Individual Mindfulness-Based Cognitive Therapy and Cognitive Behavior Therapy for Treating Depressive Symptoms in Patients With Diabetes: Results of a Randomized Controlled Trial

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Diabetes Care 2014;37:2427–2434 | DOI: 10.2337/dc13-2918

OBJECTIVE

Depression is a common comorbidity of diabetes, undesirably affecting patients' physical and mental functioning. Psychological interventions are effective treatments for depression in the general population as well as in patients with a chronic disease. The aim of this study was to assess the efficacy of individual mindfulness-based cognitive therapy (MBCT) and individual cognitive behavior therapy (CBT) in comparison with a waiting-list control condition for treating depressive symptoms in adults with type 1 or type 2 diabetes.

RESEARCH DESIGN AND METHODS

In this randomized controlled trial, 94 outpatients with diabetes and comorbid depressive symptoms (i.e., Beck Depression Inventory-II [BDI-II] ≥14) were randomized to MBCT (*n* = 31), CBT (*n* = 32), or waiting list (*n* = 31). All participants completed written questionnaires and interviews at pre- and postmeasurement (3 months later). Primary outcome measure was severity of depressive symptoms (BDI-II and Toronto Hamilton Depression Rating Scale). Anxiety (Generalized Anxiety Disorder 7), well-being (Well-Being Index), diabetes-related distress (Problem Areas In Diabetes), and HbA_{1c} levels were assessed as secondary outcomes.

RESULTS

Results showed that participants receiving MBCT and CBT reported significantly greater reductions in depressive symptoms compared with patients in the waiting-list control condition (respectively, $P = 0.004$ and $P < 0.001$; d = 0.80 and 1.00; clinically relevant improvement 26% and 29% vs. 4%). Both interventions also had significant positive effects on anxiety, well-being, and diabetes-related distress. No significant effect was found on HbA_{1c} values.

CONCLUSIONS

Both individual MBCT and CBT are effective in improving a range of psychological symptoms in individuals with type 1 and type 2 diabetes.

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Received 13 December 2013 and accepted 27 April 2014.

Clinical trial reg. no. NCT01630512, clinicaltrials.gov.

This article contains Supplementary Data online at http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dc13-2918/-/DC1.

A slide set summarizing this article is available online.

Depression is a common and persistent condition in patients with diabetes, with major depression diagnosed in 11% of all patients and depressive symptoms in 31% (1). Alongside its contribution to decreased quality of life, coexisting depression in diabetes may represent a great burden for patients' health and the health care system. Depression has been related to lower adherence to medication, dietary and exercise recommendations, poorer glycemic control, and increased health care costs (2,3). The high comorbidity of depression in diabetes and the potential negative health consequences warrant the identification of effective treatments to improve patient functioning. Both antidepressant medication and psychological treatment have been found effective for treating depression (4), yet the latter is preferred by the majority of diabetic patients (5).

One potential effective psychological treatment consists of mindfulness-based cognitive therapy (MBCT). In the last decade, application of MBCT for the treatment of a wide variety of psychological disorders, including depressive symptoms, has grown exponentially. MBCT focuses on cultivating mindfulness, which can be defined as being aware of the present moment by means of paying attention on purpose and without judgment (6). Several meta-analyses have demonstrated that MBCT results in reduction of depressive symptoms and increases in well-being in a variety of populations (7–9). However, little is known about the applicability and effectiveness of MBCT in patients with diabetes. So far, only one randomized controlled trial (RCT) has investigated the effects of MBCT in patients with diabetes, demonstrating a reduction of depressive symptoms and anxiety as well as an increase in quality of life (10).

Usually, MBCT is delivered in a group format. Yet, not all participants experience this as beneficial (11), and a group of patients prefers individual treatment to group MBCT (12). This is in line with a study on psychological treatment preferences in general, demonstrating that 70% of people preferred individual treatment above group treatment (13). This motivated us to investigate the effectiveness of an individual MBCT program. In a pilot RCT, we found that patients in the individual MBCT condition showed greater reductions in depressive symptoms and diabetes-related distress compared with a waiting-list condition (14). These positive results warrant further investigation of the efficacy of individual MBCT for patients with diabetes, which is the focus of the current trial.

