



Short communication

## Mindfulness-based cognitive therapy for people with diabetes and emotional problems: Long-term follow-up findings from the DiaMind randomized controlled trial



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### ABSTRACT

**Objective:** The DiaMind trial showed beneficial immediate effects of mindfulness-based cognitive therapy (MBCT) on emotional distress, but not on diabetes distress and HbA<sub>1c</sub>. The aim of the present report was to examine if the effects would be sustained after six month follow-up.

**Methods:** In the DiaMind trial, 139 outpatients with diabetes (type-I or type-II) and a lowered level of emotional well-being were randomized into MBCT (n = 70) or a waiting list with treatment as usual (TAU: n = 69). Primary outcomes were perceived stress, anxiety and depressive symptoms, and diabetes distress. Secondary outcomes were, among others, health status, and glycemic control (HbA<sub>1c</sub>).

**Results:** Compared to TAU, MBCT showed sustained reductions at follow-up in perceived stress ( $p < .001$ ,  $d = .76$ ), anxiety ( $p < .001$ , assessed by HADS  $d = .83$ ; assessed by POMS  $d = .92$ ), and HADS depressive symptoms ( $p = .004$ ,  $d = .51$ ), but not POMS depressive symptoms when using Bonferroni correction for multiple testing ( $p = .016$ ,  $d = .48$ ). No significant between-group effect was found on diabetes distress and HbA<sub>1c</sub>.

**Conclusion:** This study showed sustained benefits of MBCT six months after the intervention on emotional distress in people with diabetes and a lowered level of emotional well-being.

**Trial registration:** Dutch Trial Register NTR2145, <http://www.trialregister.nl>.

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### Introduction

The prevalence of emotional distress in people with diabetes is relatively high (i.e., diabetes-specific emotional distress approximately 18% [1], anxiety symptoms approximately 40% [2] and depressive symptoms 20–40% [1,3]) and is associated with negative outcomes, such as lower quality of life, suboptimal self-care behaviors and glycemic control, risk of adverse cardiovascular outcomes, and higher mortality rates [4–8]. A new promising psychological intervention in people with diabetes with emotional problems is the mindfulness-based cognitive therapy (MBCT) program. It has been used in various chronically ill populations, effectively decreasing feelings of distress, anxiety, and depression [9]. A previous report from the current study showed that MBCT, immediately at post intervention, was associated with a significant reduction in perceived stress, anxiety and depressive symptoms in people with diabetes and lowered level of emotional well-being [10]. However, it is yet unclear if the beneficial effects are sustained over a longer period of time.

One randomized trial in cancer patients did not find sustained effects of MBCT on perceived stress, anxiety or depressive symptoms after six month follow-up [11], while other studies in different patient groups did show maintained improvements in psychological distress after six or twelve months [12–14]. In people with type-II diabetes, only one previous study reported longer-term outcomes. That study showed an effect on levels of depression one year after the intervention [15], although no sustained effects were found on levels of stress. The present study attempts to extend these findings by also including people with type-I diabetes and to examine the effect on symptoms of anxiety and diabetes-specific distress.

### Method

The Diabetes and Mindfulness (DiaMind) study design, a randomized controlled trial (approved by the Medical Ethics Committee of the St. Elisabeth Hospital in Tilburg) has been discussed in detail elsewhere [16]. Adults with diabetes (type 1 or type 2) with low levels of emotional well-being (as evidenced by a score of < 13 on the WHO-5 well-being Index) were recruited from outpatient diabetes clinics. Eligible patients who agreed to participate (n = 139) were randomized to a waiting list, treatment-as-usual, (TAU: n = 69) or to an MBCT group (n = 70),

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**Table 1**  
Demographic and clinical characteristics of MBCT and TAU group

	MBCT (n = 70)	TAU (n = 69)	p <sup>a</sup>
Mean age, years (SD)	56 (13)	57 (13)	.62
Male, n (%)	33 (47)	37 (54)	.45
High education <sup>b</sup> , n (%)	31 (44)	28 (41)	.66
Working, n (%)	28 (40)	19 (28)	.12
Living with a partner, n (%)	51 (73)	53 (77)	.59
Diabetes type 2, n (%)	52 (74)	45 (65)	.41

MBCT – mindfulness-based cognitive therapy group; TAU – waiting list (usual care) control group.

