RESEARCH PROTOCOL

Evaluation of acceptance and usability of an app promoting healthy behaviours amongst young women at increased risk of breast cancer

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2) INTRODUCTION

It is estimated that around 20% of breast cancers (BC) in the UK are preventable through adherence to appropriate health behaviours, i.e., healthy diet, physical activity, limited alcohol, not smoking, and that women at increased risk of BC could benefit from greater decreases in risk than the general population via health behaviour changes. Young women (age <35 years) who are at increased risk of developing BC currently receive little or no information regarding health behaviours and BC risk, or support for behaviour change. This feasibility study aims to explore whether a novel app is acceptable to women at increased risk and could potentially engage them with improved health behaviours which could reduce their future risk of BC.

3) BACKGROUND

The importance of health behaviours for BC prevention

Breast cancer (BC) is the most frequent female malignancy worldwide, with over two million diagnoses annually worldwide and over 55,000 diagnoses in the UK[1]. These figures are predicted to increase[2].

Recent overviews estimate potentially modifiable health behaviours to be responsible for a high proportion of BC in the UK (~20%)[3]. Overweight/obesity and weight gain through adulthood are responsible for around 8%, 8% is associated with alcohol intake, while not breastfeeding is responsible for 5%[3]. Other health behaviours that increase risk include smoking and lack of physical activity (PA)[4]. Each 5 kg gain in weight in adult hood is associated with a 6% increased risk in post-menopausal BC (RR 1.06 [95% CI 1.05-1.08])[4].

A significant proportion of BC cases, around 38%, occur in the 18% of women who are at increased risk (>17% lifetime risk) due to family history, mammographic density and single nucleotide polymorphisms (SNPs)[5]. Health behaviours have been shown to increase risk to an equal or greater extent in women with a family history of BC compared to those without. Prospective data from combined studies in Australia, US and Canada (n=15,550) found higher levels of PA reduced BC risk similarly in women with and without a FH of BC[6]. The US Women's Health Initiative – Observational Study (n=85,644) found that adhering to three 'breast healthy' behaviours of <7 alcoholic drinks per week, >100 minutes moderate/vigorous exercise per week and maintaining healthy range BMI (18.5-24.9 kg/m^2) at baseline and throughout non-pregnant adulthood was similarly associated with a lower BC risk for women with family history of later onset (>45 years) BC and for those without[7]. Analysis of UK Generations Study data (n=102,927) showed that smoking increases relative risk more in women with a family history of BC compared to women without[8]. An Australian cohort study (n=16,035) found that overweight and obesity has a greater proportional effect on increasing BC risk amongst women already at increased risk due to family history compared with women from the general population. They concluded by stating "maintaining a healthy weight throughout adult life is of clinical significance for all women, and especially those with a family history of breast cancer"[9]. Targeting health behaviour interventions to women at increased risk of BC could have a significant impact on reducing rates because even the same relative reduction in risk will lead to greater absolute reductions.

Current health behaviours amongst women at increased risk

Many women known to be at increased risk attend Family History, Risk and Prevention Clinics (FHRPCs) of which there are around 90 in the UK, including our own based at The Nightingale Centre,

Wythenshawe Hospital, Manchester University NHS Foundation Trust (MFT). According to NICE guidance, FHRPCs should provide advice on health behaviours to lower BC risk[10] but few do in practice due to limitations on time, skills and resources. Analyses of BMI and health behaviour data from women at increased risk (mean age 41.2, SD 3.5 years) in our clinic at The Nightingale Centre highlighted the prevalence of unhealthy health behaviours which were comparable to the general population, i.e. almost 60% had overweight or obesity, 30% did not meet physical activity recommendations, and 45% exceeded alcohol recommendations[11]. Thus, there is an unmet need to provide cancer prevention health behaviour programmes for women at increased risk.

We have previously shown that significant weight gain occurs between the ages of 18 and 35 years in women[12]. Once weight is gained, it is very difficult to lose. This project is focussed on women aged <35 years to improve health behaviours and try to prevent weight gain in this population at increased BC risk, rather than deal with weight problems once they have occurred.

The need for a health behaviour app

Our interview study amongst women at increased risk aged 25-35 years from our FHRPC showed these women were interested in joining a programme to promote health behaviours and prevent weight gain which was accessed via an app[13]. Further Public and Patient Involvement (PPI) work with women aged 25-35 years from our FHRPC who had been a healthy weight at age 18 years but had since gained at least a stone in weight also showed support for an app.

Whilst there are a number of apps already on the market that aid weight loss there are currently no apps designed to prevent weight gain. A search of the literature revealed no publications on development of such apps, therefore there is nothing that is currently suitable for testing in FHRPCs. There are many BC information and prevention apps which only provide static information, for example on risk factors and health behaviour advice. None are interactive and grounded in recognised psychological theory; therefore they are unlikely to elicit behaviour change. The content of such apps has not been reviewed but a brief look at descriptions on the Google Play store indicates that they are not likely to be evidence-based, for example “Breast Cancer” app contains details of ‘foods that cause breast cancer’, “Breast Cancer Stages, Signs, Food and Meal Plan” app contains ‘30 foods [to] reduce breast cancer risk’, and “Breast Cancer Guide” app states that ‘85% of all breast cancer cases are caused by factors other than heredity, such as environmental toxins, bad eating habits, and stress’. This conflicts with current evidence about modifiable BC factors mentioned above.

Development of the current app

We have developed an app using a co-design process involving young women from the FHRPC. Our multi-disciplinary team has previous experience of developing health apps. Inclusion of behavioural psychologists with expertise in developing digital health interventions in our project team has ensured that the app is grounded in psychological theory therefore more likely to be effective.

The aim of the app is to improve health behaviours, i.e. healthy eating, alcohol, PA, smoking cessation and breastfeeding, and prevent weight gain. The app includes encouraging self-monitoring and goal setting, and provides education. Social/peer support is provided via a private Facebook group.

Testing the complex intervention

Evidence generation will follow "Evidence Standards Framework for Digital Health Technologies" guidance by NICE[14] to evidence tier 3a, for example involving experienced health professionals in the app, design, development and testing, involving users with acceptability testing (the purpose of this study), ensuring content is accurate and up-to-date, and demonstrating its effectiveness. This will help to ensure that the correct evidence is gathered to enable future use of the app in the NHS. The intervention is "complex" as it has a number of interacting components (information provision, social/peer support, goal setting) and a number of outcomes (weight, alcohol, PA, healthy eating, smoking)[15]. Therefore we will follow "Developing and evaluating complex interventions: the new Medical Research Council guidance"[15]. This study forms part of assessing feasibility before the evaluation phase.

4) STUDY OBJECTIVES

4.1. Aims

1. To assess the acceptability and usability of the app to young women at increased risk of BC
2. To assess the feasibility of study procedures before running a future efficacy study using the app as an intervention

4.2. Objectives

1. Explore views of users of the experiences during and after using the app
2. Explore views of users on their experience of the two different recruitment procedures (targeted mailshot, or social media, newsletters and websites), and the online consent procedure.
3. Interpret user data from the app including frequency and patterns of use of the different functions
4. Analyse recruitment data to explore how the two different recruitment procedures could be improved for the next study
5. Assemble a list of suggested changes to recruitment and consent procedures, and to the app, to be considered before the next study.
6. Quantify health care professional (HCP) time required for administering the private Facebook chat group, and through e-mail/private message support.
7. Quantify researcher time required for cleaning and analysis of app data.

5) STUDY DESIGN & PROTOCOL

5.1 Participants

The study will recruit 35 young women (≤35 years) who are at increased risk of BC.

5.2 Study Intervention and/or Procedures

The participant journey is as shown in Figure 1. Procedures are listed in Table 1.

Figure 1: Participant journey

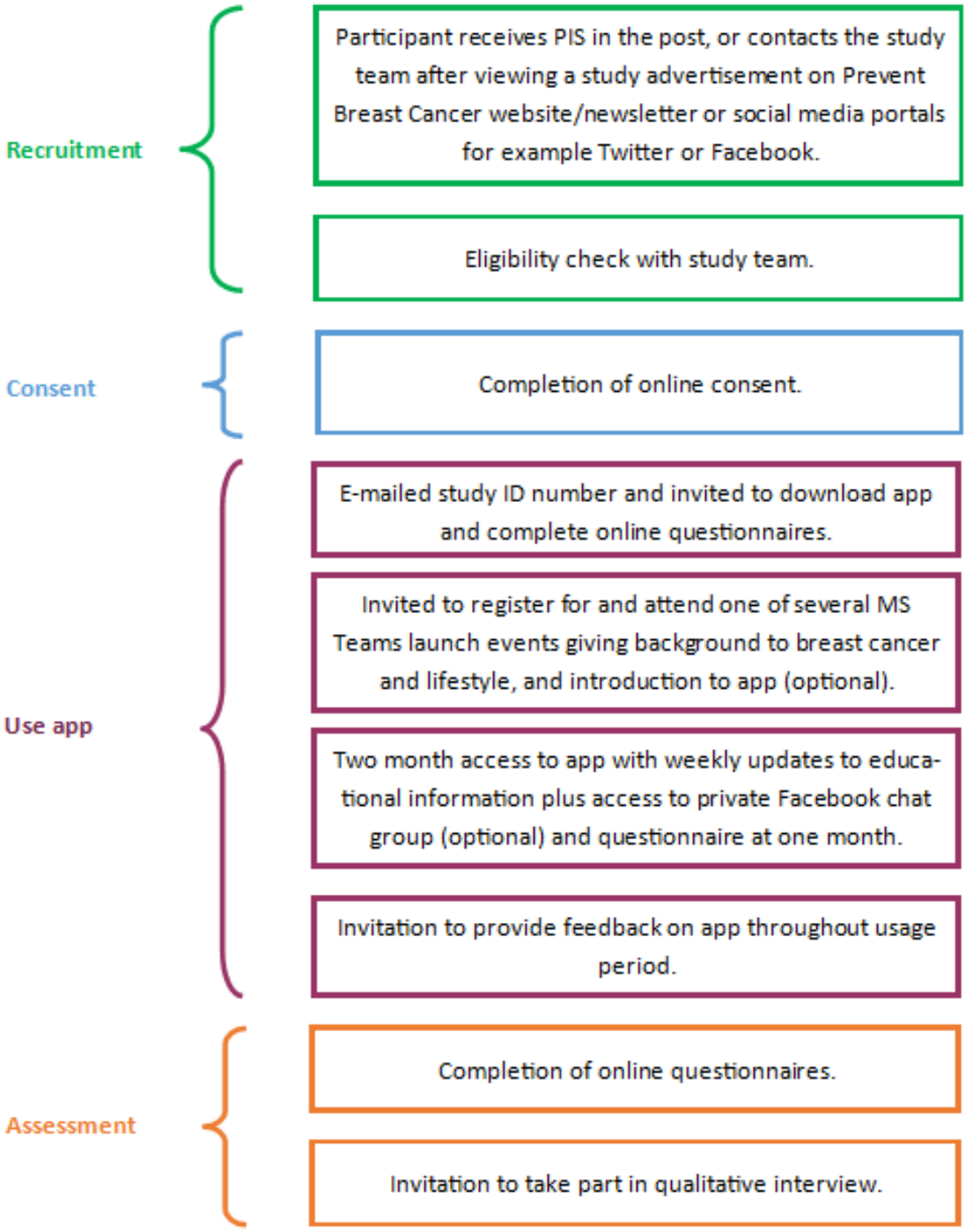

Table 1: List of participant procedures.

Procedure	Frequency and time point(s)	Duration	Location
Receives participant information sheet (PIS)	x1 at recruitment	15 minutes to read	In post, or by e-mail. Location of reading it is participant's choice.
E-mails study team so show interest	x1 at recruitment	2 minutes	Online: location is participant's choice.
Phone call from study team to check eligibility and explain next steps	x1 at recruitment	20 minutes	Participant's choice based on their chosen time, e.g. home, work.
Completion of online consent	x1	10 minutes	Online: location is participant's choice.
Receives e-mail with their unique study ID and links to download app, join private Facebook group and complete questionnaires as below.	x1	1 minute	Online: location is participant's choice.
Download and set up app	x1	15 minutes	Location is participant's choice.
Follow invite link to join private Facebook group	*Optional* x1	5 minutes	Location is participant's choice.
Completion of Demographics and Health Behaviours Questionnaire	x1 after consent (baseline)	10 minutes	Online: location is participant's choice.
Completion of BC risk beliefs questionnaire	x2 after consent (baseline) and at 2 months	10 minutes	Online: location is participant's choice.
Completion of Mobile Application Rating Scale (uMARS)[16] questionnaire	x2 at 1 and 2 months	10 minutes	Online: location is participant's choice.
MS Teams starter group session	*Optional* x1 after baseline questionnaires submitted	45 minutes	MS Teams: location is participant's choice.
Submit health behaviour logs	x0-8 depending on chosen frequency (between weekly and monthly)	10 minutes	Via app: location is participant's choice.
Read posts on private Facebook group and post or 'react' (e.g. like) to the posts of others (optional)	*Optional* 0+ after joining Facebook group	1+ minutes	Via private Facebook Group: location is participant's choice.
Completion of app feedback questionnaire	*Optional* x1+ as and when wishes to give feedback on app during study	5 minutes	Online: location is participant's choice.
Read educational material on app	x0-8+ depending on chosen frequency	10 minutes	Via app: location is participant's choice.

Qualitative interview – up to 20 women (optional and if invited)	*Optional* x1 after study completion	1 hour	Patient choice (home or remote via MS Teams or phone)
Receive and read questionnaire reminder e-mail if doesn't complete a questionnaire after ~3 days	0-5	1 min	Location is participant's choice.
Receive a questionnaire reminder phone call if doesn't complete a questionnaire after ~5 days	0-5	5 min	Location is participant's choice.

5.3 Questionnaires

All questionnaires will be hosted on Qualtrics. Non-responders will receive an e-mail reminder 3 days after questionnaire is due, and a telephone reminder after 5 days. These durations may change due to weekends and holidays.

5.4 Prevent: The Healthy Living App

The app was built by software developers in ResearchIT at the University of Manchester and includes self-monitoring of health behaviours, goal setting, education and feedback.

