

Protocol for non-CTIMPs

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

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Protocol authorised by:

Name & Role	Date	Signature
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Study Management Group

Chief Investigator: Dr Gaby Judah

Co-investigators: Ada Humphrey, Amish Acharya

Statistician: Roberto

Study Management: Ada Humphrey, Amish Acharya

Study Coordination Centre *(may not be applicable)*

For general queries, supply of study documentation, and collection of data, please contact:

Study Coordinator: Dr Gaby Judah

Address: 10th Floor QEQM, St Mary's Hospital, W2 1NY

Tel:

Registration:

E-mail: g.judah@imperial.ac.uk

Clinical Queries

Clinical queries should be directed to Amish Acharya who will direct the query to the appropriate person.

Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Research Governance and Integrity Team

Imperial College London and Imperial College Healthcare NHS Trust

Room 215, Level 2, Medical School Building

Norfolk Place

London, W2 1PG

Tel: 0207 594 1862

[Imperial College - Research Governance and Integrity Team \(RGIT\) Website](#)

Funder

[Who is funding the study]

This study is funded by NIHR through the Patient Safety Research Collaboration at Imperial College London.

This protocol describes the Investigating the use of image interventions alongside usual invitations to facilitate attendance at Breast Cancer Screening study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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GLOSSARY OF ABBREVIATIONS

BCT	Behavioural Change Technique
ICL	Imperial College London
NHS	National Health Service
NHSBSP	NHS Breast Screening Programme
NHSE	NHS England
RCT	Randomised Controlled Trial

KEYWORDS

Breast cancer screening, uptake, behavioural science.

STUDY SUMMARY

TITLE	Investigating the use of image-based interventions alongside usual invitations to facilitate attendance at Breast Cancer Screening
DESIGN	Randomised Controlled Trial
AIMS	To determine the impact of including an image-based intervention using behavioural science, upon the uptake of breast cancer screening
OUTCOME MEASURES	Primary: percentage uptake of the invitation to screen. Secondary: percentage uptake of the invitation to screen amongst population subgroups (e.g. by demographic factors, and by invitation type).
POPULATION	All women aged between 50 and 70, invited to screen in the London and southeast breast cancer screening region.
ELIGIBILITY	Eligible to attend the NHSBSP in London and southeast during the study period.
DURATION	18 months

REFERENCE DIAGRAM

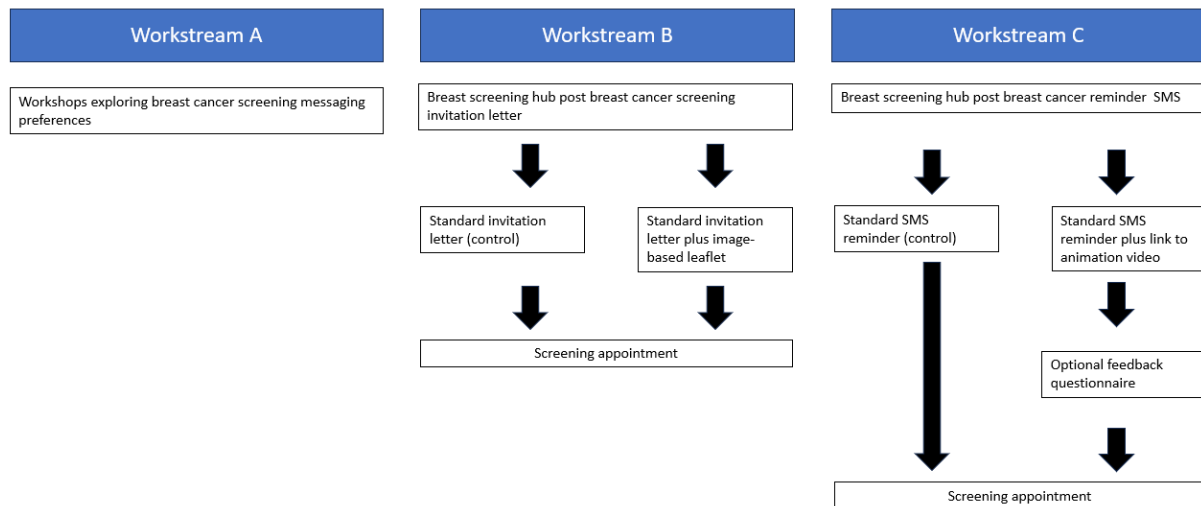


Figure 1 Reference diagrams for study workstreams and trial arms

1. INTRODUCTION

1.1. BACKGROUND

[To include: review of previous studies, disease particulars, incidence, current treatment options, risks and benefits]

Breast cancer is the most common cancer in the UK, with 1 in 8 women affected during their lifetime¹, and is one of the leading causes of death in women under 50 in the UK². Whilst survival rates are high, the 5-year survival rate at stage 1 and 2 are 98.2% and 89.5% respectively, this drops to 72.2% at stage 3 and 26.6% at stage 4³. 39.4% (around 18,800) of breast cancer cases were diagnosed at stage 1 in England in 2018. The NHS Breast Cancer Screening Programme (NHSBSP) invites women aged 50 to 70 years old every three years to a mammogram. By enabling earlier detection, it is estimated that the NHSBSP saves 1,300 lives per year⁴.

Despite the potential benefits of breast cancer screening, attendance is falling. Coverage rates have fallen nationally by 10.2% between 2016 and 2022⁵. London has shown particularly poor rates (55.5%), with coverage in 2022 below the acceptable target of 70%⁵. The COVID-19 pandemic has exacerbated these trends with an estimated 1 million mammograms missed, due to the cessation of screening to minimise transmission risk^{6,7}. Counteracting these trends is a significant public health priority.

Furthermore, there is increasing concern regarding the socio-demographic inequalities in breast screening uptake. For example, the odds of attendance amongst those from the most

deprived areas is 5% lower than those from less deprived areas^{8,9}. In addition, in one study in London, the adjusted odds of attendance were almost three times higher amongst White British, compared to Asian women, and six times higher than Black women¹⁰. The barriers faced by these groups need to be appreciated, and any intervention to increase attendance ensure that inequalities are not widened¹¹.

1.2. RATIONALE FOR CURRENT STUDY

[To include: research question and hypothesis]

A previous study based at Imperial looked at the impact of a behavioural change informed animation sent via a link in an invitation SMS on breast cancer screening uptake. This was compared within a three-armed RCT looking at the impact of the use of a behavioural change informed SMS, a behavioural change informed SMS including a link to the animation, and the normal breast cancer screening invitation SMS. The video was designed based on a series of workshops and interviews with participants from underserved groups. There was no significant difference in attendance of breast cancer screening between the three trial arms. However, amongst a multiply underserved group (i.e., those from high IMD decile 1-5 and non-White ethnicity) the behavioural SMS + animation group had a 5.2% higher attendance compared to controls; however, this was not significant, possibly due to the low numbers in this cohort which made up only 13.3% (n=1,201) of the total sample population (Group 1 attendance 77.8% v. Group 2 attendance 78.4% v. Group 3 attendance 83.0%, $\chi^2= 3.41$, df=2, P=0.17). The study was not powered to assess any impact in this subgroup.

The animation link sent via SMS led to low click through (5.8% of those who received the link visited the page), but of those who did, 40% who answered the questionnaire at the end said that the video made them more likely to attend screening and 80% said they learnt something new from the video. This suggests that for those who did watch the animation it may have influenced their screening behaviours. One possible reason for low click through includes digital access, such as device type and data usage. Digital access and use are known to be lower in older age groups, and lower socioeconomic groups¹². This suggests that alternative forms of non-digital communication may be best suited to these populations. This study will trial a non-digital form of the animation video, using an image-based leaflet based on narratives and images from the video, inserted into invitation letters, to investigate whether exposure to an image-based leaflet leads to a statistically significant increase in breast cancer screening attendance. This will be compared with a re-trial of the original video animation sent via a link in SMS reminders for breast cancer screening appointments. During workstream A workshops we will explore with participants how to change the message in which the video link is shared to encourage click through to the video. We will also be testing the video intervention on a population outside of London – in Southeast England, in order to explore whether this intervention has a different impact within a population with different demographics, most notably higher likelihood of digital engagement. This will allow us to better understand the impact of using different modalities of image-based interventions to improve breast cancer screening uptake.

2. STUDY OBJECTIVES

The primary object is to determine the impact of behavioural science informed image-based interventions included alongside usual invitations and SMS reminders, upon uptake of breast cancer screening. Secondary objectives involve how this impact on attendance differs

between population subgroups including people from differing demographic groups and IMD deciles.

3. STUDY DESIGN

[Type of study: eg tissue collection, physiological, epidemiological etc]
[Duration]

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 the 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 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 which was not included in workstream B) will be an RCT of the inclusion of a link to a video animation added to usual care SMS reminders for breast cancer screening. The standard SMS message sent by the screening service will also have small changes made to it, in order to ensure compatibility with the intervention SMS (see appendix 1) 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, who 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 workstream B and C will be randomised using simple randomisation method in a 1:1 fashion to either intervention arm or usual care. Randomisation will utilise 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. This will be undertaken by the screening hub 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 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 prior to 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 updated 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, 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 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 inclusion of a link in SMS reminders. We 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 are able to 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 as this will allow us to power for subgroup analysis in an underserve group (IMD 1-5 and non-white ethnicity, who it is estimated make up 13.3% of the total sample) to detect a 2.5%¹ effect size. 9,669 per trial arm (total sample size of 19,338) will be 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.

3.1. STUDY OUTCOME MEASURES

[Are there endpoints to the study?] List the primary and secondary outcomes measures.

The primary outcome of this study is the percentage uptake of breast cancer screening, three months after the initial invitation letter.

Secondary outcomes will involve how the uptake differs according to:

¹ The higher figure of 2.5% has been used based on previous data from trialling of the animation video link sent in an SMS message which found a 5.2% increase in uptake in this underserved group (IMD 1-5, non-white ethnicity).

- demographics (e.g. ethnicity, deprivation)
- attendance history (previous non-attendee, recurrent attendee, first-time invitee)

We will also collect qualitative data on perceptions of the video shared in workstream C through an online questionnaire.

We will also repeat the primary analysis to determine the uptake at 6 months. These timepoints were chosen firstly from the literature which suggests the impact of behavioural interventions occurs in the acute decision workstream, but also following discussion with the screening service where 6 monthly reporting coincides with a key performance indicator.

4. PARTICIPANT ENTRY

4.1. PRE-REGISTRATION EVALUATIONS

For Workstream A, workshop participants will be invited through community groups working with underserved communities in the locality of the screening services taking part in the trials, some of whom were consulted in the creation of the original animation video and online workshop. We will also invite workshop participants through PPIE platforms including VOICE and People in Research.

In workstreams B and C as participants will be those invited as part of the NHSBSP, no additional pre-registration evaluations will be required.

Participants answering the online questionnaire about the animation video in workstream C will be invited through a link on the animation video page.

4.2. INCLUSION CRITERIA

The inclusion criteria will match those used by the NHSBSP, as all invitations will come directly from the programme, as per usual care. These include:

- Aged between 50 to 70 at the time of invitation
- Lives within London screening region
- Registered as female with GP

Inclusion criteria for workstream A workshops will be as follows:

- Aged between 47 and 73 (as per the Age extension for breast cancer screening which stopped due to covid)

The focus will be on recruiting an underserved population through community groups or PPIE forums such as VOICE or People in Research— as this is the population being targeted through the intervention.

4.3. EXCLUSION CRITERIA

The exclusion criteria will match those used by the NHSBSP, as all invitations will come directly from the programme, as per usual care. These include:

- Previous attendance at breast screening in the current (3-year cycle)

- Opted out of receiving SMS messages
- Opted out of screening
- Previous bilateral mastectomy

4.4. WITHDRAWAL CRITERIA

[Describe procedures for stopping early]

As messages will be sent through the NHSBSP and undertaken as part of the usual care process the withdrawal criteria will match those of the screening service. Individuals can opt-out of screening at any time throughout the process and will be excluded. No data for those who highlight opt-outs will be held or analysed by researchers. The opt-out decision will be retained by screening services, and they will not be contacted with the messages. This process involves either indicating opt-out through the national data opt-out (should they wish not for their data to be used) or by contacting the London or southeast breast cancer screening service using the details provided on their invitation letter. Individuals can also opt out of receiving SMS messages, including reminders from the breast cancer screening service. Those who have opted out will not have data passed to researchers for analysis. However, following pseudonymisation it will not be possible for researchers to identify individuals who wish to have their data withdrawn.

