ISRCTN49632858 https://doi.org/10.1186/ISRCTN49632858

COPD in Primary Care Study

Submission date
19/12/2012

Recruitment status
No longer recruiting

Registration date
19/12/2012

Overall study status
Completed

Last Edited
21/06/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Long term illness affects the way people see themselves and the way they cope with living with their illness every day. This research is looking to see if structures could be put in place to help people have a better quality of life and care instead of having to use emergency or out-of-hours health services. For the last 2 years, we have been carrying various studies which have been looking at the kinds of healthcare that people with chronic long term illness receive, how they cope with their illness and how they cope emotionally. From this work we know that the care for people with chronic illness is poorly co-ordinated and we believe that if this care was better organised it may on some occasions avoid people having to seek emergency help. We have also found out that 40% of people living with chronic obstructive pulmonary disease (COPD) report symptoms of depression and anxiety, but are rarely offered any help with this aspect of their illness. Those people who report symptoms of anxiety and depression are also more likely to use emergency care. In this study we are trying to find out whether providing more co-ordinated care for people with COPD plus the opportunity to have specific psychosocial treatment if they need it, results in improved quality of life for people with COPD and a reduced need to use emergency care, because their condition is being managed more appropriately in primary care.

Who can participate?
Patients 18 years or over at selected GP Practices who have a dignosis of chronic obstructive pulmonary disease and are listed as such on the GP database will be invited to participate in this study.

What does the study involve?
The study will involve the research team investigating whether the management of people who have chronic obstructive pulmonary disease (COPD) can be enhanced by improving systems within general practices, and by offering additional help to people with COPD who are suffering from anxiety and depression. We are interested in finding out whether better management in primary care results in better quality of life for people and less need to seek emergency treatment. Some of the practices in the study will carry on as normal and will not change their management of COPD whilst others will introduce an enhanced management programme. To find out whether the enhanced programme actually works we will compare people with COPD in practices with and without the enhanced programme.

What are the possible benefits and risks of participating?
There are no direct benefits from taking part in the study, but some patients may experience some improvements in thier care if they are in a practice that is implementing the enhanced care programme. However, the practices are chosen by chance so this may or may not happen. Also, there are no particular risks to taking part; for most participants the completion of the assessment questionnaires should not result in any form of major distress.

Where is the study run from?
Manchester Mental Health and Social Care Trust, Manchester Primary Care Trust, and the Universities of Manchester and Liverpool.

When is the study starting and how long is it expected to run for?
The study started on the 5th November 2012 and will run for 12 months.

Who is funding the study?
The project is being funded by the National Institute of Health Research and is part of a wider programme of research called CHOICE (Choosing Health Options in Chronic Care Emergencies)

Who is the main contact?
Cara Afzal
cara.afzal@mhsc.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Ms Cara Afzal

Contact details
Manchester Mental Health & Social Care Trust
Rawnsley Building
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL
+44 (0)161 276 5389
cara.afzal@mhsc.nhs.uk

Additional identifiers

Protocol serial number
13167

Study information

Scientific Title

A singlecentre, exploratory, cluster randomised controlled trial of a complex psychosocial intervention for the management of COPD

Study objectives
A complex psychosocial intervention for patients with COPD in primary care will reduce the use of unscheduled care (urgent care) over a 12 month period.

More detail can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=13167

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester East, 24th February 2012, ref: 12/NW/0068

Study design
Randomised interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression

Interventions
We plan to undertake an exploratory cluster randomised controlled trial in primary care to evaluate a psychosocial intervention for patients with COPD. The intervention is at the level of the practice. Intervention practices all receive training and workshops to improve the care of patients with COPD. This involves better systems to detect when patients have received urgent care, better screening for depression and improved practice communication. Patients with COPD who are found to have depression will be offered treatment by practice based liaison health workers. The practices in the control limb of the trial will continue to deliver their usual care for COPD patients, without any additional intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Use of unscheduled care

Key secondary outcome(s))
1. Use of scheduled care
2. Health status (EQ5D; The EuroQoL Group 1990)
3. Severity of COPD (Eisner et al. 2005)

4. Quality of life (Chronic Respiratory Questionnaire; Williams et al. 2001)
5. Hospital Anxiety and Depression Scale (Zigmond and Snaith 1983)
6. Qualitative study to explore the acceptability of the training and support offered to practices (primary care staff) and patients' experiences of the psychosocial intervention and care from their practice.

Primary and secondary outcomes measured at baseline and 12 months

Completion date
31/01/2014

Eligibility

Key inclusion criteria
1. All patients must have chronic obstructive pulmonary disease
2. All patients must be 18 years or over and be able to read and write
3. We will use MMHSCT Linkworkers where appropriate so that patients, who do not have a good command of English, can still participate in the project
4. The COPD liaison workers will be able to access Link workers for any patients identified in the GP practice to be eligible for their service
5. Male or female participants

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. People below the age of 18 years
2. People with learning disabilities, dementia or brain damage
3. Patients who lack capacity to consent in research
4. People who are deemed to be too physically unwell by their GP to participate in the research
5. People who are considered at risk of suicide such that referral to mental health crisis services are warranted or admission to an inpatient psychiatric bed.

Date of first enrolment
05/11/2012

Date of final enrolment
31/01/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Mental Health & Social Care Trust
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Manchester Mental Health & Social Care Trust (UK)

Funder(s)

Funder type
Government

Funder Name
NIHR - Central Commissioning Facility (UK) ref: RP-PG-0707-10162

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	06/10/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes