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An evaluation of the cost effectiveness of single test screening spirometry in the early diagnosis and management of Chronic Obstructive Pulmonary Disease (COPD) in primary care

Submission date 30/09/2004	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Stopped	
Last Edited 01/11/2011	**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
N0375126454

Study information

Scientific Title

Study objectives
Does knowledge of an abnormal spirometry result significantly improve smoke stop rates for smokers aged 35-75?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory: Chronic obstructive pulmonary disease (COPD)

Interventions
Subjects will be recruited opportunistically in primary care. On average each practice is expected to recruit between 80-90 individuals. Subjects who accept will then be randomised to receive or not receive spirometry at the start of the HTQ programme. Both groups will be assessed on generic quality of life (QoL) and anxiety. Practice nurses will be trained and administer all questionnaires and tests, for which they will receive a payment. At 12 months subjects in both groups will be reviewed and receive spirometry and repeat QoL and anxiety questionnaires.

Please note, this trial was stopped due to lack of funding.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2002

Completion date
01/06/2004

Reason abandoned (if study stopped)
Lack of funding

Eligibility

Key inclusion criteria
All smokers with 20 pack years plus, aged between 35 and 75, presenting in primary care to the HTQ Programme will be eligible for entry into the trial. All subjects recruited to the HTQ programme who fulfill the eligibility criteria will be invited to take part in the study.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Eg breathlessness
2. Terminally ill
3. Subjects with prior knowledge of spirometry status

Date of first enrolment
01/06/2002

Date of final enrolment
01/06/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Stirchley Medical Practice
Telford
United Kingdom
TF3 1FB

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Shrewsbury and Telford Research and Development Consortium (UK)

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