5. ADVERSE EVENTS

5.1. DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

5.2. REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

5.3.1 Non serious AEs

All such events, whether expected or not, should be recorded- it should be specified if only some non-serious AEs will be recorded, any reporting should be consistent with the purpose of the trial end points.

5.3.2 Serious AEs

An SAE form should be completed and emailed to the Chief Investigator within 24 hours. However, relapse and death due to breast cancer, and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the London Surrey REC where in the opinion of the Chief Investigator, the event was:

- 'related', i.e., resulted from the administration of any of the research procedures; and
- 'unexpected', i.e., an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all related and unexpected SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs
RGIT@imperial.ac.uk
CI email (and contact details below)
Fax: xxx, attention xxx
Please send SAE forms to: xxx
Tel: xxx (Mon to Fri 09.00 – 17.00)

6. ASSESSMENT AND FOLLOW-UP

[Will there be a follow up? When and what will their assessments consist of? Efficacy assessments, if applicable, should be included] Describe how incidental findings will be identified, reviewed and reported, and to which individuals they will be reported to (i.e. GP, clinical care team).

[Definition of end of study]

The end workstreams B and C of the study will be 6 months after initiation of the interventions. Following this period, we will undertake an assessment of the uptake of screening by participants.

Feedback from participants who have watched the video provided in the SMS reminder message will be sought. This will involve anonymised feedback regarding an individual's opinions on the content, characters, and style of the video. This feedback will be hosted on the video website and will be optional. Informed consent will be sought for the completion of this anonymous questionnaire.

7. STATISTICS AND DATA ANALYSIS

[Statistical plan, eg sample size calculation and data analysis.]

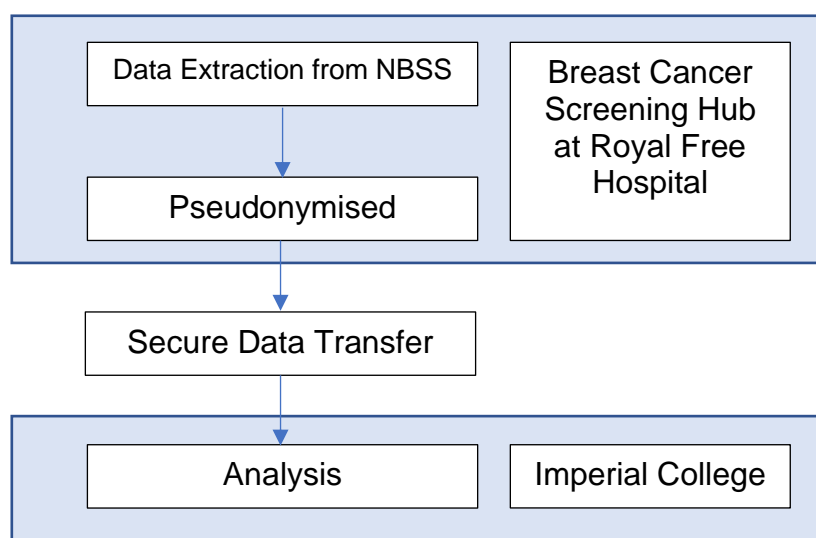
There will be two arms in the RCT, the control and the intervention group in both workstreams B and C. Based upon previous studies, and what would constitute a clinically meaningful effect size a power calculation has been conducted¹³. In workstream B assuming a 5% type 1 error probability, 80% power, and an effect size of 2.5% (determined through a literature search and previous trial of the animated video), results in a minimum sample size of 23,233 people per trial arm (46,466 overall) which will allow us to power for subgroup analysis in an underserved group (IMD 1-5, non-white ethnicity) who it is estimated make up 13.3% of the total sample size.

In workstream C assuming a 5% type 1 error probability, 80% power, and an effect size of 2% (determined through a literature search and previous trial of the animated video), results in a minimum sample size of 9,669 people per trial arm (19,338 overall). Because the underserved population (IMD 1-5, non-white ethnicity) are estimated to make up a smaller proportion of overall sample size we will not aim to power for subgroup analysis in workstream C.

Chi-squared non-parametric statistics will be used to determine whether effects are significant. Secondary outcomes will examine the impact upon attendance amongst subgroups including those with different invitation type and from different demographic groups. A regression model will be developed to test these secondary hypotheses.

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

Figure 2 Demonstrating data flow of project.



Variables that will be extracted for analysis will include:

1. Demographics

- Age at invitation
- Index of Multiple Deprivation (derived from postcode)
- Ethnicity
- Previous attendee/non-attendee/first-time invitee

2. Invitation

- Screening service location

3. Outcome

- Attendance at booked appointment

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

8. REGULATORY ISSUES

8.1. ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the London Surrey Research Ethics Committee (REC) and Health Research Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2. CONSENT

(If study does not involve consent, this section is not relevant)

Written consent will be taken for people participating in workstream A workshops. For in-person workshops information sheets will be provided to potential participants by the community groups from which they're recruited. They will be asked to sign an informed consent form prior to the workshop beginning – an opportunity for asking questions will be provided at the beginning of workshops. For online workshops participants will be provided with information sheets and asked to return a digital copy of a signed consent form before joining the workshop call.

No consent will be sought from participants taking part in the intervention RCT in workstreams B and C, as the act of alerting them to differing message contents can impact upon their behaviour and may bias results. For example, alerting participants to a breast screening project using invitation inserts to improve uptake, may act as a prompt for individuals who may have not attended to attend – skewing the study results. Furthermore, there is a need to test such invitation changes as a population-level intervention, to see if it has an overall effect. Basing such testing on small groups that have explicitly consented, will likely bias findings, and ignore the impact upon under-represented groups. Moreover, the current project is simply adding an additional insert based on a video approved by NHSE to the usual invitation in workstream B, and changing the video provided in reminder SMS message in workstream C

to one already approved by NHSE. Screening services have the capacity to autonomously change the content of screening reminders, for example in response to fluctuating uptake or change health policies on a local level. Explicit consent therefore is not being sought for this project, as it does not diverge from the existing care that individuals currently receive. Not requiring consent is in keeping with existing projects that have received ethical approval and been conducted in England on the use of behavioural science messaging^{14,15}.

Written consent will also be sought from the online feedback form for the video intervention. Participants will be free to withdraw from completing this questionnaire at any time, or not to undertake the survey at all should they wish. Consent to enter the study will be sought from each participant only after a full explanation has been given and time allowed for consideration. An online participant consent will be obtained. The right of the participant to refuse to participate without giving reasons will be respected.

8.3. CONFIDENTIALITY

Pseudonymised data is data that can be linked back to a person (e.g. coded data). It is considered both personal and identifiable data. Anonymised data is data that has no code and cannot be linked back to a person (e.g. aggregated data for publication, data without a code that cannot be linked back to a person)

Data from workstream A workshops will be anonymous and any identifiable information such as references to particular geographical areas removed.

Data from the intervention RCT (workstream B and C) will be pseudonymised, with the code retained by the NHS Screening Service for their purposes, researchers will not have access to this so will not be able to de-anonymise data. It will be extracted from the NBSS system with identifiers removed and transferred to the Big Data and Analytical Unit (BDAU) Secure Environment (SE) at Imperial College London for analysis. The BDAU SE is an ISO 27001 certified research environment and holds a "Standards Met" status for NHS Data Security and Protection Toolkit (EE133887-BDAU).

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

8.4. INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

8.5. SPONSOR

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

8.6. FUNDING

xxx are funding this study. [Any per participant payments, investigator payments should be detailed here]

NIHR are funding this research through the Patient Safety Research Collaboration.