Recent reviews and meta-analyses strongly recommend comparing MBCT not only to a passive control group but also to an active evidence-based intervention (15,16). In the treatment of depressive symptoms, the most frequently applied and evidence-based treatment is cognitive behavior therapy (CBT) (17). CBT has been related to significant improvements in psychological symptoms in patients with a diversity of somatic diseases, especially when delivered individually (18). Regarding CBT in patients with diabetes and comorbid depression, five RCTs have investigated and demonstrated its efficacy (19–23). Thus, CBT is characterized as the gold standard against which to assess the efficacy of a relatively new and promising intervention like MBCT.

As MBCT combines mindfulness with elements from CBT, MBCT and CBT can be regarded as related therapies. Yet, the treatment components and overall aim of the interventions are distinct. MBCT mainly involves practicing meditation and yoga exercises to increase awareness and acceptance of dysfunctional thoughts and accompanying negative emotions (6). CBT encourages patients to maintain and increase the frequency of pleasant activities and to lower negative mood by changing the content of dysfunctional thoughts into more helpful thoughts (24). To date, only one small RCT directly compared group MBCT to group CBT in people with depression, demonstrating that both interventions were equally efficacious (25). No RCT of CBT and MBCT has been conducted in patients with diabetes.

The purpose of the current Mood Enhancement Therapy Intervention Study was to examine the effectiveness of individual MBCT and CBT for depressive symptoms in patients with diabetes in comparison with a waiting-list control condition. We hypothesized that both MBCT and CBT were more effective than a waiting-list control condition, with neither MBCT nor CBT being superior over the other. The secondary objective was to investigate the effects of MBCT and CBT in improving anxiety, well-being, and diabetes-related distress. In addition, we explored the effects of MBCT and CBT on glycemic control, as indicated by HbA_{1c} values. When proven efficacious, individual MBCT can be established as a sound alternative to CBT for treating depressive symptoms in patients with diabetes and thereby improving quality of psychological care. This availability of distinct evidence-based effective interventions is particularly important given the finding that preferences and attitudes toward treatment can influence treatment outcome (26).

RESEARCH DESIGN AND METHODS

Study Design

The Mood Enhancement Therapy Intervention Study is a multicenter RCT with three conditions, namely MBCT, CBT, and a waiting-list control condition. We chose the latter control condition rather than treatment as usual for ethical reasons, as all participants had elevated levels of depressive symptoms at randomization. The study protocol received ethical approval from the Medical Ethical Committee of the University Medical Center Groningen and was conducted in accordance with the principles of the Declaration of Helsinki (version 2008) and the Medical Research Involving Human Subjects Act. A detailed description of the design has been published elsewhere (27).

Participants

Eligible participants were patients with type 1 or 2 diabetes diagnosed at least 3 months prior to inclusion, aged between 18 and 70 years, and having symptoms of depression as indicated by a Beck Depression Inventory-II (BDI-II) score of $\geq$14. Exclusion criteria were not being able to read and write Dutch, pregnancy, severe psychiatric comorbidity, acute suicidal ideations, receiving an alternative psychological treatment during or $<$2 months prior to starting participation in the study, and unstable treatment with an antidepressant in the last 2 months prior to inclusion in the study.

Procedure

Patients were recruited from June 2011 to February 2013 at four hospitals

primarily in the northern part of the Netherlands (see Supplementary Data for a list of participating investigators). Recruitment took place through standard screening at outpatient clinics, referral by physician, and self-referral. When patients had elevated levels of depressive symptoms, they were invited for an intake, during which they were screened again and assessed for eligibility. Patients who fulfilled our criteria and gave written informed consent for participation were included in the study. Patients in the MBCT and CBT conditions were assessed before randomization and start of treatment (premeasurement) and immediately after ending of treatment (postmeasurement; on average, 3 months after the first assessment). Patients assigned to the waiting-list control condition undertook a baseline assessment (premeasurement) and an assessment at the end of the 3-month waiting period (postmeasurement).

Randomization

Computerized randomization was carried out stratified by sex, use of antidepressant medication, and baseline BDI-II score. Before randomization, patients were blinded for the treatment condition. Accordingly, patients did not receive any specific information about the type of intervention or the waiting-list condition. They were only told that they were to be randomized to a psychological treatment that focuses on reducing depression and that treatment was to start within 3 months after randomization.

Interventions

Intervention Conditions

Both MBCT and CBT are protocolized interventions aimed at reducing depressive symptoms. The treatments were delivered individually in eight weekly sessions of 45–60 min. Patients were also instructed to do daily homework for 30 min. Both interventions were delivered by trained therapists who received supervision every 3 weeks throughout the intervention period. MBCT was based on the protocol as developed by Segal et al. (28). The central components of MBCT were formal meditation, yoga exercises, and informal daily mindfulness practices. CBT was based on the protocol developed by Beck et al. (24). The main components of CBT were behavioral activation and cognitive restructuring. A description of the protocols can be found in Supplementary Table 1.

To assess adherence, all treatment sessions of patients who provided consent for this were videotaped. In addition, patients were asked to report their daily homework practice on weekly evaluation forms. Based on ratings of the videotaped sessions by two independent observers, we found that therapists' adherence to the treatment manuals was sufficiently good (85% in MBCT and 83% in CBT). Also, patients' homework compliance was sufficient (61% in MBCT and 79% in CBT).

Waiting-List Condition

Participants in the waiting-list condition received no psychological intervention for 3 months.

Assessments

Descriptive Measures

Data on the following demographic variables were collected through self-report questionnaires: age, sex, education, marital status, and occupation. Disease-specific characteristics were retrieved from patients' records, namely time since diagnosis, type of diabetes, treatment regimen, comorbidities, complications, and BMI. For 14 patients, we could not access the medical records, and thus this information was retrieved from the questionnaire.

Primary Outcome Measure

The primary outcome measure, severity of depressive symptoms, was assessed with the BDI-II (29). The BDI-II is a 21-item self-report questionnaire, scored on a four-point scale ranging from 0 ("not at all") to 3 ("most of the time"). It measures symptoms of depression such as sadness, loss of interest, and hopelessness during the last 2 weeks. A score from 14–19 indicates mild depression, a score from 20–28 moderate depression, and a score $\geq$29 indicates severe depression. The reliability of the BDI-II was good in the current study (α = 0.84).

In addition to the self-report depression measurement, and in order to assess depressive symptoms in a more objective manner, symptoms were also measured using the Toronto Hamilton Depression Rating Scale (HAM-D7) (30). This semistructured clinical interview was administered by trained psychologists at pre- and postmeasurement. At premeasurement, the assessors of the HAM-D7 were blinded to the treatment condition. However, at postmeasurement, the HAM-D7 was administered together with an evaluation of the treatment for individuals randomized to MBCT or CBT, and therefore, the assessors were not blinded. The HAM-D7 consists of seven items about depressed mood, feelings of guilt, and anxiety during the last week. The items are scored on a five-point scale, ranging from 0–4 (except for one item, which ranges from 0–2). A sum score of $\geq$4 represents mild depression, a score between 12 and 20 moderate depression, and a score $>$20 represents severe depression. Reliability in the current study was acceptable (α = 0.65).

Secondary Outcome Measures

The Well-Being Index (WHO-5) was used to assess emotional well-being (31). This self-report instrument consists of five items that are scored on a six-point scale from 0 ("not present") to 5 ("constantly present"). The items are about positive mood, vitality, and general interest in relation to the last 2 weeks. The total sum score is converted to a score between 0 and 100, with a score $\leq$50 indicating poor well-being. In this study, the scale's reliability was good (α = 0.82).

Anxiety was assessed by means of the Generalized Anxiety Disorder 7 (GAD-7), a seven-item self-report instrument (32). Respondents are asked to report the frequency with which they experience worrying and feeling restless, annoyed, or afraid during the last 2 weeks. Each item is scored 0 ("not at all") to 3 ("nearly every day"). A total sum score of $\geq$5 indicates mild anxiety, a score of 11–15 moderate anxiety, and a score of $>$15 indicates severe anxiety. Cronbach α in this study was good (α = 0.88).

