

Maintenance schedules following pulmonary rehabilitation

Submission date 23/04/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/04/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/06/2015	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00925171

Protocol serial number
7914

Study information

Scientific Title
The effects of maintenance schedules following pulmonary rehabilitation in patients with chronic obstructive pulmonary disease

Study objectives

The primary aim is to compare the effectiveness of maintenance pulmonary rehabilitation (PR) sessions at 3, 6 and 9 months following a PR course compared to standard care in a randomised prospective study of patients with chronic obstructive pulmonary disease (COPD). This will be assessed, at 12 months following the initial course, in terms of disease specific health related quality of life as assessed by the dyspnoea domain of the chronic respiratory questionnaire, shuttle walk test, muscle strength, fat free mass, anxiety and depression scores, and exacerbation frequency.

More details can be found here: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=7914>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 1 REC, 16/06/2009, ref: 09/H0304/40

Primary study design

Interventional

Study design

Randomised interventional treatment trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Respiratory, Primary Care Research Network for England; Subtopic: Not Assigned, Respiratory (all Subtopics); Disease: Respiratory, All Diseases

Interventions

A revision pulmonary rehabilitation session which lasts 2 hours and takes place every 3 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Change from baseline in the dyspnoea domain of the Chronic Respiratory Questionnaire (CRQ)

Key secondary outcome(s)

Change in:

1. Other domains of CRQ
2. Endurance shuttle walk test
3. Muscle strength
4. Fat free mass
5. Body mass index

6. Quality Adjusted Life Years (QALY) gained (estimated from EQ-5D data)
7. Hospital anxiety and depression score (HADS)
8. Changes in medication and NHS Resource Utilisation including hospitalisations, health professional contact, medication and adverse events
9. Muscle strength and endurance (in a subgroup only)

Completion date

30/06/2012

Eligibility

Key inclusion criteria

1. Male or female, aged more than 35 years
2. Physician labelled diagnosis of COPD, emphysema or chronic bronchitis
3. Ex or current smoker of more than 20 pack years
4. Forced expiratory volume in one second (FEV1) less than 80% of predicted
5. Patients may be taking long or short acting bronchodilators and/or inhaled or oral corticosteroids and/or theophyllines
6. Patients having attended at least 60% of the exercise sessions in the initial PR (This is an inclusion criterion for randomisation to receive maintenance PR or standard medical care but not entry into the study)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Significant cardiac or pulmonary disease other than COPD such that COPD is the minor contribution to the patients' symptoms
2. Myocardial infarction within the previous 6 months or unstable angina
3. Respiratory infection defined as cough, antibiotic use or purulent sputum within 4 weeks prior to randomisation
4. Severe or uncontrolled co-morbid disease, which is likely to affect the outcome of the study
5. Abnormalities in cognitive functioning that would limit the patient's ability to undertake the procedures required in the study
6. Unable to give written informed consent

Date of first enrolment

01/07/2009

Date of final enrolment

30/06/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of East Anglia

Norwich

United Kingdom

NR4 7TJ

Sponsor information

Organisation

Norfolk and Norwich University Hospital NHS Foundation Trust (UK)

ROR

<https://ror.org/01wspv808>

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

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	11/03/2015		Yes	No