Mindfulness-Based Cognitive Therapy (MBCT) and Cognitive Behavioral Therapy (CBT) for Depression in Patients after Cancer: a randomized controlled trial

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Primary Objective- To assess short and long-term effects of individual Cognitive Behavioral Therapy (CBT) and individual Mindfulness-Based Cognitive Therapy (MBCT) in reducing depressive symptoms in cancer patients with clinically significant...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON44159

Source
ToetsingOnline

Brief title
MBCT and CBT for depression in patients after cancer

Condition

- Mood disorders and disturbances NEC

Synonym
depressed mood, depression

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: Cancer, Cognitive behavioral therapy, Depression, Mindfulness

Outcome measures

Primary outcome

Depressive symptom severity.

Secondary outcome

Anxiety, fear of recurrence, fatigue.

Study description

Background summary

Depression is highly prevalent in cancer patients. MBCT and CBT are evidence-based psychological treatments for reducing depressive symptoms in the general population, but its efficacy for patients with cancer needs more evidence. This longitudinal study aims to investigate the effectiveness of MBCT and CBT in reducing depressive symptoms, in cancer patients between one and five years after completing curative cancer treatment and had no evidence of disease recurrence at inclusion. Also patients* satisfaction with treatment will be investigated. Furthermore, potential moderators and mediators of intervention effects as well as cost-effectiveness will be examined.

Study objective

Primary Objective
- To assess short and long-term effects of individual Cognitive Behavioral Therapy (CBT) and individual Mindfulness-Based Cognitive Therapy (MBCT) in reducing depressive symptoms in cancer patients with clinically significant depressive symptoms, compared to a treatment as usual (TAU) control condition. We hypothesize that CBT and MBCT are more effective than the TAU condition in reducing depressive symptoms in cancer patients.

Secondary Objectives
- To examine predictors of treatment effects of CBT and MBCT: (1) baseline levels of depressive symptoms, (2) baseline levels of secondary outcomes, (3) history of depression.

- To examine mediators of treatment effects of CBT and MBCT: (1) behavioral activation, (2) repetitive negative thinking, (3) mindfulness, (4) expectations of improvement.
- To examine patients* acceptability of CBT and MBCT.
- To examine the cost-effectiveness of CBT and MBCT.

Study design

In a randomized controlled trial, patient will be assigned to one of three conditions: MBCT, CBT, or TAU control condition. We plan to include 64 patients per condition (total 192 patients).

Intervention

The intervention consists of 8 weekly individual sessions of MBCT or CBT, with each session lasting 60 minutes. For both interventions, a structured protocol is available.

Study burden and risks

The burden for patients consists of completing a written questionnaire at five points in time, with time costs per assessment of around 30 minutes and a structured clinical interview at threetime points, lasting about 15 minutes each. Furthermore, 2/3 of patients receive treatment in which techniques are used that have proven to be effective in the treatment of depression and prevention of recurrence of depression (time costs: 8 weekly sessions of 60 minutes each, approximately 30 minutes of daily homework). We know of no negative effects of these treatments. Therefore, we consider the risks of this study to be low, as patients are primarily asked to invest time and effort.

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

Completion of curative cancer treatment (for primary diagnosis of cancer or possible recurrence of cancer) at least one year ago and no longer than five years ago.
Currently no active cancer.
Age >= 18 and <= 75 years at the time of diagnosis of cancer.
Depressive symptoms as assessed by PHQ-9 score >= 10 (indicating presence of at least mild depressive symptoms).
Being able to read, write, and speak Dutch.

Exclusion criteria

Severe psychiatric co-morbidity (i.e. acute suicidal ideations or behavior, recently experienced psychosis, diagnosis of schizophrenia, bipolar disorder, drug abuse or substance dependence, serious cognitive or neurological problems).
Receiving psychological treatment for depressive symptoms, currently or less than two months prior to study participation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2015
Enrollment:	192
Type:	Actual

Ethics review

Approved WMO Date:	08-09-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-10-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-12-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL49111.042.14