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Chest symptoms that call for action

Submission date 11/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/04/2009	**Overall study status** Completed	
Last Edited 26/04/2018	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims:
As a country, we are making efforts to diagnose lung cancer at the earliest possible stage, because we believe that this will increase options for treatment and improve chances of survival. Not only do we have to take action within the health service to speed up investigations, but we must also find ways to make sure that people with important symptoms seek help quickly. Nearly all people with lung cancer have symptoms for many weeks before seeing a doctor. These symptoms are not very remarkable and usually are not lung cancer, but they are worth investigating if they persist.
This project aims to evaluate whether an educational programme, designed with the help of patients and specialists to be delivered in general practice, can reduce the time people take to see a doctor when they develop important symptoms.

Who can participate?
Patients registered at two general practices in Northeast Scotland, who are aged 55 years or older and are, or have been, heavy smokers.

What does the study involve?
The study is a randomized trial. This means that people who enroll in the trial will be divided into two groups. They will have to accept an equal and random chance of being allocated to one or other group and will not be allowed to choose. One group will receive the new educational programme. This involves a consultation with a nurse at their general practice and a self help manual to take home. The other group will not receive the educational programme, but will receive all their usual care at their general practice. All people in the trial will be asked to complete questionnaires at the beginning and after one and six months. They will also have data collected from their general practice case notes on consultations they make at the practice during the year before and after the start of the trial.

What are the possible benefits and risks of participating?
We dont expect any large benefits or risks from participating in the study. People who receive the educational programme may find it helpful; some may find it worrying, we wont find out until after the study.

Where is the study run from?
The Centre of Academic Primary Care, University of Aberdeen.

When is study starting and how long is it expected to run for?
The trial started on 1 August 2007 and ran for three years. Recruitment for the trial commenced in mid 2008 and the trial ended 18 months later.

Who is funding the study?
Cancer Research UK

Who is the main contact?
Neil Campbell
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PRGS/043/07

Study information

Scientific Title
Reducing time to presentation with symptoms of lung cancer: phase II complex intervention study

Study objectives
A theoretically-based educational intervention in primary care has potential to reduce time between onset of, and presentation with, lung cancer symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee, 14/06/2007, ref: 07/SO801/45

Study design
Phase ll randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Lung cancer (and other lung diseases)

Interventions
A complex intervention to be delivered in two general practices (rural and urban), targeted at 210 high risk patients (greater than 55 years, smokers and ex-smokers). The intervention has been developed using a causal modelling approach and uses evidence-based behavioural interventions. Key components will:
1. Increase the salience and personal relevance of symptoms
2. Improve knowledge of symptoms
3. Reinforce the benefits of early intervention in lung cancer and other lung diseases
4. "Sanction" early consultation and encourage sanctioning by others
5. Tackle barriers to consulting, and
6. Provide personalised action plans

To optimise implementation a focus group study will identify barriers and facilitators. A phase II randomised trial will evaluate how the intervention affects consulting behaviour. Qualitative parallel interviews with 10 professionals, 10 participants in the randomised trial, and 10 additional patients exposed to intervention will explore positive and negative reactions to the intervention.

Computer generated random numbers will be used to allocate half the participants at each general practice into intervention and control groups. We will stratify by practice because consulting behaviour differs in rural and urban areas. The trial will be open to participants, who will be aware of whether they have been invited to the intervention or not. Quantitative data

collection and entry will, however, be conducted blind to group allocation. Intervention participants will be asked to attend a single nurse consultation. They will be provided with the manual to keep. Our control group will receive usual primary care. All participants will complete questionnaires at three time points: baseline, one month, and six months. Additionally, participants will be asked to complete a short questionnaire each time they consult general practice with respiratory symptoms. The study period for each participant will last approximately six months. Data on total general practice consultations, and chest X-ray and hospital referrals/appointments will be collected from general practice case notes. Quantitative data will be entered anonymously onto an Access database. 10% will be second keyed and discrepancies noted. Descriptive statistics will be used for recruitment rates. For trial outcomes, control and intervention groups will be compared using the chi-square and t-tests and multiple logistic and linear regression used to adjust for general practice and other relevant confounders. Transformations and non-parametric tests will be used where appropriate. Transcribed qualitative data from interviews will be analysed to identify themes that can inform the overall research process as well as questionnaire and intervention content. Data on the research process, including suggestions on improvements will be collated and taken into consideration in development of any future phase III trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportions of participants consulting within a week of haemoptysis or four weeks of other guideline symptoms (symptoms recommended for investigation in SIGN or Cancer Research UK guidelines on lung cancer) during the six-month period of follow up.

Secondary outcome measures
Measured by postal questionnaire at baseline, one month and six months:
1. Intentions to consult under various conditions - using methods found to give valid and reliable results
2. Self efficacy - questions adapted from standard measures, taking account of barriers to consultation identified during focus groups
3. Knowledge of symptoms and risk factors - using questions developed during our previous study
4. Cancer worry scale - a six-item scale found to have good reliability (most recently Cronbach's a = 0.83 and test-retest reliability = 0.74)
5. Hospital Anxiety and Depression questionnaire

Measured at other timepoints:
6. Reasons for consultation will be investigated using short questionnaires after each consultation (explanations for symptoms considered, expectations from consultation, prompts received to consult, and resources used to decide)
7. Health service use (general practice consultations, and chest X-ray and hospital referrals /appointments) will be collected from general practice case notes at the end of the study period
8. Trial process outcomes. Recruitment rates, response rates, and problems encountered during recruitment, implementation of the intervention, and data collection will be noted throughout the course of the study.

Overall study start date
01/08/2007

Completion date
31/07/2010

Eligibility

Key inclusion criteria
Long-term smokers (at least 20 pack years) aged 55 years or over, either sex, including ex-smokers if their cessation date is within 10 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
210

Key exclusion criteria
1. Housebound
2. Terminally ill
3. Have dementia

Date of first enrolment
01/08/2007

Date of final enrolment
31/07/2010

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Aberdeen
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AB25 2AY

Sponsor information

Organisation
University of Aberdeen (UK)

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Sponsor type
University/education

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ROR
https://ror.org/016476m91

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C542/A8695)

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2013		Yes	No