conditions. Such women may benefit the most from lifestyle modification. Additionally, the effect of weight changes on blood pressure was not investigated.

This systematic review aimed to collate the evidence around lifestyle interventions during pregnancy for women with chronic hypertension and/or pre-existing diabetes (DM and T2DM), two clinically well-defined, long-term conditions. Identifying the 'active' components of interventions that lead to behaviour change is vital to build knowledge, allow for accurate replication of effective interventions and subsequently, implementation into practice [24,25]. Owing to this importance, the behaviour change techniques (BCT) utilised within the included studies were identified.

The review set out to answer the following research questions:

1. What evidence exists around lifestyle interventions in pregnancy for those with chronic hypertension and/or pre-existing diabetes and what behaviour change techniques are utilised in these interventions?
2. What effect do lifestyle interventions in pregnancy have on gestational weight in pregnant women with chronic hypertension and/or pre-existing diabetes?
3. What effect do lifestyle interventions in pregnancy have on blood pressure in pregnant women with chronic hypertension and/or pre-existing diabetes?

2. Methods

The protocol was registered prospectively on PROSPERO (CRD42021244694). PRISMA (Preferred Reporting Items for Systematic Reviews and meta-Analyses) and SWiM (Synthesis Without meta-analysis) guidelines were used for reporting [26,27].

2.1. Literature search

Medline, Embase, Web of Science, CINHAL, and PsycINFO were searched from inception to April 2021. LG devised the search strategy and conducted the search (April 2021) with support from a specialist librarian (Supplementary Table 1). MeSH terms and keywords with all possible synonyms and spellings were used with Boolean operators. No language or time limits were applied. This was complemented by hand searching the reference lists of similar and recent systematic reviews identified through the databases. The references of IPD meta-analysis were preferentially screened as well as recent, high quality systematic reviews [28]. Grey literature was screened and potentially eligible ongoing studies were followed up throughout the review process to assess for inclusion.

2.2. Study selection

Randomised controlled trials (including cluster RCTs), in any setting, that included pregnant women with chronic hypertension and/or those with a pre-existing diagnosis of diabetes (DM or T2DM) were included [8–10].

When it was not clear if the study included women with CH and/or pre-existing diabetes and the study included more than 200 participants, authors were contacted for clarification. In a sample with less than 200 participants, authors were pragmatically contacted if there was estimated to be, based on information available, at least 10 participants with either of these conditions in the sample.

Lifestyle interventions were included if delivered during the antenatal period and aimed to change behaviour or knowledge about diet, physical activity, gestational weight or a combination of these. Interventions that included self-monitoring or self-management were only included if directly influencing a lifestyle behaviour (as opposed to titration of medication or to inform clinical management). Comparator interventions included routine antenatal care (as described by trialists), minimal intervention or an active comparator, for example, provision of a food diary or a visit from an interventionist that was additional to routine care.

2.3. Outcomes

Studies that reported gestational weight and/or blood pressure change were included. Change was considered as the documented weight and blood pressure measurements closest to booking and closest to delivery as reported by authors. Where available, process outcomes including acceptability, feasibility and behavioural outcomes were collected. Important fetal, maternal and neonatal outcomes, as prioritised by an expert consensus, were collected when available [29]. These included the development of preeclampsia and pregnancy induced hypertension (where applicable), gestation diabetes mellitus (where applicable), preterm delivery and caesarean section, intrauterine death, small or large for gestational age, and admission to neonatal unit.

2.4. Data extraction and quality assessment

Two authors independently screened studies using a decision aid to ensure consistency (LG, RP). Discrepancies were resolved through discussion with the wider review team (NMA, KT, RJM) and reasons for exclusions documented.

Following identification of eligible studies, key study characteristics were collected and intervention characteristics were extracted independently and used the Template for Intervention Description and Replication (TIDieR) framework [30] (LG, RP). The BCT taxonomy was used to code the interventions [31]. Protocols and supplementary materials were consulted when coding BCT to provide more detail (Supplementary Table 2). Coding was completed independently by two reviewers (LG, RP), interpretations were compared to ensure consistency, and this was followed by a discussion with the wider members of the review team (KT, NMA).

Studies were judged independently to be at low, unclear or high-risk of bias using the Cochrane risk of bias assessment tool [32] (LG, RP).

This includes four domains: random sequence generation; allocation concealment; blinding of outcome assessment; and incomplete outcome data. Performance bias was not assessed due to the nature of behavioural interventions.

2.5. Analysis

As we anticipated moderate to high heterogeneity, a random effects meta-analysis for change in mean gestational weight and blood pressure was planned. Due to the high clinical heterogeneity in the data retrieved and the lack of available data for the population of interest for this review, a meta-analysis would have been inappropriate and a narrative synthesis was undertaken [33]. Data is presented in tables, structured according to population characteristics, beginning with those that have more directness in relation to the review question (i.e. included only, or a subgroup for those with chronic hypertension and/or pre-existing diabetes). Vote counting assisted in indicating evidence of intervention effect on weight and blood pressure. Microsoft Excel 2016 supported data synthesis.

Intervention characteristics including BCT and intervention intensity, as defined a priori (Supplementary Table 3), were tabulated and discussed narratively.

3. Results

Following de-duplication, 1464 articles were screened for eligibility, 209 full text articles were screened and subsequently, nine studies were included (Fig. 1). Grey literature and hand searching generated no further studies.

Studies were included where authors confirmed inclusion of pregnant women with chronic hypertension and/or pre-existing diabetes even if no subgroup data was available. This was a deviation from the protocol in order to incorporate all available evidence of interventions that included the population of interest for the review. This aimed to help build the knowledge base and guide and inform further research in this group. Where authors were not able to clarify the inclusion of participants with chronic hypertension or pre-existing diabetes, the studies were excluded.

3.1. Study and participant characteristics

Included studies randomised a total of 7438 pregnant women with the sample size ranging from 20 to 2212 women (Table 1). Seven were standard RCTs [34–40] and two were cluster RCTs [41,42]. The studies were conducted in Australia, Finland, Brazil, the UK and the USA. One study was international and included nine European countries (Table 1).

Eight studies were mixed pregnant populations that included pregnant women with chronic hypertension and/or pre-existing diabetes [34–38,40–42]. One study included a pregnant population with pre-existing diabetes [39]. All but two studies [38,39] excluded pregnant women with pre-existing diabetes.

3.2. Risk of bias

Eight studies were judged as low risk of bias [34–38,40–42] and one judged as unclear risk [39] because of the limited information provided by authors (Table 2). Authors judgement for each domain is available in Supplementary Table 4.

3.3. Intervention characteristics

Intervention procedures varied including the primary target

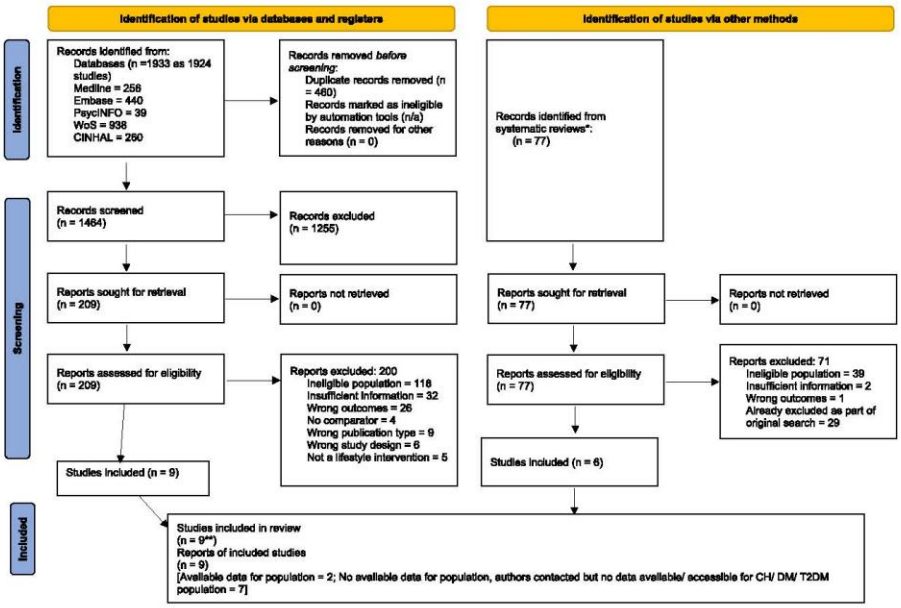

Fig. 1. PRISMA flow diagram of the systematic search and selection of relevant studies. Adapted from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. *systematic reviews identified in search, narrowed to IPD, most recent and most recent Cochrane review. **Complete overlap with studies identified via other methods.

Table 1
Overview of randomised controlled trials included in review.

Study (Author, Year)	Country, year, design	Population	Study groups	Primary outcomes	Aim of trial and authors conclusion on weight and blood pressure (for total study population)
Studies that provide data on pregnant women with chronic hypertension and/or pre-existing diabetes					
Simmons et al., (2017) [40]	9 European countries 2012–2015 RCT	436 pregnant women. 41 women with chronic hypertension. Women with pre-existing diabetes excluded.	Healthy eating and/or physical activity (3 intervention arms) Usual care	GWG at 35 to 37 weeks, fasting glucose and HOMA-IR (Homeostatic Model Assessment for Insulin Resistance) at 24 to 28 weeks.	Test the effect of 3 lifestyle interventions in reducing GDM. Gestational weight change – Positive – the intervention (HE + PA) was effective compared to control in limiting GWG. See Table 4 for weight change in participants with chronic hypertension. Systolic and diastolic blood pressure change – Not an outcome.
Ney, 1982 [39]	USA Dates not stated. RCT.	20 pregnant women. 10 women with type 1 diabetes. 10 women with type 2 diabetes. No information on chronic hypertension.	HCF (High carb, high fibre diet) Control diet (Usual care for diabetes management)	Diabetic control.	Compared diets on various quantitative criteria of diabetic control. Gestational weight change - Positive – GWG was significantly lower in intervention arm compared to control. See Table 4 for weight change in participants with existing diabetes. Systolic and diastolic blood pressure change – Not an outcome.
Studies that provide data on the number of participants with chronic hypertension and/or pre-existing diabetes but no outcome data available					
Watter et al., (2019) [36]	UK 2014–2016 RCT	1252 pregnant women. 58 women with chronic hypertension. Women with pre-existing diabetes excluded.	ESTEEM (Effect of Simple, Targeted Diet in Pregnant Women With Metabolic Risk Factors on Pregnancy Outcomes) intervention Usual care	A composite outcome combining gestational diabetes or preeclampsia and a composite outcome combining stillbirth, SGA or admission to neonatal unit.	Assessed whether a Med diet reduces adverse outcomes in high-risk women. Gestational weight change – Positive – women allocated to the intervention gained less gestational weight. Systolic and diastolic blood pressure change – Not an outcome.
Nascimento et al., 2011 [38]	Brazil 2008–2010 RCT	82 women pregnant. ~23 women with pre-existing diabetes (Not exact number (only % given). ~37 women with chronic hypertension (Not exact number (only % given).	Study group Usual care	GWG during the programme and excessive maternal weight gain.	To evaluate the effectiveness and safety of physical exercise on outcomes and quality of life on maternal/perinatal outcomes. Gestational weight change – Positive when stratified by BMI group – overweight women from the study group (n = 9) gained less gestational weight than the control group (n = 5). There was no significant difference in GWG between groups when data was analysed as a whole. Systolic and diastolic blood pressure change – No effect - The intervention did not affect systolic or diastolic arterial blood pressure.
Studies that include women with chronic hypertension but provide no further detail on these participants (pre-existing diabetes excluded from these studies)					
Dodd et al., (2014) [35]	Australia 2008–2011 RCT	2212 pregnant women. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Lifestyle advice Usual care	Incidence of infants born large for gestational age.	To assess whether dietary and lifestyle advice to limit GWG in overweight and obese women improves maternal, fetal and infant outcomes. Gestational weight change – No effect – There was no difference in total GWG between the groups. Systolic and diastolic blood pressure change – Not an outcome.
Dodd et al., (2019) [34]	Australia 2014–2017 RCT	641 pregnant women. Women with chronic hypertension included but no data collected. Women with pre-	Lifestyle advice Usual care	Proportion of infants with birth weight > 4 kg.	To evaluate the effect of dietary and exercise advice among pregnant women of normal BMI, on pregnancy and birth outcomes. Gestational weight change – No effect –

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Table 1 (*continued*)

Study (Author, Year)	Country, year, design	Population	Study groups	Primary outcomes	Aim of trial and authors conclusion on weight and blood pressure (for total study population)
		existing diabetes excluded.			There were no differences between the groups for total GWG. Systolic and diastolic blood pressure change – Not an outcome.
Hedderson et al., (2018) [41]	USA 2011–2012 Cluster RCT	2014 pregnant women with gestational diabetes. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Tailored letter Usual care for gestational diabetes management	The proportion of women meeting the IOM guidelines for second and third trimester appropriate weekly rate of weight gain from gestational diabetes diagnosis to delivery. *To note: this study evaluated one element of a larger trial that involved a postnatal intervention with a primary goal of reducing postpartum weight retention.*	To evaluate if a tailored letter improves GWG among women with gestational diabetes. Gestational weight change (note: authors report % meeting IOM guidelines for appropriate weekly rate of GWG) – Positive - The intervention group had a statistically significant 8 % increased likelihood of meeting the IOM guidelines for appropriate weekly rate of GWG. Systolic and diastolic blood pressure change – Not an outcome.
Luoto et al., (2011) [42]	Finland 2007–2009 Cluster RCT	399 pregnant women. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Intervention group Usual care	Proportion of women with gestational diabetes and new-borns birthweight.	To evaluate whether intensive lifestyle counselling could prevent the development of gestational diabetes and large for gestational age. Gestational weight change – No effect – Total GWG did not differ significantly between the groups. Systolic and diastolic blood pressure change – Not an outcome.
McCarthy et al., (2016) [37]	Australia 2011–2012 RCT	382 pregnant women. Women with chronic hypertension included but no data collected. Women with pre-existing diabetes excluded.	Serial self-weighing and simple dietary advice Usual care	A composite of one or more obstetric complication (gestational diabetes, pregnancy induced hypertension, Mode of Delivery other than spontaneous vaginal delivery, postpartum haemorrhage, 3rd/4th degree tear, admission to intensive care unit, high dependency unit stay > 6 h, maternal death).	To determine the effect of the intervention on obstetric outcomes. Gestational weight change – No effect – Mean GWG was not significantly different between groups. Systolic and diastolic blood pressure change – Not an outcome.

Abbreviations: HE, Healthy Eating; PA, Physical Activity; GWG, Gestational Weight Gain; BMI, Body Mass Index; IOM, Institute of Medicine.

Table 2
Risk of bias of included studies.

Risk of bias domain	Number of studies ($n = 9$)		
	Low risk	Unclear risk	High-risk
Overall risk of bias	8	1	0
Random sequence generation (selection bias)	8	1	0
Allocation concealment from person randomising participants (selection bias)	7	2	0
Blinding of outcome assessment (detection bias)	5	4	0
Incomplete outcome data (attrition bias)	9	0	0
Selective reporting (reporting bias)	9	0	0
Other bias	7	2	0

behaviour or focus of the intervention (i.e. diet, physical activity, weight or a combination of these), delivery method, number, frequency and duration of intervention sessions, delivery personnel, intervention intensity and inclusion or absence of a theoretical underpinning (Table 3).

Comparators were described as usual or standard care that reflected current clinical practice and guidelines but were minimally described by most authors. Generally, comparators either did not include dietary, physical activity, or GWG guidance or only minimal advice. Two studies included usual care for a diabetic population that included monitoring blood sugars and dietary advice.

3.4. Gestational weight change

All studies reported gestational weight change as an outcome. One study presented this as the proportion of women meeting the Institute of Medicine guidelines for weekly rate of GWG [41]. Two studies provided subgroup data on the target population [39,40]. Simmons et al., (2017) found women with chronic hypertension in the intervention groups gained less gestational weight overall than those in the control group [40]. The least weight was gained in the intervention arm that included both the diet and physical activity component (Table 4). Ney et al., (1982) found that the participants (pregnant women with pre-existing diabetes) gained less gestational weight in the dietary intervention group [39] (Table 4).

The remaining studies reported outcomes for the total, i.e. mixed populations, and are summarised as having 'no effect' (i.e. no difference between the groups) or a 'positive' effect (Table 1). Two studies [36,41] reported a positive effect of the intervention on GWG and four studies [34,35,37,42] found no effect of the intervention on attenuation of GWG. Nascimento et al., (2011) found a positive effect for women who were overweight ($n = 9$) when data were stratified by BMI but when data was analysed as a whole, no effect was observed [38].

3.5. Blood pressure change

Nascimento et al., (2011) reported systolic and diastolic blood

Table 3
Intervention characteristics of included studies using TIDIER framework.

Study	Groups	Interventions							Sessions		
	Comparator Intervention	Underlying theory (why)	Content (what)	Provider (including training if provided)	Mode (How)	Location (where)	Duration/ Gestation at recruitment	Intensity	Number/ Frequency	When or at what gestation	Length per session
Studies that provide data on pregnant women with chronic hypertension and/or pre-existing diabetes											
Simmons et al., (2017) [40]	Usual care	N/A	Usual care	Midwife or obstetrician	N/A	Hospital or maternity practice	Recruited < 19 + 6/40 Intervention complete by 35/40.	N/A	N/A	N/A	N/A
	Healthy eating (HE) Physical activity (PA)	Patient empowerment Cognitive behavioural technique	HE - lower carbohydrate, lower fat, and higher protein diet. Focus on portion size to limit calories.	Health coach –training program included observed session.	F2F (individual) Telephone			3	5 F2F sessions <4 phone calls	Participants preference and availability of coach	30–45 min <20 min
	Healthy eating and physical activity (HE and PA)	Motivational interviewing	GWG of 5 kg. Handbook, educational materials and scales provided PA - aerobic and anaerobic PA promoted. GWG of 5 kg. Materials as per HE plus pedometer/Dyna-bands. HE and PA – above two interventions combined.	Standardisation sessions every 6 months. Selected on natural ability to be emphatic, background in either behavioural change, HE and/or PA. Training on MI technique	Mail				Mail contacts (no. undefined)		N/A
Ney, 1982 [39]	Control diet (usual care for women with diabetes)	N/A	Encouraged a diet commonly prescribed in pregnancy Caloric intake based on weight gain and activity levels and a GWG of 20-30lbs. Personal counselling and management according to lab and clinical data.	Usual diabetic team reviewed lab tests and clinical data.	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	High carb, high fibre diet	None described.	As above but nutrition counselling to encourage a daily intake of 60 g-70 g of dietary fibre and 65 % calories from available carbohydrates. Unprocessed wheat bran and/or muffins provided to have 3x a day.	Usual diabetic team reviewed lab tests and clinical data. Interventionist unclear.	F2F (individual) Telephone	Clinical research centre and High-risk obstetric clinic	Mean 16 ± 2.3 weeks	3	Undefined	Weekly Regular phone contact	Undefined
Studies that provide data on the number of participants with chronic hypertension and/or pre-existing diabetes but no outcome data available											
Watter et al., (2019) [36]	Current clinical practice	N/A	Dietary advice as per UK national recommendations for antenatal care and weight management	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Mediterranean-style diet	Social cognitive theory	Supported to follow the diet. Personalised SMART goals. Mixed nuts, extra virgin olive oil provided. Culturally adapted recipes	Trial dietician and trained researchers/ allied health professionals.	F2F (1 individual and 2 group) Telephone	Unclear	From 18 weeks gestation Endpoint unclear.	3	3 F2F 2 phone calls	18/40 20/40 28/40 24/40 32/40	Unclear

(continued on next page)

Table 3 (*continued*)

Study	Groups	Interventions							Sessions		
	Comparator Intervention	Underlying theory (why)	Content (what)	Provider (including training if provided)	Mode (How)	Location (where)	Duration/ Gestation at recruitment	Intensity	Number/ Frequency	When or at what gestation	Length per session
			and grocery list. Group sessions, partners involved. Educational materials.								
Nascimento et al., 2011 [38]	Control group	N/A	Routine prenatal advice (standardised nutritional counselling).	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Study group (Exercise counselling)	None described.	Counselling and education on recommended GWG and PA. Exercise journal and home exercises.	Trained physical therapist.	F2F (individual and group).	Unclear	Mean duration 12.3 weeks	2	Weekly Home exercise 5x/wk	Weekly	40 min classes
Studies that include women with chronic hypertension but provide no further detail on these participants (pre-existing diabetes excluded from these studies)											
Dodd et al., (2014) [35]	Standard care	N/A	State wide perinatal practice (no routine provision of diet, exercise or GWG advice).	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Lifestyle advice	Stage theories of health decision making	Dietary advice consistent with Australian standard, individualised information on meal plans, healthy recipes, simple food substitutions, snacking, eating out, food preparation. Encouraged to increase walking and incidental activity. Workbook to monitor progress.	Trained research assistants and research dietician.	F2F (individual) Telephone	Unclear	Recruited between 10 and 20/40	3	3 F2F 3 phone calls	Initial session within 2 weeks of randomisation 28, 36/40 22, 24, 32/40 phone calls	Unclear
Dodd et al., (2019) [34]	Standard care	N/A	Standard care (no routine provision of advice related to diet, exercise or GWG).	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Lifestyle advice	Stage theories of health decision making	Dietary advice consistent with Australian guidelines emphasising balance, reduce energy dense foods and increase fibre. SMART goals, significant other involved.	Trained research assistants and research dietician	F2F (individual) Telephone	Unclear	Recruited between 10 and 20/40	3	3 F2F 3 phone calls	Initial session shortly after trial entry then at 28, 36/40 20, 24, 32 weeks follow up phone calls.	Unclear
Hedderson et al., (2018) [41]	Usual care for women with GDM	N/A	Health education materials as per usual care. Up to two calls/week to review blood glucose and lifestyle advice. Nurses and dieticians available by phone. No advice on GWG.	Nurse	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Tailored letter			N/A	Postal letter	N/A		1			N/A

(continued on next page)

Table 3 (*continued*)

Study	Groups	Interventions							Sessions		
	Comparator Intervention	Underlying theory (why)	Content (what)	Provider (including training if provided)	Mode (How)	Location (where)	Duration/ Gestation at recruitment	Intensity	Number/ Frequency	When or at what gestation	Length per session
		None described. (To note: this was one element of an intervention, the postnatal component involved counselling and has a theoretical basis)	A tailored letter with 6 messages: weight history, goal GWG specific to BMI, pregnancy weight goal, weight management recommendation, lifestyle tips, risk information on weight gain.				After GDM diagnosis		1 mailed letter	Shortly after GDM diagnosis	
Luoto et al., (2011) [42]	Usual care group	N/A	Usual care (some dietary counselling and follow up of GW but little PA advice).	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Intensive counselling	PRECEDE-PROCEED and Stages of Change	Counselling on BMI-specific GWG to meet and to increase/maintain/adjust leisure time PA. Counselling to achieve a healthy diet based on Finnish guidelines and diabetes prevention research. Discussed barriers, opportunities for change. Notebooks to monitor behaviours objectives. Optional group exercise sessions.	Nurses and physiotherapists.	F2F, messages, telephone	Maternity clinics of primary healthcare centres.	8–12/40 until 37–39/40.	3	5 counselling sessions. Monthly (optional) group sessions	8–12/40 16–18/40 22–24/40 32–34/40 36–37/40	First session = 20–30 min then 10–15 min 2 h group sessions
McCarthy et al., (2016) [37]	Standard care	N/A	Information card with booking BMI and advice on target GWG. No regular weighing.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Serial self-weighing and simple dietary advice	None described.	Information card with booking BMI and advice on target GWG. Card included weight management advice based on the Australian Guide. Dietary advice given, encouraged serial self-weighing. Stickers on AN notes to encourage discussion about weight with care providers.	Research midwife.	F2F (individual).	Unclear	From 14/40 until delivery.	2	1	Unclear	30 min
Summary		Underlying theory	Focus/content of intervention	Providers	Mode of delivery	Location	Duration	Intensity	–	–	–
		5 with a theoretical basis	GWG only = 0 Diet only = 4 PA only = 0 GWG, diet, PA = 3	Research midwives nurses, research assistants, dieticians, physical therapists,	In-person and remote (calls, messages, mail) = 6	Where provided included: healthcare	Most recruited from 8 to 20/40 and sessions (if > 1) often	Level 1 = 1 Level 2			

(*continued on next page*)

Table 3 (*continued*)

Study	Groups	Interventions							Sessions		
	Comparator Intervention	Underlying theory (why)	Content (what)	Provider (including training if provided)	Mode (How)	Location (where)	Duration/ Gestation at recruitment	Intensity	Number/ Frequency	When or at what gestation	Length per session
			GWG, diet = 2 GWG, PA = 2 Diet, PA = 0	trained health coaches	In-person only = 2 Remote only (via a posted letter) = 1	facilities (hospital or midwife clinic) and a clinical reseach centre.	continued until around term.	= 2 Level 3 = 6			

Abbreviations: HE, Healthy Eating; PA, Physical Activity; GW, Gestation Weight; GWG, Gestational Weight Gain; P2F, Face to face.

pressure change, for the total population, from 16 weeks gestation to 40 weeks gestation. No statistical data was extractable or available upon request from authors [38]. Authors stated that the intervention did not affect systolic or diastolic arterial blood pressure. The remaining studies did not collect or report blood pressure data as a primary or secondary outcome.

3.6. Behaviour change techniques

Eight studies gave sufficient information to code the BCTs in the interventions [34–38,40–42]. The 93 BCT's were collated into 14 domains to present more consolidated results [31]. Studies included between five and eight different behaviour change categories (Supplementary Table 5). The most common techniques, used in all eight of the coded interventions, were 'Goals and Planning', 'Shaping knowledge' and 'Comparison of outcomes' (Fig. 2). 'Feedback and monitoring' was coded in seven interventions. Four domains, 'Reward and threat', 'Regulation', 'Scheduled consequences' and 'Covert learning', were not identified in any of the coded studies.

