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Artificial intelligence to help healthcare professionals detect cancer in the UK breast screening programme

Submission date
03/11/2025

Recruitment status
Not yet recruiting

Registration date
26/11/2025

Overall study status
Ongoing

Last Edited
26/11/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Artificial Intelligence (AI) is being used more commonly in the NHS. The EDITH study is looking to see how well AI could support the breast screening programme in the UK. It will test how AI can help NHS trained experts to look for cancer in mammograms.

Who can participate?
We plan to have 660,000 women take part in the study from approximately 30 breast screening centres in the UK. Women will be informed about the study when they get their screening (mammogram) invitation letter.

What does the study involve?
Within the study, some women will receive standard breast screening, where two NHS experts look at the breast images for signs of cancer. Other women will receive AI-assisted breast screening, where the AI helps the NHS expert(s) by also looking for signs of cancer. We will try out two different types of AI-assisted breast screening. The first type will involve the use of AI after the NHS expert to look for cancers that they might have missed. The second type will involve AI being used first to say whether there is a high or low risk of cancer. All images will be read by a human expert with final decisions about cancer detection made by standard human arbitration.
Women will be followed up until their screening episode is closed and then for a further four years through the screening programme and cancer registries to ascertain if they develop a cancer in the future.
Results from the three groups will be looked at to see how well humans combined with AI assistance works compared to the human readers alone and the costs and benefits of this.

What are the possible benefits and risks of participating?
There is a possible benefit in taking part in the EDITH study as some studies have shown increased cancer findings when AI is used. The information gained from this study should help improve the screening service offered to women in the future.
AI may highlight more areas as high likelihood of cancer than human experts. Some of these may

not be cancer. This may mean more women are recalled for additional testing than if AI is not used. Some women may feel anxious and/or worried if they are asked to attend additional follow-up tests. The mammography and any further testing are part of your routine care and helps the experts examine the breast more thoroughly. In most cases there is no abnormality to be found.
These procedures use ionising radiation to form images of the breast and provide NHS trained experts with clinical information. Ionising radiation may cause cancer many years or decades after the exposure. The majority of participants in this study will not undergo any additional procedures. For those participants the chance of this happening is the same whether they take part in the study or not. Participants who may not have been recalled for additional testing, but are recalled due to participation in the study, will undergo additional exposure to ionising radiation. The risk arising from these additional exposures is extremely small.

Where is the study run from?
University of Warwick and Cambridge University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2025 to July 2029

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
University of Warwick study team, edith@warwick.ac.uk

Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Central Portfolio Management System (CPMS)
CPMS 59556

National Institute for Health and Care Research (NIHR)
NIHR162840

Integrated Research Application System (IRAS)
336814

Study information

Scientific Title
Early Detection using Information Technology in Health (EDITH)

Acronym
EDITH

Study objectives
1. To integrate AI into the NHSBSP to measure the difference in clinical and cost-effectiveness between three study arms: replacing the second reader with AI (intervention 1); using AI for triage (intervention 2); and the current double reading pathway (control)
2. To understand differences in accuracy by AI vendor, mammographic acquisition system and by population subgroup (e.g. age, ethnicity, breast density, socioeconomic status) in a nested test accuracy study
3. To develop a comprehensive post-market surveillance methodology for national rollout
4. To monitor barriers to participation in women opting out
5. To calculate the cost of the current pathway using two readers compared with replacing the second reader with AI or using AI for triage from the perspective of the NHS

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/11/2025, East of England - Cambridge East Research Ethics Committee (2 Redman Place, Stratford, London, EC20 1JQ, United Kingdom; +44 (0)207 104 8096; cambridgeeast.rec@hra.nhs.uk), ref: 25/EE/0197

Study design
Randomized; Interventional; Design type: Screening, Imaging

Primary study design
Interventional

Study type(s)
Screening

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

Interventions
EDITH is a multi-centre, pragmatic, cluster, randomised controlled trial (RCT). Cluster will be at the clinic day level including 660,000 women across approximately 30 screening centres with opt-out consent. Each centre will undertake all three trial arms with one approved AI tool randomly allocated to be used at the centre. All women who attend participating screening centres will take part in the study, unless they opt-out.

Cluster randomisation will be allocated 1:1:1 ratio across:
Control arm: women will receive standard breast screening, where two NHS experts look at the breast images for

signs of cancer.
Two groups of women (intervention arms) will receive AI-assisted breast screening, where the AI helps the NHS expert(s) by also looking for signs of cancer.

Intervention arm 1: AI is used after the NHS expert has looked for cancer and will look for cancers that they might have
missed.

Intervention arm 2: AI is used first before NHS experts look at the mammograms to say whether there is a high or low likelihood of cancer. This information is then used by the NHS experts, with knowledge of the AI decision available to them. If the likelihood is low one NHS expert will read the images and if the likelihood is high two experts will read the images, before a decision is made whether to recall women for further tests. In both cases, if there is disagreement on whether to recall women for further tests the case will go to arbitration (this is a process where a single third expert or panel of human experts review the images and make a final decision whether to recall the woman). Where the AI score shows a very high likelihood of cancer, the images will always go to arbitration.

In all arms, all images will continue to be looked at by at least one human expert with final decisions about cancer detection made by at least two human experts.
A nested test accuracy study comparing AI systems from participating vendors will be undertaken towards the end of the study to establish which AI tool performs best with each of the mammography vendors. This is a retrospective sub-study of mammograms from the main study taking place towards the end of the trial. This study has no impact on patient care pathway, as it does not involve any further contact with participants.
A qualitative study exploring women's reasons for opt-out and acceptability of AI in breast screening will be undertaken
in a small number of women.
A health economic evaluation will be undertaken to evaluate the cost-effectiveness of implementing different AI systems and AI pathways and includes a (a) micro-costing study to calculate the resource use and cost of using AI to read mammograms; and (b) a qualitative study to identify barriers and facilitators to the introduction of AI which will inform the health economic model.

The trial is designed to answer whether each intervention is more clinically effective than current practice. This will be assessed using a randomised controlled trial design – the gold standard method for generating the strongest possible evidence. The inclusion of a control arm (double reading by two human experts) allows us to directly compare current cancer detection and recall rates with those achieved in the intervention arms, where AI is integrated into the screening pathway. We will use hierarchical models to assess the primary outcomes (cancer detection rate and recall rate). Hierarchical models are statistical methods used to account for clustering in data – in this trial, clustering occurs when women are grouped into clinic days contained within screening centres. In addition, an intention-to-treat analysis will be performed, meaning all participants will be analysed according to their randomised intervention, regardless of whether the intervention was delivered as intended. For instance, if AI is unable to read a mammogram – for example, due to breast implants or the mammogram being acquired via a method other than the standard 2D digital four-view mammography – the woman will receive standard care (double reading by two human experts) but will be treated as if she had received the intervention to which she was assigned.

Each intervention arm will be compared separately with the control arm. For cancer detection, we will assess superiority. A difference of at least 1 additional cancer detected per 1000 women

screened, compared to the control arm, will be considered clinically meaningful. This difference was chosen to align with the difference in cancer detection rate observed in MASAI, a Swedish trial of AI in breast screening [https://pubmed.ncbi.nlm.nih.gov/37541274/]. Thus, the null hypothesis is that the difference in cancer detection rate between the intervention arm and the control arm is less than 1 cancer per 1000 women screened (in either direction), and the alternative hypothesis is that this difference is greater than or equal to 1 cancer per 1000 women screened (in either direction). For recall, we will assess non-inferiority. If the intervention arm results in no more than 2 additional recalls per 1000 women screened, compared to the control arm, it will be considered non-inferior. This margin was established in consultation with PPIE representatives and researchers. Thus, the null hypothesis is that the intervention leads to more than 2 additional recalls per 1000 women screened (in the positive direction only), and the alternative hypothesis is that it results in 2 or fewer additional recalls per 1000 women screened (in the positive direction only).

Intervention Type
Other

Primary outcome(s)
1. Cancer detection rate (CDR) measured as cancers detected out of all women screened
2. Recall rate measured as women recalled out of all women screened

Primary analysis will be at the end of the 4-year trial before interval cancers have been captured. The final analysis will be when all women have undergone a second round of screening or more than 3 years follow up to capture interval cancer rates.
The nested test accuracy study will take place towards the end of the trial.

