Maintenance schedules following pulmonary rehabilitation

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00925171

Secondary identifying numbers 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

Study design

Randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Primary outcome measure

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

Secondary outcome measures

Change in:

- 1. Other domains of CRO
- 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)

Overall study start date

01/07/2009

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

Age group

Adult

Sex

Both

Target number of participants

Planned sample size: 165

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

England

United Kingdom

Study participating centre University of East Anglia

Norwich United Kingdom NR4 7TJ

Sponsor information

Organisation

Norfolk and Norwich University Hospital NHS Foundation Trust (UK)

Sponsor details

Colney Lane Colney Norwich England United Kingdom

NR4 7UY

Sponsor type

University/education

Website

http://www.nnuh.nhs.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

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?
Results article	results	11/03/2015		Yes	No