PAM study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21029

Source
NTR

Brief title
PAM study

Health condition

Breast cancer, cognitive problems, borstkanker, cognitieve problemen

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU)
Source(s) of monetary or material Support: KWF

Intervention

Outcome measures

Primary outcome

Primary outcome parameters are: cognitive functioning (the total recall score of the HVLT-R as our primary outcome measure) and self-reported cognitive complaints (MDASI-MM module, 2 symptom severity questions on memory and attention and 6 symptom interference items).

Secondary outcome

Secondary parameters include overall cognitive functioning measured by standard

neuropsychological tests, brain structure and function (3 Tesla brain MRI), anthropometrics, physical fitness, QOL, fatigue, anxiety and depressive symptoms, and work performance.

Study description

Background summary

Rationale: Increased survival of breast cancer patients has put more emphasis on studying long-term consequences of treatment and quality of life (QOL). A recently established long-term consequence of breast cancer treatment is cognitive decline. Up to 60% of breast cancer patients treated with chemotherapy may be confronted with cognitive problems as assessed with neuropsychological tests, which can persist up to 10 years after treatment. Cognitive problems reduce QOL, daily functioning and work performance. Therefore, interventions to preserve or enhance cognition are urgently needed. A promising non-pharmacological option for cognitive problems in breast cancer patients is physical exercise. In older persons and patients with neurological disease evidence accumulates of positive effects of exercise on cognition. Therefore, we will investigate the effects of exercise in breast cancer patients with cognitive problems. Further, since imaging studies have documented brain changes associated with chemotherapy, we will also assess the effects of exercise on brain structure and function. These imaging data may provide insights into the neurobiological mechanisms underlying cognitive recovery in these patients. Furthermore, we are specifically interested in the effects of exercise on brain structure and function in these patients.

Study design: Randomised controlled trial, with a waiting list control group

Study population: Breast cancer patients adjuvantly treated with chemotherapy (with or without endocrine therapy), 2-4 years after diagnosis, aged 30-75 years, no indication of relapse or metastases and self-reported cognitive problems confirmed by neuropsychological tests.

Intervention: A 6-month exercise program consisting of aerobic and strength exercise supervised by a physiotherapist (2 hrs/w) and Nordic or Power walking (2 hrs/w). Controls will be asked to retain their usual physical activity level.

Main study parameters/endpoints:

Primary outcome parameters are: cognitive functioning (the total recall score of the HVLT-R as our primary outcome measure) and self-reported cognitive complaints (MDASI-MM module, 2 symptom severity questions on memory and attention and 6 symptom interference items).

Secondary parameters include overall cognitive functioning measured by standard neuropsychological tests, brain structure and function (3 Tesla brain MRI), anthropometrics, physical fitness, QOL, fatigue, anxiety and depressive symptoms, and work performance.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Burden:

- Study participation takes time, especially for patients in the intervention group.

Patients will visit the UMC Utrecht for measurements at baseline and after the intervention period. Each visit will take 3 hours.
Patients in the intervention group are invited to participate in a 6 month exercise program of 4 hours weekly (2 hours at a physiotherapy centre and 2 hours Nordic or Power walking). Burden of travelling to the training facilities will be reduced by offering the exercise program at physiotherapist centers nearby the patients' home.

- Injuries due to exercise can occur, to minimize the risk the intensity of the exercise program will be gradually increased during the study and supervised by a physiotherapist.

- One of the measurements at the UMC Utrecht is a brain MRI. The scan time of the MRI takes 45325 min.

- Every patient will be asked to wear an accelerometer for 2two times one weeks.

- During the blood draws, a haematoma can occur after blood sampling.

- Incidental findings can arise in the different measurements (e.g. maximal exercise testing; brain MRI), which will be reported to participants.

Benefit:

- We expect that the exercise program will have a beneficial effect on the patients' health status.

Study objective

We hypothesize that exercise training positively affects cognitive functioning measured by standard neuropsychological tests, especially learning and memory. Furthermore, we hypothesize that exercise training will result in the following changes on brain MRI:

- increased brain volume, including the hippocampus (the hippocampus is especially involved in memory and learning)

- increased connectivity of white matter (especially connections with the hippocampus)

- increased brain perfusion

Study design

Basline, 6 months

Intervention

A 6-month exercise program consisting of aerobic and strength exercise supervised by a physiotherapist (2 hrs/w) and Nordic or Power Walking (2 hrs/w). Controls will be asked to retain their usual physical activity level.

Contacts

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Eligibility criteria

Inclusion criteria

cancer patients adjuvantly treated with chemotherapy with or without endocrine therapy, 2-4 years after cancer diagnosis, 30-75 years of age, no indication of relapse or metastases, exercise ¡Ü 150 min/week,
self-reported cognitive problems, lower than expected performance on neuropsychological testing, mastering the Dutch language and willing to be randomly assigned to one of the two study arms.

Exclusion criteria

We will exclude patients with known neurological conditions and/or diseases that affect cognition (e.g. dementia, MS, TBI), disorders that might impede exercise participation, contra indications for MR imaging, treated for breast cancer in both breasts; and patients switching from Tamoxifen to aromatase inhibitors during the study period or four months before

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2016
Enrollment:	180
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-10-2016
Application type:	First submission

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
NTR-new	NL5924
NTR-old	NTR6104
Other	METC 16/450 : CCMO NL57754.041.16

Study results

Summary results
N/A