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Acceptability of radiofrequency assessment of breast density

Submission date 09/04/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/04/2025	**Overall study status** Completed	
Last Edited 18/11/2026	**Condition category** 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 September 2026.

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

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Scientific, Principal investigator

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Integrated Research Application System (IRAS)
349447

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
Current study objectives as of 17/11/2026:
1. To assess the acceptability to women of receiving Mi~Scan® breast density assessments in community settings.
2. To assess the acceptability to women of receiving Mi~Scan® breast density assessments in the primary care setting.
3. To assess the acceptability to women from Black, Black British and Caribbean or African ethnic minority backgrounds of receiving Mi~Scan® breast density assessments.
4. To assess the acceptability to healthcare professionals of delivering Mi~Scan® breast density assessments in primary care and community settings.
5. To assess the performance and safety of the Mi~Scan® device in assessment of breast density in primary care and community settings.
6. To explore the views of staff and volunteers from community-based organisations of being involved in the study.

Previous 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

Primary study design
Observational

Study design
Cross-sectional cohort study

Study type(s)
Other, Screening

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

Interventions
Current methodology as of 17/11/2026:
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.

We will also conduct semi-structured interviews with staff and volunteers from community-based organisations who supported with the recruitment and study delivery in community settings to explore their views about the study. Insights from these individuals should inform wider application of community-based approaches to health research recruitment and delivery.

Previous methodology:
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Intervention Type
Other

Primary outcome(s)
1. Acceptability to women of receiving Mi~Scan® breast density assessments in primary care and community settings measured using data collected by the questionnaire and focus group at immediately following the Mi~Scan® breast density assessment for the questionnaire and at follow-up for the focus group data collection

Previous primary outcome as of 18/11/2026:
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)
1. Comparison of participant demographic characteristics (ethnicity, BMI, and IMD quintiles) by source of recruitment (community versus primary care) and by ethnicity (Black versus other ethnicities), measured using participant demographic data collected by the questionnaire at immediately following the Mi~Scan® breast density assessment

2. Comparison of participants in terms of acceptability scores, according to (a) source of recruitment (community versus primary care) and (b) ethnicity (Black versus all other ethnicities), measured using acceptability scores collected by the questionnaire at immediately following the Mi~Scan® breast density assessment

3. Device safety (primarily assessed through adverse events (AE) and serious adverse events (SAE)), measured using data collected on the number of AE/SAE, the pain and discomfort domains collected by the questionnaire and two 5-point Likert-scale items at throughout the study (AE/SAE) and immediately following the Mi~Scan® breast density assessment

4. Device performance (breast density data) compared with Mi~Scan® validation data from the Leeds study (NCT04894955) measured using the Mi~Scan® device; breast density will be measured using and processed using Micrima's in-house density algorithm, at during the study appointment

5. Healthcare professional and community organisation representatives' views towards the device and being involved in the study, measured using data collected during qualitative interviews and analysed using reflexive thematic analysis at following their involvement in the study

Previous key secondary outcomes as of 18/11/2026:
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
25/09/2026

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
240

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
31/07/2026

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