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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

Registration date
01/05/2014

Overall study status
Completed

Last Edited
13/02/2017

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Dr Simon Dupont, simon.dupont@nhs.net
Dr Claire Howard, choward1@nhs.net

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet: simon.dupont@nhs.net or choward1@nhs.net

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

Secondary outcome measures
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.

Overall study start date
01/08/2010

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

Age group

Adult

Sex
Both

Target number of participants
200

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
England

United Kingdom

Study participating centre
Department of Clinical Health Psychology
Uxbridge
United Kingdom
UB8 3NN

Sponsor information

Organisation
Central & North West London NHS Foundation Trust (UK)

Sponsor details
Central and North West London NHS Foundation Trust Innovation Scheme
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/10/2014

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