The Problem Areas In Diabetes (PAID) was used to measure diabetes-related distress (33,34). The PAID consists of 20 items, which are rated on a five-point scale. The scoring ranges from 0 ("not a problem") to 4 ("serious problem"). The items cover various common negative emotions related to living with and managing diabetes. The sum of all items is

transformed into a scale from 0–100, with scores of ≥40 being used to define patients at risk for high diabetes-related distress. The internal consistency was excellent in the current study ($\alpha = 0.95$).

Finally, glycemic control, indicated by HbA_{1c} values, was retrieved from patients' records. As premeasurement, the average of all assembled values of 0–6 months prior to intervention was used, and as postmeasurement, we used the average of all values between 1 and 6 months after the intervention.

Sample Size Calculation

The sample size calculation was based on expected differences in the level of posttreatment depressive symptoms between the waiting-list control group and either MBCT or CBT. Assuming a statistical power of 0.8 and an α of 0.05, 42 participants were required in each group, enabling us to detect differences with an effect size of 0.6 (35).

Statistical Analyses

All analyses were performed based on the intention-to-treat method. Missing values were estimated by means of multiple imputations using the linear regression method. We performed sensitivity analyses based on participants with no missing data and datasets with 5 and 20 imputations. As analyses revealed a similar pattern of results, 5 complete datasets were imputed after 20 iterations. SPSS Statistics 20 (SPSS Inc.) was used for all analyses, and all according assumptions were met. ANOVAs and χ^2 tests were used to analyze if there were differences at baseline between the groups regarding demographic and clinical variables as well as primary and secondary outcome measures. Separate ANCOVAs were performed for MBCT and CBT to examine the effects of the interventions in comparison with the waiting-list condition. Postmeasurement values of the primary and secondary outcomes were used as dependent variables, condition was used as factor, and premeasurements of the outcomes were used as covariate. Between-group effect sizes were calculated using Cohen d, with values ranging from 0.2 to 0.5 indicating small effects, values from 0.5 to 0.8 indicating moderate effects, and values >0.8 indicating large effects (36). Clinically relevant improvement was defined as having improved and being recovered. A postmeasurement score below the cutoff of the primary outcome measure (i.e., BDI-II <14) indicated improvement. Recovery was calculated by the Reliable Change Index, which refers to the difference between an individual's pre- and postmeasurement scores, divided by the SE of the difference. A score >1.96 indicates recovery (37).

RESULTS

Recruitment and Attrition

As is shown in Fig. 1, 3,145 patients were routinely screened at a hospital, and 14 referred themselves in awareness of their treating physician. Of the 2,266 patients who completed and returned the screening questionnaire, 613 (27%) had an elevated score (BDI-II ≥14). Less than half ($n = 255$) accepted the invitation for a face-to-face intake. An additional six patients were referred by their physician for an intake. During the intake, patients were screened again and elaborately assessed for eligibility. Almost one-third of the patients ($n = 78$) who received an intake were not eligible for the trial, and an additional one-third ($n = 89$) did not agree to participate, mostly because they did not feel the need for treatment. Finally, 94 patients gave consent and were randomized: 31 participants to MBCT, 32 participants to CBT, and 31 participants to the waiting-list control condition. In both MBCT and CBT, nine patients did not finish the intervention (i.e., received less than six sessions). Reasons for dropout were intervention content related (MBCT: $n = 4$; CBT: $n = 3$), lack of time (MBCT: $n = 3$; CBT: $n = 2$), severe illness (MBCT: $n = 1$; CBT: $n = 2$), improvement of depression after a few sessions (MBCT: $n = 1$; CBT: $n = 1$), and no interest in participating in research anymore (CBT: $n = 1$). Two participants in the MBCT condition and four participants in both CBT and the waiting-list condition did not fill in the postmeasurement questionnaire.

Baseline Characteristics

Table 1 provides an overview of the baseline characteristics of the participants. There were no statistically significant differences among the three conditions regarding the demographic or clinical baseline characteristics as well as primary and secondary outcomes measures (averages shown in Table 2).

Primary Outcome Measures

The mean scores and the outcomes of the statistical analyses are presented in Table 2. When comparing MBCT and CBT to the control condition, both intervention groups had significantly less depressive symptoms than the control group at postmeasurement ($P = 0.004$ and $P < 0.001$, respectively). The effect sizes of the change from pre- to postmeasurement between MBCT and CBT versus the waiting list were large (Cohen d = 0.80 and d = 1.00, respectively). Given the difference in effect sizes between the two interventions, we also compared effects of the MBCT and CBT group directly and found no significant differences ($P = 0.34$; not shown in Table 2). Assessing depressive symptoms with the HAM-D7 revealed similar results: both MBCT and CBT had significantly higher outcome improvement than the waiting-list condition ($P < 0.001$ and $P = 0.001$, respectively). The between-group effect sizes in comparison with the waiting list were large (MBCT, d = 1.17; CBT, d = 1.09).

Secondary Outcome Measures

The results of the secondary outcome measures are also presented in Table 2. When comparing MBCT and CBT with the waiting list, individuals in both MBCT and CBT had a larger improvement in levels of well-being (both $P < 0.001$), anxiety ($P = 0.004$ and $P = 0.01$, respectively), and diabetes-related distress ($P = 0.02$ and $P = 0.04$, respectively). Between-group effect sizes were large for well-being and anxiety (range Cohen d = 0.82–0.97) and moderate for diabetes-related distress (d = 0.52 and d = 0.57). HbA_{1c} levels did not change after MBCT or CBT ($P = 0.92$ and $P = 0.72$, respectively).

Clinically Relevant Improvement

Clinically relevant improvement was found in 26% of the participants after MBCT and 29% of the participants after CBT versus 4% of the patients in the waiting-list condition. When comparing the percentages in the intervention conditions to the control condition, the differences were significant (MBCT vs. waiting list: $P = 0.02$; CBT vs. waiting list: $P = 0.009$).

