

Using oxygen to improve exercise performance in patients with cystic fibrosis

Submission date 22/06/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 16/07/2019	Overall study status Completed	
Last Edited 23/10/2020	Condition category Nutritional, Metabolic, Endocrine	

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 increase 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

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 measure

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.

Secondary outcome measures

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.

Overall study start date

09/11/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

11

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

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D9

Sponsor information

Organisation

School of Health and Human Performance, Dublin City University

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Sponsor type

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ROR

<https://ror.org/04a1a1e81>

Funder(s)

Funder type

Charity

Funder Name

Cystic Fibrosis Hopesource Foundation in Ireland

Results and Publications

Publication and dissemination plan

We are going to submit it in a special review "Application of high-intensity training methods in clinical populations - concepts, progress, and challenges" in Sports Science, Medicine and Rehabilitation journal in BMC open access.

Intention to publish date

10/07/2019

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