NHS

THE SUMMIT STUDY

IT'S ABOUT TIME

DETECT EARLY. TREAT EARLY.
LET'S TACKLE CANCER.

INFORMATION FOR GP PRACTICES

GRAIL

UCL

NHS
University College London Hospitals
NHS Foundation Trust

THE SUMMIT STUDY - A SUMMARY

What is the SUMMIT Study?

The SUMMIT Study is a large-scale study involving 50,000 people aged 50-77 living in north and east London. Half of the participants will be people who currently smoke or have smoked regularly in the past (Group A) and the other half will be those who do not have significant smoking histories (Group B).

Why are we conducting the study?

The study has two main aims: the first is to detect lung cancer early using the proven method of low-dose CT (LDCT) screening of at-risk individuals. The second aim is to support the development of a new blood test for the early detection of lung and other cancers.

Why should your practice take part?

Eligible patients from your practice with significant smoking histories will be offered a free Lung Health Check, including spirometry and a respiratory health assessment. If they consent they will also be offered an LDCT scan - a highly effective method to identify early lung cancer that is being offered as standard of care for at-risk individuals in the USA and Canada.

Those patients who do not have a significant smoking history, and are not eligible to have an LDCT, will be able to take part in the development of an early cancer detection blood test by donating blood samples, which may help to develop a test to detect lung and other cancers earlier when they can be more successfully treated. We have worked hard to ensure the study is safe, convenient for participants and minimally disruptive for primary care. Please read on for further information.

THE SUMMIT STUDY - THE DETAILS

The study, step by step

All GP practices in north and east London will be invited to join the study. We will ask practices to register as a Participant Identification Centre (PIC) for the study, by signing a PIC agreement. This will act as a data processing agreement between the study team and enrolled GP practices. This process will be facilitated by Noclor (a primary care research support service) on the study's behalf.

Once established as a PIC site, practices will receive posters to be displayed in their premises so that patients who do not wish to be contacted can opt out.

The SUMMIT Study project team will visit each practice to identify potential participants from the practice registry. We will write to them on behalf of their registered GP, on the practice letterhead, to invite them to book an appointment at a study site via our dedicated administrative call centre. GP practices will not need to vet or pre-invite participants from their lists (see below for more details).

Group A: Individuals with significant smoking histories will be offered a lung health check, which includes a brief respiratory consultation, and measurement of blood pressure, BMI and spirometry. This information will be reported back to their GP by letter whether they participate in the study or not. They will then be offered participation in the SUMMIT Study and fully consented if they choose to take part. Consented participants will have a blood sample taken, complete an electronic questionnaire, and have an LDCT. Participants will also be given advice on lung health and referral to local smoking cessation services if applicable.

Participants will be asked to return for two further annual visits; some may have further LDCT scans, and all will donate blood samples and fill out questionnaires. The study team will look after most incidental findings.

Group B: Individuals who do not have a significant smoking history will be invited to take part in the SUMMIT Study to develop an early cancer detection blood test by donating their blood samples. If they consent to taking part in the study, they will have a blood sample taken and complete an electronic questionnaire. Participants will be asked to return for two further annual visits to provide blood samples.

All participants will receive a £20 shopping voucher in thanks for their participation.

The active phase of the study will last 3.5 years. Participants will be followed up thereafter through national data registries, for example the National Cancer Registration and Analysis Service (NCRAS) and NHS Digital data.

The SUMMIT Study collaboration

The study is a collaboration between:

- University College London (UCL): academic clinicians and researchers have been involved in the design of this study, which has been subject to a rigorous ethical approval process
- University College London Hospitals NHS Foundation Trust (UCLH): specifically, staff delivering the project via the study sites
- GRAIL: a U.S. based healthcare company who is funding the study and will be using the blood samples for research focused on developing a blood test for early cancer detection.

And you - our north and east London primary care colleagues.

What is the role of GPs and primary care staff in this study?

We have designed the study to minimise any additional work for our GP and primary care colleagues. GP participation will involve the following steps:

- We will arrange a convenient time with your practice for a member of our project team to visit the practice to identify eligible patients.
- They will need access to your computer system, a desk and access to a networked PC for around 1 hour.
- Once we have details of your eligible patients, we will write to them to invite them for either a lung health check (Group A) or to participate in the study by donating blood samples (Group B).
- For a sub-sample of potential participants, we will send a brief, optional UCL survey to understand reasons for non-attendance to the lung health check. This will inform any future screening programme.
- At a later stage, a member of the study team will return to your practice to extract further health data on consented participants.
- You will be remunerated by the study team and the NIHR in thanks for your participation.

FREQUENTLY ASKED QUESTIONS

Are GPs allowed to share patient data with the SUMMIT Study project team?

Yes. We have gained approval from the Confidentiality Advisory Group (part of the Health Research Authority) to collect personal identifiable information of potentially eligible participants from participating GP practices. GP practices will sign a Participant Identification Centre Agreement, which serves as the basis for a transfer of data between the GP practice and our study team. All Information Technology for the study has been developed to NHS Information Governance and IT standards, and all data will be handled according to the General Data Protection Regulation (GDPR). For further information on our data handling and IT systems, please visit the SUMMIT Study website at www.summitstudy.co.uk

What happens if you find something on an LDCT?

We will keep you and your patients updated with the results of your patients' scans via letter. If we find any concerning features, we will refer participants to their preferred hospital for further appropriate investigation. Incidental pulmonary nodule findings will be followed up within the study.

Will I find out the results of the blood samples taken at the consultation appointment?

No, the blood samples will be sent to GRAIL for analysis as part of GRAIL's efforts to develop a blood test for early detection of cancer. This blood test is not yet validated for clinical use and thus no results of the test will be returned to you or the participants.

What if patients contact us about the SUMMIT Study?

Participants will be given detailed information at their consultation, including a study telephone number to call and a website address.

Who can I contact if I've got questions about the study?

For further in-depth information about the study, please see the SUMMIT Study website at www.summitstudy.co.uk or contact the SUMMIT Study team on uclh.HCPsummitstudy@nhs.net

For more information visit:

www.summitstudy.co.uk

Or email:

uclh.HCPsummitstudy@nhs.net

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