Participants who participate in the workshops in Workstream A will be compensated for their time with vouchers amounting to £25/hour plus any travel expenses.

8.7. AUDITS

The study may be subject to audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Dr Gaby Judah.

10. PUBLICATION POLICY

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.

11. REFERENCES

¹ 'Cancer Research UK. *Breast cancer statistics* [Internet]. 2015 [cited 2023 October 5]. Available from: <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer>

² Breast cancer now. 'Breast cancer facts and statistics'[internet]. 2023 [cited 2023 October 5]. Available from: <https://breastcancernow.org/about-us/media/facts-statistics>

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⁴ NHS. *How to decide if you want breast screening* [Internet]. 2021 [cited 2023 October 5]. Available from: <https://www.nhs.uk/conditions/breast-screening-mammogram/how-to-decide-if-you-want-breast-screening/>

⁵ NHS Breast Screening Programme Statistics. Interactive report for annual data [internet]. 2023 [cited 2023 October 5]. Available from: <https://app.powerbi.com/view?r=eyJrIjoieYTFmMjVjYWVlN2MwZS00NWRmLWE0YzAtMmIxNzYxMjdmNWM4IiwidCI6IjUwZjYwNzFmLWJiZmUtNDAxYS04ODAzLTY3Mzc0OGU2MjllMmI0Oj9>

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- ⁶ Griffin S. Pause in breast cancer screening is opportunity to re-evaluate programme, says critic. *BMJ*. 2020 Oct 1;371:m3810.
- ⁷ Breast Cancer Now. *Breast screening and coronavirus: up to 1.5 million fewer women seen by screening services since they restarted* [Internet]. 2021 [cited 2023 October 5]. Available from: <https://breastcancernow.org/about-us/news-personal-stories/breast-screening-coronavirus-15-million-fewer-women-seen-screening-services-they-restarted>
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- ¹² OFCOM, Digital exclusion A review of Ofcom's research on digital exclusion among adults in the UK, March 2022, available at https://www.ofcom.org.uk/data/assets/pdf_file/0022/234364/digital-exclusion-review-2022.pdf [cited 13 October 2023]
- ¹³ Acharya A, Sounderajah V, Ashrafian H, Darzi A, Judah G. A systematic review of interventions to improve breast cancer screening health behaviours. *Prev Med*. 2021; 153:106828
- ¹⁴ Huf S. The use of behavioural sciences in targeted health messages to improve the participation in cervical and breast screening programmes [Internet]. 2017 [cited 2021 Dec 15]. Available from <https://ethos.bl.uk/OrderDetails.do?uin=uk.bl.ethos.784282>
- ¹⁵ Kerrison RS, Shukla H, Cunningham D, Oyebo O, Friedman E. Text-message reminders increase uptake of routine breast screening appointments: a randomised controlled trial in a hard-to-reach population. *Br J Cancer*. 2015 Mar;112(6):1005–10.

EXAMPLE APPENDICES

Appendices should be additional information to the protocol and can consist of:

-
- Common Terminology Criteria for Adverse Events (NCI CTC)
 - RECIST criteria
 - WHO / ECOG Performance status
 - PIS, Consent form, GP letter (although may be more practical to have them separate)
 - Expected side effects
 - Schedule of events table

Appendix 1. SMS messages

Current SMS:

Dear Client, your appointment is scheduled for 29/05/2024, 14:48, Egham Sports Centre Mobile Unit. Please call 0333 200 2062 to change your appointment if you have had a mammogram anywhere within the last 6 months. Thank you.

Updated standard option SMS:

Dear Client, your breast screening appointment is at 29/05/24, 14:48, Egham Sports Centre Mobile Unit. If you need to reschedule your appointment, or have had breast screening anywhere in the last 6 months, please call 0333 200 2062. Thank you.

Intervention option SMS:

Dear Client, your breast screening appointment is scheduled for 29/05/24, 14:48, Egham Sports Centre Mobile Unit. If you need to reschedule or have had breast screening anywhere in the last 6 months, please call 0333 200 2062. Watch this video to learn more about screening: <https://bit.ly/breast-screening-video>