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Trial of lung rehabilitation customised for interstitial lung disease

Submission date
20/03/2017

Recruitment status
No longer recruiting

Registration date
08/05/2017

Overall study status
Completed

Last Edited
24/05/2024

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Idiopathic pulmonary fibrosis (IPF) is a disease where the lungs scar for unknown reasons making breathing difficult. IPF has a high mortality rate (death rate) of 50% in the first five years after being diagnosed. The current IPF treatments do not lead to major changes in quality of life or improve chances of survival. It is known that patients with lung disease overall are less healthy and usually become “out of shape”. Exercises and pulmonary rehabilitation (exercises to improve breathing) are known to help patients with other lung diseases but there are few studies to see if patients with IPF could benefit from this type of treatment. The aim of this study is to develop a pulmonary rehabilitation for patients with IPF that includes education, exercise, breathing and relaxation techniques, as well as nutritional and psychological (mental) instructions.

Who can participate?
Adults aged 40 and older who are diagnosed with IPF.

What does the study involve?
Participants are asked to fill out a questionnaire about breathlessness, their quality of life and their levels of tiredness. They also undergo a walking test, breathing test, muscle force test, blood tests and breathing muscles test. Participants are then randomly allocated to one of two groups. Those in the first group undergo a weekly programme that includes home exercises, walking exercises and one supervised session of education, exercises and relaxation. This is done eight weeks. Those in the second group undergo the same eight week programme as the first group but they also receive respiratory muscle training (breathing training) twice a day for 30 breaths long. Participants then repeat the assessments from the beginning of the study to see if they have any changes in their breathing ability and their health levels.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating. Participants may feel some discomfort when giving blood samples.

Where is the study run from?
Newcastle University (UK)

When is the study starting and how long is it expected to run for?
April 2016 to March 2022

Who is funding the study?
Royal Embassy of Saudi Arabia - Cultural Bureau in London (UK)

Who is the main contact?
1. Mr Maher AlQuaimi (Scientific)
2. Dr Christopher Ward (Scientific)
3. Dr Ian Forrest (Scientific)
4. Dr Anne-Marie Bourke (Scientific)

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A proof of concept trial of pulmonary rehabilitation with inspiratory muscle training in interstitial lung disease in a hospice and home setting

Study objectives

1. A tailored rehabilitation program for Interstitial lung disease (ILD) and Idiopathic pulmonary fibrosis (IPF) is feasible
2. A tailored hybrid rehabilitation program (home setting, hospice care setting) for ILD and IPF is feasible
3. An inspiratory muscle training is feasible in ILD and IPF

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Authority, NHS, UK, 03/04/2018, ref: 18/NE/0037

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Interstitial lung disease including idiopathic pulmonary fibrosis

Interventions
Participants are randomly allocated to one of two groups using a computer generated randomisation list.

Control Group (Group 1): Those in the first group receive a tailored rehabilitation programme for eight weeks. This involves a repeated weekly programme consisting of two unsupervised home exercise sessions, four days of targeted walking exercises and one supervised session. The supervised session consists of an education talk followed by an exercise session and a relaxation session. This is done in a hospice care setting.

Intervention Group (Group 2): Those in the second group do the same as the first group. In addition, they receive respiratory muscle training taking place at 40% of inspiratory muscle pressure. This is done twice a day and each session will be 30 breaths long.

Participants are also asked to fill out questionnaires on breathlessness, quality of life and fatigue prior to the the study and after the study. They also are assessed using a walking test, breathing test, muscle force test, blood extraction, and breathing muscles force test prior to the study and after the study.

Intervention Type
Behavioural

Primary outcome measure
1. Number of people recruited is measured using the study records at baseline and eight weeks
2. Number of people who complete the study is measured using study records at baseline and eight weeks

Secondary outcome measures
1. Inspiratory muscle pressure (IMP) is measured using the POWERbreathe KH2 machine at baseline and eight weeks
2. Palliative care needs (patients' physical symptoms, psychological, emotional and spiritual, and information and support needs) is measured using the palliative care outcome scale (IPOS) at week one, two, three, four, five, six, seven and eight.
3. Breathlessness and other symptoms of IPF are measured using the K-Bild questionnaire at baseline and eight weeks
4. Quadriceps, elbow, and shoulder muscles strength is measured using microFET device at baseline and eight weeks
5. Anxiety and depression is measured using the Hospital anxiety and Depression Scale at baseline and eight weeks
6. Biomarkers are measured using blood samples at baseline and eight weeks
7. Fatigue is measured using the Fatigue Severity Scale at baseline and eight weeks
8. Lung volumes and capacities are measured using spirometry at baseline and eight weeks
9. Lung diffusion capacity is measured using the diffusion capacity to carbon monoxide at baseline and eight weeks
10. Walking distance assessment is measured using the six-minute walk test at baseline and eight weeks

Overall study start date
01/04/2016

Completion date
10/03/2022

Eligibility

Key inclusion criteria
1. Working diagnosis of IPF or ILD made by a multi-disciplinary team
2. MRC dyspnoea score is between 2 to 5
3. Aged 40 or older

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
36

Total final enrolment
34

Key exclusion criteria
1. Uncontrolled hypertension
2. Uncontrolled cardiac disease
3. Inability to perform exercises, for example: neuromuscular or orthopeaedic diseases
4. Inability to follow instructions, for example: learning difficulty
5. Inability to commit to transportation to the exercise facility during the study
6. Participation in pulmonary rehabilitation in the last 6 months
7. History of syncope on exertion

Date of first enrolment
01/08/2017

Date of final enrolment
01/08/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal Victoria Infirmary Hospital
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Marie Curie Hospice
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Sponsor information

Organisation
Newcastle University

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Sponsor type
University/education

Website
http://www.ncl.ac.uk/icm/

Funder(s)

Funder type
Government

Funder Name
Royal Embassy of Saudi Arabia - Cultural Bureau in London

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/04/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Maher AlQuaimi, malquimi@gmail.com

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
Other unpublished results			24/05/2024	No	No