ISRCTN55846300 https://doi.org/10.1186/ISRCTN55846300

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

Submission date
05/06/2014

Recruitment status
No longer recruiting

Registration date
05/06/2014

Overall study status
Completed

Last Edited
25/08/2023

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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

Secondary outcome measures
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. VO2max-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

Overall study start date
02/05/2014

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

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
England

United Kingdom

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)

Sponsor details
Research Office
Cranmer Terrace
London
England
United Kingdom
SW17 0RE
-
nazzouzi@sgul.ac.uk

Sponsor type
University/education

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

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?
Abstract results	abstract	16/05/2016		No	No
HRA research summary			28/06/2023	No	No
Results article		22/08/2023	25/08/2023	Yes	No