

The COPD Breathlessness Manual: Cognitive-behavioural manual versus information booklets on health service use, mood and health status in patients with chronic obstructive pulmonary disease (COPD)

Submission date 24/04/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/05/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/02/2017	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Chronic obstructive pulmonary disease (COPD) is a costly long term condition associated with frequent Accident & Emergency (A&E) and hospital admissions. Psychological difficulties such as anxiety, panic and depression, which are high in COPD as well as inadequate self-management, can amplify this picture. We are carrying out a study to evaluate a newly developed cognitive-behavioural guided self-help intervention called The COPD Breathlessness Manual which targets the psychological management of breathlessness and COPD in the context of preventing unnecessary A&E attendance and hospital admissions. The COPD breathlessness manual will be compared to information booklets to see if it is more effective at reducing hospital use and associated NHS costs as well as improving mood and health status.

Who can participate?

The COPD manual study aims to recruit about 220 men and women, with a confirmed diagnosis of COPD and a self-rating of moderate breathlessness from a range of GP practices in a London Borough.

What does the study involve?

Over a period of 1.5 years participants will be invited by letter to participate in the trial. Opt ins will be telephoned to discuss the trial, check they meet the criteria and to arrange a home visit. The group to which a participant is allocated to will be decided by a process called randomisation, which is like a coin toss. Both groups will receive a 90 minute home visit involving obtaining signed informed consent, measures at the start of the study, a semi-structured interview, and introducing the intervention. Participants will be encouraged to follow their programme at home for approximately one hour per day (broken up throughout the day) over a five week period. They will receive two 30 minute telephone call booster sessions at week three and six.

At the end of the study, we will compare the number of A&E attendances, hospital admission, length of stay and associated NHS costs 12 months before study participation and 12 months afterwards. We will also measure anxiety, depression and health status at the start of the study, at 6 weeks on completion of the intervention as well as six months. We will collect participant feedback on their intervention.

What are the possible benefits and risks of participating?

The intended benefit is that by focusing on and learning more about breathlessness and COPD it will reduce the severity of breathlessness and any anxiety and frustration associated with it. It may also reduce the amount of medical care required. It is possible that focusing on breathlessness may mean participants are more aware of it. Further support can be arranged if necessary.

Where is the study run from?

The study was set up by the Department of Clinical Health Psychology at The Hillingdon Hospital, Central & North West London NHS Foundation Trust (UK). The participants come from a number of GP practices in a London Borough.

When is study starting and how long is it expected to run for?

From August 2010 to July 2012. Recruitment started mid-2011 and participants were enrolled for one year.

Who is funding the study?

Funding has been provided by Central & North West London NHS Foundation Trust (UK).

Who is the main contact?

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Dr Claire Howard, choward1@nhs.net

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

HOWCC10001

Study information

Scientific Title

The COPD Breathlessness Manual: A randomised controlled trial to test a cognitive-behavioural manual versus information booklets on health service use, mood and health status in patients with chronic obstructive pulmonary disease

Acronym

COPD Manual

Study objectives

Hypothesis:

The COPD breathlessness manual will result in a greater reduction in A&E visits, hospital admissions and length of stay as well as a greater improvement in mood and health status compared to information booklets.

Null hypothesis:

There will be no difference between groups on outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Central London REC 3 Research Ethics Committee, 24/05/2010, ref: 10/H0716/22

Study design

One year parallel group trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Chronic Obstructive Pulmonary Disease

Interventions

Participants will be randomised to receive either The COPD Breathlessness Manual: A cognitive behavioural guided self help manual or COPD information booklets. They will be guided through their intervention by a facilitator in the form of one home visit and two telephone call follow ups. They will be encouraged to work through their intervention in their own time at home over a five week period.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The change in the number of A&E attendances over a 12 month period from pre to post intervention.

Key secondary outcome(s)

The change in number of hospital admissions, number of hospital bed days, anxiety, depression and health status pre and post intervention. Mood and health status were collected with questionnaires at timepoints baseline, 6 weeks and 6 months.

Completion date

31/07/2012

Eligibility

Key inclusion criteria

1. A diagnosis of COPD
2. A self-rating of breathlessness on the Medical Research Council (MRC) dyspnoea scale of 3,4 or 5
3. Willingness to participate
4. Ability to provide informed consent
5. Ability to read and write in English or with assistance

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Known psychosis and personality disorders
2. Receiving psychological therapy
3. Participating in Pulmonary Rehabilitation or within the previous six months
4. Cognitive impairment, dementia
5. Verbal and/or written communication problems

Date of first enrolment

01/08/2010

Date of final enrolment

31/07/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Clinical Health Psychology

Uxbridge

United Kingdom

UB8 3NN

Sponsor information

Organisation

Central & North West London NHS Foundation Trust (UK)

ROR

<https://ror.org/05drfg619>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Central & North West London NHS Foundation Trust (UK) - Innovations Scheme; Application number 19

Results and Publications

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	16/10/2014		Yes	No