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# Acceptability of radiofrequency assessment of breast density

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| **Submission date**<br>09/04/2025 | **Recruitment status**<br>Recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>10/04/2025 | **Overall study status**<br>Ongoing | |
| **Last Edited**<br>18/11/2025 | **Condition category**<br>Cancer | |

## Plain English summary of protocol

Background and study aims
Breast cancer affects 1 in every 7 women in the UK and is the most common cause of death in women aged 35 to 49 years old. Younger women who are more likely to develop breast cancer may be identified earlier by having a breast cancer risk assessment. This means they could be offered earlier screening and prevention measures to increase their chance of survival. One of the strongest risk factors for breast cancer is called breast density. This is measured using mammograms (breast X-rays), which are used in breast cancer screening. One problem with using mammograms as part of breast cancer screening is that women need to have a second appointment at a specialist centre. However, women in this age group are likely to be employed, have children and other care responsibilities. This presents a barrier to attending screening in this group. Previous research has found that women would prefer risk assessments to be completed in a single appointment. A company called Micrima Ltd. have developed a desktop device to assess breast density. This device offers a painless, simple and quick density score for women without needing a mammogram. In this study, we plan to assess the acceptability of the Mi~Scan® device to patients and healthcare professionals. We will also conduct interviews with healthcare professionals to explore their views regarding the acceptability and usability of the Mi~Scan® device.

Who can participate?
The following criteria must be met for entry to the study:
1. Born biologically female
2. Aged 30-49 years at time of consent
3. Able to provide informed consent
4. Registered at participating GPs if recruited via the primary care route.

What does the study involve?
We will recruit 240 women to undergo the Mi~Scan® breast density assessment and complete a short questionnaire. We will recruit approximately half (i.e. 120) of the women in general practice settings and half (i.e. 120) in community settings. A sub-sample of (up to) 24 women who had the Mi~Scan® procedure will participate in focus groups. Women will be suitably reimbursed in the form of shopping vouchers for taking part.

What are the possible benefits and risks of participating?
Women who take part will be contributing to research aimed at identifying women who are at most risk of developing breast cancer, before it happens. The results of this study may help women in their community so that more women survive breast cancer in the future.
As women will be undressed to the waist for the procedure, they may feel embarrassed. However, the person conducting the scan will be a woman who is a qualified health professional with lots of experience working with women. During the focus group, there is a risk that women may find some of the topics slightly distressing, for example, if they know anyone who has been impacted by breast cancer. There is a distress policy in place and women will be provided with information on organisations in Manchester that can offer support.

Where is the study run from?
The University of Manchester (UK)

When is the study starting and how long is it expected to run for?
November 2024 to November 2025

Who is funding the study?
1. Greater Manchester Cancer Alliance (UK)
2. The Sarah Harding Breast Cancer Appeal Fund (UK)
3. National Institute for Health and Care Research (NIHR) Manchester Biomedical Research Centre (BRC) (UK)

Who is the main contact?
Dr Sacha Howell, sacha.howell@nhs.net

# Contact information

### Type(s)
Scientific, Principal investigator


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Public


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# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**Integrated Research Application System (IRAS)**
349447

**ClinicalTrials.gov (NCT)**
Nil known

# Study information

**Scientific Title**
A study to determine the acceptability to patients and NHS staff of radiofrequency assessment of breast density (Mi~Scan®) in primary care and the community setting

**Study objectives**
To assess the acceptability to 30-49 year old women receiving and healthcare professionals delivering a new breast density scan (Mi~Scan®).

**Ethics approval required**
Ethics approval required

**Ethics approval(s)**
approved 21/03/2025, West of Scotland REC 4 (1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; +44 (0)141 314 0213; ggc.wosrec4@nhs.scot), ref: 25/WS/0016

**Study design**
Cross-sectional cohort study

**Primary study design**
Observational

**Study type(s)**
Other, Screening

## Health condition(s) or problem(s) studied
Early detection of breast cancer risk in younger women

## Interventions
A cross-sectional cohort of 240 women, aged 30 to 49 years, will be recruited to undergo the Mi~Scan® breast density assessment. We anticipate recruiting approximately half (i.e. 120) of the women in GP settings and half (i.e. 120) in community settings (non-medical, local facility). Further, we will aim to recruit a minimum of 60 women (25%) of Black ethnicity. The Mi~Scan® procedure will be delivered by healthcare professionals in both GP and community settings. Following the Mi~Scan® procedure, participants will complete a short questionnaire on their views on acceptability and to collect demographic information.

A sub-sample of women who had the scan will take part in follow-up focus groups (total sample of up to 24 women, up to 8 women in each focus group). Focus groups will help to understand the extent to which women found the Mi~Scan® procedure acceptable with regards to the device itself, the location of the scan, and the interaction with the healthcare professional. These focus groups would help to inform whether any changes in the approach are likely to be required to make the procedure more acceptable to women.

