The Effects of a Mindfulness-Based Intervention on Emotional Distress, Quality-of-Life, and HbA₁c in Outpatients With Diabetes (DiaMind)

A randomized controlled trial

OBJECTIVE—Emotional distress is common in outpatients with diabetes, affecting ~20–40% of the patients. The aim of this study was to determine the effectiveness of group therapy with Mindfulness-Based Cognitive Therapy (MBCT), relative to usual care, for patients with diabetes with regard to reducing emotional distress and improving health-related quality-of-life and glycemic control.

RESEARCH DESIGN AND METHODS—In the present randomized controlled trial, 139 outpatients with diabetes (type 1 or type 2) and low levels of emotional well-being were randomized to MBCT (n = 70) or a waiting list group (n = 69). Primary outcomes were perceived stress (Perceived Stress Scale), anxiety and depressive symptoms (Hospital Anxiety and Depression Scale), mood (Profiles of Mood States), and diabetes-specific distress (Problem Areas In Diabetes). Secondary outcomes were health-related quality-of-life (12-Item Short-Form Health Survey), and glycemic control (HbA₁c). Assessments were conducted at baseline and at 4 and 8 weeks of follow-up.

RESULTS—Compared with control, MBCT was more effective in reducing stress (P < 0.001, Cohen d = 0.70), depressive symptoms (P = 0.006, d = 0.59), and anxiety (P = 0.019, d = 0.44). In addition, MBCT was more effective in improving quality-of-life (mental: P = 0.003, d = 0.55; physical: P = 0.032, d = 0.40). We found no significant effect on HbA₁c, or diabetes-specific distress, although patients with elevated diabetes distress in the MBCT group tended to show a decrease in diabetes distress (P = 0.07, d = 0.70) compared with the control group.

CONCLUSIONS—Compared with usual care, MBCT resulted in a reduction of emotional distress and an increase in health-related quality-of-life in diabetic patients who had lower levels of emotional well-being.

Emotional distress, which can consist of symptoms of depression, anxiety, and diabetes-specific distress affects ~20 to 40% of outpatients with type 1 or type 2 diabetes (1–3), making it a common comorbid health problem in these patients. Emotional distress results in lower quality-of-life (4) and more negative appraisals of insulin therapy (5). In addition, depression is associated with suboptimal self-care behaviors (6), suboptimal glycemic control (7), adverse cardiovascular outcomes, and higher mortality rates (8,9). Although the emotional problems in diabetic patients have received increasing attention in the last decade, they are still often not recognized in clinical practice and remain untreated (10).

Previous research has shown that antidepressant medication and cognitive behavioral therapy are effective treatments for major depression in diabetic patients (11,12). However, the use of antidepressant medication is often accompanied by serious side effects, and a substantial percentage of the patients (~30–50%) do not respond to treatment or they relapse (13). Hence, we need to conduct new studies testing new treatments for emotional distress in diabetes. Because the number of diabetic patients is rapidly increasing, we need to develop interventions that are not only effective but also affordable. Web-based therapies and group therapies are good candidates.

One easily accessible group intervention that proved successful in reducing emotional distress and improving quality-of-life in nonpatients and in diverse patient groups (14–16) is Mindfulness-Based Cognitive Therapy (MBCT) (17). MBCT is an 8-week protocolized group therapy program that combines meditation exercises with elements of cognitive therapy. The central component of this intervention is the cultivation of mindfulness. This can be defined as the self-regulation of one’s attention focusing on direct experience, while adopting a curious, open, and accepting attitude toward these experiences, especially one’s psychological processes, such as thoughts and feelings (18). A recent meta-analysis has shown medium- to large-effect sizes for mindfulness-based interventions in reducing symptoms of anxiety and depression (19).

Two other studies examined the effect of a mindfulness-based intervention on emotional distress in people with diabetes (20,21). In one uncontrolled study, the mindfulness group showed a significant...
Results of the Diabetes and Mindfulness study

decline in depressive symptoms at post-
intervention and in HbA1c at the 1-month
follow-up (20). The other study found no
significant effects directly after the inter-
vention, but significant improvements in
depressive symptoms (Cohen d = 0.71)
and mental health-related quality-of-life
(d = 0.54) were reported at the 1-year
follow-up (21). The results of these studies
are in line with the notion that mind-
fulness-based interventions could be
adequate in reducing emotional problems
in people with diabetes. However, the
presence of emotional distress was not
an inclusion criterion in either study,
and only the latter study was a random-
ized controlled trial (21).

Studies testing the effectiveness of a
mindfulness-based intervention in out-
patients with type 1 diabetes are still
lacking. Therefore, the purpose of the
current study was to test the effectiveness
of MBCT for people with type 1 or type 2
diabetes and comorbid emotional dis-
tress. The primary outcome was the effect
on emotional distress, including symp-
toms of depression, anxiety, diabetes-
specific distress, and general perceived
stress. Secondary outcomes were health-
related quality-of-life and glycemic con-
trast. The central component of the
program was the development of mind-
fulness, which was done by practicing
several meditation exercises. A specific
theme was also discussed in each session
(e.g., “how to cope with thoughts”). At the
end of the sessions, the participants re-
ceived homework assignments that took
about 30 min, 5 days/week. Instead of one
whole-day session, which is part of the
original program, a 2-hour booster ses-
tion was added 3 months after the end
of the intervention as a means to boost
mindfulness practice. All sessions were
supervised by certified psychologists
who had at least 4 years of personal ex-
perience with mindfulness practice and also
completed at least one certified mindful-
ness instructors training of 8 days in the
Netherlands.

Randomization
After completion of the baseline assess-
ment, participants were randomized ac-
cording to a 1:1 ratio within blocks of 4 to
receive MBCT or TAU. A random list was
prepared by an independent statistician
using PASW Statistics 17 software with a
random number generator.

Outcome measures
The primary outcome assessment for
MBCT and TAU took place at pre- (T1),
mid- (at 4 weeks: T2), and postinterven-
tion (at 8 weeks: T3). The secondary
outcome, health-related quality-of-life,
was only assessed at T1 and T3. HbA1c
values were looked up pre- and postinterven-
tion, but within a wider period of time
(see below).

Demographic and clinical variables.
Demographic and clinical variables, such as
existing diabetes complications and comorbid conditions, were collected by
means of a questionnaire, which the
participants completed during the base-
line assessment. HbA1c was retrieved
from the hospitals’ computerized patient
records. The policy in the outpatient
diabetes clinics is to measure HbA1c every 3
months. Because HbA1c reflects the state
of the preceding −2 to 3 months, the
value for the preintervention assessment
was obtained between 24 weeks before
and 1 week after the start of the interven-
tion, and this period for the postinterven-
tion measures was between 6 and 24
weeks after the intervention.

Emotional distress. We defined emo-
tional distress as symptoms of anxiety,
depression, and/or diabetes-specific dis-
tress and operationalized the concept by
means of four questionnaires. We
included the Dutch version of the Perceived
Stress Scale to measure general perceived
stress, defined as the degree to which
situations in one’s life are appraised as
stressful (e.g., “lately, how often have
you felt nervous and stressed?”). The
items of the present 10-item version of
the Perceived Stress Scale are answered
on a 5-point Likert scale, ranging from
“never” (0) to “very often” (4) (26). The
Cronbach α was 0.81 in this sample.

The Hospital Anxiety and Depression
Scale (HADS) was included to measure
symptoms of anxiety (e.g., “Worrying
thoughts go through my mind”) and de-
pression (e.g., “I feel as if I am slowed
down”) (27). Both subscales comprise
seven items that are answered on a
4-point Likert scale of 0 to 3. The score
range for the anxiety and the depressive
symptoms subscales is 0 to 21. The Cron-
bach α in this sample was 0.75 for the
anxiety and 0.81 for the depression sub-

class.
POMS. We decided to include both scales in the study because they have complementary qualities: whereas the HADS is a more used and well-known instrument in medical settings, the POMS has three additional subscales and appears to be more sensitive for change (29).

The Dutch version of the Problem Areas In Diabetes Survey (PAID) was included to measure diabetes-specific distress. This scale consists of 20 statements about common negative feelings related to living with diabetes (e.g., “Feeling depressed when you think about living with diabetes,” “Feeling discouraged with your diabetes regimen”) (30). The items are rated on a 6-point Likert scale (1 “not a problem”; 6 “a serious problem”). To facilitate interpretation, the PAID scores were transformed to a 0–100 scale (31). A higher score indicates more distress, with a cutoff score of 40 indicating seriously elevated diabetes distress (32). The Cronbach α in this sample was 0.91.

Health-related quality-of-life. The Dutch version of the 12-item Short-Form Health Survey was included to assess health-related quality-of-life. The 12 items of this self-report scale are grouped into two component summary scores: a physical and a mental component score. Both component scores are measured on a scale from 0 to 100, with a high score indicating good health-related quality-of-life. The Dutch 12-item Short-Form Health Survey has established reliability and validity (33).

Data analyses
The χ² test or the Fisher exact test, as appropriate, were used to examine differences on discrete variables. Possible differences on continuous variables were examined with the Student t test for independent samples. Mixed-models analyses (SPSS 18 software) were used to test the differences between groups on the dependent variables (time × group interaction effect). We used mixed-models analysis instead of repeated-measures ANOVA to make more efficient use of our data with likely occasional missing values. In sensitivity analyses, linear regression analyses on change scores were conducted after multiple imputation was used to address missing data. In instances when the groups differed on pretreatment variables, these variables would be included as covariates. Age, sex, and comorbidity were regarded as important variables to be included as covariates at all occasions (23). All analyses were based on the intention-to-treat approach.

To determine clinically significant change, we followed the definition of Jacobson et al. (34). The first step was to identify participants who had moved outside the range of the “dysfunctional population” at postintervention assessment (the “recovered” participants) by using a cutoff score of ≥8 on both subscales of the HADS (35). The second step was to identify individuals who showed a significant improvement at postintervention. Therefore, for each individual, we calculated the Reliable Change Index (RCI = \( x_2 - x_1 / SD_{diff} \)) on the HADS (36). The participants who both “recovered” and showed a “significant improvement” were considered as being “clinically significantly improved.”

Results
Recruitment and attrition

Figure 1 displays the participants’ flowchart. Of 5,710 diabetic patients who were assessed for eligibility, 1,299 (23%) were directly invited by the researcher, diabetes nurse, or secretary in the outpatient diabetes clinic during a regular appointment, and 4,411 (77%) were invited by an invitational letter. Of the latter group, the response rate was 43% (n = 1,898). Of the remaining 3,197 patients, 2,126 (67%) did not meet inclusion criteria (e.g., they had good to optimal emotional well-being), 638 (20%) declined to participate, and 294 (9%) were excluded because of other reasons, including insufficient patient information or inability to contact the patient. The two main reasons for decline were no interest or no need for an intervention, and practical problems, such as being too busy to follow the intervention or not being able to attend the meetings.

In the MBCT group, 2 patients (3%) dropped out before the start of the intervention, 13 (19%) before the fourth session, and 5 (7%) between the fourth and the eighth session. Of the remaining 50 participants, 41 (82%; 59% of total MBCT group) attended at least six of the eight sessions. The overall average attendance was 5.5 (SD, 2.5) sessions. Seven patients (10%) in the TAU group dropped out of the study. Ten dropouts in the MBCT group continued to fill in the questionnaires. Eventually, we missed data of 9 participants (MBCT: n = 3; TAU: n = 6) at T2, and of 16 participants (MBCT: n = 7; TAU: n = 9; Fig. 1) at T3.

Participants who prematurely stopped with the intervention were less likely to have a partner (55% vs. 80%, P = 0.034) and to have prior experience with meditation (5% vs. 31%, P = 0.022). The MBCT and TAU participants who did not complete the T3 assessment were younger (P = 0.028) and had a higher score on the POMS fatigue subscale at baseline (P = 0.007). They were also less likely to have a partner (53% vs. 77%, P = 0.042) and more likely to use psychotropic medication (47% vs. 18%, P = 0.010) and to smoke (40% vs. 14%, P = 0.010).

The Hba1c data were missing for 20 participants at T1 (MBCT: n = 7; TAU: n = 13) and for 42 participants at T3 (MBCT: n = 18; TAU: n = 24). There were no significant differences regarding our outcomes between participants of which the Hba1c measurement was or was not available.

Characteristics of study participants

The baseline characteristics of the sample, stratified by group (MBCT or TAU), are presented in Table 1. At baseline, there were no statistically significant differences between the two groups on demographic and clinical variables.

Effect on primary outcome emotional distress

The mean scores of MBCT and TAU on the emotional distress measures are presented in Table 2. Mixed-models analyses showed that the individuals in the MBCT group had a significantly larger decrease in levels of perceived stress over time compared with TAU (P < 0.001). The effect size of the difference from pre- to postintervention between the two conditions was medium to large (Cohen d = 0.70). Post hoc between-subject analyses indicated that the groups differed at postintervention (P < 0.001) but not at T2 (P = 0.204).

The analyses also showed a significant effect of MBCT on depressive symptoms (HADS) compared with TAU (P = 0.006), with a medium effect size (Cohen d = 0.59; Fig. 2A). This difference between groups was already significant at T2 (P = 0.011), as post hoc analyses revealed, but was increased at postintervention (P < 0.001). The results on the depression subscale of the POMS were comparable, but with a larger effect size (Cohen d = 0.71; Table 2).

Concerning symptoms of anxiety (HADS), there was a significant improvement in the MBCT group compared with TAU (P = 0.019). The effect size was small.
Results of the Diabetes and Mindfulness study

Figure 1 — Flow diagram of patient enrollment, allocation, and attrition.

to medium (Cohen $d = 0.44$; Fig. 2B). Post hoc analyses showed a trend for significance at T2 ($P = 0.064$) and a significant difference at postintervention ($P = 0.001$). The results on the anxiety subscale of the POMS were comparable, but the effect size was larger (Cohen $d = 0.82$; Table 2). Similar results were also obtained for the POMS subscale of fatigue (Table 2).

In contrast, there was no significant difference between MBCT and TAU on diabetes-specific distress ($P = 0.488$, Cohen $d = 0.21$). Post hoc analyses revealed that there was a significant decrease in diabetes-specific distress over time in the MBCT group ($P = 0.003$), whereas the TAU group showed a trend for a significant decrease over time ($P = 0.072$). Because the participants were selected on general emotional distress, a considerable percentage (52%) did not have elevated diabetes distress at baseline. Therefore, we conducted an ad hoc subgroup analysis in participants with elevated diabetes distress levels (PAID ≥40). This analysis revealed a trend for a significant mean (SD) reduction in the MBCT group [35 (20)] compared with the TAU group [49 (17); $P = 0.066$], with a moderate to large effect size (Cohen $d = 0.70$).

Clinical significance

At baseline, 81 participants (MBCT: $n = 40$; TAU: $n = 41$) had a score above the anxiety cutoff at baseline and 71 (MBCT: $n = 33$; TAU: $n = 38$) had a score above the depression cutoff. In the MBCT group, 37% of these participants showed a clinically significant improvement on symptoms of anxiety compared with 5% in the TAU group ($P = 0.001$, $\varphi = 0.39$) and 27% on symptoms of depression versus 8% in the TAU group ($P = 0.064$, $\varphi = 0.26$).

Effect on secondary outcomes health-related quality-of-life and HbA1c

Mixed-models analyses showed that the MBCT group had a significantly more strongly improved mental quality-of-life ($P = 0.003$; Cohen $d = 0.55$) as well as physical quality-of-life ($P = 0.032$; Cohen $d = 0.40$) compared with the TAU group (Table 3). Mixed-model analyses showed no significant difference in HbA1c change in MBCT compared with TAU ($P = 0.346$; Cohen $d = 0.14$; Table 3). Post hoc analyses revealed that there was no significant difference in HbA1c over time in the MBCT group ($P = 0.366$), whereas the TAU group showed a trend for a significant increase in HbA1c over time ($P = 0.064$).

Sensitivity analyses

Sensitivity analyses based on multiple imputation data showed highly similar results; for example, all significant results reported above were also significant except for physical quality-of-life, which became marginally significant ($P = 0.057$). In addition, sensitivity analyses in which diabetes type and the diabetes type-by-time interaction were included as covariates revealed highly similar results. The diabetes type-by-time interaction was not significant in any analysis (all $P > 0.05$), showing that results were similar for both types.

CONCLUSIONS

—The present report describes the results of the DiaMind study. This study’s main objective was to test the effectiveness of MBCT in
improving the emotional well-being of distressed diabetic patients. The findings were largely in line with our hypotheses regarding the effect of the intervention on emotional well-being and quality-of-life. Patients receiving MBCT showed significantly larger decreases in perceived stress, symptoms of depression and anxiety, and had significantly better improvements in health-related quality-of-life compared with those in the TAU group. The effect sizes were medium to large. To the best of our knowledge, this is the first randomized trial to find immediate effects of a mindfulness-based intervention on emotional well-being and quality-of-life in outpatients with type 1 and type 2 diabetes.

The participants in the MBCT group showed approximately seven times more likely to show a clinically significant improvement at postintervention in symptoms of anxiety and three times more likely to show this improvement in symptoms of depression compared with the participants in the TAU group. Although the effect sizes were medium, the difference for depressive symptoms was almost significant. This can probably be considered as a power problem, because only approximately half of the participants scored above the HADS cutoff score of anxiety and depressive symptoms at baseline.

Interestingly, although the MBCT group also showed a significant reduction in diabetes-specific distress over time, we did not find a significant difference between MBCT and TAU at postintervention for this outcome. General emotional distress was an inclusion criterion, yet only a fraction of the participants (48%) experienced elevated diabetes distress (PAID ≥40). Hence, the nonsignificant finding could be caused by a floor effect. When we tested the effect of the intervention in the subgroup with elevated diabetes distress at baseline, the results revealed that MBCT reduced the diabetes distress with a moderate to large effect size compared with TAU. However, this finding was not statistically significant, probably due to a lack of statistical power, given the smaller size of this subsample.

No significant difference was observed between the groups regarding change in HbA1c. Although the MBCT group showed no significant change in levels of HbA1c from pre- to postintervention, the control group showed marginally significant increased values at postintervention. The nonsignificant difference between the MBCT and TAU groups is in line with the discrepancy in findings regarding the effect of psychological interventions on HbA1c in patients with diabetes, with one meta-analysis finding an effect (36) and one systematic

Table 1—Demographic and clinical characteristics of MBCT and TAU groups

<table>
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<tr>
<th>Measure</th>
<th>Group</th>
<th>Pre</th>
<th>Mid</th>
<th>Post</th>
<th>Time effect</th>
<th>Time × treatment effect</th>
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<td></td>
<td></td>
<td>n = 70</td>
<td>n = 69</td>
<td>F</td>
<td>P</td>
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<td>Age (years), mean (SD)</td>
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<td></td>
<td></td>
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<td>Male, n (%)</td>
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<td>33 (47)</td>
<td>37 (54)</td>
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<td>High education, † n (%)</td>
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<td>31 (44)</td>
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<td>Working, n (%)</td>
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<td>28 (40)</td>
<td>19 (28)</td>
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<td>53 (77)</td>
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<td>Children living at home, n (%)</td>
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<td>23 (33)</td>
<td>19 (28)</td>
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<td>Diabetes type 2, n (%)</td>
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<td>52 (74)</td>
<td>45 (65)</td>
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<td>HbA1c, (mmol/mol), mean (SD)</td>
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<td>59.0 (13)</td>
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<td>HbA1c, (%)</td>
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<td>7.5 (1)</td>
<td>7.6 (1)</td>
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<td>Complications, n (%)</td>
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<td>32 (46)</td>
<td>33 (48)</td>
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<td>Comorbidity, n (%)</td>
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<td>Past psychological treatment, n (%)</td>
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<td>39 (56)</td>
<td>44 (64)</td>
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<tr>
<td>Use of psychotropic medication, n (%)</td>
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<td>18 (26)</td>
<td>12 (17)</td>
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<td>Meditation experience, n (%)</td>
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<td>16 (23)</td>
<td>11 (16)</td>
<td>0.30</td>
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*χ² for nominal variables and t test for continuous variables. †High-level professional education and university.

Table 2—Mean (SD) scores and results of mixed-models analyses for primary outcomes

<table>
<thead>
<tr>
<th>Measure</th>
<th>Group</th>
<th>Pre</th>
<th>Mid</th>
<th>Post</th>
<th>Time effect</th>
<th>Time × treatment effect</th>
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<td></td>
<td>n = 70</td>
<td>n = 69</td>
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<td>P</td>
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<tr>
<td>Stress‡</td>
<td>MCBT</td>
<td>19.5 (6.0)</td>
<td>17.3 (6.9)</td>
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<td>17.40</td>
<td>&lt;0.001</td>
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<td>TAU</td>
<td>20.5 (5.9)</td>
<td>19.1 (6.4)</td>
<td>19.6 (6.7)</td>
<td>2.14</td>
<td>0.13</td>
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<td>Anxiety§</td>
<td>MCBT</td>
<td>8.4 (3.3)</td>
<td>7.5 (4.1)</td>
<td>6.3 (3.5)</td>
<td>13.26</td>
<td>&lt;0.001</td>
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<td>TAU</td>
<td>9.2 (3.6)</td>
<td>9.0 (3.7)</td>
<td>8.7 (4.1)</td>
<td>0.98</td>
<td>0.38</td>
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<td>AnxietyII††</td>
<td>MCBT</td>
<td>20.3 (4.5)</td>
<td>19.0 (5.2)</td>
<td>17.3 (4.1)</td>
<td>24.04</td>
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<td>TAU</td>
<td>20.1 (4.4)</td>
<td>20.0 (4.6)</td>
<td>19.7 (5.1)</td>
<td>0.64</td>
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<td>Depression‡</td>
<td>MCBT</td>
<td>7.9 (3.8)</td>
<td>6.4 (4.3)</td>
<td>5.4 (4.1)</td>
<td>14.96</td>
<td>&lt;0.001</td>
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<td>TAU</td>
<td>8.9 (3.9)</td>
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<td>8.5 (4.7)</td>
<td>0.61</td>
<td>0.55</td>
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<td>DepressionII††</td>
<td>MCBT</td>
<td>25.3 (5.8)</td>
<td>23.5 (6.4)</td>
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<td></td>
<td>TAU</td>
<td>26.6 (6.3)</td>
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<td>0.41</td>
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<td>Diabetes distress‡</td>
<td>MCBT</td>
<td>34.3 (17.8)</td>
<td>28.1 (16.4)</td>
<td>27.8 (20.6)</td>
<td>6.42</td>
<td>&lt;0.01</td>
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<td></td>
<td>TAU</td>
<td>36.1 (18.9)</td>
<td>31.8 (18.9)</td>
<td>33.3 (22.0)</td>
<td>2.76</td>
<td>0.07</td>
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<td>Fatigue‡</td>
<td>MCBT</td>
<td>22.9 (5.5)</td>
<td>20.3 (5.9)</td>
<td>19.5 (5.1)</td>
<td>14.14</td>
<td>&lt;0.001</td>
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<tr>
<td></td>
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<td>23.4 (6.4)</td>
<td>23.0 (6.8)</td>
<td>22.5 (6.9)</td>
<td>1.07</td>
<td>0.35</td>
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*The effect size (Cohen d) was calculated on pre- to postintervention change scores. †95%CI of the effect size. ‡From the Perceived Stress Scale. §From HADS. ††From POMS. ¶From PAID survey.
review (37) and another meta-analysis finding no effect (38). One possible explanation for the absence of a decrease in the current study is that poor glycemic control was not an inclusion criterion, and so the mean (SD) HbA1c at baseline [59 mmol/mol (13) or 7.6% (1.2)] was slightly above target level. This fairly good baseline glycemic control contrasts with previous studies in the latter meta-analysis. Future research in a group with poor glycemic control should examine this possibility.

As mentioned before, only two other studies have tested the effectiveness of mindfulness therapy for patients with diabetes. Hartmann et al. (21) did not find significant reductions in depressive and stress symptoms or an increase in health-related quality-of-life compared with usual care directly after the intervention, whereas improvements for some of these outcomes were found at the 1-year follow-up. The main explanation for the difference in findings compared with the DiaMind study may be because the presence of emotional distress was an inclusion criterion in the current study. Rosenzweig et al. (20) did show a reduction in depressive symptoms and general psychological stress, but not in anxiety symptoms, in diabetic patients immediately after the intervention. However, they did not use a randomized controlled design, had a small sample size, and again, the presence of emotional distress was not an inclusion criterion.

The DiaMind study had a number of limitations. First, selection bias may have affected our results, because only a small portion of the patients we assessed for eligibility decided to participate in the trial. Therefore, generalizability of the findings is limited to diabetic patients who are open to participate in a psychological intervention. This effect applies for all psychological interventions but perhaps even more strongly for one based on mindfulness, although care was taken to use more neutral terms in communication to patients, such as “attention” or “attention exercises” instead of “mindfulness” or “meditation.”

**Table 3—Mean (SD) scores and results of mixed-models analyses for secondary outcomes**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Group</th>
<th>Pre</th>
<th>Post</th>
<th>Time effect</th>
<th>Time × treatment effect</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>F</td>
<td>P</td>
<td>F</td>
<td>P</td>
</tr>
<tr>
<td>Quality-of-life‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental component</td>
<td>MBCT</td>
<td>33.9 (11.0)</td>
<td>42.9 (10.7)</td>
<td>37.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>TAU</td>
<td>32.5 (11.6)</td>
<td>35.7 (12.5)</td>
<td>7.85</td>
<td>0.01</td>
</tr>
<tr>
<td>Physical component</td>
<td>MBCT</td>
<td>41.5 (9.9)</td>
<td>43.5 (10.5)</td>
<td>5.04</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>TAU</td>
<td>38.9 (11.4)</td>
<td>38.5 (11.7)</td>
<td>0.42</td>
<td>0.52</td>
</tr>
<tr>
<td>HbA1c mmol/mol</td>
<td>MBCT</td>
<td>58.6 (12.6)</td>
<td>59.6 (12.1)</td>
<td>0.83</td>
<td>0.37</td>
</tr>
<tr>
<td></td>
<td>TAU</td>
<td>59.3 (12.9)</td>
<td>61.8 (16.4)</td>
<td>3.64</td>
<td>0.06</td>
</tr>
</tbody>
</table>

*The effect size (Cohen d) was calculated on pre- to postintervention change scores. †95% CI of the effect size. ‡From 12-item Short-Form Health Survey.
Second, the study had a significant dropout rate in the MBCT group: ~26% (n = 18) stopped participating in the program. Although the dropout rate is comparable to some studies (14,15), it is relatively high compared with other studies (39,40). A possible explanation is that the participants were approached, instead of being the requesting party. Fortunately, efforts to collect the data of all randomized participants, even when treatment was prematurely terminated, were fruitful: 59% (n = 10) of the dropouts of the MBCT group were willing to continue to fill in the questionnaires.

Third, we did not investigate and control for changes in medication for diabetes or mental health.

Fourth, we used a nonactive control group design, which can lead to differences between the two conditions in attrition and in expectancy effects (placebo vs. nocebo) resulting in a risk of an overestimation of the treatment effect. However, we decided to use this design, because 1) we wanted to test the effectiveness of MBCT for patients with diabetes relative to usual care instead of comparing it with another psychological intervention, and 2) in this sample of patients with emotional problems, we felt it would be unethical to use a placebo intervention. Future studies should incorporate active control groups to examine to what extent our findings are mindfulness specific.

Finally, a substantial number of missing data were present for HbA1c due to unavailability of the measurements in the predefined time span in the patient information databases. The policy in the outpatient diabetes clinics is to measure HbA1c every 3 months. However, this is not always feasible in practice; therefore, we had lower statistical power to measure significant differences between the two conditions.

In conclusion, the DiaMind study demonstrated that MBCT could be used to treat comorbid emotional problems in patients with type 1 or type 2 diabetes. The emotional well-being and quality-of-life of these patients increased compared with the control group, whereas no significant effect was found for diabetes-specific distress and HbA1c, possibly due to a floor effect. MBCT may be offered as part of standard care to diabetic patients with emotional problems. However, the implementation of a group MBCT intervention may be more feasible if mixed chronic disease patient groups are formed. Although this should be tested in future research, such an approach is expected to be as effective as the present one focusing on patients with diabetes because 1) mindfulness-based interventions are broadly applicable, and 2) previous studies have found these interventions are effective in other chronic disease patient groups (41). In addition, given the prospected increase in people with diabeties and the increasing health care costs, it will be worthwhile to examine the effectiveness of Internet-based mindfulness therapy also.

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J.v.S. researched data and wrote the manuscript. I.N. researched data, contributed to discussion, and reviewed and edited the manuscript. V.J.P. and F.P. contributed to discussion and reviewed and edited the manuscript. M.C.B., R.J.E., P.F.S., and A.W.T. reviewed and edited the manuscript. J.v.S. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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