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Review Article

Mindfulness-based interventions for adults with type 2 diabetes mellitus: A systematic review and meta-analysis

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) can lead to macro- and microvascular complications. Mindfulness-based interventions (MBIs) may improve metabolic and psychological health in individuals with T2DM. We aimed to assess the efficacy of MBIs for management of T2DM.

Methods: We searched five databases and two trial registries using a comprehensive search strategy developed by a multidisciplinary team including an information scientist. We included randomised controlled trials (RCTs) investigating MBIs for important clinical outcomes including psychological outcomes, quality of life, glycaemic control and cardiovascular risk factors in adults with T2DM. Where possible, random effects meta-analyses were conducted. The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach was used to assess certainty of the evidence.

Results: We included 31 RCTs (2337 participants: 1107 intervention, 1230 control). We found very low certainty evidence that MBIs may reduce stress (standardized mean difference (SMD) –1.01, confidence interval (CI) –1.91 to –0.20, 8 trials, n = 528), depression (SMD –1.26, CI –2.08 to –0.43; 7 trials, n = 570) and anxiety (SMD –0.67, CI –1.27 to –0.08; 4 studies, n = 255) at end of treatment compared to waitlist control/usual care. MBIs may have a small effect on HbA1c and systolic/diastolic blood pressure at end of treatment compared to waitlist control/usual care (HbA1c mean difference (MD) –0.44, 95 % CI –0.71 to –0.17, 9 trials, n = 734; low certainty evidence). There was very low certainty evidence that MBIs + lifestyle may have no effect on HbA1c or body weight compared to lifestyle alone.

Conclusion: MBIs may have clinical benefits (particularly psychological) for adults with T2DM, but lack of certainty in the evidence precludes clinical recommendations.

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1. Introduction

Type 2 diabetes mellitus (T2DM) is an endocrine disorder affecting almost half a billion individuals worldwide.[1] Suboptimal T2DM management can lead to serious macro- and micro-vascular complications. 'Lifestyle' self-management interventions including diet and/or exercise modification are cornerstone therapies for the prevention and management of T2DM. However, these therapies rely on adoption and sustained self-management to improve cardiometabolic outcomes. Further, many studies have reported that people with T2DM experience barriers to exercise adoption and diet modification.[2,3] Individuals with T2DM with comorbid obesity often cite physical and psychological discomfort as internal barriers to exercise,[4] and similar findings have been reported in regard to diet modulation.[5] Other factors such as inability to recognise and respond to internal cues of hunger[6] and impaired emotional regulation may lead to overeating through behaviours such as emotional- and stress-eating.[7] It has been hypothesised that mindfulness-based interventions (MBIs) may serve as the link between behaviour change

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adoption and long-term adherence, by improving overall levels of chronic psychological stress and resilience to the physical and emotional discomforts that come with lifestyle change and long-term self-management.[8]

Meditation refers to a broad set of practices that involve intentional self-regulation of attention for a variety of aims, including inducing physiological relaxation, via autonomic nervous system regulation, and improving well-being and emotional balance.[9-11] Mindfulness meditation originated from Eastern/Buddhist culture and is the practice of slowing the rate of breath, engaging the senses, and self-regulating attention to focus on the present moment experience with an orientation of curiosity, openness, acceptance, non-reactivity and non-judgement, regardless of whether an experience is seen as pleasant or unpleasant.[9,12-13] Self-regulation of attention involves sustained attention, attention switching, and the inhibition of elaborative processing.[12]

Indeed, evidence from systematic reviews suggests that mindfulness meditation in the general population can improve eating behaviours and increase physical activity[14-19] by teaching participants to become more accepting of the physical discomfort of portion control and physical exercise. MBIs have been shown to reduce body weight,[20] stress,[21] symptoms of depression[22] and anxiety,[23] and improve general psychological health[24] in the general population. In individuals with T2DM, MBIs may improve some aspects of quality of life although this evidence is limited.[25,26] Reductions in catecholamines have been described after mindfulness practice[27] which have strong implications for glycaemic control.[28]

The first clinical mindfulness program to be developed was a standardised intervention named Mindfulness-Based Stress Reduction (MBSR), an eight-week program which integrates Buddhist insight meditation, embodiment practices such as yoga, and modern psychological education about stress and stress coping.[29] Mindfulness-Based Cognitive Therapy (MBCT) is another mindfulness-based program that incorporates aspects of cognitive behavioural therapy.[30] There is now a considerable variety of MBIs, with many adapting the MBSR regimen, for example, by decreasing the duration, or delivering through digital means.[31]

It is important to evaluate a range of MBIs for clinical effectiveness in T2DM to inform practice. There have been two meta-analyses published in 2021 which reported conflicting results for glycemic control[32,33] but did not report on cardiovascular disease (CVD) risk factors. Because CVD remains the leading cause of death in people with T2DM,[34] it is also important to evaluate MBIs for their effects in improving CVD risk factors. Currently, only two systematic reviews on MBIs for T2DM have been conducted which include cardiovascular risk factors such as blood pressure.[16,35] Noordali et al conducted a systematic review on the effectiveness of MBIs in reducing diabetes-related physiological and psychological outcomes in adults with type 1 or type 2 diabetes mellitus and provided a narrative synthesis of 11 studies. Only one study reported a significant reduction in body weight post-intervention while three other studies did not report a change in weight. Blood pressure reductions were reported in two out of three studies.[16] Massey et al conducted a systematic review on wellbeing interventions (e.g. positive psychology interventions, mindfulness-based interventions) for type 1 or type 2 diabetes mellitus, and also provided a narrative synthesis of 18 randomised and non-randomised studies on MBIs, including three that examined body weight as an outcome measure. Because Massey et al included the same studies as Noordali et al, the conclusions for body weight were the same.[35] However, these were narrative syntheses only and no meta-analyses were conducted. Moreover, they were both conducted some years ago with Massey et al searching up until October 2017 and Noordali et al up until May 2015. Therefore, there is a need for an updated review incorporating meta-analysis for a broad range of clinical outcomes where possible. The aim of this systematic review and meta-analysis is to assess the effects of mindfulness-based interventions for adults with type 2 diabetes mellitus (T2DM) on quality of life, psychological outcomes, glycaemic control, and CVD risk indicators.

2. Methods

We have previously published our protocol[36] and followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 reporting guideline (Supplementary material).

2.1. Eligibility criteria

We included randomised controlled trials (RCTs) that met the following criteria:

- *Participants:* studies on adults (older than 18 years) with T2DM. We excluded studies that included participants without T2DM e.g. type 1 diabetes, unless outcomes for the subgroup of people with T2DM were available separately.
- *Interventions:* studies that used MBIs defined as all interventions that described mindfulness meditation as the main component, utilised formal mindful meditation techniques such as the body scan, mindful breathing or mindful movement, and where the primary aim of the intervention was to cultivate mindfulness. Mindfulness must have been defined as both present-moment awareness and nonjudgement. Interventions that were based on mindfulness meditation techniques as the main component, and which included additional components such as psychotherapy were included (including MBCT). We excluded interventions described as yoga or tai chi, even though mindfulness is recognised as a central feature of these practices, unless mindfulness was specified as a main component or focus of the practice (e.g. mindful yoga). We also excluded psychotherapy interventions as a main component that incorporated a mindfulness component. These include Acceptance and Commitment Therapy (ACT), and Dialectical Behavioural Therapy (DBT). These therapies are more commonly associated with traditional cognitive behavioural therapy, although they draw on 'mindful' principles within a larger suite of techniques but without an explicit focus on mindfulness meditation practice.[29,31,37] We also excluded interventions that do not have a primary aim of cultivating mindfulness, such as Mindful Self Compassion which has the primary aim of cultivating self-compassion.[38] These interventions are considered to be mindfulness-informed interventions rather than mindfulness-based.[29]
- *Comparators:* we included studies that compared MBIs against minimal intervention (e.g. single session at baseline), usual care, waitlist control, active control, or psychosocial interventions.
- *Outcomes:* we included studies that reported on the following outcomes:
  - *Primary outcomes:* health-related quality of life, psychological outcomes
  - *Secondary outcomes:* Complications of diabetes, Glycaemic control: evaluated using glycosylated haemoglobin A1c (HbA1c), adverse events, all-cause mortality, cardiovascular risk factors.

2.2. Search strategy

Our search strategy was developed by a multidisciplinary team including endocrinologists, exercise physiologists and general practitioners, together with an information scientist.

2.3. Information sources

We searched the following sources from the inception of each database to 12 September 2023 and placed no restrictions on the language of publication:

- Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Register of Studies Online (CRSO);
- MEDLINE (Ovid MEDLINE ALL 1946 to September 11, 2023);
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature);

- PsycInfo (Ovid APA PsycInfo 1806 to September Week 1 2023);
- Web of Science Clarivate (Science Citation Index, Social Science Citation Index, Emerging Citation Index);
- ClinicalTrials.gov (www.clinicaltrials.gov); World Health Organization International Clinical Trials Registry Platform (ICTRP) (www.who.int/trialsearch/).

For detailed search strategies, see Supplementary material.

2.3.1. Searching other resources

We attempted to identify other potentially eligible studies by searching reference lists of included studies, systematic reviews, meta-analyses, and health technology assessment reports.

2.3.2. Selection process

Two review authors (CE, AS, IAK) independently screened the abstract, title, or both, of every record retrieved by the literature searches in duplicate using Covidence software.[39] Full text records were also independently screened in duplicate. We resolved disagreements through consensus or by recourse to a third review author (MA).

2.4. Data collection process

2.4.1. Data extraction and management

For studies that fulfilled our inclusion criteria, two review authors (CE, AS, MA, RM, MP, IAK, DN, VR) independently extracted key information on participants, interventions and comparators. We contacted authors of included studies to obtain additional information. We did not use abstracts or conference proceedings for data extraction unless full data were available from study authors.

2.4.2. Data items

We extracted data on the following outcomes:

- *Primary outcomes:* health-related quality of life, psychological outcomes (stress, anxiety, depression)
- *Secondary outcomes:* Complications of diabetes, glycaemic control: evaluated using glycosylated haemoglobin A1c (HbA1c), adverse events, all-cause mortality, cardiovascular risk factors (systolic and diastolic blood pressure, weight, body mass index (BMI), waist circumference, hip circumference, lipid levels).

Data were extracted for all time points that were reported. We report on end-of-treatment outcomes, and short-term (up to 24 weeks post end of treatment), medium term (follow-up ≥ 24 weeks and up to 52 weeks post end of treatment), and long-term follow-up (≥ 52 weeks). We extracted data on participant and study characteristics including country, setting, eligibility criteria, and intervention/comparator details.

2.4.3. Study risk of bias assessment

Two review authors (CE, AS, MA, RM, MP, IAK, DN, VR) independently assessed risk of bias for each included study using the Cochrane Risk of Bias 1 tool. Risk of bias assessment is described in detail in Appendix 2 of our protocol.[36] In particular, adequate *random sequence generation* was defined as any method that generates an allocation sequence that produces comparable groups. These included drawing lots, using a random number table, shuffling cards or envelopes, throwing dice, and using software to generate an allocation sequence. Methods such as alternation (e.g. according to day of attendance at a clinic), or allocation by preference, were assessed as high risk. Adequate *allocation concealment* was defined as any method that removed the ability to foresee intervention allocations in advance, during enrolment, and which removed the chance of being changed after assignment. These included use of a central allocation (e.g. telephone), sealed opaque envelopes, and allocation using software. Other bias was assessed as any other potential source of bias related to specific study design used, or any other serious problem not otherwise included by the other domains. We resolved disagreements by consensus or by consulting a third review author (MA/CE).

2.4.4. Effect measures

When at least two included studies are available for a comparison of a given outcome, we attempted to express dichotomous data as a risk ratio (RR) with 95 % confidence intervals (CIs). For continuous outcomes measured on the same scale (e.g. HbA1c), we estimated the intervention effect using the mean difference (MD) with 95 % CIs. For continuous outcomes that measure the same underlying concept (e.g. health-related quality of life) but used different measurement scales, we calculated the standardised mean difference (SMD). Meta-analyses are displayed as forest plots.

2.4.4.1. Unit of analysis issues. We took into account the level at which randomisation occurred, such as cross-over studies, cluster-randomised trials, and multiple observations for the same outcome. Where more than one comparison from the same study was eligible for inclusion in the same meta-analysis, we either combined groups to create a single pair-wise comparison, or we appropriately reduced the sample size so that the same participants do not contribute data to the meta-analysis more than once (splitting the 'shared' group into two or more groups). This approach was taken for the study by Mahdi et al,[40] as there were two intervention groups (one delivered online, and one face-to-face). For the main comparison, we combined the findings from the two intervention groups and compared these with the combined findings of the two control groups (psychological therapies and usual care) as per the Cochrane handbook's formula. We also applied this approach to data from Sogol et al where there were two comparators (waitlist control and psychological therapies).[41] We halved the sample size for the control group in the comparisons where two intervention groups had been included. Although the latter approach offers some solution for adjusting the precision of the comparison, it does not account for correlation arising from inclusion of the same set of participants in multiple comparisons.

2.4.5. Assessment of heterogeneity

In the event of substantial clinical or methodological heterogeneity, we did not report study results as the pooled effect estimate in a meta-analysis. We took into account a visual examination of the variability in point estimates and the overlap in confidence intervals. We used the I^2 statistic to estimate the degree of heterogeneity present among the trials in each analysis. If we identified substantial unexplained heterogeneity, we reported it and explored possible causes by prespecified subgroup analysis.

2.4.6. Assessment of publication bias

If we could include 10 or more studies that investigate a particular outcome, we aimed to use funnel plots to assess small-study effects. Since none of the outcomes were reported by 10 or more studies, we did not undertake funnel plots.

2.4.7. Data synthesis

We planned to undertake a meta-analysis only if we judged the participants, interventions, comparisons and outcomes to be sufficiently similar to ensure a result that is clinically meaningful. Unless good evidence showed homogeneous effects across studies of different methodological quality, we primarily summarised data using a random-effects model.[42] We interpret random-effects meta-analyses with due consideration for the whole distribution of effects and presented a confidence interval. Revman Web was used for meta-analysis.

2.4.8. Subgroup analysis and investigation of heterogeneity

We expected the following characteristics to introduce clinical heterogeneity, and we planned to carry out subgroup analyses for these, including investigation of interactions.[43]

- Gender
- Mode of delivery (face to face vs non face to face)

- Type of mindfulness intervention: MBSR, MBCT, mindful yoga, other (not adapted from MBSR), brief intervention (<30 min on any one occasion, <100 min per week, up to four weeks duration).[44]
- Type of control (minimal intervention, usual care, wait list control, active control, psychosocial intervention).

2.4.9. Sensitivity analyses

We conducted *post-hoc* sensitivity analyses excluding Hartmann et al for HbA1c at medium-term follow-up, because data for Hartmann et al at this time point were transformed from median and interquartile range (IQR).

2.4.10. Certainty assessment

We presented the overall certainty of the evidence for each outcome specified below, according to the GRADE approach, which takes into account issues related to internal validity (overall risk of bias, inconsistency, imprecision, publication bias) and external validity (such as directness of results). Two review authors (MA, CE) independently rated the certainty of the evidence for each outcome. We resolved any differences in assessment by discussion or by consultation with a third review author (AS).

2.5. Differences between protocol and review

We removed the outcome 'socioeconomic effects' as the methods for this outcome were not fully developed in the initial protocol. We specified that the effect measure for dichotomous outcomes as risk ratios. We restricted sensitivity analysis to studies of overall low risk of bias and excluding trials where we had to transform skewed data. This was because of the small number of studies per comparison (<10).

We redefined the timing of our outcomes based on whether outcomes were measured at end of treatment or follow-up post end-of-treatment.

We amended the primary and secondary outcomes based on the large number of trials that reported on psychological outcomes and the few trials reporting on complications. We also considered complications to be not as relevant for MBIs compared to pharmacological interventions. Therefore, we moved complications to secondary outcomes. As it was not possible to combine the numerously reported psychological outcomes with the different quality of life scales, we defined psychological outcomes as an additional primary outcome. Finally, we updated the guidance on GRADE methods.

3. Results

We identified 1384 records through database searching and one record through other sources (a search for publications reporting on registered trials). After duplicates were removed, 843 records were available for screening, of which 719 were ineligible after title and abstract screening. From the remaining 124 records that were subjected to full-text screening, we excluded 69 records and included 55 records reporting on 31 individual completed studies. Six studies required translation from Persian[41,45-49] and one study from Chinese.[50] See Fig. 1 for the PRISMA flow diagram of study selection and Supplementary material for a list of excluded studies and reasons for exclusion.

Most data were obtained from published literature. Additional subgroup data for people with T2DM only was obtained via correspondence to the authors for HbA1c only for the Van Son trial.[51] Data on study period and length of follow-up were obtained directly from authors for Saskikumar et al's 2022 publication.[52] Data from Saslow et al and Hecht et al was obtained as unpublished data directly from authors and from online clinical trial registry data.[53,54] Studies were conducted in a number of countries: Australia,[55] China,[50,56-61] Germany,[62] India,[52,63,64] Iran,[40,45-49,65-69] the Netherlands,[51] South Korea,[70] Taiwan,[71] Thailand[72] and the USA.[53,54,73] See Table 1 for characteristics of included studies.

3.1. Study characteristics

Twenty-eight studies were parallel randomised-controlled trials and three were cluster-randomised trials.[67,70,71] Whereas one study was not specifically reported to be a cluster-randomised trial, it appeared to use this study design as the study authors described allocating intervention or control to two health centers to avoid contamination.[67] We used data for three arms from two studies[41,70] and from four arms for one study.[40]

3.2. Participant characteristics

The studies included 2337 participants with T2DM (1107 intervention, 1230 control). A total of 2096 participants (1002 intervention, 1094 control) finished the studies. Sample sizes ranged from 30–140 participants randomised. Mean age ranged from 41.3 years (y)[47] to 78.9 y.[71] Two studies (n = 138) only enrolled women.[49,67] Mean duration of diabetes ranged from 5.9 y[73] to 14.1 y.[61] We also note that a number of studies specifically enrolled people with comorbidities i.e. psychological comorbidities,[45,47,51,52,58,64,68] arthritis,[57] diabetic peripheral neuropathy,[59,61] hypertension,[52,63] lower extremity arterial disease[50] and microalbuminuria.[62] One study enrolled people with a BMI > 25 kg/m^2 [54] and one study enrolled people with BMI > 27 kg/m^2.[73]

3.3. Interventions

Out of 31 studies, 13 studies delivered Mindfulness-Based Stress Reduction or programs based on MBSR[40,45,48,52,57,58,62-65,67,68,70] with three delivering diabetes education as a co-intervention in both groups.[57,58,70] Seven studies delivered Mindfulness-Based Cognitive Therapy or programs similar to MBCT.[46,47,49,51,56,66,69] Zarifsanaiey delivered a program referred to as mindfulness training with components including raisin meditation, breathing meditation, informal practice, mindful seeing and hearing, sitting meditation, "familiarised with the realm of depression, anxiety and rumination", mindful walking, and cognitive behavioural therapy.[69] Given the authors specifically reference MBCT in their introduction, and included cognitive behavioural therapy, it was determined that this program was similar to MBCT. Eleven studies delivered a range of other MBIs including mindful eating[53,54,73] In terms of delivery, 24 studies delivered face-to-face intervention programs.

3.4. Outcomes

Studies reported on diabetes-specific quality of life, generic quality of life, diabetes distress, anxiety, depression and stress, systolic and diastolic blood pressure, body weight, and HbA1c. No studies collected adverse event outcomes or socioeconomic effects. Mortality, complications and lipids were collected by one study.[62] Outcomes were collected at end-of-treatment for all trials except Chen et al (2020) who collected outcomes at 3 weeks post end of treatment (EOT)[71] and Sukchaisong[72] who collected data at 4 weeks post EOT. In total, 13 studies collected follow-up data after end-of-treatment, ranging from 3 weeks[71] to 2 years and 10 months post EOT.[62] Saslow et al and Hecht et al also collected data during the 12-month intervention period.[53,54]

3.5. Risk of bias assessment

For an overview of review authors' judgements about each risk of bias item for individual studies and across all studies, see Fig. 2a/b. Less than half (15/31) of studies reported an acceptable method of random sequence generation. Less than a quarter (7/31) of studies described an acceptable method of allocation concealment. One study[72] was rated at high risk of selection bias due to allocation according to alternating

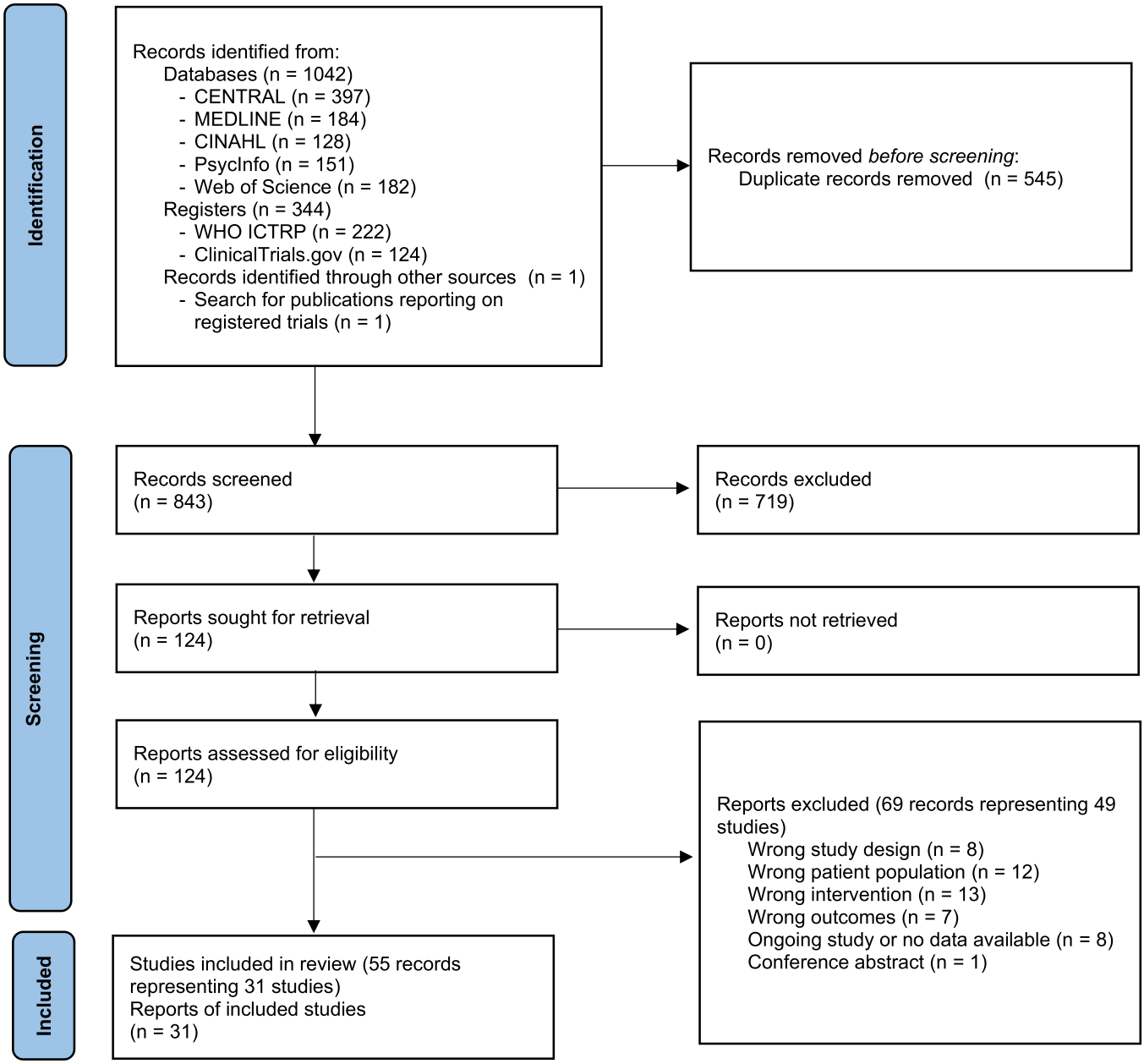

Fig. 1. PRISMA flow diagram of study selection.

weeks of clinic appointment. None of the studies were able to blind participants to treatment allocation therefore all studies are at high risk of bias for performance bias for all outcomes. Less than a quarter (6/31) of studies reported relatively low attrition rates of between 3.3 % to 11 %. Two studies reported attrition rates of around 18–22.5 %. The remaining studies reported very high attrition rates, including four studies reporting rates of >30 %[48,54,70,73] or did not report attrition at all. Nine studies were at low risk of bias for selective outcome reporting. Two studies were rated at high risk of other bias due to the lack of adjustment for clustering in analysis despite studies being designed and conducted as cluster RCTs.[67,70]

3.6. Effects of interventions

3.6.1. Generic quality of life

Both trials examining quality of life delivered MBSR. We are uncertain if MBSR has an effect on physical (SMD 0.17, 95 % CI –0.43 to 0.78; 2 RCTs, n = 130; I^2 = 43 %; very low certainty evidence, Fig. 3a) or mental (SMD 0.63, 95 % CI –0.42 to 1.68; 2 RCTs, n = 130; I^2 = 76 %; very low certainty evidence, Fig. 3b) domains of generic QoL at end of treatment compared to waitlist control/usual care. See Supplementary material for details of assessment of certainty of evidence.

3.6.2. Diabetes distress

In pooled analyses, we are uncertain if MBIs are effective for diabetes distress compared to control (SMD –0.98, 95 % CI –2.51 to 0.55; 4 trials, n = 255; I^2 = 96 %; very low certainty evidence, Fig. 3c) at end of treatment or at short-term follow-up (SMD –1.62, CI –3.47 to 0.24; 3 RCTs, n = 200; I^2 = 97 %; very low certainty evidence, Fig. s1a). Subgroup analysis for diabetes distress by type of intervention at end of treatment (EOT) was statistically significant for subgroup differences ($p < 0.00001$) but did not explain sources of heterogeneity, and only one trial was included for the intervention types of MBCT and Other MBIs,

Table 1
Characteristics of included studies.

First author, year; Country/setting; Language of publication (if not English)	Characteristics of participants; Mean age; Female/male	Sample size (randomised)	Intervention; duration of intervention; delivery; other details (if not standard program)	Comparison	Outcomes	Follow-up
Armani 2018[65] Iran/Outpatient clinic	People with T2DM 53.48 y (intervention), 59.03 y (control) Female gender: 72.4 % intervention, 90 % control	60	MBSR; 8 weeks; face to face	Usual care	Depression (HDRS) and anxiety (HARS); HbA1c	EOT (8 weeks), 3 months post EOT
Bao 2022[56] China/inpatient	People with T2DM recruited from inpatient ward 56.43 y (intervention), 58.82 y (control) Female: 63.3 % (intervention), 55.2 % (control)	68	MBCT; 2 weeks; face to face while inpatient	Usual care (routine diabetes education)	Diabetes distress (Diabetes Distress Scale)	Hospital discharge/EOT (~2 weeks) and 1 month after discharge
Chen 2020[71] Taiwan/Long term care facilities	People with T2DM >65 yo, Living in LTCF 78.85 y (intervention), 78.95 y (control) Female gender: 64.6% intervention, 65.2 % control	140	Mindfulness NOS (included mindful deep breathing relaxation); 9 weeks; face to face Each weekly session included 30 mins of mindful deep breathing relaxation and 60 mins of practising mindfulness activities	Usual care	Depression (DASS 21), HbA1c	12 weeks (3 weeks post EOT)
Chen 2021[57] China/inpatient	People with T2DM and comorbid arthritis including rheumatoid arthritis, psoriatic arthritis 63.98 y (intervention), 64.11 y (control) Female gender: 44.6 % intervention, 40.43 % control	94	MBSR + diabetes education; 8 weeks; face to face and electronic (manuals, videos, and social media "WeChat")	Education alone - Intensive education about arthritis and diabetes, pathogenesis, clinical manifestations, drug guidance and complications	QoL (Diabetes Specific Quality of Life scale)	EOT (8 weeks)
Fatemeh 2019[45] Iran/Diabetes society	People with T2DM and poor sleep quality/high anxiety, depression and stress scores Participant details NR	30	MBSR; 8 weeks; delivery NR	Usual care	Stress, anxiety and depression (DASS-21)	EOT (8 weeks)
Fatemeh 2021[46] Iran/Diabetes centre	Women with T2DM 93 % were 20-40 y (intervention), 87 % (control) 100 % were female	30	MBCT; 8 weeks; face to face	Usual care	Positive and negative affect (PANAS)	EOT (8 weeks)
Ge 2020[50] China/inpatient	People with T2DM and Lower Extremity Arterial Disease who were inpatients on endocrinology ward 57.5 y (intervention), 58.62 y (control) Female: 48 %	100	Mindfulness based on meta-awareness training + IPC; 12 weeks; face to face and through social media platform "WeChat" Mindfulness training was based on "meta awareness" that combines attentional control, receptive attitudes and responsiveness, a dynamic self and reflection on values. Components included body scan, mindful breathing exercises, informal meditation, Recognition Thinking and Direct Perception Experience Calendar, Walking meditation, Choiceless Awareness meditation, mindful yoga. Delivered face to face while an inpatient followed by home practice 45 mins daily and group mindfulness through "WeChat" once a week post discharge.	IPC alone	Diabetes distress (Diabetes Distress Scale) and HbA1c	EOT (12 weeks)

(*continued on next page*)

Table 1 (*continued*)

First author, year; Country/setting; Language of publication (if not English)	Characteristics of participants; Mean age; Female/male	Sample size (randomised)	Intervention; duration of intervention; delivery; other details (if not standard program)	Comparison	Outcomes	Follow-up
Gholamnejad 2023[47] Iran/outpatient Persian	People with T2DM and comorbid depression (moderate-severe based on Beck Depression Inventory II) 43.4 y (intervention), 41.3 y (control) Female: NR	30	MBCT; 8 weeks; delivery NR, presumed face to face	Usual care/no intervention	HbA1c	EOT (8 weeks)
Guo 2022[58] China/inpatient	People with T2DM who were inpatients on endocrinology ward, Diabetes Distress Scale-17 score >3 61.12 y (intervention), 63.7 y (control) Female sex: 58 % intervention, 48 % control	100	MBSR; 8 weeks; face to face while inpatient and remotely via social media "WeChat"	Usual care (routine diabetes education)	Diabetes distress (Diabetes Distress Scale), BP, HbA1c	EOT (8 weeks), 1 month post EOT
Hartmann 2012[62] Germany/outpatient	People with T2DM and proven microalbuminuria 58.7 y (intervention), 59.3 y (control) Female sex: 24 % intervention, 19 % control	110	MBSR; 8 weeks with booster session at 6 months; face to face	Usual care	Generic QoL mental, physical (SF12), stress, depression (PHQ), BP, BMI, lipids, complications, mortality	EOT (8 weeks), 1 year, 3 years
Hecht 2022[53] USA/outpatient (University centre for integrative medicine)	People with T2DM and HbA1c > 6.5 % 59.0 y (intervention), 57.9 y (control) Female sex: 64.5 % intervention, 68.3 % control	125	EatRightNow (mindful eating intervention) + diet intervention; 12 months; face to face and via an app Components included meditation exercises such as body scan; mindful eating approaches such as paying attention and noticing habit loops, disrupting emotional and stress eating, delivered weekly (1hr mindfulness, 1 hr diet instruction) for 12 weeks followed by 9 x monthly sessions for the remainder of the study year	Diet intervention only (carbohydrate-restricted diet with 10 % of kcal coming from carbohydrate, and basic behavioural strategies delivered face to face in a group setting for 12 × 1 hour weekly sessions followed by 9 × 1 hr monthly sessions)	Stress (Perceived Stress Scale), Weight, HbA1c	3, 6, 12 months (EOT at 12 months)
Hosseini 2021[66] Iran/health centres	People with T2DM 42.5 y (intervention), 41.7 y (control) Female: 44 % overall	30	MBCT; 8 weeks; face to face and prerecorded CDs	Waitlist control	Wellbeing (Ryff Wellbeing Scale), HbA1c	EOT (8 weeks)
Jung 2015[70] South Korea/Community health centres and hospitals	People with T2DM > 6 months duration 67 y (intervention), 68.33 y (walking group), 68.47 y (usual care)	84	MBSR; 8 weeks; face to face and via audio CDs	Walking group + usual care (education) OR usual care alone The walking group received instruction on proper walking techniques and were encouraged to walk briskly during the week while wearing a pedometer. They attended weekly meetings where they shared experiences of walking, and kept walking diaries as well as were monitored by weekly telephone interviews.	Diabetes distress (Diabetes Distress Scale), stress (Perceived Stress Response Inventory)	EOT (8 weeks)
Kumar 2017[63] India/rural community setting	People with T2DM and hypertension (systolic 140-159 mmHg, diastolic 90-99 mmHg) Age NR Female: 61.1 % intervention, 60 % control	40	MBSR; 8 weeks; delivery NR, presumably face to face	Waitlist control	Systolic and Diastolic BP	EOT (8 weeks)

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Table 1 (*continued*)

First author, year; Country/setting; Language of publication (if not English)	Characteristics of participants; Mean age; Female/male	Sample size (randomised)	Intervention; duration of intervention; delivery; other details (if not standard program)	Comparison	Outcomes	Follow-up
Mahdi 2019[40] Iran/outpatient	People with T2DM and HbA1c > 7.5 % Mean age NR Female: 76 % intervention (Social Network Mindfulness group), 80 % intervention (Mindfulness group), 65 % control (Acceptance Commitment Therapy/ACT group), 75 % control (usual care)	80	Social network based mindfulness intervention; 8 weeks; online (Telegram social network) Content was based on MBSR. Components included information on mindfulness, breathing meditation, body scan, sitting meditation, hatha yoga, mindful walking, raisin meditation. Participants connected via online social network as a group for feedback and questions/answers. They received an online mindfulness training package including text, audio, image, video and animation. Mindfulness training in person; 8 weeks; face to face. Based on MBSR.	Usual care OR ACT; 8 weeks; delivery NR, presumably face to face	HbA1c	EOT (8 weeks), 1 month post EOT
Miller 2012[73] USA/recruited from local medical practices	People with T2DM and BMI > 27, HbA1c > 7 % 53.9 y (intervention), 54.0 y (control) Female: 63 % intervention, 64 % control	68	MB-EAT-D (Mindfulness-based Eating Awareness Training for Diabetes); 3 months; face to face and home practice with CD-ROMs Components included guided meditation oriented towards the experiences and emotions associated with food intake. Participants were encouraged to cultivate mindful awareness related to eating. Basic information on medical nutrition therapy was also provided.	Diabetes self-management education; 3 months; face to face	BMI, Body weight, waist circumference, HbA1c	EOT (3 months), 3 months post EOT
Mohammad 2018[48] Iran/diabetes centre Language: Persian	People with T2DM > 1 year duration 54.3 y (intervention), 50.76 y (control) Female gender: 60 % intervention, 69.2 % control	30	MBSR; 8 weeks; face to face	Usual care	Generic QoL (SF36)	EOT (8 weeks)
NikkahRavari 2020[67] Iran/health centres	Women with T2DM > 6 months and HbA1c between 7-9 % 56.4 y (intervention), 57.7 y (control) 100 % female	108	MBSR; 12 weeks; face to face for 8 weeks then home exercises for 4 weeks	Usual care	Depression/Anxiety/Stress (DASS-21), HbA1c	EOT (13 weeks)
Pearson 2018[55] Australia/outpatient clinic	People with T2DM attending outpatient clinic ie poorly controlled/vascular complications/recent severe hypoglycemia etc. 57.5 y (intervention), 61.1 y (control) Female gender: 61 % intervention, 39 % control	74	Mindfulness NOS; 8 weeks; audio CD Participants were provided with an audio CD with recordings of guided breath awareness meditation together with an instruction sheet. Participants meditated 30 mins a day.	Usual care	QoL (PAID), Depression/Anxiety/Stress (K10), systolic and diastolic BP, HbA1c	EOT (8 weeks) and 4 weeks post EOT
Sasikumar 2017[64] India/rural community setting	People with T2DM >1 year, high stress levels (stress score ≥15) Mean age NR Female gender: 60 % intervention, 61.1 % control	40	MBSR; 8 weeks; face to face	Waitlist control	Depression (CES-D) and stress (Perceived Stress Scale)	EOT (8 weeks), 1 month post EOT
Sasikumar 2022[52] India/rural community setting	People with T2DM and moderate stress levels (Perceived Stress Scale ≥15) Mean age NR Female gender: 55 % intervention, 59 % control	138	MBSR; 8 weeks; face to face	Waitlist control	Depression (CESD), stress (Perceived Stress Scale), systolic and diastolic BP, HbA1c, BMI	EOT (8 weeks), 6 months post EOT

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Table 1 (*continued*)

First author, year; Country/setting; Language of publication (if not English)	Characteristics of participants; Mean age; Female/male	Sample size (randomised)	Intervention; duration of intervention; delivery; other details (if not standard program)	Comparison	Outcomes	Follow-up
Saslow 2022[54] USA/online	People with T2DM and BMI > 25, HbA1c > 6.5 Mean age: 54.1 y Female gender: 71 %	39	Mindfulness information + lifestyle intervention; 12 months; online including videos and handouts Mindfulness intervention was based on MB-EAT (mindfulness-based eating). Participants were provided with mindfulness information (mini meditations) and guided mindful eating exercises as well as general mindfulness topics such as how to respond vs how to react.	Lifestyle intervention alone (very low carbohydrate diet); 12 months; online Participants were taught to follow a very low carbohydrate diet and taught to be more physically active.	Depression (PHQ), HbA1c, % weight loss	4 months, 8 months, EOT (12 months)
Sayadi 2022[68] Iran/outpatient	People with T2DM and moderate anxiety and depression, severe stress 68.04 y (intervention), 67.52 y (control) Female gender: 52 % intervention, 60 % control	56	MBSR; 8 weeks; online (via Whatsapp)	Usual care	Stress, anxiety and depression (DASS-21)	EOT (8 weeks), 3 months post EOT
Sogol 2020[41] Iran/NR Language: Persian	People with T2DM 50.23 y (intervention), 52.08 y (psychological wellbeing training), 51.20 y (waitlist control) Female: 44 % intervention, 52 % psychological wellbeing training, 48 % waitlist control	75	Based on Mindfulness-based Relapse Prevention; 5 weeks; face to face Components included breathing meditation and body scan. Content included exploring restlessness and mental wandering, awareness of thoughts, self-care, dealing with anxiety using mindfulness.	Psychological wellbeing training; 5 weeks; face to face. Based on the theory proposed by Ryff and Singer. Components included accepting one's positive and negative attributes, past mistakes, learning to love onself and creating a positive attitude towards oneself, emotional intelligence, utilising optimism and positive thinking. Waitlist control	Anxiety (Anxiety Inventory 6)	EOT (5 weeks)
Sukchaisong 2022[72] Thailand/outpatient	People with T2DM and HbA1c > 7.5 % 63.8 y (intervention), 63.4 y (control) Female gender: 80 % intervention, 77.5 % control	80	Mindfulness-based diabetes self and family management support program; 11 weeks; face to face Based on the Information Motivation Behaviour Skills model to identify determinants of behavioural changes in people with chronic conditions. Components included knowledge and skill training for disease management; mindfulness practice with breathing meditation and body scan; mindful eating practice.	Usual care	HbA1c	16 weeks (4 weeks post EOT)
Tabadkan 2019[49] Iran/public sports organisation Language: Persian	Women with T2DM 56.17 y (intervention), 52.25 y (control) 100 % female	30	MBCT; 8 weeks; delivery NR	Usual care	Stress (PSS-4)	EOT (8 weeks), 3 months post EOT
VanSon 2013[51] Netherlands/outpatient	T1D/T2DM with low levels of emotional wellbeing 74 % and 65 % of the intervention and control groups had T2DM respectively. 56.3 y (intervention), 57 y (control) Female: 52 % intervention, 46 % control	97	MBCT; 8 weeks with a booster session at 3 months post-intervention; face to face	Usual care	HbA1c	Between 24 weeks - 1 month before the intervention and 6–24 weeks after the intervention

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Table 1 (*continued*)

First author, year; Country/setting; Language of publication (if not English)	Characteristics of participants; Mean age; Female/male	Sample size (randomised)	Intervention; duration of intervention; delivery; other details (if not standard program)	Comparison	Outcomes	Follow-up
Weng 2022[59] China/outpatient	People with T2DM and diabetic peripheral neuropathy 42.9 y Female: 60 %	120	Mindfulness based on meta-awareness + aerobic exercise; 12 weeks; face to face as well as WeChat and telephone follow-up Mindfulness training was based on meta-awareness and included body scan and breathing meditation with the topics of awareness and autopilot model, live in ideas, accepting and letting go. Combined with aerobic exercise.	Usual care	QoL (Diabetes Specific Quality of Life Questionnaire)	12 weeks
Xiao 2018[60] China/diabetic patient counselling centre	People with T2DM and HbA1c 7-8.5 % 45.1 y (intervention), 44.7 y (control) Female: 39 % intervention, 42 % control	47	Mindfulness NOS; 10 weeks; delivery NR "Modified Mindfulness Program" including breathing meditation, body scan, sitting meditation, informal practice.	Usual care	HbA1c	EOT (10 weeks) and 8 months post EOT
Yue 2023[61] China/outpatient	People with T2DM and diabetic peripheral neuropathy 60.57 y Female gender: 45.8 %	90	Mindfulness NOS + Tai Chi; 12 weeks; delivery NR but presumably face to face Components included breathing meditation, body scan, and informal practice.	Tai Chi alone or usual care	QoL (Diabetes Quality of Life questionnaire)	EOT (12 weeks)
Zarifsanaiey 2020[69] Iran/outpatient	People with T2DM > 1 year 48.3 y (intervention), 49.5 y (control) Female: 65 %	136	Mindfulness NOS; 8 weeks; face to face "Mindfulness training" including breathing meditation, sitting meditation, informal practice, and CBT	Usual care	Happiness Level, HbA1c	EOT (8 weeks)

BMI, body mass index; BP, blood pressure; CBT, Cognitive Behavioural Therapy; CES-D, Center for Epidemiological Studies Depression; DASS 21, Depression Anxiety and Stress Scale 21; DSQL, Diabetes Specific Quality of Life scale; EOT, end of treatment; HARS, Hamilton Anxiety Rating Scale; HbA1c, glycated hemoglobin; HDRS, Hamilton Depression Rating Scale; K10, Kessler Psychological Distress Scale; MBCT, Mindfulness-Based Cognitive Therapy; MB-EAT-D, Mindfulness-Based Eating Awareness Training for Diabetes; MBSR, Mindfulness-Based Stress Reduction; NOS, Not otherwise specified; NR, Not reported; PAID, Problem Areas in Diabetes; PHQ, Patient Health Questionnaire; PSS-4, Perceived Stress Scale 4; QoL, quality of life; SF-36, 36-Item Short Form Survey; T1D, Type 1 diabetes mellitus; T2DM, Type 2 diabetes mellitus; y, years.

limiting our ability to make conclusions. Meta-analysis was only possible with two trials examining MBSR, with no difference between groups (SMD –1.55, 95 % CI –4.79 to 1.69; 2 trials; n = 138; I^2 = 98 %; very low certainty evidence, Fig. 3c).

See Supplementary material for follow-up and further subgroup analyses.

3.6.3. Stress

In pooled analyses, MBIs may reduce stress (SMD –1.01, 95 % CI –1.81 to –0.20; 8 RCTs, n = 528; I^2 = 94 %; very low certainty evidence, Fig. 3d) at end of treatment, but the evidence is very uncertain. This effect may not persist at short-term (SMD –1.53, 95 % CI –3.31 to 0.25; 3 RCTs, n = 118; I^2 = 93 %; very low certainty evidence, Fig. s1b) or medium-term follow-up (SMD –1.76, 95 % CI –3.71 to 0.19; 2 RCTs, n = 230; I^2 = 97 %; very low certainty evidence, Fig. s2a) where there was no difference between groups found although the evidence is very uncertain. In subgroup analyses, meta-analyses were only possible for studies on MBSR at end of treatment. MBSR may reduce stress (SMD –1.27, 95 % CI –2.32 to –0.21; 6 RCTs, n = 267; I^2 = 92 %; very low certainty evidence, Fig. 3d). Subgroup differences were statistically significant, however this is limited by the fact that two intervention types (MBCT and Other) are represented only by single trials.

We are uncertain if there is a difference between MBIs + diet and lifestyle vs diet and lifestyle alone for stress scores after 3 months (MD 0.63, 95 % CI –1.25 to 2.51; 1 RCT; n = 122, very low certainty evidence) or 6 months (MD 0.59, 95 % CI –1.31 to 2.49; 1 RCT; n = 122) of treatment during a 12-month treatment period. We are uncertain if MBIs + lifestyle improve stress scores more than lifestyle alone (MD 1.25, 95 % CI –0.73 to 3.23; 1 RCT; n = 113; very low certainty evidence) at the end of treatment (12 months).

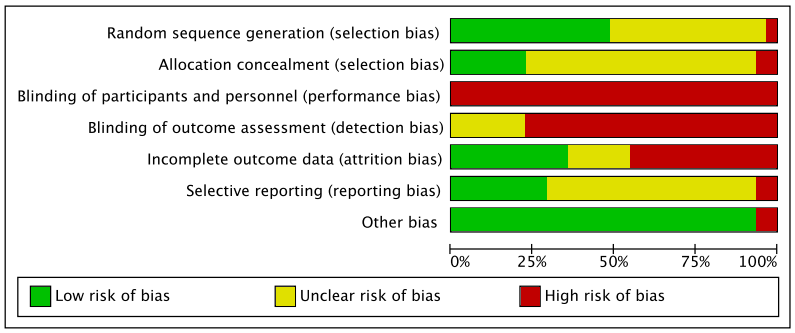
3.6.4. Depression

In pooled analyses, MBIs may reduce depression symptoms at end of treatment (SMD –1.26, 95 % CI –2.08 to –0.43; 7 RCTs, n = 570; I^2 = 95 %; very low certainty evidence, Fig. 3e) compared to waitlist control/usual care but the evidence is very uncertain. This effect did not appear to persist at short-term follow-up (SMD –3.10, 95 % CI –8.89 to 2.68; 2 RCTs, n = 96; I^2 = 98 %, very low certainty evidence, Fig. S1c) or medium-term follow-up (SMD –1.71, 95 % CI –3.96 to 0.54; 2 RCTs, n = 216; I^2 = 98 %; very low certainty evidence, Fig. S2b) noting the limited number of studies that collected follow-up data.

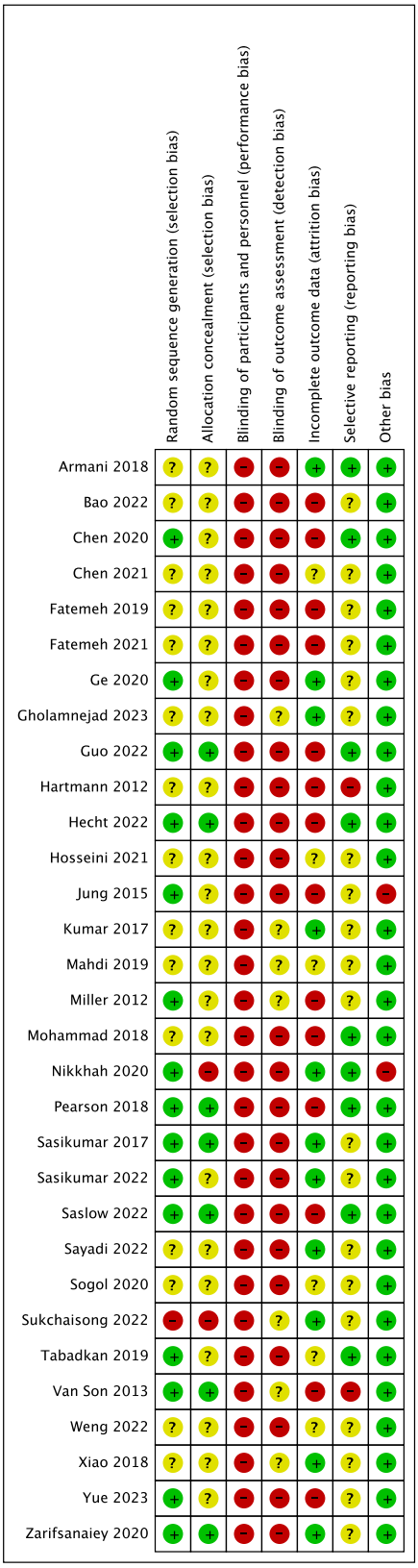
In subgroup analyses, there was no statistically significant differences between subgroups for intervention type, however this is limited by the fact that only one trial studied a non-MBSR intervention. Meta-analysis was possible for trials using MBSR, suggesting that MBSR may reduce depression symptoms at end of treatment (SMD –1.49, 95 % CI –2.67 to –0.30; 5 RCTs, n = 399; I^2 = 96 %; low certainty evidence, Fig 3e).

3.6.5. Anxiety

In pooled analyses, MBIs may reduce anxiety at end of treatment compared to waitlist control/usual care (SMD –0.67, 95 % CI –1.27 to



a Risk of bias graph



b Risk of bias summary

Fig. 2. Risk of bias graph and summary.

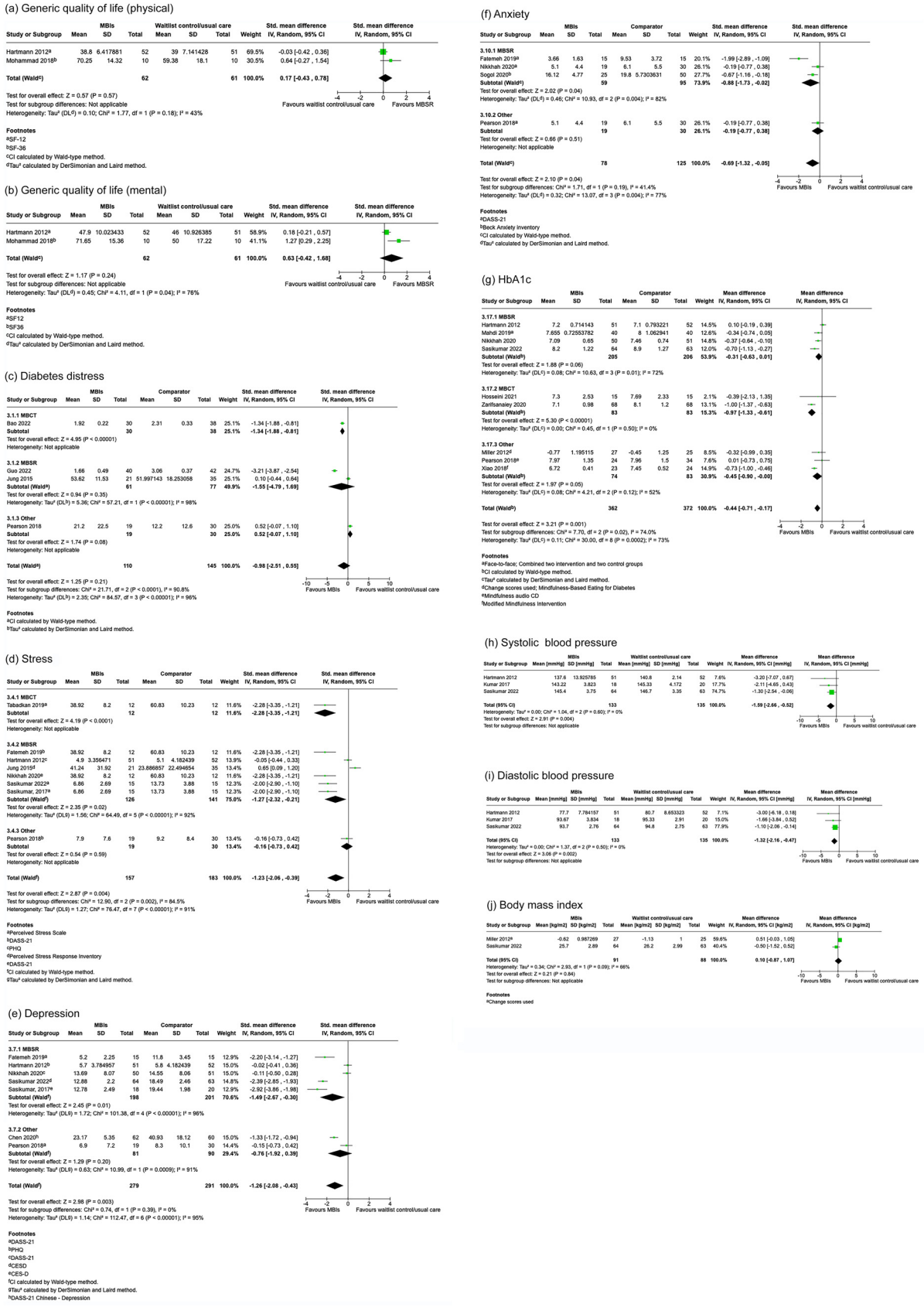


Fig. 3. Mindfulness-based interventions vs waitlist control/usual care at end of treatment. (a) Generic quality of life (physical); (b) Generic quality of life (mental); (c) Diabetes distress; d. Stress; (e) Depression; (f) Anxiety; (g) HbA1c; (h) Systolic blood pressure; (i) Diastolic blood pressure; (j) Body mass index.

–0.08; 4 RCTs, $n = 255$; $I^2 = 78\%$; very low certainty evidence, Fig. 3f) but the evidence is very uncertain. Pearson et al reported no difference between MBIs and usual care at 1-month post-intervention (MD –1.50, 95 % CI –4.69 to 1.69; 1 RCT, $n = 58$). There were no subgroup differences for intervention type at end of treatment, noting that this analysis is limited due to only one trial using a non-MBSR intervention. Meta-analysis was possible for trials using MBSR, suggesting that MBSR may reduce anxiety at end of treatment compared to waitlist control/usual care (SMD –0.88, 95 % CI –1.73 to –0.02; 3 RCTs, $n = 154$; $I^2 = 82\%$; very low certainty evidence, Fig 3f).

3.6.6. Adverse events

No studies reported on this outcome.

3.6.7. Glycaemic control

In pooled analyses, MBIs may have a small effect on HbA1c at end of treatment compared to usual care/waitlist control (MD –0.44, 95 % CI –0.71 to –0.17, 9 RCTs, $n = 734$; $I^2 = 73\%$; low certainty evidence, Fig. 3g). We are uncertain if MBIs have an effect on HbA1c at short-term follow-up compared to usual care/waitlist control (MD –0.31, 95 % CI –0.79 to 0.16; 7 RCTs, $n = 513$; $I^2 = 76\%$; very low certainty evidence, Fig. S1d). MBIs may have a large effect on HbA1c at medium-term follow-up compared to usual care/waitlist control (MD –0.96, 95 % CI –1.80 to –0.11; 3 RCTs, $n = 277$; $I^2 = 96\%$; very low certainty evidence, Fig. S2c) but the evidence is very uncertain. There was no significant difference between MBSR and usual care at 2 or 3 year follow-up for HbA1c (effect size 0.27 and 0.36 for 2 and 3 year follow-up respectively, $p \geq 0.05$) based on the one trial by Hartmann et al.[27]

Subgroup analyses at end of treatment was statistically significant for intervention type. MBSR did not reduce HbA1c compared to waitlist control/usual care (MD –0.31, 95 % CI –0.63 to 0.01; 4 RCTs, $n = 411$; $I^2 = 72\%$, low certainty evidence, Fig 3f), while MBCT may more effective than waitlist control/usual care for reducing HbA1c (MD –0.97 %, 95 % CI –1.33 to –0.61; 2 RCTs, $n = 166$; $I^2 = 0\%$; very low certainty evidence, Fig 3f).

At short-term follow-up there were no statistically significant subgroup differences for type of intervention, with none of the intervention subgroups (MBCT, MBSR, or Other) demonstrating superiority of the intervention over comparator. At medium-term follow-up there was a statistically significant difference between intervention subgroups suggesting no effect for MBSR compared with waitlist control/usual care (MD –0.63, 95 % CI –1.29 to 0.02; 2 RCTs, $n = 230$; $I^2 = 88\%$; very low certainty evidence, Fig S2) although we note small numbers and only one trial in the "other" subgroup.

We are uncertain if MBIs + lifestyle are superior to lifestyle alone for reducing HbA1c during treatment at short-term (MD –0.18, 95 % CI –1.69 to 1.32; 2 RCTs; $n = 131$; $I^2 = 80\%$; very low certainty evidence, Fig. S3a) or medium-term follow-up (MD 0.04, 95 % CI –1.02 to 1.11; 2 RCTs; $n = 123$; $I^2 = 50\%$; very low certainty evidence, Fig. S4a) during a 12-month treatment period, or at end of treatment (12 months) (MD 0.04, 95 % CI –1.28 to 1.36; 2 RCTs; $n = 113$; $I^2 = 91\%$; very low certainty evidence, Fig. 4a).

3.6.8. Complications

One study[62] reported on complications of T2DM. At one year there were no reports of ischemic heart disease in either group. At three years, there were five events of ischemic heart disease (non-fatal) in the MBSR group and six in the usual care group. There were two events of stroke in the MBSR group and none in the usual care group.

3.6.9. All-cause mortality

One study reported on all-cause mortality at three years[62]. We are uncertain if there is a difference in all-cause mortality between MBSR and usual care at three year follow-up (OR 0.89, 95 % CI 0.12 to 6.61; 1 RCT; $n = 89$, very low certainty evidence). All deaths recorded were due to ischemic heart disease.

