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High-intensity interval exercise after stroke

Submission date 07/10/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 15/10/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/10/2020	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
High-intensity interval training (HIIT) has emerged as a potentially effective method for increasing cardiorespiratory fitness (CRF) among clinical populations, but its effectiveness remains to be demonstrated among stroke patients. The aim of the study is to compare the effect of a 6-month HIIT program with a moderate-intensity continuous training (MICT) program and a control group in terms of CRF, cardiovascular risk factors, cognitive function, anxiety and depression markers with a 12-month follow-up in patients with prior ischemic stroke or transient ischemic attack (TIA).

Who can participate?
Patients aged 40 and over who had an ischemic stroke or TIA at least 3 months ago

What does the study involve?
Participants are randomly allocated to one of the three groups: HIIT, MICT or control. The HIIT intervention involves an exercise program consisting of three weekly aerobic sessions including a combination of HIIT performed under clinical supervision at the university kinesiology clinic and MICT sessions performed at home. HIIT is done on an ergocycle (exercise bike). Exercise time progresses from 20 to 40 minutes over the intervention and is adjusted according to the participant's tolerance and the progress of the protocol. Participants are asked to perform their MICT sessions at home. MICT includes 30 minutes of aerobic exercise at a moderate intensity determined by the participants' perceived exertion. The MICT intervention consists of an exercise program involving three weekly aerobic sessions including a combination of one MICT session performed under clinical supervision at a university kinesiology clinic and two MICT sessions performed at home. Supervised exercise is done on an ergocycle. Exercise time progresses from 20 to 40 minutes over the intervention and is adjusted according to the participant's tolerance. The two other MICTs are done at home and include 30 minutes of aerobic exercise at a moderate intensity determined by participants' perceived exertion. The control group do not receive any physical activity counselling or interaction with study personnel between evaluations. Cardiorespiratory fitness tests are performed at the start, after the 6-month intervention, and after 12 months. The acceptability of the two exercise programs is evaluated at 12 months.

What are the possible benefits and risks of participating?
Participants in the HIIT or MICT group may benefit from an improvement of physical and health

condition caused by the regular physical activity practice. Risks of participation are minimal, but they include dizziness, faintness, abnormal blood pressure, nausea, muscle cramps, or musculoskeletal injury. The risks of complications requiring hospitalization, acute myocardial infarction, or sudden death during or immediately after a stress test are ≤ 0.2%, 0.04%, and 0.01%, respectively. The serious event rate is generally considered to be 1/10,000. These hazards are minimal and every precaution will be taken to minimize these risks.

Where is the study run from?
University du Québec à Trois-Rivières (Canada)

When is the study starting and how long is it expected to run for?
January 2018 to July 2019

Who is funding the study?
Université du Québec à Trois-Rivières (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
High-intensity interval training after stroke: a randomized controlled trial

Acronym
ACCTI-AVC

Study objectives
It is hypothesized that the High-Intensity Interval Training (HIIT) program would be more effective than continuous exercise training for increasing cardiorespiratory fitness and secondary outcome measures due to higher cardiovascular stimulation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 24/09/2018, Université du Québec à Trois-Rivières Comité d'éthique de la recherche avec des êtres humains (CEREH) (Comité éthique de la recherche (secrétariat), 3351 boul des Forges, CP 500, Université du Québec à Trois-Rivières, Trois-Rivières (Québec), Canada; +1 (0)819 376 5011, poste 2129; CEREH@uqtr.ca), ref: CER-17-241-10.04
2. Approved 31/05/2018, CIUSSS-MCQ University Hospital (Bureau intégré de l'éthique, Direction de la qualité, évaluation, performance et éthique, Centre intégré universitaire de santé et de services sociaux de la Mauricie-et-du-Centre-du-Québec (CIUSSS MCQ), 2700 boul. des Forges, bureau 302, Trois-Rivières (Québec), G8Z 1V2, Canada; +1 (0)819 478-6464, poste 26478; 04ethiqueciussssmcq@ssss.gouv.qc.ca), ref: CÉR-2017-002

Study design
Single-center 1-year follow-up randomized control trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Ischemic stroke or transient ischemic attack

Interventions
A 6-month exercise program with either continuous exercise or a combination of high-intensity training combined with continuous exercise training.

The 1-year follow-up randomized control trial is performed with participants randomly allocated to one of the three groups: HIIT (a combined program that includes HIIT and MICT), MICT (a standard exercise prescription) or control (no exercise prescription). The allocation ratio is 1:1:1, and randomization is performed by a web-based randomization system following the baseline evaluation. Age, sex and diagnosis (stroke or TIA) are controlled in the randomization.

The HIIT intervention involves an exercise program consisting of three weekly aerobic sessions including a combination of HIIT performed under clinical supervision at the university kinesiology clinic and MICT sessions performed at home. The choice of a combination program was to create a realistic exercise program that can be used in a clinical setting so that patients would not always be dependant on clinical supervision. Therefore, the program is designed to enable participants' autonomy by reducing supervision over time. HIIT is done on an ergocycle and includes several bouts at 95% of peak power output (PPO) interspersed with a 60-sec recovery. Time at 95% of PPO progresses from 30-sec to 60-sec. Exercise time progresses from 20 to 40 minutes over the intervention and is adjusted according to the participant's tolerance and the progress of the protocol. Participants are asked to perform their MICT sessions at home. MICT includes 30 minutes of aerobic exercise at a moderate intensity determined by participants' perceived exertion.

The MICT intervention consists of an exercise program involving three weekly aerobic sessions including a combination of one MICT session performed under clinical supervision at a university kinesiology clinic and two MICT sessions performed at home. Supervised exercise is done on an ergocycle at 50% of PPO. Exercise time progresses from 20 to 40 minutes over the intervention and is adjusted according to the participant's tolerance. The two other MICTs are done at home and include 30 minutes of aerobic exercise at a moderate intensity determined by participants' perceived exertion.

The control group do not receive any physical activity counselling or interaction with study personnel between evaluations.

Intervention Type
Behavioural

Primary outcome(s)
Cardiorespiratory fitness measured with peak oxygen uptake (VO2 peak) at the university hospital. The GTX protocol was performed on a semi-recumbent ergocycle with 12-lead ECG monitoring (MAC 5500HD, GE Healthcare, USA). The cadence was maintained at 60 rpm; power started between 0 watts and 60 watts depending on the participant's capacity and increased

progressively by 10 watts per minute. These tests were performed at baseline (T0) after the 6-month intervention (T6), and after 12 months (T12) at the university or hospital.

Key secondary outcome(s))
Measured at baseline (T0) after the 6-month intervention (T6), and after 12 months (T12):
1. Resting systolic and diastolic blood pressure measured twice on each arm with the participant in a sitting position. The result was the average of the two measures taken with an automated sphygmomanometer (HEM-907XL, Omron IntelliSense, USA) in accordance with the recommendations of the Canadian Education Hypertension Program. The resting heart rate was simultaneously recorded and the average was reported.
2. Low-density lipoprotein (LDL), high-density lipoprotein (HDL), triglycerides, total cholesterol and HbA1c analyzed with standardized procedures at the Centre Hospitalier Universitaire régional de Trois-Rivières, Québec, Canada
3. Waist circumference measured in a standing and relaxed position using a flexible measuring tape
4. Body weight and height measured with a stadiometer (402LB, Health-o-meter, USA) and used to calculate body mass index (BMI)
5. Body fat mass calculated with bioelectrical impedance (BC-418, TANITA, USA)
6. Self-reported physical activity recorded with the Godin Leisure-Time Exercise Questionnaire (GLTEQ)
7. Functionality and frailty assessed with the Short Physical Performance Battery (SPPB)
8. Psychological distress assessed with the Hospital Anxiety and Depression Scale (HAD)
9. Cognitive function assessed with the Montreal Cognitive Assessment (MoCA)
10. Acceptability of the intervention assessed with a French version of the Treatment Acceptability and Preferences Questionnaire (TAPQ) at the 12-month evaluation by an independent evaluator

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Ischemic stroke or TIA with a minimum of 3 months post event and no maximum
2. Age 40 years and over
3. Ambulatory capacity over 10 min with or without assistive devices as needed
4. Not currently participating in formal rehabilitation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment

Key exclusion criteria
1. TIA with either isolated sensory symptoms, visual changes or vertigo
2. Presence of brain hemorrhage, vascular malformations, tumor, abscess or other major non-ischemic cerebral disease
3. Cognitive impairment limiting task comprehension
4. Any musculoskeletal troubles that prevent physical activity practice
5. Lower extremity claudication
6. All absolute contraindications to exercise testing according to the American College of Sports Medicine

Date of first enrolment
10/01/2018

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
Canada

Study participating centre
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Sponsor information

Organisation
Université du Québec à Trois-Rivières

ROR
https://ror.org/02xrw9r68

Funder(s)

Funder type
University/education

Funder Name
Université du Québec à Trois-Rivières

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		18/05/2016	16/10/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes