Cognitive Bias Modification: Exploring the effects of a computer-based cognitive bias training in oncology patients at risk for depression and anxiety symptoms -(OncoCogTrain)

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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. Here we are collaborating with the Oncology department of the...

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

Summary

ID

NL-OMON46229

Source
ToetsingOnline

Brief title
Cognitive Bias Modification in oncology patients

Condition

- Other condition

Synonym
cancer, chemotherapy

Health condition

niet-specifieke kanker

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Euregio Rijn-Waal INTERREG VA Zorg verbindt WP14

Intervention

Keyword: anxiety, depression, distress, oncology

Outcome measures

Primary outcome

The primary objective of our study is to measure changes in depressive and

anxiety symptoms from pre to post CBM training.

Secondary outcome

Our secondary aim is to explore patient*s psychological- and cognitive

processes, and course of oncology treatment as factors of our intervention.

Study description

Background summary

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. We need a less burdensome and less verbal treatment option for these patients.Computer-based cognitive trainings have been proven to be effective in affective disorders and there are promising results also in breast cancer patients.

Study 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. Here we are collaborating with the Oncology department of the VieCuri Hospital (Venlo).

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.

Intervention

Randomly assigned, half of the patients will 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.

Study burden and risks

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.

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

- 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

Exclusion criteria

- Impossibility to obtain a valid informed consent
- Insufficient comprehension of the Dutch language
- IQ estimate < 80 points

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2020
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	22-05-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-09-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-01-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-07-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29198
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68493.091.18
OMON	NL-OMON29198