

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

### Participant Information Sheet

You are being invited to take part in a study to test whether a health app is acceptable to young women at increased risk of breast cancer. Before you decide whether to take part, it is important for you to understand why the study is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

#### **1. About the study**

➤ **Who will conduct the study?**

The study is led by **Mary Pegington** ([lifestyleresearch@nhs.net](mailto:lifestyleresearch@nhs.net)), Breast Cancer Research Dietitian in the School of Cancer Sciences at The University of Manchester and at The Nightingale Centre, Wythenshawe Hospital (Manchester University NHS Foundation Trust or MFT). Other members of the study team are:

**Dr Alan Davies**, Senior Lecturer in Health Data Science, The University of Manchester

**Dr Julia Mueller**, Research Associate, MRC Epidemiology Unit, The University of Cambridge

**Dr Michelle Harvie**, Research Dietitian, The Nightingale Centre at Wythenshawe Hospital, MFT

**Professor David French**, Professor of Health Psychology, The University of Manchester

**Professor Tony Howell**, Professor of Medical Oncology, University of Manchester / The Nightingale Centre at Wythenshawe Hospital, MFT

**Dr Sacha Howell**, Senior Lecturer and Honorary Consultant in Medical Oncology, The University of Manchester / The Christie NHS Foundation Trust / The Nightingale Centre at Wythenshawe Hospital, MFT

**Professor Gareth Evans**, Consultant Clinical Geneticist, The Nightingale Centre at Wythenshawe Hospital, MFT

A Clinical Trials Administrator from MFT will be assisting with administration on the study.

➤ **What is the purpose of the study?**

We have developed an app to help promote healthy behaviours amongst young women at increased risk of developing breast cancer. Healthy behaviours such as eating healthily and staying a healthy weight, getting plenty of exercise and not drinking too much alcohol could lower the chances of developing breast cancer. We now wish to find out whether women find the app acceptable and user-friendly, and how we can improve it.

➤ **Am I suitable to take part?**

You can join the study either if:

- You attend the breast cancer Family History, Risk and Prevention Clinic at The Nightingale Centre, Wythenshawe Hospital, Manchester

**OR**

- You are at increased risk according to the guidelines below.

We hope that 35 women will join the study.

➤ **Am I at increased risk of breast cancer?**

If you have received an invite letter for the study from The Family History, Risk and Prevention Clinic at The Nightingale Centre, Wythenshawe Hospital then you are at increased risk and can join the study.

If you have heard about the study from somewhere else then you are at increased risk if you have:

- one first-degree female relative<sup>†</sup> diagnosed with breast cancer younger than age 40 years **or**
- one first-degree male relative diagnosed with breast cancer at any age **or**
- one first-degree relative with breast cancer in both breasts where the first cancer was diagnosed younger than age 50 years **or**
- two first-degree relatives, or one first-degree and one second-degree\* relative, diagnosed with breast cancer at any age **or**
- one first-degree or second-degree relative diagnosed with breast cancer 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 breast cancer at any age.

<sup>†</sup> first degree female relative = mother, sister, daughter

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

Please contact the study team if you are unsure about your risk, or if you have any of the below in your family which may affect your risk:

- a relative who has had breast cancer in both breasts
- male breast cancer
- ovarian cancer
- sarcoma in a relative younger than 45 years
- glioma or childhood adrenal cortical carcinomas
- complicated patterns of multiple cancers at a young age
- two or more relatives on the father's side of the family
- you have Jewish ancestry

➤ **Will the outcomes of the study be published?**

The study will show whether the app is or is not acceptable to young women. The study will be written up and published in scientific journals and on the trial registry [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and may be presented at scientific conferences. You and the other participants will not be identified in any publication or presentation. At your request we will contact you with the study findings once they are published.

➤ **Who has reviewed the study?**

The study has been reviewed by NHS Wales Research Ethics Committee 3, reference 22/WA/0164.

➤ **Who is funding the study?**

This study is funded by the NIHR Manchester Biomedical Research Centre.

## **2. What would my involvement be?**

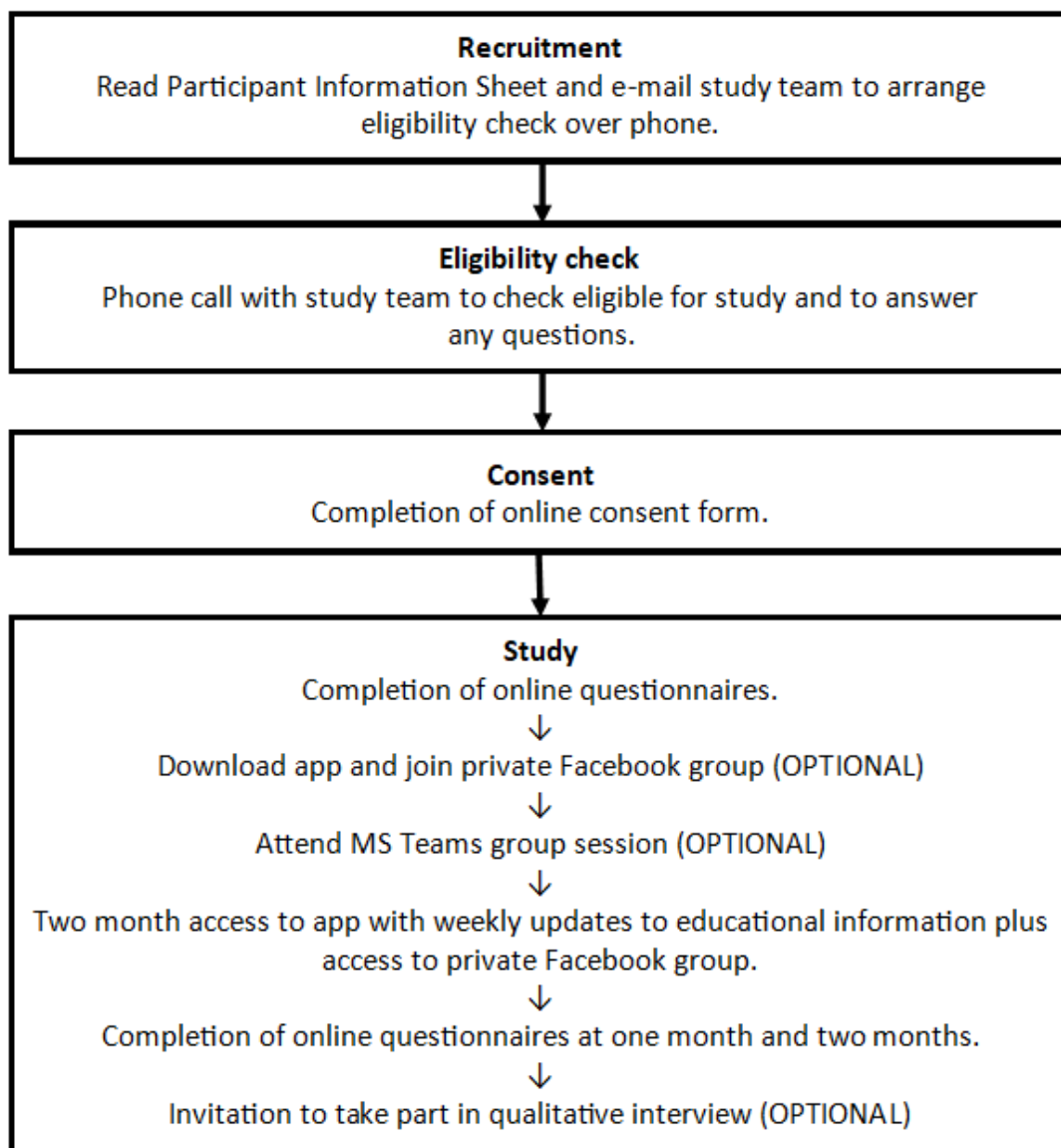
➤ **What would I be asked to do if I took part?**

The study pathway is shown in the diagram below. After you have completed the online consent form, you will be asked to complete some questionnaires before you download the app and join the private Facebook group (joining the Facebook group is optional). We ask you to use the app and Facebook group for two months and answer some more questionnaires at one month and at the end. The app contains information about what you can do to reduce your risk of breast cancer and encourages you

to regularly monitor your health behaviours such as exercise and weight by logging them in the app. You can use the app and Facebook group as much or as little as you like in the two months. If you do not have a Facebook account or do not wish to join the private group you are still welcome to join the study and use the app.

You will be invited to an optional online group session at the start of your time on the study with other young women who are at increased risk of breast cancer. In this session you will meet some of the researchers, learn why health behaviours such as staying a healthy weight and not drinking too much alcohol are important when you are at increased risk of breast cancer, and have a chance to meet other young women in the study. If you do not wish to attend this session you are still welcome to join the study. The session will last around 45 minutes and will happen in the evening on Microsoft Teams. You will be able to join the group session via a link and do not need to have Microsoft Teams installed on your device, or have a Microsoft Teams account to be able to join. The session will not be recorded.

After you have used the app for two months you may be invited to take part in an interview with a specialist researcher. The interview is optional and we aim to interview up to 20 women.



You do not need any special experience to take part. The researchers are looking for women from different backgrounds with varying skills and experiences to offer their opinions and feedback. Everyone taking part will be treated with complete respect and your opinions and experiences will be listened to without judgement.

➤ **Tell me more about the private Facebook group**

You will be invited to join the Facebook group which is only open to women in the study who have been invited by the study team. The Facebook group is ‘private’ meaning that no-one can see that you are a member of the group or any posts in the group unless they are also in the group. The group is also ‘hidden’ meaning that only members of the group can see that the group exists on Facebook. Therefore conversations within the group will only be visible to other women in the study. We will use this group to share health information and stimulate discussion of health topics amongst the study participants. A member of the study team will be in the group and will be able to answer questions and ensure accuracy of any information being shared. We hope that this group will be a friendly and welcoming forum where you will find support from other young women who are at increased risk of breast cancer.

➤ **Tell me more about the interviews**

The location of the interview is your decision: your home, remotely on Microsoft Teams, or over the phone. If face-to-face meetings are not recommended because of the COVID-19 pandemic, or if you do not live in/near Manchester, the interview can take place on Microsoft Teams or phone. It will take place at a time convenient to you and will last around 60 minutes but can be shorter or longer depending how much you want to say. The interview will be done by a trained interviewer from the University of Manchester.

During the interview you will be asked a number of questions about the study, your beliefs about breast cancer and health behaviours, the app and Facebook group. The researcher will ask open questions which will allow you to discuss your experience and opinions. There are no right or wrong answers. All interviews will be recorded (sound only, no video will be taken).

➤ **Tell me more about the questionnaires**

There are four questionnaires in the study which are all to be completed online and are detailed below.

Questionnaire	Description	Time point	How long will it take to complete each time?
Demographics and Health Behaviours Questionnaire	This questionnaire asks for your address, date of birth, GP details, height and weight, weight when you were age 18, current health behaviours such as smoking and alcohol intake, information about you such as who you live with at home and your ethnic group	Once: after consent	10 minutes
Breast cancer risk beliefs questionnaire	This questionnaire asks what you think affects risk of breast cancer	Twice: after consent and at 2 months	10 minutes
Mobile Application Rating Scale (uMARS) questionnaire	This questionnaire asks about your opinions on the app, such as whether you are happy with the amount of interaction you get from it, and whether you think it is easy to navigate and contains good quality information	Twice: at 1 and 2 months	10 minutes

App feedback questionnaire	This questionnaire goes through the different parts of the app allowing you to score them and suggest changes you would like to see.	Optional – you can complete this at any point during the study if you wish to give feedback on the app	5 minutes
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➤ **What contact will I have with the study team and health professionals?**

- You will have e-mail and phone contact with the study team before you consent to the study.
- If you choose to attend the optional MS Teams session and/or join the private Facebook group these are run by the study team.
- We will e-mail you a link to complete the online consent form, as well as a list of questions on the consent form for your records.
- After you have completed the online consent form we will email you your unique study identification number and a link to download the app to your phone.
- We will e-mail you links to complete the study questionnaires when they are due.
- We will e-mail you a copy of the letter we send to your GP when you join the study.
- If you don't complete the study questionnaires we will aim to e-mail you after 3 days and phone you after 5 days to remind you and see if we can solve any problems you might have with them.
- During the study we will contact you by e-mail to offer support, e.g. by e-mail or offering a phone consultation with Mary Pegington, if we notice that your weight increases by 5% from the first weight you entered (e.g. an increase from 60 to 63 kg, or 9 st 6 lb to 9 st 13 lb), or if you drink more than 14 units of alcohol per week for three weeks. If we contact you, you can decide whether you wish to have this additional support.
- If we would like to interview you we will contact you by phone to invite you. If you would like to take part this can be arranged at a time and place to suit you.

➤ **Will I be compensated for taking part?**

There is no compensation for taking part in the study.

➤ **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. You can contact Mary Pegington by e-mail ([lifestyleresearch@nhs.net](mailto:lifestyleresearch@nhs.net)) if you would like to take part. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the study once it has been anonymised as we will not be able to identify your specific data. It will also not be possible for us to remove any of your posts, 'likes' or comments from the private Facebook group as only you can do this. You are able to remove these at any time. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

➤ **What if I am not eligible?**

We will go through the eligibility questions over the phone. If you are not eligible to join the study we will ask if we can keep the answers you have given to the eligibility questions so that we can report in our results the number of women interested in the study, and the reasons why interested women could not join. We will not keep your name, so no-one will be able to link the information we keep back to you. If you do not want us to keep this anonymous information we will destroy it.

➤ **What are the possible benefits of taking part?**

We hope that you will learn more about what you can do to reduce your risk of developing breast cancer, and the app will support you in making changes to your health behaviours. You will have the

opportunity to meet other young women who are at increased risk of breast cancer and the private Facebook group will offer peer and health care professional support. You will be contributing to breast cancer research and helping to shape future research using the app.

➤ **What are the possible disadvantages and risks of taking part?**

You may find taking part in the group session or the discussions on the Facebook group upsetting, for example if the conversations are around the experience of having family members with breast cancer and this brings back upsetting memories for you. The experienced study team will be on hand to speak to, or we can support you in accessing psychological support including free NHS counselling (information on how to access this is available here: <https://www.nhs.uk/mental-health/talking-therapies-medicine-treatments/talking-therapies-and-counselling/nhs-talking-therapies/>).

➤ **Where can I go for more information and support?**

You can find information on the signs and symptoms of breast cancer on the Prevent Breast Cancer website (<https://preventbreastcancer.org.uk/about-breast-cancer/signs-symptoms/>). If you have any concerns about symptoms or about your family history, speak to your GP.

### **3. Data Protection and Confidentiality**

➤ **What information will you collect about me?**

If you take part in this study we will need to collect information that could identify you, called “personal identifiable information”. Specifically, we will need to collect your:

- Name
- Date of birth
- Address and postcode
- Telephone number
- GP name and practice address
- Record of consent
- Ethnicity
- Information that you post within the private Facebook group
- Health and health behaviour information

This information will be accessed by members of the study team. If you take part in an interview, the researcher will record your interview using either an encrypted audio recorder for phone and face-to-face interviews or Microsoft Teams audio recording facility for interviews held on Microsoft Teams. The recording will be named with your unique study identification number instead of your name. The interview will be transcribed (written out) and the recording deleted. Any identifiable information will be removed from the transcribed document and you will be allocated a pseudonym (fake name) to protect your identity. As with the nature of interview research, we may wish to use quotes in reports, publications or presentations but you will not be identified. Anonymous transcripts of all the interviews will be kept on a secure University of Manchester drive.

➤ **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

➤ **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](#). If you would like more general information on how researchers use data about patients, please visit: [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)

Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the study team.

➤ **Will my General Practitioner (GP) be informed of my participation in the study?**

Yes, your GP will be informed. We will ask for your address and your GP details so that we can write to your GP and you will receive a copy of the letter.

➤ **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this study. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

- All e-mails to you will be via the secure nhs.net e-mail address ([lifestylesearch@nhs.net](mailto:lifestylesearch@nhs.net)) which is hosted on secure NHS servers.
- A download of your completed online consent form stored separately for 2 years on secure servers belonging to The University of Manchester.
- No pictures or recordings of the optional online group session will be taken.
- When you consent to the study you will be given a unique study identification number that is only known to the study team (known as pseudonymised).
- You will enter your unique study identification number instead of your name when you complete the online questionnaires. The information we download from the app and from the private Facebook group will also be stored using this number instead of your name.
- The optional online group session will be led by Mary Pegington and may involve other members of the study team who are employed by organisations other than the University of Manchester and MFT (see list of study team) who have appropriate approvals to work on the study.
- When the study is complete (the final interview has taken place) the data will be made anonymous and the study team will no longer be able to link your data to you. After this point you will not be able to request that your data is withdrawn from the study.
- Individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the study is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a study participant.
- If you participate in an interview on Microsoft Teams it will be recorded in Microsoft Teams and your personal data will be processed by Microsoft. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the Microsoft Teams platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

- If you participate in an interview on the phone or face-to-face this will be recorded on an encrypted audio recording device, downloaded to secure University of Manchester drives as soon as possible, and deleted from the device.
- The sound recording of all of the interviews will be transferred securely to a company approved by the University of Manchester who will 'transcribe' (transfer the sound recording into a written document) the interview and transfer this securely back to the study team for analysis. Recordings and transcriptions will be transferred securely and the company will have signed an agreement with the University of Manchester which includes confidentiality clauses.
- At the end of the study we will download the data from the Facebook group (comments, posts and 'likes' or other reactions) and store these in anonymous form (all names and identifying information removed) before we analyse them.
- We will keep the anonymised dataset on University of Manchester secure servers for 10 years after the end of the study.
- At the end of the project we will store all of the data online in "Figshare" at the University of Manchester Library. All of this data will be anonymous, e.g. there will be no names, postcodes etc. This is standard practice in research so that other researchers can access our anonymised data and use it for further research or to check our results.
- If, during the study, we have concerns about your safety or the safety of others, we will inform your GP.
- If, during the study, you disclose information about any current or future illegal activities, we have a legal obligation to report this and will therefore need to inform the relevant authorities.
- Individuals from the University of Manchester, MFT or regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident.

#### **4. What if I have a complaint?**

##### ➤ **Contact details for complaints**

If you have a complaint that you wish to direct to members of the study team, please contact:

**Mary Pegington, Research Dietitian:** [lifestyleresearch@nhs.net](mailto:lifestyleresearch@nhs.net)

**If you wish to make a formal complaint to someone independent of the study team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact:**

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: [research.complaints@manchester.ac.uk](mailto:research.complaints@manchester.ac.uk) or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email [dataprotection@manchester.ac.uk](mailto:dataprotection@manchester.ac.uk) or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office about complaints relating to your personal identifiable information](#). Tel 0303 123 1113.

In the unlikely event that something does go wrong and you are harmed during the study you may have grounds for a legal action for compensation against the University of Manchester but you may



have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

## **5. Additional information regarding COVID-19**

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this study will be conducted that ensures we are adhering to the latest government advice in relation to social distancing as well as taking all reasonable precautions in terms of limiting the spread of the virus. If you have any additional queries about any of the information provided, please contact the study team.

➤ **Are there any additional considerations that I need to know about before deciding whether I should take part?**

You will only have face-to-face contact with the study team if you opt to and are chosen to be interviewed and the interview happens at your home. If it is appropriate, for example if you are in a vulnerable group or have symptoms of COVID-19 or if government guidelines limit non-essential travel, we will do the interview by phone or Microsoft Teams instead.

➤ **What additional steps will you take to keep me safe while I take part?**

If you have a face-to-face interview we will follow public health guidelines that are current at that time. This may involve wearing face masks, staying the recommended distance away from each other, and ensuring adequate ventilation.

➤ **What if I have additional queries?**

If you have additional queries about these COVID-19 measures please contact: Mary Pegington, Research Dietitian: [lifestyleresearch@nhs.net](mailto:lifestyleresearch@nhs.net)

## **6. Contact Details**

If you have any questions about the study or if you are interested in taking part then please contact: **Mary Pegington, Research Dietitian: [lifestyleresearch@nhs.net](mailto:lifestyleresearch@nhs.net)**