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The evaluation of a 12-week partially supervised, self-regulated exercise intervention in patients with cystic fibrosis

Submission date
06/02/2020

Recruitment status
No longer recruiting

Registration date
24/02/2020

Overall study status
Completed

Last Edited
24/02/2020

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cystic fibrosis (CF) is a genetically inherited disease that primarily affects the lungs and digestive system.

Ireland has the highest incidence of CF in the world with 1 in every 19 Irish people carrying one copy of the defective gene that causes CF. Treatments that help people with cystic fibrosis improve health, ease symptoms, and increase life expectancy include daily medications, physiotherapy, respiratory training, and nutrition. Symptoms of the disease can make it difficult for people with CF to engage in regular physical activity. However, regular physical activity can reduce medical problems and have a significant impact on improving a patient's quality of life and life expectancy. The benefits of physical activity in patients with CF include increased exercise tolerance, respiratory muscle endurance and sputum expectoration (ejecting phlegm or mucus from the throat or lungs by coughing, hawking, or spitting), reduced rate of decline in lung function, improvements in fluid balance and retention of serum electrolytes, as well as lower risk of death.

Although physical activity is a well-established mode of therapy for people with CF, there is a large gap in our understanding of what constitutes the optimal exercise program for improving functional capacity and optimizing health-related quality of life and life expectancy. Ideally, exercise programs should be enjoyable, easily incorporated into day-to-day life, connect people with cystic fibrosis with friends and family, and improve quality of life.

The purpose of this study is to design, implement and evaluate the efficacy of a 12-week cystic fibrosis-specific, partially supervised and self-regulated exercise intervention on functional capacity and health-related quality of life. Following the intervention, the exercise group will be invited to participate in a feedback interview, to further evaluate the efficacy of the program.

Who can participate?
Adults with Cystic Fibrosis

What does the study involve?
Participants will be allocated randomly to either be in the exercise or no change groups.

Participants will make two visits, separated by 7 days, to the testing site before they start the exercise program for a series of physical and psychological assessments. Participants will wear an accelerometer for the 7 day period between these visits to assess physical activity and sedentary behaviour.

Participants in the exercise group will also receive an exercise manual (hardcopy) and access to an online exercise diary for a 12 week period. Over this period, the exercise group will receive a Fitbit device, to track daily steps and active minutes.

After the 12 weeks of either the exercise program or no change, participants will make another two visits, separated by 7 days, to the testing site where they will complete the same series of physical and psychological assessments. Participants will again wear an accelerometer for the 7 day period between these visits to assess physical activity and sedentary behaviour.

What are the possible benefits and risks of participating?
Benefits: Participants will receive a copy of their results in a report format, summarizing information such as body composition, pulmonary function score, muscular strength and cardiovascular fitness.
Risks: Exercise carries with it a very small risk of abnormal heart rhythms, heart attack, or death in less than one in 30,000 patients. In patients with established chronic illness the risk is higher. The yearly incidence of cardiac arrhythmias during exercise testing and physical conditioning in people with CF was 0-0.1% and matches that of the healthy population. An emergency room and automated external defibrillator (AED) are available onsite. The research team are appropriately qualified and experienced working with clinical populations in a safe and professional manner.

Where is the study run from?
Dublin City University (Ireland)

When is the study starting and how long is it expected to run for?
January 2020 to July 2020

Who is funding the study?
Cystic Fibrosis Ireland and The Mater Foundation (Ireland)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

An evaluation of the efficacy of a 12-week partially supervised, self-regulated exercise intervention on physiological and psychometric indices in patients with cystic fibrosis: a randomized-controlled trial

Acronym
CF-Ex

Study objectives
The partially supervised, self-regulated exercise programme will enhance functional capacity and quality of life in patients with cystic fibrosis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/01/2020, Dublin City University Research Ethics Committee (Research and innovation support, Dublin City University, Dublin 9, Ireland; +35317008000; research@dcu.ie), ref: DCUREC/2019/186

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
Participants will make two visits, separated by 7 days, to the testing site (DCU) at baseline and post-intervention for a series of physiological and psychometric assessments. Participants will wear an accelerometer for the 7 day period between visits to assess physical activity and sedentary behaviour at baseline and post-intervention.

Participants will be randomized (1:1) into intervention (exercise) or control (usual care) groups upon completion of visit 2 at baseline.

The exercise arm will receive a Fitbit device, to objectively track daily steps and active minutes, to wear for the 12-week intervention period. Participants in the exercise group will also receive an exercise manual (hardcopy) and access to an online exercise diary.

The control arm will continue with usual care.

Intervention Type
Behavioural

Primary outcome measure
Cardiorespiratory fitness measured using cardiopulmonary exercise test with monitoring of ventilatory gases, heart rate (ECG), blood pressure and oxygen saturation at baseline and 12 weeks

Secondary outcome measures
1. Anthropometry measured using a stadiometer, electronic scales, bioelectrical impedance and waist-to-hip ratio conducted using tape-measurements at baseline and 12 weeks
2. Muscle strength measured using sit-to-stand and biodex isokinetic dynamometry for lower extremity strength and hand-grip dynamometry for upper body strength at baseline and 12 weeks
3. Pulmonary function assessed using spirometry (EasyOne Air device) at baseline and 12 weeks
4. Physical activity assessed using accelerometry (ActivPAL) at baseline and 12 weeks
5. Quality of life evaluated using a CF-specific questionnaire (CFQ-R) at baseline and 12 weeks

Overall study start date
09/09/2019

Completion date
09/07/2020

Eligibility

Key inclusion criteria
1. Established diagnosis of cystic fibrosis (positive sweat chloride or genetic identification test)
2. Residing in the Republic of Ireland
3. ≥ 18 years of age
4. Lung function scores of ≥ 50% predicted
5. Must not have undergone lung transplantation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 participants

Key exclusion criteria
1. Undergone lung transplantation
2. Culturing MRSA, NTM or Burkholderia Cepacia

Date of first enrolment
07/01/2020

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
Ireland

Study participating centre
Dublin City University
Glasnevin
Dublin
Ireland
9

Sponsor information

Organisation
Dublin City University

Sponsor details
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Sponsor type
University/education

Website
https://www.dcu.ie/

ROR

https://ror.org/04a1a1e81

Funder(s)

Funder type
Charity

Funder Name
Cystic Fibrosis Ireland

Funder Name
The Mater Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
09/07/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other