

High-intensity interval exercise after stroke

Submission date 07/10/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/10/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English Summary

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 $\leq 0.2\%$, 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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

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

Acronym

ACCTI-AVC

Study hypothesis

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

See additional files

Condition

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 measure

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.

Secondary outcome measures

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

Overall study start date

10/01/2017

Overall study end date

31/07/2019

Eligibility

Participant 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

Age group

Adult

Sex

Both

Target number of participants

The minimal size targeted was 45 participants (15 in each group)

Total final enrolment

52

Participant 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

Recruitment start date

10/01/2018

Recruitment end date

31/07/2018

Locations**Countries of recruitment**

Canada

Study participating centre

Université du Québec à Trois-Rivières

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Sponsor type

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Funder(s)**Funder type**

University/education

Funder Name

Université du Québec à Trois-Rivières

Results and Publications**Publication and dissemination plan**

1. One paper in preparation in a peer-reviewed journal
2. One presentation at a scientific conference

Intention to publish date

31/01/2021

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

[Participant information sheet](#)

Details

Date created

18/05/2016

Date added

16/10/2020

Peer reviewed?

No

Patient-facing?

Yes