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Availability of free door-to-door transport to increase the attendance of breast screening appointments in Yorkshire

Submission date 13/02/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 19/02/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 30/06/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Breast cancer is the most commonly diagnosed cancer in women in Yorkshire, causing more than 800 deaths per year in the region. Breast screening is one of the key tools to help diagnose breast cancer at an early stage and improve survival rates. Across Yorkshire, in the 3 years up to 2019/20 an average of 28.6% of invited women had not attended their appointment. Among the non-attenders, a major reason was the difficulty in travelling to the appointment. This study will assess whether offering free, bookable, door-to-door transport to and from breast cancer screening appointments could increase the number of women attending screening. The study will compare providing participants with a free bookable door-to-door transport service alongside the routine breast screening invitation letter with a control group who will only receive the routine breast screening invitation letter. This is an essential first step to understanding the feasibility of the trial procedures and intervention delivery and will give a signal of the effectiveness and cost-effectiveness and provide data to inform sample size calculations for a future definitive study.

Who can participate?

Women who meet the age criteria for the national breast screening programme (50 – 70 years old) and who are due to be invited to attend a routine screening appointment during the intervention window.

What does the study involve?

GP practices located in East Riding of Yorkshire or Kingston Upon Hull will be allocated to the intervention group or the control group. Women registered at GPs in the intervention group will receive information about booking free transport alongside their breast screening invitation. Women registered at GPs in the control group will receive the breast screening invitation as normal with no additional offer of transport. The researchers will collect routine screening attendance data from the NHS Breast Screening Programme and also the deprivation scores for the residential locations and participants' ethnicity data from NHS England. In addition, they will

assess how women have travelled to the screening sites using travel surveys. They will interview a sample of women from the intervention group and transport providers to assess the acceptability of the intervention.

What are the possible benefits and risks of participating?
Women registered at GP practices in the intervention group will directly benefit from the offer of free door-to-door transport to get to and from their breast screening appointments. The researchers expect at least one additional woman to receive a breast cancer diagnosis following attending a screening appointment within the feasibility trial. It is expected that providing free transport will increase the overall screening rates, resulting in earlier breast cancer diagnosis and improved survival rates. The findings from this study will inform a larger study. The future benefits include the submission of a funding application in Year 3 for the future definitive trial targeting Yorkshire. There is also potential to expand and apply the findings from this study to other cancer screening programmes where people have to travel to the screening provider (e.g. cervical, lung, prostate and colorectal cancer).

Where is the study run from?
University of Hull (UK)

When is the study starting and how long is it expected to run for?
June 2023 to January 2026

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Dr Charlotte Kelly, charlotte.kelly@hyms.ac.uk

Study website
https://hhtu.hull.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
330790

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 57905, Grant Code: RA/2022/R2/104

Study information

Scientific Title
Evaluating the effectiveness and acceptability of free door-to-door transport to increase the uptake of breast screening appointments in Yorkshire: a cluster randomised GP pilot trial

Acronym
DOORSTEP

Study objectives
Breast cancer is the most commonly diagnosed cancer for women across Yorkshire with around 4,300 women diagnosed each year(1). Breast cancer survival rates are highly associated with stage at diagnosis: five-year survival for women diagnosed at Stage I is 97.9%; at stage IV, it is 26%. The NHS breast screening programme started as a tool to ensure that more breast cancers were diagnosed at earlier stages. Whilst all eligible women between the ages of 50 and 70 years are invited to a breast screening appointment (on a 3-yearly schedule), in Yorkshire only 71.4% attended their appointment. On average in England, 8.4 breast cancers are diagnosed for every 1000 women screened. With approximately 197,000 women not attending in Yorkshire over three years this translates to a potential 1,655 breast cancer cases that could have been diagnosed earlier through the screening service if the screening appointment had been attended. Public Health England recommends that 70% of women attending a screening appointment is an acceptable threshold, but that 80% is achievable. Currently, Yorkshire is significantly below this achievable threshold and there is substantial variation in attendance rates across the region. Reasons for women not attending screening appointments include; not feeling at risk, previous negative experiences, language barriers, embarrassment or difficulties getting there. One of the most common barriers is difficulty in accessing the screening facilities either directly (e.g. due to the cost of transport) or indirectly (e.g. having other time commitments). A number of studies have identified that living further from a breast screening site is associated with being less likely to attend. One possible approach for increasing screening uptake rates is to target interventions that ensure women can get to breast screening facilities at a reasonable cost, in a reasonable time and with reasonable ease. The introduction of mobile breast screening vans targeted reducing the distance needed to travel by bringing breast screening facilities to local communities. However, constraints on where they can be located due to the van size, need for access to electricity and parking for operational staff and attendees have resulted in them not always being located in sites that are easy to get to without a car, or are based in areas unfamiliar to the women who need to attend. Additional measures such as

providing transport to reduce the physical barrier between home and screening site are still needed to allow some women to attend their appointments. Providing free door-to-door transport to get people to healthcare appointments for those who would otherwise find it difficult is not a new idea. The Yorkshire Ambulance Service carries out around a million non-emergency journeys each year transporting patients to hospital appointments. Women attending a routine breast screening appointment are not eligible to access this free transport service. A number of studies have investigated interventions to target improving access to screening appointments including providing taxis, bus passes and transport vouchers. To increase the uptake of breast screening in inner city Cardiff, Bell et al. provided women in three GP practices with a package of measures that included the offer of transport to the screening centre. The intervention resulted in a 15% increase in attendance at screening compared to the previous screening rate for these GP practices. However, as this was not an RCT there was no control group and the transport offer was part of a package of measures, so the direct impact on attendance was not assessed. We hypothesise that offering a free, easily accessible door-to-door transport service will improve breast screening rates in Yorkshire. We are proposing this feasibility trial as there is currently a lack of robust evidence to support the commissioning of this service for attendance at screening.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/02/2024, London - Harrow Research Ethics Committee (Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8154, +44 (0)207 104 8357, +44 (0)207 104 8137; harrow.rec@hra.nhs.uk), ref: 24/LO/0037

Study design
Randomized; Interventional; Design type: Process of Care, Other

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
The intervention is the offer of free door-to-door transport to a routine breast screening appointment for all eligible women registered at GP practices randomised to the intervention

arm of the trial. All women registered with GP practices in the intervention arm will be given information on how to book transport to their appointments. The information will be delivered through a letter (detailing the offer) that is included at the same time as the screening invite letter sent by the Humberside BSS. The transport offer will include being driven from home (or workplace) to the appointment, the driver will wait for the appointment to finish (around 15 minutes) and drive the participant back. We are working with taxi companies based in the two areas of East Riding of Yorkshire (ERY) and Kingston-Upon-Hull (Hull). The transport provider will provide transportation services, including any drivers licensed to carry out private hire bookings in accordance with the Private Hire Vehicle Regulations. The transport providers will be finalised when we know which GP practices have been recruited to the trial as they cover specific areas. The trial will cover the costs of the journeys.

The free transport will be offered with the first HEY screening invitation letter sent to the women. If the women didn't attend the first appointment offered, then a second invitation will be sent routinely from the screening service, and free transport will be offered at this stage again. If the women don't attend the second appointment offered by the HEY screening service, then no further appointment will be sent by the screening service. The women can then use the free transport up to 6 months from the first invitation letter if they subsequently book the screening appointment themselves.

If any of the participants in the intervention arm need a technical recall or recall for further assessment a free transport will be offered by the DOORSTEP study for these appointments. Sometimes further assessment may take longer, in this case, the taxi driver will not wait at the centre but a return taxi will be booked in a timely manner.

The study is a cluster-randomised feasibility trial, with clustering at the level of GP practice. We will recruit 8 GP practices to this study GPs will be allocated to the intervention group and the control group. A GP cluster randomised design has been proposed instead of individual patient level randomisation for two reasons: the complexity of individual randomisation and preparation of letters with/without transport information for the screening service; and the letter inviting women to book transport may be shared or discussed between women who are registered at the same practice or live in the same area leading to trial contamination. Known issues of requiring larger sample sizes and recruitment bias in cluster RCTs are mitigated as all women at intervention practices will receive the intervention letter and anonymised routinely collected outcome data is being obtained.

Women at participating GP practices will receive the standard screening invitation letter at the usual planned time from the screening service with women registered at an intervention GP practice receiving additional information about the transport booking instructions.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
As a feasibility trial, the primary aim is to assess the feasibility of conducting the future definitive RCT. The primary feasibility outcomes are summarised along with criteria that will be used as a guide for progression to a future definitive Phase III trial and described here:
1. Number of GP practices that agreed to participate and were randomised ahead of the

scheduled breast screening invitation window
2. Percentage of women invited from GP practices located in the 10% most deprived areas
3. Percentage of intervention invites sent out by the BSS to all women during the scheduled breast screening invitation window
4. Percentage of women who requested transport who were transported to and from their appointment by the service
5. Acceptability of the intervention to the women and the service providers
6. Completion and transfer of the screening and transport service data when required for analysis
All measured at the end of the study

Secondary outcome measures
The secondary outcomes are summarised below and are the intended outcomes for the definitive trial, and the data that will help inform sample size calculations for the Phase III trial.
1. Screening uptake rates: percentage attendance at screening appointments, exploring if there is a signal of efficacy (increase in screening rates in the transport intervention arm compared to usual care)
2. Transport intervention uptake rates
3. Cost-effectiveness: estimates of the cost-effectiveness of the transport intervention
All measured at the end of the study

Overall study start date
01/06/2023

Completion date
31/01/2026

Eligibility

Key inclusion criteria
1. GPs located in East Riding of Yorkshire or Kingston Upon Hull
2. Whose women meet the age criteria for the national breast screening programme (between 50 and 70 years old) and are due to be invited to attend a routine screening appointment during the intervention window

Participant type(s)
Patient

Age group
Adult

Lower age limit
50 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
Planned Sample Size: 8000; UK Sample Size: 8000

Key exclusion criteria
1. GP practices located outside of the set geographical area
2. Women with non-routine screening appointments

Date of first enrolment
12/06/2024

Date of final enrolment
01/03/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
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Sponsor information

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University of Hull

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Sponsor type
University/education

Website
https://www.hull.ac.uk

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/10/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available to maintain the confidentiality of all participant data in accordance with the General Data Protection Regulation Act (2018) and not reproduce or disclose any information by which participants could be identified. Confidentiality will be maintained at all times.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol file	version 1.1	20/01/2024	18/02/2025	No	No