ISRCTN10364896 https://doi.org/10.1186/ISRCTN10364896

Supporting people in Yorkshire who smoke to Quit: the YorQuit study

Submission date 26/11/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/12/2024	**Overall study status** Ongoing	
Last Edited 28/05/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Lung cancer rates are higher in Yorkshire than in the rest of the UK, but deaths from lung cancer can be prevented by screening, and a national screening programme has now been recommended. Evidence shows that adding stop-smoking support to screening can increase the number of lives saved. However, it is still unclear how best to deliver smoking cessation alongside screening to make sure this is effective, affordable for the health service, and deliverable.

NHS England is developing a mobile phone app to deliver stop-smoking support alongside existing local stop-smoking services; however, the effectiveness of digital technologies has not been tested in a lung screening setting. Other evidence has shown that telephone support from a dedicated stop-smoking team attached to screening services can be highly effective. Finally, there is good evidence from other settings (e.g. pregnancy) that financial incentives such as shopping vouchers are effective, but this has not been tested in a lung screening setting. This study will compare stop-smoking services delivered through a mobile phone app and existing local services, against telephone support from a dedicated stop-smoking team. In addition, it will test the added benefit of a modest financial incentive for people who successfully quit.

Who can participate?

Participants will be attendees of one of three lung health check programmes across Yorkshire: Hull, Bradford, and Leeds. People who are contacted as part of the lung health check programme will be offered to participate in the trial if they are aged 55-74 at the time of consent, and if they are current smokers.

What does the study involve?

Participants will be randomly placed into one of three groups: 1) to receive support from local stop-smoking services, plus the offer of a free subscription to the Smoke Free app; 2) to receive support from YorQuit smoking cessation practitioners; or 3) to receive support from YorQuit smoking cessation practitioners, plus receiving shopping vouchers if they successfully quit and provide a breath test to confirm this. Participants can expect to complete three short questionnaires over 12 months.

What are the possible benefits and risks of participating?
One benefit of taking part is the chance to change smoking behaviours and improve health. Positively changing smoking behaviours may reduce the risk of health complications from smoking-related diseases. Another benefit of taking part is that participants receive one-to-one behavioural support from stop-smoking advisors, as well as free aids to help them quit.

No risks are expected from taking part in this study.

Where is the study run from?
The study is sponsored by the University of Nottingham. The Chief Investigator works at the University of Nottingham. The study is organised and managed by the York Trials Unit.

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

Who is funding the study?
The study is funded by Yorkshire Cancer Research.

Who is the main contact?
Professor Rachael Murray, rachael.murray@nottingham.ac.uk.

Study website
https://www.york.ac.uk/healthsciences/research/trials/ytutrialsandstudies/trials/yorquit/

Contact information

Type(s)
Principal Investigator

Contact name
Prof Rachael Murray

ORCID ID
https://orcid.org/0000-0001-5477-2557

Contact details
University of Nottingham Clinical Sciences Building, Nottingham City Hospital, Hucknall Road
Nottingham
United Kingdom
NG5 1PB
+44 (0)1158231389
rachael.murray@nottingham.ac.uk

Type(s)
Scientific

Contact name
Miss Rebekah Howell

ORCID ID
https://orcid.org/0009-0000-0160-4293

Contact details
Trial Coordinator, York Trials Unit, Department of Health Sciences, 1st Floor ARRC, University of York
York
United Kingdom
YO10 5DD
+44 (0)1904 323909
Rebekah.howell@york.ac.uk

Type(s)
Scientific

Contact name
Prof Matthew Callister

Contact details
Consultant in Respiratory Medicine at Leeds Teaching Hospitals NHS Trust and Honorary Professor at the University of Leeds. Department of Respiratory Medicine, Leeds Teaching Hospital NHS Trust, St James's University Hospital
Leeds
United Kingdom
LS9 7TF
+44 (0)113 206 6037
matthew.callister@nhs.net

Type(s)
Public, Scientific

Contact name
Mrs Lesley Sinclair

Contact details
Trial Manager, York Trials Unit, Department of Health Sciences, Ground Floor ARRC, University of York
York
United Kingdom
YO10 5DD
+44 (0)1904324158
Lesley.Sinclair@york.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
341699

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS 65486, Yorkshire cancer research Grant Code: RA/2023/R2/113