5.5 The Private Facebook Group

Membership of the private Facebook group is by invite only and the account will be set to only allow invitation by the group administrator(s). Upon receiving an e-mail invite, participants can request to join and the group administrator(s) will then approve the participants' request. Participants will join using their personal Facebook account. The Facebook group is 'private' meaning that only invited members can see what members post, comment on and share within the group, and only invited members can see the list of members in the group. The Facebook group is also 'hidden' meaning that only current, invited or former members of the group can see the group's name and description, and can find the group in search, and only former members of the group can request to join. The participant's membership of the group and any posts they make within the group are not visible on their profile. However, this is a group chat and comments written will be visible by all other members of the study who have joined the private group and participants will be reminded of this and also that no personal details (e.g. address, family details) should be posted. University of Manchester "Social Media and CCTV – Guidelines for use in research" (display.aspx (manchester.ac.uk)) will be followed. Any participant posting inappropriate content or comments will be removed from the group by the administrator, contacted by e-mail explaining why they have been removed, but will be allowed to remain in the study.

A post about the weekly educational topic will be added to the Facebook group once a week. This could be, for example, a poll or request for recipe exchange. The moderator(s) will check the group at least once daily including weekends and reply to comments and private messages.

5.6 Qualitative study plan

We will undertake up to 20 semi-structured interviews at the end of the two month study. Sampling will be purposive, aiming to obtain women with a range of ages and ethnicities.

The interviews will be conducted by a University of Manchester qualitative health psychology researcher and the topic guide has been produced in conjunction with the research study team. Interview data will be digital audio-recorded (using encrypted audio recorder for phone and face-to-face interviews and Microsoft Teams audio recording facility for interviews held on Microsoft Teams) and downloaded to secure University of Manchester drives as soon as possible, and deleted from the device and Teams account. They will be transcribed verbatim using a University of Manchester approved professional transcription service. We will follow University of Manchester guidance: "Taking recordings of participants for research purposes SOP (The University of Manchester)". The transcription service have signed an agreement with the University which includes confidentiality clauses. Transfer of recordings to the transcription service will be in line with University of Manchester guidance which allows the use of either University of Manchester Dropbox Service or Zendto.

The Interview schedule contains a list of questions to be discussed in this study. The work will remain flexible with respect to participants' commitments, but we will cover the main topics outlined below. It is common in qualitative data collection methods to develop topics and questions as new ideas emerge from early data collection. Therefore, we may add new questions and refine topics as the interviews progress and data collection continues thus improving participant understanding of questions/understanding participant experiences fully.

The focus of these interviews is to explore participants' experience of using the app, the usability of this app, whether it has been useful to them in changing their health behaviours (e.g. healthy eating, PA, alcohol intake), and understand how the app may have influenced health behaviours or feelings towards breast cancer.

5.7 End of Study Procedures

The end of the study is defined as when the last participant has completed their interview.

Weekly educational information within the app, and associated post of the private Facebook group will continue until all participants have had two month access to the app. Once all interviews are complete, all participants will be e-mailed to inform them that the study is complete, any entries they make in the app will no longer be monitored, and all participants will be removed from the private Facebook group. HCP monitoring of the private Facebook group will happen until this point. It is not possible to withdraw access to the app from participants' phones. Access to the app and private Facebook group will continue beyond two month access so that participants can still access at the time of their interview.

In the case of premature study closure, participants will be informed by e-mail and in a post on the private Facebook group after which access to the private Facebook group will be withdrawn.

6) STUDY PARTICIPANTS

6.1 Inclusion Criteria:

- Female
- Age 18-35 years
- Live in the UK
- Moderate or high risk of BC (see 6.5 for definition)

- Ability to communicate in English
- Ability to download and use an app (available on both ioS and Android)

6.2 Exclusion Criteria:

- Previous BC (other cancers will not be excluded)
- Previous preventative mastectomy
- Currently trying to gain weight
- Previous weight loss surgery
- Currently taking weight loss medication, prescribed (for example orlistat, liraglutide, Naltrexone/Bupropion [Mysimba]) or other
- Have a medical condition that influences diet and weight, for example, diabetes, inflammatory bowel disease or cystic fibrosis
- Current diagnosis of a psychiatric disorder, for example bipolar psychotic disorder or current self-harm
- Current alcohol or drug dependency
- Current or previous diagnosis of an eating disorder

6.3 Recruitment:

Participants at moderate or high risk of BC will be recruited in 2 different ways:

- Receiving a targeted mailshot from the FHRPC – cover letter and PIS
- Viewing advertisement on Prevent Breast Cancer website/newsletter or on other websites and social media platforms such as Facebook and Twitter.

Recruitment from within the FHRPC

We have previously successfully recruited to research studies using mailshots to FHRPC participants. Other methods of recruitment will be used to expand diversity within the recruited population as it is known that the ethnicity of clinic attendees is mainly white. We aim to recruit around 30 women via the FHRPC mailshot and around 5 women from outside of the FHRPC via novel methods to make up the cohort of 35 women.

Invitation letters will be sent from the FHRPC at MFT only to women recorded as being moderate or high risk on the FHRPC database (≥17% or 1 in 6 lifetime risk). Based on previous experience regarding study recruitment using mailshot within the FHRPC a 15% uptake is expected therefore 200 letters will be posted to recruit 30 women. There are currently >1,000 women <35 years on the FHRPC database. Should recruitment not have been achieved within 4 weeks, a further mailshot will be done with the aim of completing recruitment. The number of letters posted will be based on the percentage uptake figure so far achieved.

Recruitment from outside of the FHRPC

Advertising on social media will follow University of Manchester "Social Media and CCTV – Guidelines for use in research" (display.aspx (manchester.ac.uk)), i.e. a personal account will not be used and specific individuals will not be targeted for recruitment. Interested potential participants will be asked to contact the study team by e-mail and will receive the PIS or can view it via the ISRCTN website where it will be attached to the study record.

All potential recruits

A date/time for telephone eligibility check will be organised by e-mail for completion of Screening Proforma. This phone call will be with Mary Pegington (Research Dietitian and study CI) to check eligibility and explain the study process. They will be asked if they have read and understood the PIS. There will be ample opportunity within this call for potential participants to ask questions. If they are interested in proceeding they will be e-mailed instructions to complete online consent (together with a Word document listing the questions that will be on the consent form that they can keep for their records), after which they will be provided links to download the app and complete the online questionnaires. We will ensure that there are at least 24 hours between receiving the PIS and receiving the link for the consent form by e-mail. In the intervening time there will be a telephone conversation to check eligibility and answer any questions.

In order to report uptake to the study and reasons for screen fail, if participants are not eligible we will ask if we can keep the answers they have given to the eligibility questions and record their verbal consent. With their consent we will complete all of the eligibility questions with them. By doing this we will identify and report multiple reasons for screen failure. We will not keep their name so that the information is anonymised. If they do not consent to us keeping this anonymous information we will destroy it.

6.4 Recruitment of women from outside of the FHRPC

Women recruited from outside of the FHRPC will be accepted if they meet the criteria for referral to Secondary Care as detailed in section 1.3.3 of NICE Clinical Guideline 164 "Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer"[10]. Women without a personal history of BC meeting the following criteria will be eligible:

- one first-degree[†] female relative diagnosed with BC at <40 years **or**
- one first-degree male relative diagnosed with BC at any age **or**
- one first-degree relative with bilateral BC where the first primary was diagnosed at <50 years **or**
- two first-degree relatives, or one first-degree and one second-degree[*] relative, diagnosed with BC at any age **or**
- one first-degree or second-degree relative diagnosed with BC at any age and one first-degree or second-degree relative diagnosed with ovarian cancer at any age (one of these should be a first-degree relative) **or**
- three first-degree or second-degree relatives diagnosed with BC at any age.

[†] first-degree relative = mother/father, sister/brother, daughter/son

[*] second degree relative = grandparent, grandchild, aunt/uncle, niece/nephew, half-sister/half-brother

Potential participants who are unsure of whether they meet the above criteria will be encouraged to contact the study team for clarification on whether they are eligible, particularly if any of the below are present within their family:

- bilateral BC
- male BC
- ovarian cancer
- Jewish ancestry
- sarcoma in a relative younger than age 45 years
- glioma or childhood adrenal cortical carcinomas

- complicated patterns of multiple cancers at a young age
- paternal history of BC (two or more relatives on the father's side of the family).

One of the FHRPC clinicians (e.g. Professor Tony Howell, Professor Gareth Evans, Dr Sacha Howell) will provide final decision on eligibility where family history does not clearly fit with the NICE referral guidelines.

6.5 Verification of risk for women recruited outside of the FHRPC

Before consent we will only verify family history verbally with the participant during completion of the Screening Proforma. It is recognised that this could result in individual(s) joining the study who do not meet the above NICE criteria, for example because of false information given by the participant due to deception or misunderstanding[17]. The risk this poses to the study is considered minimal due to the low possibility of this occurring. The risk to participants admitted erroneously to the study is also considered low as this is not a medical intervention and any distress would be dealt with in the same way for all participants by following the Distress Protocol document. A participant found to be not at increased risk of BC after consent to the study will be contacted before removal from the study and support will be provided by signposting to relevant agencies, e.g. their GP, or free counselling via the NHS.

6.6 Referral to FHRPC for women recruited outside of the FHRPC

Women identified as being at increased risk of breast cancer will be advised to seek referral to a local NHS FHRPC via their GP for full assessment and verification of family history, and the ability to access risk reducing treatments / enhanced screening as applicable. This will not a requirement to join the study and will not delay their commencement of the study.