3.7. Process outcomes

Simmons et al., (2017) reported data on retention rates and found that 78 women withdrew before the final oral glucose tolerance test of which 21 % had chronic hypertension ($p = 0.02$) [40]. Process outcomes were reported in the remaining eight studies but no detail about the characteristics of women (i.e. whether they had hypertension or diabetes) were described and therefore not reported here.

3.8. Behavioural outcomes

Whilst all studies targeted changes in diet or physical activity, none of the included studies reported the changes in dietary intake and physical activity levels for women with chronic hypertension and/or pre-existing diabetes.

3.9. Clinical maternal and fetal outcomes

Watter et al., (2019) reported maternal and fetal outcomes for women with chronic hypertension including pre-eclampsia, gestational diabetes, small for gestational age and admission to neonatal unit (Supplementary Table 6) [36]. No differences between the groups were found. The remaining included studies reported some or all of the pre-specified maternal and fetal outcomes to be collected in the review but data was available only for the total participant population and therefore not reported here.

4. Discussion

4.1. Principle findings

Whilst there were many studies reporting interventions to promote lifestyle change during pregnancy, there were no studies that focused specifically on pregnant women with chronic hypertension. One study focused on women with pre-existing diabetes and the remaining studies included mixed pregnant populations. Authors often did not collect or report key baseline characteristics, including key chronic conditions, making the decisions on inclusion and exclusion of participants with these conditions difficult. Where this information was present, women with chronic conditions were often excluded from trials or if not, no subgroup analysis was performed. Gestational weight change was frequently reported but blood pressure change was limited to one study. The findings of this review indicate a lack of clarity and data on the effect of lifestyle interventions in pregnant women with chronic hypertension and/or pre-existing diabetes, thereby exposing key gaps in the literature.

Table 4
Gestational weight change for included studies that included analysis of participants with chronic hypertension and/or pre-existing diabetes.

Study ID (Author, year)	No. participants	GWG end points	Control group (kg) Mean ± SD	Intervention group(s) (kg) Mean ± SD		
Ney *et al.*, (1982) [39]	20 participants type 1 or type 2 diabetes.	Maternal weight gain during pregnancy. End points not defined.	Control group ($n = 9$) 15.9 ± NR	High carb, high fibre diet ($n = 11$) 11.8 ± NR		
Simmons *et al.*, (2017) [40]	436 randomised in total 41 women randomised with chronic hypertension	Weight at baseline (study entry) and weight between 35 and 37 weeks.	Usual care ($n = 9$) 11.2 ± 5.4	Health eating and physical activity intervention ($n = 12$) 4.9 ± 3.9	Healthy eating intervention ($n = 9$) 8.4 ± 5.0	Physical activity intervention ($n = 11$) 7.7 ± 4.7

Abbreviations: NR Not reported. GWG Gestational weight gain.

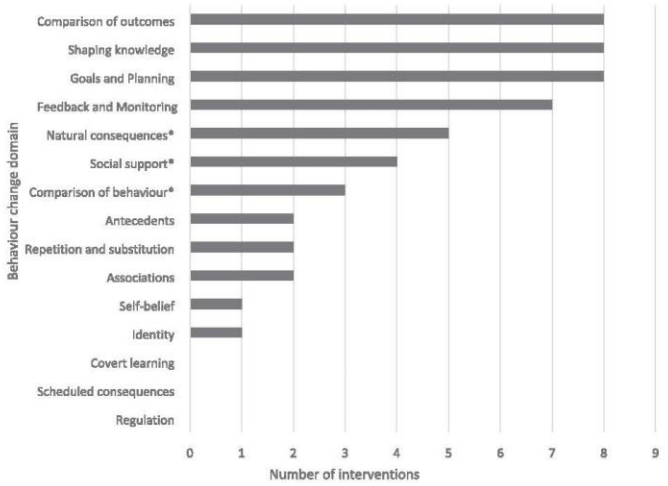

Fig. 2. Frequency of use of each behaviour change domain. Note: *Includes one study with the related BCT offered in the optional group session.

4.2. Comparison with literature

Previous reviews have established that interventions that incorporate components of diet and physical activity have a modest effect on GWG in the general pregnant population or those who start pregnancy overweight or with obesity [20,22,23]. A review conducted by the i-WIP collaboration also found few studies included or provided information on those with pre-existing conditions and the interventions were not specifically designed for this population. Perhaps due to their different inclusion criteria to this review or ability to access additional data, the i-WIP group conducted a subgroup analysis on women with pre-existing hypertension and diabetes in an attempt to determine, the currently unknown, intervention effects in this population. One-hundred and twenty-eight women (2.9 % of women in the subgroup analysis) were included in this analysis and no differential intervention effects were found, i.e. those in the intervention group gained less gestational weight than the control. Combining the findings of both reviews, we can confidently say that there is a lack of focus on pregnant women with these pre-existing conditions, who may benefit the most from lifestyle interventions.

The Mediterranean diet is known to reduce blood pressure in high-risk groups outside of pregnancy [43]. The ESTEEM trial, included in the review, investigated the effect of a Mediterranean style diet [36]. In their sample of pregnant women with metabolic risk factors, authors found mothers in the intervention group gained less gestational weight than the control (MD −1.2 kg, 95 % CI −2.2 to −0.2) and it reduced the odds of gestational diabetes (aOR 0.65, 95 % CI 0.47–0.91). The intervention had no significant effect on preeclampsia or any individual components of the composite offspring outcome. These data were not included in the current review as analysis included the total participant population. As well as the Mediterranean diet, authors are increasingly exploring the effect of other dietary patterns in both low and high-risk pregnant populations on various clinical and metabolic outcomes [44–48]. Studies indicate that diet during pregnancy has a role in promoting cardiovascular health where adherence to certain diets has the potential to improve maternal and offspring outcomes, support gestational weight management, glycaemic control and reduce blood pressure. As there continues to be evidence for the positive effect of specific dietary patterns that modify risk factors and support disease management, the current review now indicates that it is pertinent to test and understand the effect of these on important subgroups where there is potential to delay disease progression.

Understanding and describing key behaviour change techniques used within interventions is an important step in developing future effective interventions. Two existing systematic reviews examined the effectiveness of BCT on GWG [49,50]. There is cross-over with the most frequently identified BCT found in the current review. Although, unlike these reviews, we were unable to determine the effectiveness of the techniques, we further the existing evidence-base by presenting the most frequently utilised techniques that should continue to be tested so that the core active components can be determined and, in turn, ensure the implementation of effective interventions into practice.

5. Strengths and limitations

This is the first systematic review to examine the effect of lifestyle interventions in a high-risk pregnant population who have chronic hypertension and/or pre-existing diabetes. Although studies of mixed populations were included, the focused review has helped identify significant gaps in this area of research. The review offers new insights and a new angle in which researchers should consider in future work in this area.

Robust methods were used including duplicate screening and data extraction with regular discussions on discrepancies to improve reliability. Authors were contacted pragmatically and grey literature and the reference lists of recent and similar systematic reviews were searched. Risk of bias was assessed independently and the majority of studies were classified as low risk of bias therefore any bias present was unlikely to alter the conclusions made.

Insufficient reporting of inclusion and exclusion criteria in many studies created challenges during the review process and required reviewers to make several assumptions based on the available data. Unlike women with pre-existing diabetes, it was not always clear if women with chronic hypertension were included or excluded in the sample despite contacting authors hence assumptions had to be made. Future authors should provide greater clarity in eligibility criteria for this population.

Pregnant women with chronic hypertension and/or pre-existing diabetes were included in the review. Although these populations share similar characteristics, differences exist. However, insights from diabetes research are often translated to hypertensive populations, perhaps because lifestyle modification is important in the management of both and is recommended first line treatment in general practice. This suggests that including populations with pre-existing conditions in one review, and acknowledging the relationship between them, is a reasonable approach and has been noted in other studies [20,51–53]. Furthermore, transparency in our reporting shows clearly the inclusion or exclusion of each of the two populations in each study and data has not been aggregated; reducing misinterpretation of the review findings.

There was insufficient data to perform a random effects meta-analysis and a narrative synthesis was more appropriate to address the review question. Transparency in reporting the findings helped avoid over-interpretation of included studies that had less directness in answering the review question (i.e. being explicit about studies that included mixed pregnant population). This narrative synthesis has provided a useful presentation of the evidence-base; vital in advancing the research field.

5.1. Implications for future research

Authors should attempt to collect and publish baseline data on important pre-pregnancy medical conditions, including hypertension and where they are excluded this should be clear in the eligibility criteria. If women with chronic medical conditions are included, authors should be encouraged to publish the necessary data to perform additional subgroup analysis to support the collation of evidence on these small, but important, groups. Blood pressure is an important and routinely collected clinical parameter. Collecting this data could help in determining how improvements in diet and physical activity levels may affect blood pressure during pregnancy and into the postnatal period. Development of isolated interventions in pregnancy that consider individual conditions appears limited. Further consideration to conduct primary studies examining the effect of lifestyle interventions in important subgroups, by harnessing the knowledge from non-pregnant high-risk populations, is warranted.

6. Conclusion

The findings of this systematic review have indicated that there is a shortage of primary interventional studies examining the effect of lifestyle interventions in high-risk pregnant populations who enter pregnancy with chronic conditions. Regular exclusion of this important group, or omission of this detail in describing participant characteristics, hinders the ability to understand what is most effective for women who may benefit the most from lifestyle modification to reduce the risk of adverse pregnancy outcomes as well as improve long-term cardiovascular health.

7. Contributors

LG, NMA, KT and RJM contributed to creating the research question and parameters of the review, including the search strategy. LG conducted the search with assistant from a specialist librarian, Nia Roberts. LG and RP reviewed the titles, abstracts and full text of articles identified during screening. Disagreement on reviewed articles were resolved by consensus or discussion with KT, NMA and RJM. Data extraction was completed by LG and RP. Narrative synthesis was conducted by LG and reviewed by NMA, KT and RJM. Drafting the manuscript was led by LG with critical revisions by all authors. LG is the guarantor for this research.

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Richard J. McManus has received BP monitors for research use from Omron and is working with them to develop a telemonitoring system for use in primary care. He receives no personal payment for such work. All other authors declare no competing interests.

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Availability of data

Available upon reasonable request from the corresponding author.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.preghy.2022.12.004.

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Appendix 2 PROSPERO Record

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PROSPERO
International prospective register of systematic reviews

A systematic review to identify the behaviour change techniques utilised in antenatal lifestyle interventions to manage gestational weight and blood pressure in a pregnant population at high risk of cardiovascular disease

Citation

Lucy Goddard, Rajan Patel, Nia Roberts, Katherine Tucker, Nerys Astbury, Richard McManus. A systematic review to identify the behaviour change techniques utilised in antenatal lifestyle interventions to manage gestational weight and blood pressure in a pregnant population at high risk of cardiovascular disease. PROSPERO 2021 CRD42021244694 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021244694

Review question

1. What effect do lifestyle interventions in pregnancy have on gestational weight in women at high risk of cardiovascular disease?

2. What effect do lifestyle interventions in pregnancy have on blood pressure during pregnancy in women at high risk of cardiovascular disease?

3. What behaviour change techniques are utilised in these interventions?

Searches [1 change]

The search strategy was developed with the support of an outreach librarian who specialises in the field. Five databases will be searched from inception to the present: MEDLINE, Embase, Web of Science, CINAHL, and PsycINFO.

MeSH terms will be used where possible and different search terms will be combined by Boolean operators.

The following PICOS framework will be used to form the basis of the search terms:

Population: Pregnant women at high risk of cardiovascular disease - Chronic hypertension; Pre-gestational diabetes (Type 1 or type 2).

Intervention: Lifestyle interventions - diet; physical activity; self-management/ self-monitoring or multicomponent interventions.

Comparator: Usual antenatal care or an active comparator.

Outcome: Gestational weight, systolic and diastolic blood pressure and behaviour change techniques. I will also look at process, behavioural, maternal, fetal and neonatal outcomes.

Study design: Randomised controlled trials.

Grey literature will be screened for inclusion but if studies do not provide sufficient information, which cannot be obtained from authors, they will be excluded. However, when consolidating results of the review, the evidence from these papers will be considered to reduce publication bias.

Eligible trials will also be sought through hand searching the reference lists of included papers and forward citation searching.

No language or time limits will be applied to the search.

Similar systematic reviews on the topic will be used as reference.

If appropriate, searches will be rerun to ensure an up-to-date evidence base is gathered at the point of analysis.

If a study includes mixed populations of both eligible and ineligible participants and a subset of data from the eligible participants cannot be retrieved from the paper or authors, the study will be excluded as there is little certainty that the population will be relevant to the review question.

Types of study to be included

Randomised controlled trials including cluster RCTs will be included.

Condition or domain being studied

Women with chronic hypertension or pre-gestational diabetes have an increased risk of cardiovascular disease and, on entering pregnancy, face a significant risk of adverse perinatal outcomes. Women with these chronic conditions, which frequently coexist, may also be living with overweight or obesity. Appropriate gestational weight gain (GWG) is important for all women but some suggest more stringent weight control during pregnancy for women with comorbidities is required to help manage risk. Evidence suggests that lifestyle interventions in pregnancy lead to a modest reduction in GWG but the efficacy of interventions designed for pregnant women at high risk of CVD remains to be determined. In a non-pregnant high risk population, lifestyle interventions that lead to body weight reduction have been shown to reduce blood pressure. Although weight gain, as appose to weight loss, is a normal physiological process during gestation, there is cause to explore the effect of lifestyle interventions on weight and blood pressure in a high risk pregnant population. To enhance the practical utility of the review, it aims to identify the behaviour change techniques utilised within interventions. This will be an important contribution to the existing evidence base as well as assist in the design of future interventions.

Participants/population

Pregnant women at high risk of cardiovascular disease: Women with pre-gestational diabetes (type 1 or type 2 diabetes) or chronic hypertension (as defined by the individual study) including hypertension that is present at, or prior to the booking appointment, or before 20 weeks gestation.

Any setting including community, primary and secondary care will be considered.

Intervention(s), exposure(s) [1 change]

Interventions will include any lifestyle interventions implemented during the antenatal period. Lifestyle interventions, delivered alone or in combination that aim to change a woman's behaviour or knowledge in relation to diet or physical activity will be included. Both those delivered remotely and face to face will be included. Multicomponent lifestyle interventions that incorporate regimens of self-monitoring and self-management will only be included when directly influencing a lifestyle behaviour, i.e. diet or physical activity. Where self-monitoring or self-management interventions are to inform the titration of medication or clinical management but no lifestyle behaviour is directly targeted, these will be excluded.

Interventions that assess the provision and intake of dietary supplements such as vitamin D or fish oil will be excluded as they do not reflect practices that are typically considered to be part of traditional lifestyle interventions. Pharmacological interventions will also be excluded.

Comparator(s)/control

All types of comparator will be included including usual antenatal care or an active comparator.

Context

Any setting including community, primary and secondary care.

Main outcome(s)

Mean gestational weight change (kg).

Mean change in systolic and diastolic blood pressure (mmHg) from early pregnancy (closest to booking) to late pregnancy (closest to delivery).

Type, quantity and combination of behaviour change techniques (using BCTTv1, Michie et al., 2013) utilised within the intervention.

Michie, S., et al. (2013). "The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions." Ann Behav Med 46(1): 81-95.

Measures of effect

It is anticipated that trials will report different end points for gestational weight gain. Therefore, the documented weight closest to booking which may be pre-gestational and the documented weight closest to delivery will be used. This may or may not be immediately post-intervention. If a study reports the proportion of women exceeding or meeting gestational weight gain guidelines but not weight values, authors will be contacted where possible to obtain data on mean weight.

Additional outcome(s)

Process outcomes including acceptability (attendance, attrition) and feasibility (fidelity and adherence).

Behavioural outcomes including change in dietary intake and change in physical activity.

Clinical outcomes: Maternal, fetal and neonatal outcomes will be collected where data is available, including the development of preeclampsia and pregnancy induced hypertension, gestational diabetes mellitus, preterm delivery and caesarean section (elective and emergency), intrauterine death, small for gestational age, large for gestational age and admission to NICU. These outcomes have been identified as a priority when evaluating lifestyle interventions in pregnancy. Although the outcomes were developed for analysis of individual participant data, it was deemed appropriate for the current review due to the low incidence, but high importance, of these outcomes in pregnancy.

Measures of effect

Behavioural outcomes will be measured by change from baseline (closest to booking) to last follow up (closest to delivery).

Data extraction (selection and coding)

After de-duplication, two authors will screen the title and abstract of all studies retrieved through the searches. An eligibility flow diagram with a clear description of inclusion and exclusion criteria will be used to ensure consistency between reviewers. If deemed relevant, full text articles will be reviewed for inclusion. Any discrepancies will be resolved through discussion with a third reviewer. Reason for exclusion will be documented. A software package (Covidence) will be used to filter articles and to assist in the development of a PRISMA flowchart of the selected studies for inclusion.

Following identification of included articles, one reviewer will independently extract relevant data and this will be checked by a second reviewer using a standardised, piloted data extraction form. Key information to be extracted include study location, number of participants, baseline characteristics, population specific characteristics (i.e. hypertension or diabetes) and data on the above outcomes. Interventions will be reported using the Template for Intervention Description and Replication (TIDieR) framework. This will provide detail on the theory or rationale for the intervention, materials and procedures used, provider training or expertise, frequency, modality and location of intervention delivery, modifications made and finally, if intervention adherence or fidelity was assessed. The type of behaviour change techniques used in the intervention will be coded using the Behaviour Change Taxonomy.

Where insufficient detail is provided or where detail is ambiguous, authors will be contacted. Should a two week period pass with no reply, a second attempt will be made. Following this, articles will be reassessed for inclusion or exclusion.

Risk of bias (quality) assessment

The Cochrane risk of bias assessment tool will be used (Higgins et al., (2011). This includes 4 domains: random sequence generation; allocation concealment; blinding of outcome assessment; and incomplete outcome data. Studies will be judged to be at low, unclear or high risk of bias independently by one reviewer and checked by another. When discussing and interpreting the results, the impact of risk of bias will be considered.

Higgins, J.P.T., et al., The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ, 2011. 343: p. d5928.

Strategy for data synthesis

The characteristics of included studies will be tabulated with the behaviour change techniques utilised within each intervention and these will be discussed narratively. Studies will also be tabulated according to intervention intensity which will be based on pre-specified categories developed a priori.

If there are enough studies that can be pooled, a random effects meta-analysis will be performed for change in mean gestational weight, change in mean blood pressure and maternal and neonatal outcomes, only if the data are suitable to do so (Higgins et al., 2019). The interpretation of intervention effect will depend on the level of heterogeneity which is expected to be moderate to high, hence the chosen method of a random effects meta-analysis.

Higgins, J.P., et al., Cochrane handbook for systematic reviews of interventions. 2019: John Wiley & Sons.

Analysis of subgroups or subsets

To investigate heterogeneity of effects, subgroup analysis will be carried out for women in different BMI categories, type of intervention and intervention delivery, intervention intensity (based on pre-specified levels), chronic condition and type and number of behaviour change techniques used. Age, ethnicity and socio-economic group will also be analysed as subgroups should this information be available.

Sensitivity analysis will be performed to exclude studies at high risk of bias.

Contact details for further information

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Organisational affiliation of the review

Nuffield Department of Primary Care Health Sciences, University of Oxford

https://www.phc.ox.ac.uk/

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Dr Katherine Tucker. Nuffield Department of Primary Care Health Sciences, University of Oxford

Dr Nerys Astbury. Nuffield Department of Primary Care Health Sciences, University of Oxford

Professor Richard McManus. Nuffield Department of Primary Health Care Sciences, University of Oxford

Type and method of review

Intervention, Systematic review

Anticipated or actual start date

31 March 2021

Anticipated completion date [1 change]

01 August 2022

Funding sources/sponsors

LG is funded by the National Institute for Health Research (NIHR) Applied Research Collaboration (ARC) studentship. RP is funded by the NIHR. KT and RM have received funding from the NIHR ARC Oxford and Thames Valley. NA is funded by the NIHR Oxford Biomedical Research Centre (BRC)

Conflicts of interest

Richard McManus has received BP monitors for research use from Omron and is working with them to develop a telemonitoring system for use in primary care. He receives no personal payment for such work.

Yes

Language

English

Country

England

Stage of review [1 change]

Review Completed published

Details of final report/publication(s) or preprints if available [1 change]

Goddard L, Patel R, Astbury NM, Tucker K, McManus R. Evidence of lifestyle interventions in a pregnant population with chronic hypertension and/or pre-existing diabetes: A systematic review and narrative synthesis. Pregnancy Hypertension. 2022 Dec 24.

https://doi.org/10.1016/j.preghy.2022.12.004

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Behavior Therapy; Blood Pressure; Body Weight; Body Weight Maintenance; Cardiovascular Diseases; Diabetes Mellitus, Type 1; Diabetes Mellitus, Type 2; Disease Management; Female; Gestational Weight Gain; Healthy Lifestyle; Humans; Hypertension; Life Style; Maternal Health; Pregnancy; Prenatal Care; Risk; Risk Factors; Risk Reduction Behavior; Treatment Outcome

Date of registration in PROSPERO

30 March 2021

Date of first submission

26 March 2021

Stage of review at time of this submission [1 change]

Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	Yes
Risk of bias (quality) assessment	Yes	Yes
Data analysis	Yes	Yes

Revision note

Review completed and published.

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication

details in due course.

Versions

30 March 2021

14 July 2021

17 January 2023

Appendix 3 PRISMA 2020 Abstract Checklist

Section and Topic	Item #	Checklist item	Reported (Yes/No)
TITLE			
Title	1	Identify the report as a systematic review.	Yes
BACKGROUND			
Objectives	2	Provide an explicit statement of the main objective(s) or question(s) the review addresses.	Yes
METHODS			
Eligibility criteria	3	Specify the inclusion and exclusion criteria for the review.	Yes
Information sources	4	Specify the information sources (e.g. databases, registers) used to identify studies and the date when each was last searched.	Yes
Risk of bias	5	Specify the methods used to assess risk of bias in the included studies.	No
Synthesis of results	6	Specify the methods used to present and synthesise results.	Yes
RESULTS			
Included studies	7	Give the total number of included studies and participants and summarise relevant characteristics of studies.	Yes
Synthesis of results	8	Present results for main outcomes, preferably indicating the number of included studies and participants for each. If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (i.e. which group is favoured).	Yes
DISCUSSION			
Limitations of evidence	9	Provide a brief summary of the limitations of the evidence included in the review (e.g. study risk of bias, inconsistency and imprecision).	Yes
Interpretation	10	Provide a general interpretation of the results and important implications.	Yes
OTHER			
Funding	11	Specify the primary source of funding for the review.	Yes
Registration	12	Provide the register name and registration number.	Yes

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Appendix 4 PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Title "Evidence of lifestyle interventions in a pregnant population with chronic hypertension and/ or pre-existing diabetes: A systematic review and narrative synthesis. "
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	-
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Introduction
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Introduction
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Methods, study selection Methods, analysis
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Methods, literature search Supplementary table 1, Example search strategy (Medline)
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplementary table 1, Example search strategy (Medline)

Section and Topic	Item #	Checklist item	Location where item is reported
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Methods, study selection Methods, data extraction and quality assessment
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Methods, data extraction and quality assessment Methods, study selection
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Methods, outcomes
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Methods, data extraction and quality assessment
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Methods, data extraction and quality assessment
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	N/A
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Refer to SWiM checklist
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Refer to SWiM checklist
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Methods, analysis
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Refer to SWiM checklist
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A

Section and Topic	Item #	Checklist item	Location where item is reported
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Refer to SWiM checklist
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Results Figure 1, PRISMA flow diagram of the systematic search and selection of relevant studies
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	N/A
Study characteristics	17	Cite each included study and present its characteristics.	Results, study and participant characteristics Table 1, Overview of randomised controlled trials included in review
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Results, Risk of bias Table 2 Risk of bias in included studies Supplementary file 4 Risk of Bias in included studies and authors justification
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	See SWiM checklist
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	N/A
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A

Section and Topic	Item #	Checklist item	Location where item is reported
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	See SWiM checklist
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	See SWiM checkilst
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Discussion, comparison with literature
	23b	Discuss any limitations of the evidence included in the review.	Discussion
	23c	Discuss any limitations of the review processes used.	Discussion, Strengths and limitations
	23d	Discuss implications of the results for practice, policy, and future research.	Discussion, implications for future research
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Methods
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Methods
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Results
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Funding and Acknowledgements
Competing interests	26	Declare any competing interests of review authors.	Competing interests
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Availability of data

Appendix 5 SWIM Checklist

The citation for the Synthesis Without Meta-analysis explanation and elaboration article is: Campbell M, McKenzie JE, Sowden A, Katikireddi SV, Brennan SE, Ellis S, Hartmann-Boyce J, Ryan R, Shepperd S, Thomas J, Welch V, Thomson H. Synthesis without meta-analysis (SWiM) in systematic reviews: reporting guideline BMJ 2020;368:l6890

SWiM is intended to complement and be used as an extension to PRISMA			
SWiM reporting item	**Item description**	**Page in manuscript where item is reported**	**Other***
Methods			
1 Grouping studies for synthesis	1a) Provide a description of, and rationale for, the groups used in the synthesis (e.g., groupings of populations, interventions, outcomes, study design)	Methods, study selection Methods, analysis	
	1b) Detail and provide rationale for any changes made subsequent to the protocol in the groups used in the synthesis	N/A	
2 Describe the standardised metric and transformation methods used	Describe the standardised metric for each outcome. Explain why the metric(s) was chosen, and describe any methods used to transform the intervention effects, as reported in the study, to the standardised metric, citing any methodological guidance consulted	N/A	
3 Describe the synthesis methods	Describe and justify the methods used to synthesise the effects for each outcome when it was not possible to undertake a meta-analysis of effect estimates	Methods, analysis	

4 Criteria used to prioritise results for summary and synthesis	Where applicable, provide the criteria used, with supporting justification, to select the particular studies, or a particular study, for the main synthesis or to draw conclusions from the synthesis (e.g., based on study design, risk of bias assessments, directness in relation to the review question)	Methods, analysis	
SWiM reporting item	**Item description**	**Page in manuscript where item is reported**	**Other***
5 Investigation of heterogeneity in reported effects	State the method(s) used to examine heterogeneity in reported effects when it was not possible to undertake a meta-analysis of effect estimates and its extensions to investigate heterogeneity	Methods, analysis Table 30 Overview of randomised controlled trials included in review. Table 3 Intervention characteristics of included studies using TiDIER framework	
6 Certainty of evidence	Describe the methods used to assess certainty of the synthesis findings	N/A	
7 Data presentation methods	Describe the graphical and tabular methods used to present the effects (e.g., tables, forest plots, harvest plots). Specify key study characteristics (e.g., study design, risk of bias) used to order the studies, in the text and any tables or graphs, clearly referencing the studies included	Methods, analysis Table 31 Overview of randomised controlled trials included in review. Table 3 Intervention characteristics of	

		included studies using TiDIER framework	
Results			
8 Reporting results	For each comparison and outcome, provide a description of the synthesised findings, and the certainty of the findings. Describe the result in language that is consistent with the question the synthesis addresses, and indicate which studies contribute to the synthesis	Results	
Discussion			
9 Limitations of the synthesis	Report the limitations of the synthesis methods used and/or the groupings used in the synthesis, and how these affect the conclusions that can be drawn in relation to the original review question	Discussion, strengths and limitations	

PRISMA=Preferred Reporting Items for Systematic Reviews and Meta-Analyses.
*If the information is not provided in the systematic review, give details of where this information is available (e.g., protocol, other published papers (provide citation details), or website (provide the URL))

Appendix 6 Example search strategy

1	*Pregnancy/*
2	*Pregnant Women/*
3	*Pregnant wom*n.mp.*
4	*"pregnan*".m_titl.*
5	*"gestation*".m_titl.*
6	*maternal.m_titl.*
7	*prenatal.m_titl.*
8	*antenatal.m_titl.*
9	*pre-natal.m_titl.*
10	*ante-natal.m_titl.*
11	*4 or 5 or 6 or 7 or 8 or 9 or 10*
12	*1 or 2 or 3*
13	*exp Life Style/*
14	*Lifestyle.mp.*
15	*lifestyle intervention.mp.*
16	*life style intervention.mp.*
17	*lifestyle modification.mp.*
18	*life style modification.mp.*
19	*non-pharmaceutical.mp.*
20	*nonpharmaceutical.mp.*
21	*lifestyle program*.mp.*
22	*life style program*.mp.*
23	*lifestyle change.mp.*
24	*life style change.mp.*
25	*behavio* change.mp.*
26	*behavio* intervention.mp.*
27	*behavio* program*.mp.*
28	*health program*.mp.*
29	*exp Health Promotion/*
30	*health education/ or consumer health information/ or patient education as topic/*
31	*health counse?ling.mp.*
32	*patient education as topic/ or pamphlets/ or exp Video Recording/*
33	*((exercis* or physical activ*) adj3 (educat* or promot* or intervention?)).tw.*

34	*((educat* or promot*) adj3 (intervention? or program*)).tw.*
35	*(dvd? or video* or leaflet? or pamphlet? or ((written or educational or promotional) adj2 (information or material?))).tw.*
36	*behavior therapy/ or cognitive behavioral therapy/ or psychotherapy, brief/*
37	*counseling/ or directive counseling/ or motivational interviewing/ or distance counseling/*
38	*(((behav* or cognitiv*) adj2 (therap* or intervention? or program*)) or cbt).tw.*
39	*(counsel* or coach*).ti. or ((counsel* or coach* or mindfulness) adj2 (intervention? or program*)).tw.*
40	*motivat*.ti. or (motivation* adj2 (support* or interview* or intervention? or program*)).tw.*
41	*(brief adj2 intervention?).tw.*
42	*((selfdirect* or self direct* or selfmotivat* or self-motivat* or selfcare or self care) adj2 (intervention? or program*)).tw.*
43	*(home adj2 (exercis* or physical* activ*)).tw.*
44	*((remote or online or virtual or digital or electronic or internet or web* or computer based) adj2 (therap* or counsel* or intervention? or program*)).tw.*
45	*Remote Consultation/ or Telemedicine/*
46	*(telemed* or tele-med* or telehealth* or tele-health* or ehealth or e-health or mhealth or m-health).tw.*
47	*(smartphone* or mobile phone* or cell phone* or cellular phone* or tablet computer* or mobile app* or handheld device*).tw.*
48	*((web or internet) adj2 based).tw.*
49	*diet/ or diet, carbohydrate loading/ or diet, diabetic/ or diet, atherogenic/ or diet, carbohydrate-restricted/ or diet, cariogenic/ or diet, fat-restricted/ or diet, gluten-free/ or diet, high-fat/ or diet, high-protein/ or diet, high-protein low-carbohydrate/ or diet, mediterranean/ or diet, protein-restricted/ or diet, reducing/ or diet, sodium-restricted/ or dietary approaches to stop hypertension/ or diet, healthy/*
50	*((diet* or nutrition*) adj3 (educat* or promot* or intervention?)).tw.*
51	*nutrition therapy/ or diet therapy/ or caloric restriction/*
52	*exp Dietary Approaches To Stop Hypertension/*
53	*DASH diet.mp.*
54	*(health* adj2 (promot* or educat*)).mp.*
55	*exp Metabolic Syndrome/ or diabetes mellitus/ or exp diabetes mellitus, type 1/ or exp diabetes mellitus, type 2/*

56	*syndrome x.mp.*
57	**Metabolic Diseases/*
58	*hypertens*.mp.*
59	*55 or 56 or 57 or 58*
60	*11 or 12*
61	*randomized controlled trial.pt.*
62	*controlled clinical trial.pt.*
63	*randomized.ab.*
64	*clinical trials as topic.sh.*
65	*randomly.ab.*
66	*trial.ti.*
67	*61 or 62 or 63 or 64 or 65 or 66*
68	*exp animals/ not humans.sh.*
69	*67 not 68*
70	*13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54*
71	*59 and 60 and 69 and 70*

Appendix 7 Sources used for data extraction

Primary study	Additional sources
H. Al Wattar, B., et al. (2019). "Mediterranean-style diet in pregnant women with metabolic risk factors (ESTEEM): A pragmatic multicentre randomised trial." PLoS medicine 16(7): e1002857.	Al Wattar, B. H., et al. (2016). "Effect of simple, targeted diet in pregnant women with metabolic risk factors on maternal and fetal outcomes (ESTEEM): study protocol for a pragmatic multicentre randomised trial." BMJ Open **6**(10): 9.
	Al Wattar, B. H., et al. (2017). "Mediterranean diet based intervention in pregnancy to improve maternal and fetal outcomes: Methodological challenges and lessons learned from the multicentre ESTEEM study." Contemporary Clinical Trials Communications 6: 72-77.
Simmons, D., et al. (2017). "Effect of Physical Activity and/or Healthy Eating on GDM Risk: The DALI Lifestyle Study." Journal of Clinical Endocrinology & Metabolism 102(3): 903-913.	Jelsma, J.G., van Poppel, M.N., Galjaard, S. et al. DALI: Vitamin D and lifestyle intervention for gestational diabetes mellitus (GDM) prevention: an European multicentre, randomised trial – study protocol. BMC Pregnancy Childbirth 13, 142 (2013).
Dodd, J. M., et al. (2019). "A Randomised Trial to Optimise Gestational Weight Gain and Improve Maternal and Infant Health Outcomes through Antenatal Dietary, Lifestyle and Exercise Advice: The OPTIMISE Randomised Trial." Nutrients 11(12): 16.	Dodd, J. M., et al. (2018). "Optimising gestational weight gain and improving maternal and infant health outcomes through antenatal dietary, lifestyle and physical activity advice: the OPTIMISE randomised controlled trial protocol." BMJ Open 8(2): e019583.
Dodd, J. M., et al. (2014). "Antenatal lifestyle advice for women who are overweight or	Dodd, J. M., et al. (2011). "Limiting weight gain in overweight and obese women during pregnancy to improve

obese: LIMIT randomised trial." BMJ (Clinical research ed.) 348: g1285.	health outcomes: the LIMIT randomised controlled trial." BMC Pregnancy and Childbirth 11(1): 79.
Hedderson, M. M., et al. (2018). "A Tailored Letter Based on Electronic Health Record Data Improves Gestational Weight Gain Among Women With Gestational Diabetes Mellitus: The Gestational Diabetes' Effects on Moms (GEM) Cluster-Randomized Controlled Trial." Diabetes Care 41(7): 1370-1377.	N/A
Ney, D., et al. (1982). "Decreased insulin requirement and improved control of diabetes in pregnant women given a high-carbohydrate, high-fiber, low-fat diet." Diabetes Care 5(5): 529-533.	N/A
Nascimento, S. L., et al. (2011). "The effect of an antenatal physical exercise programme on maternal/perinatal outcomes and quality of life in overweight and obese pregnant women: a randomised clinical trial." Bjog-an International Journal of Obstetrics and Gynaecology 118(12): 1455-1463.	N/A
Luoto, R., et al. (2011). "Primary Prevention of Gestational Diabetes Mellitus and Large-for-Gestational-Age Newborns by Lifestyle Counseling: A Cluster-Randomized Controlled Trial." PLoS medicine 8(5): 11.	Luoto, R. M., et al. (2010). "Prevention of gestational diabetes: design of a cluster-randomized controlled trial and one-year follow-up." BMC Pregnancy Childbirth 10: 39.
McCarthy, E. A., et al. (2016). "Self-weighing and simple dietary advice for overweight and obese pregnant women to reduce obstetric complications without impact on quality of life: a randomised controlled trial." BJOG : an	N/A

international journal of obstetrics and gynaecology 123(6): 965-973.

Appendix 8 Risk of Bias in included studies and authors justification

RISK OF BIAS IN INCLUDED STUDIES AND AUTHORS JUSTIFICATION

	Selection Bias		**Detection bias**	**Attrition Bias**	**Reporting Bias**	**Other bias**	**Authors support for judgement**
	Random sequence generation	Allocation concealment from person randomising participants	Blinding of outcome assessment	Incomplete outcome data	Selective reporting		
Ney et al., (1982)	U	U	U	L	L	U Limited information given meaning some domains difficult to judge.	Patients were randomly assigned but no detail on how this was done or who this was performed by. No detail on how outcomes were collected. No drop outs and outcomes listed in methods are provided in results. Unclear information across domains.
Simmons et al., (2017)	L	L	L	L	L	L NI	Clearly explain randomisation process using a computerised random generator and sealed opaque envelopes which was communicated to participants via the coach. The staff assessing outcomes were unaware of treatment allocation and statistical analyses were blinded. Drop outs were well described by authors with

							drop outs per group <50% and between groups was <20%. Primary outcome for GWG was planned and reported.
Watter et al., (2019)	L	L	U	L	L	L NI	Randomisation process clear. Blinding of outcome assessors not clear. Total number lost to follow up <50% and the difference between groups was <20%. Primary endpoint was changed but this is clearly reported and explained by authors acknowledging potential bias's. All other outcomes planned were clearly reported.
Nascimento et al., (2011)	L	L	U	L	L	L NI	Randomisation process clearly described. Unclear if outcome assessors were blinded. Self-report bias. Loss to follow up described with <50% lost to follow up and difference between groups was not >20%. The outcomes listed in the methods were all reported.
Dodd et al., (2014)	L	L	L	L	L	L NI	Randomisation process clearly described. Outcome assessors blinded to treatment allocation. Loss to follow up clearly reported with overall drop outs <50% and difference between groups not >20%. All outcomes plans reported. Weight outcomes were included in a post hoc analysis.

Dodd et al., (2019)	L	L	L	L	L	L NI	Randomisation process clearly described. Outcome assessors blinded to treatment allocation. Loss to follow up clearly reported with overall drop outs <50% and difference between groups not >20%. All outcomes plans reported.
Hedderson et al., (2018)	L	L	L	L	L	L NI	Randomisation process clearly described by authors. Outcome data collected by a blinded assessor. Intervention a one off letter but outcome data collected for almost all participants, reasons for missing outcome data given. Outcomes planned reported in paper.
Luoto et al., (2011)	L	U	U	L	L	L NI	Unclear how allocation was applied to the municipalities and by whom. Self-report weight and physical activity increases detection bias and as the intervention group received much more contact time this could cause bias. Overall loss to follow up is <50% and difference between the groups in not >20%. Outcomes planned are reported or reported in seperate papers but this is documented by authors.

McCarthy et al., (2016)	L	L	L	L	L	U There was some cross-over with most women in the control group weighing themselves more than twice and more frequently that what is expected in usual antenatal care.	Randomisation process well described. Clearly describe who was blinded to outcome. Loss to follow up <50% and difference between groups <20%. 18.1% did not provide weight at 36 weeks gestation but instances of missing data were even across groups. All outcomes reported.

Abbreviations: L – Low; U = Unclear; H = High; NI None identified

Appendices: Chapter 3

Appendix 9 Manuscript Goddard et al., 2023

Goddard et al. BMC Pregnancy and Childbirth (2023) 23:164
https://doi.org/10.1186/s12884-023-05343-9

BMC Pregnancy and Childbirth

RESEARCH Open Access

Clinical guidelines for the management of weight during pregnancy: a qualitative evidence synthesis of practice recommendations across NHS Trusts in England

Lucy Goddard*, Nerys M. Astbury, Richard J. McManus, Katherine Tucker and Jennifer MacLellan

Abstract

Background Women who enter pregnancy with a Body Mass Index above 30 kg/m^2 face an increased risk of complications during pregnancy and birth. National and local practice recommendations in the UK exist to guide healthcare professionals in supporting women to manage their weight. Despite this, women report inconsistent and confusing advice and healthcare professionals report a lack of confidence and skill in providing evidence-based guidance. A qualitative evidence synthesis was conducted to examine how local clinical guidelines interpret national recommendations to deliver weight management care to people who are pregnant or in the postnatal period.

Methods A qualitative evidence synthesis of local NHS clinical practice guidelines in England was conducted. National Institute for Health and Care Excellence and Royal College of Obstetricians and Gynaecologists guidelines for weight management during pregnancy constructed the framework used for thematic synthesis. Data was interpreted within the embedded discourse of risk and the synthesis was informed by the Birth Territory Theory of Fahy and Parrat.

Results A representative sample of twenty-eight NHS Trusts provided guidelines that included weight management care recommendations. Local recommendations were largely reflective of national guidance. Consistent recommendations included obtaining a weight at booking and informing women of the risks associated with being obese during pregnancy. There was variation in the adoption of routine weighing practices and referral pathways were ambiguous. Three interpretive themes were constructed, exposing a disconnect between the risk dominated discourse evident in the local guidelines and the individualised, partnership approach emphasised in national level maternity policy.

Conclusions Local NHS weight management guidelines are rooted in a medical model rather than the model advocated in national maternity policy that promotes a partnership approach to care. This synthesis exposes the challenges faced by healthcare professionals and the experiences of pregnant women who are in receipt of weight management care. Future research should target the tools utilised by maternity care providers to achieve weight management care that harnesses a partnership approach empowering pregnant and postnatal people in their journey through motherhood.

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Keywords Qualitative evidence synthesis, Pregnancy, Weight management care recommendations, Clinical guidelines, Birth Territory Theory

Background

Less than half of women in the UK enter pregnancy with a Body Mass Index (BMI) below 30 kg/m^2 [1]. Risks associated with a raised BMI include gestational diabetes, pre-eclampsia, postpartum haemorrhage, prolonged labour, birth defects and fetal macrosomia [2, 3]. Although well documented within the literature, a lack of awareness of the risks of obesity in pregnancy and challenges surrounding losing weight preclude many women from weight loss attempts prior to conception [4, 5].

Maternity health care professionals indicate a lack of confidence, knowledge and skill as significant barriers to delivering effective and supportive weight management care [6]. As a result, women report inconsistent advice, confusion over the information they do receive and a lack of support from healthcare professionals despite wanting weight management advice [7–10]. This leads women to seek information from other sources, and can induce anxiety around weight gain [9, 11].

The UK National Institute for Health and Care Excellence (NICE) and Royal College of Obstetricians and Gynaecologists (RCOG) have produced guidelines for weight management before, during and after pregnancy [12, 13]. They provide recommendations for maternity practitioners in how to deliver safe care for women classified as obese (BMI $\geq$ 30 kg/m^2) at the start of pregnancy. Based on the best available research evidence and expert consensus, these national guidelines are interpreted by NHS Trusts in England to fit the local context, population, resources and infrastructure. They turn best practice recommendations into practical actions at the interface of maternity care delivery, supporting practitioners to support women and birthing people in optimum weight management.

The aim of this review was to analyse how local NHS clinical guidelines for weight management during pregnancy and the postnatal period interpret national guidance, synthesising findings to extend interpretation of observed variations between and within national and local guidelines.

Methods

Design

We performed a qualitative evidence synthesis of local NHS clinical practice guidelines using the framework analysis approach of Gale et al. (2013) and synthesis method of Thomas and Harden (2008) [14, 15]. Analytical rigour and transparency were ensured through careful documentation of the synthesis process described here.

Search method

We approached a purposive sample of NHS Trusts across England. A sample of at least 28 Trusts was selected pragmatically by the principle researcher (LG) aiming to ensure representation of Trusts from the seven NHS regions in order to provide adequate variation of the pre-specified attributes [16]. These attributes were considered to potentially influence the results and included rural/ urban setting, catchment population size, number of births per year and university/ teaching status. Guidelines were downloaded from their website or an application was made through a Freedom of Information process (email or online form) between 1st April and 1st June 2021. In the case of non-responders, a Trust within the same region of similar size and university status was contacted. Upon receipt of each guideline, the associated Trust was assigned a unique sequential code to ensure anonymity.

Quality appraisal

The purpose of this review was not to judge the quality of the existing guidelines but rather sought to present what is currently recommended and examine the content of the guideline. Therefore, no quality appraisal was performed.

Data abstraction

Narrative sections of the localised guidelines were extracted and entered verbatim into NVivo for coding (QSR International Pty Ltd. (2020) NVivo (released in March 2020)).

Synthesis

Narrative data were coded into a deductive framework of 18 pre-defined categories, constructed from the recommendations of the NICE Weight management in pregnancy guideline and the RCOG Care of Women with Obesity in Pregnancy guideline by the principle researcher (LG) [12, 13] (Table 1). Descriptive memos for each category supported consistency in coding. Each pre-defined category, and the coded text within it, was extracted and imported into Excel (Microsoft Excel 2016) to generate a matrix, enhancing visualisation for data comparison and interpretation. Cells were tagged with direct quotes or important interpretations,

Table 1 Framework based on pre-specific categories constructed from NICE and RCOG guidelines

NICE/ RCOG recommendation (category)	Description and instruction
Address any concerns about physical activity in pregnancy	NICE: "Advise that moderate-intensity physical activity will not harm her or her unborn child."
	This includes reassuring women about the safety of physical activity in pregnancy
Addressing a woman's concerns	NICE: Be "…sensitive to any concerns she may have about her weight."
	Any discussion on the sensitive manner in which conversations about weight should be had and the importance of communication between the woman and healthcare professionals
Advice on benefits of healthy diet and physical activity	NICE: "Advise that a healthy diet and being physically active will benefit both the woman and her unborn child during pregnancy and will also help her to achieve a healthy weight after giving birth."
	Discussions with the healthcare professional around healthy eating and being physically active that is not specific. Code as 'Specific dietary or physical activity advice' if specific advice is given
Behaviour change advice	"Evidence-based behaviour change advice includes: understanding the short, medium and longer-term consequences of women's health-related behaviour helping women to feel positive about the benefits of health-enhancing behaviours and changing their behaviours recognising how women's social contexts and relationships may affect their behaviour helping plan women's changes in terms of easy steps over time identifying and planning situations that might undermine the changes women are trying to make"
	Only code this if it does not fit into any other code. For example, if they are provided with individualised advice, code only as 'Practical and tailored information'. This is because this code describes the way in which advice (within the other codes) may be provided
Breastfeeding	NICE: "Midwives and other health professionals should encourage women to breastfeed. They should reassure them that a healthy diet and regular, moderate-intensity physical activity and gradual weight loss will not adversely affect the ability to breastfeed or the quantity or quality of breast milk."
	RCOG: "Obesity is associated with low breastfeeding initiation and maintenance rates. Women with a booking BMI 30 kg/m2 or greater should receive appropriate specialist advice and support."
Dieting or weight loss in pregnancy	NICE: "Dieting during pregnancy is not recommended as it may harm the health of the unborn child."
	RCOG: "Anti-obesity or weight loss drugs are not recommended for use in pregnancy."
	Any recommendation that refers to dietary programmes/ diets that promote weight loss
Discuss her current eating habits and physical activity levels	NICE: "At the earliest opportunity, for example, during a pregnant woman's first visit to a health professional, discuss her eating habits and how physically active she is. Find out if she has any concerns about diet and the amount of physical activity she does and try to address them."
Dispelling myths	NICE: "Dispel any myths about what and how much to eat during pregnancy. For example, advise that there is no need to 'eat for two' or to drink full-fat milk. Explain that energy needs do not change in the first 6 months of pregnancy and increase only slightly in the last 3 months (and then only by around 200 cal per day)."
Explaining risks	NICE: "Explain to women with a BMI of 30 or more at the booking appointment how this poses a risk, both to their health and the health of the unborn child. Explain that they should not try to reduce this risk by dieting while pregnant and that the risk will be managed by the health professionals caring for them during their pregnancy."
	Do not code if risks are only stated at the beginning of the guideline (as part of the introduction). It should be clear whether risks are discussed with the woman
Height and weight at the first contact	NICE: "Measure weight and height at the first contact with the pregnant woman" "Weight, height and BMI should be recorded in notes, the woman's hand-held record and the patient information system"
Not within NICE or RCOG recommendations	Anything that is related to weight management that is not referred to by NICE or RCOG guidelines

Table 1 (continued)

NICE/ RCOG recommendation (category)	Description and instruction
Practical and tailored information	NICE: "Offer practical and tailored information. This includes advice on how to use Healthy Start vouchers to increase the fruit and vegetable intake of those eligible for the Healthy Start scheme (women under 18 years and those who are receiving benefit payments)."
	Any guideline that indicates providing personalised or tailored advice based on the individual woman. If this is coded, check for code "Discuss her current eating habits and physical activity levels"
	If women are referred to a dietician or other programme it is likely they will receive personalised advice however for the purpose of examining the guideline only and therefore, first line of care, do not code if not explicitly described that advice is personalised or tailored
Recommended weight gain ranges	NICE: "Many pregnant women ask health professionals for advice on what constitutes appropriate weight gain during pregnancy. However, there are no evidence-based UK guidelines on recommended weight-gain ranges during pregnancy."
	RCOG: "There is a lack of consensus on optimal gestational weight gain. Until further evidence is available, a focus on a healthy diet may be more applicable than prescribed weight gain targets."
	Code if weight gain thresholds are given (and which ones, i.e. IOM) even if the lack of evidence on weight gain ranges is acknowledged
Referrals	NICE "Offer women with a BMI of 30 or more at the booking appointment a referral to a dietitian or appropriately trained health professional for assessment and personalised advice on healthy eating and how to be physically active."
	Does not include obstetric or anaesthetic referrals for risk assessment or birth planning. Only referrals relating to weight management
	Code even if guideline is not clear about who the referral is for or who/ where they are being referred
	Code if weight management programmes are highlighted, for example, Slimming World, even if there isn't a formal referral process described
Signposting to reputable sources of information	NICE "Reputable sources of information and advice about diet and physical activity for women before, during and after pregnancy include: The Department of Health's 'The pregnancy book' and 'Birth to five' and the NHS eat well website." "Advise her to seek information and advice on diet and activity from a reputable source"
	Code if women are provided with a Trust leaflet/ signposted to Trust website to access content on weight management during pregnancy but do not code if these resources only detail obstetric or anaesthetic risks
Specific dietary or physical activity advice	NICE: Specific dietary advice, e.g. eat fibre rich foods, eat at least 5 portions of fruit and vegetables each day, avoid increasing calorie intake. Specific physical activity advice e.g. 150 min of exercise per week
Weighing women	NICE: "Do not weigh women repeatedly during pregnancy as a matter of routine. Only weigh again if clinical management can be influenced or if nutrition is a concern"
	RCOG: "For women with obesity in pregnancy, consideration should be given to reweighing women during the third trimester to allow appropriate plans to be made for equipment and personnel required during labour and birth"
	Code if women are weighed throughout pregnancy with information on recommended gestations
	Code if recommendation is risk assessment weight in the third trimester as this is a weight that would influence clinical management. However, it is important to note, this is not for weight management purposes. For example, it is not for the purpose of starting a conversation with the woman about her diet and physical activity levels
Weight management postpartum	NICE: "Encourage them to lose weight after pregnancy."
	RCOG: "Women should be supported to lose weight postpartum and offered referral to weight management services where these are available."
	Code both those that recommend providing healthy lifestyle advice and those that signpost women to other healthcare professionals/ weight management services

in order to capture nuances and ambiguity between guidelines. This led to collapse and refinement of categories into broad descriptive themes. Reflexivity was practiced throughout the data synthesis, supported by discussions with the full research team. Interpretations were informed by risk discourse and the Birth territory

Theory, to synthesise the descriptive themes into three analytical themes that structure the presentation of our synthesis findings [17, 18].

Theoretical framework

Identification of a theoretical underpinning is vital in midwifery research to tackle and explore complex phenomena, such as weight management, as it ensures findings consider different perspectives; essential to improve care practices and thus, women's experiences [19]. Birth Territory Theory (BTT), chosen as the theoretical framework here, concerns the balance of power in the birth room and how maternity professionals can support and work in partnership with women [17, 18]. 'Midwifery guardianship', the theories key concept, exemplifies integrative power described as when the power between all present during care is equal and the shared, desired outcome is for the woman to feel confident and empowered. In contrast, disintegrative power disables the woman's confidence in her abilities to achieve a positive pregnancy and birth experience and can induce the woman to become passive in her own care. Disintegrative power, enacted through medical surveillance, draws closely on the concept of risk embedded in maternity services [20, 21].

The Birth Territory theory and the concepts within it, reflect the ambition of UK maternity policy to listen to, understand and work in partnership with each individual woman to ensure a positive pregnancy and birth experience whilst minimising poor outcomes. Thus, the BTT was appropriate to provide an in-depth interpretation of the synthesis findings in the context of current midwifery practice.

Results

A total of 29 hospital NHS Trusts were contacted and 28 guidelines received (Fig. 1, Additional file 1). Nine were classified as rural or remote, and 14 as University or teaching hospitals, with five classified as both rural or remote with University or teaching status. The number of hospitals within individual Trusts ranged from one to eight, with number of births for the year 2019–2020 ranging from 955 to 14,270 (Table 2) [22–24]. All the guidelines received classified women with obesity as having a BMI $\geq$ 30 kg/m^2, with the exception of one guideline (Guideline C) classifying women as obese with a BMI $\geq$ 35 kg/m^2, for the purpose of the guideline.

The synthesis of local clinical guideline interpretations of national guidance to deliver weight management care to people who are pregnant or in the postnatal period identified three core themes:

1. *Recommendations at odds with a partnership approach to care*
2. *Advocating surveillance – to what end?*
3. *Discretionary and ambiguous pathways*

Recommendations at odds with a partnership approach to care

Healthcare professionals are advised in national guidance to discuss weight in a sensitive manner and allow opportunities for a woman to raise the concerns she may have about her lifestyle and the ways to address these [12, 13]. The local guidelines reflected this in varying degrees in their weight management recommendations. Ten emphasised the importance of sensitive and respectful conversations around weight where the language used was an important contributor to achieve a good relationship with the woman that laid the foundation for an equalised partnership (Guideline H, I, L, M, S, X, Y, Z, AA, BB). Seven guidelines further emphasised the importance of this to empower women (Guideline S, Z, AA, BB, H, M), to encourage active engagement in care (Guideline AA, BB, H, M, Z), and to promote a positive pregnancy and birth experience (Guidelines L, H). Three guidelines highlighted the sensitive nature of conversations around weight stigma and the lower self-esteem that may be experienced by women of a higher weight (Guideline L, M and I). An awareness of weight stigma and lower self-esteem was not addressed in twenty-five guidelines. A clinical approach was advocated in five guidelines where additional mental health screening was recommended (Guideline J, N, P, X, Z). This reflects RCOG recommendations that as women with a BMI above 30 kg/m^2 are at an increased risk of mental health problems, they should be screened for these during pregnancy, without necessarily exploring the source of the mental distress [13].

Twenty-seven of the 28 guidelines recommended healthcare professionals discuss the risks associated with obesity during pregnancy with some recommending to explain "*the ways in which they [the risks] may be minimised*" or management strategies to reduce the risks (Guidelines A, C, D, E, F, L, Q, U, Z). Guidelines mostly provided a list of possible risks for healthcare professionals to discuss, with one guideline (Guideline N) advising a sticky label, listing the risks, be placed in the women's hand-held notes. 5/28 guidelines provided risk calculations alongside at least one complication (Guidelines M, O, V, X, Y). No guideline offered a risk assessment framework to help healthcare professionals frame risk, or guidance on how risks may be minimised. Guideline H recommended that women should be advised of the risks but be reassured that most women with a raised BMI have straightforward pregnancies and healthy babies.

Table 2 Characteristics of NHS Trusts in England who provided guidelines

Code allocated to NHS Trust	Number of births per year[a]	Rural or remote[b]	Teaching/ University status	No. main hospital sites within Trust	Name of guideline
B	955	Remote	No	1	Standard Operational Procedure for the Management of Pregnancy Women whose Body Mass Index is $\geq$ 30 kg/m^2
H	1295	Remote	No	1	Obesity in Pregnancy guideline
Y	1650	Remote	No	1	Guideline for the Management of obesity during pregnancy
AA	1925	No	No	1	Obesity in pregnancy birth and postnatal period
C	1960	Rural	No	1	Clinical guideline for the management of Obesity in Pregnancy
L	3775	No	Yes	1	Obesity in pregnancy, labour and puerperium
X	5840	No	No	1	The management of obesity in pregnancy
K	2580	No	Yes	2	Care of Pregnant Women with a Raised BMI $\geq$ 30 kg/m^2
Q	3440	No	Yes	2	BMI Management in Pregnancy
E	4065	No	No	2	Raised Body Mass Index in Pregnancy
O	4270	Rural	Yes	2	Obesity: Management of Pregnant Women with a Raised BMI at Initial Consultation
BB	5125	Rural	Yes	2	Assessing and managing extremes of BMI in pregnancy
F	1495	No	No	3	Obesity in Maternity Care Guideline
A	2825	Remote	Yes	3	Obesity in Pregnancy
G	3805	No	No	3	Management of Obesity in Pregnancy Guideline
S	4010	Rural	Yes	3	Increased Body Mass Index (BMI) in Pregnancy, Labour and Post Delivery Clinical Guideline
J	4955	No	No	3	Management of obese women in pregnancy
U	5585	No	No	3	Obese Pregnant Women
W	5910	No	No	3	Management of Women with Obesity in Pregnancy
M	6310	No	No	3	Obesity in pregnancy
N	9030	No	No	3	Care of women with obesity in pregnancy
R	5230	No	Yes	4	BMI: Optimal weight for pregnancy and childbirth. Guidelines for women with BMI > 30 kg/m^2
Z	14,270	No	Yes	4	Obesity in Pregnancy
T	8960	No	Yes	5	Obesity in Maternity
I	6007	No	Yes	6	Raised BMI during pregnancy
D	4820 4540 Figures from two merged Trusts	No	Yes	7	Obesity in Pregnancy
P	4420	Remote	Yes	8	Obesity guidelines
V	7640	No	Yes	1	Management of a pregnancy for women with a BMI > 30 kg/m^2
Total = 28	N/a	9 rural/ remote	14 University/ teaching hospitals	N/a	N/a

[a] SOURCE: NHS Digital 2019/20

[b] Rural is classed as the top 10% of Trusts with the highest proportion of patients living in rural areas in 2018/19, calculated from Hospital Episode Statistics. Remote is classed as those with 'unavoidable small hospitals' (SOURCE: Nuffield Trust)

This is unlike the general tone around risk observed in the majority of guidelines but paid attention to how risk information is translated by a woman who may already be feeling vulnerable. Conversely, it could cause confusion in why risk is discussed if most women experience no complications or alternatively, provide false reassurance regarding their potential for poorer outcomes [25].

Advocating a healthy lifestyle and the provision of practical advice on how to improve dietary intake and activity levels are recommended in national guidelines [12, 13]. Informing women of the benefits of adopting health behaviours during pregnancy was recommended in most local guidelines (26/28) but were limited in how they could work with women to achieve this. Seven guidelines offered brief recommendations on what a diet should consist of and recommendations for physical activity but overall information on how to translate this into the reality of women's lives was not evident (Guideline F, J, K, M, X, Y, Z).

According to national guidance, healthcare professionals should tailor weight management advice to the individual needs of birthing people, enlisting behaviour change knowledge and techniques to provide an individualised approach to care [12]. At a local level, three guidelines mirrored this more collaborative approach (Guideline E, F, G). They recommended healthcare professionals to initiate questions about the woman's own personal lifestyle, offering a woman an opportunity to frame their experience in a non-judgemental space; exemplifying midwifery guardianship. Three guidelines recommended addressing women's concerns around physical activity (Guideline F, I, M) or weight (Guideline F, M) but no guidelines made recommendations to address women's concerns specifically about her diet. Understanding the woman and providing an opportunity to listen to her concerns is central to ensuring equality in care. Guideline G described behavioural techniques such as goal setting to support women to makes changes and expressed that *"every contact with women during pregnancy…is an opportunity for tailored health promotion"*. Practical steps to identify barriers to behaviour change with women and make plans to overcome them were not clear in any guideline.

Twenty-two guidelines advised midwives to signpost women to reputable sources about healthy lifestyles during pregnancy. As stated in guidance, all women should be provided with accurate and *accessible* information but only one guideline explicitly identified leaflets that were provided in different languages (Guideline S). It was not evident in other guidelines that there was leaflet provision for those whose first language was not English. If supported with good communication, providing leaflets can be useful in providing women with information and tools to engage in healthy behaviours during pregnancy. However, if it is not reinforced with a conversation and incorporated into the woman's individual context, it risks being discarded [26].

Advocating surveillance – to what end?

National guidance recommends that an accurate height and weight should be obtained at the first antenatal contact and a further weight in the third trimester should be considered to plan for appropriate equipment and personnel for birth [12, 13]. Additional weight measurements should only be taken when *"clinical management can be influenced or if nutrition is of concern"*. All 28 guidelines recommended a baseline BMI to be calculated at the booking (27/28) or first scan (1/28) appointment. An initial weight measurement is part of the risk assessment to determine the appropriate clinical pathway for the woman and her pregnancy as women with a higher BMI have poorer outcomes and therefore should have increased surveillance [13]. The majority of guidelines (24/28) recommended further weight measurements with 13 aligning with national guidance to re-weigh for risk assessment purposes or if nutrition was a concern (Guidelines E, F, G, J, M, N, O, Q, V, W, Z, AA, BB). Eleven recommended healthcare professionals to monitor weight throughout pregnancy (Guideline K, R, H, I, L, P, S, T, U, X, Y). The purpose of re-weighing was clear in only two guidelines to support weight management (Guideline K and R). Women need clear and consistent messaging to feel encouraged and supported. Re-weighing with no given rationale can take away a woman's sense of control especially as the guidance on how to act on a weight measurement was not clear in any guideline. Monitoring weight throughout pregnancy strongly speaks to the idea that pregnancy is an opportunity for increased surveillance to bring the body back to the "norm" and to identify when further surveillance or intervention is needed in order to guarantee safety as defined by the medical system. Weighing women for the purpose of clinical management, such as for drug calculations, is an example of this and has an important role in ensuring the woman receives appropriate and safe care. However, weighing women with no rationale or no subsequent guidance could be interpreted as controlling the pregnancy but to no clear advantage to the woman or the healthcare professional. For some women, weighing can induce feelings of shame and guilt and this needs considering within the recommendation when there is no clear pathway following a measurement.

National guidance does not provide weight gain thresholds for pregnancy because it concludes that there is no evidence or a lack of consensus on optimal gestational weight gain [12, 13]. Whilst 15 guidelines acknowledged

this, eight guidelines recommended weight gain thresholds (Guideline I, M, Q, AA, J, R, X, Y). These were based either on the Institute of Medicine guidelines or on recommendations of which the source was unclear [27]. Current maternity care in the UK sits within a discourse of risk that perhaps explains the advocacy or attempts to adopt weight gain thresholds but we do not have the evidence in which to determine what a healthy gain looks like. This non-conclusive evidence results in recommendations lacking information about what to do should a woman fall above or below thresholds. This challenges the healthcare professional's ability to support the woman effectively, thus, putting at risk the trusting relationship.

Discretionary and ambiguous pathways

National guidance recommends a referral should be offered to women with a BMI of 30 kg/m^2 or above at booking and then again in the postnatal period [12, 13]. A dietician or appropriately trained healthcare professional can then perform an assessment and provide personalised advice on a healthy lifestyle. Referrals for additional weight management support were suggested (21/28) but clear eligibility criteria and how to initiate the referral were frequently missing or unclear. Table 3 displays a breakdown of the suggested places for referral. Referrals were sometimes at the healthcare professional's discretion to consider whether it was necessary and was dependent on resources or availability of services in the area. Referral pathways could have an important role in offering women an opportunity for more specialised or individualised care regarding her weight that may not be possible in routine appointments. Only Guideline R had a clear referral process where attendance at a specific workshop was requested via the midwife as early as possible. An additional referral was offered to women with a BMI above 25 to funded weight management services that included either one-to-one telephone support with a specialist midwife or support from a dietician via an App, depending on the area.

National guidance recommends that healthy lifestyle messages should be reinforced in the postnatal period and women should be advised to seek further support to manage weight or dietetic advice [12, 13]. This was recommended in 23 guidelines. Pregnancy is a life event for the woman and her family that continues beyond the remit of maternity service provision. The transition in services after birth is a tentative period as intervention, advice and information is often suspended or orientated toward the baby meaning women can feel a sudden loss of support and advice. Guideline I recommended that healthcare professionals write to the GP to consider measures to help with weight reduction. This transfer and sharing of information with the woman's GP could provide a useful support link when women no longer fall within the scope of maternity services. Clear referral pathways after birth are essential in upholding the important health messaging established during pregnancy that are fundamental in determining the potential course of subsequent pregnancies. Breastfeeding was advocated, specifically in relation to supporting weight management, in four guidelines. (Guideline A, D, G, R).

Discussion

Key findings

While local recommendations were largely reflective of national guidance, our synthesis has exposed a disconnect between the partnership approach emphasised in national maternity policy, and the risk dominated discourse of local practice recommendations for weight management during pregnancy. The most consistent recommendations were to obtain a weight measurement at booking, inform women of the benefits of a healthy lifestyle and of the risks associated with being obese during pregnancy. Specific, practical advice about how to achieve a healthy lifestyle was lacking, there was variation in the adoption of routine weighing practices and referral pathways were ambiguous.

The Birth Territory Theory challenges the focus on surveillance and risk observed in the majority of guideline recommendations. In contrast but in alignment with the BTT, few guidelines promoted or facilitated an individualised or partnership approach; a characteristic of midwifery guardianship that displays an awareness of

Table 3 Types of referrals suggested in the guidelines

Referral type	Number of Trusts	NHS Trust Code
Dietician/ dietetic service	15	B, E, F, H, I, K, L, N, Q, R, X, Y, Z, AA, BB
Weight management programme (unspecified)	3	G, A, AA
Weight management programme offered within the Trust[a]	8	D, F, K, L, M, O, Q, R,
Weight management programme offered in the community[b]	5	K, O, P, R, U

[a] Specified antenatal classes, workshops, specialist midwife follow-up or similar

[b] Community programmes including Slimming World ($n = 3$) or Weight Watchers ($n = 1$)

the sensitive and emotive nature of weight management conversations.

Existing literature

Healthcare professionals face significant personal and contextual barriers to having conversations about weight during pregnancy [28–30]. Barriers include a lack of knowledge, skill, confidence and a fear of stigmatising women who enter pregnancy with obesity. The focus on risk, absence of clear instruction on providing behaviour change advice, unclear pathways and omission of practical lifestyle advice on how to work with women to manage weight that was observed in the local guidelines offers explanation to why such barriers may exist. Weight management advice is often sought by women but insensitive counselling around weight and in particular, risk, and the medicalisation of these pregnancies can result in depersonalisation of care and feelings of shame and guilt [6, 8, 31]. Creating a non-judgemental space, where a woman feels safe to discuss her concerns with the healthcare professional is fundamental within conversations about weight that do not induce weight stigma. However, local guidelines appear to fail healthcare professionals in advocating midwifery guardianship.

Local clinical guidelines derive from a medical perspective in which healthcare professionals dictate the course of clinical management, intervention and treatment based on the best available evidence. However, weight management is complex and incorporates biological, psychological, environmental and social factors, and the guidelines examined often overlooked these factors and were orientated around risk and surveillance. Focus on risk disempowers women and elevates anxiety [26]. During risk conversations, women can feel judged for their weight that can affect her decisions during pregnancy and if complications arise, made to feel they are to blame [25]. Pregnant women understand risk in a context specific way dependent on their previous experiences and socio-cultural factors emphasising the importance of individual assessment and framing of risk around the woman's cultural and social context to support her sense making [32]. Women want constructive advice to follow new information about her risk and the omission of this detail creates challenges for healthcare professionals to ameliorate the anxieties created by risk counselling [33]. Clinical guidelines can support the complex interplay between scientific evidence, healthcare provider's expertise and the woman's preferences by considering how each recommendation and the evaluated outcome may support, or inhibit, personalised and sensitive conversations that would instigate a partnership approach to care [34].

Implications for research and practice

Reconceptualising weight management care to align with the partnership approach that enacts midwifery guardianship is warranted. Whilst we work in a medical system that utilises clinical guidelines to inform healthcare professionals, recommendations must consider how a woman's social, environmental and psychological context can be considered in order to reduce weight stigmatisation, increase her choice and empower her. To achieve the partnership approach that maternity care policy advocates, the manner in which weight conversations in pregnancy are had, the subsequent communication of practical, individualised advice as well as the dominant risk-focus of the guidelines must be re-examined.

Implementing evidence-based recommendations must be complemented by equipping healthcare professionals with specific training to increase skills, knowledge and confidence, frequently identified as barriers to providing supportive weight management care. This includes offering professionals support in communicating risk about weight in a way that the woman can make sense of considering her values, beliefs and preferences to dissipate feelings of anxiety or guilt. Co-designing clinical guidelines with women who have experienced pregnancy with obesity or excessive gestational weight gain could be fundamental in the design of tools we use to deliver weight management care.

Strengths and limitations

To our knowledge, this is the first study to use a theoretical framework to understand weight management guidelines that are used across different NHS Trusts in England. Adding to existing evidence surrounding weight management care provision during pregnancy, this study helpfully adds a new perspective that challenges current practices by highlighting the disconnect between the ambition of maternity policy and guideline recommendations. It has also provided some context for the barriers faced by healthcare professionals as well as the experiences of pregnant women; providing momentum for ongoing inspection of national and local clinical guidelines that may hinder progression towards supportive, collaborative weight management care that empowers women.

A purposive sample generated a well-represented national picture of guidelines from all seven NHS regions in England. Maternity units in Scotland, Wales and Northern Ireland were not included due to the differences in NHS or non-NHS healthcare structures, which would have made comparability with NICE and RCOG guidelines difficult. Therefore, a study comparing local guidelines beyond England may be warranted.

Using the NICE and RCOG guidelines as a deductive analysis framework was useful to ensure we explored all aspects of weight management care. However, we did not include associated guidelines in our framework such as 'Maternal and child nutrition' [PH11], 'Antenatal care' [NG201] or 'Postnatal care' [NG194] guidelines [35–37]. It is important to acknowledge that they may provide additional detail on the care women receive. However, the focus of this synthesis was weight management and therefore, to ensure the study had a clear focus on this, other guidelines were not used in the framework for analysis.

Conclusion

Our guideline synthesis has shown that locally interpreted weight management guidelines are rooted in a risk discourse, rather than a partnership approach that is advocated in maternity policy. This disconnect could explain the rifts in weight management care delivery that is evidenced in existing literature. Although some consistent recommendations existed and were reflective of national guidance, ambiguous care pathways and unclear recommendations prevailed that would hinder a healthcare professionals ability to translate these into practice. Future research should address the tools in which maternity healthcare providers use to provide weight management care and a revaluation of the system in which they work in order to achieve the ambition for all pregnant and postnatal people to receive sensitive, personalised and safe weight management care.

Abbreviations

BMI	Body Mass Index
NICE	National Institute for Health and Care Excellence
GWG	Gestational Weight Gain
RCOG	Royal College of Obstetricians and Gynaecologists
NHS	National Health Service
BTT	Birth Territory Theory
IOM	Institute of Medicine

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12884-023-05343-9.

Additional file 1: Figure 1. A map of NHS Trusts in England contacted for guidelines. Map created with ZeeMaps (www.zeemaps.com).

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Authors' contributions

LG, KT, NMA, RJM conceived and designed the study; LG collected the data and conducted the analysis, JM supported interpretation of data; LG and JM drafted the manuscript with input from NMA, KT and RJM. All authors have approved the submitted version and agree to be personally accountable for their own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

Authors' information

LG, the principle researcher, is a registered midwife currently undertaking a PhD. Regular discussions with JM, a qualitative researcher with a midwife/nurse background, and the wider research team were held during interrogation of the data where interpretations were derived from the perspective of healthcare professional and researcher.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Appendices: Chapter 4

Appendix 10 Online survey



DAPHNY: Diet and Activity for Pregnancy Hypertension (Version 1.0)

Welcome to the DAPHNY survey!

*If you have **long-term high blood pressure** (chronic hypertension) and you have experience of this during a **current** or **previous pregnancy**, we would love to hear from you!*

Chronic hypertension is defined as high blood pressure that is present before pregnancy or occurs before 20 weeks of pregnancy.

Women who have long-term high blood pressure (also known as chronic hypertension) are at increased risk of complications during pregnancy. Having a healthy diet and doing more physical activity can help people to keep their blood pressure within a healthy range. We would like your help to understand women's current knowledge and behaviours around lifestyle change in pregnancy.

The results of this survey will help us understand women's views which will inform the

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development of a lifestyle App that aims to support pregnant women with long-term high blood pressure.

If you would like to know more about the study, please email **daphny@phc.ox.ac.uk.**

The survey is anonymous and we will not be able to identify you. By taking part in the survey, you are agreeing for us to use your responses in our research.

To help us make sure we get responses from lots of different people, we will ask some questions about your background, you do not have to answer these. Your information is held and used in compliance with the Data Protection Act 2018.

The survey should take about 15 minutes to complete. Your participation is voluntary and you are free to withdraw at any point by closing the web browser. Your responses will be submitted when you click 'Finish' on the final page.

Thank you for your interest in the survey. Please click 'Next' and we will ask a couple of questions to check you can take part!

---

*If you need an interpreter or would like to access the survey in an alternative format, please email **daphny@phc.ox.ac.uk** or call **01865 XXXXX.***

A quick check to make sure you can take part

I confirm that I have long-term high blood pressure (chronic hypertension) and that I have current or past experience of this during pregnancy (within the last three years) *
Required

- Yes
- No

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A quick check to make sure you can take part

My high blood pressure was identified: * *Required*

- ○ When I was not pregnant
- ○ When I was pregnant before I was 20 weeks
- ○ After I was 20 weeks pregnant but it did not resolve after pregnancy
- ○ None of the above

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A quick check to make sure you can take part

I am happy to take part. * *Required*

- ○ Yes
- ○ No

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About you

To help us understand who responds to the survey, we will ask some questions about your background. We will not be able to identify you.

What is your age? * *Required*

- ○ <18 years old
- ○ 18 - 24 years old
- ○ 25 - 34 years old
- ○ 35 - 49 years old
- ○ >50 years old
- ○ I prefer not to say

Are you currently pregnant? * *Required*

- ○ Yes
- ○ No

What date is your baby due?

Dates need to be in the format 'DD/MM/YYYY', for example 27/03/1980.

(dd/mm/yyyy)

How many times have you been pregnant? * *Required*

- ○ 1 (this is my first pregnancy)

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- 2 or more

Please enter your weight (kilograms or stone and pounds) (If you do not know your weight or you would prefer not to say, please select 'Next') *Optional*

Please select unit used

- Kilograms (kg)
- Stone and pounds (st, lb)

Please enter your height (cm or feet and inches) (If you do not know your height or you would prefer not to say, please select 'Next') If you did not enter your weight, you do not need to answer this question. *Optional*

Please select unit used

- Centimeters (cm)
- Feet and inches (ft, in)

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Lifestyle

Do you know how lifestyle factors such as diet and physical activity affect blood pressure? * *Required*

- I know a lot
- I know quite a bit
- I know a little
- I don't know anything

Do you know what the DASH diet is? (DASH stands for Dietary Approaches to Stop Hypertension and outside of pregnancy has been shown to reduce blood pressure) * *Required*

- Yes, I know what the DASH diet is
- Yes, I've heard of the DASH diet but I don't know what it is
- No, I have never heard of the DASH diet
- I'm not sure

Do you know about the relationship between salt intake and blood pressure? * *Required*

- Yes
- No
- I'm not sure

When you were **first diagnosed** with high blood pressure, did a healthcare professional talk to you about a healthy lifestyle including diet and physical activity levels? *

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Required

- ○ Yes
- ○ No
- ○ I'm not sure

Did you make any lifestyle changes **because you were diagnosed with high blood pressure?** *Select all that apply.* ✱ *Required*

- ☐ I have not made any lifestyle changes
- ☐ I made healthier dietary choices
- ☐ I ate less salt
- ☐ I actively managed stress
- ☐ I did more exercise
- ☐ I managed my weight (i.e. lost weight or maintained current weight)
- ☐ I cut down on alcohol
- ☐ I drank less caffeine (tea or coffee)
- ☐ I drank less caffeine (cola, energy drinks or similar)
- ☐ I reduced or stopped smoking
- ☐ Something else that is not listed here

If you selected 'something else', please describe what this was.

You selected 'I made healthier dietary choices', please select from the options below any actions you took to support this.

- ☐ Reduced intake of confectionary items (sweets, chocolate, biscuits, cake)

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- [ ] Reduced intake of processed meats
- [ ] Reduced intake of sugary drinks
- [ ] Added less salt to meals
- [ ] Reduced intake of foods with a lot of salt
- [ ] Reduced intake of takeaway meals
- [ ] Ate out at restaurants less often
- [ ] Something else

Please describe.

During pregnancy, did a midwife or healthcare professional discuss **your** lifestyle with you including your diet and exercise levels? * *Required*

- ( ) Yes
- ( ) No

How many times and where did these discussions happen?

- ( ) At one antenatal appointment
- ( ) At more than one antenatal appointment
- ( ) At antenatal education classes
- ( ) At both antenatal class(es) and antenatal appointment(s)

Did you make any lifestyle changes **because you were pregnant**? *Select all that apply.* * *Required*

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- ☐ I did not make any lifestyle changes
- ☐ I made healthier dietary choices
- ☐ I ate less salt
- ☐ I actively managed stress
- ☐ I did more exercise
- ☐ I managed my weight (i.e. lost weight or maintained current weight)
- ☐ I cut down on alcohol
- ☐ I drank less caffeine (tea or coffee)
- ☐ I drank less caffeine (cola, energy drinks or similar)
- ☐ I reduced or stopped smoking
- ☐ Something else that is not listed here

If you selected 'something else', please describe what this was.

