Face-to-Face and Internet-Based Mindfulness-Based Cognitive Therapy Compared With Treatment as Usual in Reducing Psychological Distress in Patients With Cancer: A Multicenter Randomized Controlled Trial

Félix Compen, Else Bisseling, Melanie Schellekens, Rogier Donders, Linda Carlson, Marije van der Lee, and Anne Speckens

ABSTRACT

Purpose
Mindfulness-based cognitive therapy (MBCT) has been shown to alleviate psychological distress in patients with cancer. However, patients experience barriers to participating in face-to-face MBCT. Individual Internet-based MBCT (eMBCT) could be an alternative. The study aim was to compare MBCT and eMBCT with treatment as usual (TAU) for psychological distress in patients with cancer.

Patients and Methods
We obtained ethical and safety approval to include 245 patients with cancer with psychological distress (≥11 on the Hospital Anxiety and Depression Scale) in the study. They were randomly allocated to MBCT (n = 77), eMBCT (n = 90), or TAU (n = 78). Patients completed baseline (T0) and postintervention (T1) assessments. The primary outcome was psychological distress on the Hospital Anxiety and Depression Scale. Secondary outcomes were psychiatric diagnosis, fear of cancer recurrence, rumination, health-related quality of life, mindfulness skills, and positive mental health. Continuous outcomes were analyzed using linear mixed modeling on the intention-to-treat sample. Because both interventions were compared with TAU, the type I error rate was set at \( P \leq 0.025 \).

Results
Compared with TAU, patients reported significantly less psychological distress after both MBCT (Cohen’s \( d \), 0.45; \( P < 0.001 \)) and eMBCT (Cohen’s \( d \), 0.71; \( P < 0.001 \)). In addition, post-treatment prevalence of psychiatric diagnosis was lower with both MBCT (33% improvement; \( P = 0.030 \)) and eMBCT (29% improvement; \( P = 0.076 \)) in comparison with TAU (16%), but these changes were not statistically significant. Both interventions reduced fear of cancer recurrence and rumination, and increased mental health–related quality of life, mindfulness skills, and positive mental health compared with TAU (all \( P \geq 0.025 \)). Physical health–related quality of life did not improve (\( P = 0.343 \)).

Conclusion
Compared with TAU, MBCT and eMBCT were similarly effective in reducing psychological distress in a sample of distressed heterogeneous patients with cancer.

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INTRODUCTION

From 2025 onward, 20 million people worldwide will be diagnosed with cancer each year.\(^1\) Approximately one third of patients with cancer suffer from significant psychological distress,\(^2\) resulting in reduced quality of life, decreased compliance with medical care, and prolonged duration of hospital stay.\(^3,4\) The prevalence of psychiatric disorders in oncologic settings is 30% to 40%.\(^5\) Effective and accessible interventions are needed to reduce psychological distress and psychiatric disorders in patients with cancer.

Mindfulness-based interventions (MBIs)\(^6,6\) such as mindfulness-based cognitive therapy (MBCT), teach participants to be more mindful in daily life through meditation exercises, yoga, group discussions, and didactic teaching.\(^6\) A 2012 meta-analysis of randomized controlled trials (RCTs) of MBIs in 955 patients with cancer found significant improvements in depressive and anxiety symptoms.\(^7\) Since then, a number of RCTs have confirmed this.\(^8-13\)
However, because MBIs typically require in-person attendance at classes over several weeks, many patients with cancer experience barriers to participation. These may include impairments due to illness and anticancer treatments, adverse effects that result in advice to avoid groups of people, or limited transportation options. Consequently, uptake of face-to-face interventions for patients with cancer has been lower than, for instance, telephone-based interventions.

In contrast, Internet-based interventions are easily accessible and save traveling time. Therapist-guided Internet interventions have been shown to be effective for psychiatric and somatic conditions. Although evidence for Internet-based MBIs (eMBIs) in cancer is scarce, one controlled study of 62 patients found that synchronous videoconferencing sessions led to significant improvements in mood, stress symptoms, and mindfulness skills. In addition, an uncontrolled cohort of 257 fatigued patients showed significant improvements in fatigue and psychological distress after individual eMBCT.

To date, no study has simultaneously compared the effectiveness of both MBCT and Internet-based MBCT (eMBCT) with treatment as usual (TAU). The primary aim of this RCT was to investigate whether MBCT and eMBCT were each superior to TAU in reducing psychological distress in a sample of distressed patients with cancer. Moreover, we hypothesized that there would be a reduction of psychiatric diagnoses, fear of cancer recurrence, and rumination, and an improvement in health-related quality of life, mindfulness skills, and positive mental health in both interventions compared with TAU. We explored moderators of intervention dropout and outcome in the interventions: sex, age, cancer diagnosis, anticancer treatment intent, psychiatric diagnosis, neuroticism, and therapist.

PATIENTS AND METHODS

Trial Design
A three-armed multicenter, parallel group RCT was conducted to compare the effectiveness of MBCT and eMBCT with TAU in reducing psychological distress in patients with cancer. Anticipated dropout rates were 15% in MBCT and TAU, and 30% in eMBCT. Given the anticipated dropout rates, the allocation ratio was 1:1:2:1. Patients randomly assigned to receive TAU were secondarily randomly assigned to MBCT or eMBCT, to be given after the TAU period of 3 months. The study was approved by the ethical review board of the Radboud University Medical Center (CMO Arnhem-Nijmegen 2013/542). All centers provided local ethics approval. The study was registered on Clinicaltrials.gov (NCT02138513) shortly after the start of recruitment and was reported following CONSORT guidelines. A protocol article was published in advance of trial completion.

Participants
Inclusion criteria were (1) a cancer diagnosis, any tumor type or stage, at any time, receiving or not receiving treatment; (2) a score of ≥11 on the Hospital Anxiety and Depression Scale (HADS); (3) computer literacy and Internet access; (4) ability to participate in both MBCT and eMBCT; and (5) good command of the Dutch language. Exclusion criteria were (1) severe psychiatric morbidity, such as suicidal ideation and/or current psychosis; (2) change in psychotropic medication within a period of 3 months before baseline; and (3) previous participation in four or more sessions of an MBI.

Procedure
Patients were recruited from April 2014 to December 2015 via health care professionals in six centers (n = 64; 26%) via online media (n = 49; 20%), offline media (n = 44; 18%), patient associations (n = 43; 18%), and peers (n = 27; 11%). Eighteen patients (7%) could not remember how they heard about the study. Interested patients filled out the HADS on the research Web site. Patients with HADS ≥11 received a phone call from one of the researchers, during which the remaining inclusion and exclusion criteria were assessed. Once patients provided oral and written consent and had completed the baseline assessment, they were randomly assigned to MBCT, eMBCT, or TAU and informed about their allocation by E.B.

Intervention
Face-to-face MBCT. The MBCT protocol was tailored to patients with cancer by including cancer-related psychoeducation and adapted movement exercises. The MBCT consisted of eight weekly 2.5-hour group sessions, a 6-hour silent day, and daily home practice assignments guided by audio files. Each participant in both interventions received a folder with information on each session.

Internet-based mindfulness-based cognitive therapy. The eMBCT was delivered individually and included weekly asynchronous written interaction with a therapist over e-mail. Patients were granted access to a secure Web site containing material for 8 weeks plus a silent day and an inbox. Each session included an introduction and daily meditation exercises with meditation audio files. Patients were asked to practice and fill out practice diaries on a daily basis. They were provided with (fictional) patients’ descriptions to emphasize common experiences and clarify the use of the diaries. Patients were given written instructions after week 5 to prepare for their silent day at home. In the week of the silent day, patients were provided with a program similar to the MBCT silent day. At the end of the silent day, eMBCT patients wrote about their experiences in an essay. The therapist provided written feedback on the completed forms and the essay via the secured inbox on a prearranged day of the week. Having completed four or more sessions of MBCT was defined as a minimum adequate dose in both interventions.

Treatment as usual. TAU consisted of all health care that patients usually received. Except for not participating in MBIs during the study period, there were no restrictions on health care utilization. Data on health care utilization were gathered using the Trimbos/iMTA questionnaire for Costs associated with Psychiatric illnesses.

Therapists
Fourteen therapists participated: seven provided both interventions, two only provided MBCT, and five only provided eMBCT. All therapists fulfilled the criteria of the UK Mindfulness-Based Teacher Therapist Network Good Practice Guidelines for teaching MBIs. Three full-day supervision meetings were held during the intervention phase of the trial. All face-to-face MBCT sessions were videotaped to evaluate therapist competency using the Mindfulness-Based Interventions-Teachers Assessment Criteria. Therapist competency levels were determined by two independent therapists who evaluated two random sessions from each of the nine therapists providing face-to-face MBCT (who treated 80.8% of all patients receiving either intervention). Interrater reliability was .72. Of the nine therapists rated, four were considered proficient (n = 64 patients), three were considered competent (n = 64 patients), and two were considered beginner (n = 7 patients).

Measures
Primary outcome. Psychological distress was measured with the HADS, a 14-item self-report scale designed to assess anxiety and depression in medical outpatients. It has good psychometric properties in the general medical population, including patients with cancer in palliative care. The internal consistency in this sample was high (α = .87).
Secondary outcomes. Psychiatric diagnosis was assessed by the Structured Clinical Interview for DSM-IV-TR Axis I Disorders.29 The Structured Clinical Interview for DSM-IV-TR Axis I Disorders was administered by a trained interviewer who completed a Master in Behavioral Science degree (F.C.), supervised by either an experienced psychiatrist (E.B. or A.S.) or psychologist (M.v.d.L.). All interviews were audiorecorded. Fear of cancer recurrence was assessed with the severity subscale of the Fear of Cancer Recurrence Inventory.30 31 Rumination was measured by the rumination subscale of the Ruminative and Reflection Questionnaire;26 health-related quality of life was measured by the mental and physical scales of the Short-Form 1232 using Dutch norm scores from a clinical sample;33 mindfulness skills were measured by the Five Facet Mindfulness Questionnaire-Short Form;33 and positive mental health was measured by the Mental Health Continuum-Short Form.36 As a potential moderator, neuroticism was measured by the Neuroticism Extraversion-Openness-Five Factor Inventory.37 Further details of the measures used are included in the study protocol (Data Supplement).21

Sample Size
The sample size calculation was based on previous postintervention HADS scores of patients with cancer who received MBCT at the Helen Dowling Institute (mean, 10.6; standard deviation [SD], 6.4) compared with those who had not received it (mean, 14.8; SD, 8.1). With 90% power, 65 patients per condition were needed. Because of anticipated differential dropout rates among treatment arms, the recruitment target was 245 patients: 76 in each of the MBCT and TAU arms, and 93 in the eMBCT arm.

Randomization and Blinding
Once patients provided oral and written consent and completed the baseline assessment, they were randomly assigned to MBCT, eMBCT, or TAU by a computer-generated allocation sequence designed by an independent biostatistician. This custom software was accessed by one of the researchers (E.B.) via a study-specific Web site. Randomization was carried out with a fixed block size of 16 stratified for region and minimized for sex, cancer diagnosis (breast vs other), and anticancer treatment intent (curative vs palliative). After randomization, E.B. informed patients of their allocation by e-mail. E.B. planned and invited participants to the follow-up assessments; the standardized psychiatric interviews were conducted by F.C. and research assistants who were blinded to treatment allocation. Both E.B. and F.C. instructed patients not to mention their treatment condition at the beginning of each psychiatric interview.

Statistical Analysis
Statistical analyses were carried out using Statistical Package for the Social Sciences (SPSS) version 22 (SPSS, Chicago, IL). Differences among conditions in demographic and clinical variables were tested by χ² analysis and t tests. Continuous outcomes were analyzed with linear mixed modeling in a model with uncorrelated residual errors and random intercepts, including group allocation and its interaction with time and stratification (region) and minimization (sex, cancer diagnosis, anticancer treatment intent) variables as fixed factors. Because both MBCT and eMBCT were compared with TAU, the two-sided type 1 error rate was corrected to .025 for the two direct (MBCT and eMBCT) comparisons with TAU. All reported analyses used the intent-to-treat sample. The standardized psychiatric interviews were conducted by F.C. and research assistants who were blinded to treatment allocation. Both E.B. and F.C. instructed patients not to mention their treatment condition at the beginning of each psychiatric interview.

RESULTS

Study Sample
In total, 532 patients were screened with the HADS (Fig 1), of whom 98 (18.4%) were excluded for scoring < 11. Of 434 patients who were contacted by telephone, 24 (5.5%) were excluded because of previous experience with mindfulness, 22 (5.1%) could not be contacted, and 95 (21.9%) declined participation because of possible traveling distance (n = 55; 12.7%); strong randomization preference (n = 12; 2.8%), of whom four had a preference for eMBCT and eight for in-person group MBCT; and scheduling difficulties (n = 11; 2.5%). Of the remaining 293 patients, another 10 (3.4%) could not be contacted, and 38 (13.0%) declined participation after the baseline assessment. There were no significant differences in mean HADS scores between the 133 decliners (mean, 20.4; SD, 5.6) and those who were randomly assigned (mean, 20.6; SD, 6.2). In total, 245 patients with cancer were randomly assigned to MBCT (n = 77), eMBCT (n = 90), or TAU (n = 78). The three conditions did not differ in terms of baseline demographic or clinical characteristics (Table 1). The number of months between baseline and postintervention assessments did not differ between MBCT (mean, 5.4; SD, 2.3) and eMBCT (mean, 5.9; SD, 1.8; P = .13), but was higher in both intervention conditions than in TAU (mean, 3.5; SD, 0.9; P < .001).

Seventy of 77 patients (90.9%) started MBCT, and 71 (92.2%) completed four or more sessions (mean, 7.9; SD, 1.3; Fig 1). Eighty-two of 90 patients (91.1%) started eMBCT and 71 completed four or more sessions (mean, 8.6; SD, 1.2). The amount of estimated daily minutes of mindfulness practice did not differ significantly between MBCT (n = 56; mean, 30.6; SD, 26.0) and eMBCT (n = 70; mean, 28.7; SD, 29.3; P = .69). Withdrawals from the interventions were significantly higher in the eMBCT than in the MBCT group: χ²(1, n = 167) = 3.92 (P = .047). Nonresponse on the post-treatment assessment was substantial (16.9% in MBCT, 16.7% in eMBCT, and 10.3% in TAU) but did not differ significantly among conditions (P = .41). Nonresponders were more often female (P = .033) and had less education (P = .037) than responders.

Health Care Utilization
There were no significant differences in health care utilization between the intervention and TAU groups (Table 2), except for the proportion of patients receiving outpatient treatment (eg, chemotherapy), which was higher in the TAU group.
Fig 1. CONSORT diagram (n = 245). HADS, Hospital Anxiety and Depression Scale; MBCT, mindfulness-based cognitive therapy; TAU, treatment as usual.
**Safety**

A total of 21 severe adverse events unrelated to the intervention were reported in the MBCT (n = 6), eMBCT (n = 9), and TAU (n = 6) groups (Appendix Table A1, online only). One severe adverse event occurred during the study period: a patient died after being randomly assigned as a result of illness.

**Intervention Outcomes**

In between-group comparisons of both interventions compared with TAU, patients in the MBCT and eMBCT conditions reported significantly less psychological distress postintervention than did those receiving TAU, with small to medium effect sizes (Cohen’s d, .45 and .71, respectively; Table 3; Fig 2). The proportion of patients demonstrating reliable improvement was significantly greater in MBCT than TAU (36% v 14%; chi^2[1, n = 134] = 8.44; P = .004) and in eMBCT than TAU (37% v 14%; chi^2[1, n = 145] = 9.95; P = .002). Improvement in rates of psychiatric diagnosis favored both interventions compared with TAU but were not statistically significant (MBCT: 32% v 16%; chi^2[1, n = 126] = 4.73; P = .030; and eMBCT: 29% v 16%; chi^2[1, n = 138] = 3.15; P = .076).

