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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_{1c}. 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_{1c}).
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_{1c}.
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.

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[a]
Mean age, years (SD)	56 (13)	57 (13)	.62
Male, n (%)	33 (47)	37 (54)	.45
High education[b], 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.
[a] Chi-square for nominal variables and *t*-test for continuous variables.
[b] 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_{1c} 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

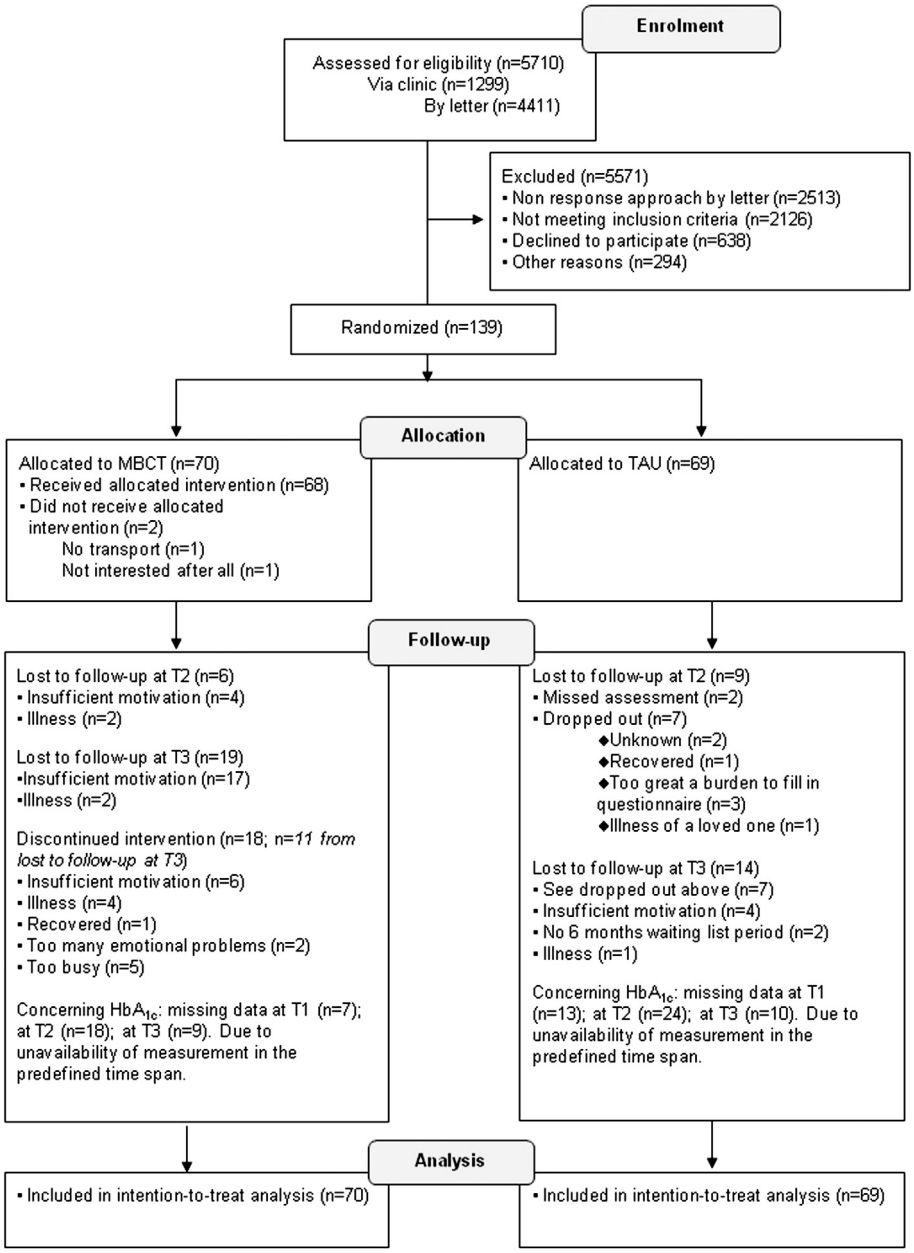

Fig. 1. Flow diagram of patient enrolment, allocation, and attrition. MBCT — mindfulness-based cognitive therapy intervention group; TAU — waiting list (usual care) control group. T1 — baseline assessment; T2 — post intervention assessment; T3 — six months follow-up assessment. The *lost to follow-up*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

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