Study information

Scientific Title
Randomised controlled trial to test the effects of smoking cessation interventions for smokers attending for lung cancer screening in Yorkshire (YorQuit)

Acronym
YorQuit

Study objectives
The study hypothesis is that providing gold-standard stop-smoking support delivered via telephone, by an SCP specifically trained to work with people who smoke and are at high risk for lung cancer, will be more acceptable and effective than referral to a community stop-smoking service and/or use of a digital app. Further, the study hypothesis is also that the provision of a financial incentive for successful quitting will further increase quit rates, over and above gold standard stop smoking support delivered via telephone alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/01/2025, East Midlands - Leicester South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8193; Leicestersouth.rec@hra.nhs.uk), ref: 24/EM/0267

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

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

Smoking cessation interventions for smokers attending for lung cancer screening

Interventions

The commencement of the smoking cessation intervention (CSCI) will begin in all treatment arms after the 2-week set-up period post-randomisation.

Once consent has been obtained, baseline data will be collected by the Study Support Worker (SSW). The baseline questionnaire contains questions about demographics, smoking history and motivations. This will take approximately 15 minutes to complete and will be completed over the phone with the participant. The SSW will enter the answers directly into the electronic Case Report Form (eCRF) in REDCap. Once this has been completed, randomisation will take place (in real-time online during the phone call). The participant will then be informed which arm they have been allocated to. Participants randomised to treatment group 1 will be informed that their details will be passed to the local stop-smoking service who will be in touch in due course (unless they decline). Participants will also be asked whether they wish to receive and use a free stop-smoking mobile phone app. If so, they will be provided with a QR code/clickable link to download the app and can organise a phone call with the app team to talk them through app set-up if required. Participants randomised to treatment groups 2 or 3 will be informed to expect a telephone call from a YorQuit SCP within 1-2 working days. All consenting participants will be informed that they will be contacted in approximately 4 weeks, 3 months and 12 months post-CSCI to ascertain their smoking status through follow-up questionnaires, each taking approximately 15 minutes to complete. Participants have the option to complete follow-up questionnaires online, by post, or over the phone with a researcher.

TRIAL / STUDY TREATMENT AND REGIMEN

TREATMENT GROUP 1: DIGITAL APP AND REFERRAL TO COMMUNITY STOP SMOKING SERVICES.
Study participants will be referred to their local stop-smoking services as per current recommendations for people attending TLHC. In addition, participants who have access to a smartphone will also be offered a 12-week subscription to the “Smoke-Free” digital app. The app is not currently part of standard care. As part of the smoke-free app subscription participants will be provided with pharmacotherapies (Bupropion, Varenicline or Cytisine (where available)) or NRT and or E-cigarettes plus an ‘onboarding’ session to support with downloading, installing, and using the app. Participants will have access to the full app features for 12 weeks, after which they can continue with the free features or purchase a subscription.

TREATMENT GROUP 2: TELEPHONE INTERVENTION
Participants randomised to treatment group 2 will receive an initial telephone consultation with a YorQuit SCP, trained to NCSCT standards. The SCP will explain, advise, and deliver smoking cessation support in accordance with NHS Stop Smoking Service best practice (and NICE NG209 guidance). This will include the use of one-to-one behavioural support and the provision of pharmacotherapy. Pharmacotherapy will take the form of either single or dual NRT and/or E-cigarettes. Bupropion, Varenicline or Cytisine (where available) will also be recommended to patients who are not contraindicated by the SCP and if agreeable prescribed by the GP /secondary care team. If the participant requests NRT and/or E-cigarettes (a choice of liquid flavours will be available) a supply of products will be posted to the participant’s home address. The support described will be delivered for as long as required by the participant for up to a maximum of 12 weeks from CSCI, including weekly phone calls with the SCP or on an alternate schedule according to participant preference. During these phone calls the SCP will discuss any concerns or queries, deliver behavioural support, change quit aids if necessary, and/or order more aids to be delivered to the participant.

TREATMENT GROUP 3: TELEPHONE INTERVENTION PLUS FINANCIAL INCENTIVE
Study processes in arm 3 will be the same as described for treatment group 2. In addition, participants will be informed that they will be provided with a financial incentive in the form of a Love2shop or Amazon voucher if they are (carbon monoxide) CO-validated (65 years), gender (male/female) and smoking status (quit, not quit, or quit and relapsed).

Interviews:
Interviews with treatment group 1 (digital app and/or referral to community stop smoking services) (n=20) participants will seek to collect information relating to the acceptability of a digital app and its usability for the target population. We will explore barriers and facilitators to app use and whether the app has influenced change in the participant's smoking status /behaviour. We will also interview those who declined to use the app and also those referred to a local smoking cessation service. These interviews will provide a richer understanding of issues in accessing and engaging with a digital smoking cessation app for a TLHC population. Interviews with participants enrolled in treatment group 2 (telephone intervention) (n=20) will seek to understand participant's views of telephone support for smoking cessation and explore the acceptability and feasibility of this mode of delivery. For participants from treatment group 3 (telephone intervention plus financial incentive) (n=20), we will explore the above-mentioned topics from treatment group 2 as well as what impact a financial incentive has on a participant's smoking status and motivation to stop smoking. Interviews will also explore whether the interventions have any anticipated impact on subsequent screening participation. Interviews with those who declined (n=15) to take part in the trial, will be used to explore their reasons for doing so. Additionally, the interview will cover topics such as the importance of smoking, readiness to quit and confidence in quitting. Interviews will be carried out by telephone or Zoom /Microsoft Teams, according to preference. Participants will be offered a shopping voucher to compensate them for their time. Best efforts will be made to conduct interviews within a two-week timeframe from the study time points (i.e. 4-week interviews will take place 4 – 6 weeks following the target quit date). Encrypted digital recorders will be used and files will be uploaded to the secure University network as soon as possible.

PARTICIPANT DURATION:
Stop smoking support will be provided for as long as the participant requires, up to a maximum of 12 weeks. Follow-up contact will be requested at 4-weeks, 3-months and 12-months post CSCI via questionnaires. For participants invited for interviews as part of the process evaluation, these will take place within a two-week window where possible at 4-weeks, 3-months, and 12-months post CSCI.

Intervention Type
Mixed

Primary outcome measure
7-day point prevalent carbon monoxide (CO) validated smoking cessation at three months after the CSCI measured using a carbon monoxide breath test at 3 months post-CSCI

Secondary outcome measures
1. Uptake of stop-smoking support offered measured using self-report questionnaires, app usage data and Smoking Cessation Practitioner (SCP) CRFs at 4 weeks, 3 months and 12 months
2. 7-day point prevalent CO validated and self-reported abstinence from smoking at 4 weeks after the CSCI measured using a carbon monoxide breath test at 4 weeks post-CSCI
3. 7-day point prevalent self-reported abstinence from smoking 3-months after the CSCI measured using a self-reported questionnaire at 3 months post-CSCI

4. 7-day point prevalent CO validated and self-reported abstinence from smoking 12 months after the CSCI measured using self-reported questionnaires and carbon monoxide breath tests and 3- and 12-months post-CSCI
5. Prolonged CO validated and self-reported abstinence from smoking 3- and 12-months postCSCI measured using self-reported questionnaires and carbon monoxide breath tests and 3- and 12-months post-CSCI
6. Acceptability of the intervention delivered in each treatment group measured using qualitative interviews at 4 weeks, 3 months and 12 months
7. Reasons for decline in those not accepting stop smoking support measured using aggregate screening log data at one time point
8. Health-related quality of life measured using self-report questionnaires (EQ-5D-5L) at baseline, 4 weeks, 3 months and 12 months
9. Use of smoking cessation support and other healthcare resources – measured using self-report questionnaire baseline, 4 weeks, 3 months and 12 months

Overall study start date
01/04/2024

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Smoked at least one cigarette in the last 7 days at the point of consent
2. 55-75* years of age
3. Able to provide informed consent
* The TLHC programme offers screening to people up to 74 years and 364 days. The upper age of 75 is used here to allow people to be included in YorQuit if they become 75 between first contact and consent to the YorQuit study.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
55 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Planned Sample Size: 1935; UK Sample Size: 1935

Key exclusion criteria

1. Inability to provide informed consent
2. Previously randomised to YorQuit

Date of first enrolment
28/05/2025

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Nottingham

Sponsor details
E-floor, Yang Fujia Building Jubilee Campus, Wollaton Road
Nottingham
England
United Kingdom
NG8 1BB
-
sponsor@nottingham.ac.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/01ee9ar58

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 peer-reviewed journal

Intention to publish date
14/02/2028

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