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Investigating the use of image-based communication to improve uptake of breast cancer screening

Submission date 13/03/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/05/2024	**Overall study status** Ongoing	
Last Edited 03/04/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Breast cancer is the most common cancer in the UK, and is one of the leading causes of death in women under 50 in the UK. The NHS Breast Cancer Screening Programme (NHSBSP) invites women aged 50 to 70 years old every three years to have a mammogram. By enabling earlier detection, it is estimated that the NHSBSP saves 1, 300 lives per year. Currently, screening services use letter invitations and SMS reminders to facilitate attendance. Coverage rates have fallen nationally by 10.2% between 2016 and 2022. London has shown particularly poor rates (55.5%), with coverage in 2022 below the acceptable target of 70%. Behavioural science is a field that looks at understanding why people act in particular ways. It has already been successfully applied to improve health behaviours such as hand washing and healthy eating. Recent studies have shown that behavioural science can be applied to breast screening messages to facilitate the uptake of invitations. However, the use of plain text invitations limits which barriers to screening can be addressed, and what techniques can be used. Images-based messaging provides a key delivery mechanism that may enable more complex and different combinations to be employed and overcome some of the key barriers to breast screening uptake. There is, however, a lack of data regarding the impact of sending a behavioural science-informed image-based communication upon attendance at breast cancer screening programmes. This study aims to investigate the impact of a behavioural science-informed image-based leaflet (based on a previously trialled animation video) alongside the usual invitation, compared to the usual invitation letter alone. This will be compared with the impact of the digital animation video sent via SMS reminder through one of the hubs not included in the letter trial.

Who can participate?

Women eligible for the NHSBSP aged 50 to 70 years old; women aged 47 or over 73 years old are eligible for the workshops

What does the study involve?

This study aims to improve breast cancer screening uptake through three main activities:

Workstream A: This involves workshops to understand people's preferences regarding breast cancer screening invitations and refine interventions based on images.
Workstream B: This includes a randomized controlled trial (RCT) where some participants will receive a traditional screening invitation, while others will receive an invitation with an image-based leaflet. The leaflet is based on an animated video previously tested to improve screening uptake.
Workstream C: This part of the study will also be an RCT, but it focuses on including a link to an animation video within SMS reminders for breast cancer screening. Participants will be randomly assigned to receive either standard SMS reminders or reminders with the animation video link.

The study will take place in the London and Southeast screening region of the NHSBSP. The Royal Free Hospital will handle administrative aspects, while SMS reminders will be managed separately. Participants will be randomly allocated to different groups using a computerized system.

Feedback from previous studies and consultations with various groups, including underserved populations, have shaped the content of the interventions. The materials will be translated into multiple languages to ensure accessibility.

Data will be collected to assess the effectiveness of the interventions, with a focus on specific demographic groups. The study aims to enroll a total of 46,466 participants for Workstream B and 19,338 for Workstream C.

What are the possible benefits and risks of participating?
The possible benefits and risks of participation in workshops:
Workshop participants will be given £50 to thank you for their time (£25 per hour), and to help them to take part if they would like to, their travel expenses using public transport can also be covered. They may learn things during the workshop which will help them to make informed choices about their health. They will also be helping the team improve breast screening materials that may benefit others in the future.

The possible benefits and risks of participation in the RCT:
RCT participants will be helping the team to generate an understanding of which breast cancer screening communication materials are most effective in improving uptake- especially amongst underserved groups. A potential risk is that the intervention being trialled deters women from uptake of breast cancer screening thereby reducing their likelihood of breast cancer screening.