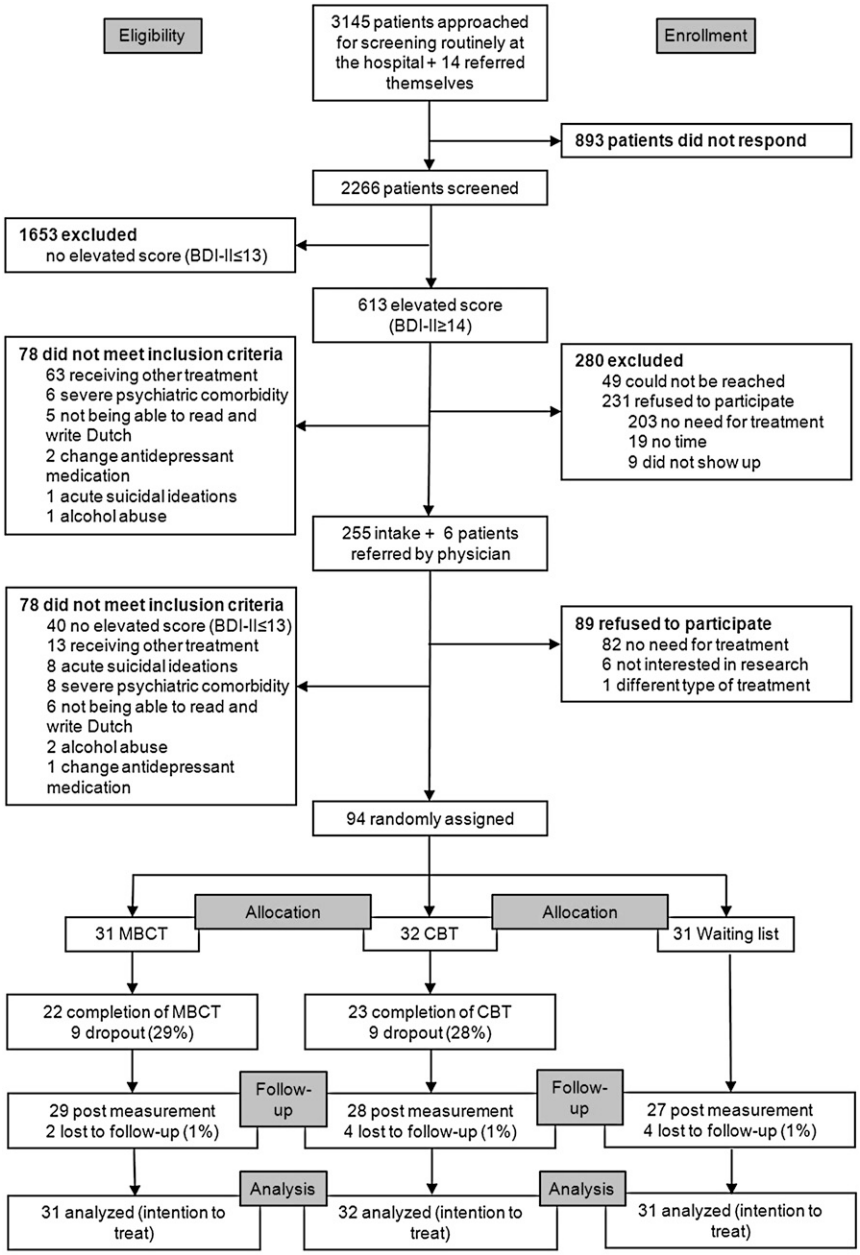

Figure 1—Participant recruitment and flow through the study.

CONCLUSIONS

This is the first RCT that investigated the effectiveness of individually delivered MBCT and CBT in reducing depressive symptoms in outpatients with type 1 and type 2 diabetes. Concordant with our hypothesis, results indicated that both MBCT and CBT were effective in reducing depressive symptoms compared with a waiting-list control condition, with neither MBCT nor CBT being superior over the other. MBCT and CBT were also effective in improving a wider range of patient-relevant outcomes, including increases in well-being and reductions in anxiety and diabetes-related distress. No effects were found for HbA_{1c} values.

Given the high prevalence and burden of depressive symptoms in patients with diabetes, a key finding of this RCT is that patients receiving one of the psychological interventions reported greater reductions in depressive symptoms in comparison with the control condition. Our findings are in line with Manicavasgar et al. (25), demonstrating effectiveness of group MBCT and CBT in reducing depression. These and our findings show that CBT is effective but not superior to some other active treatments (38). Our results are innovative, as this is the first RCT study on the effectiveness of the individual delivery of MBCT, with currently only evidence for the effectiveness of group-based MBCT. We are aware that our results should be replicated to draw more firm conclusions. Yet, it is promising, given the well-known effectiveness of CBT, especially when individually delivered (18), that individual MBCT was as effective. Taking into account the differences in treatment focus and components of MBCT and CBT, our results imply that two evidence-based distinct types of

Table 1—Baseline characteristics

	MBCT (*n* = 31)	CBT (*n* = 32)	Waiting list (*n* = 31)	Total (*n* = 94)*
Age (years), mean (SD)	49.8 (13.3)	54.6 (11.3)	54.7 (10.5)	53.1 (11.8)
Sex, *n* (%)				
Male	17 (55)	16 (50)	15 (48)	48 (51)
Female	14 (45)	16 (50)	16 (52)	46 (49)
Education, *n* (%)				
Lower level vocational school	8 (26)	10 (31)	5 (16)	23 (25)
Secondary education/advanced level vocational school	14 (45)	15 (47)	18 (58)	47 (50)
Higher or university education	9 (29)	7 (22)	8 (26)	24 (25)
Employment, *n* (%)				
Employed	16 (52)	15 (47)	21 (68)	52 (55)
Not employed	15 (48)	17 (53)	10 (32)	42 (45)
Relationship status, *n* (%)				
In a relationship	24 (77)	22 (69)	21 (68)	67 (71)
Not in a relationship	7 (23)	10 (31)	10 (32)	27 (29)
BMI, mean (SD)	29.3 (7.6)	31.9 (6.6)	30.6 (8.4)	30.6 (7.6)
Type of diabetes, *n* (%)				
Type 1	15 (48)	11 (34)	11 (36)	37 (39)
Type 2	16 (52)	21 (66)	20 (65)	57 (61)
Diabetes treatment, *n* (%)				
Oral medication	4 (13)	4 (12)	4 (13)	12 (13)
Oral medication and insulin	10 (32)	14 (44)	11 (36)	35 (37)
Insulin	17 (55)	14 (44)	16 (51)	47 (50)
Time since diagnosis (years), mean (SD)	17.8 (13.0)	15.0 (11.4)	17.0 (11.4)	16.6 (11.9)
Diabetes complications, *n* (%)†				
One or more complications	9 (29)	13 (40)	9 (29)	31 (33)
No complications	22 (71)	19 (60)	22 (71)	63 (77)
Comorbidity, *n* (%)				
One or more comorbidities	14 (45)	18 (56)	18 (58)	50 (53)
No comorbidity	17 (55)	14 (44)	13 (42)	44 (47)
Antidepressant use at trial entry, *n* (%)				
Usage	2 (7)	5 (16)	3 (10)	10 (11)
No usage	29 (93)	27 (84)	28 (90)	84 (89)

