Effects of mindfulness-based intervention on glycemic control and psychological outcomes in people with diabetes: A systematic review and meta-analysis

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Keywords

Diabetes, Meta-analysis, Mindfulnessbased intervention

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ABSTRACT

Aims/Introduction: Psychological therapies have showed benefits for both glycemic control and psychological outcomes in people with diabetes. However, the effects of mindfulness-based intervention (MBI) on glycemic control and psychological outcomes are inconsistent across studies, and the evidence for MBI has not been summarized. We aimed to identify the effects of MBI on glycemic control and psychological outcomes in people with diabetes by carrying out a systematic review and meta-analysis.

Materials and Methods: Six databases (Pubmed, Embase, CINAHL, Cochrane, Web of science and PsycINFO) were searched from inception to October 2019. Randomized controlled trials of MBI for people with type 1 and type 2 diabetes were included. Two authors independently extracted relevant data and assessed the risk of bias, with a third reviewer as arbitrator. Subgroup analyses and sensitivity analyses were also carried out. **Results:** Eight studies with 841 participants met the eligibility criteria. Meta-analysis showed that MBI can slightly improve glycosylated hemoglobin (HbA1c; -0.25%, 95% confidence interval [CI] -0.43 to -0.07) and diabetes-related distress (-5.81, 95% CI -10.10 to -1.52) contribute to a moderate effect size in reducing depression (standardized mean difference -0.56, 95% CI -0.82 to -0.30) and stress (standardized mean difference -0.53, CI - 0.75 to -0.31). Subgroup analyses showed greater HbA1c reductions in subgroups with baseline HbA1c levels <8% and follow-up duration >6 months. Mixed effects were observed for anxiety.

Conclusions: MBI appears to have benefits on HbA1c, depression, stress and diabetesrelated distress in people with diabetes. More rigorous studies with longer follow-up duration are warranted to establish the full potential of MBI.

INTRODUCTION

People with diabetes are more likely to suffer from clinically significant psychological disorders than those without the disease¹⁻⁴. Results from the literature showed that psychological disorders contributed to poor self-care, worsened blood glucose levels, diminished quality of life and increased healthcare costs^{5,6}. The American Diabetes Association "Standards of Medical Care in Diabetes-2020" included psychosocial care as a part of recommended therapy in diabetes management⁷. Hence,

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psychosocial care has been considered an essential component of successful diabetes management.

One potential effective psychological treatment consists of mindfulness-based intervention (MBI). In recent years, MBI has been successfully implemented to improve psychological health and coping skills⁸ in a range of clinical populations, including chronic disease⁹, pain disorders¹⁰ and cancer¹¹. Encouragingly, the benefits of MBI for psychological disorders have been found in people with diabetes^{12–14}. In addition, a few studies suggested that MBI might have a favorable effect on glycemic control in people with diabetes¹⁵. Previous studies

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© 2020 The Authors. Journal of Diabetes Investigation published by Asian Association for the Study of Diabetes (AASD) and John Wiley & Sons Australia, Ltd This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made. supposed that psychological interventions, such as cognitive behavioral therapy (CBT) and problem solving, improved glycemic control in people with diabetes through improving adherence to medical care and the ability to manage negative emotions^{16,17}. However, the mechanisms responsible for the effects of psychological interventions, including MBI on glycemic control, were uncertain. Mindfulness is defined as "the awareness that emerges through paying attention on purpose, in the present moment and non-judgmentally to things as they are"18. MBI refers to those interventions in which mindfulness practices are explicitly taught as a key ingredient in the treatment ^{19,20}. It is known that diabetes as a disease affects both body and mind, requiring considerable physical, emotional, and psychological accommodation and coping²¹. MBI increases levels of mindfulness and non-judgmental acceptance, and decreases negative reactivity and repetitive negative thinking, which in turn lead to positive outcomes²². Commonly used MBIs include mindfulness-based stress reduction (MBSR), mindfulness-based cognitive therapy (MBCT) and mindfulness-based eating awareness training (MB-EAT). MBSR usually includes a body scan, meditation, and informal daily mindfulness practice to overcome pain, stress and illness.²³ MBCT is quite similar to MBCT, but MBCT does not include the loving kindness meditation instructions²³. MB-EAT includes reducing episodes of overeating and improving disordered eating behaviors through mindful meditation^{23,24}. Usually, MBI entails participating in group-based weekly 1-2 -h long sessions for a period of 8 weeks^{23,25}. Several studies modified MBI slightly to make it more feasible and acceptable, including changing the period of intervention²⁶, delivering MBI through audio compact disc²⁷or providing intervention for individuals instead of a group¹³.

Although MBI is considered as a promising therapy for psychosocial problems^{28,29}, and has become increasingly popular and available in recent years, the effects on both psychological outcomes and glycemic control among people with diabetes are mixed³⁰, especially for glycemic control^{12,14,15}. In addition, existing reviews on MBI for people with diabetes are limited, and do not provide firm conclusions on its effectiveness on glycosylated hemoglobin (HbA1c), depression, stress, anxiety and diabetes-related distress. One systematic review showed that MBI appeared to have psychological benefits reducing depression, anxiety and distress symptoms, but no glycemic control benefits were observed³¹. Only one meta-analysis tested the effects of MBI on HbA1c and diabetes-related distress, which included non-randomized controlled trials³⁰. It is worth noting that the mixed interventions were not excluded in that meta-analysis, making it difficult to draw reliable conclusions on the specific effects of MBI due to the contamination. In addition, diabetesrelated distress was the primary outcome in that meta-analysis, other common psychological outcomes (i.e., depression, stress and anxiety) were not tested.

Given the mixed results on glycemic control and psychological outcomes of MBI and limited meta-analysis of MBI among people with diabetes, there is a need to quantitatively analyze evidence based on randomized controlled clinical trials (RCTs) to determine its pooled effectiveness among people with diabetes. As such, this systematic review aimed to identify the effects of MBI on HbA1c, depression, stress, diabetes-related distress and anxiety in adults with diabetes.

METHODS

The protocol of this review was registered in PROSPERO (CRD42020159088). This study followed the Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) statement and checklist.

Data sources and search strategy

Six databases were searched (Pubmed, Embase, CINAHL, Cochrane, Web of science and PsycINFO) for studies from inception and to 16 October 2019. We designed strategies that included Medical Subject Headings; keywords were searched, such as "diabetes," "T2DM," "T1DM," "IDDM," "NIDDM," "mindfulness*," "MBI," "meditation," "MBSR," "MBCT," "MB-EAT," "mind body therapies" and comprehensive combinations of these search terms. The detailed search strategy can be found in Table S1. A manual search of reference lists of shortlisted articles for relevant reviews was also carried out to identify additional studies.

Study selection

Studies meeting the following inclusion criteria were included: (i) individuals aged >18 years with type 1 or type 2 diabetes; (ii) interventions included any interventions that MBI was a major component of, such as MBSR, MBCT and MB-EAT; (iii) studies that compared MBI with usual care, wait-list control, no intervention or health education without any mindful component; (iv) studies reported on at least one of the outcomes of depression, stress, anxiety, distress and glycemic control (HbA1c); and (v) studies that were RCTs published in English. Exclusion criteria were as follows: (i) individuals with gestational diabetes or prediabetes; (ii) exercise-focused intervention programs with mindfulness as a component, mixed interventions (i.e., Tai Chi and meditation), because these interventions might result in contamination for the specific effects of MBI; and (iii) dialectical behavior therapy, and acceptance and commitment therapy, because these two therapies stemmed from different theoretical roots compared with other commonly used MBIs²⁰. Two authors independently searched the literature and assessed the studies. Any disagreements were resolved through discussion with a third reviewer.

Data extraction

Data from the included studies were independently extracted by two authors using a standardized data extraction form guided by the Cochrane Handbook³². These two authors reviewed the collected data twice to ensure extraction accuracy. Extracted data included study setting, design, duration, sample size, participant demographics (i.e., age, sex), intervention characteristics (i.e., frequency, duration of each mindfulness session, intervention type), control characteristics, dropout rate and outcomes measures. When a study included multiple control arms, we utilized the control arm with the best matched comparison (i.e., waiting-list control, patient education group). Study authors were contacted by email to provide additional data when the data was incomplete. Because three studies reported the standard error or 95% confidence interval for depression, stress, anxiety and HbA1c^{14,26,33}, missing standard deviations in those studies were imputed by calculation based on the Cochrane Handbook³².

Quality assessment

Two authors independently assessed quality using the Cochrane risk of bias tool, which included the items of random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting, and other bias. Any discrepancies in data extraction or quality assessments were discussed and resolved by a third reviewer.

Statistical analysis

Pooled analyses were carried out on Review Manager (version 5.3, The Cochrane Collaboration, Copenhagen, Denmark), as recommended by the Cochrane Handbook. Meta-analyses were based on a random effects model to obtain more conservative estimates. Changes in outcomes, or outcomes at follow up, were compared between groups. The pooled intervention effect estimates for HbA1c and distress were calculated by mean difference (MD), and the pooled intervention effect estimates for other outcomes, including depression, stress and anxiety, were calculated by standardized MD (SMD), as those outcomes were measured by different scales. The SMD, also known as the Cohen's d, was used to evaluate the magnitude of effect size (0.2 represented a small effect, 0.5 a moderate effect and 0.8 a large effect)³⁴.

Heterogeneity was identified by Cochran's Q-test and I^2 statistics, where $I^2 > 50\%$ and a P-value of Q-test <0.10 showed heterogeneity between studies. Possible sources of heterogeneity were explored by subgroup analyses and sensitivity analyses. In this review, the subgroups formed were based on previous metaanalysis results^{35–37}, including baseline HbA1c level, baseline psychological status and duration of follow up. Initially, the diabetes type was considered as a factor to carry out subgroup analysis, as previous meta-analysis of diabetes psychological interventions showed different pooled results among type 1 and type 2 diabetes patients^{16,38,39}. However, no study included in the present review reported outcomes on people only with type 1 diabetes, making it impossible to identify diabetes type-specific effects of MBI. Sensitivity analyses were also carried out based on the study characteristics (i.e., duration of intervention time). The funnel plots for assessing publication bias were not carried out, as available trials were <10. When quantitative synthesis was not appropriate, a narrative synthesis was carried out instead.

RESULTS

Study selection and characteristics

The literature search and selection process are shown in Figure 1. Of the 1,874 potentially relevant records identified and screened, 103 records were eligible for full text review and 92 were excluded. Finally, 11 articles describing eight different studies with 841 participants were selected for inclusion in the review^{12–15,24,26,27,33,40–42}. The number of participants ranged from 24 to 139 in each study. Four studies had a mixture of type 1 and type 2 diabetes patients; four studies only included type 2 diabetes patients. The details of the characteristics of the included studies can be found in Table 1.

Studies carried out various forms of mindfulness-based intervention, including MBSR (3 studies), MBCT (2 studies), mindful eating (1 study), combination of MBSR and MBCT (1 study), and unspecific mindfulness-based intervention (1 study). Those three MBSR studies focused on body and meditation practices^{14,33,40}; two MBCT studies delivered intervention integrating MBSR and CBT^{13,41}. One mindful eating intervention study applied mindful meditation to eating²⁶; one unspecific mindfulness-based intervention study guided mindfulness practice and breath awareness²⁷. The duration of intervention ranged from 8 weeks to 3 months, with sessions varying from 30 min to 150 min. All studies delivered the sessions face-to-face, except one study²⁷ through audio compact disc. Five studies provided group-based intervention^{12,14,26,33,40}, and three studies provided individual intervention^{13,27,41}. Psychological outcomes were measured by different tools. A summary of the outcome data from all studies can be found in Table S2.

Risk of bias

Seven studies detailed their random sequence generation process, and four studies carried out allocation concealment^{12,14,27,40}. One study documented participants' blinding¹³, and another study blinded the MBI provider²⁷. Three studies blinded the outcome assessors and were rated a low risk of detection bias^{14,27,40}. Five studies carried out intention-to-treat analysis, Six studies^{12–14,27,33,41} reported attrition rates of <20%, and two studies^{26,40} reported attrition rates of >20%, but no significant difference between groups regarding attrition rates. Hence, all studies were rated as a low risk of attrition bias. Three studies published or registered a protocol and reported all prespecified outcomes (Table 2).

Effects of MBI on outcomes

HbA1c

Seven studies measured HbA1c^{12,14,15,26,27,33,42}, and only one study reported a reduction of HbA1c in participants accepting MBI¹⁵. After pooling, the mean reduction in HbA1c was 0.25% (95% CI –0.43 to –0.07; P = 0.006), with no substantial heterogeneity between studies ($I^2 = 0\%$; P = 0.92; Figure 2a).

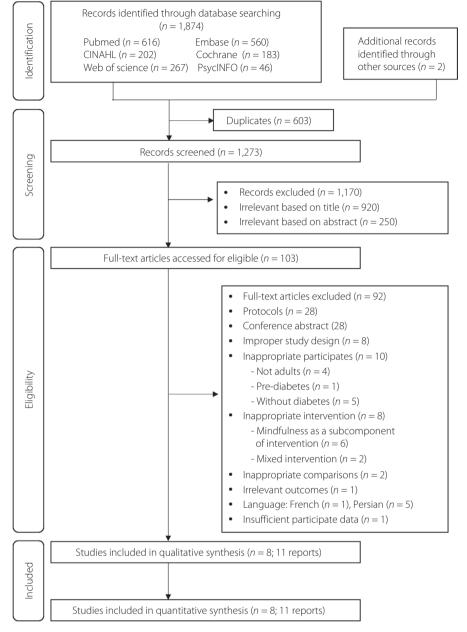


Figure 1 | Flow diagram of included studies.

Depression

Eight studies measured depression using five tools (Patient Health Questionnaire, Beck Depression Inventory-II, 21-item Depression, Anxiety and Stress Scale, Center for Epidemiologic Studies Depression Scale, and the Hospital Anxiety and Depression Scale)^{12–14,24,27,33,41,42}. The overall pooled effect size for depression was moderate (SMD –0.56, 95% CI –0.82 to –0.30; P < 0.0001; Figure 2b). However, substantial heterogeneity was found between the studies ($I^2 = 59\%$; P = 0.02).

Stress

Seven studies measured stress using three tools (Patient Health Questionnaire, 21-item Depression, Anxiety and Stress Scale and Perceived Stress Scale)^{12,14,15,27,33,40,42}. The overall pooled effect size for stress was moderate (SMD -0.53, CI -0.75 to -0.31; P < 0.00001). However, the heterogeneity test was contradictory by Cochran's Q-test (P = 0.08) and I^2 statistics ($I^2 = 47\%$; Figure 2c).

Table 1 Summary of basic study characteristics	ULTITIALY UL N											
Author (year)	Study design	Country, recruitment setting	Diabetes type	No. participants	Mean age of participants (years)	Male participants (%)	Intervention group	Comparison group	MBI protocol	Assessment time points	Outcomes	ITT analysis
Hartmann et al, (2012); Kopf et al, (2014)	2-arm RCT	Germany, outpatient dinic	Type 2	Total: 110 IG: 53 CG: 57	Total: not reported IG: 68.7 CG: 59.3	Total: 78.2% IG: 75.5% CG: 80.7%	MBSR	usual care	once weekly over 8 weeks, followed by one booster session after 6 months	Baseline, Postintervention, 1-year, 2-year, and 3-year follow up	Depression (PHQ-9), Stress (PHQ-9), HDA1c	Yes
Jung et al., (2015)	3.aim RCT	South Korea, outpatient dinics	Type 2	Total: 84 1G. 28 CG1: 28 CG2: 28	Total: 66.27 1G 67.00 CG1: 63.33 CG2: 68.47	Total: 48.2% IG: 47.6% CG1: 50% CG2: 47.1%	MBSR	CG1: walking group CG2: patient education group	twice per week for 8 weeks and learned 8 K-MBSR themes. Each theme was introduced and practiced twice in 1 week Each theme lasted between 60–120 min.	Baseline Postintervention	Stress (Diabetes Distress Scale)	2 Z
Miller et al, (2012); Miller et al, (2014)	2-arm RCT	USA, not specified	Type 2	Total: 68 1G32 CG36	Total: Not reported I.G. 53.9 C.G. 54.0	Total36 <i>8</i> % 1G:37.0% CG:360%	Mindful Eating Intervention	Smart Choices DSME- based intervention	eight weeky and 2 biweeky 25-h sessions, and meditation with a compact disc 6 days/week and to practice mini-meditations before meals	Baseline, Postintervention, 3 months follow up	Depression (BDHI), anxiety (Beck Anxiety Inventory), HDA1c	9 Z
Nathan <i>et al</i> , (2017)	2-arm RCT	Canada, endocrine and cliabetes center, community	Type 1 or type 2	Total: 66 IG: 33 CG: 33	Total: 5 <i>9,7</i> IG: 59,8 CG: 59,8	Total: 44.0% IG: 50.0% CG: 37.5%	MBSR	wait-list control	8 weekly, 25-h sessions and 1 6-h session on a weekend day midway through the course.	Baseline, at the time of randomization, 2 weeks, 3 months	depression (PHQ-9), stress (PSS), HbA1c	°Z
Pearson et <i>dl.</i> (2018)	2-arm RCT	Australia, ourpatient dinics	Type 2	Total: 74 1G. 38 CG. 36	Totał: Not reported I.G. 57.5 C.G. 61.1	Total53.7% IG. 38.7% CG. 66.7%	A novel approach to delivering a mindfulness- based intervention	usual care	30 min a day over 8 weeks to listen to the audio compact disc guided mindfulness	Baseline, 8 weeks, and 12 weeks	Depression (DASS-21), Anxiety (DASS-21), stress (DASS-21), distress (PAID), HDA1c	Yes
Schroevers et al., (2015)	2-arm Pilot RCT	the Netherlands, outpatient clinic	Type 1 or type 2	Total:24 ।G. 12 CG:12	Total: Not reported IG: 54.9 CG:55.9	Total: 58% IG: 58% CG: 58%	individual MBCT	wait-list control	eight weekly individual sessions of 60 min	Baseline, Postintervention, 3 months after the intervention	Depression (CES-D), distress (PAID),	Yes
Tovote et al., (2014)	3-arm RCT	the Netherlands, outpatient dinics	Type 1 or type 2	Tota!94 1G. 31 CG1: 32 CG2: 31	Total: 53.1 16. 49.8 CG1: 54.6 CG2: 54.7	Total: 51% IG: 55% CG1: 50% CG2: 48%	MBCT	CG1: cognitive behavior therapy CG2: waiting-list control	eight weekly sessions of 45–60 min	Baseline, Postintervention (on average, 3 months after the first assessment)	Depression (BDHI), Anxiety (GAD-7), distress (PAID), HDA1c	Yes

van Son <i>et al</i> , (2013); van	2-arm RCT	the Netherlands, outpatient clinics	Type 1 or		participants (years)							
Son <i>et al.</i> (2014)			type 2	Total:139 I.G. 70 C.G. 69	Totak Not reported IG: 56 CG: 57	Totał: 50.4% KG: 54% CG: 54%	MBCT + MBSR	wait-list control	8 weekly 2-h sessions, a 2-h booster session was added 3 months after the end of the intervention	Baseline, 4 weeks, 8 weeks and 6 months follow up	Depression (HADS), Anviety (HADS), (HADS), Stress (PSS), Distress (PAID), HbA1c	¥es
Total <i>n</i> = 8 and Stress { IG, interven [*] Stress Redu	; 11 reports. Scale; DSME, Ition group; II Iction; PAID, F	Total $n = 8$; 11 reports. BDI-II, Beck Depression Inventory-II; and Stress Scale; DSME, Diabetes Self-Management Educati IG, intervention group; ITT analysis, intention-to-treat analys Stress Reduction; PAID, Problem Areas in Diabetes Survey, I	ression Inver anagement ition-to-treat n Diabetes S	ntory-II; CES-E Education; G, analysis; K-N urvey; PHQ-9), Centre for E AD-7, Generali 1BSR, Korean A 3, Patient Healt	pidemiologic ized Anxiety I Mindfulness-B th Questionn	: Studies Depre Disorder 7; HAL based Stress Rec aire; PSS, Percei	ssion Scale; CG, DS, The Hospital Juction; MBCT, N ived Stress Scale;	Total <i>n</i> = 8; 11 reports. BDI-II, Beck Depression Inventory-II; CES-D, Centre for Epidemiologic Studies Depression Scale; CG, comparison group; DASS-21, the 21-item Depression, Anxiety and Stress Scale; DSME, Diabetes Self-Management Education; GAD-7, Generalized Anxiety Disorder 7; HADS, The Hospital Anxiety and Depression Scale; HbA1c, glycosylated hemoglobin; IG, intervention group; ITT analysis, intention-to-treat analysis; K-MBSR, Korean Mindfulness-Based Stress Reduction; MBCT, Mindfulness-Based Cognitive Therapy; MBSR, Mindfulness-Based Stress Reduction; PAID, Problem Areas in Diabetes Survey; PHQ-9, Patient Health Questionnaire; PSS, Perceived Stress Scale; RCT, Randomized Controlled Trial.	ASS-21, the 21-iter on Scale; HbA1c, ç nitive Therapy; MI introlled Trial.	n Depression, Jlycosylated h 3SR, Mindfuln	Anxiety emoglobin; ess-Based
Table 2 R	tisk of bias of	Table 2 Risk of bias of individual studies according to the	es accordino	a to the Coc	Cochrane quideline	ā						
Study		Random se generation	Random sequence generation		Allocation concealment		Blinding of oarticipants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective tta reporting	ting	Other bias
Hartmann 6	Hartmann <i>et al. (2</i> 012)	LInclear	,		l Inclear	Hinh		l Inclear	WC	MO		l Inclear
Juna <i>et al.</i> . (2015)	(2015)	Low			Low	Hiah		Low	Low	Unclear	ar	Unclear
Kopf et al., (2014)	(2014)	Unclear	١٢	5	Unclear	High		Unclear	Low	High		Unclear
Miller et al., (2012)	(2012);	Low		IJ	Unclear	High		Unclear	Low	Unclear	ar	Unclear
Miller et al., (2014)	(2014)	Low		j	Unclear	High		Unclear	Low	Unclear	ar	Unclear
Nathan <i>et al.</i> , (2017)	<i>дІ.</i> , (2017)	Low		ΓC	Low	High		Low	Low	Low		Unclear
Pearson <i>et al.</i> , (2018)	<i>al.</i> , (2018)	Low		ΓC	Low	Low		Low	Low	Low		Unclear
Schroevers	Schroevers et al., (2015)	Low		n	Unclear	High		Undear	Low	Unclear	sar	Unclear
Tovote et al., (2014)	1, (2014)	Low		n	Unclear	Low		High	Low	High		Unclear
van Son <i>et al.</i> , (2013)	<i>al.</i> , (2013)	Low		Γc	Low	High		Unclear	Low	Low		Unclear
van Son <i>et al.</i> , (2014)	<i>al.</i> , (2014)	Low		Γc	Low	High		Unclear	Low	Low		Unclear

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(a)	Min	dfulne	SS	C	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl
Hartmann 2012	7.2	1.01	52	7.5	1.14	51	18.4%	-0.30 [-0.72, 0.12]	
Kopf 2014	7.1	1.02	52	7.5	0.96	51	21.8%	-0.40 [-0.78, -0.02]	
Miller 2012	-0.83	1.25	27	-0.67	1.2	25	7.2%	-0.16 [-0.83, 0.51]	
Nathan 2017	-0.31	1.31	30	0.07	0.58	32	12.3%	-0.38 [-0.89, 0.13]	
Pearson 2018	7.97	1.35	31	7.96	1.5	36	6.9%	0.01 [-0.67, 0.69]	
van Son 2013	7.6	1.1	70	7.8	1.5	69	16.7%	-0.20 [-0.64, 0.24]	
van Son 2014	7.6	1.1	70	7.7	1.5	69	16.7%	-0.10 [-0.54, 0.34]	
Total (95% CI)			332			333	100.0%	-0.25 [-0.43, -0.07]	▲
Heterogeneity: Tau ² =				P = 0.9	92); I ² =	: 0%			-2 -1 0 1 2
Test for overall effect:	Z = 2.74 (ł	$^{\circ} = 0.0$	06)						Favours mindfulness Favours control

(b)	Min	dfulne	SS	С	ontrol			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Hartmann 2012	5.3	3.46	52	7.3	4	51	14.7%	-0.53 [-0.92, -0.14]	
Miller 2014	-3.37	6.08	27	-5	5.95	25	11.1%	0.27 [-0.28, 0.81]	
Nathan 2017	-4.75	4.82	30	0.06	4.77	32	11.5%	-0.99 [-1.52, -0.46]	
Pearson 2018	6	6.4	31	7.5	8.1	36	12.6%	-0.20 [-0.68, 0.28]	
Schroevers 2015	14.4	7.5	12	23.6	7.4	12	6.2%	-1.19 [-2.07, -0.31]	
Tovote 2014	17.1	11.9	31	23.5	10.3	31	11.9%	-0.57 [-1.08, -0.06]	
van Son 2013	5.4	4.1	70	8.5	4.7	69	16.0%	-0.70 [-1.04, -0.36]	
van Son 2014	5.2	3.6	70	8.2	4.5	69	16.0%	-0.73 [-1.08, -0.39]	-
Total (95% CI)			323			325	100.0%	-0.56 [-0.82, -0.30]	•
Heterogeneity: Tau ² =	0.08; Chi	² = 17.	04, df =	7 (P = 0	0.02); l ²	² = 59%			-4 -2 0 2 4
Test for overall effect:	Z = 4.24 (P < 0.0	001)						
									Favours mindfulness Favours control

