(Cost) effectiveness of Mindfulness-Based Cognitive Therapy (MBCT) in cancer patients: a superiority trial of online versus face-to-face treatment versus treatment as usual (TAU).

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

Summary

ID

NL-OMON40225

Source
ToetsingOnline

Brief title
(Online) Mindfulness-Based Cognitive Therapy in cancer patients

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
Fear and depression, psychological wellbeing

Health condition

depressieve stemmingstoornissen en -afwijkingen

Research involving
Human

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Pink Ribbon

Intervention

Keyword: Anxiety and depression, Cancer, E-health, Mindfulness

Outcome measures

Primary outcome

Anxiety and depression as assessed by the Hospital Anxiety and Depression-scale (HADS). The HADS is a self-report questionnaire that comprises 14 items measuring feelings of generalized fear and depressive symptoms. The HADS is considered a reliable and valid instrument for assessing anxiety and depression in medical patients and is sensitive to change (Herrmann, 1997; Bjelland et al., 2002). This instrument was also validated in a palliative cancer population (Akechi, 2006).

Secondary outcome

Fear of cancer recurrence (FRCI), mental health (MHC-SF), cost-effectiveness (as assessed by health-related quality of life (EQ-5D + SF-12) and health care consumption (TIC-P)), mindfulness skills (FFMQ-SF), rumination (RRQ), patient-health care professional working alliance (WAI-S), group cohesion (GCQ-22), trainer competence and perceived trainer competence (MBI-TAC), personality (NEO-FFI), qualitative semi-structured interviews.

Weekly measurements will be done by the MAAS and the PANAS.

Study description

Background summary

During the past 20 years the survival rate of cancer has increased due to advancements in the diagnosis and treatment of cancer. Therefore, cancer is increasingly approached as a chronic illness. After diagnosis the 5 year survival rate is about 70% (Mitchell, Ferugson, Gill, Paul & Symonds, 2013). In the coming years the incidence and surival rates will increase even further. As a consequence, more people will receive a cancer diagnosis and more people will have to deal with the consequences of cancer. The Dutch Cancer Foundation, by means of illustration, expects an increase of the absolute 10-year prevalence of cancer from 420.000 people in 2009 to 660.000 in 2020 (Signaleringscommissie KWF Kankerbestrijding, 2011).

A significant share of the cancer patients suffers from psychological complaints. Recent figures show that the mean prevalence of depression in cancer patients is estimated between 8 and 24% depending on the diagnostic instrument used.

This process of ilness has different stages, the diagnostic phase, treatment phase, post treatment phase and revalidation afterwards. Sometimes it means living in fear of cancer recurrence. About 15% of the breast cancer patients has psychological complaints during the diagnostic phase, and 15 % of them develop psychological symptoms after treatment (Henselmans et.al., 2010)

Since the absolute prevalence of cancer is rising, the request for psychological help for cancer patients will rise too in the upcoming years. Therefore, we are in need of effective and broadly available psychological services.

Study objective

The current study aims at investigating whether individual mindfulness-based cogntiive therapy (MBCT) online and MBCT offered face-to-face in groups are superior to a waiting list-control group in terms of improvement of depression and anxiety, fatigue, psychological health, quality of life, mindfulness skills and cost-effectiveness. We will also examine the predictors and mediators of treatment effect in both individual MBCT online and MBCT group training. With regard to prediction of treatment effect, we will investigate socio-demographic variables such as age and education level. With regard to mediation, we will look at mindfulness skills, working alliance between client and professional and group cohesion.

Study design

A three-armed (group/online/TAU) randomized, waiting-list-controlled study

Intervention

The face-to-face group MBCT training will consists of 8 weekly sessions of 2,5 hours each and a silent day of 6 hours of meditation practice. Participants will be asked to practice at home for 45 minutes, 6 days a week. They will receive CD sets with exercises to support this. The individual online MBCT programme will have the same content as the face-to-face MBCT.

In the individual online condition, clients will practise exercises at home guided by audio files and written instructions that are included in a reader. For example, clients will start the intervention by studying the reader*s chapter for that first week and by downloading an MP3 file with the body scan exercise, which they are asked to practice every day for 45 minutes. They register their experiences in their homework logs during the week. The therapist will react to the homework logs with a written reply, sent to the patient on a predetermined day of the week. Patients continue with the next week by downloading a new chapter of the reader and new mindfulness exercises for that week, and so on for all nine weeks. Clients can only continue with the next session after they have recorded their homework experiences of the previous week. Clients complete the programme in 9-12 weeks.

Study burden and risks

This study involves capacitated adults and therapeutic research. Participation is free of charge. There are no indications that there are risks related to the intervention. Participating in this study can be time consuming, as participants will be interviewed on several occasions, they will fill out several questionnaires at different time points. These questionnaires contain questions that might be confronting for the participant, as they confront the participant with her current situation. However, we do not expect this to be harmful.

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

Included are all patients:;-with a diagnosis of cancer (any stage)
-who are suffering from psychological distress (total HADS score >=11),
-who, if using psychopharmacological medication, have been on a stable dose for at least three months
-who have access to internet and are computer literate
-who are capable of filling out questionnaires in Dutch.
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Exclusion criteria

Excluded are all patients with;- Previous experience with mindfulness
- severe psychiatric comorbidity such as psychoses and suicidal ideation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2015
Enrollment:	245
Type:	Actual

Ethics review

Approved WMO Date:	21-02-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-06-2014
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

No registrations found.

In other registers

Register	ID
CCMO	NL46338.091.13