*Groups did not significantly differ ($P > 0.05$ in all cases) on any of the demographics and clinical characteristics. †Included diabetes complications are: retinopathy, neuropathy, nephropathy, and diabetic foot.

psychological interventions can be offered to patients with diabetes. An important next step would be to investigate possible moderators of effectiveness; that is, factors related to the differential effectiveness of MBCT and CBT within certain subgroups of patients (i.e., for whom is which intervention more beneficial?).

Besides depressive symptoms, we were also interested in a possible wider effect of MBCT and CBT on other indicators of functioning. It is clinically relevant to observe that both MBCT and CBT significantly increase well-being and reduce anxiety and diabetes-related distress. These findings are consistent with previous research showing that psychological interventions focusing on depressive symptoms can also improve anxiety and quality of life (10,20). Results are also in line with previous studies in patients with diabetes investigating either MBCT or CBT, also showing reductions in diabetes-related distress (14,19). Taken together, MBCT and CBT not only reduce depressive symptoms, but also improve other psychological outcomes.

Explorative analysis showed no significant reductions in HbA_{1c} values either in MBCT or in CBT. This finding is concordant with two previous RCTs on MBCT (10) and CBT (19) that did not find an effect on glycemic control. A recent review and meta-analysis studied the impact of psychosocial interventions on both psychological and physical health in patients with diabetes (39). No interventions were identified that were effective for both medical and mental outcomes at the same time. Altogether, our findings and previous results suggest that alleviating depressive symptoms through psychological interventions like MBCT or CBT does not automatically translate into improved self-care and subsequent glycemic control (4).

A methodological challenge in the investigation of improvements in HbA_{1c} levels is that the HbA_{1c} level is an average value over the previous 3 months. In this study, HbA_{1c} was only included for exploratory reasons in order to burden the patients as little as possible. Therefore, HbA_{1c} values were obtained from patients' medical records instead of scheduling additional measurements at designated time points. Consequently, our HbA_{1c} values are crude indications of HbA_{1c} values in the months preceding and following the two active interventions. Also, as patients in the waiting-list condition received care directly after patients in the active conditions had finished the intervention, it was not possible to compare CBT and MBCT with the control condition regarding changes in HbA_{1c} values.

