ISRCTN13013437 https://doi.org/10.1186/ISRCTN13013437

Testing whether adding a quick tummy scan to routine lung cancer screening can help detect other serious illnesses earlier

Submission date 12/08/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 09/09/2025	**Overall study status** Ongoing	
Last Edited 17/11/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Early detection through screening can improve cancer survival by identifying it when it's most treatable. The NHS now offers Lung Cancer Screening (LCS) assessments to people aged 55–74 years who have ever smoked. Those at higher risk of lung cancer are offered a lung scan. This group also has a high risk of developing abdominal cancers, such as kidney cancer. A recent study explored whether it would be feasible to extend the lung scan to include the abdomen. Results showed most participants supported this addition, and the number of serious findings was similar to those detected in UK breast or bowel cancer screening programmes. However, the abdominal scan was only offered on the day of the lung scan, giving little time for people to consider their decision. The process also added too much time to be practical for widespread implementation.
This new study will:
1. Test whether mentioning the possible abdominal scan in the initial LCS invitation affects participation in LCS assessments.
2. Test new processes to assess if the abdominal scan can be added to the lung scan with minimal extra time.
3. Check if participants can be split between the lung scan only group and lung and abdominal scan group using an approach called 'cluster randomisation'. This will be important in case a bigger trial is needed.
4. See whether the additional processes are acceptable

Who can participate?
People aged 55-70 years who are invited to the first round of the NHS Lung Cancer Screening (LCS) programme in one of West Yorkshire and Harrogate Cancer Alliance’s LCS or Humber and North Yorkshire Cancer Alliance’s LCS programme during the study period.

What does the study involve?
The study involves receiving the standard LCS invitation letter which informs the recipient that they may be eligible to be invited to have an abdominal scan at the same time as the lung scan. If they are eligible and accept the invitation to have the abdominal scan at the same time as the

lung scan they will receive results of the abdominal scan and if there are any abnormal findings this will be followed up and the patient will enter the NHS standard treatment pathway to receive any necessary investigations and treatments.

What are the possible benefits and risks of participating?
The possible benefit of participating is the early detection of abdominal diseases such as cancers or abdominal aortic aneurysms which will lead to earlier treatment and a better chance of a positive outcome.
The main risks of participating in this study are those associated with having a non-contrast abdominal (i.e. tummy area) CT scan, specifically:
1. The risks of investigations and/or treatment needed for any abnormal findings seen on the abdominal CT scan
2. The risk of harm from finding and treating slow-growing cancers that may never cause problems
3. The psychological worry resulting from the screening findings
4. The risk of cancers caused by radiation from the scan.

Where is the study run from?
The study is sponsored by University of Cambridge and recruits participants from the Lung Cancer Screening programmes in Yorkshire.

When is the study starting and how long is it expected to run for?
November 2024 to October 2027

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

Who is the main contact?
Prof. Grant Stewart, gds35@cam.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Grant Stewart

ORCID ID
https://orcid.org/0000-0003-3188-9140

Contact details
Department of Surgery
University of Cambridge
Box 202
Level E9 Addenbrooke’s Hospital
Hills Road
Cambridge
United Kingdom

CB2 0QQ
+44 (0)1223769002
gds35@cam.ac.uk

Type(s)
Scientific

Contact name
Dr Michelle Clark

ORCID ID
https://orcid.org/0000-0003-0134-5564

Contact details
Project Manager
Department of Surgery
University of Cambridge
Box 202
Level E9 Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ
-
mc2634@cam.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT07171190

Integrated Research Application System (IRAS)
357376

Central Portfolio Management System (CPMS)
61626

Grant Code
RA\2024\R2\107

Study information

Scientific Title
Targeted abdominal CT in conjunction with lung cancer screening – a pilot study (TACTICAL1): a randomised controlled pilot study of adding abdominal non-contrast CT to lung cancer screening CT thorax amongst high lung cancer risk ever-smokers aged 55-70 years

Acronym
TACTICAL1

Study objectives
The Yorkshire Kidney Screening Trial (YKST) showed that adding an abdominal non-contrast CT (ANCCT) scan to lung cancer screening (CT Thorax) is feasible and can help detect other serious abdominal conditions like kidney cancer and abdominal aortic aneurysms.

TACTICAL1 is a pilot study of adding ANCCT to NHS Lung Cancer Screening (LCS) Low Dose CT scan (LDCT) thorax in two cancer alliances LCS (West Yorkshire and Harrogate Cancer Alliance and Humber and North Yorkshire Cancer Alliance).

TACTICAL1 study hypothesis:
We seek to demonstrate, in a pilot randomised control trial (RCT), if this process can be rolled out into the LCS environment with a near-future goal of undertaking a definitive RCT to assess if the major diseases can be detected significantly earlier (called a "stage shift") and if screening leads to improved disease specific survival.

TACTICAL1 study rationale:
TACTICAL1 aims to test the full process of adding abdominal scans to lung screening to ensure it works smoothly, doesn’t reduce participation or slow down scanning, and is acceptable to both patients and healthcare staff. It will also test the method of randomly assigning participants to receive either a lung scan only or both lung and abdominal scans, in preparation for a larger future study.

This study plans to:
1. Test whether mentioning that an abdominal scan may also be offered within the initial lung cancer screening invitation affects the number of people agreeing to the lung cancer screening assessment.
2. Test new processes to assess if the abdominal scan can be added to the lung scan with minimal extra time.
3. Check if participants can be split between the lung scan only group and lung and abdominal scan group using an
approach called 'cluster randomisation'. This will be important to test in case a bigger trial is needed.
4. Assess if these additional processes are acceptable to participants and healthcare professionals involved in the processes of the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/07/2025, North-West Preston REC (2 Redman Place, Stratford, London E20 1JQ, UK; +44 (0)207 104 8364, +44 (0)2071048037, +44 (0)207 104 8181; preston.rec@hra.nhs.uk), ref: 25/NW/0185

Primary study design
Interventional

Study design
Randomized; Interventional; Design type: Screening, Imaging

Study type(s)
Screening

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

Interventions
The TACTICAL1 study participants are high lung cancer risk ever-smokers aged 55-70 years 364 days taking part in the first round of a West Yorkshire and Harrogate Cancer Alliance LCS and a Humber and North Yorkshire Cancer Alliance LCS. The study has two randomisations: (i) Individual randomisation to receive an invitation letter for LCS (standard of care; invitation control) versus invitation letter for LCS with potential for an additional abdominal scan (invitation intervention). This is to ensure that mentioning the additional scan is not detrimental to LCS uptake. (ii) Cluster randomisation to being offered a CT Thorax only during the LCS assessment (standard of care in LCS; scan control) or offered both CT Thorax and ANCCT during this assessment (scan intervention). This is to pilot this randomisation approach with the near-future aim of a fully powered study. The study includes an embedded process evaluation.

There are three major elements to the logistics of TACTICAL1:
1. Adding ANCCT to the LCS process: from invitation to completion of the ANCCT, the existing NHS LCS programmes for the two sites will be leveraged. These LCSs are part of NHS England's national programme and as such, follow NHS England's standard protocol.
2. Downstream processes from the scan: reporting of the ANCCT, informing participants of results, dealing with abnormalities and making appropriate referrals into the existing NHS standard pathway of care are new TACTICAL1 specific processes, separate to the LCS, which will be tested and evaluated.
3. Additional non-clinical TACTICAL1 processes: Observations, questionnaires and time-and-motion studies of the end-to-end process together with health care professionals (HCP) and participant invitations to and conducting of qualitative interviews on acceptability of the process are additional non-clinical TACTICAL1 activities undertaken by the TACTICAL1 research team.

Participants will receive a phone call and answer some initial screening questions to assess their risk of lung cancer and their eligibility for screening (eligibility for LCS and for TACTICAL1). Participants will be randomised in two stages, as detailed above. Participants will attend LCS and receive either CT thorax alone, or CT thorax plus ANCCT. The CT thorax and ANCCT will be reported by radiologists and triaged according to their findings with outcome driven actions, based on the previously performed YKST. Those with normal scans or abnormal findings of no concern (for example benign cysts, small stones (<5 mm), anatomical variants) will be sent a 'normal' letter, using templates based upon those used in YKST. The remaining participants will be discussed in an Imaging Review Meeting (IRM), attended by a research nurse and a consultant. Participants will be referred into the standard NHS Standard Care Pathway, with participant results letters, GP letters and referral letters written and sent by the site research team as appropriate. There will be a 6-month follow-up for all participants in the scan intervention group who are reviewed at the IRM with a finding requiring further action. No long-term follow-up assessment will be undertaken for all other participants.

As part of the process evaluation, a researcher will spend two days at each of the LCS scanning units. The researcher will time the various activities which occur during TACTICAL1 on the scanning unit to assess how processes could be streamlined. All HCP participating in this study will be invited to participate in an interview with a member of the research team. In addition, paper questionnaires will be provided to scanning unit staff for them to complete one each at the end of every scanning day. They will focus on throughput, any delays and causes, and perception of feasibility.

The researcher will also conduct semi-structured interviews with study participants to explore reasons for declining ANCCT. Up to 10 people will be interviewed and if sufficient numbers, they will be purposively sampled for variation in age and sex. Additionally, semi-structured interviews will be undertaken with study participants who consented to have the ANCCT (purposive sample of up to 20 individuals).

Intervention Type
Other

Primary outcome(s)
1. Attendance rate at the LCS phone call of those receiving the TACTICAL1 invitation letter offering an additional scan of the abdomen, if eligible, versus those sent the standard LCS invitation letter. Descriptive analyses will first be used to summarise the attendance rate at the LCS phone call of those sent the invitation letter versus those sent the control letter. A non-inferiority test will be conducted using a one-sided 97.5%
confidence interval approach. The primary analysis will involve a difference-in-proportions test comparing the response rates between the control and intervention groups. If the lower bound of the confidence interval for is greater than -5% then non-inferiority will be concluded. If non-inferiority is demonstrated, a subsequent superiority test will be conducted to assess whether the proportion in the intervention group is significantly higher than in the control group, using a one-sided test at the 2.5% level. As this is a hierarchical testing approach, no adjustment for multiple comparisons is required when proceeding from non-inferiority to superiority testing. For each of the two sites, we will present aggregated data on the proportion of those in the invitation control group and invitation intervention group who attend for a LCS risk assessment. The proportions will be reported with 95% confidence intervals. We will additionally report the proportion of participants in each group by age, sex, smoking status, ethnicity, education level and socio-economic status.
2. Successful cluster randomisation of participants into scan control and scan intervention groups, demonstrated by groups of similar size and demographics. Baseline characteristics of those randomised will be compared.
3. Number of participants scanned per day, time and motion study to evaluate impact, from invitation to scan, of adding ANCCT processes to the existing LCS processes, and impact on overall throughput of LCS plus data from daily short questionnaire completed by LCS and Scanning unit staff capturing perceived impact of TACTICAL activities on throughput. A comparison of the number of scans performed in a day over the study period will be made with the number of scans in a period immediately before and/or after the study. The mean number of scans performed per day will be compared using an unpaired T-test. The time impact from invitation through to scan of adding ANCCT processes to the existing LCS processes, and impact on overall throughput of LCS will be assessed through analysis of the LCS assessment recordings, the field notes taken during observations on the scanning unit visit days, together with data from daily short questionnaire completed by Scanning unit staff on the number of scans undertaken.
4. Qualitative and quantitative acceptability to participants and health care professionals of the key processes in combined thorax and abdominal screening, including: Data on the acceptability to participants and health care professionals of the key processes in combined thorax and abdominal screening will come from qualitative and quantitative assessment. The qualitative (verbatim transcripts made from the recordings of semi-structured interviews, text from observational field notes, reflective memos, field notes from informal interviews) data will be thematically analysed based on Braun and Clarke's Principles. Quantitative (Likert scores from questionnaires, time for activities) data, calculated as described above, will be combined with the qualitative with a convergent mixed-methods approach. The qualitative and quantitative

data will be combined through a narrative and via 'joint display': creating a visual map of the process and highlighting key additional steps, their impact and strategies to overcome any barriers. Analysis will be supported by NVivo software and relevant theories will be incorporated as necessary through abduction.
Over 75% of participants responding that they are satisfied or very satisfied with the process will be taken to be acceptable.

Key secondary outcome(s)
The proportion of participants accepting the offer of ANCCT will be recorded. Success will be determined by at least 80% of participants being offered the ANCCT, accepting the invitation and attending the scan.

Completion date
30/10/2027

Eligibility

Key inclusion criteria
To be randomised at the individual level to receive an invitation letter for LCS (standard of care; invitation control) versus an invitation letter for LCS with potential for an additional abdominal scan (invitation intervention):
1. Be eligible to be invited to the first round of a West Yorkshire and Harrogate LCS or a Humber and North Yorkshire Cancer Alliance LCS (i.e. have been identified as a smoker or ex-smoker and registered as living within the relevant LCS catchment area)
2. Be registered with a GP in England
3. Be aged 55-70 years 364 days old at the date of invitation

To be eligible for the cluster level randomisation the participant must:
1. Have been individually randomised to the invitation intervention arm
2. Have booked in for an LCS assessment

To receive the CT Thorax plus ANCCT, the participant must:
1. Have been randomised to the scan intervention cluster
2. Be invited to attend for an LDCT Thorax based upon scores on either PLCOM2012 or Liverpool Lung Project (LLP) risk prediction models (PLCOM2012 risk of >=1.51% over 6 years or LLPver2 5-year risk of >=2.5%) (17) during the LCS assessment.
3. Have attended the lung scan appointment
4. Have given electronic or written informed consent to participate

For the process evaluation:
Healthcare professionals:
Healthcare professionals involved in the delivery of LCS in any of the study areas who agree to take part.

Participants:
People individually randomised to the invitation intervention arm who attend the LCS assessment or the scanning unit within the study period and who agree to be interviewed.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
55 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
For the individual level randomisation to invitation control or invitation intervention:
1. None

For the cluster level randomisation to scan intervention or scan control existing LCS exclusion criteria:
1. Participant does not have capacity to give consent (standard criteria for assessing capacity apply)
2. Weight or physical size exceeds restrictions for the scanner (>200 kg)
3. Participant unable to lie flat
4. Poor physical fitness such that treatment with curative intent would be contraindicated
5. Participants who have had a full CT Thorax that meets the image reconstruction parameters of the programme in the last 12 months are not excluded from the lung screening programme, but would have their CT Thorax appointment deferred until 12 months have elapsed since that last scan, provided they still meet all inclusion criteria and have no exclusion criteria – if the deferred appointment is within the timeframe for TACTICAL1, they remain eligible but if deferred appointment is outside the timeframe for TACTICAL1 they would not be eligible.

Additional TACTICAL1 exclusion criteria:
1. Had an abdominal CT in the previous 12 months or has one booked within the next 3 months

Date of first enrolment
31/10/2025

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
NHS West Yorkshire Integrated Care Board
White Rose House
West Parade
Wakefield
England
WF1 1LT

Sponsor information

Organisation
University of Cambridge

ROR
https://ror.org/013meh722

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Grant Stewart (gds35@cam.ac.uk). This will be anonymised aggregate data and shared in an Excel or similar file format. It will be available for 5 years once the study has been published.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.1	21/07/2026	17/11/2026	No	No
Study website			30/12/2025	No	No