A pilot randomized controlled trial on the feasibility and efficacy of an exercise intervention to improve cognitive functioning in patients with glioma

Published: 27-06-2013
Last updated: 24-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40500

Source
ToetsingOnline

Brief title
Effects of exercise on cognitive function in glioma patients

Condition

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

Synonym
glioma; brain tumour

Health condition

cognitieve stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: cognitive functioning, exercise, glioma, quality of life

Outcome measures

Primary outcome

Primary outcome measures will include indicators of feasibility (accrual, adherence, compliance and attrition) and (size of the effect on) performance scores on neuropsychological testing (attention, memory and executive function).

Secondary outcome

Secondary outcome measures will include performance measures of physical fitness as measured with CPET (cardiorespiratory exercise testing on a cycle ergometer with ECG and gas exchange measurement), and self-report questionnaires of subjective cognitive functioning, fatigue, sleep, mood and quality of life.

Study description

Background summary

Many patients with glioma, the most common type of primary brain tumors, suffer from cognitive deficits. Recent findings indicate that physical exercise may be effective in delaying or ameliorating cognitive decline, in particular in older adults and select neurological patient populations. Exercise interventions in

patients with cancer already demonstrated to have beneficial effects on physical fitness, fatigue, psychological well-being, and quality of life. Therefore, positive, broad effects of exercise on cognitive functioning, physical fitness, fatigue, mood and quality of life in patients with primary brain tumors are expected. Since there are no previous studies on exercise in this patient group, this study will examine the feasibility of such a physical exercise intervention for the improvement of cognitive functioning.

Study objective

The objective of this pilot randomized controlled trial (RCT) is to assess the feasibility and to determine the effect size of a physical activity/exercise program in improving objective cognitive functioning and reducing self-reported cognitive symptoms and fatigue, and improving sleep, mood and quality life of patients with low-grade glioma, and a subgroup of patients with anaplastic glioma.

Study design

The study is designed as a *randomized*, single-blind controlled trial. Of the 170 patients that will be screened telephonically, with neuropsychological testing and with CPET, 60 patients will be randomized with minimization. Forty patients who will assigned to the intervention group will undergo the 6-month home-based exercise intervention. Twenty patients in the active control group will be advised to walk regularly based on brochures from 30minutenbewegen.nl. All primary and secondary outcomes will be assessed at baseline (T0; prior to randomization), and at completion of the 6-month exercise intervention (T1), and at a similar time-point for patients in the active control group. These will include indicators of feasibility (accrual, adherence, compliance and attrition), subjective and objective physical fitness measures, neuropsychological performance scores, and self-reported cognitive symptoms and mental wellbeing.

Intervention

Patients in the intervention group will undergo a 6-month home-based exercise intervention. An individual exercise prescription will be based on the patients* level of aerobic fitness (VO2peak) as measured with cardiopulmonary testing (CPET) at baseline. Patients will exercise (e.g., running, biking, swimming) three times per week for 6 months. Session duration will vary between 20 minutes and 45 minutes. Exercise duration will be progressed during the first 6 weeks, and exercise intensity will be progressed from week 6-12, while maintaining exercise duration. Over the course of the six months of the program, intensity will be progressed in a non-linear way from 55% to 80-85% of the heart rate corresponding to VO2peak at the CPET. During the exercise activities, patients will wear a combination of a training watch with heart

rate monitor and GPS which will register heart rate, route, speed and distance.
In addition, the participant will regularly receive phone calls by the physical therapist.

Patients in the active control group will be advised to walk regularly based on brochures they will receive, downloaded from 30minutenbewegen.nl, and will regularly receive phone calls from the research team.

Study burden and risks

Participants of both groups undergo a telephonic screening, and 2 neuropsychological assessments at the patients* home, each consisting of a maximum of 10 tests, with a maximum duration of 2 hours per assessment. A total of 14 questionnaires can be filled in afterwards (1.5 hour). These assessments will require some mental effort from patients. In addition, patients will undergo 2 CPETs in a Sports Medical Center in the proximity of their home, which will require physical effort for approximately 10 minutes. Based on the CPET outcome, the intervention group will undergo an individually tailored (and therefore most safe), home-based, intensive exercise program (total duration of 49 hours in 6 months; plus some additional time for phone contact with physical therapist), whereas the control group will be advised to walk regularly as prescribed by the Dutch public guidelines for healthy physical activity.

Broad benefits for patients in the intervention group are expected on physical fitness, cognitive function, fatigue, sleep, mood and quality of life, and will outweigh the small risks of exercise (of which the most severe can be safely detected prior to intervention start by CPET). The additional risks that patients face from the intervention are risks on sports injuries, and falls. Risk of injury is minimized by a thorough physical examination at the screening phase by a physician in the Sports Medical Center, by the build-up of the exercise program (e.g., by keeping the intensity level low during the first weeks), and by the (distant) monitoring by the physical therapist.

Patients from the control group who complete all study assessments will receive a Polar training watch with heart rate monitor, and an individualized exercise prescription based on the CPET-outcome, if they wish to. These patients will not receive any further supervision by the research team.

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

Adult patients with supratentorial glioma, in particular:
(1a) histologically proven low-grade glioma (LGG; astrocytoma, oligodendroglioma, oligo-astrocytoma), or presumed (i.e., suspected) LGG based on both clinical and MR imaging features (>18 years of age < 70); or
(1b) anaplastic glioma (anaplastic astrocytoma, anaplastic oligodendroglioma, anaplastic oligo-astrocytoma) under age 50 and with good performance status (KPS > 70),
who:
(2) have been clinically stable for a minimum of 6 months prior to study entry (as determined by recent CT or MR imaging); and
(3) have had no anti-tumor treatment during that period of time (i.e., surgery, radiotherapy, chemotherapy, corticosteroids); and
(4) are interested in undergoing a physical exercise program; and
(5) have a relative VO2peak (% predicted based on variables such as age and gender) that leaves room for further improvement of cardiorespiratory fitness.

Exclusion criteria

Potentially eligible patients will be screened for the presence of comorbid conditions that would contraindicate participation in a physical activity/exercise program. This includes patients with serious orthopedic conditions or motor deficits, and patients with serious cardiovascular, cardiopulmonary and neurological conditions (or risks) who would not be able to train at the intensity level required by the programs. Patients judged to have psychiatric (including alcohol and drug abuse) or severe cognitive problems that would preclude them from program participation will be excluded from the study. For assessment purposes, study participants will need to have basic fluency in the Dutch language.
In addition, patients who report to engage in vigorous exercise (>=7 METs (Metabolic equivalents of task)) for more than 20 minutes on at least 3 days per week on a regular basis will be excluded from participation, as there will be no room for further improvement of aerobic fitness.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2013
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO Date:	27-06-2013
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-10-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-04-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	21-05-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	28-05-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	10-06-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	17-09-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)

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	NL44024.008.13