6.7 Concerns or queries about services offered by the FHRPC (from both participants and non-participants)

For example, questions about eligibility for chemoprevention will be discussed anonymously with FHRPC staff and an appropriate response relayed to the individual. FHRPC patients with queries about their treatment, e.g. unsure when their next mammogram is due, will be reminded of the contact details for the FHRPC.

6.8 Reimbursement

There are no payments for taking part in the study.

6.9 Participants who withdraw consent (or lose capacity to consent):

Participants can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected. Participants can request that any data collected on them during their time in the study is destroyed. If it is brought to the attention of the research team that a participant has lost capacity to consent during the study, for example by the participant's GP, they would be withdrawn from the study. No further data would be collected. Once data has been anonymised it will not be possible to remove it. As only the participant can delete their own Facebook data (i.e. posts/comments/reactions/private messages they have made within the private Facebook group), their Facebook data will remain in the group for analysis (unless they remove it) and they are made aware of this on the PIS.

7) OUTCOME MEASURES

Table 1: Outcome measures and how they will be evaluated

Process to evaluate	Method of data collection	Aims to explore	Method of analysis / data to be presented	Timepoint of analysis
Recruitment methods	Recruitment data Interviews	Recruitment source of the participants Acceptability of recruitment procedure	Recruitment data, e.g. percentage response to mailshot, percentage uptake, breakdown of numbers recruited via each method Analysis of qualitative interviews	At end of recruitment phase Interviews at end of study
Consent method	Interviews	Acceptability of consent procedure	Analysis of qualitative interviews	Interviews at end of study
App: participant views	Interviews, final questionnaire, app feedback questionnaires, feedback received by e-mail	Acceptability of the app, barriers and facilitators to engagement, likes and don't likes within app, usability, likelihood of extended use.	Analysis of qualitative interviews, Analysis of final questionnaire and app feedback questionnaires: e.g. functions most liked, suggested changes.	Middle, during and end of study
App: participant usage	App usage data	Frequency of use, pattern of use across the two months, interaction with components within app.	Analysis of app analytics. • Number of times visited the app • Clicks on links within the app to external sites • Clicks from notifications • Clicks on help buttons • Flow through the app (which screens in which sequence) • Duration spent on each page / on the app in total	End of study
App: completion of information including logs	Download of completed information including logs	Correct completion of the settings information and completion frequency of the logs	Actual vs chosen frequency of completion of logs and change over time. Any errors in information inputted e.g. kg entered as stones and pounds. Number of logs completed for each health behaviour.	End of study

Process to evaluate	Method of data collection	Aims to explore	Method of analysis / data to be presented	Timepoint of analysis
HCP time required	HCP time logs	HCP time required for moderating Facebook chat group, and through e-mail/private message support.	Breakdown of HCP time spent in total and per person on moderating Facebook chat group, responding to private messages and e-mails.	End of study
Engagement with the Facebook group	Download of data from the group.	Number of participant interactions in the Facebook group, pattern of interactions over the two months.	Analysis of Facebook download (see 9.1.1)	End of study
Time needed to collect, clean and analyse data	Staff time logs	Estimate of staff time and costs for larger study	Breakdown of staff time spend on the study, including cleaning the app data.	End of study

8) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

Table 2: Data collection methods

Method of data collection	Source data	Confidentiality plan
Recruitment data	Screening Proforma E-mails from interested participants to secure nhs.net e-mail address	Screening Proformas will be completed directly on to the University of Manchester secure server. E-mails will be kept on the secure server until recruitment data is entered for full reporting of study recruitment data[18, 19]. E-mails to the NHS.net e-mail address are stored on NHS servers.
Information held on app	Information completed by participants on app, e.g. health logs, entered onto app by participants (see separate document: "App screenprints"). When participants enter data into the app it is stored on the University of Manchester secure 'Storage Connect' drive Participants do not enter their name on to the app. Data downloaded from University of Manchester 'Storage Connect' drive that comes from app entries.	Data from completed logs saved on 'Storage Connect' which is a secure University of Manchester drive. Data will be held in anonymous form without names therefore downloads will also be anonymous. Anonymous data downloads will be held on the University of Manchester secure server for analysis.
Questionnaires	Questionnaires completed by participant via Qualtrics, a GDPR-compliant online survey tool approved by University of	Data will be downloaded from Qualtrics in anonymous form and stored on secure University of Manchester servers.

