A community champion led breast cancer screening intervention for underserved groups

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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:

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Funder

This study is funded by NIHR through a Population Health Research Grant.

This protocol describes the study "A community champion led breast cancer screening intervention for underserved groups" 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

BCS	Breast Cancer Screening
BCT	Behaviour Change Techniques
IMD	Index of Multiple Deprivation
HOT	Health Outreach Team
HES	Hospital Episode Statistics
IPW	Inverse Probability Weighting
LA	Local Authority
LBCS	London Breast Cancer Screening
PPI	Patient and Public Involvement
PPIE	Patient and Public Involvement and Engagement
NHS	National Health Service
NHSE	NHS England
NHSBSP	NHS Breast Screening Programme
TDF	Theoretical Domains Framework
BDAU	Big Data & Analytical Unit
RDN	Research Delivery Network
NIHR	National Institute for Health and Care Research
GP	General Practice/practitioner
QALYs	quality-adjusted life years
FAQs	Frequently Asked Questions
ICS	Integrated Care System
NWL	North West London
CRUK	Cancer Research UK

KEYWORDS
Breast Cancer screening, community intervention, women's health, co-production, behaviour change

STUDY SUMMARY

TITLE A community champion led breast cancer screening intervention for underserved groups

DESIGN A pragmatic, non-randomised evaluation of whether a behavioural science informed intervention, co-designed with eligible underserved groups (minority ethnicity, low IMD), delivered by community champions in Hounslow, increases breast cancer screening (BCS) uptake in these populations and overall.

AIMS **To test the impact of an intervention package delivered through community champions on breast cancer screening (BCS) uptake in underserved populations.**

1. To determine whether a 6-month community champion delivered intervention in a London borough increases BCS uptake
    - in general in the borough
    - in specific and combined underserved groups (minority ethnicity, IMD deciles 1-3)?
2. To examine the cost effectiveness of a community champion delivered intervention on BCS uptake
3. To measure the exposure to the intervention, and to test whether exposure is associated with more positive attitudes to BCS, intentions to screen and self-reported screening behaviour.

OUTCOME MEASURES Primary Outcome: Uptake of BCS, within 3 months of initial invitation.

Secondary Outcomes:

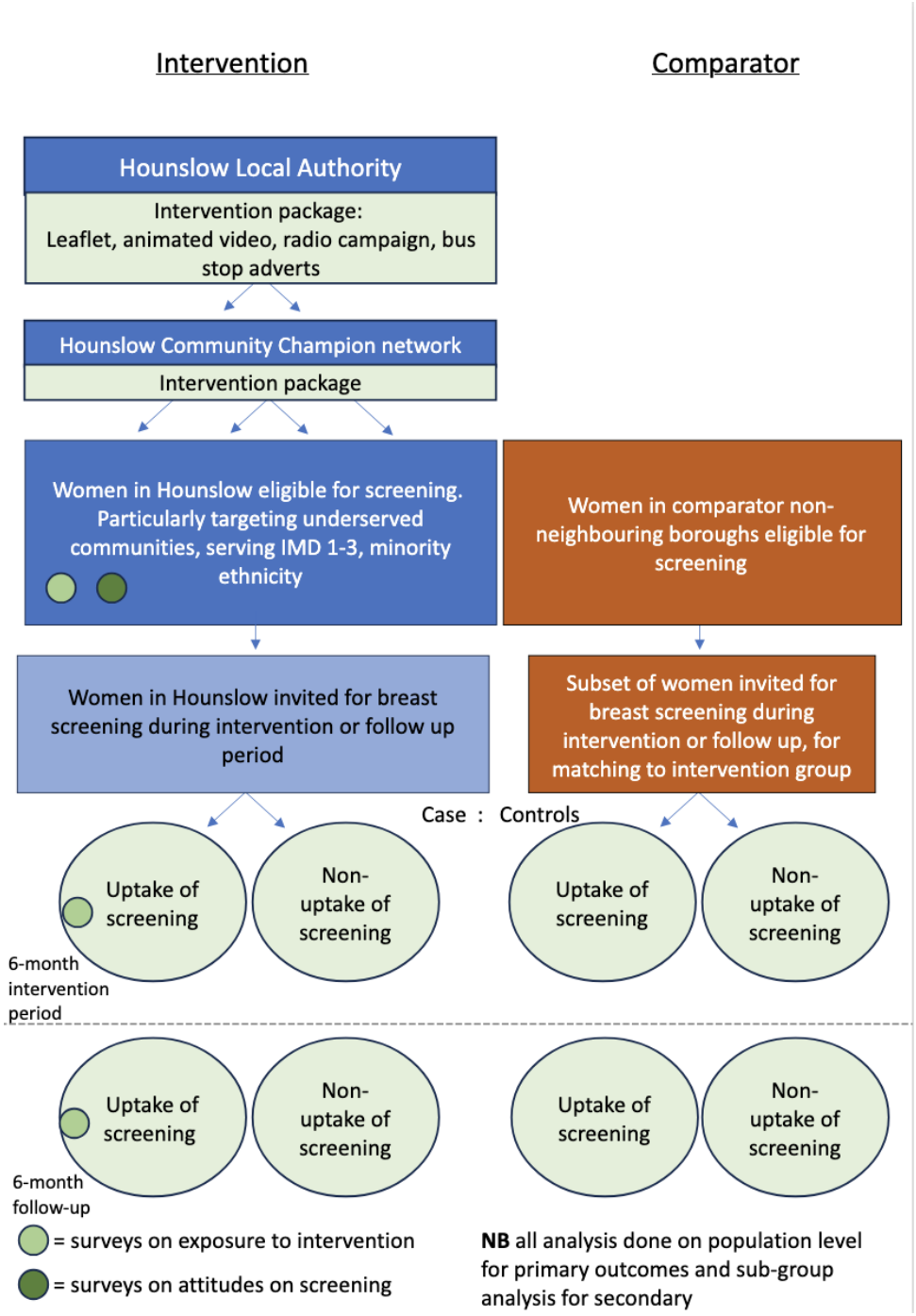
a) Uptake of BCS within 3 months of initial invitation amongst low-uptake subgroups
b) Exposure to the BCS intervention materials, attitudes to screening, intentions to screen and self-reported screening uptake

POPULATION All women in Hounslow, and comparator London boroughs eligible for BCS (age 50-70)

ELIGIBILITY Women in Hounslow (and comparator London boroughs) eligible for BCS invited for BCS during the intervention period

DURATION The intervention and assessment period will be 6 months, with 6 months follow up without promotion of the intervention. The data linkage and outcome analysis needed to assess longer term impact on screening uptake will take an additional 18 months following the end of the intervention. Therefore, the overall study duration is 2.5 years.

REFERENCE DIAGRAM



1. INTRODUCTION

1.1 Background

By 2028, the UK government aims that 75% of cancers should be detected at an early stage. Cancer screening forms a central part of this public health policy[1]. Breast cancer is the most common cancer in the UK, with 1 in 8 women affected during their lifetime[2]. Screening detects breast cancer at earlier stages. The 5-year survival rates for diagnosis at stage 1 and 2 are 98.2% and 89.5% respectively, but this drops to 72.2% at stage 3 and 26.6% at stage 4[3]. In 2018, 39.4% (around 18,800) of breast cancer cases were diagnosed at stage 1 in England. By enabling earlier detection, it is estimated that the National Health Service (NHS) breast screening programme saves 1,300 lives per year[4].

Despite the benefits of breast cancer screening (BCS), attendance is falling[5]. London rates (56% in 2023) are far below the NHS target of 70%[5]. There are socio-demographic inequalities in uptake[6] — in London odds of attendance in women from Indices of Multiple Deprivation (IMD) quintiles 1/2 is 11% lower than quintiles 4/5[7], and adjusted odds of attendance are almost 3 times higher amongst White British, than Asian women, and 6 times higher than Black women[8]. Those in most deprived areas have 5-year survival 7.8% lower than in the least[9]. Increasing uptake in underserved groups will diagnose breast cancer earlier, improving outcomes and reducing inequalities. Public Health England (PHE) Screening inequalities strategy (2020)[10] and CRUK 'manifesto for health'[11] prioritise equitable and increased screening uptake.

A recent report on population screening[12] recommends efforts to engage multiply underserved groups, and powering for subgroup comparisons in trial design. An NHSE review of cancer screening programmes in England[13] recommends creating links with faith leaders, community groups and relevant organisations to tackle inequalities. The proposal addresses barriers to BCS in underserved groups through an intervention delivered via community channels. In 2018[14] there were over 100 interventions to increase BCS in London, yet none promoting screening and funded by local authorities (LAs) were evidence-based. Many London councils[15], the Breast Screening Health Inequalities Advisory Group, and Community of Practice recommend community engagement to improve screening awareness. Transformation Partners in Health and Care[13] identified 18 interventions targeting BCS in North-West London (NWL) including 3 in Hounslow.

Our previous systematic review of patient–facing interventions designed to increase BCS attendance, found that of the 80 interventions (reported across 54 studies), only 50% were found to be effective. Interventions using the Behaviour Change Techniques[16] of 'self-belief', 'social support', and 'covert learning' improved attendance more than referring to consequences for the individual of non-attendance, and 65% (n=20) of interventions using 'credible source' were effective. These findings can be used to inform more effective interventions.

Our previous work included development and RCT of an animated intervention to increase breast cancer screening uptake, sent as a link with SMS reminders for screening[17]. The video was co-designed, and based on findings on barriers and facilitators to screening[18]. Despite positive feedback on the intervention, it did not increase uptake, and fewer than 6% women clicked on the link. A subsequent interview study (paper in prep) identified that women want to receive screening materials from people they trust. Therefore, a community champion model of intervention dissemination may lead to greater engagement with an intervention, and be more likely to increase uptake.

1.2 Rationale for Current Study

Our review of trial registrations on ISRCTN/clinicaltrials.gov of community engagement interventions for cancer screening (09/04/2024) identified a protocol[19] for a feasibility study of a cancer symptom awareness campaign to support the rapid diagnostic centre referral pathway in a socioeconomically deprived area of Wales. No studies looking specifically at cancer screening were identified. Therefore, evaluation of the impact on BCS uptake of a multifaceted campaign, co-designed and delivered to a range of underserved populations, through community champions is novel. The most similar existing work is by Haynes et al.,[20] yet this took place in the USA, the intervention was primarily delivered through events rather than including any social marketing, and this only targeted a single underserved subgroup (women of African heritage). Our proposed study aims to be broader in terms of population addressed and is likely to be more flexible and scalable.

Netto et al.,[21] identified five principles for adapting behavioural interventions for minority ethnic communities. Our co-produced intervention and champion model of delivery meets all five: identifying and addressing barriers to participation; use of community resources; development of acceptable communication materials; working with cultural/religious values; and accommodating varying cultural identification. The community champion model facilitates adapting the intervention to specific community needs and priorities. Findings can be applied to other areas to drive sustainable change at low cost e.g. increase BCS nationally/adapt to other screening/vaccine uptake.

The aim of this study is to test the impact of an intervention package delivered through community champions on breast cancer screening (BCS) uptake in underserved populations

2. STUDY OBJECTIVES

Primary Objective:
To determine whether a 6-month community champion delivered intervention in a London borough increases BCS uptake

. in general in the borough

. in specific and combined underserved groups (minority ethnicity, IMD deciles 1-3)?

Secondary objectives:

1) To examine the cost effectiveness of a community champion delivered intervention on BCS uptake

2) To measure the exposure to the intervention, and to test whether exposure is associated with more positive attitudes to BCS, intentions to screen and self-reported screening behaviour.

3. STUDY DESIGN

3.1 Design and theoretical/conceptual framework

This study is a pragmatic, non-randomised evaluation of whether a behavioural science informed intervention, co-designed with eligible underserved groups (minority ethnicity, low IMD), delivered by community champions in Hounslow, increases BCS uptake in these populations and overall. We will test for impact on BCS uptake (using London Breast Cancer Screening (LBCS) programme data), and associated costs to the patient, community leaders and the NHS. A quasi-experimental study design using a difference-in-difference design with inverse probability weighting (IPW) will allow us to estimate the effect of the intervention in Hounslow by comparing it to the BCS uptake in a matched population in comparator boroughs (see section 7: data analysis). Surveys will assess self-reported intervention exposure and impact of exposure on BCS attitudes and intentions. The intervention will be delivered and evaluated for 6 months, plus evaluation for 6-month post-intervention follow up. We will assess intervention cost effectiveness from the perspective of the patient and NHS.

The intervention uses behavioural science to co-design resources promoting breast cancer screening (BCS), including an animation, leaflet, and local outreach (e.g., bus adverts, radio).

3.1.1 Setting/context

The intervention will be delivered in the London borough of Hounslow. Hounslow was chosen given low BCS levels (2023 coverage 52.9%)[6], high ethnic diversity (55.9% ethnic minorities[22]) and high levels of deprivation (23% IMD 1-3[23]). Intervention delivery will focus on areas in the borough of high ethnic diversity, and the 11 Hounslow neighbourhoods in the most deprived 20% in England[24].

3.1.2 Study population

All women in Hounslow eligible for BCS (aged 50-70) will be the subject of the research as intervention participants. The comparator group will be women from other London boroughs which have comparable demographics and screening uptake levels to

Hounslow. Selected boroughs will not be neighbouring Hounslow, to minimise risk of intervention spillover.

While the intervention is aimed at women eligible for screening in Hounslow, the intervention target population will include a broader demographic, in order to increase awareness around the importance of breast screening, to increase social support and encouragement (e.g. from partners, friends, children of screening-eligible women). The intervention will particularly target communities in IMD deciles 1-3, and minority ethnicity groups. The population will be reached through the community champion intervention approach described below.

3.2 Intervention

The intervention will consist of a set of behavioural science informed, co-designed materials as an intervention package. These will be disseminated by a community engagement approach. The two aspects of the intervention (resources and community champions approach) will be discussed in turn below.

3.2.1 *Intervention resources*

We co-designed an **animated video**[25] (Follow link to watch) intervention with professional designers (see Figure 1), with subtitles translated into 16 languages to encourage BCS uptake.

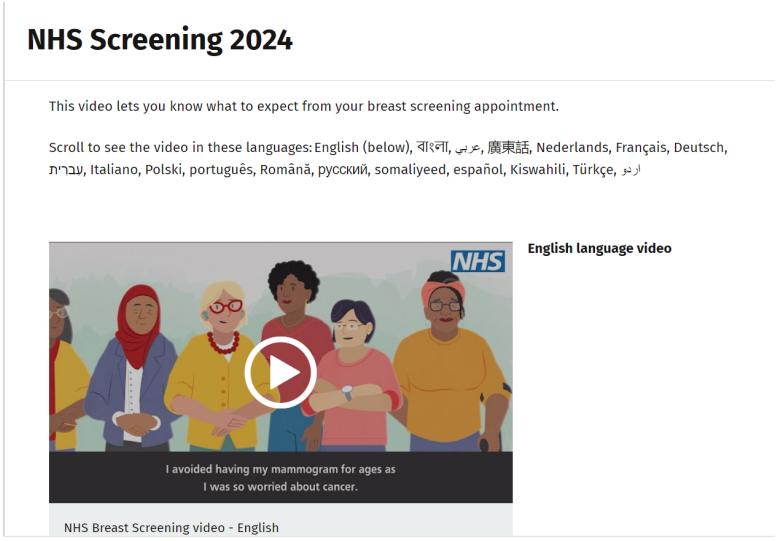


Figure 1 Landing page with video in English

We co-designed a **leaflet** through 3 workshops with women in Northwest and East London based on and using images from the video, to address barriers to accessing the video online, and preferences for hard copy information (see Figure 2) expressed during an interview study we conducted. This is available in four languages: English, Bengali, Arabic and Turkish — additional relevant translations will be produced for Hounslow as required. We will further refine the leaflet, and also create a wallet card

containing the same information, through patient and public involvement activities in Hounslow. Leaflets and wallet cards will have the link and QR code to the animated video.

Figure 2: Leaflet mock-ups in English

Bus stop adverts will be created using imagery from the video/leaflet, to display on busy roads in areas of higher deprivation.

As recommended by Hounslow LA based on previous health campaigns, we will facilitate **local radio campaigns** e.g. on RadioJackie (weekly listenership 123,000), and faith-based stations e.g. Al Mustafa Trust Radio, HOPE radio, using community champions and local clinicians as trusted channels to increase campaign exposure.

3.2.2 Community engagement approach

The way in which the intervention resources will be disseminated, is a key part of the intervention, as the Community Champion model helps to create trust in the information resources being shared. Additionally, community champions will receive training on commonly asked questions about BCS and will therefore be able to complement the intervention materials with further information and explanation.

Hounslow Local Authority (LA) has developed a multi-pronged engagement plan to reach a range of underserved women through community champions. As part of this we will work closely with Hounslow LA's Health Outreach Team (HOT), a community-based service that provides residents with information on local health and wellbeing support services. The HOT will help us in both disseminating materials and by recruiting community champions from faith groups and community organisations. Community groups suggested by Hounslow LA include She-wise, Ekta, Darpan, and Truinjan Women.

The community engagement approach will use other existing assets of Hounslow LA: their network of over 140 "Community connectors"; contact lists of neighbourhood-based community and faith groups; voluntary organisations; and local businesses e.g. salons. Champions will be recruited from these channels, who will disseminate intervention materials via their networks, to build on existing trust in a scalable and cost-effective way.

Champions will be given training, to disseminate resources in an appropriate way for their community (e.g. WhatsApp groups, Facebook, emails, in-person events) with cultural sensitivity, to women eligible for BCS as well as those who may influence their decision making e.g. family members.

Training sessions will be organised flexibly with several dates and times made available). The training will also be recorded, and clear written guides will be given, to support those who are not able to attend any of the training sessions. Frequently Asked Questions (FAQ) sheets on BCS will be given to anyone involved in intervention material dissemination.

The intervention video will be shared by digitally engaged community connectors via their networks, and community organisations on their social media pages or other communication channels. It will also be screened in the Treaty centre (Hounslow's central shopping centre) in the HOT office, which has a street facing screen, as well as on tablets available to the public within their office. Additionally, we plan to deliver the intervention materials (e.g. a 30 second clip of the video) as targeted adverts on social media via the council advertising network.

3.3 Data collection

3.3.1 Screening uptake data

Data on screening uptake for the intervention and control boroughs, for both the intervention and follow-up periods, will be obtained through the LBCS hub. Data will be requested for Hounslow, and all other London boroughs and screening services.

As ethnicity data is only stored once people have interacted with the breast screening service (i.e. attended screening), we will apply to link this data with Hospital Episode Statistics (HES) (inpatient and outpatient records), to ensure high levels of ethnicity data. We will apply for 5 years of HES data to maximise chances of recording ethnicity data across the sample.

All data will be transferred in anonymised format (i.e. without name, NHS number, postcode or date of birth) to Imperials' Big Data & Analytical Unit (BDAU) Secure Environment. The Imperial College London's Big Data & Analytical Unit (BDAU) Secure Environment (SE) is a secure research environment, providing a standard operating/access model, secure data storage and processing environment, and analysis software. It is ISO 27001 certified (Alcumus ISOQAR Ltd. - certificate number 15484_ISN_001) and compliant with NHS England Data Security and Protection Toolkit (organisation code EE133887-BDAU)

3.3.2 Survey data

In addition to the screening uptake data, we will collect survey data. We will survey 900 women in Hounslow: 400 at a screening site, and 500 in the community. Both surveys will take less than 10 minutes to complete completed on a tablet. Online consent will be taken in the first part of the survey. Entry will be incentivised by entry into a lottery for a £50 voucher using a separate form. Screening site surveys will assess exposure to the intervention, in order to identify which intervention resources or dissemination methods were most frequently encountered.

Screening site surveys (N=400) will collect demographic data, assess exposure to BCS campaigns (our intervention and others), ask which resources (e.g. leaflet, video) they encountered, and via which channels (e.g. faith groups, community centres). This will suggest the more impactful materials, to support funding prioritisation for LAs interested in implementing the intervention post-trial. Screening site surveys will take place over 3 months, during the second half of the intervention period. This timing means that women at the screening site should have been exposed to the intervention both prior to receiving their invitation and between the time of the invitation and their appointment. Women living in Hounslow will be recruited in the waiting room before or after their screening appointment, at the screening site Heart of Hounslow Centre for Health and Hanwell Clinic. They will be asked if they want to take part, and whether they live in Hounslow and will complete the short survey on a tablet computer. If recruitment takes place on two of the three clinics per week, and 50-60% women attending clinics complete the study, it is estimated that the sample size should be reached in 10 weeks. We will also apply for National Institute for Health and Care Research (NIHR) Portfolio adoption, so will have Research Delivery Network (RDN) support for screening site survey data collection.

Community surveys (N=500) will assess intervention exposure across different demographics, and association between exposure and intention to screen, and between exposure and self-reported screening attendance. In addition to demographic data, self-reported screening uptake, and questions about exposure to different

aspects of the intervention, participants will answer Likert-style questions on intentions to screen and barriers or facilitators to BCS, based on the Theoretical Domains Framework[41]. Community surveys will take place immediately following the end of the intervention (first three months of follow up), to see whether they remember the intervention over the short term, whilst allowing for maximum possibility of exposure during the intervention period. Survey recruitment will be supported by the HOT, and will take place at community events, on the streets in relevant target areas, and in the HOT offices.

We will conduct two focus groups of community champions after the intervention to understand experiences of sharing the resources, and feedback and reactions received to these. Focus groups will take place in person in a convenient Hounslow location, with 6-8 participants per group. Participants will be reimbursed £25 for participation.

3.4 Study outcome measures

Primary outcome: Uptake of BCS, within 3 months of initial invitation in general population

Secondary outcomes: Uptake of BCS, within 3 months of initial invitation in low-uptake subgroups including women from areas of high deprivation (IMD1-3) and ethnic minority groups.

As we cannot know whether all eligible women in Hounslow, including those in the underserved population, were exposed to the intervention, survey data will assess intervention exposure and self-reported intention to screen, reported screening uptake and barriers/facilitators to screening.

4. PARTICIPANT ENTRY

4.1 Pre-registration evaluations

Participants for uptake data will be those invited as part of the NHS Breast Screening Programme (NHSBSP), no additional pre-registration evaluations will be required.

Participants for community surveys will be women eligible for BCS in Hounslow.

Participants for Screening site surveys will be women eligible for BCS living in Hounslow who are attending a BCS site.

4.2 Inclusion criteria

To identify women eligible and invited for BCS, inclusion criteria will match those used by the NHSBSP, as all invitations will come directly from the programme, as

per usual care. Inclusion for the study (those whose BCS uptake data is included in primary analysis) will include any woman in Hounslow LA who is invited for BCS during the intervention period and those invited for screening at the same time in non-neighbouring comparator boroughs.

Inclusion criteria is therefore as follows:

- Aged between 50 to 70 at the time of invitation
- Registered as female with their General Practitioner (GP)
- Has not had a double mastectomy
- Registered address in Hounslow, or comparator boroughs
- Invited for BCS during 6-month intervention and 6-month follow-up period

Inclusion criteria for both surveys will be eligibility for BCS: registered with GP as female, aged 50-70, not had double mastectomy, and living in Hounslow.

4.3 Exclusion criteria

Exclusion criteria for the primary analysis of uptake will match those used by the NHSBSP, as all invitations for screening 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

Exclusion criteria for surveys will be women who are not registered with a GP as female, are not aged 50-70, or have had a double mastectomy, not living in Hounslow

4.4 Withdrawal criteria

Screening uptake: Data is anonymised data extracted from the screening service on uptake.

Surveys: Those who do not complete the survey will be considered to have withdrawn and their data will be removed.

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.

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.

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 <name of REC> where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie 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)

Please send SAE forms to: xxx

Tel: xxx (Mon to Fri 09.00 – 17.00)

6. ASSESSMENT AND FOLLOW-UP

The intervention and assessment period will be 6 months, with 6 months follow up without promotion of the intervention, to assess longer term effect of the intervention on screening uptake. The end of the study will be 2.5 years after the intervention period ends and data analysis is complete. This includes 6 months of intervention, 6 months follow up, a 3-month time lag for appointment invitation to uptake/non-uptake, 3 months for data access, 5 months for data linkage with NHSE ethnicity variable, and 6 months of trial outcome analysis.

We will conduct two focus groups for community champions who wish to share their views in more detail. Any detrimental impact of exposure on uptake will be assessed through the outcome and survey analysis.

7. STATISTICS AND DATA ANALYSIS

Sample size calculation

Primary analysis

Every 6 months 3,481 invited for BCS in Hounslow - sufficient for population level analysis. With a 1:3 ratio of cases (Hounslow) to controls (comparator boroughs), we will have 95% power to detect a 3.5% increase in uptake (realistic for a multi-modal intervention[26]), assuming a 53%[5] control group uptake (representative of lower-uptake LBCS services).

Comparator data

We will use data from London boroughs with similar demographics (IMD and ethnicity) and BCS uptake to Hounslow (non-neighbouring boroughs, to minimise risk of intervention spillover) as a comparator group in order to estimate the causal effect of our intervention. Comparator boroughs already identified are Tower Hamlets, Hackney, Newham and Islington, due to similar BCS uptake rates 52.2-54.9%, and similar demographic variables including poverty rates and non-white ethnicity levels. Across these four comparator boroughs 16,286 people are invited for screening in a 6-month period.

Sub-group analysis deprivation

Population data for Hounslow[27] indicates 19% of eligible women live in IMD 1-3 areas, giving an estimate of 661 women IMD 1-3 invited for BCS in Hounslow during a 6-month period. With a 1:3 intervention to control ratio for this analysis we have 83% power to detect a 6.5% increase in uptake from 53% to 59.5%.

Sub-group analysis ethnicity

Based on screening hub data for West London 54.1% of those invited for BCS (2023/24) are non-White (including British/Irish/other White) meaning in a 6-month period we can estimate that 1883 non-white women are invited for BCS in Hounslow. Using a 1:3 intervention to control ratio we have 86% power to detect a 4% increase in the intervention group from a baseline uptake of 53%.

Survey sample size

The screening site survey analysis will be descriptive, in order to assess levels of exposure to the intervention, and which intervention components had greater reach. Therefore, formal power calculations are not required, and 400 participants was felt to be sufficient for the descriptive analysis. The community survey (N=500) is powered to assess increase in intention to screen, (measured on a 5-point Likert scale), assuming 0.05 type-I error, and 80% power. Based on previous research we can expect the survey answers to have a standard deviation of 1.4 [28]. Given a difference in mean intention of 0.5 between individuals reporting being exposed/unexposed to the intervention, a sample of 330 would detect differences given 25% of the sample being exposed to the intervention, and a sample of 248 could detect a difference given 50% of the sample exposed to the intervention. For a 0.4 difference in intention score, a sample of 514 would be needed given 25% intervention exposure, 426 for 35% intervention exposure, and 386 for 50% intervention exposure. Therefore, a sample of 500 is likely to be sufficient for detecting expected group differences.

Data analysis

Data analysis uptake data

Primary and secondary analyses of uptake will use a difference-in-difference design[29].

Primary analysis will compare likelihood of attending BCS between women in Hounslow and the comparator boroughs comparing before and after the intervention. The outcome is binary, of attendance at the breast screening appointment. Covariates included in the regression are:

1. Demographics
    - Age at invitation
    - Index of Multiple Deprivation (derived from postcode)
    - Ethnicity (supplemented through data linkage with HES)
    - Previous attendee/non-attendee/first-time invitee

To estimate the effect of the intervention relative to the baseline differences across boroughs we will use a difference-in-difference design with inverse probability weighting of propensity scores[30]. For each person in Hounslow and the comparator boroughs, propensity scores for receiving the intervention will be calculated using

logistic regression including the following variables: age, ethnicity (obtained through screening data linked with HES), IMD decile, previous screening attendance, distance to screening site, and public transport accessibility score (available from Transport for London). The treatment effect will be calculated by creating a logistic regression model including attendance to the BCS service as the outcome variable, a binary indicator for the intervention group and a binary indicator for the time period (pre or post intervention) and a binary, along with an interaction term between intervention and time period. Each person will be weighted using inverse probability weighting of the propensity score[30]. Weighting will ensure the calculation of an average treatment effect which corrects for bias in the variables included in the propensity score estimation. Further unmeasured confounding effects will be estimated using the methods proposed by VanderWeele et al. *(*2011)[31], including calculation of the E-value to give an estimation of the strength of evidence for a causal effect of the intervention[32].

Secondary analysis will compare BCS uptake in underserved populations: i) non-white ethnicity and ii) IMD 1-3 in intervention versus comparator groups. The methods used to assess the impact on these populations will be the same as described for the primary analysis.

Data analysis surveys

We will conduct descriptive statistics of survey responses from screening sites to examine intervention exposure rates and conduct a two-proportion Z-test to identify significant exposure differences to different intervention resources or dissemination channels, and differences in exposure rates in different demographic groups.

For surveys in community settings. we will create self-reported exposed/non-exposed groups. We will descriptively assess proportions of people reporting exposure to the intervention. Chi squared-tests will compare intention to be screened and reported barriers and facilitators to BCS between self-reported exposed/non-exposed groups. Regression analysis will assess impact of exposure on intention, controlling for demographic co–variates. If sufficient survey participants were invited to BCS in the previous 3 months, Chi-squared tests will identify self-reported uptake differences based on intervention exposure.

The focus groups of community champions at the end of the study will be audio recorded and transcribed verbatim, then analysed using inductive thematic analysis[33], to understand experiences of sharing the intervention materials, and to consider any ways in which the support or information provided could be improved.

Data storage

Data and all appropriate documentation will be stored for a minimum of 10 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 xxx 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

No consent will be sought from participants who may be exposed to the community-based intervention, as the act of alerting them to their exposure to the intervention can impact upon their behaviour and may bias results. For example, alerting participants to a breast screening project using wallet cards 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 community-based interventions 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. 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[34].

Electronic consent will be taken from people participating in the surveys using Qualtrics. Participants will be free to withdraw from completing this survey at any time, or not to undertake the survey at all should they wish. Consent will be sought from each participant only after a full explanation has been given and time allowed for consideration. The right of the participant to refuse to participate without giving reasons will be respected. For a similar study run by Imperial of a Breast Cancer Screening Intervention, using a digital Qualtrics survey, the HRA REC (Surrey) requested that the informed consent procedure be streamlined to remove a lengthy Patient Information Sheet in order to reduce patient burden. We were advised that as this survey was fully anonymous, that a short data storage statement followed by a tick box to give consent would be sufficient for this sort of data collection. Participants will be given the chance to enter their email into a separate form (not linked to the surveys) in order to enter a prize draw for a £50 voucher. This separate form will include a short data privacy statement and a link for further information.

Community champions invited to take part in focus group discussions will receive a participant information sheet in advance of giving consent through written informed consent form. Consent will be sought from each participant only after a full explanation has been given and time allowed for consideration. The right of the participant to refuse to participate without giving reasons will be respected.

8.3 Confidentiality

Screening uptake data 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 – see figure 3. 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 a secure research environment, providing a standard operating/access model, secure data storage and processing environment, and analysis software. It is ISO 27001 certified (Alcumus ISOQAR Ltd. - certificate number 15484_ISN_001) and compliant with NHS England Data Security and Protection Toolkit (organisation code EE133887-BDAU).

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

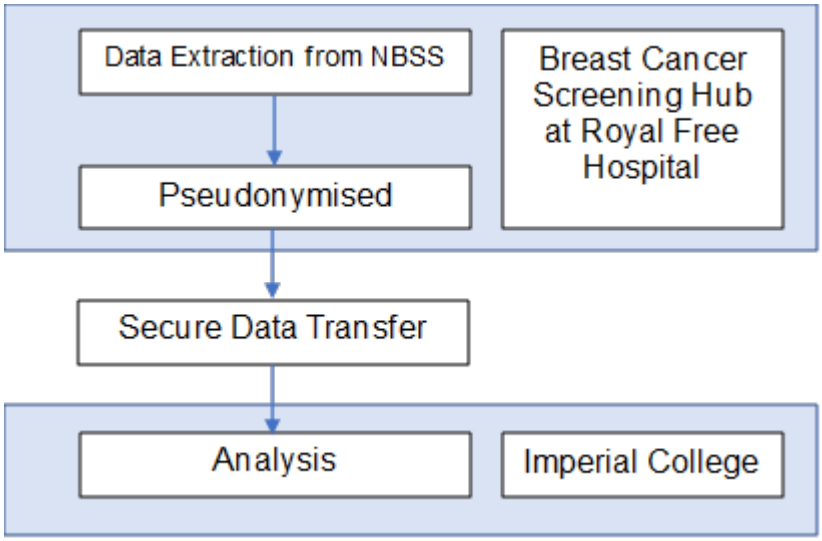


Figure 3 Demonstration of data flow of project

8.4 Indemnity

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study/ Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Resolution for NHS Trusts in England, which apply to this study (delete as applicable)

8.5 Sponsor

Imperial College London/Imperial College Healthcare NHS Trust (delete as applicable) 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

NIHR are funding this study through a National Institute for Health Research (NIHR) Population Health Research Grant (Number:164908)

8.7 Audits

The study may be subject to audit by Imperial College London/ Imperial College Healthcare NHS Trust under their remit as sponsor and other regulatory bodies to ensure adherence to Good Clinical Practice 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, Imperial College London.

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 and an intervention toolkit to facilitate wider roll out. No identifiable data will be used in any publication.

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1. APPENDIX

GANNT CHART

Activity	2025	2026				2027				2028	
	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Ethics											
Intervention refinement- PPIE											
Trial set up											
Intervention delivery											
Surveys at screening site											
Surveys in community											
Follow up											
Data access from NBSS					*						
Survey analysis											
DARS application											
Data linkage with NHSE ethnicity variable											
Trial outcomes analysis											
Economic evaluation											
Write up / output production											

* time lag between invitation to be screened and appointment non/uptake