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Targeted case finding for chronic obstructive pulmonary disease (COPD) in primary care

Submission date
08/08/2012

Recruitment status
No longer recruiting

Registration date
08/08/2012

Overall study status
Completed

Last Edited
08/10/2020

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
This study is designed to identify people who may have a lung disease called chronic obstructive pulmonary disease (COPD). COPD affects 5-10% of people worldwide, is rising in prevalence, and is a leading cause of death. In the UK it costs the NHS over £800 million per year. There is however much uncertainty about the natural history of COPD, how to approach early identification of patients, and what treatments are effective in early disease. There is significant under diagnosis of COPD patients and this represents a group of people who could benefit from treatment by their GP. There is increasing interest in finding these patients but no evidence as to which approach to case finding would be most effective or cost-effective. The aims of the study are to determine whether targeted case finding is more effective and cost-effective than current practice, to find out the relative effectiveness and cost-effectiveness of two alternative methods of targeted case finding, and to obtain patients views about the process.

Who can participate?
Potential participants will be identified through GP practice registers and anyone who is potentially eligible will be screened by the GP before being invited to take part. Patients must be aged between 40 and 79 years with no clinical diagnosis of COPD.

What does the study involve?
Participating practices will be randomly allocated to either the targeted group or the routine care group. Patients in the routine care group will not have to do anything. There will be no changes to their care. Patients in the targeted group will fill out a questionnaire either at home or at the surgery (once) and if they say they have respiratory symptoms in the questionnaire they will have a one-time simple lung function test. This lung function test will take about half an hour and will be at their local or nearby surgery. It will require patients to take a standard dose of a salbutamol inhaler prior to taking the test. A few additional questions on their health and personal information will be requested at this point. For all participants, further medical information at the start and end of the study will be sought from their GP, which will be anonymous until they provide consent. Finally, about 80 of the study patients will be invited to be interviewed, either in their own home or in the surgery as preferred. The aim of this is to explore participants' perceptions and understanding of the case finding process and its consequences, any barriers to attendance and participation, and for those who attend the lung

function test, what their perceptions are of being either disease free or labelled with a new disease. Patients who have lung function test results which indicate that they may have COPD will be referred back to their GP for management. They will also have the chance to take part in another linked study. Further information from GP records on how they are being managed will also be collected 1 year after their diagnosis.

What are the possible benefits and risks of participating?
The benefits of participating will include additional monitoring of their health status and the possibility of earlier treatment for COPD identified through the study. Patients may also have the chance to take part in a linked study which will provide them with more detailed and more regular monitoring and health assessment. There are no risks from the methods involved. The lung function test may detect previously undiagnosed COPD that requires treatment. With the patients agreement, we will pass these details onto their GP for further consideration.

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

When is the study starting and how long is it expected to run for?
The study started in August 2012 and end in April 2015.

Who is funding the study?
National Institute of Health Research (NIHR) (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12825

Study information

Scientific Title
TargetCOPD: a randomised controlled trial of targeted case finding for COPD versus routine practice in primary care

Study objectives
Chronic obstructive pulmonary disease (COPD) places an increasing burden on the NHS, largely due to repeated inpatient admissions as the disease progresses. Although diagnosed COPD is estimated at 1.3% of the population, it is widely accepted that 50-80% of patients with clinically significant disease are not diagnosed and therefore unable to access effective treatments. Within the UK and elsewhere, there is increasing pressure to find these patients, both from patient groups and strategic documents.

TargetCOPD will compare the benefits and cost-effectiveness of two alternative case-finding approaches for identifying undiagnosed COPD in general practice. Using a cluster randomised controlled trial (RCT) design in 56 West Midlands general practices, over the next three years we will assess both approaches (targeted case finding vs usual care).

Patients between 40 and 79 years who are current or ex-smokers will be invited to participate. Using an individual patient RCT nested in the targeted arm, we also plan to compare the effectiveness and cost-effectiveness of active case finding using a postal questionnaire, and opportunistic case finding at usual surgery consultations.

Patients who report positive respiratory symptoms will be invited for further spirometric assessment to ascertain whether they have COPD or not. We will compare which method is the most effective and cost-effective in identifying new patients, possibly allowing earlier treatment. We will also explore patients views on this process by inviting some patients for face to face interviews.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands Solihull, 08/03/2012, ref: 11/WM/0403

Study design
Randomised interventiona trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

GP practice

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Case finding for COPD. Eligible patients in the targeted arm of the study will receive a questionnare in the post about their lung health; if they respond with respiratory symptoms, they are invited for spirometry. Patients in this arm are also flagged in the GP's computer and if they come into practice for any reason, they are given a questionnaire.

Eligible patients in the opportunistic arm are flagged in the GP computer and given the questionnaire if they show up in the GP practice for any reason.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Economic evaluation of case finding for COPD by different methods; Timepoint(s): Cost per case identified

Secondary outcome measures
No secondary outcome measures

Overall study start date
06/08/2012

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Patients that are registered with a GP in the West Midlands area
2. Aged between 40 and 79 years
3. Must have a history of ever smoking
4. Must not have a diagnosis of COPD or asthma
5. They must have the ability to give informed consent

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 76608

Key exclusion criteria
1. Participants with serious life threatening disease or other condition that could interfere with participation in the study, e.g. patients wih terminal cancer or dementia
2. Diagnosed asthmatics/COPD

Date of first enrolment
06/08/2012

Date of final enrolment
02/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Lung Improvement Studies (BLISS)
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
School of Health and Population Sciences
Birmingham

England
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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/schools/haps/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) - Central Commissioning Facility (CCF) ref: RPPG010910061

Results and Publications

Publication and dissemination plan
To be confirmed at a later date
Data may be made available on request, we have a process for engagement, collaboration on our website: http://www.birmingham.ac.uk/research/activity/mds/projects/HaPS/PHEB/BLISS/index.aspx

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/10/2014		Yes	No
Results article	results	01/09/2016		Yes	No
Results article	results	05/10/2020	08/10/2020	Yes	No