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Working together against COPD

Submission date
06/03/2017

Recruitment status
No longer recruiting

Registration date
20/03/2017

Overall study status
Completed

Last Edited
22/08/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name given to a collection of diseases which affect the lungs. It is characterised by breathlessness, cough and excess mucus production and is often caused by smoking. Many people with chronic obstructive pulmonary disease (COPD) are affected by anxiety and/or depression and their illness can feel burdensome both physically and emotionally. One main treatment for patients with COPD is pulmonary rehabilitation (PR); a program of exercise, education and support that is used in patients with COPD to help them improve their physical condition. PR aims to help break the cycle of physical disability, associated anxiety, despondency, inactivity and isolation. Although PR is known to be an effective treatment for COPD, many patients unfortunately do not take part in or complete treatment programs, particularly those with anxiety and depression. This study is looking at a cognitive behavioural approach (CBA) program (a type of mental health therapy which aims to help people change the way they think and behave), which links into and enhances the benefits of PR, with the aim of reducing mild/moderate anxiety and/or depression in people with moderate to severe COPD.

Who can participate?
Adult patients with COPD who have mild anxiety and/or depression and their carers.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual care only. Those in the second group receive the CBA treatment program. This involves between five and eight 30-40 minute weekly sessions from trained respiratory health care professionals. 10-15 minute weekly telephone follow ups are also scheduled with patients if they decide to attend the PR programme after completion of the CBA intervention. At the start of the study and then after six and 12 months, participants in both groups are followed up to assess their anxiety and/or depression levels. In addition, carers of patient participants are also invited to the join the study (with patient permission) and are interviewed about their experiences of being a carer and their mental wellbeing.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part in the trial but the information collected and feedback provided will help to improve the care of people with COPD in future. There are no notable risks involved for those taking part in the study, however, if during the one-to-one

sessions or interview a participant says something that may indicate a risk to themselves or others, their GP or other healthcare professional will be contacted so appropriate arrangements can be made.

Where is the study run from?
Pulmonary rehabilitation (PR) services within NHS Trusts in England (UK)

When is the study starting and how long is it expected to run for?
November 2013 to July 2021

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Ms Ratna Sohanpal (public)
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2. Professor Stephanie Taylor (scientific)
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Study website
http://www.blizard.qmul.ac.uk/research-project/1481-tandem.html

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
32713

Study information

Scientific Title
A tailored, cognitive behavioural approach intervention for mild to moderate anxiety and/or depression in people with chronic obstructive pulmonary disease (COPD): a randomised controlled trial

Acronym
TANDEM COPD

Study objectives
The aim of this study is to evaluate a psychological cognitive behavioural approach (CBA) intervention, which links into and optimises the benefits of pulmonary rehabilitation (PR), with the aim of reducing mild to moderate anxiety and/or depression in people with moderate to severe chronic obstructive pulmonary disease (COPD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Queen Square Research Ethics Committee, 27/02/2017, ref: 17/LO/0095

Study design
Randomised; Interventional; Design type: Treatment, Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Anxiety and/or depression in people with chronic obstructive pulmonary disease (COPD)

Interventions
Following patient recruitment and collection of baseline data, participants will be randomised to the TANDEM intervention or usual care (control) using minimisation with a random element: this will be done in order to minimise potential imbalances at baseline for anxiety (HADS-A), depression (HADS-D), dyspnoea (mMRC) and smoking. The randomisation will be at the individual patient level with 1.25:1 allocation ratio.

TANDEM intervention: Participants in the intervention arm will receive between 5 and 8 (depending on individual patient need) approx. 40 minute long, weekly, one-to-one cognitive behavioural approach (CBA) sessions by a TANDEM trained respiratory health care professionals (termed 'facilitators') prior to commencement of pulmonary rehabilitation. Following completion of the patient facing intervention, participants may attend routine pulmonary rehabilitation at their local service. In the gap between the intervention being finished and pulmonary rehabilitation commencing, participants will receive one-to-one phone calls by the facilitators on a weekly basis (duration of each call approx.10-15 minutes). Weekly phone calls will continue whilst the participant is attending pulmonary rehabilitation and for 2 weeks after its completion.

Usual care (Control group): Participants in the control arm will follow local arrangements for the provision of pulmonary rehabilitation referred to the service (including any psychological treatment provided routinely in that service). In agreement with the local service (who may prefer to use their own materials), participants will be offered the British Lung Foundation DVD on living with COPD and additional booklets on COPD and pulmonary rehabilitation.

All participants will be followed up at 6 and 12 months post enrolment.

Intervention Type
Other

Primary outcome measure
Anxiety and depression are measured using the Hospital Anxiety and Depression Scale (HADS) subscales (HADS-A and HADS-D) at baaseline, 6 and 12 months.

Secondary outcome measures
Patient outcomes:
1. Degree of breathlessness is measured by the modified Medical Research Council (mMRC) Breathlessness scale at baseline only.
2. Depression is measured using the Beck's Depression Inventory-II (BDI-II) at baseline, 6 and 12 months.
3. Anxiety is measured using the Beck's Anxiety Inventory (BAI) at baseline, 6 and 12 months
4. Respiratory health-related quality of life is measured using the St George's Respiratory Questionnaire (SGRQ) at baseline, 6 and 12 months
5. Illness perception about COPD is measured using the Brief-Illness Perception Questionnaire (B-IPQ) at baseline, 6 and 12 months
6. Social engagement is measured using the Health Education Impact Questionnaire (heiQ) at baseline, 6 and 12 months
7. Functional/social activity is measure using the Time Use Survey at baseline, 6 and 12 months

Carer outcomes:
1. Carer burden is measured using the Zarit Burden Interview (ZBI) (22 item) at baseline, 6 and 12 months
2. Carer mental well-being is measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) (14 item) at baseline, 6 and 12 months

Overall study start date
08/11/2013

Completion date
31/07/2021

Eligibility

Key inclusion criteria
Patients:
1. Adults with a confirmed diagnosis of COPD, post bronchodilator FEV1/FVC ratio <70%
2. Moderate or severe COPD severity on spirometry, FEV1 30-80% predicted
3. Patients with probable mild or moderate anxiety as determined by the Hospital Anxiety and Depression Scale-Anxiety Subscale (HADS-A) scores ≥8 to ≤15; and/or probable mild or moderate depression as determined by Hospital Anxiety and Depression Scale-Depression Subscale (HADS-D) scores ≥8 to ≤15
4. Eligible for attendance at their local pulmonary rehabilitation service at the time of randomisation i.e. 12 months have elapsed since last undertook pulmonary rehabilitation or participant has another indication for pulmonary rehabilitation referral (e.g. recent deterioration; recent hospitalisation with an acute exacerbation of COPD)

Carers:
Identified by a participant with COPD in the study as a 'particular family caregiver or friend who helps them' whom they would be happy for us to invite to join the study.

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 430; UK Sample Size: 430

Total final enrolment
428

Key exclusion criteria
Exclusion Criteria - Patients:
1. Patients with both HADS-A score and a HADS-D score < 8 (within normal range)
2. Unable to give valid consent
3. HADS depression or anxiety subscale score greater than 15 (suggestive of possible severe anxiety/depression)
4. Severe uncontrolled psychological or psychiatric disorder that would make them unsuitable for the intervention
5. Ineligible for pulmonary rehabilitation at their local PR service at the time of randomisation (typically if they had undertaken a course of PR in the last 12 months and there were no new clinical indications for PR). Patients who have been offered PR previously but declined the offer will not be excluded.
6. A co-morbidity so severe it would prevent the patient from engaging fully in the intervention/ control
7. Patients with moderate/severe cognitive impairment
8. In receipt of a psychological intervention primarily directed at helping to manage anxiety or depression in the last 6 months (Those on antidepressants/ anxiolytics not excluded)
9. Patients currently involved in another clinical trial related to COPD (to reduce study participation burden on participants)
10. Not sufficiently fluent in English to be able to complete the questionnaires (the questionnaires are supervised self-complete, but can be read to participants if necessary, so poor literacy would not exclude individuals who are otherwise sufficiently fluent in English)

Exclusion Criteria - Carers:
1. Unable to give valid consent
2. Not sufficiently fluent in English to be able to complete the questionnaires

Date of first enrolment
03/04/2017

Date of final enrolment
19/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Community cardio-respiratory service, Imperial College Healthcare NHS Trust
St Mary’s Hospital,
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
Acute COPD Early Response Service (ACERS), Homerton University Hospital NHS Foundation Trust
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
Glenfield General Hospital
University Hospitals of Leicester NHS Trust
Groby Road
United Kingdom
LE3 9QP

Study participating centre
Loughborough Hospital
Leicestershire Partnership NHS Trust,
Hospital Way
Loughborough
United Kingdom
LE11 5JY

Study participating centre
Pulmonary rehabilitation service, St Thomas' Hospital
Guy's and St Thomas' NHS Foundation Trust,
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre

Atrium Health Ltd
Centre for Exercise and Health Unit 1,
University Hospitals Coventry and Warwickshire NHS Trust,
Watch Close
Coventry
United Kingdom
CV1 3LN

Study participating centre
South Warwickshire Rehab service
Warwick Hospital,
South Warwickshire NHS Foundation Trust,
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
King's College Hospital NHS Foundation Trust
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Ln
Bracknell
Reading
United Kingdom
RG12 1BQ

Study participating centre
Southern Health NHS Foundation Trust
Moorgreen
Botley Road
West End
Southampton
United Kingdom
SO30 3JB

Study participating centre
North Bristol NHS Trust
Southmead Rd
Bristol
United Kingdom
BS10 5NB

Study participating centre
Sandwell and West Birmingham NHS Trust
Dudley Rd
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B18 7QH

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Queen Mary Innovation Centre
Joint Research Management Office (JRMO)
Lower Ground Floor
5 Walden Street
London
England
United Kingdom
E1 2EF
+44 20 7882 7265
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Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of anticipate at least five peer-reviewed scientific publications from this project. These will focus on the protocol, the pilot/feasibility study, development of the intervention, clinical effectiveness of intervention and cost-effectiveness analysis paper.

Intention to publish date
31/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository [Secure virtualised environment at the Barts Cancer Centre (BCC)] All trial data supported by Pragmatic Clinical Trials Unit is stored here.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1	09/02/2017	20/03/2017	No	Yes
Protocol article	protocol	06/01/2020	08/01/2019	Yes	No
Statistical Analysis Plan	statistical analysis plan	15/10/2020	22/10/2020	No	No
Other publications	intervention development	06/04/2021	08/04/2021	Yes	No
Other publications	development of methods and recommendations for research design	06/06/2022	07/06/2022	Yes	No
		05/05	14/11		

Abstract results		/2022	/2022	No	No
Abstract results		05/05/2022	14/11/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		17/01/2024	22/01/2024	Yes	No
Other publications	qualitative evaluation	21/08/2024	22/08/2024	Yes	No