We will conduct semi-structured interviews with healthcare professionals involved in the study to explore the acceptability of the Mi~Scan® device in primary care and community settings. This will include the healthcare professionals who have conducted the scans and managerial representatives from the GP surgeries involved in the study. These individuals should provide useful information on the acceptability of the Mi~Scan® procedure from the healthcare professional's perspective. This will help to inform the implementation of the Mi~Scan® breast density device in routine healthcare.

## Intervention Type
Other

## Primary outcome(s)
Acceptability of the Mi~Scan® device, measured using the standard Theoretical Framework for Acceptability questionnaire at baseline, immediately after participants have had the breast density scan

## Key secondary outcome(s))
Safety and performance of the Mi~Scan® device, measured using the following measures, all recorded at a single timepoint:
1. The reporting of adverse events: the number of adverse events and serious adverse events recorded through the study will be recorded and summarised using descriptive statistics.
2. The pain and discomfort domains of the questionnaire as the device should not cause any physical discomfort or pain. As such, the two questions on the 5-point Likert scale that imply there was some pain ("I found the scan to be a painful procedure" answers "strongly agree" and "agree") or discomfort ("I found the scan to be a comfortable procedure" answers "Strongly disagree" and "disagree") will be recorded as a percentage of the total responses in a descriptive analysis.
3. Focus group data: the focus groups with women who had the scan will explore the acceptability of general device performance and safety
4. Interview data: interviews with healthcare professionals who delivered the scans will explore the acceptability of general device performance and safety

### Completion date
28/02/2026

## Eligibility

### Key inclusion criteria
1. Born biologically female
2. Aged 30-49 years at time of consent
3. Able to provide informed consent
4. Registered at participating GPs if recruited via primary care route

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
30 years

### Upper age limit
49 years

### Sex
Female

### Total final enrolment
0

### Key exclusion criteria
1. Prior breast cancer diagnosis
2. Have had both breasts removed (a double mastectomy)
3. Are known to be currently pregnant (does not require pregnancy test) or breastfeeding
4. Are already under follow-up in breast cancer family history clinic or have a known mutation in a high-risk cancer gene such as BRCA1 or BRCA2
5. Have any implantable electronic devices (e.g., a cardiac pacemaker or implanted defibrillator)
6. Have non-removable nipple piercings or body modifications
7. Have had breast implants or augmentation surgery
8. Were not born biologically female
9. Have areas of broken skin on breast or armpit
10. Have conductive or electronic (tech) tattoos
11. Inability to understand written and verbal English

### Date of first enrolment
01/05/2025

### Date of final enrolment

28/02/2026

# Locations

## Countries of recruitment
United Kingdom

England

## Study participating centre
**Manchester Integrative Medical Practice at Moss Side Health Centre**
20 Monton Street
Manchester
England
M14 4GP

## Study participating centre
**Surrey Lodge Medical Centre**
11 Anson Road
Manchester
England
M14 5BY

## Study participating centre
**The Arch Medical Practice**
Hulme Medical Centre
175 Royce Road
Hulme
Manchester
England
M15 5TJ

## Study participating centre
**Hawthorn Medical Centre**
Unit K, Fallowfield Shopping Centre
Birchfields Road
Fallowfield
Manchester
England
M14 6FS

**Study participating centre**
**World Harvest Christian Centre Manchester**
21 Seymour Road, South Clayton
Manchester
England
M11 4PG

**Study participating centre**
**Kath Locke Community Health and Resource Centre**
123 Moss Lane East, Hulme
Manchester
England
M15 5DD

**Study participating centre**
**Transformation Community Resource Centre**
1st Floor, Richmond House, 11 Richmond Grove
Manchester
England
M13 0LN

**Study participating centre**
**The Robert Darbishire Practice**
Rusholme Health Centre
Walmer Street
Rusholme
Manchester
England
M14 5NP

**Study participating centre**
**Gorton Central**
Highmead Street
Abbey Hey
Manchester
England
M18 8PE

**Study participating centre**
**Moss Side Library and Leisure Centre**
Library & Leisure Centre

Hulme High Street
Hulme
Manchester
England
M15 5NN

**Study participating centre**
**Brunswick Parish Church**
Brunswick Street
Manchester
England
M13 9SX

**Study participating centre**
**Alfurqan Islamic Centre**
42 Great Southern Street
Manchester
England
M14 4EZ

**Study participating centre**
**Nasrul-Lahi-il-Fathi (NASFAT) Manchester Central**
2 Off Regent Street
Droylsden Road
Manchester
England
M40 1PW

**Study participating centre**
**Wonderfully Made Woman**
Unit 80
Cariocca Business Park
2 Sawley Road, Miles Platting
Manchester
England
M40 8BB

# Sponsor information

**Organisation**

University of Manchester

**ROR**
https://ror.org/027m9bs27

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Greater Manchester Cancer Alliance

**Funder Name**
The Sarah Harding Breast Cancer Appeal

**Funder Name**
National Institute for Health and Care Research (NIHR) Manchester Biomedical Research Centre (BRC)

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (Figshare at The University of Manchester).

**IPD sharing plan summary**
Stored in publicly available repository

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |