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Evaluation of an online intervention to encourage early help-seeking for lung cancer symptoms

Submission date
09/05/2017

Recruitment status
No longer recruiting

Registration date
22/05/2017

Overall study status
Completed

Last Edited
31/07/2019

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Research has shown that people with lung cancer often wait for several months after first noticing symptoms, and this can make it more difficult to treat the disease. This study explores ways in which online information about lung cancer symptoms can be presented to encourage people to see their doctor earlier. Lung cancer patients were interviewed in an earlier study and some of them had used the Internet to look up their symptoms, and this influenced their decision to see their doctor. A website about lung cancer has been designed to encourage people to see their doctor earlier when they have worrying symptoms. This new website uses psychological techniques to influence peoples' beliefs about going to their doctor. The aim of this study is to compare this new website against other versions of the website which don't use these psychological techniques, to see if they have any effect on peoples' intention to make an appointment to have their symptoms checked.

Who can participate?
Patients aged over 18 with possible lung cancer symptoms (e.g., long-standing cough, feeling out of breath, discomfort in the chest, shoulder or back)

What does the study involve?
Participants are randomly allocated to one of four groups, to receive information about lung cancer that is either tailored to individual users (based on their age, smoking and reported symptoms) or not, and that either includes components based on psychological techniques or does not.
Intervention Group: Information is tailored and includes psychological components
Control Group 1: Information is untailored and includes psychological components
Control Group 2: Information is tailored and does not include psychological components
Control Group 3: Information is untailored and does not includes psychological components
All participants are followed up 3 weeks later to assess their intention to seek medical help.

What are the possible benefits and risks of participating?
It is not known whether the study will help the participants but they may find the information

provided on the website useful in deciding whether to see a GP about their symptoms. It is not the aim to ask any questions or provide any information that might be upsetting or stressful, but some participants may feel worried about lung cancer after viewing information on our website.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
March 2017 to December 2017

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Ms Julia Mueller

Study website
www.when2go-study.co.uk

Contact information

Type(s)
Public

Contact name
Ms Julia Mueller

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1354978

Study information

Scientific Title
Evaluation of a web-based intervention to encourage early help-seeking in people with symptoms indicative of lung cancer: a randomised controlled trial

Study objectives
The aim of the study is to determine whether information tailoring, and addition of theory-based components to information about lung cancer impacts on individuals' intention to seek medical help.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Pilot study: University Research Ethics Committee 1 (University of Manchester), 30/09/2015, ref: 15353
2. Full trial: University Research Ethics Committee 1 (University of Manchester), 29/03/2017, amendment ref: 2017-1224-2093

Study design
2x2 randomised factorial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
Available via www.when2go-study.co.uk

Health condition(s) or problem(s) studied
Lung cancer

Interventions
The intervention consists of information about lung cancer symptoms, risk factors and a recommendation of when medical advice should be sought. The information is tailored to individual users (based on their age, smoking status and reported symptoms) and also includes components based on psychological theory, to target beliefs people hold about help-seeking. Thus this intervention involves two factors: information tailoring and presence of theory-based components. It is designed to encourage help-seeking for potential lung cancer symptoms.

Participants are randomised to the four study groups using a block randomisation procedure (in blocks of two):
Intervention Group: Information is tailored, and includes theory-based components

Control Group 1: Information is untailored, and includes theory-based components
Control Group 2: Information is tailored, and does not include theory-based components
Control Group 3: Information is untailored, and does not includes theory-based components

For each study group, the intervention duration is approximately 15 minutes. All participants are followed up 3 weeks after the intervention.

Intervention Type
Behavioural

Primary outcome measure
1. Intention to seek medical help, measured on an 11-point scale at baseline pre-treatment and immediately post-treatment, and, if applicable, at 3 week follow-up. Intention will not be measured again at follow-up if participants report already having sought help at this point
2. Reported help-seeking, measured by asking participants whether they have discussed their symptoms with a health professional (yes/no) at 3-week follow-up

Secondary outcome measures
1. Beliefs and attitudes towards help-seeking, measured using Theory of Planned Behaviour questionnaire at baseline, post-treatment
2. Cancer risk perception, measured using a single item with a 7-point scale at baseline, post-treatment

Overall study start date
01/03/2017

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Over the age of 18
2. Lives in the UK
3. Experiencing any of the following symptoms:
3.1. A cough (whether dry and tickly or with phlegm)
3.2. A long-standing cough that changes or gets worse
3.3. Feeling out of breath
3.4. Discomfort in the chest, shoulder or back
3.5. Coughing up phlegm with a blood in it (even if just a few specks)/spitting blood
3.6. Changes in your voice
3.7. Unexplained weight loss or unexplained loss of appetite
3.8. Swelling of face and neck
3.9. Persistent/recurring chest infection
3.10. Tiredness or lack of energy
3.11. Changes in the appearance of fingers or fingernails (such as a softening of the nailbed, stronger than normal curving of the fingernails, or thickening of the fingertips so that the shape looks like an upside down spoon)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
236

Total final enrolment
130

Key exclusion criteria
1. Individuals under the age of 18
2. Individuals who do not live in the UK
3. Individuals who are not experiencing any relevant symptoms

Date of first enrolment
01/06/2017

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester

Sponsor details

Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal and in a PhD dissertation, approximately 1 year after completion of the trial.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

As of 12/12/2018:
The datasets generated during and/or analysed during the current study are not expected to be made available as the ethics documentation does not state that data will be shared in a public repository.

Previous IPD sharing statement:
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		11/12/2018	11/12/2018	No	No
Results article	results	01/02/2019	31/07/2019	Yes	No