ISRCTN68654480 https://doi.org/10.1186/ISRCTN68654480

Maintenance schedules following pulmonary rehabilitation

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Not Applicable

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 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)

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