In relation to any options listed in question 15, was there anything that was particularly difficult or prevented you from making positive lifestyle choices? * *Required*

- ○ Not applicable (I did not make any changes)
- ○ Yes
- ○ No

Please describe.

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For the following, please state the degree to which you agree or disagree.

	✱ Required						
	Strongly disagree	Somewhat disagree	Disagree	Neither agree or disagree	Agree	Somewhat agree	Strongly agree
I lead a healthy lifestyle and there is nothing I would change	○	○	○	○	○	○	○
It is important to have a healthy lifestyle for my blood pressure	○	○	○	○	○	○	○
It was/ is important for my own long term health that I have a healthy lifestyle during pregnancy	○	○	○	○	○	○	○

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It was/ is important for my baby's health that I have a healthy lifestyle during pregnancy	○	○	○	○	○	○	○
I felt/ feel confident during pregnancy to make healthy lifestyle choices	○	○	○	○	○	○	○
I felt/ feel motivated during pregnancy to make healthy lifestyle choices	○	○	○	○	○	○	○

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Use of technology during pregnancy

Did you/ do you use pregnancy Apps which focus on a healthy lifestyle (diet and/ or exercise)? * *Required*

- ○ Daily
- ○ Almost everyday
- ○ Once a week
- ○ Less than once a week
- ○ I did not/ do not use pregnancy Apps

Please describe the features that you liked or enjoyed.

Please describe any features you disliked or would change

Do you currently use a smartwatch/ fitness watch/ activity tracker (e.g. Apple watch, FitBit)? By 'use', we mean beyond just using it as a clock where any feedback may inform the way you live. * *Required*

- ○ Yes
- ○ No

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How often do you take note of how many steps you do per day (either on your phone or on an activity tracking device)? * *Required*

- ○ Every day or most days
- ○ Occasionally
- ○ Not very often
- ○ Never

Is there any technology that would help you to have a healthy lifestyle during pregnancy?

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Weighing during pregnancy

How often have you been weighed/ were you weighed by a healthcare professional during pregnancy? * *Required*

- ○ Never
- ○ Once
- ○ Twice
- ○ 3 to 5 times
- ○ More than 5 times
- ○ I'm not sure

Has or did a healthcare professional discuss healthy weight gain during pregnancy with you? * *Required*

- ○ Yes
- ○ No
- ○ I'm not sure

Did you/ do you weigh yourself regularly during pregnancy? * *Required*

- ○ No, I did not/ I don't weigh myself
- ○ Daily
- ○ Weekly
- ○ Monthly
- ○ Less often

Did weighing yourself make you change your eating habits or physical activity levels?

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- ○ Yes
- ○ No
- ○ I'm not sure

Please state the extent to which you agree or disagree with the following statements.

** Required*

	Strongly disagree	Somewhat disagree	Disagree	Neither agree or disagree	Agree	Somewhat agree	Strongly agree
I would want to weigh myself throughout pregnancy	○	○	○	○	○	○	○
I would want to be weighed throughout pregnancy by a healthcare professional	○	○	○	○	○	○	○

Please use the space below if there anything else you would like to add relating to weighing during pregnancy.

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Additional questions

The following few questions will ask more about your lifestyle. These won't take long and we would really like to encourage you to complete these to help us have more of an understanding.

The survey responses will not be submitted until you press 'Finish' so please click through to the end of the survey to ensure you share your answers with us. Thank you.

During an average week, how often do you eat a serving of vegetables? One serving could be a portion of peas, salad, carrots, broccoli etc. (not potatoes)

- ○ Once a week or less/ never
- ○ Once a day
- ○ Two servings each day
- ○ More than two servings each day

During an average week, how often do you eat a serving of fruit? One serving could be an apple, banana, orange or a handful of grapes/berries.

- ○ Once a week or less/ never
- ○ Once a day
- ○ Two servings each day
- ○ More than two servings each day

During an average week when you are feeling well, how active are you? Physical activity is anything that's makes you breathe faster and feel warmer, e.g. brisk walking, running, swimming, an active job, football etc.

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	Inactive (less than 30 minutes of physical activity a week)	Moderately active (between 30 and 60 minutes of physical activity a week)	Active (between 60 and 150 minutes or more of physical activity a week)
During pregnancy	○	○	○
Outside of pregnancy	○	○	○

Do you feel you can spend money on buying healthy food?

- ○ Yes, this is not a problem for me
- ○ Sometimes this stops me being able to buy healthy food
- ○ No, I do not feel I can afford healthy food

Do you feel you can spend money on physical activity classes or exercise equipment?

- ○ Yes, this is not a problem for me
- ○ Sometimes this stops me being able to do more exercise
- ○ No, I do not feel I can afford exercise classes or equipment needed to carry out physical activity
- ○ N/A, I do not feel I need to spend money in order to do exercise

During pregnancy, did you/ do you self-monitor your own blood pressure at home?

- ○ I do not/ did not self-monitor my blood pressure at home
- ○ Daily
- ○ Weekly

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- Less often

Were you advised to do so by a healthcare professional or was this of your own accord?

- A healthcare professional advised me to self-monitor my blood pressure
- I decided to self-monitor my blood pressure
- I'm not sure

Outside of pregnancy, did you/ do you self-monitor your blood pressure at home?

- I do not/ did not self-monitor my blood pressure at home
- Daily
- Weekly
- Less often

Were you advised to do so by a healthcare professional or was this of your own accord?

- A healthcare professional advised me to self-monitor my blood pressure
- I decided to self-monitor my blood pressure
- I'm not sure

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Support during pregnancy

Where do you look for information about what you should eat during pregnancy and what exercise you should do? *Select all that apply.*

- ☐ My midwife/ obstetricians
- ☐ GP
- ☐ NHS website
- ☐ Friends/ family
- ☐ Pregnancy Apps
- ☐ Online
- ☐ Leaflets provided at hospital
- ☐ Other

Please describe.

Are you part of any online support groups for pregnant women with high blood pressure?

- ○ Yes
- ○ No

Please name.

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Do you see value in a support group for pregnant women with high blood pressure?

- ○ Yes
- ○ No
- ○ No opinion

What would support you to have a healthy lifestyle during pregnancy? Please be as specific as possible.

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You have almost completed the survey. We hope you can answer the remaining questions which will help us know who has responded to the survey. We will not be able to identify you.

Which of the following best describes your ethnic origin?

- White
- Mixed/ multiple ethnic groups
- Asian/ Asian British
- Black/ African/ Caribbean/ Black British
- Other ethnic group
- I prefer not to say

White

If you selected Other, please specify:

Mixed/ multiple ethnic group

If you selected Other, please specify:

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Asian/ Asian British

If you selected Other, please specify:

Black/ African/ Caribbean/ Black British

If you selected Other, please specify:

Other ethnic group

If you selected Other, please specify:

Which of the following best describes the highest level of education you have completed?

- No formal qualifications
- Vocational qualifications
- GSCE, O-level, or CSE

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- A-level or equivalent
- Professional qualifications
- First degree
- Post-graduate or above
- I prefer not to say

Have you been diagnosed or told by your doctor that you have any of the following?

- Type 1 diabetes
- Type 2 diabetes
- Gestational diabetes (Diabetes in pregnancy)
- I don't have any of these conditions

Is there anything else about yourself that you feel is relevant to this survey? Please explain, for example, any physical or technical difficulties completing the survey.

You have finished the survey! Please click 'Finish' to submit your responses.

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Thank you!

Thank you for completing the survey. We really appreciate your time.

Please share the survey with others who may have experience of long term high blood pressure during pregnancy.

If you would like to find out more about this work. Please visit our website: Link or contact our research team: daphny@phc.ox.ac.uk

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Key for selection options

38.a - White

English, Welsh, Scottish, Northern Irish or British
Irish
Gypsy or Irish Traveller
Other

38.b - Mixed/ multiple ethnic group

White and Black Carribean
White and Black African
White and Asian
Other

38.c - Asian/ Asian British

Indian
Pakistani
Bangladeshi
Chinese
Other

38.d - Black/ African/ Caribbean/ Black British

African
Caribbean
Other

38.e - Other ethnic group

Arab

Other

Appendices: Chapter 5

Appendix 11 DAPHNY Study protocol

Date and version No: 08.04.22 Version 1.0

Study Title: Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

Internal Reference Number / Short title: DAPHNY: Diet and Activity for Pregnancy Hypertension

Ethics Ref:

IRAS Project ID: 307929

Date and Version No: 08.04.22 Version 1.0

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Chief Investigator Signature:	The approved protocol should be signed by author(s) and/or person(s) authorised to sign the protocol

Please declare any/no potential conflicts of interest.

No conflicts of interest.

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Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, HRA (where required) unless authorised to do so.

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1. KEY STUDY CONTACTS

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Sponsor	University of Oxford
Funder(s)	NIHR ARC
Academic Advisor(s) or Supervisor(s)	Professor Richard McManus Dr Katherine Tucker Dr Nerys Asbury Dr Jennifer MacLellan

2. LAY SUMMARY

Background

It is important that pregnant women with long-term high blood pressure (chronic hypertension) are encouraged during pregnancy to adopt healthy eating patterns and have good physical activity levels. These healthy lifestyle behaviours have been shown to support appropriate weight gain during pregnancy and, in non-pregnant populations, have shown to help blood pressure control. Positive lifestyle behaviours thereby, have the potential to improve health outcomes for both the mother and baby.

Pregnant women with chronic hypertension may benefit the most from additional lifestyle support during the antenatal period. However, there are only a few digital lifestyle interventions that have been designed or tested to support this important population.

Aims

We will work with pregnant women who have experience of chronic hypertension during pregnancy and their antenatal healthcare providers to answer the following research question: What is the optimum digital lifestyle intervention for pregnant women with chronic hypertension?

Design and methods

Three workstreams will be performed including an online survey for women, focus groups with healthcare professionals, and interviews with women. We will gain valuable feedback from participants throughout each workstream to continuously modify and develop the digital intervention.

Patient and Public Involvement (PPI)

Two PPI groups have taken place with pregnant women, or recently pregnant women, who have chronic hypertension. We discussed women's thoughts and views on a digital lifestyle intervention. These discussions informed initial ideas, components and functions that will be explored during the development of the intervention. We will continue to engage with two named PPI representatives as the project progresses.

Dissemination

The research team will share the results of the work at conferences and with relevant charities, for example Action on Pre-eclampsia. The work will also be shared within maternity units and via online platforms including Twitter and Facebook groups which are accessed by women and healthcare professionals.

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3. SYNOPSIS

Study Title	**Optimising lifestyle behaviours during high risk pregnancies: mixed methods intervention development**
Internal ref. no. / short title	DAPHNY: Diet and Activity for Pregnancy Hypertension
Sponsor	University of Oxford
Funder	NIHR ARC studentship
Study Design, including methodology	Mixed methods study: Workstream 1: Online cross-sectional survey for women Workstream 2: Healthcare professional focus groups Workstream3: Early feasibility testing incorporating think-aloud interviews and individual interviews with women
Study Participants, including sampling strategy	Pregnant women (or those who have been recently pregnant) with chronic hypertension Healthcare professionals
Sample Size	Workstream 1: Online cross-sectional survey for women – at least around 100 responses Workstream 2: Healthcare professional focus groups - 15-20 participants across 4-5 groups Workstream 3: Early feasibility testing - 10-20 women for think-aloud interviews and a different 10-20 women during further feasibility testing and individual interview
Planned Study Period	01/04/2022 to 30/12/2024
Planned Recruitment period	April 2023 - December 2024
Aim/Research Questions/Objectives	
Primary aim	To work with pregnant women who have chronic hypertension and healthcare professionals to design and develop a digital lifestyle intervention to ensure its delivery, interface, content, and usability is maximally acceptable, feasible and accessible.
Overarching research question	What is the optimum digital lifestyle intervention for pregnant women with chronic hypertension?
Research questions	• What are the current health behaviours and barriers and facilitators towards lifestyle change in those who have chronic hypertension and been pregnant? • What are the key intervention features and components required to support women's overall understanding, use and engagement with the digital intervention? • What are the potential barriers and facilitators for women and healthcare professionals to support the use of the intervention?

	• What are the views and experiences of women who use and engage with the intervention and do they engage with it as intended?
Objectives	• To explore current knowledge, understanding, behaviours, as well as potential barriers and facilitators, towards making lifestyle changes in pregnancy. • To explore how a digital lifestyle intervention can be optimised for pregnant women with chronic hypertension. • To explore the healthcare professionals role in supporting a lifestyle intervention in pregnancy. • To explore the views and experiences of women who use the intervention. • To provide an indication of the Apps accessibility and acceptability to inform whether to proceed to a feasibility study. • To develop a theoretical framework that captures the processes and mechanisms that lead to positive health behaviour change.



4. ABBREVIATIONS

APEC	Action on Preeclampsia
CH	Chronic Hypertension
CI	Chief Investigator
COM-B model	Capability, Opportunity, Motivation and Behaviour model
CRF	Case Report Form
BCT	Behaviour Change Techniques
BCW	Behaviour Change Wheel
BP	Blood Pressure
DASH	Dietary Approaches to Stop Hypertension
DBP	Diastolic Blood Pressure
GWG	Gestational Weight Gain
mmHg	Millimetre mercury
MoSCoW	Must have, Should have, Could have, or Won't have
MRC	Medical Research Council
NICE	National Institute of Health and Clinical Excellence
SMBP	Self-monitoring of blood pressure
HCPs	Health Care Professionals
PBA	Person based approach
PPI	Patient and public involvement
RGEA	Research Governance, Ethics & Assurance Team, University of Oxford
HRA	Health Research Authority
ICF	Informed Consent Form
NHS	National Health Service
RES	Research Ethics Service
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
PIS	Participant Information Sheet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SBP	Systolic Blood Pressure

5. BACKGROUND AND RATIONALE

The population and problem to be addressed

Women who become pregnant and who are living with existing medical conditions face significant emotional and physical stresses throughout their journey to motherhood. Pregnancy presents a unique opportunity to re-engage and empower these women to establish positive health behaviours; enhancing their own health and the health of their offspring.

Chronic hypertension affects 3-5% of pregnancies, representing a small, but growing, proportion of women who need additional support and close antenatal surveillance [1, 2]. This is due to the increased risk of adverse maternal and neonatal outcomes that this group face [3]. Women with chronic conditions may approach pregnancy with different motivations for lifestyle change to those with conditions isolated to pregnancy such as gestational hypertension or pre-eclampsia. The later onset of these conditions in pregnancy and the likely urgency of pharmacological treatment and medical intervention may mean initiating lifestyle change may be less easily implemented in this population, at this point. Blood pressure management is of long-term importance to those with chronic hypertension and the motivation to maintain good blood pressure control and potentially reduce medication administration during pregnancy could provide a unique opportunity to promote healthy lifestyle behaviours.

The role of lifestyle interventions in hypertension

There is an established body of evidence supporting the role of diet and physical activity in blood pressure control where healthy lifestyle changes improve disease management and the quality of life in hypertensive populations [4, 5]. A large systematic review that included 105 trials and 6805 participants found statistically significant reductions in systolic blood pressure following improved dietary intake (-5.0mmHg; 95% CI: 3.1–7.0) and increased physical activity levels (-4.6mmHg; 95% CI: 2.0–7.1), where a decrease of at least 1-5mmHg is considered clinically relevant [5, 6]. In view of the



evidence, adults with hypertension are encouraged to adopt a healthy diet, an active lifestyle, among other health promoting lifestyle changes [7].

Hypertension management during pregnancy largely focuses on pharmaceutical treatment, often due to the acute nature of pregnancy where a sudden, rapid, and dangerous, rise in blood pressure may occur. Broad recommendations of care suggest that healthcare professionals should advise women with hypertension in pregnancy about weight management, exercise, healthy eating, and lowering salt intake [8]. Specific and practical guidance on the best ways in which to go about this is lacking. Numerous trials have tested the effect of lifestyle interventions delivered during the antenatal period on gestational weight gain (GWG) and maternal and neonatal outcomes. The effect on clinical outcomes remains to be determined but overall, interventions have resulted in a modest reduction in excessive gestational weight gain when compared to usual care, in the general pregnant population [9, 10]. The importance of appropriate GWG is important for all women regardless of BMI but especially important in those managing high blood pressure who are already at risk of adverse outcomes. Pregnant women with chronic hypertension are an important subgroup who may benefit the most from lifestyle modification, as observed outside of pregnancy, but to our knowledge, there has been minimal focus on designing high quality, effective and implementable lifestyle interventions for this group during pregnancy.

Why this intervention development work needed

Few lifestyle apps that are freely available for pregnant women to use are based on robust scientific evidence, they often lack the incorporation of behaviour change techniques and regulation of content as well as lacking screening for comorbidities [11-13]. A recent randomised controlled trial in Dublin, Ireland, examined the effect of a "Healthy Lifestyle Package" that included an education session and use of an App on the incidence on gestational diabetes [14, 15]. The App was designed for an obese pregnant population at risk of developing gestational diabetes and provided low glycaemic recipes and exercise tips. They found that women who received the intervention did not gain as much weight



and had improved diet and exercise behaviours but it did not affect the rate of women diagnosed with gestational diabetes. Knowledge can be gained from this study as they importantly incorporated behaviour change techniques in the design of the intervention, essential for understanding the mechanisms in which the intervention leads to behaviour change. Digital interventions, including mobile Apps, are increasingly available and used by pregnant women therefore it is essential these are developed, alongside the target population, to ensure they are used as intended, they are engaging, useful, safe and acceptable [16]. Robust research is needed to substantiate the use, worth and impact of lifestyle Apps during pregnancy whilst focusing on and working closely with important subgroups such as women living with chronic hypertension.

An innovative digital lifestyle intervention for women with chronic hypertension during pregnancy will be developed. The intervention, which will take the form of a Smartphone App, will focus on lifestyle behaviours such as dietary intake and physical activity and may involve self-monitoring of behaviours throughout pregnancy. The aim of the work is to design and develop an intervention with women and their healthcare professionals that supports and encourages long-term positive lifestyle change to improve obstetric and neonatal outcomes, with the potential to change the course of cardiovascular risk progression.

Brief description of study methods

The digital intervention will be developed and designed alongside the target population and their primary care givers to generate feedback that will enhance the usability and acceptability, and thereby overall effectiveness, of the intervention.

An online cross-sectional survey will be administered to capture current knowledge and experience of lifestyle change in and outside of pregnancy for women with hypertension. Focus groups with healthcare professionals will be conducted to explore views on the intervention, whether it would add to the existing care that is provided to these women and any potential barriers that need to be considered. Following this, early feasibility testing will be carried out. Firstly, think-aloud individual



interviews will be undertaken with women. Examples of potential components to include within the App and design ideas will be explored through these interviews. Then a different group of women will be invited to use a draft version of the App for a short period. Qualitative individual interviews will then be conducted to provide insight which will support further development of the App. It is hoped that the findings of the current study may lead to a definitive trial to determine if diet and lifestyle modification can improve outcomes for women with chronic hypertension in pregnancy

6. AIM / RESEARCH QUESTIONS / OBJECTIVES

Overarching aim
To work with pregnant women who have chronic hypertension and healthcare professionals to design and develop a digital lifestyle intervention to ensure its delivery, interface, content, and usability is maximally acceptable, feasible and accessible.
Research questions
Overarching research question: What is the optimum digital lifestyle intervention for pregnant women with chronic hypertension? • What are the current health behaviours and barriers and facilitators towards lifestyle change in those who have chronic hypertension and been pregnant? • What are the key intervention features and components required to support women's overall understanding, use and engagement with the digital intervention? • What are the potential barriers and facilitators for women and healthcare professionals to support the use of the intervention? • What are the views and experiences of women who use and engage with the intervention and do they engage with it as intended?
• To explore current knowledge, understanding, behaviours, as well as potential barriers and facilitators, towards making lifestyle changes in pregnancy. • To explore how a digital lifestyle intervention can be optimised for pregnant women with chronic hypertension. • To explore the healthcare professionals role in supporting a lifestyle intervention in pregnancy. • To explore the views and experiences of women who use the intervention. • To provide an indication of the Apps accessibility and acceptability to inform whether to proceed to a feasibility study. • To develop a theoretical framework that captures the processes and mechanisms that lead to positive health behaviour change.

7. STUDY DESIGN

7.1 Methodology and procedures

Theoretical framework

The UK Medical Research Council framework for developing and evaluating complex interventions promotes the application of theory to support intervention design [17]. This is essential in order to evaluate and identify key intervention components and the associated mechanisms that lead to behaviour change. Therefore, the current work will draw upon and consider theoretical perspectives in order to identify key behavioural constructs that will underscore each component of the App that lead to positive lifestyle behaviours during pregnancy.

The behaviour change wheel methodology will be considered to describe the behaviour system that is key to the lifestyle intervention [18, 19]. Drawing upon the behaviour change wheel is appropriate because of its incorporation of other theories and it is a commonly used process in developing health promoting interventions. At the core of the behaviour change wheel is the COM-B model which stands for Capability, Opportunity, Motivation and Behaviour. It is a framework for understanding behaviour where all three influence behaviour directly and indirectly. The taxonomy of behaviour change techniques can be mapped against this framework, and thereby each intervention component, to theorise causal mechanisms that lead to behaviour change [20]. This is essential to developing, refining and enhancing an intervention that has potential for wide-scale implementation.

A process of logic modelling will be used to systematically make connections between intervention activities, the key behavioural constructs and the desired behavioural and patient outcomes. An introductory logic model has been formulated to hypothesise how the intervention may work (Figure 1). As the intervention is developed, the logic model will evolve and the iterations will be informed by the findings of the studies.

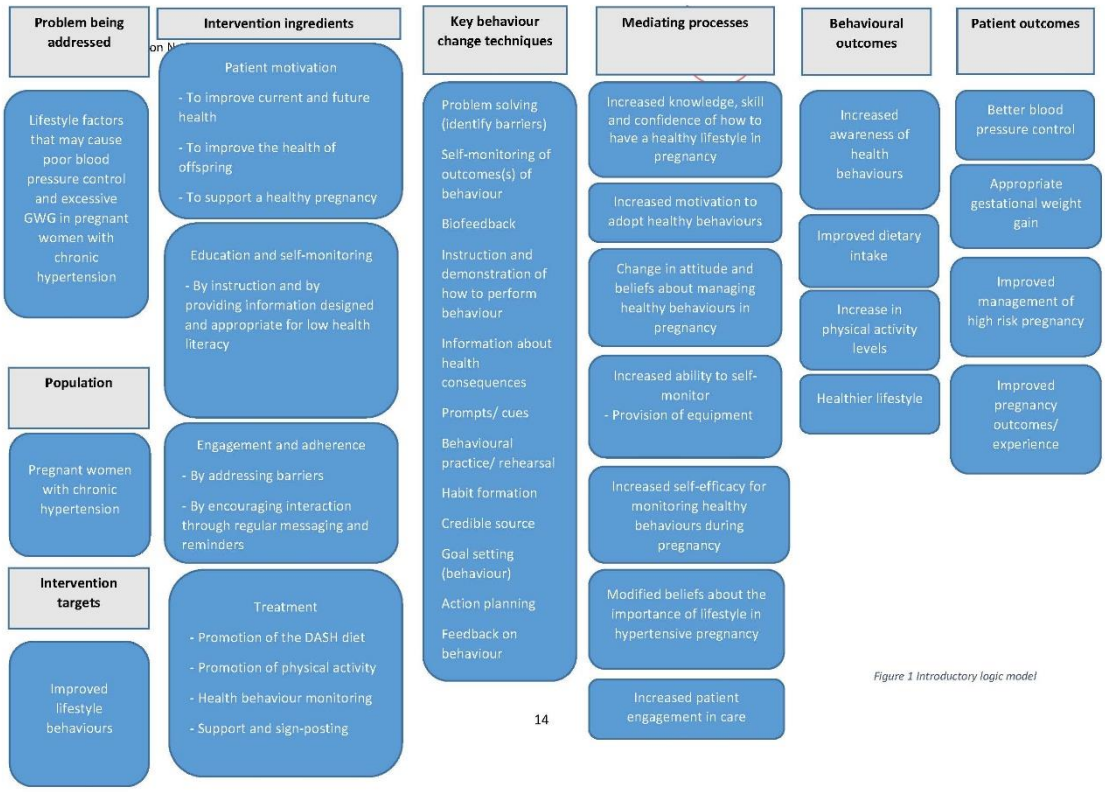

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Figure 1 Introductory logic model



Development of the initial intervention

Previous and ongoing work within the wider research group has involved the development of a blood pressure self-monitoring App for pregnant women, self-monitoring blood glucose for pregnant women at risk of or with diabetes and an App that is currently being tested to increase physical activity amongst women with gestational diabetes [21-23] (StayActive, unpublished). These similar interventions have incorporated user feedback to ensure a theoretical understanding of the mechanism of action of the intervention that result in behaviour change and to ensure user acceptability and satisfaction. Knowledge gained from this work and working with colleagues involved in this work, which includes experts in intervention development, engineering as well as healthcare professionals, will be essential in supporting the development of the lifestyle App.

Two PPI groups were held with women who have been diagnosed with chronic hypertension and were either recently delivered (within the last 12 months) or currently pregnant. They all had experience of using a mobile App to self-monitor blood pressure that was developed by the research team.

The group discussion explored their experiences and their thoughts relating to a lifestyle intervention to support blood pressure control. Overall, the women were keen to receive more dietary and physical activity advice during pregnancy. Most reported they had received little lifestyle advice when they were diagnosed with hypertension and also during pregnancy. Due to life-long medication prescription, many had disassociated their lifestyle habits with their blood pressure. The women indicated that having a platform that promoted positive health behaviours appropriate for pregnancy in conjunction with seeing trends in blood pressure measurements would highlight this important, but often overlooked, relationship. The group also discussed the ways in which lifestyle advice could be provided in a useful and engaging format as well as the potential barriers. Feedback from these PPI groups informed the initial ideas, components and functions to be explored during the development of the intervention. Two named PPI representatives will be invited to join team meetings and review study material to provide vital insight. The research team includes midwives, obstetricians and a GP who will provide perspectives from a healthcare professional point of view.

As there are no specific dietary or physical activity recommendations for a hypertensive pregnant population, evidence for the non-pregnant hypertensive population will be considered and adapted as appropriate when planning the core intervention features. In addition to this, NICE guidelines and trials that have been undertaken within pregnancy to support healthy lifestyles and gestational weight management will be consulted to inform key intervention components.

The main outcome for the development work is to 1) design, adapt and develop the intervention to ensure it is maximally acceptable and feasible and 2) elicit the views of high-risk pregnant women and their healthcare providers on a digital lifestyle intervention delivered during the antenatal period.

Study outline

The intervention and materials will be iteratively developed and refined throughout, using a mixed methodology. The methods adopted reflect the person-based approach; enhancing the acceptability and feasibility of an intervention prior to a full trial to increase its chances of success [24]. Three key workstreams will be undertaken for this study. This includes an online cross-sectional survey for women, focus groups with healthcare professionals and an early feasibility testing period with women involving individual interviews. Each workstream is described in detail below.

Online cross-sectional survey for women (Workstream 1)

An online cross-sectional survey will be promoted for eligible women to complete. The survey is a researcher developed survey that has been piloted with the DAPHNY study team and wider research team. The survey was also piloted with PPI representatives to test comprehensibility and acceptability. The online survey provides an opportunity to reach a wide and diverse population which may be a limitation of the other methods within the development work due to the nature of smaller sample sizes. The survey will capture the existing knowledge, understanding, views and experiences of lifestyle change and current health behaviours in the context of hypertension and pregnancy. The survey will not ask specific questions about the design of the intervention but capturing this information will support the theoretical understanding by identifying existing behaviours and potential influences, barriers and facilitators on these behaviours.

Study participants: We will aim for 375 responses with a minimum of 96 responses to have a 95% confidence interval and a 5-10% margin of error around the estimate of the proportion of women prepared to make a lifestyle change during pregnancy. This estimation is based on previous surveys concerning women's motivation and ability to change lifestyle behaviours during pregnancy [25, 26]. We will create a statistical analysis plan to look at differences between groups such as by BMI, age or parity. The inclusion and exclusion criteria are detailed in Table 1.

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Table 1 Inclusion and exclusion criteria for the Online survey for women (Workstream 1)

Inclusion	Exclusion
Women who have experience of having chronic hypertension during pregnancy (current or previous experience of this within the last 3 years).	N/A
≥18 years of age	

Sampling strategy and data collection methods: Women will be recruited through a variety of methods including some or all of the following, convenience, snowball or purposive. Response rate and response representation will be monitored throughout to inform sampling method.

Data will be collected through an online, survey platform. The survey tool is approved by the University's Information Security Team. Participants will be able to complete the survey on a mobile, tablet or computer/ laptop.

Recruitment: A poster will be displayed at participating maternity units and also on social media with a link or QR code for women to access and complete the survey. Women will be encouraged to share the survey with others. Online platforms such as Facebook, Twitter, a departmental newsletter and other channels such as relevant charity groups, e.g. APEC, will be contacted to promote the survey. Members of the research team and healthcare professionals at participating sites will signpost women to the survey. Attendance at local community antenatal/ postnatal clinics will be considered to encourage recruitment where necessary.

Screening and eligibility assessment: On entering the survey, participants will be provided with information about the study including the inclusion criteria. A tick box will confirm they have understood this information, are eligible and agree to take part.

Data analysis: Data from the survey platform will be exported to Excel. Analysis using STATA software with categorical data presented as frequency and percentages. Continuous data will be presented as mean (standard deviation) or median (interquartile range). Free text responses will be transferred to NVivo 12 software and a content and thematic analysis will be performed.

Healthcare Professional focus groups (Workstream2)

Focus groups will be carried out with healthcare professionals including midwives and obstetricians who have experience of delivering care to women with chronic hypertension. Focus groups are a

frequently used methodology within healthcare research as they can effectively address underlying issues in intervention delivery and implementation [27].

The group will be introduced to the intervention and provided with the background and rationale to the suggested intervention content and features. Potential intervention components will be shown to the group to stimulate discussion. Discussions will explore their views of the intervention such as any challenges in supporting women using the App and whether it is a useful and a beneficial addition to the care that is currently provided. The ways in which to overcome any potential barriers will be explored. We will explore whether there are any components or features of the App which they would prioritise, omit or add. These are important discussions as digital interventions have the potential to be embedded within existing care pathways and therefore they must be considered important and be supported by healthcare professionals who women view as credible sources of health information.

Individual interviews, instead of focus groups, will be considered based on staff availability.

Study participants: 15-20 participants across 4-5 focus groups. The inclusion and exclusion criteria are detailed in Table 2.

Table 2 Inclusion and exclusion criteria for Healthcare Professional focus groups (Workstream 2)

Inclusion	Exclusion
Healthcare professional who has experience of or is likely to care for pregnant women with hypertension	N/A
Participant is willing and able to give informed consent for participation in the study	

Sampling strategy and data collection methods: A purposive sample of healthcare professionals from participating maternity units will be recruited. Data will be collected either in-person or remotely and audio recordings will capture the discussions that are had.

Recruitment: We will work closely with the relevant site investigators who will facilitate access to staff teams. A poster displayed on staff noticeboards as well as an internal staff mail out through collaboration with site investigators will explain the study and provide the contact details of the researcher to promote participation. Interested staff can contact the study team directly who can provide the participant information sheet and consent form. Alternatively, members of the research team who work at the participating sites may approach staff to get their permission for the main researcher to contact them about the study and arrange a time to meet. Focus groups may take place online or in person at the study site. The sample of healthcare professionals will aim to include



healthcare professionals of different seniorities and experience. An enrolment questionnaire before each focus group will elicit this information.

Screening and eligibility assessment: No formal screening procedures will be required for the focus group as healthcare professionals will be self-selected.

Data analysis: Each focus group will be audio recorded and fully transcribed. NVivo software package will be used to organise and manage the dataset. An iterative approach to data analysis will take place so that changes are made as part of an ongoing process throughout intervention development. A quantitative content analysis of the transcriptions will identify any practical recommendations relating to the intervention and will ensure that feedback is considered and any modifications are explored through further focus groups [28, 29]. A thematic analysis will be undertaken to facilitate the theoretical understanding of the implementation of the intervention [30]. Data analysis has the potential to explore the way in which different professionals deliver information and the dynamic between the professional (midwife or obstetrician) and patient. Focus groups will take place until data saturation has been reached.

Early feasibility testing (Workstream 3)

Firstly, think-aloud individual interviews will be carried out with women. The participants will freely look at, and explore the mock up of the App. They will provide immediate feedback on the design, content and functions. This method will capture immediate reactions where the participant can verbalise their thoughts. Semi-structured questions will support the sharing of insight about their views of the components of the intervention, content, format, frequency of messaging and prompts and anything that is not clear or could be improved.

Participants will provide feedback and necessary, realistic and workable changes will be made throughout to improve the intervention. Comments and suggested changes will be assigned a priority using the MoSCoW technique which stands for Must have, Should have, Could have, or Won't have [31]. Each draft mock up of the intervention will be discussed with up to around 5 different women to allow general consensus on any modifications of the App before agreeing changes. Up to around 20 women will be interviewed or until no significant new feedback is emerging [32]. It is anticipated that there will be around three rounds of think-aloud interviews but this will depend on the feedback received.

Following think-aloud interviews, participants will be invited to use a draft version of the App, within a 6 week period. Through interaction with the App, participants may make lifestyle changes meaning this part of the development work will generate a deeper understanding of the acceptability and

feasibility, highlighting any practical issues, relating to use of the intervention. After the period of use, participants will take part in an individual semi-structured interview to elicit detailed feedback. Their overall experience of using the draft App will be explored including likes and dislikes, any barriers to making the recommended lifestyle changes and how these may be overcome. Non-engagement with any component of the App will be explored if possible. App data will quantify user engagement including when and for how long women engage with different parts of the App and if relevant how many times self-monitoring data was inputted. This information may provide data that could support the design of a future feasibility study.

Study participants: Around 10 to 20 women will be recruited for the think-aloud interviews. This number is based on previous think-aloud studies performed by the research team [21, 32].

A different group of around 10-20 women will be invited to use the draft App and then they will take part in an individual interview. This is based on previous work that aimed to develop a digital intervention for the management of hypertension [32].

The inclusion and exclusion criteria are detailed in Table 3.

Table 3 Inclusion and exclusion criteria for early feasibility testing (Workstream 3)

Inclusion	**Exclusion**
Think-aloud interviews:	
1. Participant is willing and able to give informed consent for participation in the study.	
2. ≥18 years of age	
3. Pregnant women diagnosed with chronic hypertension.	
4. A woman who has been pregnant within the last 12 months who has chronic hypertension.	
Qualitative individual interviews following intervention testing period:	
1. 1-3 above	
2. Own and use a smartphone that is compatible with the App	

Sampling strategy and data collection methods: Purposive sampling will take place to encourage diversity within the sample to ensure the views and experiences of different women are explored.

For the think-aloud interviews, data will be collected via observation and interview. Data will be recorded via field notes and audio recordings.



For the individual interviews after the intervention testing period, data will be collected via the draft App and audio-recorded interviews. Usage data will be accessed and collected.

Recruitment: Women will be purposively sampled and we will seek to obtain a diverse sample in terms of parity, gestation, ethnicity, age, experience of self-monitoring and attitudes to technology. An enrolment questionnaire and discussion during the interviews will elicit this information. Women will be recruited in person or remotely from participating maternity units.

Screening and eligibility assessment:

Only women who are aware that they may be approached about participating in research studies will be screened for eligibility. A professional with the appropriate legal basis for approaching women for example a research midwife or member of the usual care team will screen the medical records where necessary to identify eligible women. We will work closely with site investigators to help identify and approach eligible women. The research midwife or staff member may ask women for permission for the main researcher to contact them about the study. Participant information sheets, consent forms and study materials will be provided if the woman is interested in participating and arrangements will be made for enrolment. Recruitment posters detailing the contact details of the study team will be used at all sites. The interviews will take place remotely or in person.

Data analysis: All interviews will be audio-recorded and fully transcribed and the data transferred to NVivo for analysis. All transcriptions will be anonymised (identifiable data removed) and participant transcripts will be given a study identification number to allow discussion between team members.

The think-aloud studies will be analysed using an iterative approach. A quantitative content analysis will be conducted to identify practical recommendation and a thematic analysis will be performed to support the theoretical understanding of the intervention. The researcher will work through each transcript and tabulate suggested changes according to the MoSCoW technique described previously. All positive perspectives and barriers will be tabulated. Solutions will be discussed within the research team and recorded and, where appropriate, modifications to the App will be made. Each version of the App will be tested with up to around 5 women. This iterative process will continue with up to around 20 women or until no significant new changes are being suggested.

The individual interviews with women following a short period of use will be analysed using content and thematic analysis. Themes will be mapped against the theoretical frameworks which will ensure key behaviour change techniques and constructs involved are considered and identified.

To ensure internal reliability, themes identified will be discussed with the research team including PPI representatives to ensure all perspectives on the findings are considered.

App usage data, which will be quantifiable upon completion of the study, includes how many times the women accessed the App, how long women accessed the App (and each section), and if relevant, how often self-monitoring data were inputted. These will be analysed using STATA software.

8. ADDITIONAL STUDY ACTIVITIES

8.1 Informed consent

Online cross-sectional survey for women (Workstream 1)

Implied consent is adequate as this a low risk online survey with no collection of personal data that will make a person identifiable. The survey will begin with written information about the research to adequately inform potential respondents of the reasons for the survey. It will clearly state that the survey responses are anonymous and that they may withdraw, by closing the web browser at any time. There will be a tick box confirming that they meet the inclusion criteria and agree to take part. Contact details of the research team will be clear so that interested participants may contact the team with any questions.

Healthcare professional focus groups and early feasibility testing (Workstream 2 and 3)

Before commencement of any study activity informed consent will be obtained.

The consent process will either be

a) For participants who are recruited in person and/ or where focus groups/ interviews are conducted in person – Potential participants will be provided with the participant information sheet and informed consent form. This will provide information on the nature of the study; what it will involve for the participant (including audio recordings); the implications and constraints of the protocol; any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal. The participant will be allowed time to consider the information, and the opportunity to question a member of the research team to decide whether they will participate in the study. Consent will be obtained at the time of recruitment or at the focus group or interview. A written informed consent will be obtained by means of participant dated signature and dated signature of the person who presented and obtained consent.

b) For participants who are recruited remotely and/ or where focus groups/ interviews are conducted remotely – Potential participants will be provided with the participant information sheet and informed consent form. This will provide information on the nature of the study; what it will involve for the participant (including audio recordings); the implications and constraints of the protocol; any risks



involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal. The participant will be allowed time to consider the information and a contact number/ email will be provided if they wish to discuss the study and ask questions. If they were recruited in person but consent was not obtained, they will be asked to return this via email or via a member of the study team or usual care team. Alternatively, or if they were recruited remotely, a verbal consent process will take place prior to the commencement of the focus group or interview.

In all cases, a copy of the signed informed consent form will be provided to the participant and the original will be retained at the University of Oxford.

8.2 Subsequent visits

Participating women will be required to participate in one study "visit" which may be in person or remote. Participating women in workstream 3 who will be using the draft App, will be required to attend an additional study "visit" which may be in person or remote. This is so that the study team can set up the draft App on the participants phone. Alternatively, and where appropriate, this will take place at the point of consent.

8.3 Discontinuation/ withdrawal of participants from study

Each participant has the right to withdraw from the study at any time without penalty or prejudice. Upon withdrawal, participants will be asked whether their data may be retained. If they choose to withdraw entirely, the data from that participant will be excluded from the analysis and audio recordings and associated transcripts will be deleted where possible. It may not be possible to completely exclude all material from a focus group where an individual's data might impinge on or be directly related to that of other participants. The reason for withdrawal by researcher will be recorded in a study file if this information is volunteered.

8.4 Definition of End of Study

The end of study is the point at which all the study data has been entered and queries resolved.

9. DATA MANAGEMENT

9.1 Access to Data

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.



9.2 Data Recording and Record Keeping

The survey tool is approved by the University's Information Security team. The survey tool is only accessible through a password protected log in accessible only by the research team. The survey data will be exported to NVivo and Excel where data will be stored safely and securely in a file on University password protected computers.

All interviews and focus groups will be audio recorded and transferred to a secure University server. They will be transcribed onto electronic forms by a member of the research team or transcribers who are approved by the University of Oxford who are fully compliant with GDPR. Identifiable information will be removed and replaced with a study code as soon as it is possible to do so. Once the transcription has been checked by the research team, audio recordings will then be deleted from the secure server. Transcripts, with the study code, will be kept for 3 years after the study has ended. NVivo software package will be used to organise the data. Underlying data will be stored in password protected files with strong participant identifiers kept separately from the rest of the data.

Data that is collected in order to set up participants on the App, such as phone numbers, will be stored securely on University servers behind NHS firewalls and owned by the University of Oxford. Identifiable information will be removed and replaced with a study code as soon as it is possible to do so. This information will be stored for 3 years after the end of the study.

Participants who consent to being approached about future research studies will made aware that their contact details will be held on secure University, password protected computers. Consent forms for these participants will be kept separately until the time comes when their details are removed from this register.

10. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, relevant regulations and standard operating procedures.

11. ETHICAL AND REGULATORY CONSIDERATIONS

The studies are unlikely to cause any significant harm to participants. Discussing healthy lifestyles can be an emotive topic in pregnancy. The CI is a registered midwife and will ensure appropriate training in undertaken to address any concerns if raised by the women and these will be escalated as necessary. Interviews and focus groups will be terminated early if a participant wishes for this.

Concerns will be immediately raised with the lead supervisor (and GP), Professor Richard McManus and discussed with the relevant site contact, when appropriate. Confidentiality will be maintained were possible and consent forms will clearly state this to participants.

11.1 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

11.2 Approvals

Following Sponsor approval the protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and HRA (where required) and host institutions for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

11.3 Other Ethical Considerations

During the intervention testing period, participants may actively change lifestyle behaviours. It is possible that monitoring health behaviours may increase anxiety and reduce quality of life in participants but previous work has found this is not consistently the case [33-35]. Women with high risk pregnancies may have heightened sensitivities during pregnancy. As the intervention material and content will have been designed and developed alongside the target population, every effort will have been made to ensure materials are reasonable, acceptable and respectful.

The dietary component of the intervention may be informed by the DASH diet which stands for Dietary Approaches to Stop Hypertension. If followed formally, this diet would require calculations for required calorie intake and recommendations for portion sizes. This will not be performed, only the principles of the diet will be promoted such as an emphasis on increased fruit and vegetable intake, reduced intake of processed foods and reduced salt intake. There has been minimal testing of the DASH diet during pregnancy but the existing observational evidence and small trials conducted in pregnant populations have not identified any serious adverse events or concerns caused by the diet [36-39]. The DASH dietary information will be modified to account for the nutritional requirements and considerations needed during pregnancy.

All participants will receive usual antenatal care from their midwife and obstetrician. It will be made clear to women that they should contact their healthcare professional if they have any pregnancy related concerns.



If any of the research team observe, or are told about any practice that is concerning, this would be raised immediately with the CI's supervisor (and GP) Professor Richard McManus. If the information is considered to be concerning, then this would be addressed by contacting a relevant contact (Principal Investigator) at the relevant Trust and discussing it with them. In the unlikely event of situations that may be of a more serious nature, then the relevant authorities would be notified, e.g. the GMC, police or social services. The consent forms will make it clear to participants that while the researchers will maintain their duty of research confidentiality to participants as far as possible, that if very poor care or abuse is identified then the researchers will report this.

11.4 Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

11.5 Participant Confidentiality

The study will comply with the UK General Data Protection Regulation (UK GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number (or pseudonym) only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

Participants will be assured that all discussions during the focus groups and interviews will be kept entirely confidential. A group agreement within the focus group to maintain confidentiality between the professionals present will be made clear at the start of the session.

Publication of direct quotes may be included in project outputs. All identifying information will be removed to protect their identity.

11.6 Expenses and Benefits

Women participating in workstream 3 will receive an online shopping voucher worth £10 as compensation for their time.

12. FUNDING AND INSURANCE

12.1 Funding

The study is funded by the NIHR ARC studentship which expires September 2023.

12.2 Insurance

The University of Oxford maintains Public Liability and Professional Liability insurance which will operate in this respect.

12.3 Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

13. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the NIHR ARC studentship. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

14. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the trial.

15. ARCHIVING

Study data will be held securely at the University of Oxford for 3 years after the end of the study and then will be destroyed.



16. REFERENCES

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17. APPENDIX A: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

List details of all protocol amendments here whenever a new version of the protocol is produced. This is not necessary prior to initial REC / HRA submission.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee and HRA (where required).

Appendix 12 Sponsor approval

RESEARCH SERVICES
UNIVERSITY OF OXFORD

Research Governance, Ethics & Assurance
Boundary Brook House
Churchill Drive
Headington, Oxford
Oxon
OX3 7GB

To whom it may concern

Date: 11/04/2022

Title: Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

PID: 16076

Protocol Date 8th April 2022/Version:1.0

The above study has been designed by Miss Lucy Goddard and colleagues at the University of Oxford and funded by the National Institute for Health Research (NIHR). I confirm that the University will accept the role of Research Sponsor of this Study and will comply with the requirements of the UK Policy Framework for Health and Social Care Research October 2017.

Insurance-provided indemnity arrangements are in place for the project with Newline Underwriting Management Ltd., at Lloyd's of London.

Sponsorship is confirmed subject to the condition that the following are sent to Research Governance, Ethics & Assurance for review prior to submission to the Research Ethics Committee. Failure to do so may compromise insurance cover for the project.

- Any minor or substantial amendments
- Any extension to the study end date
- Addition of any new research site or patient identification centre

In addition, annual progress reports, the end of study notification and final report must be copied to Research Governance, Ethics & Assurance.

Lastly, where they exist, University Core SOPs must be followed by default for all clinical research sponsored by the University. Further information can be found here: https://researchsupport.admin.ox.ac.uk/ctrg/resources

Any communications relating to Research Sponsorship should be directed to the undersigned.

Yours faithfully

DocuSigned by:
1D780994FD3944A...

Nigel Wellman

Tel: +44 (0)1865 616480, Email: https://researchsupport.admin.ox.ac.uk/contacts/rgea#/

Appendix 13 NHS HRA/ REC approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Wales Research Ethics Committee 5
Bangor

Mailing address:
Health and Care Research Wales
Castlebridge 4
15-19 Cowbridge Road East
Cardiff, CF11 9AB

email:Wales.REC5@wales.nhs.uk
website: www.hra.nhs.uk

17 May 2022

Miss Lucy Goddard
PhD student
University of Oxford
Radcliffe Primary Care Building, Radcliffe Observatory Quarter, Woodstock Road, Oxford OX2 6GG

Dear Miss Goddard

Study title:	**Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention developmentDAPHNY - Diet and Activity for Pregnancy Hypertension**
REC reference:	**22/WA/0130**
Protocol number:	**N/A**
IRAS project ID:	**307929**

Thank you for your letter of 16 May 2022, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved on behalf of the PR sub-committee.

Confirmation of ethical opinion

On behalf of the Research Ethics Committee (REC), I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants

4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Social media post]		
Copies of materials calling attention of potential participants to the research [Internal email]		
Copies of materials calling attention of potential participants to the research [Posters]	1	08 April 2022
Covering letter on headed paper		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance policy]		
Initial Assessment for REC		
Interview schedules or topic guides for participants [TG WS3]	1	08 April 2022
Interview schedules or topic guides for participants [TG WS2]	1	08 April 2022
Interview schedules or topic guides for participants [TG WS3]	1	08 April 2022
IRAS Application Form [IRAS_Form_19042022]		19 April 2022
Letter from funder [Funder letter]		03 January 2022
Letter from sponsor [Sponsor letter]		11 April 2022

Non-validated questionnaire [Enrolment questionnaire WS3]	1	08 April 2022
Non-validated questionnaire [Online survey]	1	08 April 2022
Non-validated questionnaire [Enrolment questionnaire WS2]	1	08 April 2022
Other [DAPHNY_Provisional opinion]	1	13 May 2022
Participant consent form [Consent form F2F]	1	08 April 2022
Participant consent form [Consent form Remote]	1	08 April 2022
Participant information sheet (PIS) [PIS WS2]	1	08 April 2022
Participant information sheet (PIS) [PIS_Feasibility testing_Version 1.1_Clean]	1.1	10 May 2022
Participant information sheet (PIS) [PIS_Feasibility testing_Version 1.1_Tracked]	1.1	10 May 2022
Participant information sheet (PIS) [PIS_Think aloud_Version 1.1_Clean]	1.1	10 May 2022
Participant information sheet (PIS) [PIS_Think aloud_Version 1.1_Tracked]	1.1	10 May 2022
Referee's report or other scientific critique report [Peer review JS]		08 April 2022
Referee's report or other scientific critique report		
Research protocol or project proposal [Protocol]	1	08 April 2022
Summary CV for Chief Investigator (CI) [LG CV]		08 April 2022
Summary CV for supervisor (student research) [JM CV]		
Summary CV for supervisor (student research) [KT CV]		
Summary CV for supervisor (student research) [NA CV]		
Summary CV for supervisor (student research) [RM CV]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 307929	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely



Ann Parry
Approvals Specialist

Email: Wales.REC5@wales.nhs.uk

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Miss Lucy Goddard
PhD student
University of Oxford
Radcliffe Primary Care Building, Radcliffe Observatory Quarter, Woodstock Road, Oxford
OX2 6GGN/A

Email:
HCRW.approvals@wales.nhs.uk

17 May 2022 (re-issued 18 May 2022)

Dear Miss Goddard

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention developmentDAPHNY - Diet and Activity for Pregnancy Hypertension**
IRAS project ID:	**307929**
Protocol number:	**N/A**
REC reference:	**22/WA/0130**
Sponsor	**University of Oxford, Research Governance, Ethics and Assurance**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **307929**. Please quote this on all correspondence.

Yours sincerely,
Ann Parry
Approvals Specialist

Email: HCRW.approvals@wales.nhs.uk

Copy to: *Oxford University Hospitals NHS Foundation Trust, OUHFT Research and Development Department*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [mNCA]		
Copies of materials calling attention of potential participants to the research [Social media post]		
Copies of materials calling attention of potential participants to the research [Internal email]		
Copies of materials calling attention of potential participants to the research [Posters]	1	08 April 2022
Covering letter on headed paper		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance policy]		
Interview schedules or topic guides for participants [TG WS3]	1	08 April 2022
Interview schedules or topic guides for participants [TG WS2]	1	08 April 2022
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Letter from funder [Funder letter]		03 January 2022
Letter from sponsor [Sponsor letter]		11 April 2022
Non-validated questionnaire [Enrolment questionnaire WS3]	1	08 April 2022
Non-validated questionnaire [Online survey]	1	08 April 2022
Non-validated questionnaire [Enrolment questionnaire WS2]	1	08 April 2022
Organisation Information Document		
Other [DAPHNY_Provisional opinion]	1	13 May 2022
Participant consent form [Consent form F2F]	1	08 April 2022
Participant consent form [Consent form Remote]	1	08 April 2022
Participant information sheet (PIS) [PIS_Feasibility testing_Version 1.1_Clean]	1.1	10 May 2022
Participant information sheet (PIS) [PIS_Feasibility testing_Version 1.1_Tracked]	1.1	10 May 2022
Participant information sheet (PIS) [PIS_Think aloud_Version 1.1_Clean]	1.1	10 May 2022
Participant information sheet (PIS) [PIS_Think aloud_Version 1.1_Tracked]	1.1	10 May 2022
Participant information sheet (PIS) [PIS WS2]	1	08 April 2022
Referee's report or other scientific critique report [Peer review JS]		08 April 2022
Referee's report or other scientific critique report		
Research protocol or project proposal [Protocol]	1	08 April 2022
Schedule of Events or SoECAT [SoECAT]		
Summary CV for Chief Investigator (CI) [LG CV]		08 April 2022
Summary CV for supervisor (student research) [JM CV]		
Summary CV for supervisor (student research) [KT CV]		
Summary CV for supervisor (student research) [NA CV]		
Summary CV for supervisor (student research) [RM CV]		

IRAS project ID	307929

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
All sites will perform the same research activities therefore there is only one site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted but the sponsor is intending to use a separate site agreement. The sponsor has supplied the appropriate current unmodified model agreement	The sponsor has detailed its proposals with respect to whether any study funding will be provided to participating NHS organisations of this type in the relevant Organisational Information Document. This should be read in conjunction with the relevant Schedule of Events/SoECAT which details the cost implications of the study for participating NHS organisations.	A Principal Investigator should be appointed at study sites.	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre engagement - checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated they intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 14 Amendment documentation - Signed sponsor amendment tool

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	DAPHNY: Diet and Activity for Pregnancy Hypertension
IRAS project ID* (or REC reference if no IRAS project ID is available):	307929
Sponsor amendment reference number*:	Amendment 1
Sponsor amendment date* (enter as DD/MM/YY):	10 November 2022
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	1. Screenshots of the content and design of the intervention as was requested by the REC sub committee in the initial review. 2. Study document - A letter of invitation to send to eligible participants identified by staff at participanting sites. The letter will be sent with an advertisement postcard for the survey to ask if they wish to complete it. This is to increase response rate to the online survey. This is important for the study as the survey needs more responses to help with the theoretical understanding and development of the intervention.

