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Increasing informed participation in lung cancer screening using pathway navigation

Submission date 25/11/2024	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 01/05/2025	**Overall study status** Ongoing	
Last Edited 15/07/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Lung cancer is the third most commonly diagnosed cancer in the UK and the leading cause of cancer death. Survival is worse in those diagnosed at a later stage, where treatment options are limited. Many people do not have symptoms before diagnosis, particularly in earlier stages of the disease. Screening with low-dose computed tomography (CT) scanning enables detection of asymptomatic lung cancer. Trials have shown that screening reduces lung cancer deaths. In the UK, screening for lung cancer was recommended in June 2022, and a national screening programme, the Lung Cancer Screening (LCS), was implemented. Individuals aged 55-74 years who have ever smoked are invited to a telephone risk assessment, followed by a CT scan appointment if found to be high risk. Unfortunately, a significant proportion of people do not participate in lung cancer screening. The evidence suggests that higher-risk people, specifically those from socioeconomically disadvantaged and underserved populations, are less likely to attend screening appointments. Addressing non-participation is fundamental to maximise screening effectiveness and reduce health inequalities. Pathway navigation is a process involving motivational interviewing and decision coaching that aims to increase participant confidence to make an informed decision about screening participation. Preliminary studies have shown that pathway navigation improves uptake of initial lung cancer screening invitations, but this hasn't been trialled within NHS LCS, nor has it been investigated for screening follow-up appointments. IMPALA aims to assess the impact of pathway navigation within LCS. The primary outcome is attendance at subsequent LCS appointments, both baseline and follow-up. Impact on screen- and non-screen-detected lung cancer diagnosis and staging will also be evaluated. The study will also assess the implementation of pathway navigation in busy NHS services, through qualitative interviews with participants and providers, and through assessment of delivery metrics and cost-effectiveness.

Who can participate?
People aged 55 to 74 years old eligible to participate in NHS England's LCS programme who have been invited to an initial face-to-face appointment or follow-up CT scan and Did Not Attend (DNA) their scheduled LCS appointment

What does the study involve?
The navigator will contact the participant within 1-4 weeks after randomisation. If successful,

they will obtain verbal consent and deliver the intervention, which includes:
1. Introduction to the LCS (benefits and risks)
2. Discussion of personal barriers and solutions
3. Agreement to book a CT appointment
4. Willingness to be contacted for an interview study
If the participant agrees, the navigator will book the CT appointment and usual pre-appointment practices will continue.

What are the possible benefits and risks of participating?
Participants randomised to receive the intervention will receive a phone call from the pathway navigator, which will involve a discussion about lung cancer screening, identifying personal barriers and dissembling misinformation, combined with motivational interviewing. This will enable participants to make an informed decision regarding screening, and some may find the interaction helpful, reassuring or empowering. Those randomised to the control arm will receive standard care, with no additional benefit. By participating, individuals will help to optimise future LCS services, potentially facilitating participation among other people who have struggled to attend screening, thus increasing early detection rates of lung cancer and reducing deaths for future participants.

All of the people who are being contacted for this study have previously told the LCS that they are happy for their identifiable data to be used for research purposes, but they have not been specifically asked about this study before. This is to prevent things from being too burdensome, and it is known that recruiting people to a trial sometimes changes their behaviour. Everyone who receives the navigator call will be asked to specifically agree (consent) to be in the trial before the navigator gives more information about the LCS. Everyone else will receive the usual care and can opt out of the trial if they do not want to take part. Approval for this approach was sought from the 'Confidentiality Advisory Group', who provide expert advice on the use of confidential patient information. Because the study is assessing a pathway navigator phone call, there are minimal risks involved, although some people may find it difficult to talk about lung health screening. It is also possible that those participating in the qualitative interview may experience emotional distress. The interview will be conducted by a trained qualitative researcher with advanced communication skills, and an SOP has been developed for distress in qualitative interviews, with the offer to signpost to free resources.

Where is the study run from?
Southmead Hospital, UK

When is the study starting and how long is it expected to run for?
November 2024 to July 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Anna Bibby, anna.bibby@bristol.ac.uk

Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
349605

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR303200, CPMS 66929

Study information

Scientific Title

Increasing informed participation in lung cancer screening using pathway navigation . A multi-centre randomised controlled trial using a type one hybrid effectiveness-implementation design

Acronym
IMPALA

Study objectives
It is hypothesised that pathway navigation with motivational interviewing increases attendance at Lung Cancer Screening (LCS) appointments in people who have recently Did Not Attend (DNA)' d an invitation to an appointment, compared with standard care.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/03/2025, Yorkshire and the Humber – Bradford Leeds (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle Upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8083, (0)207 104 8243; bradfordleeds.rec@hra.nhs.uk), ref: 25/YH/0033

Study design
Multi-centre randomized controlled trial using a type one hybrid effectiveness-implementation design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Internet/virtual, Telephone

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Lung cancer screening

Interventions
This is a multi-centre randomised controlled trial study with decentralised/remote follow-up, assessing the impact of a pathway navigator on participation in lung cancer screening (within the Lung Cancer Screening (LCS) programme). A navigator is a trained healthcare professional who can support people to overcome barriers to attendance via motivational interviewing and practical support. The primary outcome will be attendance at their next LCS appointment, obtained from LCS records. Secondary outcomes include attendance at subsequent LCS appointments over the 24-month screening cycle (from LCS records), whether lung cancer was diagnosed, whether it was screen-detected or non-screen detected and what stage the tumour

was (obtained via data linkage with the National Cancer Registration and Analysis Service; NCRAS).

A cost-consequence analysis will be undertaken, considering all relevant and accessible costs and outcomes. We will include LCS delivery costs, collected via study records, and if accessible, the Hospital Episode of Statistics (HES) to determine secondary care costs, costed using the National Schedule of NHS Costs. An implementation analysis will be undertaken, including qualitative interviews assessing the acceptability of navigator involvement to LCS participants and staff.

People will be eligible for the study if they miss an invited CT scan appointment (baseline or follow-up) within the LCS. Individuals who have declined consent to their clinical data being used for research (recorded at initial LCS appointment and recorded on participants' electronic LCS record) or have selected the National Data Opt-out on their NHS record will not be eligible. Eligible people will be identified from the LCS clinic lists. Anyone who has not attended a scheduled LCS appointment (baseline or follow-up) will be randomised 50:50 to either usual care or to be contacted by the navigator. Usual care will follow the standard LCS provider's approach to missed appointments. This will vary between sites but will likely involve 1-2 contact attempts from the appointments team, followed by an automatic rebooked appointment. In contrast, the navigator will try and contact the participant up to five times. If contact is made, the navigator will discuss the LCS programme, identify personal barriers, and support the participant to make an informed decision about whether to attend their lung cancer screening appointment. The SOP for the navigator intervention is provided in the trial documents.

All participants will be sent a Participant Information Sheet, with a research opt-out form and Freepost envelope included. Those randomised to the intervention arm will also receive a letter with the details of their scheduled navigator appointment (telephone). If successful contact is made by the navigator, informed verbal consent will be obtained before the intervention is delivered. Individuals can withdraw from the study at any time, either during the navigator phone call or by returning the opt-out form or by contacting the opt-out telephone line, and they will continue to receive standard care.

Recruitment will take place over a 12-month period. An interim analysis evaluating the primary outcome (attendance at the next LCS appointment) will be undertaken one month after recruitment is complete. Secondary outcomes and implementation measures will be collected for a further 30 months after the end of recruitment. Full statistical analysis will take place at the end of the trial (30 months after randomisation of the final participant). Qualitative interviews will be undertaken during the recruitment period and following 6 months, and will be analysed contemporaneously.

An average-size LCS site invites 12,000 people to a scan each year. Approximately 3,200 (23%) of these do not attend the scan; of those, we would expect approximately 160 (5%) to rebook for another date/time. The lung cancer detection rate from screening is between 1.5% and 3%, and if our intervention were to increase the number of participants rebooking from 160 (5%) to 288 (9%), this could translate into an additional 2 to 4 cancer diagnoses per site, per year. The number of participants needed in each group to demonstrate a true increase in participation from 5% in the control group to 9% in the intervention group, with 90% power and a two-sided significance level of 0.05, is 1,825.

Attrition from this trial should hopefully be minimal, but we have allowed for a 10% loss. All participants will receive an opt-out form (both intervention and control), which, if completed, may not permit us to collect their data for the primary/secondary outcomes. Attrition due to

death or moving away is possible but given the short window between randomisation and primary outcome data collection, this should be relatively small. Accommodating 10% attrition and assuming equal numbers in the two groups, we would need 1004 participants per group and 2008 in total. Due to uncertainty around attendance in the control arm, an additional ~20% flex factor has been added to ensure adequate power regardless of baseline participation.

Participants who received the navigator intervention will be asked to provide their consent to be contacted in future for the qualitative sub-study. A small number (n=25) of these people will be invited to participate in a brief (30-45 minute) one-to-one qualitative interview via telephone, at a time that suits them. Navigators will also be invited to take part in qualitative interviews, as will a purposively sampled group of LCS staff (n=15). Participants in the qualitative study will be provided with a separate qualitative PIS and will be asked to provide verbal consent before proceeding with the interview. Qualitative participants will be reimbursed for their time with vouchers.

Qualitative participants excepted, people in the intervention arm will not be contacted again for research purposes once the navigator has delivered the intervention (or failed to make contact after five attempts). People randomised to receive standard care will not be contacted by the trial team at any time. All data collection will be undertaken remotely, through linkage with routinely collected clinical and LCS datasets. This approach has been chosen deliberately to minimise the demand on participants and reduce attrition or withdrawal from clinical services due to research burden. Remote follow-up through data linkage, including the use of identifiable information to enable this, was approved by PPI members.

PPI perspectives have been sought on the key ethical issues related to the trial methodology (randomisation without consent and use of identifiable information for data linkage) and are reported in section A6-2. PPI participants were also asked about their thoughts on research participation in general and about the acceptability of the navigator intervention. Their views are reported below.

Participation in research
Participants were all supportive of research in theory. Several had participated in research before, especially COVID, COPD and diabetes studies, but others had no experience of research participation. Many people expressed a wish to help others, including to improve the LCS service for future users or create better provisions for their children or grandchildren. Most people recognised that participating in research would not benefit them directly, but would be for the good of others. A few people said that being in research was good because it means more attention/ input from clinicians.

Acceptability of navigator intervention
Asked whether they would feel “hassled” if a navigator called them after they had not attended an appointment, participants all said no. One man said “as long as you made it clear it was for my benefit (health) then that would be fine.” Also, it was important for the navigator to know when to take “no” for an answer, and have thick skin if that “no” were delivered abruptly or rudely! Some people felt that if a person had made their decision not to attend LCS, then they should be left to it. The same people appreciated that people may not have all the right information, or may benefit from the opportunity to talk things through with someone who understood the service before making their decision. They agreed that these people should be offered support to allow them to make an informed choice.
One man said that he would be unhappy if he didn’t receive the navigator intervention because he felt that everyone should have help to allow them to attend LCS if they needed it. On further discussion, he recognised that resource (specifically money) limited this and that, in research, we

need to have something to compare the intervention to in order to see if it works. He was glad that the intervention would be offered to everyone if it were to become standard practice in the NHS.

Intervention Type
Behavioural

Primary outcome measure
Attendance at the subsequent (i.e. recently defaulted and rescheduled) Lung Cancer Screening (LCS) appointment measured using patient LCS records. The outcome will be binary (yes/no) and will be collected within a month of the intervention.

Secondary outcome measures
1. Attendance at 24-month LCS appointment, reported as the proportion of eligible participants measured using patient LCS records. The outcome will be binary (yes/no) as collected on routine LCS databases.
2. Attendance at 3-month interval scan, reported as the proportion of eligible participants amongst those who have been invited for an interval 3-month scan measured using patient LCS records. The outcome will be binary (yes/no) as collected on routine LCS databases.
3. Attendance at 12-month interval scan, reported as the proportion of eligible participants amongst those who have been invited for an interval 12-month scan measured using patient LCS records. The outcome will be binary (yes/no) as collected on routine LCS databases.
4. Complete attendance at LCS invitations, reported as the number of participants attending all invited LCS appointments after randomisation for which they are eligible (i.e. before death /diagnosis/moving away) measured using patient LCS records.
5. Screen-detected lung cancer diagnoses (binary: yes/no), histological sub-type (categorical: small cell, adenocarcinoma, squamous cell, NSCLC NOS and other) and stage (I - IV) measured using data from linked National Cancer Registration and Analysis Service (NCRAS) records
6. Non-screen detected lung cancer diagnoses and stage (binary: yes/no), histological sub-type (categorical: small cell, adenocarcinoma, squamous cell, NSCLC NOS and other) and stage (I - IV) measured using data from linked NCRAS records data
7. Proportion of eligible (non-randomised) individuals in the household who attend all invited LCS appointments within the follow-up period of the randomised participant measured using patient LCS records. The outcome will be binary (yes/no) as collected on routine LCS databases. Household members who have returned an ‘opt-out’ form will not be included.
8. Intervention delivery rate, defined as the number of successful navigator contacts within the eligible participant population, measured using trial records.
9. Navigator contact rate, defined as the number of contact attempts per individual measured using trial records.
10. Number of incorrect contact details so navigator contact was not possible, defined as the proportion of total participants measured using trial records.
11. Fidelity of intervention delivery, measured using data collected during structured observation of navigator phone calls.
12. Barriers and facilitators to implementation delivery, measured using data collected during qualitative interviews with navigators.
13. Acceptability of pathway navigation to participants, measured using data collected during one-to-one qualitative interviews.
14. Acceptability and feasibility of navigation for LCS staff, measured using data collected during focus groups.

Overall study start date

25/11/2024

Completion date
01/07/2028

Eligibility

Key inclusion criteria
To be eligible for IMPALA, participants must:
1. Be eligible to participate in NHS England's LCS programme, AND
2. Have been invited to an initial face-to-face appointment or follow-up CT scan, AND
3. Did Not Attend (DNA) their scheduled LCS appointment, AND
4. Have opted-in for their clinical data to be used for research at their initial LCS telephone triage appointment.

Participant type(s)
Service user

Age group
Mixed

Lower age limit
55 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
2400

Key exclusion criteria
Participants are not eligible for the trial if any of the following apply:
1. Participant declines to consent to share their data for research purposes at triage or face-to-face assessment
2. Participants have selected the National Data Opt-Out on their NHS record
3. Participant have returned their opt-out form after initial contact or randomisation
4. Participant has declined to participate in LCS with a status recording of "opt-out" on their LCS record or GP record
5. Participant's non-attendance at LCS is due to no longer being eligible e.g. moving out of the area, ageing out, or change in clinical circumstances.
6. Participant has been randomised to IMPALA following non-attendance at a previous LCS appointment.

Date of first enrolment
01/09/2025

Date of final enrolment

28/02/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Bristol NHS Trust
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
https://www.nbt.nhs.uk/

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trial findings will be presented at national and international conferences (e.g. British Thoracic Society, British Thoracic Oncology Group, European Respiratory Society). A full report will be written and submitted for publication in a peer-reviewed journal (e.g. Thorax). Participants and the public will be informed through written summaries provided to third sector organisations (e.g. Roy Castle Foundation, Asthma + Lung UK). A visual summary poster will be produced (e.g. by artibiotics) and shared with participating sites to be put up in LCS clinics, sites, and scanners. A brief summary of the trial will be posted on the Bristol ARU website.

Intention to publish date
05/09/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Anna Bibby (anna.bibby@bristol.ac.uk).

Full, anonymised data sets will be shared, provided participants have not previously opted out. Data will only be available 12 months after the trial has concluded and after publication of the main study results. Participants in the intervention arm will be asked to consent to data sharing, but those in the control arm will not. No identifiable data will be shared. Data sharing will be in line with the University of Bristol's Research Data Management and Open Data policy, and in agreement with NHS Digital. Anonymised individual patient data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Sharing regarding scientific quality, ethical requirements, and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods, and

analysis of the secondary research, e.g. a protocol for a Cochrane systematic review. Patient identifiers will not be passed on to any third parties.

IPD sharing plan summary

Available on request