

Does an individualised self-management plan help patients with chronic obstructive pulmonary disease (COPD) initiate early treatment for infective exacerbations?

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Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/07/2016	Condition category Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0236138972

Study information

Scientific Title

Does an individualised self-management plan help patients with chronic obstructive pulmonary disease (COPD) initiate early treatment for infective exacerbations?

Study objectives

To assess the effectiveness of an individualised self management plan to see if it improves patients ability to recognise early signs of an infection and self initiate treatment during an exacerbation

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Respiratory: Chronic obstructive pulmonary disease (COPD)

Interventions

Methodology

An experimental approach will be taken, using a randomised controlled trial. Participants (sample group of 40 - 20 to each arm of the study), with a diagnosis of COPD attending the nurse-led clinic at St George's Healthcare NHS Trust will be randomly selected to receive routine care versus intervention, consisting of education, issuing of a self-management leaflet, symptom card and a prescription for antibiotics and cortico-steroids. Both arms will be asked to complete two questionnaires pre and 1 month post intervention, with the intervention arm being asked to

complete a symptom diary for 6 months. Randomisation will be undertaken through using sealed envelopes. Permission is being sought from the Wandsworth Local Research Ethics Committee.

Data Collection

All patients will be asked to complete two questionnaires

1. The COPD self efficacy questionnaire (validated) (Wigal 1991)
2. A 20 question multiple choice questionnaire on the treatment of COPD
3. Demographic will be collected including severity of disease, age, sex, number of exacerbations and admissions for COPD in the previous year.

The aim is to test the participants' knowledge of COPD, its treatment, recognition of exacerbations, and confidence in self management.

Data Analysis

Data will be analysed using the Statistical Package for the Social Sciences (SPSS), using a paired T-test to analyse the questionnaires pre and post intervention.

An unpaired test will compare the two groups.

Any correlation between age, sex and severity of disease exacerbation and admission rate will be explored.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Patients knowledge of the disease and medication

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2004

Completion date

30/09/2005

Eligibility

Key inclusion criteria

Random selection using sealed envelopes to either arm of the study. Diagnosis of COPD attending nurse led clinics at Chest Clinic St Georges Hospital.

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

40

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/01/2004

Date of final enrolment

30/09/2005

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Chest Medicine**

London

United Kingdom

SW17 0RE

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

Hospital/treatment centre

Funder Name

St George's Healthcare NHS Trust (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