ISRCTN55206395 https://doi.org/10.1186/ISRCTN55206395

The Newcastle COPD CBT CARE Study

Submission date
20/10/2011

Recruitment status
No longer recruiting

Registration date
20/10/2011

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Many people in the United Kingdom with chronic obstructive pulmonary disease (COPD) also experience feeling anxious or low in their mood. This study aims to see if a treatment called cognitive behavioural therapy (CBT) can help reduce symptoms. Cognitive Behavioural Therapy (CBT) is a method used to explore how we think, feel and act when we have a physical health problem. The benefit of CBT is that it can hopefully change the way patients cope with their illness and symptoms in a practical, problem solving way.

Who can participate?
Patients can participate if they have a confirmed diagnosis of COPD, any gender and any age.

What does the study involve?
Patients are randomly allocated either self-help leaflets to work through or individual appointments with a nurse for up to six sessions of CBT. All patients are followed up after three, six and 12 months with questionnaires to assess their progress.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Royal Victoria Infirmary, New Victoria Wing, Newcastle (UK)

When is study starting and how long is it expected to run for?
June 2011 to October 2014

Who is the main contact?
Ms K Heslop

Contact information

Type(s)
Scientific

Contact name

Ms K Heslop

Contact details
Royal Victoria Infirmary
New Victoria Wing
Queen Victoria Road
Newcastle Upon Tyne
United Kingdom
NE1 4LP
-
karen.heslop@nuth.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10519

Study information

Scientific Title
A single centre randomised controlled trial to identify if cognitive behavioural therapy delivered by respiratory nurses reduces anxiety and depression in patients with chronic obstructive pulmonary disease (CBT CARE Study).

Study objectives
A single centre randomised controlled trial to identify if cognitive behavioural therapy delivered by respiratory nurses reduces anxiety & depression in patients with chronic obstructive pulmonary disease at 3, 6 & 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sunderland Ethics Committee, 25/02/2011, ref: 11/NE/0025

Study design
Randomised, interventional, treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Anxiety, depression, respiratory.

Interventions
As of 14/10/2016:

The two interventions were:
1. Group A – CBT Arm (Brief CBT treatment delivered by respiratory nurses).
Group A received a brief CBT intervention called the Lung Manual Programme plus self-help leaflets (Northumberland, Tyne and Wear Mental Health Trust leaflets on panic) and the Self-Help Toolkit were provided. Depression and low mood leaflets were provided if co-existing symptoms of depression were identified. The CBT was delivered by one of four respiratory nurses who had at least three days prior training in CBT with specific study training. Individualised treatment plans were developed to deliver between two and six sessions of CBT at two weekly intervals depending on clinical need. The first session lasted 30 to 45 minutes and follow-up sessions lasted 15 to 30 minutes. CBT therapy was administered in the hospital outpatient clinic or home setting for patients who were housebound.
2. Group B – Active control arm - Self Help Leaflets
Patients in group B were randomised to receive the same self-help leaflets as the CBT group. Patients were provided the leaflets, advised to read them thoroughly and complete the exercises within them. Patients were encouraged to contact their primary care team should further help be required.

Follow-up period: 12 months

Initial
Cognitive Behavioural Therapy, Psychological treatment for anxiety & depression.
Follow Up Length: 12 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Does CBT delivered by respiratory nurses reduce anxiety (1.5 points on HADS scale).; Timepoint (s): At 3 months

Secondary outcome measures

1. Does CBT delivered by respiratory nurses reduced anxiety & depression compared to standard care measured at timepoint(s) 6 & 12 months
2. Reduction in Hospital Anxiety & Depression Scale of at least 1.5 points compared to standard care measured at timepoint(s): 6 months & 12 months

Overall study start date
16/06/2011

Completion date
13/10/2014

Eligibility

Key inclusion criteria
1. Patient with a confirmed diagnosis of COPD (FVC/FEV1 ratio <70%, NICE, 2010)
2. People with all disease severity will be eligible including mild to moderate (FEV1 >50% predicted) and severe to very severe (<50% predicted)
3. Patients with probable anxiety as defined by Hospital Anxiety and Depression Scale Anxiety Subscale (HADSA)
scores >8
4. Willing to participate in the study and able to provide written informed consent
5. Agreed to attend a minimum of 2 and maximum of 6 CBT sessions
6. Target Gender: Male & Female
7. 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: 312; UK Sample Size: 312; Description: 156 patients randomised to either CBT treatment or usual care.

Key exclusion criteria
1. Patients with HADSA score <8 (within normal range)
2. Patients with known psychosis and personality disorders
3. Patients currently receiving psychological therapy including counselling, psychotherapy including CB
4. Patients unable to engage in CBT e.g. cognitive impairment or dementia)
5. Patients with limited verbal and/or written communication problems

Date of first enrolment
16/06/2011

Date of final enrolment
13/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary, New Victoria Wing
Queen Victoria Road
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
National Institute of Health Research (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NS

Sponsor type
Government

Website
http://www.nihr.ac.uk/

ROR
https://ror.org/0187kwz08

Funder(s)

Funder type
Government

Funder Name
NIHR/CNO Clinical Academic Training Fellowship (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/11/2013		Yes	No
Results article	results	23/11/2018	21/01/2019	Yes	No