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Increasing uptake of lung cancer screening in individuals at high risk of lung cancer

Submission date 23/09/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/09/2015	**Overall study status** Completed	
Last Edited 10/10/2023	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

This study is a randomised controlled trial to test novel invitation methods and materials designed to increase informed uptake of lung cancer screening in individuals at high risk of lung cancer. Lung cancer Low (radiation) Dose Computed Tomography (LDCT) screening has been shown to reduce the number of people who die of lung cancer and of all causes by picking lung cancer up at an earlier stage when treatment is more successful. Screening is now underway in various countries across the world. For the benefits of lung screening to clearly outweigh the harms, screening needs to be targeted at people who are at high risk. However multiple studies have shown that uptake is particularly poor in this group. Qualitative research in this area has highlighted some of the possible explanations for this. This has enabled the development of a novel method of approaching this target population. The aim of this study is is to compare lung screening uptake in people who are sent our new materials designed to improve uptake with people receiving more conventional materials.

Who can participate?

Adults aged 60 to 75 who are current smokers

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive a lung health check invitation and those in the second group receive the standard care. Participants are followed up to see if participants attended the health check two weeks after receiving the invitation,.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

University College London (UK)

When is the study starting and how long is it expected to run for?

October 2014 to December 2019

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

Who is the main contact?
Dr Mamta Ruparel

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT02558101

Secondary identifying numbers
CPMS 19480

Study information

Scientific Title
Randomised controlled trial to test novel invitation methods and materials targeted to increase informed uptake of lung cancer screening in individuals at high risk of lung cancer

Study objectives
The aim of this study is to investigate the impact of a novel invitation strategy on attendance rates to a pre-lung cancer screening lung health check appointment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Medical Research Ethics Committee, 15/07/2015, ref: 15/LO/1186

Study design
Both; Interventional and Observational; Design type: Process of Care, Screening, Cohort study; Randomized

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Topic: Cancer; Subtopic: Lung Cancer; Disease: Lung (small cell)

Interventions
Patients are individually randomised (1:1) to receive either control invitation materials or intervention invitation materials. Those who attend will undergo a "lung health check" and be invited to a baseline screening scan if eligibility criteria are fulfilled.

Control invitation materials: These are similar to standard materials used in other NHS screening programmes.

Targeted invitation materials: The intervention invitation materials are specifically designed and hypothesised to improve uptake to a pre-screening lung health check appointment.

Follow Up Length: 12 month(s)

Intervention Type
Other

Primary outcome measure
Attendance to lung health check measured approximately 2 weeks post receipt of invitation

Secondary outcome measures
1. Adverse eventsare monitored throughout the study in all participants
2. Demographics of attenders and non-attendersis determined at the initial primary care search
3. Eligibility, uptake and willingness for baseline screening scan measured at baseline (lung health check appointment)
4. Informed decision making measured at baseline lung health check appointment, the day after and 3 months after the appointment
5. Investigations and costs generated from screening determined at the end of study
6. Mortality and Survival rates determined at the end of study

7. Psychological burden of screening determined at baseline lung health check appointment, the day after and 3 months after the appointment
8. Radiological and clinical outcomes determined at the end of study
9. Smoking data, lung cancer risk and medical history determined at baseline (lung health check appointment)

Overall study start date
01/10/2014

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Aged 60 to 75 years
2. Recorded as a current smoker from 2010 or later

Participant type(s)
Patient

Age group
Adult

Lower age limit
60 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Planned Sample Size: 2000; UK Sample Size: 2000; Description: A total of 2000 patients will be invited for a lung cancer screening appointment, 1000 in each arm. This will provide 90% power to detect a significant difference in uptake of 35% vs. 42%, with 5% significance level and two-sided testing. We estimate 35% uptake in the control group with a 7% increase in uptake in the intervention group based on similar studies examining the effect on screening uptake of 'psycho-educational' materials.

Total final enrolment
1005

Key exclusion criteria
1. Active diagnosis of lung cancer or metastases
2. CT thorax within the past year
3. Inability to consent to study
4. Palliative care register
5. GP's alert to co-morbidity that contraindicates screening or treatment for lung cancer

Date of first enrolment
02/11/2015

Date of final enrolment
07/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Medicine
Rayne Building
5 University Street
London
United Kingdom
WC1E 6JF

Sponsor information

Organisation
University College London Biomedical Research Unit

Sponsor details
Ground Floor
Rosenheim Wing
25 Grafton Way
London
England
United Kingdom
WC1E 6BT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Cancer Research UK (NAEDI)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Intent to publish date: around 1 year after end of trial.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/04/2016		Yes	No
Results article	cardiovascular risk results	01/12/2019	27/05/2020	Yes	No
Results article	psychological burden results	01/12/2020	23/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Substudy results	01/06/2019	10/10/2023	Yes	No
Other publications	Substudy results	01/07/2020	10/10/2023	Yes	No
Other publications	Substudy results	14/05/2022	10/10/2023	Yes	No

Results article	nodule and cancer outcomes	05/08/2020	10/10/2023	Yes	No