Project type (select):	**Specific study**			
	Research tissue bank			
	Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	**Yes**		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	**NHS/HSC REC**			
	Ministry of Defence (MoDREC			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes		**No**	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	No	**Yes**	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes		**No**	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		**No**	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes		**No**	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes		**No**	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes		**No**	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		**No**	
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes		**No**	
Did the study involve children OR does the amendment introduce this?:	Yes		**No**	
Did the study involve NHS/HSC organisations prior to this amendment?:	**Yes**		No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes		**No**	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	**Yes**	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	**Yes**	No	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	No	No	No
Was this a "single site, self sponsored" study in England or Wales prior to this amendment?	Yes		**No**	

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1	
Area of change (select)*:	Study Documents

Specific change (select - only available when area of change is selected first)*:	Other significant change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	Screenshots of the intervention. The REC sub committee requested that the intervention content and design was submitted when further developed.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
			Remove all changes below	

Change 2				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Other significant change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	A cover letter to send with survey advertisement. The study team will provide all resources required for this. An advertisement postcard to send with the letter. Update to the recruitmnet start date to August 2022 rather than April 2023			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
			Add another change	

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:	Ronja Bahadori
Email address:	ronja.bahadori@admin.ox.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies:																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:				
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:	Y					Y				Y									C
Change 2:	Y					Y				Y									C

Overall reviews for the amendment:																
Full review:	Y					Y				Y								
Notification only:	N					N				N								
Overall amendment type:	Substantial																	
Overall Category:	C																	

Appendix 15 Amendment documentation - NHS HRA/ REC favourable opinion letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Wales Research Ethics Committee 5
Bangor

Mailing address:
Health and Care Research Wales
Castlebridge 4
15-19 Cowbridge Road East
Cardiff, CF11 9AB

email: Wales.REC5@wales.nhs.uk
website: www.hra.nhs.uk

21 December 2022

Miss Lucy Goddard
Nuffield Department of Primary Care Health Sciences
Radcliffe Primary Care Building
Woodstock Road
OX2 6GG

Dear Miss Goddard

Study title:	**Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention developmentDAPHNY - Diet and Activity for Pregnancy Hypertension**
REC reference:	**22/WA/0130**
Protocol number:	**N/A**
Amendment number:	**Amendment 1**
Amendment date:	**10 November 2022**
IRAS project ID:	**307929**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Completed Amendment Tool [307929_Amendment 1_]	1.6	10 November 2022
Copies of materials calling attention of potential participants to the research [DAPHNY_Survey postcard for sites only]	1	08 April 2022
Letters of invitation to participant [DAPHNY_Invitation to	1	07 November 2022

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

participants]		
Other [DAPHNY_content and design]	1	10 November 2022
Research protocol or project proposal [DAPHNYProtocol_Version 1.1 Clean]	1.1	15 November 2022
Research protocol or project proposal [DAPHNYProtocol_Version 1.1 Tracked changes]	1.1	15 November 2022

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS Project ID - 307929:	**Please quote this number on all correspondence**

Yours sincerely

pp SH

Ms Sumayya Mushtaq
Chair

Appendix 16 Amendment documentation - Site confirmed continued Capability and Capacity following amendment

Fri 13/01/2023 09:45

Short Sophie (R0A) Manchester University NHS FT <Sophie.Short@mft.nhs.uk>

IRAS 307929 (MFT PIN B01656) Acknowledgement of Amendment No. 1

To jenny.myers

Cc Lucy Goddard; Fairclough Andy (R0A) Manchester University NHS FT; CTRG Sponsorship Correspondence

Follow up. Completed on 13 January 2023.
You replied to this message on 13/01/2023 12:27.

Study title: Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development
Study PIN: B01656
IRAS Project ID: 307929
Amendment number: Substantial Amendment 1 (including Protocol Version 1.1)
Amendment date: 10th November 2022

Dear Professor Myers,

Manchester University NHS Foundation Trust Research Office has received correspondence informing the Trust of the above referenced amendment. We acknowledge receipt of the documents and have updated your study record as needed.

Best wishes with the continuation of your research.

Kind Regards,

Sophie Short
Research Support Officer
Pronouns: she/her

Thu 05/01/2023 08:52

Davies, Rebecca (RTH) OUH <Rebecca.Davies1@ouh.nhs.uk>

PID16076 Amendment Capacity and Capability

To MacKillop, Lucy (RTH) OUH

Cc oxfordjro@mail.studyline.uk.com; Lucy Goddard

Follow up. Start by 05 January 2023. Due by 05 January 2023.
You replied to this message on 05/01/2023 09:33.

Our reference: PID16076-A001-SI001

Dear Dr Lucy Mackillop,

Re: Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

IRAS No: 307929
Amendment Ref: PID16076-A001
Title: 10.11.2022 Substantial Amendment 1
Site Summary: 1. Screenshots of the content and design of the intervention as was requested by the REC sub committee in the initial review. 2. Study document - A letter of invitation to send to eligible participants identified by staff at participanting sites. The letter will be sent with an advertisement postcard for the survey to ask if they wish to complete it. This is to increase response rate to the online survey. This is important for the study as the survey needs more responses to help with the theoretical understanding and development of the intervention. 3. Study Recruitment start date updated in the Protocol

Amendment Capacity and Capability

Thank you for submitting your amendment to Oxford University Hospitals NHS Foundation Trust Research and Development department.

This amendment has been given the appropriate level of consideration by the R&D team, and on behalf of the Head of Research Governance I can confirm continued capacity & capability for the study.

As part of this amendment, we note the documents approved as listed:

- Ethics Approval Letter dated: 21/12/2022
- Health Research Authority approval email dated on: 21/12/2022 has been received.

Trust Management Approval and Indemnity is dependent upon completion of satisfactory compliance with Trust policies and all regulatory requirements for the conduct of clinical research.

Recruitment of participants to this study needs to be reported via the Siteline system. Contact your department Siteline administrator to request a userid. If you are unsure of your local administrator and for any queries, email support@siteline.uk.com or call 01865 221916.

Further recruitment updates will automatically be uploaded to Studyline (the R&D database) from Siteline. If you find that you are struggling to meet your targets, or become aware that you definitely won't achieve them, please also contact ResearchRecruitment@ouh.nhs.uk and we will provide support where we can.

Yours sincerely,
Becky

Appendix 17 Amendment documentation - DAPHNY Invitation to participants

Hello,

We are contacting you because from your records we can see that you are eligible to take part in the survey below. Please read below for more information from the study team.

Kind Regards,

The clinical care team at [name of Trust]

I'm Lucy, a midwife and PhD student at The University of Oxford. I am conducting an online survey as part of my research project. I am writing to **invite you to complete the online survey**.

The survey is part of a study **to design a lifestyle App with pregnant women who have high blood pressure**. The survey will help us to understand women's current lifestyle behaviours and knowledge relating to blood pressure and pregnancy.

I am reaching out to you because you have had experience of high blood pressure during pregnancy. We are really **interested to hear your views** so if you are able to, please scan the QR code or visit the website on the postcard enclosed. This will take you straight to the online survey and gives more information about the study. It should take you 10-15 minutes to complete.

Thank you for taking the time to read this letter. **Your participation is voluntary**; you are under no obligation to complete the survey and you can withdraw at any time by closing the web browser.

Taking part in this research will help us to develop an App that is relevant, useful, interesting and engaging for women in the future who experience high blood pressure during pregnancy.

Yours sincerely,

Lucy Goddard,

On behalf of the DAPHNY Study team

Appendix 18 Advertisement posters




daphny
NIHR | Applied Research Collaboration Oxford and Thames Valley
Are you a healthcare professional caring for women with chronic hypertension?
We are working with women and healthcare professionals to design and develop a lifestyle App for pregnant women with chronic hypertension.
We hope that the lifestyle App can help women make healthy lifestyle choices that support blood pressure control.
We want to talk to a group of healthcare professionals for about an hour to hear what they think about the lifestyle App.
Your opinions and insights will help us to develop a lifestyle App that is relevant and useful for a high-risk population and that supports usual care practices.
We want to hear what healthcare professionals think!
If you have any questions or if you would like to take part, please contact:
Lucy Goddard, PhD Researcher and Midwife:
daphny@phc.ox.ac.uk
01865 289215
DAPHNY HCP focus groups poster: Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development
Version/Date: Version 1.0, 08/04/2022
REC Reference number: 22/WA/0130
Chief Investigator: Lucy Goddard
IRAS Project number: 307929
UNIVERSITY OF OXFORD
NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES


daphny
NIHR | Applied Research Collaboration Oxford and Thames Valley
Are you pregnant or have you recently given birth?
Do you have long-term high blood pressure?
Pregnant women with long-term high blood pressure sometimes experience complications during pregnancy and birth.
Having a healthy lifestyle can support blood pressure control and a healthy pregnancy.
We want to understand women's current eating and exercise habits, knowledge and views around lifestyle change during pregnancy.
This information will help us to develop a Smartphone App for pregnant women with long-term high blood pressure.
Please complete our survey to tell us about your lifestyle!
If you have any questions or if you would like to take part in an interview as part of this project, please contact:
Lucy Goddard: 07849700763,
daphny@phc.ox.ac.uk,
PhD Researcher and Midwife
To access the survey, please scan the QR code or or visit:
https://bit.ly/DAPHNY
DAPHNY Survey Poster: Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development
Version/Date: Version 1.0, 08/04/2022
REC Reference number: 22/WA/0130
Chief Investigator: Lucy Goddard
IRAS Project number: 307929
UNIVERSITY OF OXFORD
NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES


daphny
NIHR | Applied Research Collaboration Oxford and Thames Valley
Are you pregnant or have you recently given birth?
Do you have long-term high blood pressure?
We would like to interview a few women for about an hour to find out their thoughts and ideas for a Smartphone App.
Pregnant women with long-term high blood pressure sometimes experience complications during pregnancy and birth.
Having a healthy lifestyle can support blood pressure control and a healthy pregnancy.
The App aims to help women make healthy lifestyle choices that support blood pressure control.
Your opinions will help us develop an App that is relevant and useful to pregnant women who have high blood pressure.
We need your help to design and develop a lifestyle App!
If you have any questions or if you would like to take part, please contact:
Lucy Goddard, PhD Researcher and Midwife:
daphny@phc.ox.ac.uk
01865 289215
DAPHNY Think aloud interviews poster: Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development
Version/Date: Version 1.0, 08/04/2022
REC Reference number: 22/WA/0130
Cheif Investigator: Lucy Goddard
IRAS Project number: 30792929
UNIVERSITY OF OXFORD
NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Appendix 19 Participant information sheets (Study 2 and 3: Component 1 and 2)

UNIVERSITY OF OXFORD
NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES
Nuffield Department of Primary Care Health Sciences
Radcliffe Observatory Quarter, Woodstock Road, Oxford. OX2 6GG
Chief Investigator: Lucy Goddard
Oxford University telephone number: 01865 xxxxxx
Email address: lucy.goddard@phc.ox.ac.uk

daphny

PARTICIPANT INFORMATION SHEET – Healthcare Professionals focus group

Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

DAPHNY: Diet and Activity for Pregnancy Hypertension

A summary of the study:

- We have been working with women and healthcare professionals to design and develop a Smartphone App.
- The Smartphone App is for pregnant women with chronic hypertension and aims to support healthy lifestyle behaviours.
- You are being invited to take part in a focus group with other healthcare professionals to discuss your views on the App.
- This will take place in-person or remotely, at a time convenient to you.
- Please take the time to read the information below about the study.
- If you would like to take part or have any questions, please get in touch!

Our contact details: Lucy Goddard (Chief Investigator), daphny@phc.ox.ac.uk

What is the purpose of the study?

Our research team are developing a digital intervention, in the form of a Smartphone App, to support women with chronic hypertension to adopt a healthy lifestyle during pregnancy.

The purpose of the study is to get valuable feedback about the App from healthcare professionals who care for pregnant women with hypertension. We want to find out what healthcare professionals think of the intervention and whether it will add to the care that is already provided for these women. This feedback will help us to develop an intervention that is acceptable and useful for a high-risk population and those who provide their antenatal care.

Why have I been invited?

You have been invited to take part because you provide care for pregnant women with hypertension in one of the maternity units that is taking part in the study. We are looking to speak to around 15 healthcare professionals including midwives and obstetricians.

Do I have to take part?

No. Taking part is voluntary. You can stop being part of the study at any time without giving a reason.

What will happen to me if I decide to take part?

If you are interested in taking part, we will arrange to meet with you and other healthcare professionals, either in-person at your maternity unit or remotely using a secure video conferencing software. We will discuss the study and you will be able to ask any questions. If you agree to take part, we will ask you to sign a consent form to say that you agree to take part in the study before beginning the study.



We will talk to you about your experience of caring for women with chronic hypertension. We will explain the rationale for the intervention and discuss the possible components and functions of the App with you. We may ask you to have a look at mock ups of App to prompt discussion around the content and we will ask your views on supporting women who may use it. The focus group will last approximately one hour.

If you cannot attend the focus group, then you may be invited to take part in a remote interview with the researcher. This will follow the same format as the focus group.

What are the possible advantages and disadvantages of taking part?

We hope that the information from this study will improve and enhance the design and development of the lifestyle App. In the long term, we hope that this will be used to better support pregnant women with chronic hypertension. We think there is little risk to you taking part in the study. The main disadvantage is that you will have to give up some of your time but we hope to make this meeting convenient for you.

Will my taking part in the study be kept confidential?

With your permission, the discussion during the focus groups will be audio-recorded. You can ask to pause the recording at any time. These recordings will be transferred to a secure University server. All identifiable information, including your name, will be removed and will be replaced with a study code as soon as it is possible to do so. A copy of the recording will be securely sent to the transcribing service that will be working on this project with us. This company has been approved by the Chief Investigators' department to undertake this type of work for research purposes. They will be asked to sign a confidentiality agreement that includes an agreement to delete all data once it has been transcribed. Once the transcription has been received by the research team, and checked against the audio recording, this recording will be removed from the secure server. Transcripts of the conversation, with a study code not names, will be kept for three years from publication or public release of the work.

Responsible members of the University of Oxford or the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Participation in future research:

If you have agreed with us to be contacted about future research, your contact details will be held separately from this study on a password protected computer within the Nuffield Department of Primary Care Health Sciences. All contact will come from our research team in the first instance. Agreeing to be contacted does not oblige you to take part in future research and you can be removed from this register at any time.

Will I be reimbursed for taking part?

Unfortunately, there will be no reimbursement for taking part in this study.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

We will be using the information you provide during the discussion in order to undertake this study. We will use the minimum personally-identifiable information possible and this information will be removed and replaced with a study code as soon as it is possible to do so. We will keep identifiable information about you for 3 years after the study has finished. If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your

details separate. All essential documents will be archived in University of Oxford approved facilities once the study is completed.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights. You can find out more about how we use your information by contacting Lucy Goddard (daphny@phc.ox.ac.uk).

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you may withdraw from the study at any time without giving reason. We will destroy identifiable research data where possible. Once the recordings of the discussion have been anonymised, the research team will be unable to link you to the discussion to enable its withdrawal.

What will happen to the results of this study?

The overall study results will contribute to a doctoral thesis at the University of Oxford. Findings may be prepared for academic publications and presented at academic conferences. We will add a link to the department website where you can access a summary of the findings. We would like your permission to use direct quotations but without identifying you in any research outputs. A copy of the doctoral thesis will be deposited both in print and online in the Oxford University Research Archive where it will be publicly available to facilitate its use in future research.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Lucy Goddard (daphny@phc.ox.ac.uk, 01865 17858) or you may contact the University of Oxford Research Governance, Ethics & Assurance Team (RGEA) office on 01865 616480, or the head of RGEA, email ctrg@admin.ox.ac.uk.

Who is organising and funding the study?

The research is being funded by the National Institute for Health Research Applied Research Collaboration. Funds have been allocated to the University of Oxford's Department of Primary Care Health Sciences. The sponsor of the study is the University of Oxford.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by XXXXXXX Research Ethics Committee.

Further information and contact details:

If you would like to take part or discuss the research with someone, please contact Lucy Goddard at daphny@phc.ox.ac.uk.

Thank you for considering taking part.

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Oxford University telephone number: 01865 xxxxxx
Email address: lucy.goddard@phc.ox.ac.uk

daphny

PARTICIPANT INFORMATION SHEET – Think-aloud interviews

Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

DAPHNY: Diet and Activity for Pregnancy Hypertension

A summary of the study:

What is the study and who is it for?

- We are working with pregnant women and healthcare professionals to design and develop a Smartphone App.
- You are being invited to take part in an interview to give researchers feedback on the Smartphone App.
- We are looking for volunteers who have been diagnosed with long-term high blood pressure and have experience of this condition during pregnancy (either you are currently pregnant or have been pregnant in the last 12 months).

Why is this research important?

- Pregnant women with long-term high blood pressure sometimes experience complications during pregnancy and birth.
- Having a healthy lifestyle can support blood pressure control and a healthy pregnancy.
- The Smartphone App will aim to support a healthy lifestyle during pregnancy.

If you would like to take part or have any questions, please get in touch!

Our contact details: Lucy Goddard (Chief Investigator), daphny@phc.ox.ac.uk

If you need an interpreter or would like to access the information in an alternative format, please email **lucy.goddard@phc.ox.ac.uk** or call **01865 17858.**

* Multilingual by Berkah Icon from NounProject.com

What is the purpose of the study?

Women who are pregnant and have long-term high blood pressure (known as chronic hypertension) require extra support and antenatal appointments throughout pregnancy. This is because they are more likely to have problems such as blood pressure becoming too high which can lead to pregnancy and delivery complications.

Research has shown us that having a healthy diet and being physically active can help people to keep their blood pressure within a healthy range. During pregnancy, women are often advised to adopt a healthy lifestyle to help lower and control blood pressure. At the moment, there is not much information for pregnant women, who have chronic hypertension, to support a healthy lifestyle which may improve blood pressure control. This study is being conducted so that we can design and develop a Smartphone App that provides an evidence-based platform to actively support women with chronic hypertension to adopt a healthy lifestyle during pregnancy.

Why have I been invited to take part?

You have been invited to take part because we are looking for women who are pregnant or have recently been pregnant who have chronic hypertension. Chronic hypertension is high blood pressure that existed before you were pregnant or before you were 20 weeks pregnant.

We would like to work with around 10 to 20 women to help us develop our Smartphone App.

Do I have to take part?

No. Taking part is voluntary. You can stop being part of the study at any time without giving a reason, and without affecting your clinical care.

What will happen to me if I take part in the research?

If you are interested in taking part, we will arrange to meet with you, either in-person or remotely using a secure video conferencing software. We will meet at a time that is convenient to you. We will discuss the study and you will be able to ask any questions. If you agree to take part, we will ask you to sign a consent form to say that you agree to take part in the study before beginning the study.

You will be asked some general questions about your blood pressure and any ways you currently manage it. You will then be provided with a draft version of the App. You will be asked to use it freely, interacting with all elements as you wish. Whilst you are doing this, we will ask you questions about its design and content. You will be able to provide feedback on any changes you think are necessary, any difficulties you encounter as well as what worked well, what you liked or disliked or anything you would add or remove. The session will last approximately one hour.

What are the possible advantages and disadvantages of taking part?

By taking part in this study you may benefit from being more informed about how to make healthy lifestyle choices during pregnancy and how this relates to your blood pressure.

We hope that developing and designing a Smartphone App alongside women will make sure it is relevant, useful, interesting and engaging. We think there is little risk to you taking part. However, lifestyle can be a sensitive topic. There is potential that those who have experienced pregnancy or birth complications may find taking part distressing. You can stop taking part in the study at any time. You will continue to receive your usual antenatal care while in this study.

Will my taking part in the study be kept confidential?

With your permission, the interview will be audio-recorded. You can ask to pause or stop the recording at any time. These recordings will be transferred to a secure University server. All identifiable information, including your name, will be removed and will be replaced with a study code as soon as it is possible to do so. A copy of the recording will be securely sent to the transcribing service that will be working on this project with us. This company has been approved by the Chief Investigators' department to undertake this type of work for research purposes. They will be asked to sign a confidentiality agreement that includes an agreement to delete all data once it has been transcribed. Once the transcription has been received by the research team, and checked against the audio recording, this recording will be removed from the secure server. Transcripts of the conversation, with a study code not your name, will be kept for three years from publication or public release of the work.

Responsible members of the University of Oxford or the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Participation in future research:

If you have agreed with us to be contacted about future research, your contact details will be held separately from this study on a password protected computer within the Nuffield Department of Primary Care Health Sciences. All contact will come from our research team. Agreeing to be contacted does not mean you have to take part in future research. You can ask for your details to be removed at any time you wish.

Will I be reimbursed for taking part?

You will receive a £10 online shopping voucher for your participation.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

We will be using the information you provide during our discussions in order to undertake this study. We will use the minimum personally-identifiable information possible and this information will be removed and replaced with a study code as soon as it is possible to do so. We will keep identifiable information about you for 3 years after the study has finished. If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database. We will keep the consent form and your details separate. All essential documents will be archived in University of Oxford approved facilities once the study is completed.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights. You can find out more about how we use your information by contacting Lucy Goddard (daphny@phc.ox.ac.uk).

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you may withdraw from the study at any time without giving reason. We will destroy identifiable research data where possible. Once the recordings of the discussion have been anonymised, the research team will be unable to link you to an interview to enable its withdrawal.

What will happen to the results of this study?

The overall study results will contribute to a doctoral thesis at the University of Oxford. Findings may be prepared for academic publications and presented at academic conferences. We will add a link to the department website where you can access a summary of the findings.. We would like your permission to use direct quotations but without identifying you in any research outputs. A copy of the doctoral thesis will be deposited both in print and online in the Oxford University Research Archive where it will be publicly available to facilitate its use in future research.

What if there is a problem?

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PARTICIPANT INFORMATION SHEET

Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

DAPHNY: Diet and Activity for Pregnancy Hypertension

A summary of the study:

What is the study and who is it for?

- We are working with pregnant women and healthcare professionals to design and develop a Smartphone App.
- You are being invited to use the App for a short period of time and then take part in an interview so we can find out about your experience.
- We are looking for volunteers who are pregnant and have been diagnosed with long-term high blood pressure.
- Interviews will take place in-person or remotely, at a time that is convenient to you.
- Please take the time to read the information below about the study.

Why is this research important?

- Pregnant women with long-term high blood pressure sometimes experience complications during pregnancy and birth.
- Having a healthy lifestyle can support blood pressure control and a healthy pregnancy.
- The Smartphone App will aim to support a healthy lifestyle during pregnancy.

If you would like to take part or have any questions, please get in touch!

Our contact details: Lucy Goddard (Chief Investigator), daphny@phc.ox.ac.uk

If you need an interpreter or would like to access the information in an alternative format, please email **daphny@phc.ox.ac.uk** or call **01865 XXXXX.**

* Multilingual by Berkah Icon from NounProject.com

What is the purpose of the study?

Women who are pregnant and have long-term high blood pressure (known as chronic hypertension) require extra support and antenatal appointments throughout pregnancy. This is because they are more likely to have problems such as their blood pressure becoming too high which can lead to pregnancy and delivery complications.

Research has shown us that having a healthy diet and being physically active can help people to keep their blood pressure within a healthy range. During pregnancy, women are often advised to adopt a healthy lifestyle to help lower and control blood pressure. At the moment, there is not much information for pregnant women, who have chronic hypertension, to support a healthy lifestyle which may improve blood pressure control.

We have been working with pregnant women and healthcare professionals who have been helping us to design and develop a Smartphone App. This App aims to actively support women to adopt a healthy lifestyle and we are conducting this study to further develop and improve the App.

Why have I been invited to take part?

You have been invited to take part because we are looking for women who are pregnant who have chronic hypertension. Chronic hypertension is high blood pressure that existed before you were pregnant or before you were 20 weeks pregnant.

We would like around 10 to 20 women to use the Smartphone App and provide feedback to help us develop it further.

Do I have to take part?

No. Taking part is voluntary. You can stop being part of the study at any time without giving a reason, and without affecting your clinical care.

What will happen to me if I decide to take part?

If you are interested in taking part, we will arrange to meet with you, either in-person or remotely using a secure video conferencing software. We will meet at a time that is convenient to you. We will discuss the study and you will be able to ask any questions. If you agree to take part, we will ask you to sign a consent form to say that you agree to take part in the study before beginning the study.