<sup>a</sup> Chi-square for nominal variables and *t*-test for continuous variables.

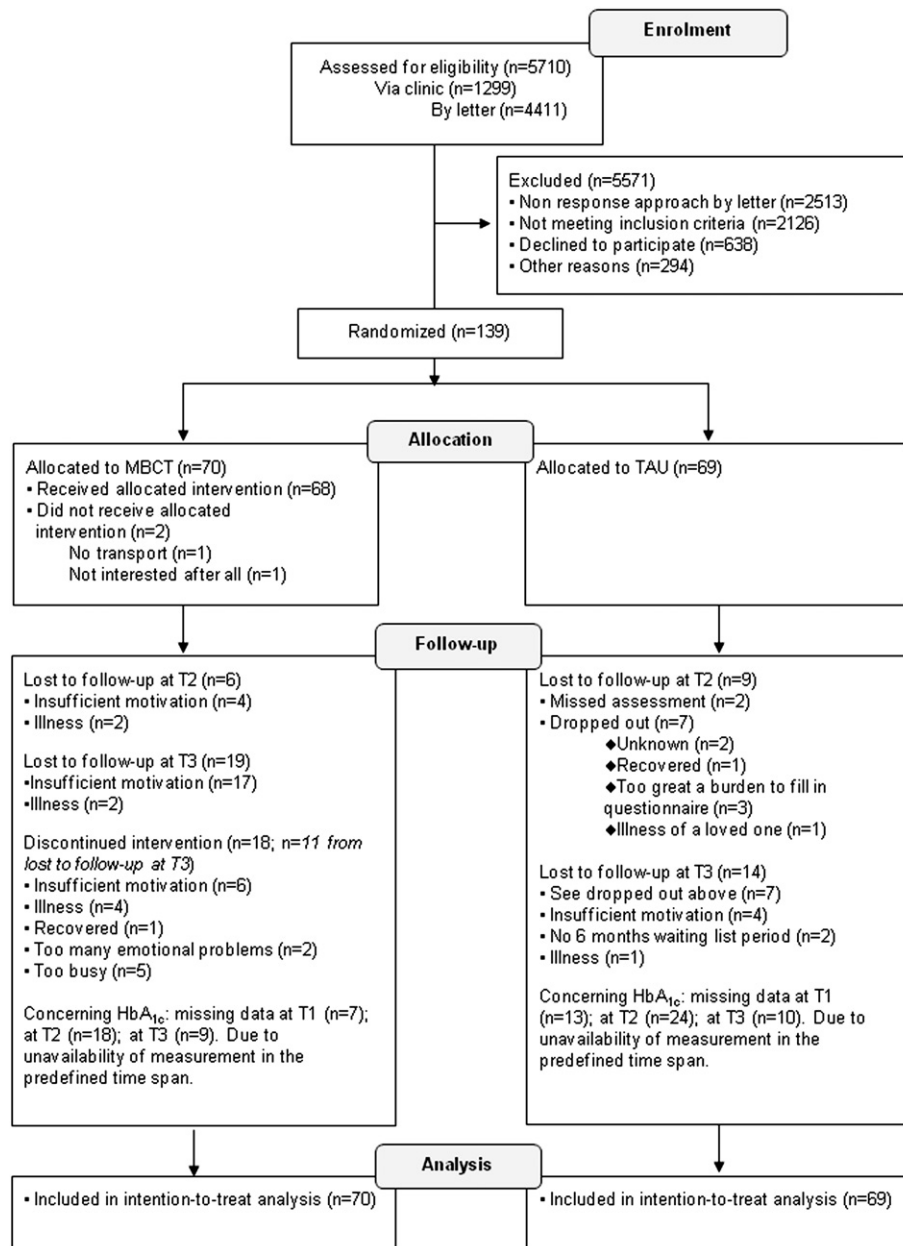
<sup>b</sup> High education: high-level vocational education and university.

consisting of eight weekly two-hour group sessions [17]. Three months after the end of the intervention a two-hour booster session had been

added. The assessment of the outcomes took place at pre- (T1) and post intervention (T2), and after 6 months post intervention (T3). Demographic and clinical variables (e.g., existence of diabetes complications and co-morbid conditions) were assessed at baseline using questionnaires, except for HbA<sub>1c</sub> values (the amount of glycated hemoglobin in blood) which were evaluated by chart review.

Emotional distress was the primary outcome, defined as symptoms of anxiety, depression and (diabetes-specific) stress [18]. The 10-item Perceived Stress Scale (PSS) (5-point Likert scale) [19] and the Hospital Anxiety (7-items) and Depression (7-items) Scale (HADS) (4-point Likert scale) [20], and the Profile of Mood States (POMS) (5-point Likert scale) [21] were used, as well as the 20-items Problem Areas in Diabetes Survey (PAID) to assess diabetes specific stress (six-point Likert scale) [22].

For secondary outcomes the following questionnaires were used: Short-Form Health Survey (SF-12) [23], Five Facet Mindfulness Questionnaire (FFMQ) (except for the subscale Describing) [24], Acceptance



**Fig. 1.** Flow diagram of patient enrolment, allocation, and attrition. MBCT – mindfulness-based cognitive therapy intervention group; TAU – waiting list (usual care) control group. T1 – baseline assessment; T2 – post intervention assessment; T3 – six months follow-up assessment. The *lost to follow-up* numbers of T2 and T3 each show the total number lost to follow-up at the consecutive time points.

and Action Diabetes Questionnaire (AADQ) [25], and the Rosenberg Self-Esteem Scale (RSES) [26]. Because our primary outcome of interest was emotional distress, the status of the variables 'diabetes distress' and 'health status' was changed from respectively secondary and primary as registered originally (Netherlands Trial Registry 2145) to respectively primary and secondary [16]. In addition, we also decided to (i) include people with type 1 diabetes to be able to examine the broader applicability of the intervention, and (ii) not measure heart rate variability to prevent loss of participants due to complex daily measurements [16].

Data analyses

SPSS linear regression analyses on change scores (T3–T1) were used to test the differences between groups on the dependent variables. All analyses were based on the intention-to-treat approach. Multiple imputation (20 imputations using the Predictive Mean Matching procedure) was used to address missing data. Given the analysis of six primary outcome measures and subsequent higher risk of a type I error, the alpha level for significance was set at 0.008 for the main analyses (Bonferroni correction of alpha of 0.05 divided by 6). Sensitivity analyses included mixed models analyses using all three time points without imputed missing values.

Cohen's *d* effect sizes were calculated on the mean change scores between T1 and T3 of the two conditions, with the following formula  $(M_{MBCT} - M_{TAU}) / \sigma_{pooled}$ . A Cohen's *d* between 0.2 and 0.5 indicates a small effect, between 0.5 and 0.8 a moderate effect, and larger than 0.8 a large effect [27].

Results

There were no significant differences between the MBCT and TAU group on baseline variables (Table 1, see also prior article [10]). Fig. 1 shows the flow of participants during the study. Participants of both conditions who did not fill in the T3 measurement, were younger ( $p = .013$ ), had a lower BMI ( $p = .006$ ), and a higher score on the HADS-A ( $p = .013$ ) at baseline. In the MBCT group, 59% of the participants attended at least 6 of

the 8 sessions (overall mean attendance was  $5.5 \pm 2.5$  sessions) and 30% attended the booster session three months after the end of the intervention.

Linear regression analysis showed a significant effect of MBCT on perceived stress from baseline to six month follow-up compared to TAU ( $p < .001$ ). The effect size of the difference from T1 to T3 between the two groups was moderate to large (Cohen's  $d = .76$ ) (Table 2). Post hoc analyses revealed that there was no significant difference between the groups in perceived stress change scores from post-intervention to six month follow-up ( $p = .49$ ), indicating a stable effect of the intervention. In addition, in the MBCT group a significantly larger reduction in depressive symptoms (HADS) from baseline to six months was found ( $p = .004$ ), with a medium effect size (Cohen's  $d = .51$ ), although when assessed by the POMS, this did not reach the Bonferroni corrected level of significance ( $p = .016$ ,  $d = .48$ ) (Table 2). Post hoc analyses did not reveal significant changes in depressive symptoms from post-intervention to six month follow-up between groups ( $p > .10$ ). Also, the MBCT group showed a larger decrease on symptoms of anxiety over time for both HADS and POMS ( $p < .001$ ). The effect size was large in both cases (Cohen's  $d > .80$ ) (Table 2). No significant changes in anxiety symptoms appeared from post-intervention to follow-up ( $p \geq .09$ ). There was no significant difference between MBCT and TAU on change in diabetes distress ( $p = .034$ , Cohen's  $d = .41$ ) from T1 to T3 (Table 2).

Regarding secondary outcomes, significant differences between the groups in change scores were found only for mental health status and mindfulness, not for the other variables (Table 2), including HbA<sub>1c</sub> ( $p = .82$ ; Cohen's  $d = .06$ ). Sensitivity analyses based on mixed models using all time points yielded similar results (e.g., all significant results mentioned above were also significant with similar effect sizes).

Discussion

The present paper shows that the reduction in perceived stress, anxiety and depressive symptoms in the MBCT group was sustained six months after the intervention (all medium to large effect sizes), although in the case depressive symptoms were assessed by POMS, the Bonferroni corrected *p*-value failed to reach significance.

In correspondence with the results that were found immediately at post intervention [10], there was no effect of MBCT on diabetes distress and glycemic control after follow-up. Since only a minority of the participants in the present sample (48%) experienced elevated diabetes distress (PAID  $\geq 40$ ) and the mean baseline HbA<sub>1c</sub> value of the two groups appeared to be already fairly good (59 mmol/mol, SD = 13; in

Table 2 Mean (SD) scores and results of linear regression analyses

Measure		Pre M (SD)	Post M (SD)	6-m FU M (SD)	Effect Group on Pre-to-6-m FU change			
					t	p	d <sup>a</sup>	
<i>Primary outcomes</i>								
Perceived stress	MBCT	19.5 (6.0)	14.4 (7.1)	13.4 (6.7)	-3.93	<.001	0.76	
	TAU	20.4 (5.9)	19.0 (6.7)	18.9 (7.0)				
HADS-anxiety	MBCT	8.6 (3.3)	6.7 (3.6)	5.4 (3.1)	-4.24	<.001	0.83	
	TAU	9.4 (3.6)	8.8 (4.1)	8.8 (3.9)				
POMS-anxiety	MBCT	20.5 (4.5)	17.4 (4.1)	16.4 (3.4)	-4.43	<.001	0.92	
	TAU	20.2 (4.4)	19.8 (5.1)	19.4 (5.0)				
HADS-depression	MBCT	8.2 (3.8)	5.6 (4.0)	5.2 (3.6)	-2.89	.004	0.51	
	TAU	9.2 (3.9)	8.6 (4.7)	8.2 (4.5)				
POMS-depression	MBCT	25.3 (5.8)	21.4 (4.5)	21.8 (4.7)	-2.41	.016	0.48	
	TAU	26.7 (6.3)	26.2 (7.0)	25.7 (7.3)				
Diabetes distress	MBCT	35.5 (17.8)	28.7 (21.0)	25.0 (19.7)	-2.12	.034	0.41	
	TAU	36.6 (18.9)	33.5 (22.0)	32.8 (20.1)				
<i>Secondary outcomes</i>								
HbA <sub>1c</sub>	mmol/mol	MBCT	59.0 (12.6)	59.3 (12.1)	59.2 (11.7)	-0.23	.816	0.06
		TAU	59.2 (13.0)	61.7 (16.4)	60.6 (16.2)			
	%	MBCT	7.5 (1.2)	7.5 (1.1)	7.6 (1.1)			
		TAU	7.6 (1.2)	7.9 (1.5)	7.7 (1.5)			
Mental health status	MBCT	32.8 (11.0)	41.1 (10.7)	42.5 (10.3)	4.24	<.001	0.77	
	TAU	31.7 (11.6)	35.0 (12.5)	33.9 (11.7)				
Physical health status	MBCT	39.4 (9.9)	40.7 (10.5)	40.4 (10.8)	2.12	.034	0.40	
	TAU	37.4 (11.4)	36.6 (11.7)	35.6 (13.0)				
Mindfulness	MBCT	96.2 (13.8)	104.6 (17.0)	108.2 (15.7)	3.46	.001	0.64	
	TAU	94.3 (12.4)	96.6 (14.1)	98.1 (13.5)				
Diabetes acceptance	MBCT	58.4 (8.6)	60.3 (8.3)	60.6 (8.5)	1.62	.105	0.32	
	TAU	58.2 (7.2)	58.7 (7.5)	58.2 (7.1)				
Self-esteem	MBCT	18.6 (5.4)	21.4 (5.3)	20.9 (5.7)	0.53	.597	0.11	
	TAU	15.9 (5.4)	17.4 (5.4)	17.7 (6.0)				

MBCT – mindfulness-based cognitive therapy group; TAU – waiting list (usual care) control group.

<sup>a</sup> The effect size (Cohen's *d*) was calculated on pre to six month follow-up intervention change scores.

general, the treatment goal is  $\leq 53$ , while in more complex diabetes it is  $\leq 64$  [28]) [10], the non-significant findings could be caused by floor effects. Future research on the effect of MBCT on diabetes distress and HbA<sub>1c</sub> should focus on people with poor glycaemic control and elevated diabetes distress at baseline.

The follow-up results of the present study are encouraging. The MBCT group maintained their gains over a period of six months with no to minimal further intervention (only 30% of the MBCT participants attended the booster session three months after the intervention), which corresponds with most of the few studies that have examined longer-term effectiveness of mindfulness-based intervention in medical patients [12,13,15]. In addition, the results are similar to the results of the few studies on long-term effectiveness of cognitive (behavioral) therapy on depressive symptoms [29], but more research is needed.

This study had several limitations. First, we had no data on (the quality/quantity of) home mindfulness practice after the intervention. Therefore, we could not distinguish the effect in the group who continued mindfulness practice after the intervention and the group who did not. Second, there was a considerable drop-out rate in the MBCT group. Around a quarter of the participants ( $n = 18$ ) stopped with the program, which however is in line with previous studies in somatic patient groups [11,30]. Third, we had no a priori plan for statistical adjustment considering the multiple primary outcomes, and finally, the use of a waiting list control group may have overestimated effect sizes due to the inclusion of non-specific treatment effects in the relative improvement of the MBCT group.

In conclusion, the current study showed sustained effectiveness of MBCT in reducing emotional distress for participants with diabetes and a lowered level of emotional well-being. Because emotional distress is related to poor diabetic outcome, MBCT might be an important additional strategy in adequately treating people with diabetes.

### Competing interest statement

The authors have no competing interests to report. It may be noted that the second author (IN) also works as mindfulness teacher for people from the general population at Aandachtcentrum Dit Moment, a private mindfulness practice in Tilburg, Netherlands.

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