Improving cognition in cancer patients

No registrations found.

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

Summary

ID

NL-OMON22663

Source
NTR

Brief title
TBA

Health condition

Non CNS cancers

Sponsors and support

Primary sponsor: Amsterdam UMC, Vrije Universiteit medical center
Source(s) of monetary or material Support: Private Funding

Intervention

Outcome measures

Primary outcome

Subjective cognitive functioning

Secondary outcome

Objective cognitive functioning,

Study description

Background summary

Rationale:
In cancer survivors, cognitive dysfunction is one of the most problematic long-term sequelae of treatment. Although cognitive side effects are most prevalent during treatment, in some cases they continue to exist long after treatment cessation. Cognitive problems not only often lead to difficulties in keeping up with social- and work demands, but they are also associated with decrements in health-related quality of life. These difficulties show the need for interventions targeted at improving cognition in cancer patients. The present study will investigate the effect of a self-motivated online lifestyle intervention, Mijn Fitte Brein (MFB) on cognition in cancer patients. Previous research has shown that MFB increased cognitive functioning in employed healthy adults. When MFB is effective in improving cognition in cancer patients returning to work, it could be used by more survivors who encounter cognitive difficulties after cancer treatment.
Objective: The objective of the study is to investigate whether the use of MFB will improve cognitive functioning in cancer patients who are returning to work, when compared to patients who receive care as usual.
Study design: randomised controlled intervention study.
Study population: adult (18+) cancer patients who are returning to work after treatment for cancer.
Intervention (if applicable): The experimental group will use MFB for six months. The control group will receive care as usual.
Main study parameters/endpoints: The main study parameter is the change in cognitive functioning between baseline and 6 months.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients in the intervention condition will use MFB for six months, both groups fill in questionnaires and undergo neuropsychological testing at baseline and after 3 (feasibility study) or 6 (main study) months. The study might confront patients with their cognitive problems and physical health, however the patient burden is expected to be minimal. To our knowledge, there are no risks associated with participation and patients' cognition and physical health could benefit from using MFB.

Study objective

It is expected that the use of the MFB intervention will improve subjective cognitive functioning.

Study design

baseline, 3 months, 6 months

Intervention

Mijn Fitte Brein online lifestyle intervention

Contacts

Public
Amsterdam UMC, VUmc
Josephine Drijver

0204444219
Scientific
Amsterdam UMC, VUmc
Josephine Drijver

0204444219

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Be employed
• Primary treatment has been completed
• Presence of cognitive complaints
• >= 18 years of age
• Written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Primary or secondary brain tumours
• Insufficient mastery of the Dutch language
• History of brain injury with loss of consciousness
• History of brain surgery
• Currently under active treatment for psychiatric disorders
• Neurodegenerative disorders
• Self-reported substance abuse
• Severe visual impairments

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-02-2020
Enrollment:	220
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	24-02-2020
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	NL8407
Other	METC VUmc : 2018.491

Study results