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Acceptability of radiofrequency assessment of breast density

Submission date 09/04/2025	**Recruitment status** 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** Ongoing	
Last Edited 10/04/2025	**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 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

EudraCT/CTIS number
Nil known

IRAS number
349447

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Community, GP practice

Study type(s)
Other, Screening

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/11/2024

Completion date
15/09/2025

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

Age group
Adult

Lower age limit
30 Years

Upper age limit
49 Years

Sex
Female

Target number of participants
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
15/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester Integrative Medical Practice at Moss Side Health Centre
20 Monton Street
Manchester
United Kingdom
M14 4GP

Study participating centre
Surrey Lodge Medical Centre
11 Anson Road
Manchester
United Kingdom
M14 5BY

Study participating centre
The Arch Medical Practice
Hulme Medical Centre
175 Royce Road
Hulme
Manchester
United Kingdom
M15 5TJ

Study participating centre
Hawthorn Medical Centre
Unit K, Fallowfield Shopping Centre
Birchfields Road
Fallowfield
Manchester
United Kingdom
M14 6FS

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

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

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

Sponsor information

Organisation
University of Manchester

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Sponsor type
University/education

Website
https://www.manchester.ac.uk/research/environment/governance/

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

Publication and dissemination plan
Planned publication (between 1-2) in peer-reviewed journals.

Intention to publish date
15/09/2026

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