ISRCTN13864650 https://doi.org/10.1186/ISRCTN13864650

Using oxygen to improve exercise performance in patients with cystic fibrosis

Submission date
22/06/2019

Recruitment status
No longer recruiting

Registration date
16/07/2019

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Previous studies have shown that aerobic exercise training provides many benefits for patients with cystic fibrosis (CF). For example, it is known to improve survival and quality of life. However, it is still not known what type of exercise training (such as aerobic or strength), and what frequency, time spent, and intensity of training will increases these benefits.
High-intensity interval training (HIIT) is an excellent form of training because it does not require a great deal of time to do it. Also, because the exercise is done at a high intensity for a short time, it does not put a lot of strain on the respiratory system (compared to other types of exercise). This is particularly important for cystic fibrosis patients because they have problems with their respiratory system.
We wanted to find out if the addition of oxygen during the training sessions would improve the length of the high-intensity session, and therefore improve the benefit of the exercise training.

Who can participate?
Patients with cystic fibrosis aged 18 years or older

What does the study involve?
Participants perform HIIT on a cycle ergometer two days per week for eight weeks. Each exercise session is about 60 minutes in duration. During the exercise, some participants will be supplemented with oxygen however, the participants will not be told this. Over the study period, the training sessions will become longer as fitness improves.

What are the possible benefits and risks of participating?
Benefits: Each patient receives a written report outlining the principle findings of the study and a brief summary of the results of his/her own tests.
Risks: Exercise testing carries a very small risk of abnormal heart rhythms, heart attack, or death in less than one in 30,000 patients. The exercise tests are carried out by experienced exercise scientists and are supervised by a medical doctor. The participant may experience some muscle soreness in his/her legs or nausea following the maximal exercise test.

Where is the study run from?
Beaumont Hospital, Dublin, Ireland

When is the study starting and how long is it expected to run for?
May 2009 to June 2010

Who is funding the study?
Cystic Fibrosis Hopesource Foundation in Ireland

Who is the main contact?
Dr Ronen Reuveny
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
001/2008

Study information

Scientific Title
High-intensity interval training (HIIT) accelerates oxygen uptake kinetics and improves exercise tolerance for individuals with cystic fibrosis – a pilot study

Acronym
SOETBCF

Study objectives
1. High-intensity interval training HIIT would reduce the VO2 mean response time (MRT) during CWR exercise
2. HIIT would increase the time to limit of tolerance during CWR exercise
3. Supplementation with O2 during HIIT would allow for more high-intensity work to be performed thereby resulting in amplification of the aforementioned training effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/03/2008 Ethics (Medical Research) Committee - Beaumont Hospital Dublin (Gillian Vale,
RCSI Beaumont Ethics, Royal College of Surgeons in Ireland Beaumont Hospital, Beaumont, Dublin 9 Ireland; 01-8092680; gvale@rcsi.ie), ref: 07/83

Study design
Interventional single center randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Cystic fibrosis

Interventions
This pilot study employed a randomised, single-blind design. Participants were randomly assigned to a group performing HIIT with O2 supplementation (O2+) or a group performing HIIT while breathing ambient air (AMB). Participants blinded to the treatment performed HIIT on a cycle ergometer two days per week for eight weeks. Each exercise session was about 60 minutes in duration.

Patients with CF were randomly assigned to a group performing high-intensity interval training with oxygen supplementation or to a group performing high-intensity interval training while breathing ambient air. Each patient chose a piece of paper from an envelope, which indicated which group they were assigned to.

Participants visited the exercise lab on three separate days before (baseline) and after the training program (12 weeks). Each visit was at least 72 hours apart. During these visits, participants performed the pre- and post-training evaluations which consisted of: Anthropometric measurements, Pulmonary function tests, Maximal exercise capacity test, VO2 kinetics.

Maximal exercise capacity test: Participants performed an incremental symptom-limited peak exercise test on an electronically-braked cycle ergometer while breathing through a full face mask. The incremental protocol was designed to ensure that participants reached limit of tolerance within 8–12 minutes. Gas-exchange data was collected during the test and measurements of O2 consumption, CO2 production, heart rate, ventilation and respiratory rate were obtained.
During the second visit, participants performed a constant work cycling test at 30% the peak work rate achieved on the incremental maximal test. Gas-exchange data were collected during the test and measurements of VO2 kinetics, CO2 production, heart rate, ventilation and respiratory rate were obtained.
During the third visit, participants performed a constant work cycling test at 70% the peak work rate achieved on the incremental maximal test. Gas-exchange data was collected during the test

and measurements of VO2 kinetics, CO2 production, heart rate, ventilation and respiratory rate were obtained.

Intervention Type
Supplement

Primary outcome(s)
Maximal exercise capacity measured using an incremental symptom-limited peak exercise test on an electronically-braked cycle ergometer while breathing through a full face mask measured at baseline and 12-weeks.

Key secondary outcome(s)
1. Anthropometric measurements: height and body mass were measured and double thickness subcutaneous adipose tissue was determined on the right side of the body using skinfold calipers, at the first visit.
2. Pulmonary function tests: spirometry and single-breath carbon monoxide diffusion capacity were measured at the first visit.

Completion date
04/07/2010

Eligibility

Key inclusion criteria
1. Diagnosis of CF that was based on clinical features, sweat test, or genotyping, and a pulmonary function test
2. Age > 18 years
3. Forced expiratory in one second (FEV1) > 30% predicted
4. Clinically stable

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
9

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
15/05/2009

Date of final enrolment
04/06/2010

Locations

Countries of recruitment
Ireland

Study participating centre
Beaumont Hospital
P.O. Box 1297
Beaumont Road
Dublin
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D9

Sponsor information

Organisation
School of Health and Human Performance, Dublin City University

ROR
https://ror.org/04a1a1e81

Funder(s)

Funder type
Charity

Funder Name
Cystic Fibrosis Hopesource Foundation in Ireland

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/04/2020	23/10/2020	Yes	No