Where is the study run from?
Imperial College London

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

Who is funding the study?
National Institute for Health and Care Research (NIHR) North West London Patient Safety Research Collaboration

Who is the main contact?
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Contact information

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
334873

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
23IC8650, IRAS 334873

Study information

Scientific Title
Investigating the use of image interventions alongside usual invitations to facilitate attendance at Breast Cancer Screening

Study objectives
Image-based interventions using behavioural science can improve the uptake of breast cancer screening, especially amongst underserved groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/03/2024, London – Surrey Research Ethics Committee (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 (0)207 104 8131; surrey.rec@hra.nhs.uk), ref: 24/LO/0185

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Home, Internet/virtual, Medical and other records, Telephone

Study type(s)
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
Screening for breast cancer

Interventions
This study will include three workstreams: A, B and C:

Workstream A will consist of workshops to explore preferences around breast cancer screening invitations and to refine image-based interventions.
Workstream B will be an RCT of an image-based leaflet included alongside usual care breast cancer screening invitation letters. The image-based leaflet will be based on the animation video included in workstream C of the trial, which was originally developed and trialled as part of a previous study based out of Imperial to improve breast cancer screening uptake.
Workstream C (conducted in a hub that is not included in workstream B) will be an RCT of the inclusion of a link to a video animation included within usual care SMS reminders for breast

cancer screening. There will be an anonymous online questionnaire at the end of the animation video which individuals can choose to take part in.

The study will be conducted as a Randomised Controlled Trial (RCT) in the London and southeast screening region of NHSBSP. The administrative hub for the NHSBSP in London is based at the Royal Free Hospital, which will oversee invitation printing, scheduling, and outcome data collation through their existing delivery systems. Workstream C will rely on SMS messages so will not require the same level of administrative centralisation.

Participants in both workstreams B and C will be randomised using a simple randomisation method in a 1:1 fashion to either intervention arm or usual care using a computerised system in which each participant who is due for screening in the study period is randomly allocated a number corresponding to the invitation they will receive according to the final digit of the NHS number. In this way, women who phone to reschedule are not reallocated to a different trial arm. The screening hub will undertake this and will be passed on to the invitation delivery service who will ensure the correct template is sent.

Written invitations are sent, as standard practice, by the NHS Breast Cancer Screening Programme (NHSBSP) to invite women to an appointment at a set time, date and location (so-called timed invitations). Following this, as part of usual care, those selected for open invitations will receive a first SMS 7 days post-written invitation. They will then receive two SMS reminders, 7 days and 2 days before the appointment, once it has been booked.

The RCT in workstream B will involve randomising participants to receive the usual care invitation (according to the timings outlined above), or a usual invitation alongside an image-based leaflet. In Workstream C participants will be randomised to receive either the usual care reminder SMS message or the usual care reminder SMS message with a link included to the behavioural science-informed animation video.

The content of the video was developed in a previous study conducted at Imperial College London. It was informed by findings from a systematic review, a survey of 1000 women, and 10 interviews and 2 focus groups with women from under-served groups. The results of these findings of determinants of breast screening uptake were used in extensive Patient and Public Involvement and Engagement work including 4 co-design workshops. Members of the public were consulted throughout the process, especially regarding the representations of individuals in the video, and the message content. The feedback received was used to alter the materials, and further feedback was received. Feedback was also sought from members of the Oremi Centre (a mental health day service specifically for African Caribbean and Arabic-speaking adults) and Gendered Intelligence (a trans-led organisation to improve the quality of life of trans people) to ensure individuals from these groups were happy with representations. Screening commissioners, led by Dr Kathie Binysh (NHS England Breast Screening Lead, London), also approved this content. The NHS Identity team provided approvals for the use of NHS logos /branding, and the team at London Northwest Healthcare NHS Trust approved the use of their name. The image-based printed intervention, trialled in workstream B is based directly on this animation video which will be re-trialled in a different population group in workstream C through the inclusion of a link in SMS reminders. The study team will work with the designers originally involved in the creation of the animation video to translate this to a leaflet format for workstream B.

Messages in the image-based leaflet will be translated into several languages based on the demographics of the screening hubs involved, to ensure people from a diverse background can understand the content.

After 3 months from the initial written invitations, data will be collated from the breast screening hub regarding whether an individual attended an appointment and whether the invitations were successfully sent. This will be repeated at 6 months corresponding to the key performance indicator of the service.
A sample size of 23, 233 per trial arm (46,466 in total) will be used in workstream B to allow us to power for subgroup analysis in an underserved group (IMD 1-5 and non-white ethnicity, who it is estimated make 13.3% of the total sample) to detect a 2.5% effect size. There will be 9,669 per trial arm (total sample size of 19,338) used in workstream C to allow 80% power to detect a 2% increase in uptake from 55% in the control group to 57% in the intervention group.

Intervention Type
Mixed

Primary outcome measure
Percentage uptake of breast cancer screening is measured as attendance (did/did not attend) using the breast cancer screening service hub data, at baseline and three months after the initial invitation letter

Secondary outcome measures
1. Percentage uptake of breast cancer screening amongst different demographic subgroups measured as attendance (did/did not attend) using the breast cancer screening service hub data at baseline and three months after the initial invitation letter
2. Perceptions of the animation video sent in workstream C measured using an online questionnaire at [timepoint]
3. Barriers to breast cancer screening uptake, and perceptions of communication materials [measured using] data collected during qualitative workshops at [timepoint]
4. Percentage uptake of breast cancer screening [measured using] at baseline and six months after the initial invitation letter

1. Percentage uptake of breast cancer screening amongst different demographic subgroups measured as attendance (did/did not attend) using the breast cancer screening service hub data at baseline and three months after the initial invitation letter
2. Perceptions of the animation video sent in workstream C measured using an online questionnaire which will be available to individuals via a landing page once they have watched the video (link provided in SMS message)
3. Barriers to breast cancer screening uptake, and perceptions of communication materials measured via focus group discussion qualitative data collected during qualitative workshops before the leaflet is made available in workstream B
4. Percentage uptake of breast cancer screening as attendance (did/did not attend) using the breast cancer screening service hub data at baseline and six months after the initial invitation letter

Overall study start date
01/03/2024

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Eligible for the NHS Breast Screening Programme (NHSBSP)
2. Aged 50 to 70 years old
3. Lives within the London screening regions included in the trial
4. Registered as female with the GP

For the workshops:
1. Registered as female with the GP
2. Lives within the London screening region included in the trial
3. Aged 47 to 73 years old

Participant type(s)
Service user

Age group
Mixed

Lower age limit
47 Years

Upper age limit
73 Years

Sex
Female

Target number of participants
65,834

Key exclusion criteria
1. Not eligible for the NHS Breast Screening Programme (NHSBSP)
2. Aged under 50 or over 70 years old
3. Does not live within the London screening regions included in the trial
4. Not registered as female with the GP

For the workshops:
1. Not registered as female with the GP
2. Does not live within the London screening region included in the trial
3. Aged under 47 or over 73 years old

Date of first enrolment
19/08/2024

Date of final enrolment
01/04/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free London NHS Foundation trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Jarvis Breast Screening Centre
60 Stoughton Road
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Funder(s)

Funder type
Government

Funder Name
NIHR North West London Patient Safety Research Collaboration

Results and Publications

Publication and dissemination plan
A robust publication policy is envisaged with aggregated unidentifiable data published in peer review journals and in conference presentations. To ensure widespread dissemination of the work to relevant stakeholders, dissemination will also include non-academic means such as blog posts. No identifiable data will be used in any publication.

Intention to publish date
01/09/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.

Data will be held in the Imperial College London's Big Data & Analytical Unit (BDAU) Secure Environment (SE) as long as necessary for the completion of the project. After the project has been completed, the original de-identified data transferred to the BDAU SE will be securely destroyed by the BDAU team. The BDAU SE user associated with this project is responsible for ensuring aggregated research outputs are retained for 10 years in the College Archives and Corporate Records Unit (https://www.imperial.ac.uk/admin-services/acru/) and in line with the College's research data management policy: https://www.imperial.ac.uk/research-and-innovation /support-for-st aff/scholarlycommunication/research-data management/imperial-pol icy/

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	27/06/2024	08/08/2024	No	No