Compared with TAU, both MBCT and eMBCT significantly reduced fear of cancer recurrence (Cohen’s d, .27 and .53, respectively), rumination (Cohen’s d, .42 and .51, respectively), and improved mental health–related quality of life (Cohen’s d, .59 and .67, respectively), but not physical health–related quality of life (Cohen’s d, .35 and .24, respectively). They also resulted in better mindfulness skills (Cohen’s d, .47 and .82, respectively) and increased positive mental health compared with TAU (Cohen’s d, .12 and .44, respectively).

**Moderation**

Exploratory analyses yielded no significant moderation of intervention dropout or primary outcome in the analyses comparing both interventions with TAU separately (all Ps > .05), except for neuroticism. In the analyses comparing either MBCT interventions with TAU, there was a significant interaction between neuroticism and intervention condition (MBCT v TAU P = .014; eMBCT v TAU P = .004). Patients scoring higher on neuroticism on baseline improved more on psychological distress in both intervention conditions than in TAU.

**DISCUSSION**

To our knowledge, this is the first study to simultaneously compare MBCT and eMBCT with TAU in a large sample of distressed heterogeneous patients with cancer. Both MBCT and eMBCT resulted in a statistically significant and clinically reliable reduction of psychological distress compared with TAU (Table 4). Both interventions demonstrated similar reductions of fear of cancer recurrence, rumination, and improvements in mental (but not physical) health–related quality of life, mindfulness skills, and positive mental health compared with TAU.

Our study confirms previous findings regarding the effectiveness of eMBIs for patients with cancer. Although the group-based setting is considered important for MBIs, this study suggests that individual guided eMBCT with limited teacher feedback is also effective, thus improving the accessibility of this intervention for patients with cancer. However, eMBCT did result in higher dropout rates than MBCT. Exploratory analyses did not yield any moderators of intervention dropout. Furthermore, qualitative research examining the reasons for dropout is critical to improve the efficacy of Web-based interventions.
independent, experienced therapists. We systematically collected data on health care utilization during the study. The study used a broad array of outcome measures, including both observer-rated interviews and self-report questionnaires. In addition to these strengths, the study has some limitations. The study was not powered to directly compare the two interventions or determine noninferiority of eMBCT to MBCT, because this would have required a larger sample size. As with other psycho-oncology research, the majority of the participants were middle-aged patients with breast cancer. Although this is in line with the characteristics of patients with cancer seeking psychosocial support, this might limit generalizability to patients with other

<table>
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<tr>
<th>Table 2. Health Care Utilization During the Intervention Period for MBCT, eMBCT and TAU Groups</th>
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<td><strong>Utilization</strong></td>
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<tr>
<td>Hospital outpatient consultation</td>
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<td>Hospital overnight</td>
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<td>Hospital outpatient treatment</td>
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<td>Hospital emergency department</td>
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<tr>
<td>Mental health care†</td>
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<tr>
<td>General practitioner</td>
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<tr>
<td>Physical therapist</td>
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<td>Complementary care</td>
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†Abbreviations: eMBCT, Internet-based MBCT; MBCT, mindfulness-based cognitive therapy; TAU, treatment as usual.

*Pearson χ² test.

†Social worker, psychologist.

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<th>Table 3. Mean Scores at Baseline and Postintervention (both listwise deletion and pooled multiple imputation scores are depicted) and Between-Group Differences for Primary and Secondary Outcome Measures</th>
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<td><strong>Outcome Measure</strong></td>
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<td>T0</td>
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<td>Primary HADS</td>
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<td>T0</td>
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<td>T1</td>
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<td>T2</td>
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<td>Secondary FCRI severity</td>
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<td>T0</td>
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<td>T1</td>
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<td>T2</td>
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<td>Secondary RRQ rumination</td>
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<td>T0</td>
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<td>T1</td>
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<td>T2</td>
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<tr>
<td>Secondary SF-12 Mental</td>
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<td>T0</td>
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<td>T1</td>
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<td>T2</td>
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<tr>
<td>Secondary SF-12 Physical</td>
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<td>T1</td>
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<td>T2</td>
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| Abbreviations: ES, effect size; Est., estimate; FCRI, Fear of Cancer Recurrence Inventory; FFMQ, Five Facet Mindfulness Questionnaire-Short Form; HADS, Hospital Anxiety and Depression Scale; eMBCT, Internet-based mindful-based cognitive therapy; MBCT, mindfulness-based cognitive therapy; MHC-SF, Mental Health Continuum-Short Form; RRQ, Rumination and Reflection Questionnaire; SD, standard deviation; SF-12, Short Form-12; TAU, treatment as usual.

*Because both MBCT and eMBCT were compared with TAU, the two-sided type I error rate was corrected to .025.
†SE for imputed means.
Because one inclusion criterion was the ability and willingness to attend both MBCT and eMBCT, the sampling frame for the current study was probably not representative of patients who would prefer eMBCT in clinical practice. Because treatment preference is often positively correlated with treatment outcome,\textsuperscript{45} we would expect that this RCT underestimated rather than overestimated the effects of eMBCT.

In terms of research implications, long-term results should be gathered to examine the stability of effects. In addition, data on cost-utility of MBIs in patients with cancer should be collected.\textsuperscript{46} Internet interventions do not involve the costs of transportation, traveling time, space, equipment, cleaning, and other overhead expenses and thus could be more cost effective. Possible mediators of the effect, such as mindfulness skills or rumination, should be further investigated.\textsuperscript{47,48} Moreover, mediation analyses could also examine possible differences in adherence in both MBCT and eMBCT.

In terms of clinical implications, implementation of eMBCT could make MBIs more accessible for patients with cancer without having to compromise intervention efficacy. However, intervention dropout could possibly be improved by the delivery mode of eMBIs.\textsuperscript{49} Qualitative work demonstrates that aspects such as the individual nature and the asynchronous interaction of the eMBCT used in this study are helpful for some patients.\textsuperscript{50} Future studies should assess how different eMBCT designs (eg, blended designs

### Table 4. Clinically Significant Improvement Measured by Jacobson-Truax Reliable Change Index on HADS and Psychiatric Diagnosis Between Baseline and Post-intervention for MBCT, eMBCT, and TAU Groups

<table>
<thead>
<tr>
<th>Improvement</th>
<th>MBCT (n = 64)</th>
<th>eMBCT (n = 75)</th>
<th>TAU (n = 70)</th>
<th>MBCT (n = 64)</th>
<th>eMBCT (n = 76)</th>
<th>TAU (n = 72)</th>
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<tr>
<td>No change</td>
<td>39</td>
<td>47</td>
<td>54</td>
<td>47</td>
<td>50</td>
<td>49</td>
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<tr>
<td>Improved</td>
<td>23</td>
<td>28</td>
<td>10</td>
<td>23</td>
<td>22</td>
<td>21</td>
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<tr>
<td>Deteriorated</td>
<td>2</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>4</td>
<td>3</td>
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Abbreviations: eMBCT, Internet-based MBCT; HADS, Hospital Anxiety and Depression Scale; MBCT, mindfulness-based cognitive therapy; TAU, treatment as usual.

*Between group $\chi^2$ tests for the respective condition compared with TAU.
combining the advantages of face-to-face and Internet-based elements) could further improve intervention accessibility, adherence, and effectiveness.

AUTHORS’ DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at jco.org.

REFERENCES


AUTHOR CONTRIBUTIONS

Conception and design: Linda Carlson, Marije van der Lee, Anne Speckens
Collection and assembly of data: Felix Compen, Else Bisseling
Data analysis and interpretation: Felix Compen, Else Bisseling, Melanie Schellekens, Rogier Donders, Marije van der Lee, Anne Speckens
Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors
MBCT and Internet-Based MBCT for Patients With Cancer

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References


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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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No relationship to disclose

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No relationship to disclose

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No relationship to disclose

Rogier Donders
No relationship to disclose

Linda Carlson
No relationship to disclose

Marije van der Lee
No relationship to disclose

Anne Speckens
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Appendix

<table>
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<th>Table A1. Adverse Events Reported per Condition</th>
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<td>Participant</td>
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<td>Intervention completer</td>
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<td>Intervention dropout</td>
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