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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Sponsor:	University of Oxford
Funder:	NIHR ARC studentship
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.

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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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.

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.

Problem being addressed

Lifestyle factors that may cause poor blood pressure control and excessive GWG in pregnant women with chronic hypertension

Population

Pregnant women with chronic hypertension

Intervention targets

Improved lifestyle behaviours

Intervention ingredients

Patient motivation

- To improve current and future health
- To improve the health of offspring
- To support a healthy pregnancy

Education and self-monitoring

- By instruction and by providing information designed and appropriate for low health literacy

Engagement and adherence

- By addressing barriers
- By encouraging interaction through regular messaging and reminders

Treatment

- Promotion of the DASH diet
- Promotion of physical activity
- Health behaviour monitoring
- Support and sign-posting

Key behaviour change techniques

Problem solving (identify barriers)

Self-monitoring of outcomes(s) of behaviour

Biofeedback

Instruction and demonstration of how to perform behaviour

Information about health consequences

Prompts/ cues

Behavioural practice/ rehearsal

Habit formation

Credible source

Goal setting (behaviour)

Action planning

Feedback on behaviour

Mediating processes

Increased knowledge, skill and confidence of how to have a healthy lifestyle in pregnancy

Increased motivation to adopt healthy behaviours

Change in attitude and beliefs about managing healthy behaviours in pregnancy

Increased ability to self-monitor
- Provision of equipment

Increased self-efficacy for monitoring healthy behaviours during pregnancy

Modified beliefs about the importance of lifestyle in hypertensive pregnancy

Increased patient engagement in care

Behavioural outcomes

Increased awareness of health behaviours

Improved dietary intake

Increase in physical activity levels

Healthier lifestyle

Patient outcomes

Better blood pressure control

Appropriate gestational weight gain

Improved management of high risk pregnancy

Improved pregnancy outcomes/ experience

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.

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).