Table 2—Results for primary and secondary outcomes

Measure	Group	Premeasurement, mean (SD)	Postmeasurement, mean (SD)	Time		Treatment†		
				t	*P* value	*F*	*P* value	d
Depression (BDI-II)	MBCT	23.6 (7.7)	17.1 (11.9)	4.75	<0.001	9.71	0.004	0.80 (0.27–1.31)
	CBT	25.6 (8.7)	17.4 (11.9)	5.58	<0.001	15.56	<0.001	1.00 (0.47–1.51)
	WAIT	24.3 (8.0)	23.5 (10.3)	0.65	0.52			
Depression (HAM-D7)	MBCT	8.9 (3.5)	4.7 (4.3)	6.33	<0.001	17.52	<0.001	1.17 (0.61–1.69)
	CBT	9.4 (3.8)	4.6 (3.4)	5.55	<0.001	13.06	<0.001	1.09 (0.55–1.60)
	WAIT	7.5 (2.8)	7.1 (3.7)	0.71	0.49			
Well-being (WHO-5)	MBCT	32.4 (18.4)	49.5 (21.5)	5.90	<0.001	17.35	<0.001	0.92 (0.39–1.43)
	CBT	26.8 (17.8)	47.4 (20.2)	6.07	<0.001	18.95	<0.001	1.02 (0.48–1.53)
	WAIT	27.7 (15.9)	30.9 (15.4)	1.09	0.28			
Anxiety (GAD-7)	MBCT	12.6 (5.3)	6.9 (4.8)	7.00	<0.001	9.60	0.004	0.98 (0.44–1.49)
	CBT	11.9 (4.9)	6.8 (5.0)	6.61	<0.001	7.42	0.01	0.82 (0.29–1.32)
	WAIT	9.8 (5.0)	8.2 (4.6)	2.37	0.02			
Diabetes distress (PAID)	MBCT	38.3 (20.9)	32.0 (21.8)	3.08	0.002	5.67	0.02	0.52 (0.01–1.02)
	CBT	42.0 (22.3)	34.0 (23.4)	2.87	0.004	5.68	0.04	0.57 (0.06–1.07)
	WAIT	35.5 (21.5)	36.0 (21.2)	−0.26	0.79			
HbA_{1c}*								
mmol/mol	MBCT	63.4 (9.6)	63.1 (10.8)	0.10	0.92			
%		8.0 (0.9)	7.9 (1.0)					
mmol/mol	CBT	67.1 (15.2)	65.9 (13.0)	0.36	0.72			
%		8.3 (1.4)	8.2 (1.2)					

WAIT, waiting list. *Not measured in the waiting-list condition. †Comparing both MBCT and CBT with the waiting-list condition.

Limitations

Although we carefully designed our study, several limitations to this study need to be acknowledged. First, we were not able to reach a fully powered sample of at least 42 participants per condition, as patient recruitment took more time than originally planned. Yet, for the actual sample size, the power was still 68%. Second, although the majority of the patients were recruited as a consecutive sample (i.e., screening; *n* = 79), a small group of participants was recruited as a convenience sample based on (self) referral (*n* = 15). The former may not be representative of treatment-seeking or clinically referred patients, while the latter sample may suffer from selection bias, hereby reducing generalizability of the results. Third, attrition rates in both MBCT and CBT were high, as only ~70% of the randomized participants completed treatment. These attrition rates are consistent with previous studies targeting distressed patients with diabetes (10,19). Screening a consecutive sample may have accounted for the dropout rate, as the majority of participants did not seek treatment themselves, but instead were approached and offered treatment. Fourth, a substantial group of patients who met the inclusion criteria refused to participate in the study because of no need for psychological treatment. Our inclusion rate is comparable to other studies using a consecutive sample method (10,40). As patients were blinded to the content of the treatment, we do not assume that refusal to participation was content related. Fifth, the fact that assessors of depressive symptoms with the clinical interview at postmeasurement were not blinded may have biased their ratings. Finally, as all participants had elevated levels of depressive symptoms at randomization, for ethical reasons, we included a waiting-list control condition rather than treatment as usual. As patients in the control condition received one of the interventions after the 3-month waiting period, long-term effects of CBT and MBCT compared with the control condition could not be assessed.

Conclusion

This is the first RCT examining the effectiveness of individual MBCT and individual CBT in reducing depressive symptoms in patients with diabetes. Results clearly suggest that MBCT as well as CBT are effective interventions in treating depressive symptoms in patients with diabetes. Given their effectiveness and the fact that both interventions are short, structured 8-week interventions delivered on an individual basis, they could be implemented in optimizing psychological care for depressed patients with diabetes.

Acknowledgments. The authors thank all of the patients who participated in the study, the psychologists who delivered the MBCT and CBT sessions, the secretaries and research assistants of the University Medical Center Groningen, the Martini Hospital Groningen, the Medical Center Leeuwarden, and the Hospital Rivierenland Tiel for the efforts.

Funding. This study was financed by the University of Groningen.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

Author Contributions. K.A.T. constructed the design of the study, researched data, and wrote the manuscript. J.F. and M.J.S. constructed the design of the study and revised the manuscript. E.S. constructed the design of the study, researched data, and reviewed the manuscript. A.C.T.M.P. reviewed the manuscript. P.M.G.E. and R.S. constructed the design of the study and reviewed the manuscript. T.P.L. participated in the design of the study and reviewed the manuscript. K.A.T. 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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