Key secondary outcome(s))
1. Arbitration rate measured as women requiring additional read by third person out of all women screened
2. Interval cancer rate measured as the number of interval cancers within 3 years out of all women screened and the next screen CDR measured using as the number of cancers detected out of all women screened at 3 years
3. Characteristics of cancers detected measured using size, type and grade
4. Outcomes by population group to explore inequalities and by breast density, measured using age, ethnicity, socioeconomic status [SES]
5. AI failure rates
6. Atypia detection (incidental findings)
7. Workload measured using e.g. reading volume, arbitration volume, recall to assessment volume
8. Reader behaviour and performance measured using e.g. AI vendor, AI threshold, batch length, time on task, reader experience and reading volume
9. Opt-out rates and reasons for opting out as a measure of acceptability in screening-eligible women (where provided by women)
10. Cost to the NHS of the three pathways
11. Cost-effectiveness by technology and population subgroup, and impact on NHS capacity
12. Test accuracy of AI from a nested test accuracy study overall and by population subgroup (e.g. age, ethnicity, breast density, socioeconomic status)

Primary analysis will be at the end of the 4-year trial before interval cancers have been captured. The final analysis will be when all women have undergone a second round of screening or more than 3 years follow up to capture interval cancer rates.
The nested test accuracy study will take place towards the end of the trial.

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Women routinely invited for NHSBSP breast screening at participating centres during the trial recruitment period, typically screening target age 50-70 years but pragmatically include all screened women even if outside target age range (for example older women are allowed to self-refer every 3 years).
2. Women whose mammograms cannot be read by AI (for instance due to cosmetic breast implants, or not having standard 2D digital four-view mammograms acquired) will be included in the main trial intention to treat analysis comparing the trial arms. In practice they are effectively a test failure and will receive standard care (two human readers) regardless of trial arm. This analysis will deliver comparison of the AI pathway as it would actually be implemented for all women in comparison to current standard practice.

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
70 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Women being screened in the moderate and high-risk screening service (separate to NHSBSP)
2. Women being screened following the very high-risk protocol (separate protocol to population risk women: annual mammography/MRI)
3. Women who have opted out from participation in the study

Date of first enrolment
01/05/2026

Date of final enrolment
30/11/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham General Hospital
Sandford Road
Cheltenham
England
GL53 7AN

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
England
SE5 9RS

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
England
EX2 5DW

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
Mid and South Essex NHS Foundation Trust
Prittlewell Chase
Westcliff-on-sea
England
SS0 0RY

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
University Hospital of Hartlepool
Holdforth Road
Hartlepool
England
TS24 9AH

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
Sandwell and West Birmingham Hospitals NHS Trust
Midland Metropolitan University Hos
Grove Lane
Smethwick
England
B66 2QT

Study participating centre
St George's Hospital
Blackshaw Road
Tooting
London
England
SW17 0QT

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
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DE22 3NE

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
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LE1 5WW

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
England
ST4 6QG

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
England
NR4 7UY

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Maidstone and Tunbridge Wells NHS Trust
The Maidstone Hospital
Hermitage Lane
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England
ME16 9QQ

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
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CV2 2DX

Study participating centre

University Hospitals Plymouth NHS Trust
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PL6 8DH

Study participating centre
York and Scarborough Teaching Hospitals NHS Foundation Trust
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YO31 8HE

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the University of Cambridge and the University of Warwick. At the end of the trial third parties may request access to the trial data and mammogram images via the Chief Investigators or the trial team at edith@warwick.ac.uk. The trial will form a Data Access Committee (which will include the Chief Investigator(s) and Trial Management Group members) to consider requests. No reasonable requests will be denied but all requests must have the approval of the Data Access Committee. Requests must be made according to Warwick Clinical Trials Unit data request Standard Operating Procedure. If any images or meta data is released to a third party, full anonymisation will take place. Participants are informed that their data may be shared anonymously with other researchers to support future research in the Patient Information Sheet.

IPD sharing plan summary
Available on request

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes