

# Feasibility of high intensity interval training in pulmonary rehabilitation programmes for patients with interstitial lung disease and preliminary efficacy of its long-term benefits

<b>Submission date</b> 05/06/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/06/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/08/2023	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Patients with interstitial lung disease (ILD) experience progressive breathlessness, tiredness and poor exercise capacity during their everyday life. As a result of these symptoms, patients tend to avoid strenuous activities and become less fit over time. This subsequently leads to even more breathlessness and tiredness during everyday activities. Pulmonary rehabilitation (PR) programmes are programmes of exercise and education that aim to break this vicious cycle and improve physical function, symptoms and self-management in ILD. A standard exercise regime in pulmonary rehabilitation involves moderate-intensity continuous training (MICT) for an hour with an increase in intensity as patients become fitter. High-intensity interval training (HIIT) is a type of exercise training shown in research studies to be superior to other types in heart failure patients and cancer survivors. Recently, HIIT was also shown to be effective in severe ILD patients before lung transplantation. In this study, we want to test the use of HIIT in pulmonary rehabilitation programmes for ILD patients and assess its long-term benefits compared to a standard exercise programme.

### Who can participate?

Patients with any type and severity of ILD.

### What does the study involve?

Participants are randomly allocated to one of two groups: either the active group undertaking HIIT or the control group undertaking standard exercise. They will be assessed on three occasions (before and after the pulmonary rehabilitation programme and 6 months later). We will assess exercise capacity, breathlessness, respiratory and muscle function, quality of life and patients' views about the programme. The pulmonary rehabilitation programme will take place twice weekly for 8 weeks.

### What are the benefits and risks to participants?

All participants will receive a personalised programme of exercise during the pulmonary

rehabilitation session and a home-based programme designed according to their individual needs. We expect that all patients will experience improvement in exercise capacity and breathlessness regardless of the group they belong to. If the intervention (HIIT) is successful, the active group is likely to experience additional benefits. All patients will benefit from the educational sessions that are part of the pulmonary rehabilitation programme. Another benefit for patients is that they will be able to express their views about their programme and care and will be encouraged to set goals to improve their quality of life. Again, this benefit is independent of the group the patients will belong to. There are no major anticipated risks from the programme and all assessments are non-invasive. Both groups, active and control, will receive the standard treatment (pulmonary rehabilitation). Both types of training have been shown to be safe in other patient groups (such as patients with heart failure) and HIIT has also been shown to be safe in severe ILD patients. We will be monitoring all parameters during exercise and patients will be able to stop if they feel discomfort. As one of the aims of this study is to monitor how long it takes for patients to reach high intensity of training and how well it is tolerated, we anticipate that extreme discomfort or pain will not occur. Patients may feel breathless during the programme but will be advised to take a break if breathlessness becomes very severe. Cardiopulmonary exercise testing (CPET) always carries a small risk of adverse effects but these are rare in patients with respiratory disease as the limitation to exercise performance is usually related to breathlessness rather than cardiac function.

When does the study take place?

The study started in March 2014 and runs until December 2015.

Where does the study take place?

The study take place at the Clinical Research Facilities and pulmonary rehabilitation gym of St George's University and St George's Hospital NHS Trust, London, UK.

Who is funding the project?

National Institute for Health Research (NIHR) (UK).

Who is the main contact?

Dr Dimitra Nikoletou

d.nikoletou@sgul.kingston.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Dimitra Nikoletou

### Contact details

Cranmer Terrace

London

United Kingdom

SW17 0RE

-

d.nikoletou@sgul.kingston.ac.uk

# Additional identifiers

## Protocol serial number

16597

# Study information

## Scientific Title

Feasibility of high intensity interval training in pulmonary rehabilitation programmes for patients with interstitial lung disease and preliminary efficacy of its long-term benefits

## Acronym

HIIT in PR for ILD; a feasibility study

## Study objectives

Patients with interstitial lung disease (ILD) experience progressive breathlessness, fatigue and poor exercise capacity during their everyday life. As a result of these symptoms, patients tend to avoid strenuous activities and become less fit over time. This subsequently leads to even more breathlessness and fatigue during everyday activities.

Pulmonary rehabilitation (PR) programmes are programmes of exercise and education that aim to break this vicious cycle and improve physical function, symptoms and self-management in ILD. A standard exercise regime in pulmonary rehabilitation involves moderate-intensity continuous training for an hour with an increase in intensity as patients become fitter.

High-intensity interval training (HIIT) is a type of exercise training shown in research studies to be superior to other types in heart failure patients and cancer survivors. Recently, HIIT was also shown to be effective in severe ILD patients before lung transplantation.

In this study, we intend to assess the feasibility of using HIIT in pulmonary rehabilitation programmes for ILD patients and assess its long-term benefits compared to a standard exercise programme. We will study 60 patients with various types of ILD who are referred to pulmonary rehabilitation and examine the recruitment, adherence and retention to our HIIT programme in comparison with a standard programme. We will also assess the long-term benefits (6 months later) of the HIIT versus standard exercise training on exercise capacity, breathlessness and quality of life. This study will provide important information to design a larger, definitive study and will inform the design of more focused exercise regimes for patients with different types of ILD.

More details can be found here: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=16597>

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

14/LO/0149; First MREC approval date 14/02/2014

## Study design

Randomised; Interventional; Design type: Treatment

## Primary study design

Intentional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Topic: Respiratory disorders; Subtopic: Respiratory (all Subtopics); Disease: Respiratory

## Interventions

HIIT in PR Active group: Patients in this group will train in a pulmonary rehabilitation programme using high-intensity interval training

MICT in PR Control group: Patients in the control group will train using moderate-intensity continuous training during their pulmonary rehabilitation programme

## Intervention Type

Other

## Phase

Not Applicable

## Primary outcome(s)

Exercise capacity: 6MWT; Timepoint(s): Pre-PR, Post-PR and 6 months after PR

## Key secondary outcome(s)

1. Breathlessness; Timepoint(s): Pre-PR, Post-PR and 6 months post PR
2. Feasibility measures (recruitment/adherence/retention); Timepoint(s): Post-PR, 6 months later
3. Quality of Life questionnaires; Timepoint(s): Pre-PR, Post-PR and 6 months later
4. Respiratory and peripheral muscle function; Timepoint(s): Pre-PR, Post-PR and 6 months later
5. VO<sub>2</sub>max-CPET; Timepoint(s): Pre-PR, post-PR and 6 months later
6. In-depth interviews; Timepoint(s): Pre-PR, post-PR and 6 months later

## Completion date

30/09/2016

## Eligibility

### Key inclusion criteria

1. Patients with varying severity of ILD (all types apart from sarcoidosis will be included). The type and severity of participants will be recorded
2. Patients whose first language is not English (we will provide interpreters to explain educational presentations and other instructions as per usual clinical practice)

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### **Key exclusion criteria**

1. Patients with sarcoidosis
2. Patients with significant comorbidities (musculoskeletal, cardiac or neurological) that interfere with patients' ability to exercise

### **Date of first enrolment**

12/06/2014

### **Date of final enrolment**

31/01/2016

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**St George's University of London (UK)**

London

United Kingdom

SW17 0RE

## **Sponsor information**

### **Organisation**

St George's University of London (UK)

### **ROR**

<https://ror.org/040f08y74>

## **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?
<a href="#">Results article</a>		22/08/2023	25/08/2023	Yes	No
<a href="#">Abstract results</a>	abstract	16/05/2016		No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No