Acceptance or challenge?
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CHAPTER 3

Individual Mindfulness-Based Cognitive Therapy for people with diabetes: A pilot randomized controlled trial

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Mindfulness, 2013
Abstract

Diabetes mellitus is a highly prevalent chronic health condition that places patients at greater risk for psychological problems. Yet, there is still a lack of empirical evidence to support the use of psychological interventions in patients with diabetes. In this trial, we examined the feasibility of a novel intervention: individual mindfulness-based cognitive therapy (I-MBCT), an adaptation of the well-known group MBCT. We examined the feasibility of screening, recruiting, randomizing, and retaining patients into the study and their acceptability of I-MBCT. Descriptive analyses were performed to explore changes in patients’ functioning over time, comparing those receiving I-MBCT with those in the waitlist control group. A sample of consecutive patients with diabetes was screened on psychological symptoms and when reporting elevated levels of symptoms, approached for the intervention trial. Patients completed self-report questionnaires pre- and post-intervention regarding psychological functioning (i.e., depressive symptoms, diabetes-related distress), mindfulness (i.e., act with awareness, accept without judgment), and attention regulation. In total, 499 patients were approached, of whom 347 patients filled out the screening questionnaire. Of these, 38 patients were eligible, and 24 were randomized in I-MBCT (n = 12) or waitlist (n = 12). Two of the 12 patients assigned to I-MBCT dropped out of the intervention. Most patients were very satisfied with I-MBCT. Preliminary analyses suggest that, compared to controls, patients receiving I-MBCT reported significant reductions in depressive symptoms and diabetes-related distress and improvements in act with awareness and attention regulation. This is the first RCT on individual-based MBCT, providing encouraging evidence for its feasibility and acceptability. Preliminary findings also suggest that I-MBCT may be associated with improvements in psychological functioning, which support larger trials on this alternative form of mindfulness-based therapy.
Introduction

Diabetes mellitus (diabetes) is a highly prevalent chronic health condition, with an estimated 19 million persons in the US diagnosed with diabetes in 2010 (Centers for Disease Control and Prevention (CDC), 2011). Diabetes may put a considerable burden on patients. Patients with diabetes have an increased risk for heart disease and stroke, and are also at risk of other complications such as loss of vision, kidney failure, nervous system damage, and amputations. Effective control of glucose can prevent or delay these complications. It is therefore of utter importance that patients follow a strict treatment regimen and guidelines regarding daily diet and exercise.

Research has found that patients with diabetes have an increased risk for developing psychological problems, especially diabetes-related distress and depression (Rustad et al., 2011). About 20-30% of patients with diabetes experience comorbid depression (Anderson et al., 2001). As such symptoms may negatively affect patients’ quality of life and adherence to treatment and increase the risk for long-term complications (Lin et al., 2004; Lustman et al., 2000); the development and testing of effective treatment to reduce psychological symptoms is imperative.

A recent meta-analysis concluded that psychological interventions are moderately effective in reducing depressive symptoms in patients with diabetes, even more than pharmacological treatment (van der Feltz-Cornelis et al., 2010). Yet, little is known about which types of psychological interventions are effective. In the general population of medically ill patients, interventions based on cognitive behavioral therapy (CBT) have yielded significant improvements in psychological symptoms, especially when individually delivered (Beltman et al., 2010). Also in patients with diabetes, there is some evidence suggesting the beneficial effect of individual CBT on patients’ psychological functioning (Lamers et al., 2011; Lustman, Griffith et al., 1998).

In recent years, there is an increased interest in the interventions integrating CBT with mindfulness. Mindfulness-based cognitive therapy (MBCT) aims to improve psychological well-being by cultivating mindfulness (Segal et al., 2002; Williams, 2008). Mindfulness can be defined as paying attention, on purpose, in the present moment, and nonjudgmentally (Kabat-Zinn, 2003). People are taught to become more attentive and aware of current experiences (e.g., sensations or emotions) and automatic reactions (e.g., rumination) and to develop a more accepting attitude towards them. Recent reviews have demonstrated the effectiveness of mindfulness-based interventions in reducing psychological symptoms in a wide range of populations, including healthy persons, those with anxiety or depressive disorders or other psychiatric conditions, or with a chronic medical condition (Chiesa & Serretti, 2009;
Hofmann et al., 2010; Ledesma & Kumano, 2009). Specifically in patients with diabetes, two recent randomized controlled trials (RCTs) found that patients receiving a mindfulness-based intervention reported reduced psychological symptoms, in terms of depression, stress, and anxiety, until one year follow-up (Hartmann et al., 2012; van Son et al., 2013).

Mindfulness-based interventions are standardly delivered in a group setting (see studies included in reviews described above). During the group sessions, participants practice mindfulness exercises and share their experiences with the exercises with the other group members (in the so-called enquiry). During enquiry, the therapist may deepen participants’ skills of mindfulness by asking explorative questions and embodying a mindfulness presence, conveying acceptance, curiosity, patience, and compassion (Crane, 2009). It has been found that hearing the experiences from others in MBCT group sessions may support and normalize own personal experiences (Griffiths et al., 2009).

However, research has demonstrated that some participants in mindfulness-based group interventions found group sharing frustrating and not beneficial (Griffiths et al., 2009). A recent study that examined people’s preferences for different types of delivery of MBCT found that a significant group of people prefers individual rather than group delivery of MBCT (Lau et al., 2012). In practice, it may also not always be possible to participate in or offer a group program. It therefore makes sense that in clinical practice, mindfulness-based interventions are currently also individually delivered, despite the lack of empirical evidence to support this. In order to fill this gap and to evaluate individual mindfulness-based interventions, we undertook the challenge to adapt the standardized treatment protocol of group MBCT for individual therapy (I-MBCT) and to evaluate its feasibility and acceptability.

Individual MBCT may be a valuable alternative approach for treating psychological symptoms. A key argument for its feasibility is that the core elements of group MBCT (i.e., cultivation of mindfulness by practicing exercises and enquiry) can also be done on an individual basis. In terms of its added value to existing techniques (often CBT based), I-MBCT puts greater emphasis on bodily awareness and bodily acceptance as well as on the awareness and acknowledgment of negative thoughts (rather than critically challenging them and analyzing their evidence). Studies on the effectiveness of mindfulness-based group interventions have demonstrated that this alternative approach of managing distressing thoughts and emotions is effective.

In sum, given that the previous studies have primarily examined mindfulness-based interventions taught in group settings, our aim was to extend the current literature on
the use of MBCT by examining its application within an individual therapy setting. The study was performed in patients with diabetes, as mindfulness-based approaches have been found particularly acceptable and useful for people with a chronic medical condition (Foley et al., 2010; Grossman et al., 2007; Grossman et al., 2010). The trial was conducted in patients with diabetes with elevated levels of psychological symptoms. Hereby, the study is in line with current scientific recommendations, advocating to only include patients with elevated levels of psychological symptoms and to exclude patients not experiencing psychological symptoms, as they may strongly suppress study outcomes (see Schneider et al., 2010).

As far as we know, this is the first randomized trial on individual MBCT. We aimed to examine the feasibility and acceptability of I-MBCT in patients with diabetes in order to inform us on the feasibility of designing a larger efficacy trial. More specifically, we examined the feasibility of screening, recruiting, randomizing, and retaining patients into the I-MBCT study and patients’ acceptability in terms of their post-intervention evaluation. Although preliminary, we were also interested to see whether I-MBCT would be associated with decreases in depressive symptoms and diabetes-related distress and increases in mindfulness and attention regulation.

**Method**

**Design**

We conducted a randomized controlled trial with two conditions as follows: individual MBCT (= active treatment group) and a waitlist control group (= offered individual MBCT after the waiting period).

**Participants**

Patients with diabetes were recruited through the diabetes outpatient clinic of the University Medical Center Groningen (UMCG), the Netherlands. We used a consecutive sampling technique. In contrast to convenience sampling based on patients’ self-referral or health care professionals’ referral, we approached all eligible patients with diabetes visiting the clinic in a certain period for screening and study recruitment (see Fleer et al., 2013, for study details). For determining initial eligibility, the patients’ medical files were reviewed, and only those fulfilling the following criteria were approached for screening: a diagnosis of diabetes, age between 18 and 70 years old, absence of serious psychiatric problems (e.g., schizophrenia, autism), absence of severe visual problems, being able to read and/or write Dutch, and not pregnant.
Procedures

The study was approved by the UMCG medical ethics committee.

Recruitment

Potentially eligible patients (based on the criteria above) received a letter two weeks prior to the appointment with their medical specialist, inviting them to complete a screening questionnaire, consisting of the Center for Epidemiologic Studies Depression Scale (CES-D), the problem areas in diabetes (PAID) and basic demographic and clinical information (see measures for more information). Patients were screened in the period between March 16 - April 3, 2009 and May 4 - June 12, 2009 (9 weeks in total). This fixed period was set ahead of time in order to meet the overall project planning and available financial means. Based on the number of patients with diabetes being treated in our hospital, we expected to screen 350 patients. Based on previous studies indicating that about 20-30% of patients with diabetes experience elevated levels of psychological symptoms (Anderson et al., 2001), we expected that of these 350 patients, at least 60 patients would be eligible and having elevated levels of psychological symptoms.

Participant recruitment and flow throughout the study is presented in Figure 1. In total, 499 patients fulfilled our initial eligibility requirements and were approached for the study by screening, with 347 patients (70% of 499) returning the screening questionnaire. Of these 347 patients, 104 patients (30%) experienced elevated levels of depressive symptoms and/or diabetes-related distress (= CES-D ≥ 16 and/or PAID ≥ 40, required for study inclusion). Of these 104 patients, 70 patients (67.3%) were identified as at risk for a clinical depression (CES-D ≥ 16), 28 patients (26.9%) were identified as at risk for both a clinical depression and high diabetes-related distress (CES-D ≥ 16 and PAID ≥ 40), and six patients (5.8%) were identified as at risk for high diabetes-related distress (PAID ≥ 40). These patients were further screened for study eligibility via an interview at the hospital. A psychologist called these patients to invite them for the interview. In total, 45 patients (43% of 104) accepted the invitation.

During the interview, patients’ problems and need for support were explored. A short standardized psychiatric interview was used to further screen out serious psychopathology (exclusion criterion) and to observe for insufficient understanding of the Dutch language (exclusion criterion). We also checked whether patients were already receiving sufficient psychological care (exclusion criterion).
Of the 45 patients interviewed, seven patients (16%) were identified as not eligible (five had serious psychopathology, two were already receiving sufficient psychological services). The remaining 38 patients (84% of 45, 8% of 499) were eligible. Five of these eligible patients were not offered I-MBCT: two patients clearly indicated that they currently had no distress and no need for help, two patients wanted somatic oriented help and were referred to a diabetes nurse and rehabilitation center respectively, and one patient indicated existential problems for which the patient wanted psychotherapy. Thus, 33 eligible patients were invited to enroll in the study and receive I-MBCT. Of these 33 patients, eight patients declined participation (four patients had currently no time/interest in therapy, two patients were interested yet unable to participate due to the distance to the hospital, and two patients explicitly stated no interest in the mindfulness approach). The 25 patients being interested were
given written information about the study trial, informed consent, and the baseline questionnaires T1 (including measures of psychological functioning, mindfulness, and attention regulation). All but one patient gave consent and filled out the baseline questionnaires. These 24 patients who gave consent were randomly assigned to I-MBCT (n = 12) or waitlist control group (n = 12). Random selection of the patients was performed using a computerized program, with stratification on baseline levels of depressive symptoms, diabetes-related distress, and gender. After randomization, patients were notified by a telephone call about the condition (i.e., I-MBCT or waitlist-control group). Those in the I-MBCT group were directly offered I-MBCT, and those patients in the control group were offered I-MBCT after filling out the T2 questionnaire, with 11 of the 12 patients starting I-MBCT after the wait period of 3 months. One patient in the waitlist group could not start because she was recovering from a shoulder injury.

Sequence of procedures
All 24 patients in the trial filled out the baseline questionnaire (T1). For patients randomized into I-MBCT, this pre-intervention assessment T1 was 2 to 3 weeks prior to the start of I-MBCT. They then started the 8-week intervention and completed a second assessment within 2 weeks after finishing the intervention (post-intervention assessment T2), and again 3 months after finishing the intervention (follow-up assessment T3). The participants in the waitlist control group also filled out the baseline questionnaire (T1) and a second assessment 12 weeks after T1 (assessment T2). Thus, T1 and T2 in the control group are comparable regarding time frame to T1 and T2 in the I-MBCT group.

Intervention
The intervention was based on the standardized and well-described 8-week MBCT group protocol as developed by Segal, Teasdale, and Williams (2002). For the current intervention, some modifications were made from the original MBCT program (see Table 1 for an overview of the eight sessions) (Schroevers & Fleer, 2009). First, the group program consisting of eight weekly sessions of 120-150 min was adapted to eight weekly individual sessions of 60 min. As a consequence, we had to shorten the duration of the exercises within the sessions and also decided to remove two exercises from the group program as follows: the cognitive exercise in session 2 and relapse prevention within session 7. Second, regarding sessions 4 and 5 of I-MBCT, the psycho-educational component was focused on a broader range of stress- and depression-related symptoms, rather than specific depression symptoms only as in group MBCT.
Moreover, instead of watching the video “Healing from within”, we introduced the reaction-response model from mindfulness-based stress reduction (Kabat-Zinn, 1990) in week 5, as the model elegantly fits with the MBCT theme of this session (“acknowledge, accept”).

We have written an extensive treatment manual, including a detailed session-by-session description, transcripts of all exercises, and descriptions of how to perform the enquiry. Five therapists conducted I-MBCT for this study. All therapists had a degree in clinical psychology, experience in delivering psychological treatment, and experience with the MBCT group program. Before delivering the I-MBCT, they received a 3-days training by an experienced qualified mindfulness therapist.

During the first session, the participants received an informational booklet and CDs with guided exercises. The CDs were based on the Dutch version of the guided exercises that accompanied Segal et al. (2002) and lasted about 30 min each. As in the group program, participants were asked to practice every day, at least 30 min, the guided mindfulness exercises on the CD, together with informal exercises such as mindful eating.

Measures
Patients filled out two different types of questionnaires. First, we used a short screening questionnaire, including two measures of psychological functioning and basic demographic and clinical information. Patients giving consent for participation in the intervention trial filled out additional questionnaires (see “sequence of procedures”), including again the two measures of psychological functioning (same as in the screening questionnaire) and measures of mindfulness and attention regulation. The post-intervention assessment of the I-MBCT participants also included an evaluation of the intervention.
### Table 1

**Individual Mindfulness-Based Cognitive Therapy program**

<table>
<thead>
<tr>
<th>Session</th>
<th>Within session program</th>
<th>Homework</th>
</tr>
</thead>
</table>
| **Session 1** | Introduction  
Bodyscan and enquiry  
Raisin exercise and enquiry  
Setting homework and providing materials | Daily bodyscan  
Daily mindful eating exercise  
Daily routine activity with awareness |
| **Session 2** | Bodyscan and enquiry  
Homework enquiry  
Short sitting meditation on breath and enquiry  
Setting homework | Bodyscan, 3 days a week*  
Short sitting meditation on breath, 3 days a week*  
Daily routine activity with awareness  
Daily pleasant event calendar |
| **Session 3** | Sitting meditation on breath and body and enquiry  
Homework enquiry  
Mindful yoga and enquiry  
Three-minute breathing space and enquiry  
Setting homework | Yoga, 3 days a week  
Sitting meditation on breath and body, 3 days a week  
Daily unpleasant event calendar  
Three-minute breathing space, 3 times a day |
| **Session 4** | Full sitting meditation and enquiry  
Homework enquiry  
Psycho-education on stress/depressive symptoms  
Mindful yoga  
Setting homework | Yoga, 3 days a week*  
Full sitting meditation, 3 days a week  
Awareness stress/depressive symptoms  
Three-minute breathing space, 3 times a day |
| **Session 5** | Full sitting meditation and enquiry  
Homework enquiry  
Psycho-education on automatic reaction versus response  
Walking meditation*  
Setting homework | Mindful walking, 3 days a week*  
Full sitting meditation, 3 days a week*  
Awareness reaction versus response  
Three-minute breathing space, 3 times a day |
| **Session 6** | Full sitting meditation and enquiry  
Homework enquiry  
Cognitive thought exercise  
Three-minute breathing space  
Setting homework | Own program for 30 minutes daily exercise  
Awareness thought patterns  
Three-minute breathing space, 3 times a day |
| **Session 7** | Full sitting meditation and enquiry  
Homework enquiry  
Activity-mood exercise  
Three-minute breathing space including taking mindful action  
Setting homework | Own program for exercise  
Awareness of activities that deplete or give energy  
List 15 pleasant activities  
Three-minute breathing space, 3 times a day |
| **Session 8** | Bodyscan and enquiry  
Homework enquiry  
Evaluation of I-MBCT |  |

*In week 2 of group MBCT, homework is daily bodyscan and daily short sitting meditation. In week 4 of group MBCT, homework is bodyscan instead of yoga. In week 5, we added walking meditation to the session and homework, whereas in group MBCT this walking exercise is planned during session 3 and homework is daily sitting meditation.*
**Psychological functioning**

Participants’ psychological functioning was measured by assessing depressive symptoms and diabetes-related distress as follows:

Depressive symptoms were assessed by the CES-D (Radloff, 1977), which consists of 20 items that can be scored on a four-point scale, ranging from 0 (rarely/none of the time) to 3 (most or all of the time). The CES-D is one of the most common questionnaires to determine the occurrence of depressive symptoms in the past week. Example items are as follows: “I felt depressed” and “I thought my life had been a failure”. A total sum-score is used (0-60), with higher scores indicating more depressive symptoms. A cutoff point of $\geq 16$ is used to define patients at risk for a clinical depression. The internal consistency of the CES-D (as measured by Cronbach’s alpha) is generally high across a variety of populations. Also, good convergent and discriminant validity have been reported (Radloff, 1977). The CES-D has been found to be sensitive to changes in depressive symptoms over time (Diehl et al., 2006). The CES-D has shown good sensitivity to measure depressive symptoms in patients with diabetes (Hermanns et al., 2006). The internal consistency of the CES-D in the current study was good ($\alpha = 0.85$).

The PAID (Polonsky et al., 1995) was used to assess diabetes-related distress. The questionnaire consists of 20 items that can be scored on a five-point scale, ranging from 0 (not a problem) to 4 (serious problem). Example items are as follows: “feeling overwhelmed by your diabetes” and “worrying about the future and the possibility of serious complications”. The sum of the 20 items is multiplied by 1.25 to yield a final score of 0-100, with higher scores indicating more diabetes-related distress. A cut-off point of $\geq 40$ is used to define patients at risk for high diabetes-related distress. It has been reported that the PAID has high internal consistency, good construct validity, and is sensitive to changes over time (Welch et al., 1997; Welch et al., 2003). The PAID has shown good sensitivity to measure diabetes-related distress in patients with diabetes (Hermanns et al., 2006). Reliability in the current study was good ($\alpha = 0.91$).

**Mindfulness and attention regulation**

Mindfulness was assessed by the five-factor mindfulness questionnaire (FFMQ), which is one of the most widely used mindfulness questionnaires (Baer et al., 2006; Veehof et al., 2011). For the current study, the following two subscales were used, based on their predictive value in the prediction of psychological symptoms: act with awareness and accept without judgment (Baer et al., 2006; Baer et al., 2008). The act with awareness subscale focuses on attention and awareness and consists of eight items (e.g., “I do not pay attention to what I am doing because I am daydreaming, worrying, or otherwise
The subscale, accept without judgment, focuses on a non-judgmental attitude of acceptance. Accept without judgment was assessed by a four-item short form (e.g., “I criticize myself for having irrational or inappropriate emotions”). For both subscales, each item is scored on a five-point scale, ranging from 1 (never or very rarely true) to 5 (almost always or always true). For both subscales, the sum score is used, with higher scores indicating more act with awareness and more accept without judgment, respectively. Adequate reliability, convergent, and discriminant validity have been reported (Baer et al., 2006; Baer et al., 2008). The FFMQ has been found to be sensitive to change (Bohlmeijer et al., 2011; Carmody & Baer, 2008). Cronbach’s alphas in this study were also adequate ($\alpha = 0.89$ for act with awareness; $\alpha = 0.75$ for accept without judgment).

As attention is an important aspect of mindfulness and the FFMQ act with awareness subscale assesses attention and awareness with negatively formulated items (thus indicating levels of mindlessness), we also included a measure of attention that is more positively formulated. The self-regulation scale (SRS) (Brown et al., 1999; Diehl et al., 2006) aims to assess the ability to focus attention on the tasks at hand and to keep a favorable emotional balance (e.g., “If I am distracted from an activity, I do not have any problem coming back to the topic quickly”). The ten items can be scored on a scale from 1 (not at all true) to 4 (exactly true). A total score is used (10-40), with higher scores indicating higher levels of attention regulation. Good internal consistency and criterion validity have been found (Diehl et al., 2006). Test-retest reliability shows that the scale is sensitive to change over time. In this study, the scale’s reliability was good ($\alpha = 0.82$).

Evaluation
During the post-intervention assessment, patients in I-MBCT also answered several self-developed multiple choice questions about the program regarding their evaluation of the duration and number of sessions, the usefulness of the different exercises (i.e., bodyscan, sitting meditation, yoga, 3-min breathing space, walking meditation, and informal daily exercises), the amount of homework exercises, how many days a week and how long each time they actually practiced, their satisfaction with the manner of the therapist giving the intervention, and their overall satisfaction with the program. Using an open-ended question, patients could also indicate whether they had missed anything during the intervention sessions.
Statistical Analyses

Descriptive statistics were performed to describe the study sample and study variables measured. We examined if there were significant differences between the intervention and the control group regarding background characteristics, using chi-square, t-tests, and analysis of variance.

Next, repeated measures ANOVAs were performed to test the effects of the I-MBCT intervention. For these analyses, we used the data collected at T1-T3 (the screening data was not used for this purpose). In order to avoid an overestimation of the effects, all analyses were according to the more conservative intention-to-treat approach, hereby including all 24 patients that were randomly assigned to I-MBCT or waitlist. Missing values were imputed for two participants who dropped out of the intervention, using last-observed response carried forward (Unnebrink & Windeler, 2001). Results from the intention-to-treat analyses were not significantly different from completer analyses, and therefore, we present the results of the intention-to-treat analyses. Separate repeated measures ANOVAs were performed for each study variable (i.e., depressive symptoms, diabetes-related distress, the two facets of mindfulness, and attention regulation), with a grouping factor (intervention versus control) and two repeated measures (two time points) for change from pre-intervention to post-intervention (T1-T2). Additional paired and independent post-hoc t-tests were performed to examine within-group and between-group differences. Paired tests were used to examine changes in study variables between post-intervention and follow-up (T2-T3).

Effect size estimates (Cohen’s d) were obtained by comparing post-intervention means and standard deviations of I-MBCT and control group, on depressive symptoms, diabetes-related distress, mindfulness, and attention regulation (using the standard formula \( d = \frac{M_1 - M_2}{s_{pooled}} \) (Rosnow & Rosenthal, 1996). Effect sizes are reported as positive in sign, if in the direction of improvement and negative, if in the direction of deterioration.

Results

Feasibility of screening, recruiting, randomizing, and retaining patients

As illustrated in Figure 1, of the 499 patients approached for the study by screening on psychological symptoms, 38 patients were eligible (representing 37% of 104 patients with elevated levels of psychological symptoms, 8% of all 499 patients approached) (see Methods for further details). Only 24 eligible patients were enrolled and randomized (63% of 38 eligible patients, 23% of 104 patients with elevated levels of
symptoms, 5% of the 499 patients approached). This sample size was much smaller than the original estimate of at least 60 patients. Reasons of the 14 eligible patients not being randomized in the I-MBCT intervention study were in most cases not directly related to the content of the intervention (i.e., mindfulness-based). Main reasons were no need for psychological assistance and a need for other types of professional support (e.g., more somatically oriented).

Ten (83%) of the 12 patients randomized to I-MBCT successfully finished the 8-week intervention. The other 2 patients dropped out of the intervention after two and three sessions, respectively, and did not complete follow-up. They said that they did not experience sufficient benefit from the intervention.

Baseline demographic and clinical characteristics

Table 2 presents baseline demographic and clinical characteristics of the 24 patients enrolled in the study. There were no significant differences between the I-MBCT and the waitlist control group in age, gender, marital status, education, type 1 or 2 diabetes, time since diagnosis, Hb1Ac, BMI, and number of comorbid illnesses. Mean age of patients was about 55 years old, patients were slightly more often male than female, with the majority having a partner (significant other) and being higher educated (i.e., having >10 years of education). Mean duration of diabetes was between 17-20 years. On average, patients were obese, and two-thirds of the patients had one or more comorbid medical conditions.

Table 2

<table>
<thead>
<tr>
<th></th>
<th>I-MBCT (n = 12)</th>
<th>Waitlist-control (n = 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age in years (SD)</td>
<td>54.9 (10.3)</td>
<td>55.9 (8.2)</td>
</tr>
<tr>
<td>Gender (% male)</td>
<td>58% (n = 7)</td>
<td>58% (n = 7)</td>
</tr>
<tr>
<td>Marital status (% partner)</td>
<td>92% (n = 11)</td>
<td>75% (n = 9)</td>
</tr>
<tr>
<td>Education (% &gt; 10 years education)</td>
<td>83% (n = 10)</td>
<td>67% (n = 8)</td>
</tr>
<tr>
<td>Type diabetes (% type 2)</td>
<td>67% (n = 8)</td>
<td>42% (n = 5)</td>
</tr>
<tr>
<td>Mean duration of diabetes in years (SD)</td>
<td>16.6 (14.4)</td>
<td>20.5 (13.7)</td>
</tr>
<tr>
<td>Mean HbA1c (SD)</td>
<td>8.2 (1.2)</td>
<td>8.1 (1.5)</td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>32.1 (5.2)</td>
<td>29.9 (6.3)</td>
</tr>
<tr>
<td>Presence of comorbid medical conditions other than diabetes (% one or more conditions)</td>
<td>67% (n = 8)</td>
<td>67% (n = 8)</td>
</tr>
</tbody>
</table>

Note. No significant differences in demographic and clinical characteristics were found between the two groups.
As we had expected a greater percentage of patients with an elevated level of psychological symptoms (as indicated by the CES-D and/or PAID) to be interested in enrollment and receiving a psychological intervention, we checked for possible differences between the 24 randomized patients with elevated levels of psychological symptoms and the 80 nonrandomized patients with elevated levels of psychological symptoms. There were no significant differences among these two groups, neither with respect to their demographic and clinical characteristics, nor regarding their levels of depressive symptoms and diabetes-related distress at the time of screening.

Acceptability

Of the ten patients completing I-MBCT, nine patients filled out an evaluation of I-MBCT, which was part of the post-intervention assessment.

Regarding the duration of 60 min and the total number of I-MBCT sessions, eight patients reported that the duration was sufficient (for one patient 60 min was too short) and seven patients indicated that the total number of sessions was good (for two patients this was too few).

Regarding the type of exercises, patients valued most of the formal exercises (i.e., the bodyscan, the 3-min breathing space, and the sitting meditation) and informal exercises (i.e., attention for daily routine activities). Yoga and walking exercises were evaluated as less useful.

Regarding homework, seven patients evaluated the amount of daily homework (i.e., 30 min or more) as sufficient (for two patients, this was too much). Regarding their actual practice during the 8-week program, five patients indicated that they in general practiced 6-7 days a week, two patients 4 to 5 days per week, and the two other patients 3 days a week or less. On average, four patients practiced 30 min or more each time and five patients between 15 to 30 min.

All nine patients were very satisfied with the contact with the therapist. Overall, seven of nine patients were very satisfied with the I-MBCT. Two patients indicated that they would have liked more time and attention for diabetes-related issues. No other issues that were missed in I-MBCT were reported.

Changes in psychological functioning, mindfulness, and attention regulation

Table 3 shows the pre- and post-intervention means and standard deviations on all study variables for both the I-MBCT and waitlist control group. There were no
significant pre-intervention differences between the two groups on any of these variables (p > 0.05).

Table 3

<table>
<thead>
<tr>
<th>Condition</th>
<th>T1 Pre-intervention</th>
<th>T2 Post-intervention</th>
<th>T3 Follow-up</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depressive symptoms (CES-D)</td>
<td>I-MBCT 22.9 (8.0)</td>
<td>14.4 (7.5)*#</td>
<td>16.2 (8.2)</td>
<td>p = 0.002</td>
</tr>
<tr>
<td></td>
<td>Waitlist 20.2 (8.7)</td>
<td>23.6 (7.4)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes-related distress (PAID)</td>
<td>I-MBCT 41.6 (15.2)</td>
<td>19.3 (14.3)*#</td>
<td>23.1 (15.2)</td>
<td>p = 0.004</td>
</tr>
<tr>
<td></td>
<td>Waitlist 39.0 (16.8)</td>
<td>35.8 (16.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mindfulness:</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Act with awareness (FFMQ)</td>
<td>I-MBCT 21.2 (6.0)</td>
<td>25.9 (5.9)*</td>
<td>27.3 (6.9)</td>
<td>p = 0.049</td>
</tr>
<tr>
<td></td>
<td>Waitlist 22.3 (4.8)</td>
<td>22.6 (4.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accept without judgment (FFMQ)</td>
<td>I-MBCT 11.3 (2.8)</td>
<td>12.3 (3.1)</td>
<td>13.5 (3.6)</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td></td>
<td>Waitlist 11.9 (2.7)</td>
<td>12.3 (2.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attention regulation (SRS)</td>
<td>I-MBCT 22.7 (4.9)</td>
<td>27.8 (7.5)*#</td>
<td>28.1 (5.9)</td>
<td>p = 0.049</td>
</tr>
<tr>
<td></td>
<td>Waitlist 20.9 (5.4)</td>
<td>21.5 (5.9)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes. * indicates a significant within-group change between T1-T2. # indicates a significant between-group difference between I-MBCT group and waitlist control group at T2 (post-intervention).

For depressive symptoms, we found a significant two-way time x condition (I-MBCT versus waitlist) interaction, F (1, 22)= 12.95, p = 0.002. Post-hoc analyses indicated that patients receiving I-MBCT showed reduced depressive symptoms from pre-intervention to post-intervention, t(11) = 2.84, p = 0.016. In contrast, patients in the waitlist control group reported a significant increase in depressive symptoms in the same time period, t(11) = -2.42, p = 0.034. At post-intervention, the I-MBCT group reported significantly less depressive symptoms than the waitlist control group, t(22) = -3.00, p = 0.007, with a large effect size (d = 1.23). From post-intervention to 3 months follow-up, the I-MBCT group did not show significant changes in depressive symptoms (p > 0.05), which represents sustained improvement in depressive symptoms over time.

For diabetes-related distress, we also found a significant two-way time x condition (I-MBCT versus waitlist) interaction, F (1, 22)= 10.21, p = 0.004. Post-hoc comparisons indicated that patients receiving I-MBCT showed reduced levels of distress from pre-intervention to post-intervention t(11) = 4.03, p = 0.002, while patients in the waitlist control group showed no significant changes in distress over time (p > 0.05). At post-intervention, the I-MBCT group reported significantly less diabetes-related distress
than the waitlist control group, \( t(22) = -2.64, p = 0.015 \), with a large effect size \( (d = 1.08) \). From post-intervention to 3 months follow-up, the I-MBCT group did not show significant changes in their level of distress \( (p > 0.05) \), which represents sustained improvement in diabetes-related distress over time.

Regarding mindfulness, we found no significant time effect, nor a significant two-way time x condition (I-MBCT versus waitlist) interaction for accept without judgment \( (p > 0.05) \). However, we found a significant two-way time x condition (I-MBCT versus waitlist) interaction for act with awareness, \( F(1, 22) = 4.34, p = 0.049 \). Post-hoc comparisons indicated that patients receiving I-MBCT showed a significant increase in act with awareness from pre-intervention to post-intervention, \( t(11) = -2.60, p = 0.025 \), while the patients in the waitlist control group reported no significant change \( (p > 0.05) \). Yet, this significant improvement in the I-MBCT group did not result in a significant difference between both groups in the post-intervention level of act with awareness \( (p > 0.05, d = 0.63) \). From post-intervention to 3 months follow-up, the I-MBCT group did not show significant changes in mindfulness, neither in act with awareness nor in accept without judgment \( (p > 0.05) \), which represents sustained levels of mindfulness over time.

We also found a significant two-way time x condition (I-MBCT versus waitlist) interaction for attention regulation, \( F(1, 22) = 4.36, p = 0.049 \). Post-hoc comparisons indicated that patients receiving I-MBCT showed increased levels of attention regulation from pre-intervention to post-intervention, \( t(11) = -2.55, p = 0.027 \), while those patients in the waitlist control group showed no significant changes in attention regulation over time \( (p > 0.05) \). These within-group differences resulted in a significant difference between the two groups in the post-intervention level of attention regulation, with the I-MBCT group being significantly better in attention regulation than the waitlist control group, \( t(22) = 2.30, p = 0.031 \), with a large effect size \( (d = 0.93) \). From post-intervention to follow-up, the I-MBCT group did not show significant changes in their level of attention regulation \( (p > 0.05) \), which represents sustained improvement in attention regulation over time.

**Discussion**

Mindfulness-based cognitive therapy (MBCT) is increasingly being used as a psychological treatment of a wide variety of symptoms. We set out with the goal to examine the possibility of offering MBCT individually (I-MBCT) rather than in the original group format. We used screening to recruit a consecutive sample of patients with diabetes with elevated levels of psychological symptoms. We tested the feasibility
of screening, recruiting, randomizing, and retaining patients into the I-MBCT study as well as the acceptability in terms of patients’ post-intervention evaluation. The main findings are that it turned out to be feasible to randomize and retain patients into this trial on I-MBCT and that their acceptability was high. The efficiency of using screening to recruit patients for the trial can, however, be questioned.

As others (e.g., Anderson et al., 2001), we found that about one-third of all screened patients reported elevated levels of psychological symptoms. Yet only about a quarter of these patients with elevated levels of psychological symptoms (representing two-thirds of all eligible patients and 5% of all patients approached) appeared to be interested and accepted participation in the I-MBCT trial. Such results raise doubts about the extent to which psychological screening is an efficient way to identify patients with diabetes with heightened psychological distress and an addressable unmet need for psychological support (for more elaborate discussions on this topic, see Fleer et al., 2013; van Scheppingen et al., 2011). For the current study on the feasibility of I-MBCT, these results bring up the question to what extent offering an individual mindfulness-based intervention had an effect on patients’ decision not to need and accept psychological care.

Currently, little in general is known about the feasibility of mindfulness-based interventions, as most studies on mindfulness-based group interventions are based on convenience samples of self-selected patients (i.e., volunteers) or no clear descriptions of patient flow is given (Wurtzen et al., 2013). It is striking that a recent RCT study on group MBCT in patients with diabetes (van Son et al., 2013), which also screened a consecutive sample of patients with diabetes on psychological well-being, found quite similar findings to the present study, with only 4% of the patients filling out a screening questionnaire that participated in the trial and received group MBCT. An RCT study by Hartmann et al. (2012) on the effectiveness of a group mindfulness-based intervention in patients with diabetes reported that about two-thirds of eligible patients (i.e., 110 of the 163 patients available for screening and meeting inclusion criteria) participated and were randomized. We also found that two-thirds of the eligible patients (i.e., 24 of the 38 patients) accepted I-MBCT. Moreover, most reasons of eligible patients who declined participation in this trial on I-MBCT were not directly related to mindfulness, but to more general factors, such as no time or interest in a psychological intervention or travel distance to the hospital. Furthermore, our dropout rate (2 of the 12 patients dropped out of the intervention) was comparable to those found in other consecutive studies on group mindfulness-based interventions (Hartmann et al., 2012; van Son et al., 2013). Some studies using a convenience sample found lower dropout rates (Foley et al., 2010; Pradhan et al., 2007). With respect to acceptability, we found that most
patients evaluated the intervention in a positive way. Patients were satisfied with the delivery in terms of the number and duration of I-MBCT sessions, the type of exercises and homework, and the contact with the therapist. Taking all these findings into account, we conclude that our findings suggest that I-MBCT is acceptable to patients with diabetes, and that it is feasible to recruit, randomize, and retain patients in a RCT trial on I-MBCT. However, one might question the feasibility of using screening as an efficient way to recruit a sufficiently large sample of patients with diabetes with elevated levels of psychological symptoms.

Although not the main goal of the study, we also wanted to know whether I-MBCT had a positive effect on patients' functioning. The results suggest that patients receiving I-MBCT reported reductions in depressive symptoms and diabetes-related distress, compared to those in the waitlist control group. We are well aware that the results from this underpowered study are preliminary and should therefore be treated with caution. Nevertheless, it is clinically relevant to see that the mean level of depressive symptoms and diabetes-related distress reduced over time in those receiving I-MBCT, and that their mean post-intervention level of depressive symptoms was below the cutoff point, indicating that the I-MBCT group was no longer at risk for clinical depression. Moreover, patients' improved psychological functioning (in terms of depressive symptoms and diabetes-related distress) was maintained in the 3 months after finishing the intervention, suggesting a sustained effect of I-MBCT on patients' functioning. These positive findings are consistent with previous studies regarding the efficacy of mindfulness-based group interventions in healthy and clinical populations (i.e., those diagnosed with a psychiatric or medical condition) (Chiesa & Serretti, 2009; Hofmann et al., 2010).

The present study’s findings also suggest that I-MBCT has a positive effect on patients’ ability to be mindful and to regulate their attention. Rather than functioning on automatic pilot, patients may learn to concentrate and to regulate their thoughts and emotions, and when distracted, to bring back attention to the current moment. This finding is consistent with studies on mindfulness-based group interventions (Carmody & Baer, 2008; Nyklíček & Kuijpers, 2008). However, we found no evidence for I-MBCT to be associated with improvements in the ability to be more accepting and less judging. This finding is in contrast to previous research on mindfulness-based group interventions (Carmody & Baer, 2008; Nyklicek & Kuijpers, 2008). At this point, again, we do not want to draw firm conclusions, and we can only speculate about the possible explanations for these discrepancies. Compared to attention regulation, it might take more mindfulness practice to learn to hold a less judgmental attitude. As group sessions in MBCT are more than twice as long as our individual sessions, and
daily homework is 45 min rather than 30 min, participants practice much more during the 8-week group intervention. It can also be argued that the sharing, validation, and support from group members play an important role in the cultivation of acceptance.

When interpreting our results, the study limitations should be taken into account. First, as only a small portion of the approached patients and only about a quarter of patients reporting elevated levels of psychological symptoms accepted to participate in the trial, the generalizability of our findings may be limited. Second, taken the low power into account, the results should be verified in larger studies. Third, all information was based on patients’ self-report, which may reflect bias in reporting (e.g., under or overreporting of psychological symptoms and misunderstanding of questionnaire items).

Having obtained these results, our next step is to conduct a larger multicenter trial on the efficacy of this individual form of mindfulness-based therapy. Not only do we aim to examine its efficacy in terms of reductions in depressive symptoms in patients with diabetes, both short-term and sustained effects, we also want to examine why and for whom it works. Therefore, individual MBCT will be compared with individual CBT, and similarities and differences in terms of efficacy and mediators and moderators of change will be examined. Besides mindfulness and attention-regulation a range of theory-driven mediators will be examined. Also, the role of the therapeutic relationship, therapists’ treatment adherence, and patients’ adherence to homework will be taken into account. In a separate study, we want to compare the efficacy of individual MBCT versus group MBCT in patients with a medical condition and comorbid depressive symptoms.

In sum, the findings provide preliminary evidence for the provision of individually delivered mindfulness-based cognitive therapy for patients with diabetes. The reported feasibility and acceptability warrant more research on this alternative form of mindfulness-based therapy in other groups of patients as well.