

# (Cost)Effectiveness of blended and unguided delivery of Mindfulness-based Cognitive Therapy versus Care as Usual for cancer patients: BUDDY project.

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Primary Objective: • Are blended MBCT and unguided online MBCT more effective than TAU in reducing psychological distress (primary outcome), and other psychological complaints and physical symptoms, and in increasing quality of life?Secondary...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON49163

### Source

ToetsingOnline

### Brief title

Blended and unguided online MBCT for cancer patients (BUDDY)

### Condition

- Other condition

### Synonym

cancer, neoplasma malignum

### Health condition

kanker

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum

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

## Intervention

**Keyword:** Blended, Cancer, Mindfulness, Online

## Outcome measures

### Primary outcome

Severity of psychological distress

### Secondary outcome

Parameters during all assessments:

- Rumination
- Fatigue severity
- Fear of cancer recurrence
- Positive mental health
- Mindfulness skills
- Decentering
- Self-compassion
- Measures of adherence (home meditation practice, engagement)
- Cost-effectiveness (Information on direct healthcare-use, Paid work-related

productivity and Health related quality of life)

Parameters during Baseline assessment:

- Age

- Gender
- Ethnicity
- Level of education
- Marital status
- Employment status
- Cancer type
- Cancer stage
- Time since diagnosis
- Types and dose of medication being used
- Previous psychological treatment

## Study description

### Background summary

Rationale: Around one in three cancer patients and survivors experience significant psychological distress. Previous research showed that mindfulness-based interventions such as mindfulness-based cognitive therapy (MBCT) can help cancer patients to relieve their distress. However, MBCT takes place in face-to-face group sessions, which are not easily accessible to all cancer patients. Blended (combination of face-to-face and online sessions) and online MBCT interventions may address this problem, however, research on effectiveness of these interventions is missing.

Hypotheses: We expect both blended and unguided MBCT to be effective in improving psychological distress and secondary (positive) outcomes compared to TAU, both at our primary endpoint, the three month follow-up, and during the nine month follow-up. Moreover, we expect both interventions to be cost-effective compared to TAU and unguided MBCT to compare favorably to blended MBCT in terms of cost-effectiveness. Analyses regarding potential treatment moderators are exploratory. Finally, we expect that both mindfulness and self-compassion can be identified as working mechanisms.

### Study objective

### Primary Objective:

- Are blended MBCT and unguided online MBCT more effective than TAU in reducing psychological distress (primary outcome), and other psychological complaints and physical symptoms, and in increasing quality of life?

### Secondary Objective(s):

- Are blended MBCT and unguided online MBCT cost-effective in comparison to TAU in terms of societal costs and QALYs at three month follow-up?
- Do the treatment effects of blended MBCT and unguided online MBCT consolidate over the course of an uncontrolled nine month follow-up?
- Are treatment effects moderated by differences in demographics, cancer or personality variables or patient expectations?
- Are mindfulness and self-compassion (assessed mid-treatment) working mechanisms of blended MBCT and unguided online MBCT?

## Study design

### Main study

We will conduct a randomized controlled trial (RCT) with three arms: blended MBCT, unguided online MBCT and TAU (see Figure 1 for a flowchart). After baseline assessment, patients will be randomized to one of these three groups. In case patients are randomized to TAU, they will also hear whether they will receive blended MBCT or unguided online MBCT after the TAU period.

Before the start of the RCT, an explorative mixed-methods pilot study will be conducted. Twenty-four cancer patients will be randomized to either blended MBCT or unguided online MBCT. They will complete questionnaires before and after participation. In addition, semi-structured interviews will be conducted. With information and data from this study, both interventions will be improved for the main RCT.

## Intervention

### Blended or standalone online Mindfulness-Based Cognitive Therapy (MBCT):

MBCT is originally a manualised group skills-training program, designed as a relapse prevention program for patients with recurrent depression. The training consists of eight weekly sessions of 2.5 hours, plus one six-hour day of silent practice. The sessions include meditation exercises (formal: bodyscan, sitting meditation, gentle movement exercises; and informal: e.g. three minute breathing space, daily activities with attention), psycho-education, and group discussion. Psycho-education included information on cognitive techniques, like monitoring and scheduling of events and identification of negative automatic thoughts. In addition to the sessions, participants are instructed to do daily home practice 45 minutes a day. Home practice consists of meditations and registration exercises. We have adapted the regular MBCT program to fit the

needs of the target group. For instance, we have included psycho-education about grief and cancer-related fatigue. Based on the results of phase 1 of this study, other minor adaptations to the intervention for the specific target group will be made if necessary.

In our study, the intervention will be delivered in a blended format, or standalone online format. The blended format consists of three group sessions (representing session 1, 5 and 8). The other sessions are delivered online and are individual. In the standalone online format, all sessions are online and individual. Each online session was built around a specific theme, for instance automatic pilot, communication or self-care. Participants are provided with information, audio files of meditations, and recording assignments around the theme of the session through a personal, secure webpage. Participants are encouraged to read the information and do the assigned meditations and recording assignments within one week. The sessions will look appealing and persuasive technologies such as reminders and video\*s will be used.

The group sessions in the blended format will be taught by experienced mindfulness trainers that are health care professionals and have experience in psycho-oncology. All mindfulness trainers fulfill the advanced criteria of the UK Network for Mindfulness-Based teachers and of the Association of Mindfulness Based Teachers in the Netherlands and Flanders. In the blended format, mindfulness trainers will provided weekly feedback on the registrations of the participants, on a set day of the week. In the standalone online format, no mindfulness trainer will be involved.

Patients can participate in both interventions alone, or together with a significant other (e.g. partner, close friend or relative).

## **Study burden and risks**

This study involves adapted versions of a therapeutic intervention that is effective for cancer patients and survivors (9). Participation is free of charge. We believe that the risks of participation are negligible. However, we will be watchful of potential adverse reactions to blended or unguided online MBCT, participants can contact the researchers during the intervention period when necessary. Participants are encouraged to respect their boundaries (both physical and psychological) and are always free to suspend or adapt the practice as needed. The burden associated with participation in MBCT is relatively high: consisting of 8 weekly group sessions of 2,5 hours and one silent day (6 hours), and home practice of about 45 minutes a day. Participation includes 4 (blended MBCT and unguided online MBCT) or 6 (TAU followed by blended MBCT or unguided online MBCT) online self-report questionnaire assessments of 1 hour. During the intervention period, short weekly assessments are also included. Although the effort requested from patients is quite high, we expect that practicing mindfulness will be associated with enduring changes in patients' coping strategies in daily life, and as a result, can increase participants' autonomy and self-efficacy.

Furthermore, we reduced burden on participants with online delivery of all assessments, reducing travel efforts.

## 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

- A cancer diagnosis, any tumor or stage
- Computer literacy and internet access
- Good command of the Dutch language
- Willingness to participate in either MBCT intervention

## Exclusion criteria

- Previous participation in MBSR or MBCT (>4 sessions)
- Severe psychiatric comorbidity that warrants acute treatment (psychosis, mania, personality disorders, suicidal thoughts)
- Alcohol or drug dependence
- Severe cognitive impairments

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	28-10-2022
Enrollment:	254
Type:	Actual

## Ethics review

Approved WMO	
Date:	15-09-2020
Application type:	First submission
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	NL73117.091.20