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FAST MRI reader training for breast cancer screening

Submission date 21/08/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/09/2019	**Overall study status** Completed	
Last Edited 29/05/2024	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Finding breast cancers early saves lives. Mammograms are the X-ray test that the NHS uses to look for early signs of breast cancer. Mammograms are better at finding some types of breast cancer than others. Unfortunately, fast growing, dangerous cancers are less likely to show up on a mammogram than slow-growing cancers. Also, half the women having breast cancer screening in the UK have enough dense (solid or tightly packed) breast tissue to hide a small cancer on their mammogram. In order to save more lives by finding fast-growing breast cancers early, we need an affordable screening test that is better than mammograms at finding cancers. We also need to know if the NHS staff who read the screening mammograms can quickly learn to interpret the new test accurately. There is a high-tech test (known as MRI) that is better than mammograms at finding breast cancers. However, each MRI scan takes about half an hour, and needs senior medical staff to interpret it. It is therefore expensive and cannot be used for everyone. FAST MRI is a quicker type of MRI that we think could be better than mammograms at finding breast cancers early.
The aim of the study is to see if NHS staff can successfully learn to use a new method of breast cancer screening to find breast cancers early.

Who can participate?
NHS staff who are currently mammogram readers at a participating centre within the NHSBSP service

What does the study involve?
We will teach staff from six NHS centres to interpret FAST MRI. The staff will already be able to read mammograms. Once trained, they will read a set of 125 FAST MRI scans, looking for signs of breast cancer. We want to see how accurate their readings are and find out if our teaching methods are good enough.

What are the possible benefits and risks of participating?
The review by the research ethics committee of our previous single centre study felt that the inclusion of staff within the study as participants could raise ethical issues such as putting pressure on staff to be involved with the study and the way that people's performance could be presented. Therefore, the ethical issues surrounding a recruitment approach for the readers

were considered in depth and led to the production of a participant information sheet about the study and consent forms which have been adapted for the current study and address the issue of coercion at recruitment. The potential risk to staff from the presentation of participants' performance at the interpretation of FAST MRI dataset task has been minimised by the participants being anonymised for participation in the study. Their performance at FAST MRI is more likely to reflect on the adequacy or otherwise of the training than on their own ability and competence, since they are all current NHS Breast Screening Programme (NHSBSP) mammogram readers (who are all subject to regular audit and quality assurance within the NHSBSP). The principal risk in this study is to participant (staff) confidentiality. We have taken steps to minimise this risk by minimising who has access to the full data set (Chief Investigator and Specialist Researcher (RG), Project Manager and Study Administrator), by using a password-protected Excel document to hold the identifiable details and corresponding anonymised participant identifier, and to keep this Excel file only on an NHS drive within NBT. All other study data will be anonymised before it is made available to the image readers or to the research staff.

Where is the study run from?
North Bristol NHS Trust, Southmead Hospital, UK

When is the study starting and how long is it expected to run for?
October 2019 to October 2022

Who is funding the study?
National Institute for Health Research, UK

Who is the main contact?
1. Dr Tony Timlin (public),
Tony.Timlin@nbt.nhs.uk
2. Dr Lyn Jones (scientific),
lyn@coppock.uk.com

Study website
https://www.nbt.nhs.uk/FASTMRI

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.2

Study information

Scientific Title
Refinement and piloting of a training programme within the NHS Breast Screening Programme (NHSBSP) workforce of image readers to enable standardised interpretation of a shortened magnetic resonance imaging scan (MRI) of the breast called FAST MRI to support the delivery of a future multicentre trial of FAST MRI versus mammogram for breast cancer screening

Study objectives
The aim of this study is to refine and pilot a training programme for FAST MRI interpretation within the NHS Breast Screening Programme (NHSBSP) workforce, to support the delivery of a future multicentre study of FAST MRI versus mammogram for breast cancer screening

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 30/08/2019, NHS London-Bromley Research Ethics Committee (Health Research Authority, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0) 207 104 8063; nrescommittee.london-bromley@nhs.net), ref: 19/LO/1473, IRAS Project ID: 25820

Study design
Interventional pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Breast cancer

Interventions
FAST MRI training

Purpose and Design:
Objective 1: To produce a training tool: In our previous study we made a teaching tool that used anonymised FAST MRI images and one-to-one hands-on workstation standardised training including a training script. During the current study we will adapt the current training tool utilising the existing anonymised images and script but incorporating them into an electronic tool that can be delivered to a classroom of up to 10 trainees at once and that automatically measures the time taken to train each trainee.

Objective 2: To deliver the standardised training to multiple NHS staff, from 6 NHS screening centres within the South West Region of England, who are mammogram readers up to a maximum capacity of 100 (which exceeds the number of mammogram readers at these centres). The training will be delivered at one of two sites within region, and 5 consecutive training dates will be offered at each site.

Objective 3: To produce an electronic version of the assessment tool that was used in the previous single centre study that can be used by trained readers, each at their own NHS centre to interpret an existing dataset of anonymised FAST MRI images of 250 breasts.

Objective 4: For trained readers to interpret the existing dataset of anonymised FAST MRI images of 250 breasts. The readers will perform this task over 6 months each at their own NHS

centre, aiming to read approximately 20 images at one sitting. Each session is likely to take less than one hour of a reader's time, and therefore approximates to a total of 12 hours of each reader's time to complete the dataset. To read the dataset, the readers who are Consultant Radiologists, Breast Clinicians or Consultant Radiographers will be expected to find time for the interpretation task within their existing Supporting Professional Activity (SpA) time. However, Advanced Practitioners and other filmreading Radiographers are unlikely to have allocated SpA within their job plans and therefore provision has been made within the grant funding to recompense them for the time taken

Added 16/06/2022:
Objective 5: The design and development of dedicated phantom breasts will form the groundwork for a standardised quality assurance programme for a future large-scale multi-centre FAST MRI study. The phantoms have the potential to be incorporated into and inform any future reviews of NHSBSP Report 68 Technical Guidelines for Magnetic Resonance Imaging for the Surveillance of Women at Higher Risk of Developing Breast Cancer. This workstream includes the design and construction of two magnetic resonance imaging (MRI) test objects (phantoms) that will be used for quality assurance (QA) tests of MR scanners participating in a future multi-centre FAST MRI study. One of these test objects will be used to assess the dynamic range of the dynamic contrast-enhanced (DCE) sequence and the other will be used to measure the resolution in 3 dimensions. The phantoms will be trialled at North Bristol NHS Trust (NBT) to finalise the design and to test for reproducibility and stability before being scanned on different MR scanners and vendors at NBT and University Hospitals Bristol and Weston NHS FT (UHBW).

Data analysis
Each reader will be asked to classify each of the 250 FAST MRI breast scans using the modified version of the MRI screening reporting categories of classification outlined in the 2012 NHSBSP guidelines for screening higher-risk women, where MRI1 and MRI2 indicate normal and benign, MRI3 indicates an indeterminate classification, and MRI4 and MRI5 indicate suspicious and definitely malignant appearances respectively. MRI classification of 4 and 5 will be considered as indicative of cancer. The true outcome result was obtained using the histology of any biopsies or normal results after 3 years of follow-up.
The accuracy of the results from the readers against the true outcome will be determined overall and within each group of readers. In addition, the sensitivity (true positive rate), specificity (true negative rate), false positive and negative rates and the positive and negative predictive values of the readers’ MRI classification with the true outcome will be calculated.

Intervention Type
Other

Primary outcome measure
Accuracy of image reading of FAST MRI by trained readers against the marked ground truth

Secondary outcome measures
1. Proportion of image readers completed their training
2. Proportion of readers completed the FAST MRI interpretation task
3. Proportion of readers achieved an acceptable level of accuracy at the task

Overall study start date
01/11/2018

Completion date

31/10/2022

Eligibility

Key inclusion criteria
1. Current mammogram readers at a participating centre within the NHSBSP service

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
50

Total final enrolment
46

Key exclusion criteria
1. Mammogram readers still undergoing training to read mammograms at the time of recruitment to this study.
2. Image Readers who interpret symptomatic mammograms and/or breast MRIs but who do not read mammograms for NHSBSP

Date of first enrolment
01/10/2019

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Cornwall Hospital
Royal Cornwall Hospitals NHS Trust, Treliske
Truro, Cornwall
United Kingdom
TR1 3LJ

Study participating centre
Great Western Hospital
Marlborough Road
Swindon
United Kingdom
SN3 6BB

Study participating centre
Musgrove Park Hospital
Parkfield Drive
Taunton
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TA1 5DA

Study participating centre
Cheltenham Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
North Bristol NHS Trust
Southmead Hospital, Westbury on Trym
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BS10 5NB

Study participating centre
Derriford Hospital
University Hospitals Plymouth NHS Trust
Derriford Road
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PL6 8DH

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
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United Kingdom
BS10 5NB
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researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.nbt.nhs.uk/research-innovation

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol and final results of this study will be published in a high-impact peer-reviewed journal. All participants will be offered a summary of the results. Results will also be promulgated to our PPI partners and other interested groups.

Intention to publish date
30/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (Sadie McKeown-Keegan (Trial Manager) Sadie.Mckeownkeegan@nbt.nhs.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/07/2022	18/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		28/05/2024	29/05/2024	Yes	No