

# The quit smoking lung health intervention trial

<b>Submission date</b> 07/06/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/06/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/07/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Smoking is a major cause of ill health including lung disease, heart disease and cancer. It is important that the NHS makes use of the best approaches to help people to stop smoking. People with a history of smoking are now being offered screening by CT scan in order to detect early lung cancer so these can be treated and cured. This screening program is also an opportunity to help people to quit smoking. The usual approach would be to direct individuals to NHS or local authority smoking cessation services. The aim of this study is to see if a more intense approach, where smokers can see a smoking cessation counsellor immediately, is more effective.

### Who can participate?

Smokers aged 55 to 75 who wish to quit who are going through the screening programme

### What does the study involve?

Participants are randomly allocated to receive either immediate smoking cessation input including pharmacotherapy (drug treatment) or usual care, which is advice and signposting to local services. Smoking rates are compared 3 months later.

### What are the possible benefits and risks of participating?

The intervention may increase the likelihood of quitting smoking.

### Where is the study run from?

Royal Brompton and Harefield NHS Foundation Trust (UK)

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

February 2018 to October 2022

### Who is funding the study?

Royal Marsden Partners (UK)

### Who is the main contact?

1. Dr Nicholas Hopkinson

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2. Dr Ahmad Sadaka  
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## Contact information

### Type(s)

Scientific

### Contact name

Dr Nicholas Hopkinson

### ORCID ID

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### Type(s)

Public

### Contact name

Dr Ahmad Sadaka

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

236191

ClinicalTrials.gov number

Secondary identifying numbers

IRAS 236191; CPMS 39463

# Study information

## Scientific Title

QuLIT – the Quit smoking Lung health Intervention Trial

## Acronym

QuLIT

## Study objectives

In people who smoke attending a lung cancer CT screening programme, does the provision of immediate smoking cessation support including pharmacotherapy compared to signposting to a smoking cessation service improve quit rates at 3 months?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 30/04/2018, South Central - Oxford C Research Ethics Committee (Level 3, Block B, Whitefriars Building, Lewins Mead, Bristol, BS1 2NT; Tel: +44 (0)20 7104 8049; Email: [nrescommittee.southcentral-oxfordc@nhs.net](mailto:nrescommittee.southcentral-oxfordc@nhs.net)), REC ref:18/SC/0236

## Study design

Randomized; Interventional; Design type: Treatment, Screening, Drug, Education or Self-Management, Imaging, Psychological & Behavioural, Complex Intervention

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

No participant information sheet available. The requirement for individual consent was waived by the ethics committee, as obtaining this would itself have been an intervention and influenced outcomes in the control group.

## Health condition(s) or problem(s) studied

Smoking cessation

## Interventions

Current interventions as of 25/06/2021:

A study comparing the effectiveness of two different smoking cessation strategies applied in a pseudo-randomised fashion. Smokers attending a lung health screening service, focussed on CT

screening to detect early lung cancer, will receive either:

1. Immediate smoking cessation input including pharmacotherapy
2. Usual care, which will be advice and signposting to local services

Limited resources mean that a specialist smoking cessation practitioner will only be available on 5 days every fortnight so treatment allocation will depend on this (i.e., which day patients attend on).

Follow up will be by a phone call at 3 months.

For participants recruited prior to March 2020 the smoking cessation intervention was delivered in face-to-face sessions. Recruitment to the study was then paused as a result of public health guidance during the COVID-19 pandemic. Recruitment then began again in January 2021 with telephone smoking cessation support offered as the method of intervention delivery.

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Follow up will be by phone call at 3 months.

## **Intervention Type**

Mixed

## **Primary outcome measure**

Quit rate in those wishing to quit, based on self-report by telephone call at 3 months following the initial screening visit

## **Secondary outcome measures**

Current secondary outcome measures as of 18/05/2022:

1. Quit rate in all screening program participants, based on self-report by telephone call at 3 months following the initial screening visit
2. Mortality at 1 year (available as part of the routine evaluation of the screening protocol)
3. Quit rate at 1 year

Exploratory outcomes:

1. The impact of the smoking cessation interventions (based on self-report by telephone call at three months) in different baseline groups including:
  - 1.1. Those with new abnormal findings found as part of screening (e.g. spirometry)
  - 1.2. Those with or without an abnormal CT finding that requires further follow up
2. The number of individuals who are smoking and who wish to quit will also be documented to provide guidance for service development and resource requirements

Previous secondary outcome measures:

1. Quit rate in all screening program participants, based on self-report by telephone call at 3

months following the initial screening visit

2. Mortality at 1 year (available as part of the routine evaluation of the screening protocol)

Exploratory outcomes:

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1.2. Those with or without an abnormal CT finding that requires further follow up

2. The number of individuals who are smoking and who wish to quit will also be documented to provide guidance for service development and resource requirements

**Overall study start date**

01/08/2018

**Completion date**

31/10/2022

## Eligibility

**Key inclusion criteria**

Current participant inclusion criteria as of 24/06/2021:

1. Participant in the clinical lung health screening programme (aged 55 to 75 years recorded as ever smokers in their medical records)

2. Current smoker

3. Only those who express a wish to quit smoking will be included in the primary endpoint analysis

Previous participant inclusion criteria:

1. Participant in the clinical lung health screening programme (aged 50 to 65 years and any history of smoking)

2. Current smoker

3. Only those who express a wish to quit smoking will be included in the primary endpoint analysis

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

55 Years

**Upper age limit**

75 Years

**Sex**

Both

**Target number of participants**

130

**Total final enrolment**

430

**Key exclusion criteria**

Non-smokers

**Date of first enrolment**

01/08/2019

**Date of final enrolment**

02/02/2022

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Royal Brompton and Harefield NHS Foundation Trust**

Fulham Road

London

United Kingdom

SW3 6NP

## **Sponsor information**

**Organisation**

Imperial College London

**Sponsor details**

South Kensington Campus

London

England

United Kingdom

SW7 2AZ

**Sponsor type**

University/education

**ROR**

<https://ror.org/041kmwe10>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Royal Marsden Partners

# Results and Publications

## Publication and dissemination plan

Current publication and dissemination plan as of 25/06/2021:

Separate results publication intended for the two different methods (face-to-face and telephone) of delivery of the smoking cessation intervention. Planned publication in a high-impact peer-reviewed journal.

Previous publication and dissemination plan:

Planned publication in a high-impact peer-reviewed journal by the end of 2021.

## Intention to publish date

31/03/2023

## Individual participant data (IPD) sharing plan

Anonymized research data will be shared with third parties via a request to the senior author (NSH).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>		28/02/2018	01/07/2019	No	No
<a href="#">Protocol file</a>	version 2	11/12/2020	30/12/2021	No	No
<a href="#">Results article</a>	Results at 3 months	01/02/2022	07/02/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>	Results at 12 months and intervention delivery method	24/10/2023	25/10/2023	Yes	No
<a href="#">Results article</a>		03/08/2022	03/07/2025	Yes	No