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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
30/09/2004	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2004	Completed	Results
Last Edited	Condition category	Individual participant data
20/07/2016	Respiratory	Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

# Type(s)

Scientific

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# Additional identifiers

#### Protocol serial number

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

#### Study type(s)

**Treatment** 

#### 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(s)

Patients knowledge of the disease and medication

#### Key secondary outcome(s))

Not provided at time of registration

#### 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

## Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

All

#### 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

**United Kingdom** 

England

Study participating centre Chest Medicine London United Kingdom SW17 ORE

# Sponsor information

## Organisation

Department of Health

# Funder(s)

## Funder type

Hospital/treatment centre

#### **Funder Name**

St George's Healthcare NHS Trust (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration