A computer-based training to prevent depression and anxiety in oncology patients

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It is hypothesised that the active CBM training condition will results in a stronger affective symptom reduction compared to the sham and no-training conditions.

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

Samenvatting

ID

NL-OMON29198

Bron
NTR

Verkorte titel
OncoCogTrain

Aandoening

Cancer

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: n.a.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Anxiety and depressive symptoms measured with the Hospital Anxiety and Depression Scale

(HADS; Zigmond & Snaith, 1983)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Patients undergoing treatment for cancer are at risk of experiencing a high symptom burden that often leads to distress and affective symptoms. While cognitive behavioral therapy has in principle been proven to be effective in reducing affective symptoms in cancer patients, this option is not easily available and sometimes too time-demanding for the patients that are focusing on their somatic therapy. Computer-based cognitive trainings have been proven to be effective in affective disorders and there are promising results also in breast cancer patients.
Objective: The purpose of our study is to test the effect of a computer-based cognitive behavioral intervention (called Cognitive Bias Modification, CBM) on affective symptoms in oncology patients.
Study design: Prospective, randomized, single centre study with an intervention and a control treatment arm. Both treatments are provided besides treatment as usual (TAU) and do not intervene with TAU. Furthermore, to examine changes in affective symptoms due to TAU versus TAU combined with the proposed CBM treatment a third nonintervention arm will be included.
Study population: We plan to enroll 120 patients in this study in whom standardized distress measures done by the oncology department of the VieCurie hospital in Venlo indicate increased vulnerability for affective symptoms.
Intervention: Patients will first be randomly assigned to either intervention or nonintervention group. Within the intervention group, half of the patients will, randomly assigned, receive treatment as usual (TAU) and perform a weekly session of the active CBM training for 4 weeks. The other half of the patients will receive a control CBM training concurrent to TAU. The brief (app. 20 minute) CBM sessions of cognitive training will be done on a computer. The sessions are planned so that they do not interfere with medical treatment patients might receive. The nonintervention group will receive no CBM training but changes in depressive and anxiety symptoms will be assessed to document natural changes of affective symptoms due to TAU.
Main study parameters/endpoints: The primary objective of our study is to measure changes in depressive and anxiety symptoms from pre to post CBM training. Our secondary aim is to explore patient’s psychological- and cognitive processes, and course of oncology treatment as factors of our intervention.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The routine clinical practice at the day of the intervention will be extended by a cognitive training that comes with neglectable risks. There is also no increased risk associated to administering a short battery of questionnaires or the intervention itself. These assessments are unobtrusive.

Doel van het onderzoek

It is hypothesised that the active CBM training condition will results in a stronger affective symptom reduction compared to the sham and no-training conditions.

Onderzoeksopzet

Baseline, post 4 sessions of CBM training, 1-week follow-up

Onderzoeksproduct en/of interventie

Cognitive Bias Modification

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Receiving current cancer treatment
- Patients with a score of 8 or higher in the HADS will be considered for participation in the study (HADS; Zigmond & Snaith, 1983). This cut-off shows good sensitivity and specificity in a somatic patient population (Bjelland et al., 2002)
- Signed informed consent form
- Minimum age of patients is 18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Impossibility to obtain a valid informed consent
- Insufficient comprehension of the Dutch language
- IQ estimate < 80 points
- Acuteness of symptoms (somatic or psychiatric) that prevent patient from attentively doing the task 20 min per day

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2019
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-06-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46229
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7831
CCMO	NL68493.091.18
OMON	NL-OMON46229

Resultaten