We will organise to meet with you, either in-person or remotely, to set up the App on your phone. You will be asked to use the App for a period of up to 6 weeks. After this, we will arrange to meet with you, either in-person or remotely to discuss your experience. We will ask you some general questions about your blood pressure and any ways you currently manage it. You will be able to tell us what worked well during your time using the App, anything that you would change and suggestions on how it could be improved. The interview will last approximately one hour.

What are the possible advantages and disadvantages of taking part?

By taking part in this study you may benefit from being more informed about how to make healthy lifestyle choices during pregnancy and how this relates to your blood pressure. We hope that developing and designing a Smartphone App alongside women will make sure it is relevant, useful, interesting and engaging. We think there is little risk to you taking part. However, lifestyle can be a sensitive topic. There is potential that those who have experienced pregnancy or birth complications may find taking part distressing. You can stop taking part in the study at any time. You will continue to receive your usual antenatal care while in this study. The possible inconvenience or difficulties with using the App will be explored as part of the study.

Will my taking part in the study be kept confidential?

With your permission, the interview will be audio-recorded. You can ask to pause or stop the recording at any time. These recordings will be transferred to a secure University server. All identifiable information, including your name, will be removed and will be replaced with a study code as soon as it is possible to do so. A copy of the recording will be securely sent to the transcribing service that will be working on this project with us. This company has been approved by the Chief Investigators' department to undertake this type of work for research purposes. They will be asked to sign a confidentiality agreement that includes an agreement to delete all data once it has been transcribed. Once the transcription has been received by the research team, and checked against the audio recording, this recording will be removed from the secure server. Transcripts of the conversation, with a study code not your name, will be kept for three years from publication or public release of the work.

Responsible members of the University of Oxford or the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Participation in future research:

If you have agreed with us to be contacted about future research, your contact details will be held separately from this study on a password protected computer within the Nuffield Department of Primary Care Health Sciences. All contact will come from our research team. Agreeing to be contacted does not mean you have to take part in future research. You can ask for your details to be removed at any time you wish.

Will I be reimbursed for taking part?

You will receive a £10 online shopping voucher for your participation.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

We will be using the information that you provide during our discussions and the data we collect via the App, such as your phone number, in order to undertake this study. Information provided on the App will be stored securely on University servers behind NHS firewalls and owned by the University of Oxford. We will use the minimum personally-identifiable information possible and this information will be removed and replaced with a study code as soon as it is possible to do so. We will keep identifiable information about you for 3 years after the study has finished. If you agree to your details being contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database. We will keep the consent form and your details separate. All essential documents will be archived in University of Oxford approved facilities once the study is completed.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights. You can find out more about how we use your information by contacting Lucy Goddard (daphny@phc.ox.ac.uk).

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you may withdraw from the study at any time without giving reason. We will destroy identifiable research data where possible. Once the recordings of the discussion have been anonymised, the research team will be unable to link you to an interview to enable its withdrawal.

What will happen to the results of this study?

The overall study results will contribute to a doctoral thesis at the University of Oxford. Findings may be prepared for academic publications and presented at academic conferences. We will add a link to the department website where you can access a summary of the findings. We would like your permission to use direct quotations but without identifying you in any research outputs. A copy of the doctoral thesis will be deposited both in print and online in the Oxford University Research Archive where it will be publicly available to facilitate its use in future research.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Lucy Goddard (daphny@phc.ox.ac.uk, 01865 17858) or you may contact the University of Oxford Research Governance, Ethics & Assurance Team (RGEA) office on 01865 XXXXX, or the head of RGEA, email ctrg@admin.ox.ac.uk.

Who is organising and funding the study?

The research is being funded by the National Institute for Health Research Applied Research Collaboration. Funds have been allocated to the University of Oxford's Department of Primary Care Health Sciences. The sponsor of the study is the University of Oxford.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by XXXXXXX Research Ethics Committee.

Further information and contact details:

If you would like to take part or discuss the research with someone, please contact Lucy Goddard at daphny@phc.ox.ac.uk.

Thank you for considering taking part.

If you are happy for your contact details to be shared with me, please complete and return the following slip.

Name:

Email:

Contact number:

These details are to be passed on to Lucy Goddard (daphny@phc.ox.ac.uk) as part of the DAPHNY study.

Appendix 20 Consent forms (remote and in-person)

UNIVERSITY OF OXFORD
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Chief Investigator: Lucy Goddard
Oxford University telephone number: 01865 xxxxxx
Email address: lucy.goddard@phc.ox.ac.uk

Insert local contact details e.g. TRUST LOGO (for multi-centre studies can be done once approval is in place)

Study Code: *Site ID Code:* *Participant identification number:*

CONSENT FORM

Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

DAPHNY: Diet and Activity for Pregnancy Hypertension

Name of Researcher:	*If you agree, please initial box*	
1. I confirm that I have read the information sheet dated..... (version.....) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.		
3. I understand that data collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities [and from the NHS Trust(s)], where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.		
4. I agree to the interview/focus group being audio recorded.		
5. I agree to take part in this study.		
Additional:		
6. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	Yes	No

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Name of Person taking Consent	*Date*	*Signature*

*When completed: 1 for participant; 1 for researcher site file (original)

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Insert local contact details e.g. TRUST LOGO (for multi-centre studies can be done once approval is in place)

Study Code: *Site ID Code:* *Participant identification number:*

CONSENT FORM

Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

DAPHNY: Diet and Activity for Pregnancy Hypertension

Researcher to seek and record informed oral consent, after participant has had sufficient time to think about whether they want to take part.

Please check the boxes to record that the question has been asked by the researcher and that the participant has responded in the affirmative:

1. Do you confirm that you have read the information sheet dated..... (version.....) for this study. Have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2. Do you understand that your participation is voluntary and that you are free to withdraw at any time without giving any reason, without your medical care or legal rights being affected?		
3. Do you understand that data collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities [and from the NHS Trust(s)], where it is relevant to your taking part in this research? Do you give permission for these individuals to have access to your records?		
4. Do you agree to the interview/focus group being audio recorded?		
5. Do you agree to take part in this study?		
Additional:		
	Yes	No
6. Do you agree to be contacted about ethically approved research studies for which you may be suitable? Do you understand that agreeing to be contacted does not oblige you to participate in any further studies?		

_____

Name of Participant

_____ _____ _____

Name of Person taking Consent *Date* *Signature*

Appendix 21 Enrolment questionnaires (Study 2 and 3)

UNIVERSITY OF OXFORD
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PARTICIPANT ENROLMENT QUESTIONNAIRE

Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

DAPHNY: Diet and Activity for Pregnancy Hypertension

To ensure views are sought from a range of healthcare professionals who work in different areas of maternity and are of different seniorities, please complete the following information.

Job title (including Band/ Grade):	Job title: Band/ Grade:	
Area of work (e.g. antenatal clinic, specialist clinic, postnatal ward, community): *Please tick the area you usually work*	Antenatal Clinic:	
	Delivery unit:	
	Antenatal ward:	
	Postnatal ward:	
	Community:	
	Rotational:	
	Specialist Clinic:	
	Other:	
How many years' experience:		

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PARTICIPANT ENROLMENT QUESTIONNAIRE

Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

DAPHNY: Diet and Activity for Pregnancy Hypertension

To help us understand who is taking part in the study, we would like to ask some questions about your background. We have used the minimum personally-identifiable information as possible.

1) What is your age?

<18 years old	Not eligible
18 – 24 years old	
25 – 34 years old	
35 – 49 years old	
>50 years old	
I prefer not to say	

2) Are you currently pregnant?

Yes	
What date is your baby due? [DD/MM/YYYY]	
No	

3) How many times have you been pregnant?

1 (this is my first pregnancy)	
Two or more	

4) When were you diagnosed with long-term high blood pressure?

	Please tick.	Any other detail relating to diagnosis
During pregnancy (this would likely have been diagnosed before you were 20 weeks pregnant or you were first diagnosed with high blood pressure during pregnancy which then did not normalise after you had had the baby)		
Outside of pregnancy		

5) Have you been diagnosed, or told by your doctor that you have any of the following? *Select all that apply.*

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Type 1 diabetes	
Type 2 diabetes	
Gestational diabetes (Diabetes in pregnancy)	
I don't have any of these conditions	
I prefer not to say	

6) Which of the following best describes your ethnic origin?

White	*Please select one of the following*
English, Welsh, Scottish, Northern Irish or British	
Irish	
Gypsy or Irish Traveller	
Any other White background	
Mixed/ multiple ethnic group	*Please select one of the following*
White and Black Caribbean	
White and Black African	
White and Asian	
Any other Mixed or Multiple ethnic background	
Asian/ Asian British	*Please select one of the following*
Indian	
Pakistani	
Bangladeshi	
Chinese	
Any other Asian background	
Black/ African/ Caribbean/ Black British	*Please select one of the following*
African	
Caribbean	
Any other Black, African or Caribbean background	
Other ethnic group	*Please select one of the following*
Arab	
Other	
I prefer not to say	

7) Which of the following best describes the highest level of education you have completed?

No formal qualifications	
Vocational qualifications	

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GCSE, O-Level, or CSE	
A-level or equivalent	
Professional qualification	
First degree	
Post-graduate or above	
I prefer not to say	

Appendix 22 Amendment documentation – DAPHNY Survey postcard for sites only



Appendix 23 Amendment documentation – DAPHNY Content and design for REC committee

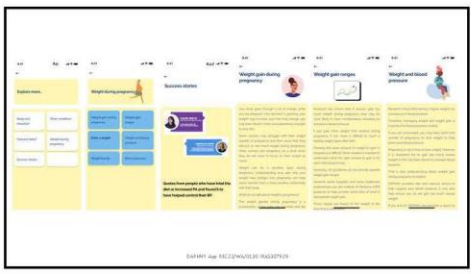
28/11/2023













1

Appendix 24 Topic guide (Study 2)

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FOCUS GROUP GENERAL TOPIC GUIDE

Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

DAPHNY: Diet and Exercise for Pregnancy Hypertension

Focus groups will be carried out with healthcare professionals including midwives and obstetricians. The aim is to elicit discussion about the intervention between professionals. The rationale for the intervention and each intervention component will be explained and described to the group. The following will be used as a guide but as the discussion develops, further questions may be explored.

Opening

Please complete 'Focus group enrolment questionnaire'

Each member of group to introduce themselves and their role in caring for women with chronic hypertension.

General

Usual care pathways for pregnant women with chronic hypertension

Current approaches and views about discussing current lifestyle habits and lifestyle change with women

Training and resources to support discussions about lifestyle

The DAPHNY App

Views on the intervention and its components including overall design and content

Barriers and facilitators to supporting women using the App

Views on how the interventions interacts with current care pathways

The DAPHNY App components

Feelings about pregnant women self-monitoring their blood pressure

Views around who should have access to monitoring readings and how often these should be monitored

Views on how self-monitoring would affect usual care pathways

Knowledge of DASH diet and possible barriers for women/ supporting women

Views on encouraging physical activity in this group

Views on proposing increased activity to these women via the intervention

Weight monitoring

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Current practices around weight monitoring during pregnancy

Current views on weight monitoring

Appendix 25 Topic guide (Study 3: Component 1)

UNIVERSITY OF OXFORD
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daphny

THINK ALOUD GENERAL TOPIC GUIDE

Optimising lifestyle behaviours during high risk pregnancies: Mixed methods intervention development

DAPHNY: Diet and Exercise for Pregnancy Hypertension

The think-aloud interview topic guide is designed to elicit discussion with pregnant women, or recently pregnant women, with chronic hypertension. The aim is to understand their views around the usefulness and acceptability of a digital interventions that promotes lifestyle changes to help control blood pressure. This will be used as a guide as the intervention develops and the questions will be prompted by the woman's interaction with the App.

Pre think-aloud questions

Please complete 'Think-aloud enrolment questionnaire'

To elicit the advice women have received about their lifestyle behaviours, in relation to their blood pressure, from healthcare professionals

Views and current practices around current blood pressure control and what they do to manage it

Views and current practices around use of technology during pregnancy

Prompts for think-aloud

Views on the intervention and its components including design and content

[Questions here will follow the women's interaction with the prototype]

Post think-aloud questions

Views on the intervention as an overall concept

Views around taking on suggested dietary and physical activity changes

Barriers and facilitators to support engagement with the intervention

Ways to overcome these barriers

Views on self-monitoring health behaviours (including weighing, blood pressure, activity) during pregnancy

Views on the prototype App components and any possible additions/ omissions that would support lifestyle change

Appendix 26 Written instructions for DAPHNY App



Welcome to the DAPHNY App!

The DAPHNY App has been designed and developed with pregnant, or recently pregnant, women who have high blood pressure and their healthcare professionals. We are now asking a group of women to use the App for a short period so that we can develop the App further. This is so that we can see whether it is useful, engaging and relevant to you!

Navigating around the App

On the homepage you will see your chosen food focus for the week and a summary of any other readings that you have entered into the App.

There are 4 main sections of the App for you to use and explore:

1. Blood Pressure Focused Foods
   - Choose a BP Food Focus to receive information and tips on different ways that you can improve the way that you eat. You can change your focus as often as you wish and you can choose which notifications you want to receive so that they are relevant to you.
   - You will find recipe ideas and information about the foods and nutrients that have been shown to have a positive effect on blood pressure.
2. Your movement portal
   - If you monitor your step count on a device, you can enter your daily step count. We can provide a pedometer if needed. You can also log other movement activities.
   - You can find out information about increasing your movement in pregnancy and how this may help your blood pressure.
3. Your blood pressure portal
   - Enter your blood pressure readings from your visits to clinic. You can view your blood pressure readings overtime.
   - You can find information about the signs and symptoms of very high blood pressure and find out why blood pressure might be affected by what we eat and how much we move.
4. Explore more
   - More information can be found out about other ways you may be able to help your blood pressure through changes to your lifestyle.
   - You can find out about weighing yourself during pregnancy and enter a weight measurement.

If you have any questions or experience any problems whilst using the App, please get in touch with me (Lucy) using the email: lucy.goddard@phc.ox.ac.uk or call or text me on: 07849700763. This number is available Monday to Friday from 9am to 5pm. For any concerns relating to your pregnancy or if you feel unwell, please call your midwife or Maternity Assessment Unit.

I hope you enjoy using the App and I look forward to hearing your views!

Appendix 27 Functionality testing instruction sheet

Rules

- '!' indicates when a participant should be a sent an automatic message
- Red highlighted text indicates erroneous data entries
- Green highlighted text indicates correct data entries

TEST PARTICIPANT 1 – RECIEVES ALL THE NOTIFICATIONS
General notifications settings

Tick to receive all notifications:

- Top tips (selection from food focus week)
- Movement motivational messages (select to receive 1 a day at 10am)
- Other motivation messages (select to receive 2 a week at 4pm)

Testing of the BP Food Portal:

Day of the week	**Suggested action**	**Expected action**	**Successful (Yes/ No)**	**Problems**
Monday	Choose a BP Food focus (choose to receive notifications, do not select any of the listed tips or facts)	! You will receive 2x notifications with a top tip or fact at 8am (Wednesday and Saturday)	Links on information pages work. If you don't select any notifications to not receive for the food focus, is it possible to not have the message 'Well done for achieving these top tips'	Did not receive on Saturday
Tuesday	Navigate to 'Take a photo' –to take a photo of a meal and give it a rating	Image to be taken, rated and stored in photo hub	Yes	On photo hub - message at the top should only appear when no photos have been taken.

				A plus button is needed. Once participant has taken and submitted a rating, can it take them straight to the photo hub?
Wednesday	Navigate to 'More resources'	Links should work	All work.	
		! 8am - Top tip notification		
Thursday	Navigate to 'Search recipes' Search for a recipe using BHF finder	Link should work	Link works. All recipe links work.	
Friday	Navigate to 'The evidence for DASH' via 'Foods to support blood pressure control'	Links should work	All links in this section work.	
Saturday	Navigate to 'Important Food Groups'	Links should work	Wholegrain page – images of cereals aren't the same size. Fruit and vegetables page – image aren't the same size. Nuts and seeds – 7th paragraph – 'Unsaturated fat have' – this needs to be 'has' -The example portions need to be in bullet	

			points like the other pages Fats and oils – most of the paragraphs on this page need a full stop at the end. Links to other pages work.	
	Navigate to 'Extra considerations in pregnancy'	Links should work	'Extra considerations for pregnancy' – 4th paragraph down, 'All pregnant *women' needs inserting. Links work	
		! 8am - Top tip notification		
Sunday	Navigate to: 'Nausea and sickness' via 'Struggling to eat well?'	Links should work	Links work.	
	Shopping tips		All fine.	

Other	Generally, can the colour of the page titles be in the same blue as the text on the page. Quite a lot of them are black.

Testing of the Blood Pressure Portal:

Day of the week	Suggested action	Expected action	Successful (Yes/ No)	Problems
Monday	Enter a blood pressure reading of 120/60	Congratulations page should appear	Yes	
Tuesday	Enter a blood pressure reading of 350/15	Error message should appear and then re-enter a normal	No error message which is fine because	

		BP reading, congratulations page should then appear	it doesn't allow you to enter it.	
Wednesday	Enter a blood pressure reading of 98/50	Congratulations page should appear*	Yes	
Thursday	Enter a blood pressure reading of 160/80	Congratulations page should appear*	Yes	
Friday	Navigate to 'Important contact numbers' , select '+' to enter a name and number, press enter	Contact should now be listed under 'Important contact numbers'	Yes	
	Enter a blood pressure reading of 60/120	This should be corrected for to be 120/60. Congratulations page should appear.	We discussed this and not implemented as its unlikely participants will do this and not a concern as it is a clinic reading.	
Saturday	Navigate to 'Chronic hypertension in pregnancy'	Links should work	There needs to be a gap in between the two paragraphs next to the image in the middle of the page.	
	Navigate to 'Medication'	Links should work	The link still doesn't work – please replace with the last link of the resources page.	
Sunday	Navigate to 'More resources'	Links should work	All links work.	

*Even though these would be classified as 'high' or 'low', the action will have already been taken as these are readings from clinic.

Testing of the Movement portal:

Day of the week	Suggested action	Expected action	Successful (Yes/ No)	Problems
Monday	Navigate to 'set a step goal' – choose a goal.	Congratulations page.	Yes	
		! 10am – receive motivational message		
Tuesday	Navigate to 'Record today's step count' Select today's date and enter the number '10' After error message, enter the number '10,000'	Error message should appear, re-enter a step count Congratulations page should appear	No error message but doesn't let you submit so this is fine	
		! 10am – receive motivational message		
Wednesday	Navigate to 'Record today's step count' Select today's date and enter the number '200,000' After error message, enter the number '6,000'	Error message should appear, re-enter a step count Congratulations page should appear	No error message but doesn't let you submit so this is fine	
		! 10am – receive motivational message		
Thursday	Navigate to 'Explore exercises classes in your area' Use the tool.	Link should work	Finder works. Some of the links don't work but this is on the NHS website itself so not possible to resolve this.	
	Navigate to 'Log other movement' and choose an activity and input the duration and enter.	Congratulations page should appear.	I cannot enter a new activity – the selection doesn't work. I can enter date	

			and duration, nothing happens when you select 'Add activity' (it should take you to summary page)	
		! 10am – receive motivational message		
Friday	Navigate to 'Pelvic pain' via 'Struggling with movement?'	Links should work	All fine.	
		! 10am – receive motivational message		
Saturday	Navigate to 'Other movement during pregnancy' via 'Struggling with movement?'	Links should work	All fine.	
		! 10am – receive motivational message		
Sunday	Navigate to 'More resources'	Links should work.	The text extends beyond the blue cardholder. All links work.	
		! 10am – receive motivational message		

Other	On the step summary page, should there be a line with the most recent step goal? Walking page – point number 14, second sentence should read – 'There are other ways you can keep moving'. The last sentence of this point should link to 'Struggling with movement' page.

	Struggling with movement page – first sentence should read 'It is important not to feel guilt**y…**'

Testing of the Explore more portal

Day of the week	**Suggested action**	**Expected action**	**Successful (Yes/ No)**	**Problems**
Monday	Navigate to 'Enter a weight' via 'weight during pregnancy' Enter a weight of 76kg	 Congratulations page should appear.	Yes	
Tuesday	Navigate to 'Enter a weight' via 'weight during pregnancy' Enter a weight of 301kg. After error message, enter a weight of 26kg. After error message, enter a weight of 63kg.	 Error message should appear. Error message should appear. Congratulations page should appear.	No error messages but it doesn't let you submit a reading.	
Wednesday	Navigate through the pages under 'More ways to lead a healthy lifestyle'	Links on the different pages should work.	All links work.	
Thursday	Navigate to 'More resources'	Links should work	All links work.	
Friday				
Saturday				
Sunday				

'Other notifications'

Expected action	Successful (Yes/ No)	Problems
You should receive 2x notifications with general motivational messages or facts during the week		

TEST PARTICIPANT 2 = RECIEVES NO NOTIFICATIONS

General notifications settings

Untick to receive all notifications:

- Top tips (selection from food focus week)
- Movement motivational messages
- Other motivation messages
- Recipe of the week

OR

Follow these instructions to turn off notifications within the different portals:

Portal	**Suggested action**	**Expected action**	**Successful (Yes/ No)**	**Problems**
BP Food Focus	Navigate to choose a BP Food focus (do not select to receive notifications)	You should not receive any notifications	Yes	
BP portal	N/A			
Movement portal	Navigate to portal homepage. Select 'No' to receiving notifications.	You should not receive any notifications	Yes	
Explore more	N/A			

Any other comments and problems encountered

	Top tips (8am)	Movement motivation messages (10am)	Other motivational messages (4pm)
Monday	X	✓	✓
Tuesday	X	✓ x2 (?phone update?)	?

Wednesday	✓	✓	✓
Thursday	X	✓	✓
Friday	X	✓	✓
Saturday	✓	✓	✓
Sunday	X	✓	✓

Appendix 28 Usability testing questions

App usability testing

The main purpose of this testing is to find out any errors or bugs, gain more understanding of your experience using the App, learn whether the product works as expected and see how user friendly it is.

Phone device – Sona Experia, Model – XQ – ASS2, Android 12

Questions	Comments
General	
What did you think of the App overall?	App has been working well apart from a few glitches. It is better than I thought. I like the 'Well done', even though its small, it still means something
What did you like the most about the App?	DAPHNY logo All the information on the BP Food Portal In pregnancy, people would tell her what to eat and it's good to have the App to come back to for information instead. Shopping tips useful. Choosing a BP Food focus – good to be able to choose which notifications you receive. Good that is it in sections because you can choose to interact with it all or just a couple Foods on a budget really good
What did you like the least about the App?	Some things you see on other Apps, I expected to see, e.g. being able to zoom in on the graphs would be good. The dates are too long on the BP graph so can't see when it was taken. Would it be possible to scroll across.
What features did you find most useful?	A lot of information so been able to find out specific things I wanted to, e.g. medication, signs and symptoms of pre-eclampsia Good to have important contact information
Navigation of the App	
Did you have any issues navigating around the App?	Back button after entering weight and steps didn't work correctly (see Interactive sections)
Did you experience any issues while navigating through the App?	In the explore more section – ways to lead a healthy lifestyle – you have to select the

	word, not the white tab for it to be selected, needs to be extended.
Did you find the App was intuitive to use?	Yes
Content of the App	
How did you find the language used throughout the App?	Nothing noticeably wrong.
Were there any pages or sections of the App that confused you?	No.
Any information missing that you expected to see?	No, it's got all the information that we discussed was missing in the BP monitoring App that would be good and useful to have.
Interaction with the App	
What areas of the App did you keep returning to?	Food Portal because it had lots of information.
Which areas of the App did you find most useful and engaging?	
Notifications	
Did you receive notifications when you expected to?	Yes, problem with notifications not going away when you click on them. There are two that are very similar
Was the frequency of notifications acceptable to you?	They all come in at the same time. Is possible to have some that come in the morning and then later on.
Interactive sections	
How did you find using the BP Food Focus section? Did you understand it?	Yes, this was clear. Because it wiggles on the home screen this is obvious to go back to it.
When you entered your blood pressure, weight or step count, did you experience any issues? If yes, please specify.	When step count and weight are entered, goes to BP Portal and gets stuck. Step count – Well done – Graph – [presses back button] - BP Portal (App stuck and has to close and reopen) Weight – Well done - [presses back button] - BP Portal (App stuck and has to close and reopen)
Links	
Did you experience any website links that did not work?	No issues – they are good to have
Design	
What did you think of the images used throughout the App?	The images are all good – good that they are cartoons, they won't offend anyone, good range of ethnicities
Were the colours acceptable to you?	Yes
Was the text font and size easy to read?	Yes
Additional comments	
Do you have any other comments that you would like to make about your experience using the App?	Expected it to ask permission to use the camera.

	Search bar for word – would be useful, not essential Weekly summary – thought there would be a graph, needs to be more visually, or possibly be able to link to the graphs on the portal pages from here

Appendix 29 Specification document

The text originally presented here cannot be made freely available via ORA because it contains intellectual property.

Appendices: Chapter 6

Appendix 30 Topic guide (Study 3: Component 2)

Feasibility testing – topic guide version 4

General

- Is there a difference between how you manage your blood pressure during and outside of pregnancy?
- How do you find managing your blood pressure during pregnancy?
    - And what helps?
- What do you hear healthcare professionals say to you about your lifestyle during pregnancy?

How the App worked in your life

- Can you tell me about how the App worked for you? (use of App and any behaviour change)
- Did you make any changes to your lifestyle because of the App?
    - Probe: if no, what would help? If yes, what was easy/ difficult?
- How did you use it your day?
- Were there any challenges with including it in your day?
- What would help you to use it?
- What would stop you from using it?
- How do you think might this work alongside the care that you receive from midwives and obstetricians?

App engagement and usage

Some questions will be informed by looking at the App usage data before the interview. For example:

- I see that you did not explore the movement area of the App, can you talk about why this may be?
- You most frequently used the BP focused food area, can you talk more about your engagement with this part of the App?
- You set a goal – what motivated you to do that?

Thinking beyond pregnancy

- What do you think would be needed for long term support for a healthy lifestyle?
- What would keep you using this after this pregnancy?