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How effective is a community based pulmonary rehabilitation programme for patients with mild to moderate chronic obstructive pulmonary disease?

Submission date
04/01/2017

Recruitment status
No longer recruiting

Registration date
17/02/2017

Overall study status
Completed

Last Edited
17/02/2017

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and 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. Pulmonary rehabilitation (PR) is a program of exercise, education and support that is used in patients with COPD to help them improve their physical condition. Hospital run pulmonary rehabilitation (PR) is recommended to be made available to all people with COPD who are receiving the best treatment for them but still feel limited by their breathlessness in performing everyday activities, however this is not practical in most healthcare settings due to lack of resources. Since 2004, Hywel Dda University Health Board has only been able offer PR to people who have moderate to severe breathlessness. Although the service is popular with patients and their carers and it has achieved results in comparison, there remains a considerable waiting list of up to 12 months. Hywel Dda University Health Board along with the Educational Programme for Patients (EPP) have developed a community based pulmonary rehabilitation programme that uses both health=care professionals and lay tutors to equally deliver the course to participants who have COPD but a mild amount of breathlessness. The aim of this study is to assess whether this program is effective at helping patients to manage their condition by looking at people who have taken part in the programme and those who have not.

Who can participate?
Adults aged 35 years and over who have COPD with mild breathlessness who are taking part in the community based pulmonary rehabilitation programme within the six months of the study and those who have signed up for community based pulmonary rehabilitation programme but do not have one in their area within the six month period.

What does the study involve?
For the participants taking part in the community based pulmonary rehabilitation programme, data about their background information and health is collected by the during community

rehabilitation programme assessments at day one, week nine and month six by the course tutors. Data from primary care (GP level) and secondary care (specialist level) is also collected by the research team by reviewing medical databases and patient medical records within three months of the patients completing the course. Participants who have signed up but can't yet access the programme continue as normal and attend appointments on day one, week nine and month six so that background and health data can be collected. The research team also reviews patient notes and medical databases within three months of the final assessment. The data collected in each group are then compared.

What are the possible risks and benefits of participating?
There are no notable benefits involves for participants. There is a small risk that completing the questionnaires in this study may be distressing for some people and participants may find attending the venue to take part inconvenient.

Where is the study run from?
The study is run from Hywel Dda University Health Board takes place in local community areas covered by the Health Board (UK)

When is the study starting and how long is it expected to run for?
March 2016 to March 2018

Who is funding the study?
EPP Cymru (UK)

Who is the main contact?
Mrs Sarah Hicks
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Contact information

Type(s)
Public

Contact name
Mrs Sarah Hicks

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Additional identifiers

EudraCT/CTIS number

IRAS number
206119

ClinicalTrials.gov number

Secondary identifying numbers
IRAS206119

Study information

Scientific Title
How effective is a COMmunity based Pulmonary rehabilitation prograAmme for patients with mild to moderate Chronic ObsTructive Pulmonary Disease? (COMPACT study)

Acronym
COMPACT

Study objectives
The aim of this study is to assess whether the community based pulmonary rehabilitation programme is effective in improving the self management skills of participants within the time period of the programme and for up to 6 months compared to a comparator group who do not undertake the programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Bridge Research Ethics Committee, 22/12/2016, ref: 16/LO/1858

Study design
Single-centre observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease

Interventions
30 people who undertake the community based pulmonary rehabilitation programme (intervention group) within a 6 month timescale and 30 people who sign up for a community based pulmonary rehabilitation programme but do not have one in their area within the 6 month period (comparator group) will be asked to have their data collected by the research team for comparison.

For those in the intervention group, health status data is going to be collected as usual during the community rehabilitation programme at assessment (Day 1, Week 9 and Month 6) by the course tutors who will be unaware of whether the group member has consented to be part of the research or not. Data from primary care and secondary care will be collected by the research team by review of medical databases and patient medical records within the 3 months post course completion.

For those in the comparator group, the health status data will be collected by the research team at assessments on Day 1, Week 9 and Month 6. The research team will also review the medical notes and medical databases within 3 months of the final assessment.

In both groups, data to be collected includes demographics, pulse, blood pressure, oxygen levels, incremental shuttle walk tests, FEV1, MRC score, EQ5D, CAT, primary care contacts, secondary care contacts including A&E attendances and OPD attendances.

Intervention Type
Behavioural

Primary outcome measure
COPD self management is assessed through review of the primary and secondary care databases by the researcher to assess the number of health care professional face to face contacts, telephone contacts and admissions to hospital during the 6 months pre / post attending a community based pulmonary rehabilitation programme.

Secondary outcome measures
1. Participants and Control group: Exercise tolerance of the Intervention group compared to the Controls is assessed using data observed during incremental walk tests at Day 1, Week 9 and 6 Months
2. Participants and Control group: General Health of the Intervention Group compared to the Control group is assessed using the validated, self completed, EQ5D questionnaire at Day 1, Week 9 and 6 Months
3. Participants and Control group: COPD symptom control of the Intervention Group compared to the Control group is assessed using the validated, self completed, COPD Assessment Test (CAT) questionnaire at Day 1, Week 9 and 6 Months
4. For participants only: The cost effectiveness of the community based pulmonary rehabilitation programme will be assessed using statistical analysis via SPSS version 22.2 (Chicago, Illinois) based upon changes in EQ5D, healthcare contacts and deaths within the 12 month research period (6 months pre course and 6 months post course)
5. For participants only, completion rates for the community based pulmonary rehabilitation programme and reasons for non completion will be assessed using the attendance register for the participants course at the 9 week assessment
6. For participants only, reasons for non completion of the community based pulmonary

rehabilitation programme will be assessed by telephone interview with the participant by the research team at the 9 week assessment

Overall study start date
23/03/2016

Completion date
31/03/2018

Eligibility

Key inclusion criteria
Cases:
1. Above 35 years old
2. Male and female
3. Clinical Diagnosis of COPD
4. MRC dyspnoea score of 1-2
5. Self enrolled onto and able to complete a community based pulmonary rehabilitation programme within 6 month time period (Jan - June 2017)

Control:
1. Above 35 years old
2. Male and Female
3. Clinical Diagnosis of COPD
4. MRC dyspnoea score of 1-2
5. Self enrolled onto but not able to start a community based pulmonary rehabilitation programme within the 6 month time period (Jan - June 2017)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30 participants in 2x case control groups

Key exclusion criteria
1. Those unwilling or unable to provide written consent.
2. Resident in an area not covered by the Hywel Dda University Health Board EPP team.
3. Those unable or unwilling to attend at least 5 of the planned 7 ‘COPD +’ sessions (Group A only).
4. MRC dyspnoea score 3-5

Date of first enrolment
10/01/2017

Date of final enrolment
30/10/2017

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Hywel Dda University Health Board
Jobswell Road
Carmarthen
United Kingdom
SA31 3BB

Sponsor information

Organisation
Hywel Dda University Health Board Research & Development Department

Sponsor details
Clinical Research Unit
Prince Philip Hospital
Llanelli
Wales
United Kingdom
SA14 8QF

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/012gye839

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Publication and dissemination plan
The results may be published in scientific journals and presented at conferences.

Intention to publish date
01/04/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Sarah Hicks (Sarah.Hicks@wales.nhs.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No