

Trial of lung rehabilitation customised for interstitial lung disease

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
20/03/2017	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
08/05/2017	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
24/05/2024	Respiratory	

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

Type(s)

Scientific

Contact name

Mr Maher Mubarak Al Quaimi

ORCID ID

<https://orcid.org/0000-0002-7583-2624>

Contact details

King Faisal Ibn Abd Al Aziz, King Faysal University

Dammam

Saudi Arabia

34212

None provided

mmalquaimi@iau.edu.sa

Type(s)

Scientific

Contact name

Dr Christopher Ward

ORCID ID

<https://orcid.org/0000-0002-6954-9611>

Contact details

Newcastle University

Institute of Cellular Medicine (Respiratory) and ICaMB

Cookson 1.072 Floor 1

Cookson Building Medical School

Newcastle upon Tyne

United Kingdom

NE2 4HH

+44 (0)191 222 8460

chris.ward@ncl.ac.uk

Type(s)

Scientific

Contact name

Dr Ian Forrest

Contact details

Royal Victoria Infirmary Newcastle upon Tyne

Department of Respiratory Medicine

Queen Victoria Road

Newcastle upon Tyne

United Kingdom

NE1 4LP

+44 (0)191 292 0149

ian.forrest@nhs.net

Type(s)

Scientific

Contact name

Dr Anne-Marie Bourke

Contact details

Marie Curie Hospice

Marie Curie Drive

Newcastle upon Tyne

Newcastle upon Tyne

United Kingdom

NE4 6SS

+44 (0)191 2191000

anne-mariebourke@nhs.net

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

34

Key exclusion criteria

1. Uncontrolled hypertension
2. Uncontrolled cardiac disease
3. Inability to perform exercises, for example: neuromuscular or orthopaedic 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

United Kingdom

England

Study participating centre

The Royal Victoria Infirmary Hospital

Queen Victoria Road

Newcastle upon Tyne

United Kingdom

NE1 4LP

Study participating centre

Marie Curie Hospice

Marie Curie Drive

Newcastle upon Tyne

United Kingdom

NE4 6SS

Sponsor information

Organisation

Newcastle University

Funder(s)

Funder type

Government

Funder Name

Royal Embassy of Saudi Arabia - Cultural Bureau in London

Results and Publications

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	
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes