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Patient self-management in primary care patients with chronic obstructive pulmonary disease (COPD)

Submission date
21/11/2013

Recruitment status
No longer recruiting

Registration date
21/11/2013

Overall study status
Completed

Last Edited
26/07/2019

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
We are conducting a study to find out the effectiveness of a nurse-led telephone-based self-management service that is designed to help people living with chronic obstructive pulmonary disorder (COPD) to improve their health-related quality of life. Findings generated from the study will contribute to existing research evidence and inform the design of self-management methods in GP surgeries for people who report only mild symptoms of their COPD.

Who can participate?
Adult patients with COPD can take part in this study.

What does the study involve?
Patients will be randomly allocated to one of two groups: self-management package or usual care. The package will include smoking cessation advice; encouragement to become physically active; medication adherence and for those patients with recurrent chest infections, action planning to identify an exacerbation early. It will be delivered by telephone by a nurse with one initial 45-60 minute consultation followed by three 15-20 minute telephone contacts over a three-month period (at about 3, 7 and 11 weeks) with individually tailored written supportive materials following telephone contacts. Data will be collected at 6 and 12 months after allocation.

What are the possible benefits and risks of participating?
Participants will receive support to self-manage their COPD. Further information about NHS services will be provided upon request. There are no known risks in taking part in this study.

Where is the study run from?
This study is run across four sites in the UK: University of Birmingham, University of Keele, University of Manchester and the University of Oxford. These four sites will be working in collaboration with general practices in their localities.

When is the study starting and how long is it expected to run for?
September 2013 to December 2016

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

Who is the main contact?
1. Professor Kate Jolly (c.b.jolly@bham.ac.uk)
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14642

Study information

Scientific Title
Patient self-management in primary care patients with chronic obstructive pulmonary disease (COPD): a randomised controlled trial

Acronym
PSM-COPD

Study objectives
The study will commence with a feasibility study followed by a randomised controlled trial of a telephone-based self-management intervention compared with usual care.

The feasibility study aims to check that the training package is appropriate and sufficient for the delivery of the intervention; that uptake and adherence to the intervention are sufficiently high; that the respiratory questionnaires are appropriate for people with mild COPD and to obtain insights into the patient experience of receiving the self-management intervention and how the intervention may affect costs and health outcomes.

RCT: Randomisation will be performed centrally by computer at the Primary Care Clinical Trials Unit, University of Birmingham. The RCT will comprise a telephone-based self-management package of 4 components compared with usual care. The 4 components are smoking cessation, promotion of physical activity, medication adherence and action planning. The primary outcome is HRQoL measured using the St Georges Respiratory Questionnaire (SGRQ).

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/WM/0206; First MREC approval date 16/07/2013

Study design
Both; Interventional; Design type: Process of Care, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Patients will be randomised to the intervention or usual care in the main trial with a 1:1 ratio. Supported self-management, Nurse-supported telephone self-management. Self-management includes 4 elements: smoking cessation, physical activity, correct inhaler technique and action planning for an exacerbation.; Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
St George's Respiratory Questionnaire (SGRQ); Timepoint(s): 6 and 12 months follow-up

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/09/2013

Completion date
30/12/2016

Eligibility

Key inclusion criteria
On COPD primary care register with MRC dyspnoea grade 1 and 2
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 553; UK Sample Size: 553; Description: Up to 30 patients will be recruited for the feasibility study, and 553 will be recruited on to the main trial.

Key exclusion criteria
1. COPD MRC grade 3 and above
2. COPD unconfirmed by post-bronchodilator spirometry (FEV1/FVC ration above 5th percentile of the predicted values for their age, height, sex and ethnicity, using the ECCS equations)

Date of first enrolment
18/03/2014

Date of final enrolment
05/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Care Clinical Sciences
School of Health and Population Sciences
Edgbaston
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Study participating centre
The University of Manchester
Centre for Primary Care: Institute of Population Health
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Study participating centre
Nuffield Department of Primary Care Health Sciences
University of Oxford

New Radcliffe House
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Study participating centre
Research Institute for Primary Care & Health Sciences
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Sponsor information

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University of Birmingham

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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - School for Primary Care Research; Grant Codes: 174

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/12/2017

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?
Protocol article	protocol	22/02/2015		Yes	No
Results article	results	13/06/2018		Yes	No
Results article	SWAT results	24/07/2019	26/07/2019	Yes	No
HRA research summary			28/06/2023	No	No