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Determining the optimal approach to identifying individuals with chronic obstructive pulmonary disease

Submission date 22/02/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2011	**Overall study status** Completed	
Last Edited 19/11/2018	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Determining the optimal approach to identifying individuals with chronic obstructive pulmonary disease: a multi-centre randomised trial

Acronym
DOC study

Study objectives
1. To identify the most effective case-finding pathway for chronic obstructive pulmonary disease (COPD). The specific health service impacts across different possible pathways for undertaking COPD case finding amongst current smokers in primary care settings will be assessed.
2. To assess the cost-effectiveness of COPD case-finding pathways. A cost-per-true-positive-case-found analysis will be undertaken and health care resource use will be incorporated.
3. To evaluate the efficiency of the 'case finding' pathway. Key factors to consider will be the quality of the forced expiratory volume in one second (FEV1)/forced vital capacity (FVC), mechanical peak expiratory flow rate (PEFR) measurements and wheezometer measurements (in relation to the reference standard).
4. To evaluate whether undergoing the diagnostic test(s) has an impact on smoking behaviour to inform future smoking cessation studies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle and North Tyneside 2 Research Ethics Committee, 29/07/2010, ref: 10/H0907/37

Study design
Multi-centre randomised 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
Chronic obstructive pulmonary disease (COPD)

Interventions
1. Participants will undertake lung function tests (i.e. peak flow measurement, microspirometry and post-bronchodilator spirometry), a wheeze-detecting device (i.e. wheezometer) and a case-finding questionnaire
2. Further questionnaires will be completed during the study; a screening questionnaire and a follow-up questionnaire.

All participants receive the case-finding tests, with half randomised to receive the tests straight away and the remainder will receive the tests approximately 6 months later.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Effectiveness of diagnostic pathways - aim to identify the most effective pathway for use as the routine service model in primary care

Secondary outcome measures
1. Cost-effectiveness of COPD case-finding pathway
2. Efficiency of COPD case-finding pathway
3. Impact on smoking behaviour

Overall study start date
01/05/2011

Completion date
01/09/2013

Eligibility

Key inclusion criteria
Current smokers aged 35 years or more who are registered with participating GP practices

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Pregnancy
2. Recent history (within 8 weeks) of myocardial infarction, stroke, pulmonary embolism, chest /abdominal surgery or eye surgery
3. Any mental or physical condition (e.g. chest/abdominal pain/stress incontinence) or any other condition which means the participant is unable to undergo the case-finding tools

Date of first enrolment
01/05/2011

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
York Trials Unit
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK)

Sponsor details
c/o Sue Final
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Sponsor type
University/education

Website

http://www.york.ac.uk/

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) - Respiratory Programme

Results and Publications

Publication and dissemination plan
The results are expected to be published in 2015

Intention to publish date
31/12/2015

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	01/06/2018		Yes	No