(c)	Min	dfulnes	iS	(Control			Std. Mean Difference Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	IV, Random, 95% CI
Hartmann 2012	5	3.03	52	6.2	3.71	52	16.0%	-0.35 [-0.74, 0.04]	
Jung 2015	-0.67	12.89	21	2.12	11.11	17	8.6%	-0.23 [-0.87, 0.42]	
Kopf 2014	5.2	4.43	52	6.3	5.13	51	16.0%	-0.23 [-0.62, 0.16]	
Nathan 2017	-4.64	8.7	30	1.75	5.24	32	11.4%	-0.89 [-1.41, -0.36]	
Pearson 2018	6.7	6.2	31	8.7	8.2	36	12.6%	-0.27 [-0.75, 0.21]	
van Son 2013	14.2	6.9	70	19.6	6.7	69	17.7%	-0.79 [-1.14, -0.44]	_ - _
van Son 2014	13.4	6.7	70	18.9	7	69	17.7%	-0.80 [-1.14, -0.45]	
Total (95% CI)			326			326	100.0%	-0.53 [-0.75, -0.31]	•
Heterogeneity: Tau ² =	= 0.04; Ch	$i^2 = 11.3$	35, df =	6 (P = 0).08); l ²	= 47%		-	
Test for overall effect:									-2 -1 0 1 2
			,						Favours mindfulness Favours control

(d)	Min	dfulne	SS	C	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Pearson 2018 Schroevers 2015 Tovote 2014 van Son 2013 van Son 2014	11.8 19.3 32 27.8 25	20.6	31 12 31 70 70	12.5 35.8 36 33.3 32.8	13.1 16.3 21.2 22 20.1	36 12 31 69 69	25.9% 10.4% 13.1% 24.2% 26.4%	-0.70 [-7.41, 6.01] -16.50 [-28.77, -4.23] -4.00 [-14.70, 6.70] -5.50 [-12.59, 1.59] -7.80 [-14.42, -1.18]	
Total (95% Cl) Heterogeneity: Tau ² = Test for overall effect:				4 (P = 0.2	23); I ² =	217 = 28%	100.0%	-5.81 [-10.10, -1.52]	-50 -25 0 25 50 Favours mindfulness Favours control

Figure 2 | Forest plot. Effectiveness of mindfulness-based intervention on (a) glycosylated hemoglobin, (b) depression, (c) stress and (d) diabetesrelated distress. Cl, confidence interval; SD, standard deviation.

Outcome	No. studies	Pooled effect estimates		Heterogen	eity
		SMD (95% CI)	<i>P</i> -value	l ²	PQ
Baseline HbA1c					
HbA1c					
<8%	4	-0.26 [†] (-0.47, -0.05)	0.01	0%	0.77
≥8%	3	0.22 [†] (0.57, 0.13)	0.22	0%	0.66
Depression					
<8%	3	-0.67(-0.87, -0.46)	< 0.00001	0%	0.73
<u>≥</u> 8%	5	-0.49(-0.98, -0.01)	0.05	73%	0.006
Stress					
<8%	5	0.55(0.84,0.27)	0.0002	60%	0.06
<u>≥</u> 8%	2	-0.57(-1.17, 0.04)	0.06	65%	0.09
Baseline psychological status					
HbA1c					
Without psychological disorder	5	-0.30 [†] (-0.52, -0.08)	0.007	0%	0.86
With psychological disorder	2	-0.15 [†] (-0.46, 0.16)	0.34	0%	0.75
Depression					
Without psychological disorder	4	-0.37(-0.85, -0.10)	0.13	74%	0.009
With psychological disorder	4	-0.72(-0.93, -0.51)	< 0.00001	0%	0.69
Stress					
Without psychological disorder	5	-0.37(-0.60, -0.15)	0.001	13%	0.33
With psychological disorder	2	-0.79(-1.04, -0.55)	< 0.00001	0%	0.97
Duration of follow up					
HbA1c					
<6 months	4	-0.21 [†] (-0.48, 0.06)	0.13	0%	0.84
≥6 months	3	-0.28 [†] (-0.52, -0.04)	0.006	0%	0.60
Depression					
<6 months	6	-0.53(-0.91, -0.15)	0.006	69%	0.007
≥6 months	2	-0.65(-0.90, -0.39)	< 0.00001	0%	0.45
Stress					
<6 months	4	-0.58(-0.91, -0.26)	0.0004	44%	0.14
≥6 months	3	-0.47(-0.82, -0.12)	0.009	62%	0.07

Standardized mean difference was used for pooled effect estimates unless otherwise indicated. [†]Mean difference was used for pooled effect estimates. CI, confidence interval; HbA1c, glycosylated hemoglobin; SMD, standardized mean difference.

Diabetes-related distress

Five studies measured distress using Problem Areas in Diabetes Survey scale^{12,13,27,41,42}. The overall pooled results showed a statistical significance in reducing distress (MD –5.81, 95% CI – 10.10 to –1.52; P = 0.008), with heterogeneity between studies ($I^2 = 28\%$; P = 0.23; Figure 2d). No subgroup analyses were carried out for diabetes-related distress, as there were fewer than six studies in the pooled meta-analysis⁴³.

Anxiety

Five studies measured anxiety using four tools (21-item Depression, Anxiety and Stress Scale, the Hospital Anxiety and Depression Scale, Generalized Anxiety Disorder, and Beck Anxiety Inventory)^{12,13,24,27,42}. Because of the varying effect measures reported across these studies, a narrative synthesis was carried out instead of meta-analysis. Two studies reported significant reduction of anxiety in the mindfulness group

compared with the control group^{12,42}. Three studies found no significant differences in anxiety between the MBI and control group^{13,24,27}.

Subgroup analyses

Three subgroup analyses were carried out to explore possible reasons for the heterogeneity (Table 3).

Baseline HbA1c

A previous meta-analysis of diabetes psychosocial interventions showed a greater effect in participants with poor baseline HbA1c levels³⁵. Therefore, we did a subgroup analysis to see if this hypothesis might also be true for MBI. As the participants in most included studies were older, we divided studies into two subgroups based on the less-stringent glycemic goals (HbA1c <8%) for older adults, as recommended by the American Diabetes Association⁴⁴. Combining studies with baseline HbA1c levels <8.0% showed greater reductions in HbA1c levels of 0.26% (95% CI –0.47 to –0.05; P = 0.01) compared with 0.22% (95% CI –0.57 to 0.13; P = 0.22) among those with baseline HbA1c levels ≥8.0%. In addition, the effects on HbA1c were no longer statistically significant in the subgroup of baseline HbA1c level ≥8% (Table 3).

Baseline psychological status

The baseline psychological status was divided into two groups: participants with baseline psychological disorders and participants without baseline psychological disorders. Three studies recruited participants with a certain baseline level of depression¹³, diabetes-related distress⁴¹ or low levels of emotional well-being¹², hence, participants in those studies were considered to have a psychological disorder. Combining studies with baseline psychological disorder showed a larger effect size for depression (SMD -0.72, 95% CI -0.93 to -0.51; P < 0.00001) and stress (SMD -0.79, 95% CI -1.04 to -0.55; P < 0.00001), with no substantial heterogeneity for both depression $(I^2 = 0\%; P = 0.69)$ and stress $(I^2 = 0\%; P = 0.97)$. Combining studies without baseline psychological disorder showed a smaller effect size for depression (SMD -0.37, 95% CI -0.85, -0.10; P = 0.13) and stress (SMD -0.37, 95% CI -1.04, -0.55; P = 0.001; Table 3).

Duration of follow up

The duration of the Diabetes Self-Management Education intervention was divided into two groups (≤ 6 months and >6 months) guided by previous meta-analysis⁴⁵. Combining studies with a longer follow-up duration (>6 months) showed a larger HbA1c reduction (MD -0.28, 95%CI -0.52 to -0.04; P = 0.006) than those with a shorter duration (≤ 6 months; SMD -0.21, 95% CI -0.48 to 0.06; P = 0.13). Additionally, studies with shorter follow-up duration showed no statistically significant effects on HbA1c (Table 3).

Sensitivity analyses

Three sensitivity analyses were undertaken to explore possible reasons for the heterogeneity and test the robustness of the results. Removing one study²⁴ with longer duration of intervention time (>8 weeks) partially explained the substantial heterogeneity for depression ($I^2 = 16\%$; P = 0.31), but not the significance or the direction of the effect (SMD -0.65, 95% CI -0.83 to -0.47; P < 0.00001). Removing one study delivering intervention through compact disc²⁷ explained all of the substantial heterogeneity for diabetes-related distress ($I^2 = 0\%$; P = 0.43), but did not change the significance or the direction of the effect (MD -7.44, 95% CI -11.58 to -3.29; P = 0.0004). Removing one study reporting improvement in HbA1c after intervention, the significance or the direction of the effect on HbA1c did not change (MD -0.21, 95% CI -0.41 to -0.01; P = 0.04).

DISCUSSION

To our best knowledge, this is the first meta-analysis of RCTs to quantify the magnitude of improvement in HbA1c, depression, stress and diabetes-related distress from MBI. The present review showed that MBI can slightly improve HbA1c and diabetes-related distress, and lead to a moderate reduction in depression and stress. Subgroup analyses showed greater HbA1c reductions in studies with baseline HbA1c level <8% and follow-up duration >6 months. Subgroup analyses also showed greater effects in participants with certain baseline psychological disorders than those without baseline psychological disorders in improving depression and stress. Mixed effects were observed for anxiety.

An important finding of the present review was that the effects of MBI on HbA1c were confirmed, although the effect size was small. This is in line with previous meta-analysis^{35,38}, which reported that psychotherapies can slightly improve HbA1c in people with diabetes. Possible mechanisms responsible for the effect on HbA1c could be that mindfulness training might assist participants to develop a healthy lifestyle or behaviors²⁷. Performing optimal behavior has been confirmed to be effective in reaching targeted HbA1c^{46,47}. Another potential pathway is through modulation of the hypothalamic–pituitary–adrenal axis and stress pathways²⁷. Jung *et al.*⁴⁰ carried out a randomized controlled trial to test the effects of MBSR on people with type 2 diabetes, and a significant reduction in cortisol levels was observed.

Subgroup analyses showed that the effects of MBI for HbA1c were found in the longer follow-up duration subgroup; however, the benefits for HbA1c were not observed in the shorter follow-up duration subgroup. These results differed from the findings reported by Uchendu et al.¹⁷, who found short-term (up to 4 months) and medium-term (up to 8 months) effects on glycemic control, and no significant effect for long-term (up to 12 months) glycemic control. This difference might be explained by the fact that the intervention approaches were different between the present review and previous systematic reviews. The present review focused on the effects of MBI, whereas previous reviews focused on CBT¹⁷. Some types of MBI, such as MBCT, were similar to CBT, but were not the same. MBI emphasized redirecting participants' attention toward the present moment, but CBT focused on reappraising and modifying thought content⁴⁸. Notably, due to the small number of studies reporting long-term outcomes of MBI, we should be cautious to draw conclusions about the long-term effects on HbA1c. Therefore, more studies are required to show whether MBI can improve glycemic control in the long term. Subgroup analyses suggested that the reduction in HbA1c was found among participants with lower baseline HbA1c levels (<8%), but not among participants with higher baseline HbA1c levels (\geq 8%). This implied that participants with better glycemic control at baseline benefitted more from MBI. MBI requires somewhat intense participation by patients in the

exercises and modules. However, individuals with HbA1c levels $\geq 8\%$ were more likely to already have diabetes complications⁴⁴, who were less motivated with lower adherence to intervention⁴⁹, which might explain the different effects in participants with different baseline HbA1c. Another explanation could be that participants with lower HbA1c levels might have better exercise habits⁵⁰, contributing to contamination of the effects of MBI.

In terms of psychological outcomes, depression, stress and diabetes-related distress were significantly improved. The present review confirmed previous findings^{30,31}, and further found that the effects of MBI on psychological outcomes might differ by different baseline psychological status. The benefits on psychological outcomes could be attributed to the effects of MBI in improving mindfulness, contributing to facilitating insight into one's emotional life, and enabling one to liberate oneself from negative and destructive mental states⁵¹. Subgroup analyses showed a larger effect size in combined studies involving participants with baseline psychological disorders than those involving participants without baseline psychological disorders, implying that participants with certain psychological disorders at baseline might benefits more from MBI. This result is consistent with a recent review on MBSR for older people, which also observed significant effects of MBSR, particularly in those with mood symptoms of distress, but limited effects on the healthy population. Similar results were also found in people with diabetes, that psychological treatment might be more efficacious for high-severity than for low-severity participants with depres $sion^{37}$. This result might be explained by the floor effects – participants without psychological disorders at baseline achieved a lower score on the psychological screening scale, leaving little room for improvement after intervention. Nevertheless, a small number of studies included in the present review might influence the reliability and generalizability of the results. Hence, caution is warranted in interpreting these findings. Mixed effects were found for anxiety, as five of the included studies measured anxiety using five different scales, making it difficult to quantify the magnitude of effects in anxiety. It should be noted that heterogeneity was found in the pooled intervention effect estimate for depression, stress and diabetes-related distress. This heterogeneity might be due to the use of a variety of measurement tools and different intervention components.

The present study had some strengths. A strength was that we only included RCTs, to guarantee the quality of evidence. The subgroup and sensitivity analyses further added to the strength of this study. However, there were some limitations in this review. First, most included studies failed to blind the participants and the intervention provider; this might increase the risk of performance bias. Second, besides a small number of trials, most included studies consisted of small samples, which might have resulted in exaggerated effect sizes and thus biased the results⁵², making it difficult to draw a robust conclusion. Third, due to a lack relevant trials, the present review did not draw conclusions on sex-specific effects, diabetes type-specific effects, and the format of MBI sessions that were most beneficial and preferred by people with diabetes. Finally, language restriction for the literature search might introduce language bias, as non-English studies with relevant outcomes were missed.

It is not clear which population groups will benefit the most from MBI (e.g., different diabetes type), and which kind of MBI is most effective (e.g., MBSR, MBCT). Additionally, the mechanism of MBI on glycemic control and psychological outcomes has not been identified. More studies with longer followup duration are required to determine the long-term impact on glycemic control and psychological outcomes. Further research is required on evaluating the impact of MBI on other important outcomes for people with diabetes, such as cost-effectiveness, self-management and health-related quality of life.

In conclusion, the present review shows that MBI can slightly improve HbA1c and diabetes-related distress, leading to a moderate effect size in reducing depression and stress. Mixed effects are found in anxiety. The effects on depression and stress are larger in participants in the baseline psychological disorder subgroup. The impact of MBI on HbA1c might differ from the duration of follow up and baseline HbA1c level.

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DISCLOSURE

The authors declare no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1 | Search strategy (Pubmed).

Table S2 | Study data (n = 8; 11 reports).