FeelFit: high-intensity interval training to improve self-reported physical fitness in brain tumor patients: a randomized controlled trial

Published: 12-10-2023
Last updated: 02-12-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON56527

Source
ToetsingOnline

Brief title
FeelFit

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, primary brain tumor

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Stichting Cancer Center Amsterdam

Intervention

Keyword: High-intensity interval training, Primary brain tumor, Self-reported physical fitness

Outcome measures

Primary outcome

The primary outcome measure is self-reported physical fitness, measured by the first question of the International Fitness Scale (IFIS), "Your general physical fitness is?" On a scale of 1 ("very poor") to 5 ("very good").

Secondary outcome

The secondary outcome measure is maximum oxygen uptake (objective physical fitness; VO2max), measured with a cardiopulmonary exercise test (CPET). In addition, a set of exploratory outcomes will be measured to examine the effects of the intervention. The measurements include a muscle strength measurement, MRI (optional), MEG (optional), neuropsychological assessment and various questionnaires. And last, focus groups will be planned to learn from patients perspectives of participating in high-intensity interval training.

Last, we ask patients in the intervention and waiting-list control group to keep an exercise diary in the first three weeks and last two weeks of the intervention period, and the last two weeks of the follow-up period.

Study description

Background summary

Patients with a brain tumor may experience decreased physical fitness during stable disease. This can affect daily functioning and quality of life. Exercise programs are an effective and structured way to increase the amount of physical activity and improve physical fitness. "High-intensity interval training" (HIIT) is a promising form of exercise that shows positive effects in other oncology patient groups.

Study objective

The primary objective is to investigate the efficacy of HIIT on self-reported physical fitness in primary brain tumor patients during stable disease. The secondary objective is to investigate the efficacy of HIIT on the maximal oxygen uptake (VO2max; objectively measured physical fitness) in primary brain tumor patients. In addition, we aim to explore additional effcts and potential working mechanisms of HIIT in primary brain tumor patients, and we aim to describe patient's perspectives of participating in high-intensity interval training.

Study design

It is a monocenter randomized controlled trial with an intervention group and a control group. The intervention group performs the exercise program, and the control group is placed on a waiting list and can still perform the exercise program after study participation.

First, patients are screened. Then the first study measurement takes place (T0) and patients are randomized into the intervention or control group. After about a week after the 12-week intervention (T1) and after 6 weeks of follow-up (T2), the other study measurements take place. After this 18-week study period, focus groups will be scheduled with the participants from the intervention group. The participants from the control group can then possibly start the training program.

Intervention

The intervention consists of performing a training program called high-intensity interval training which lasts for 12 weeks with two training sessions per week. The training sessions will be performed under supervision at the Amsterdam UMC, location VUmc. All participants (intervention and control group) also receive advice/information about the recommended amount of weekly physical activity, and are asked to keep a diary about their amount of physical

actvity during 7 weeks of the study period.

Study burden and risks

Performing the high-intensity interval training program is a safe intervention.

Patients will be screened before study participation to check for contraindications to (maximal) exercise, and to check the other inclusion and exclusion criteria. This will be done partly by a rehabilitation physician, with a cardiologist taking and assessing a resting ECG.

Patients will be randomized into an intervention group or (waiting list) control group. The intervention group performs the training program which lasts 12 weeks with two training sessions per week. Each training session will take 20-30 minutes.

Measurements will take place before the intervention, after about a week after the 12-week intervention and after 6 weeks follow-up. The measurement before and after about a week post-intervention will take about 5.5 hours each (of which approximately 1.5 hours is optional for MRI/MEG). Of these, the measurements at VUmc will take about 4 hours (of which approximately 1.5 hours is optional for MRI/MEG) and the questionnaires that can be completed from home will take 1.5 hours. The follow-up measurement will consist only of questionnaires and will take about 1.5 hours.

The measurements that will take place at VUmc are: neuropsychological assessment, MRI scan (optional), MEG (optional) and a cardiopulmonary exercise test with a muscle strength measurement.

In addition, participants from the intervention group and the control group will be asked to keep an exercise diary for 7 weeks. Keeping the diary will take a few minutes a day.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- minimum age of 18 years;
- reduced self-reported physical fitness, defined as a score of "average", "poor" or "very poor" on the first question of the International Fitness Scale (IFIS): "My general physical fitness is?";
- diagnosed with a primary brain tumor;
- stable disease, i.e. no signs of radiological or clinical tumor progression;
- no oncological treatment for at least two months prior to inclusion;
- able to speak, read and write in Dutch.

Exclusion criteria

- Karnofsky Performance Score < 70; - already participated in a HIIT program < 1 month prior; - contraindication of exercise based on the guidelines by American College of Sports Medicine (ACSM); - complaints of cardiovascular, pulmonary, and/or metabolic abnormalities or cardiovascular, pulmonary, and/or metabolic abnormalities that are not well controlled with medication, following the Lausanne protocol, in accordance with the protocol on Kwaliteitsnet *Bewegingslab ISL: beslisboom inspanningstest spiro-ergometrie-REV, serie 1* at the department of Rehabilitation Medicine in Amsterdam UMC, location VUmc.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2024
Enrollment:	36
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	12-10-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84223.018.23