	Manchester Information Governance Office.	Participants enter their study ID number when completing these, instead of their name.
App usage data	Data downloaded from University of Manchester 'Storage Connect' drive that comes from app usage tracking.	As per "Information held on app" above.
E-mails	All e-mail correspondence with participants will be via the secure nhs.net address which is hosted on secure NHS servers.	No e-mails will be printed or forwarded from this address. E-mails to the NHS.net e-mail address are stored on NHS servers.
Interviews (see document: Qualitative study plan and interview schedule)	Transcripts of interviews.	Audio-recordings and transcripts will be anonymised and held on secure University of Manchester drives. Transcription will be done by a university-approved transcription service who are under a confidentiality agreement. Transfer of recordings to the transcription service will be in line with University of Manchester guidance which allows the use of either University of Manchester Dropbox Service or Zendto. In subsequent write up, direct quotes may be used but will not be accompanied by names or other identifying information.
Facebook data	Data, e.g. the text of posts, will be copied and pasted from the private Facebook group to Excel with identifying information removed. Study ID numbers will be used instead of names. Number of reactions to each post will be entered.	No identifying information will be in the Excel document which will be saved on the secure University of Manchester servers. Access to the private Facebook group is by invite only to study participants who are reminded not to post personal information (such as address, family details).

Study data and material will be accessible by the study team and may also be looked at by individuals from the University of Manchester or from regulatory authorities, for monitoring and auditing purposes, and this may include access to personal information.

9) STATISTICAL CONSIDERATIONS

9.1 Statistical Analysis

This study is to assess the acceptability and usability of the app before a larger feasibility study is planned and as such is not powered according to the outcome measures of that larger study.

9.1.1 Quantitative analysis

Key baseline demographics and health behaviours will be presented, e.g. smoking status, alcohol intake and PA in previous week, age, living circumstances, ethnicity[20], education level, employment status, sociodemographic status (deprivation score: English Indices of Multiple Deprivation [EIMD] derived from full postcodes[21]), children, previous attendance at FHRPC, using mean (SD), median (25^{th}-75^{th} percentile), n (%) as appropriate.

Data from the private Facebook group will be extracted by copying and pasting into Excel, and anonymised. Data will be comments, posts (or descriptions of posts in the case of photo or video posts), numbers of reactions. The use of an application programme interface (API) will not be considered for this small study. Quantitative data will be presented, e.g. number of comments in reaction to weekly educational posts (total, average number per post and range, subjects evoking the highest number of comments, number of users commenting), number of posts by participants, number of likes and reactions (total, average number per post and range, subjects evoking the highest number of reactions, number of users reacting), number of private messages to the moderators (number of users messaging, total number of messages received and sent)[22]. No qualitative analysis is planned on the text.

App usage data (number of times visited the app, clicks on links within the app to external sites, clicks from notifications, clicks on help buttons, flow through the app (which screens in which sequence), duration spent on each page / on the app in total) will also be presented descriptively.

9.1.2 Qualitative analysis

Transcripts will be analysed using thematic analysis[23]. Analysis will be inductive: open-ended, exploratory, and driven by the data. Thematic analysis is arguably the foundation of all qualitative analyses. It is free from theoretical bonds and is therefore adaptable to a wide range of methodologies. This freedom of epistemology means that the qualitative data from this study can provide a parallel and complimentary perspective to the other methods of data collection being used in this study. Thematic analysis can account for both individual and group consensus, so that both convergent and divergent experiences across the corpus of the data can be taken into account as the process of analysis involves searching for all salient themes that emerge from the data. Analysis will be conducted by a trained qualitative researcher (University of Manchester staff). Codes will be discussed, revised and refined in conjunction with Professor David French.

9.2 Sample Size

The study will recruit 35 women, of which up to 20 will be interviewed. A decision on when to stop further interviews will be made when no novel insights appear in the interviews according to the concept of "information power"[24]. The study sample size of 35 will allow for a 20% drop out and selection of a range of women to interview, for example both heavy and light engagers with the app. The study is not powered to assess efficacy of the app at changing health behaviours but two months usage by 28+ users will enable the quantitative data to give helpful indications of changes required before a larger efficacy study.

10) DATA MONITORING AND QUALITY ASSURANCE

The study will be subject to the audit and monitoring regime of the University of Manchester. The Study Management Group (Section 1) is responsible for ensuring the appropriate, effective and timely implementation of the study including monitoring adherence to protocol. The day-to-day

operational management of the study is co-ordinated by Mary Pegington who reports weekly to Dr Michelle Harvie.

10.1 Data retention

The anonymised dataset will be stored on the secure University of Manchester research drive for 10 years. Consent forms will be downloaded from Qualtrics and kept on the secure University of Manchester research drive for two years after the end of the study as per University of Manchester "Records Retention Schedule" (https://documents.manchester.ac.uk/display.aspx?DocID=6514) and the file names will contain the participant initials (reflecting the name on the consent form) and not the study ID as this link is to be broken. After data analysis is complete, the fully anonymised data will be uploaded on to Figshare as per University of Manchester guidance and will remain there indefinitely (Sharing (The University of Manchester Library)).

11) SAFETY CONSIDERATIONS AND ADVERSE EVENTS

This study is considered low risk. Women in the study have a family history of BC and the study team will be sensitive regarding this – see Distress Protocol document. During the study, data on alcohol intake and weight will be downloaded weekly and if app entries indicate either 1) a weight increase of 5% from the first weight entered (e.g. an increase from 60 to 63 kg, or 9 st 6 lb to 9 st 13 lb), or 2) >14 units alcohol per week for three weeks, we will contact the participant by e-mail to offer support (by e-mail or phone consultation) and it will be the participant's choice whether to accept that support. As part of the study, signposting is available for women who wish to stop smoking or reduce alcohol intake.

Should any of the interviews take place in person we will follow the University of Manchester policy on lone working (Lone working (The University of Manchester)) for example the interviewer will use a buddy system to ensure that a designated colleague is aware of their movements. Mary Pegington will be the buddy in the first instance but if she is not available the buddy will be another member of the research team. The interviewer will provide the buddy with date, time and address of interview and name of interviewee in a password-protected document by e-mail, along with their car make, model, colour and registration. The interviewer will call the buddy before entering the property, and upon exiting the property. In the event of no response, the buddy will call the interviewer at 30 minutes after the expected time of departure from the address, and again at 60 minutes. If no response at this time they will inform the interviewee's line manager (David French) and the police. Details of all calls and attempted calls will be documented on the password-protected document. On completion of the interview and safe departure of the interviewee, the password-protected document will be deleted by the interviewer and the buddy. Appropriate procedures will be followed in pandemic conditions, for example mask wearing, space and ventilation, and sanitising of surfaces.

The risks to confidentiality are minimal as all data is entered directly on to secure electronic platforms and participants are reminded not to enter personal information (such as address, family details) on to the private Facebook group.

12) PPI INVOLVEMENT

A PPI participant is a member of the TMG and has been involved with:

- Review of the protocol

- Review of study paperwork including PIS and invitation letters

PPI participants will be reimbursed according to NIHR guidance (https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392).

13) POTENTIAL LIMITATIONS

The study is only two months long therefore we will be unable to assess app usage over a longer timeframe. However this study is not aiming to achieve that, and the questionnaires and interviews will inform whether longer term use is likely, and changes that are required to improve engagement and longevity that will be employed in the subsequent feasibility study.

14) PLANNED FUTURE STEPS

As per "Developing and evaluating complex interventions: the new Medical Research Council guidance"[15], this study forms part of assessing feasibility before the evaluation phase and after this study we plan to continue following this guidance.

Further development and testing

If this study shows that the app is acceptable to the target audience, it will be used in a future planned feasibility study. The feasibility study will in turn inform the feasibility of a larger, definitive multicentre, randomised controlled trial to test the effectiveness and cost-effectiveness of the app amongst young women at increased risk of BC.

Implementation

Should the intervention be effective it could be implemented amongst the following groups:

- Introduction to all FHRPCs in the UK
- Widen scope to women at increased risk of BC not only by means of family history, e.g. Dr Sacha Howell's project in Manchester plans identify more women at increased risk due to breast density and single-nucleotide polymorphisms (https://research.cmft.nhs.uk/news-events/new-study-addresses-early-breast-cancer-detection-in-high-risk-young-women)
- Widen scope to include women at increased risk above age 35
- Other high risk cancer groups, i.e. lynch syndrome

15) PANDEMIC CONTINGENCY PLAN

This study includes optional face-to-face interviews with all other aspects of the study being remotely-delivered. Therefore this study will be able to continue in the event of a pandemic and the option of face-to-face interviews will be withdrawn if these are no longer considered safe or not allowed under current restrictions. Interviews will instead take place via Microsoft Teams or phone.

16) PEER REVIEW

This protocol has been reviewed by all Co-Investigators. The Co-Investigators have a wide base of clinical and research expertise: behavioural psychology (Prof David French, Dr Julia Mueller), health data science (Dr Alan Davies), research dietetics (Mary Pegington*, Dr Michelle Harvie*), oncology (Prof Tony Howell*, Dr Sacha Howell*) and genetics (Prof Gareth Evans*). Five of the team are

affiliated with the FHRPC at Wythenshawe Hospital (*). We also have a PPI representative from our FHRPC as one of our co-investigators. The team have published over 1,000 peer-reviewed articles between them.

17) ETHICAL AND REGULATORY CONSIDERATIONS

NHS Research Ethics Committee and HRA approval will be obtained before commencing research.

The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

18) STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

19) FUNDING and RESOURCES

MP (CI) is funded for this study by National Institute for Health Research (NIHR) Manchester Biomedical Research Centre (BRC). Study costs are funded by NIHR Manchester BRC, for example:

- Admin time at MFT for identifying participants, posting invitation letters, tracking questionnaire completion.
- A trained qualitative researcher from The University of Manchester will design and perform the interviews, analysis, and write up.
- Research Software Engineer support at University of Manchester.

20) PUBLICATION POLICY

Following completion of the study, data will be analysed and results published in a peer-reviewed journal. If participants have given consent to be contacted with a summary of the results they will receive this after publication.

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