Improving cognition in cancer patients

Gepubliceerd: 24-02-2020 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22663

Bron
NTR

Verkorte titel
TBA

Aandoening

Non CNS cancers

Ondersteuning

Primaire sponsor: Amsterdam UMC, Vrije Universiteit medical center
Overige ondersteuning: Private Funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Subjective cognitive functioning

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

baseline, 3 months, 6 months

Onderzoeksproduct en/of interventie

Mijn Fitte Brein online lifestyle intervention

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-02-2020
Aantal proefpersonen:	220
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	24-02-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8407
Ander register	METC VUmc : 2018.491

Resultaten