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High-intensity functional interval training in heart failure

Submission date
17/02/2021

Recruitment status
No longer recruiting

Registration date
04/03/2021

Overall study status
Completed

Last Edited
08/03/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Heart failure occurs when the heart muscle is unable to pump blood around the body as well as it should. The ejection fraction of the left ventricle of the heart is a measurement of how much blood is pumped out of the left ventricle in each heartbeat, expressed as a percentage of the total amount of blood in the left ventricle of the heart. This research project aims to test a new approach to cardiovascular rehabilitation for people with heart failure with an ejection fraction between 20% and 40%. The study aims to find how effective and safe an 11-week high-intensity functional interval training program (HIFIT) would be for heart failure patients. The study will also investigate whether patients who participate in the training program experience improvements to their independence and quality of life.

Who can participate?
Heart failure (New York Heart Association class I to III) patients aged between 18 and 75 years old, who have not experienced any major cardiovascular events, hospitalization, or treatment in the last 3 months.

What does the study involve?
Patients will be assessed for heart failure and reduced ejection fraction, and if eligible to be recruited to participate in the program, will be asked to sign a consent form. All patients will be followed by the CIUSSS-MCQ cardiology team and will receive the best treatment related to their condition.

Participants will be allocated to one of two groups, with a chance of being in either group (like tossing a coin). Participants and researchers will not have a choice in the treatment given. 18 patients will be allocated to the first group, to participate in supervised high-intensity functional interval training exercise sessions 3 times a week for 11 weeks. The supervised exercise sessions will take place at the University Kinesiology Clinic at the Université du Québec à Trois-Rivières (UQTR). 12 patients will be allocated to the second group and will continue their usual treatment without the training program, which includes advice on healthy lifestyle habits.

Participants will complete assessments of their heart and lung function before and after the 11 weeks of either training or usual care.

What are the possible benefits and risks of participating?
Participation in this research project will allow participants to obtain the benefits associated with the regular practice of physical activity on improving health as well as advice from a kinesiologist on healthy lifestyle habits. Participants may also change their negative perceptions of high-intensity interval exercise and its safety. Furthermore, participants will be able to benefit from an assessment of their state of health and physical condition. Additionally, it is hoped that this study will contribute to the advancement of knowledge for scientists in this area of research.

The pre-participation assessment makes it possible to limit the potential risks, however, participation in a high-intensity physical activity program is associated with certain risks. In the situation where an adverse reaction occurs during participation in the study, where possible these will be treated. Mild to moderate complications associated with stress testing and training include chest pain and/or pressure, more shortness of breath than usual, dizziness or lightheadedness, abnormal heart rhythms, abnormal blood pressure, nausea, excessive sweating, and the risk of neurological and musculoskeletal disorders. Severe complications requiring hospitalization associated with stress tests and training are very rare but may include heart attack (may occur in approximately 0.05% of the population during stress tests) or stroke (may occur in approximately 0.003% of the population).

Blood tests at the start and at the end of the study can be inconvenient. Often discomfort may be felt when taking blood and in some cases, bruising may appear at the site where the blood test was taken and it will go away after a few days. In very rare cases, some people may experience temporary discomfort causing hot flush, weakness, and dizziness.

The dangers associated with the study are minimal and all precautions will be taken to minimize these risks. The participant is asked to inform the supervisor responsible for the training session as quickly as possible of any discomfort or pain felt during exercise or after.

Where is the study run from?
The heart failure clinic of the Centre intégré universitaire de santé et de services sociaux de la Maurie-et-du-Centre-du-Québec (CIUSSS-MCQ) (Canada) and the Trois-Rivières cardiology office (Canada)

When is the study starting and how long is it expected to run for?
From January 2018 to January 2023

Who is funding the study?
Novartis (Switzerland)

Who is the main contact?
Philippe Desilets-Beaudoin, philippe.desilets-beaudoin@uqtr.ca

Contact information

Type(s)
Scientific

Contact name
Mr Philippe Desilets-Beaudoin

Contact details

2069 rue Jean-Pierre-Blais
Trois-Rivières
Canada
G9B 2P7
+1 8196906169
philippe.desilets-beaudoin@uqtr.ca

Type(s)
Scientific

Contact name
Dr François Trudeau

ORCID ID
https://orcid.org/0000-0003-4341-2550

Contact details
Université du Québec à Trois-Rivières
3351 boulevard des Forges
Trois-Rivières
Canada
G9A5H7
+1 819 376-5011
francois.trudeau@uqtr.ca

Additional identifiers

Study information

Scientific Title
High-intensity functional interval training in heart failure with reduced ejection fraction of less than 40%

Acronym
HF-HIFIT

Study objectives
High-intensity functional interval training is safe and effective in patients with heart failure with a reduced ejection fraction while improving independence and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/05/2018, Centre intégré universitaire de santé et de services sociaux de la Mauricie-et-du-Centre-du-Québec research ethics committee (1991, boulevard du Carmel, Trois-Rivières, G8Z 3R9, Canada; +1 819-372-3133 poste 32303; ciusssmcq_bureau_integre_de_lethique@ssss.gouv.qc.ca), ref: CER-18-248-07.01

Study design

Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Secondary prevention of heart failure with a reduced ejection fraction

Interventions
Participants were recruited to the pilot study for HF-HIFIT from June 2018. This preliminary data was analysed and will be included in the results of the main trial. Recruitment to the main trial was delayed due to COVID-19 and will restart on 15/03/2021.

Participation will be required for a total period of three to four months. At baseline, participants will need to perform cardiovascular assessments before starting to participate in physical activity as part of the protocol. Participants will be randomly allocated (3:2) and will be invited to participate in either:
1. The experimental group, an 11-week high-intensity functional interval training program, with 3 sessions each week (33 sessions total)
2. The control group, to attend only once in 11 weeks in order to receive information on healthy lifestyles, with no participation in the training program

Cardiovascular health assessments will be repeated a second time after 11 weeks. The first part of the assessments will take place in the cardiology department of the CIUSSS MCQ. Different cardiovascular measurements at rest and during exercise will be collected such as heart rate, blood pressure, left ventricular (LV) stroke volume, LV cardiac output, and LV ejection fraction using the Vivid E95 device (General Electric, USA). The second part of the evaluations will take place in the respiratory therapy department of the CIUSSS MCQ. The peak power output of the lower limbs and cardiorespiratory capacity (VO2pic) will be obtained during an exercise test with a Vmax® Vyntus CPX stationary bike (Vyaire Medical, United States). A third meeting will take place at the University Kinesiology Clinic of the UQTR where weight and height will be measured in order to obtain the body mass index. Also, patients will have to perform a submaximal test, the 6-minute walk test.

Randomisation method:
A biostatistics professor was contacted to create a randomization table with 40 participants using the Excel program, this table was sent to the principal investigator. Each number from 1 to 40 corresponds to a participant. The software randomly assigned the number 1 or 2 to each of the 40 digits. These figures correspond to each of the groups, i.e. 1 for the experimental group and 2 for the control group. Therefore, when a member of the research team meets a participant and signs the information and consent form, a number is assigned, for example the fifth person to sign will have the number 5. Then, the research team member contacts the principal investigator who will be able to confirm to which group the participant will be assigned.

Intervention Type
Behavioural

Primary outcome(s)

1. Effectiveness is measured with cardiovascular tests including echography and cardiopulmonary tests such as maximal oxygen uptake (VO2max) at baseline and 3 months

Key secondary outcome(s))
1. Quality of life measured using the World Health Organization Quality of Life (WHOQOL) questionnaire at baseline and 3 months
2. Functional capacity measured using the 6-min walk test and the Timed Up and Go test at baseline and 3 months

Completion date
30/01/2023

Eligibility

Key inclusion criteria
1. Aged between 18 and 75 years
2. Stable heart failure with an ejection fraction between 20% and 40%
3. New York Heart Association (NYHA) functional class of heart failure between I and III, with optimal treatment at the maximum tolerated dose (including defibrillator or resynchronization therapy)
4. No major cardiovascular event, hospitalization, or cardiovascular intervention in the last 3 months prior to randomization without additional need for short-term (6 months) revascularization

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Inability to exercise
2. Atrial fibrillation with a ventricular response at rest >110 beats per min at rest
3. Appropriate shock of the defibrillator in the past 3 months
4. Patient dependent on the pacemaker
5. Uncontrolled diabetes
6. Insulin pump
7. Uncontrolled arterial hypertension, systolic blood pressure >160 mmHg

8. On hemodialysis
9. Left ventricular enlargement or septal enlargement (>18 mm) or any obstruction of the left ventricle
10. Right ventricular pressure >60 mmHg
11. Severe valve disease based on ultrasound diagnosis
12. Addiction to an illegal drug
13. Inability to read and understand the consent form
14. Any situation where the principal investigator perceives that the patient will not adhere to the protocol

Date of first enrolment
01/06/2018

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
Canada

Study participating centre
Centre intégré universitaire de santé et de services sociaux de la Mauricie-et-du-Centre-du-Québec
1991, boulevard du Carmel
Trois-Rivières
Canada
G8Z 3R9

Sponsor information

Organisation
Université du Québec à Trois-Rivières

ROR
https://ror.org/02xrw9r68

Funder(s)

Funder type
Industry

Funder Name
Novartis

Alternative Name(s)
Novartis AG, Novartis International AG

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

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

IPD sharing plan summary
Other