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Yorkshire Enhanced Stop Smoking (YESS)

Submission date 17/09/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/09/2018	**Overall study status** Completed	
Last Edited 17/04/2023	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
There is currently no standard of 'usual care' for offering smoking cessation (help to stop smoking) within lung cancer screening programmes. More than 4 out of 5 cases of lung cancer are caused by tobacco smoking. Stopping smoking, at any age, greatly reduces lung cancer risk. Lung cancer screening programme should provide smoking cessation support. Doing this makes lung cancer screening programmes more successful overall.
Studies have shown that when healthcare services provide personalised information on the risk of illness, more people try to quit smoking and more successfully quit smoking. The purpose of the study is to try to find out the best way of providing support to smokers who would like to quit smoking after they have had a lung health check.

Who can participate?
Anyone who had a Lung Health Check in the first 2 years of the Yorkshire Lung Screening Trial (ISRCTN42704678), who has smoked within the last month or has an exhaled carbon monoxide (CO) level of 6 ppm or above. Participants must be able to give informed consent.

What does the study involve?
All participants will get the standard best treatment. This includes a combination of behavioural support, nicotine replacement therapies (NRT) and/or an e-cigarette. Participants will be randomly allocated to standard treatment alone or standard treatment along with a personalised interaction that includes information and images from their recent lung scan. As part of the study we will contact participants at 3 and 12 months after their lung health check to complete a short questionnaire. If participants have quit smoking, they will be asked to provide us with a breath test to measure CO levels.

What are the possible benefits and risks of participating?
The information that we get from this study may help the study participants and others to stop smoking. If our study shows that we can improve the chances of staying off cigarettes after lung screening then participants will have contributed to the evaluation of a new service which could guide how smoking cessation is integrated into future lung screening programmes. The only potential disadvantages of the study are the inconvenience of us contacting study participants, of them answering our questions and providing measures of carbon monoxide.

Where is the study run from?
University of Nottingham, UK

When is the study starting and how long is it expected to run for?
The study will start in in November 2018 and will recruit participants until 31st August 2020, with data collection ending 14th March 2022.

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

Who is the main contact?
Dr Rachael Murray (public contact)
Rachael.murray@nottingham.ac.uk

Contact information

Type(s)
Public

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT03750110

Protocol serial number
18046

Study information

Scientific Title
Yorkshire Enhanced Stop Smoking (YESS): The effect of adding a personalised smoking cessation intervention to a lung cancer screening programme

Acronym
YESS

Study objectives
This study aims to address a deficiency in the evidence base by comparing a theory-based enhanced smoking cessation intervention with standard care for smokers who participate in the Yorkshire Lung Screening Trial ((YLST) ISRCTN42704678)

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Derby Research Ethics Committee, 31/08/2018, 18/EM/0199

Study design
Pragmatic parallel-group open-label randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Tobacco/nicotine dependence

Interventions
All participants:
All individuals attending for a Lung Health Check who have smoked within the last month (eligible individuals) will be offered an immediate consultation with an Smoking Cessation Practitioner (SCP), trained to National Centre for Smoking Cessation and Training standards. The SCP will explain, advise and deliver smoking cessation support in accordance with NHS Stop Smoking Service best practice (and NICE PH48 guidance) over a 4-week period. Individuals will be able to decline the offer of support should they so wish.
After the screening visit, but before the 4-week follow up, all eligible individuals will be randomised to either standard best care or intervention.
At the 4-week follow up visit (which will take place either at home, on the mobile unit or the community location according to patient preference) the SCP will collect written consent for participation in the trial and if participants agree to take part they will be treated according to their pre-assigned treatment group.

Usual care:
In accordance with current standard practice, smoking status will be assessed and validated in those reporting cessation by measuring exhaled CO. Participants who have successfully quit smoking at this point will be provided with continued pharmacotherapy/e-cigarettes and behavioural support in accordance with standard practice, and those who have relapsed to smoking encouraged to make another attempt to quit, with further behavioural support and pharmacotherapy as appropriate. All consenting participants will be contacted at 3 and 12 months after screening to ascertain current smoking status, with in-person visits for collection of exhaled CO samples arranged if abstinence is reported. Pharmacotherapy/e-cigarettes and behavioural support will continue to be offered and arranged, as outlined above.

Intervention group:
Those allocated to the intervention group will receive, in addition to usual care, the personalised

feedback outlined below:
At the 4-week follow up visit, personalised feedback from the participant's screening appointment will be provided.
The exact content of the intervention, and method of presentation is currently being refined but is likely to include:
• For participants with emphysema, an image of their own emphysematous lung compared to a library image of normal lung, or a section of their own non-emphysematous lung. Where emphysema is not present, library pictures showing normal and emphysematous lung will be used.
• For participants with coronary artery calcification, a cross-sectional segment from their chest scan (either horizontal or vertical) showing the calcium compared to a library image of coronary arteries without calcification and/or a healthy section of the participant's own heart scan. Where coronary artery calcification is not present, library pictures showing normal and calcified coronary arteries will be provided.

Sub-study:
Those who decline to see the SCP, and those who decline to take part in the YESS study will be asked to complete a short screening questionnaire to explore their reasons for this decision. Some will also be invited to take part in a sub-section of the main trial comprising of an interview (n = 30), and also asked to provide smoking status over the telephone (and CO validation in quitters) 3 and 12 months after screening.

Added 03/09/2020:
The researchers have recently made the following minor amendments to the protocol:
1. Amended consenting procedures to include taking verbal consent over the telephone If social distancing is recommended or the patient is self –isolating due to COVID-19.
2. Provide an option for the intervention leaflet to be delivered over the telephone to those patients where social distancing is recommended or patient is self –isolating due to COVID-19. In short, the Smoking Cessation Practitioner (SCP) will describe the leaflet to the patient, post the leaflet to the patient and then telephone the patient to check understanding and answer any queries.
3. CO validation of quits not collected if social distancing is recommended or the patient is self –isolating due to COVID-19.

Intervention Type
Mixed

Primary outcome(s)
7-day point prevalence of smoking cessation validated by exhaled CO at 3 months after the Lung Health Check

Key secondary outcome(s))
1. Self-reported continuous smoking cessation at 3 months after the Lung Health Check
2. Self-reported continuous cessation at 12 months after the Lung Health Check
3. CO-validated cessation at 12 months after the Lung Health Check
4. Self-reported continuous cessation at 4 weeks after the Lung Health Check
5. CO-validated cessation at 4 weeks after the Lung Health Check
6. Changes in psychological variables, including perceived risk of lung cancer, motivation to quit smoking tobacco, confidence and efficacy beliefs (self and response) at all follow up points

Added 03/09/2020:
7. 7-day point prevalent self-reported smoking cessation at 3 months after the Lung Health Check, to account for the inability to measure 12-week CO validated smoking cessation (primary outcome) in a proportion of study participants due to COVID-19 restrictions

Completion date
11/03/2022

Eligibility

Key inclusion criteria
1. Aged 55 to 80 years
2. Residing in the newly merged Leeds South & East, Leeds West or Leeds North CCG
3. Registered as a current or ex-smoker in a General Practice participating in YLST
4. Have attended 'Lung Health Check' as part of YLST, and agree to see the on-site Smoking Cessation Practitioner (SCP)
5. Smoked within the last month or have exhaled CO reading of 6 ppm or above.
6. Have capacity to provide informed consent.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
1001

Key exclusion criteria
Participants who do not meet the inclusion criteria

Date of first enrolment
05/11/2018

Date of final enrolment
24/03/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Screening Vans in the Yorkshire Lung Screening Trial; Leeds Teaching Hospitals NHS Trust
Room 07/0B/06A
Leeds Chest Clinic
Martin Wing
Leeds General Infirmary
Great George Street
LS1 3EX
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Not defined

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 the current study will be available upon request from Rachael.murray@nottingham.ac.uk after 31st December 2021 and until 2028.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/09/2020	15/09/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Co-development of an evidence-based personalised smoking cessation intervention for use in a lung cancer screening context	15/12/2022	16/12/2022	Yes	No