3.6.10. Blood pressure

MBIs may slightly reduce systolic (MD –1.59, 95 % CI –2.66 to –0.52; 3 RCTs; $n = 268$; $I^2 = 0\%$; low certainty evidence, Fig. 3h) and diastolic (MD –1.32, 95 % CI –2.16 to –0.47; 3 RCTs; $n = 268$; $I^2 = 0\%$; low certainty evidence, Fig. 3i) blood pressure at end of treatment compared to waitlist control/usual care. However, these effects did not persist at medium-term follow-up (Fig. S2d).

3.6.11. Lipids

There were no differences between MBSR and usual care for lipids at any endpoint based on one study.[27]

3.6.12. Anthropometric measures

We are uncertain if MBIs have an effect on BMI at end of treatment (MD 0.10, 95 % CI –0.87 to 1.07; 2 RCTs, $n = 179$; $I^2 = 66\%$; very low certainty evidence, Fig. 3j) compared to waitlist control/usual care. Hartmann et al reported that there was no difference between MBSR and

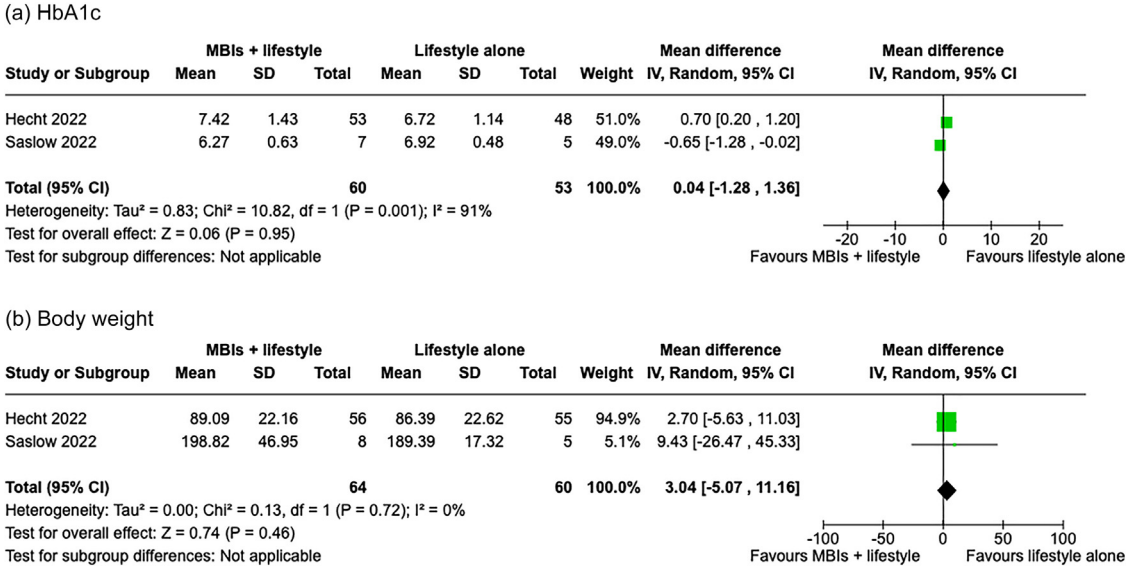


Fig. 4. Mindfulness-based interventions + lifestyle vs lifestyle alone at end of treatment. (a) HbA1c; (b) Body weight.

usual care for BMI at 1, 2 or 3 year follow-up.[62] Miller et al reported no significant differences between groups with regard to change in weight or waist circumference at end of treatment.[73] MBIs + lifestyle may not result in any differences in body weight compared to lifestyle alone at end of treatment (MD 3.04, 95 % CI –5.07 to 11.16; 2 RCTs, n = 124; I^2 = 0 %; low certainty evidence, Fig 4b).

4. Discussion

To the best of our knowledge, this was the most comprehensive review that aimed to determine the efficacy of MBIs for a broad range of health-related outcomes in T2DM. The results show that MBIs may elicit large effects on stress and depression and a moderate effect on anxiety. MBIs may have a modest effect on blood pressure and HbA1c approaching clinical significance. It is unclear if MBIs have an effect on QoL, diabetes distress, and body weight.

Ngan and colleagues published a 2021 meta-analysis involving nine studies (801 participants) which showed that mindfulness and acceptance-based interventions significantly reduced diabetes distress and HbA1c.[33] However, given their inclusion of studies using ACT as an intervention means that this review is not directly comparable to ours, as we excluded ACT and other “third wave” interventions. Ni and colleagues published a meta-analysis involving eight studies and 841 participants with T1D and T2DM which showed that MBIs can improve HbA1c (MD –0.25, 95 % CI –0.43 to –0.07, 7 trials), depression (SMD –0.56, 95 % CI –0.82 to –0.30, 8 trials) and diabetes-related distress (MD –5.81, 95 % CI –14.42 to –1.53, 5 trials).[26] We found larger effect sizes for HbA1c and depression, but our review only included people with T2DM. Additionally we included data from trials published in other languages. Contrary to our finding of a modest effect on glycaemic control, Bersch-Ferreira and colleagues meta-analysis of four randomised trials indicated that established protocols involving MBI had no effect on blood glucose or HbA1c in individuals with T2DM.[32] The discrepancy may be explained by the small number of studies in the Bersch-Ferreira meta-analysis. Our findings are specific to participants with T2DM, include both published and unpublished literature, and not limited by language.

Coupled with findings of improved perceived stress and depression, which influence glucocorticoid[28] and autonomic nervous system regulation, and can improve health-related behaviours relevant to glycaemic control, it seems plausible to speculate a mechanistic relationship between MBIs and improved HbA1c in our study. For example, during periods of increased stress, glucocorticoid and catecholamine levels become elevated, which if unresolved in a timely manner, can disturb glucose homeostasis and can lead to chronic hyperglycaemia, insulin resistance, and T2DM.[74,75] Indeed, when modelling continuous glucose for T2DM management, psychological stress predicts fluctuations in circulation glucose, independent of exercise or meal status.[76]

MBIs may also improve HbA1c through their indirect effects on promoting healthy lifestyle behaviours such as improved sleep quality and duration, physical activity, and diet quality. For example, given the effects of MBIs on sleep, it is plausible that as MBI-related improvements in sleep coincide and drive, in part, improved glucose regulation.[77] Similarly, MBIs may directly or indirectly improve depression through increased physical activity which can result in improved HbA1c. Furthermore, reducing stress and depression symptoms has been linked to improved diet quality which results in better glucose regulation (even without changes in BMI)[78]. Future studies should collect data on health-related behaviours to further explore this potential link.

This review included studies which differed in style and philosophy of MBIs as well as delivery setting, format, duration, and experience of therapists. About two thirds of included studies delivered a standardised intervention such as MBSR or MBCT with the remainder delivering a range of MBIs which were not always well described. Given the relative lack of data available, we were unable to determine which MBIs were more effective than others or whether delivery type (face-to-face or non face-to-face) plays a role in effectiveness for health outcomes from MBIs. There was high heterogeneity in many of our analyses, which we addressed through the use of random-effects meta-analyses and exploring reasons for heterogeneity through subgroup analyses. However, the certainty of evidence of our analyses was frequently downgraded due to the presence of heterogeneity. Additionally, while multiple studies excluded participants for missing two or three sessions, only two studies reported session attendance.[51,62] As a result, we cannot exclude that null-findings may be, in part, due to non-attendance. Finally, given that most studies were conducted in non-Western countries, the translatability of the findings may be more limited, as cultural differences may influence the receptiveness of participants to practise MBIs.

Of particular concern, none of the studies included this review blinded participants to treatment allocation despite the importance of active control conditions being highlighted over a decade ago.[79] MacCoon and colleagues argue that to appropriately test mindfulness as an active ingredient of MBIs, an adequate control condition for attention is required while attending to key limitations of active controls in behavioural intervention research, such as being structurally equivalent (i.e., having the same number and duration of sessions, similar experience of therapists, and format of delivery). Most data from our review are from trials that compared MBIs against no additional treatment (waitlist control/usual care). The failure to control for the attention effect from MBIs lowers certainty of the evidence and does not provide adequate information on the impact of non-specific effects of the intervention rather than the impact of the active ingredient of mindfulness meditation. Future studies need to implement active controls when assessing the efficacy of MBIs for T2DM.

Our findings highlight the great need to conduct further, well-reported and rigorously conducted randomised trials to determine the effect of MBIs on our primary and secondary outcomes, particularly on QoL, all-cause mortality, and T2DM complications, and compare against an active control. To enable comparison of QoL outcomes, future studies can use the International Consortium for Health Outcomes Measurement recommended person-centred outcome measures of QoL in people with diabetes.[80] Key questions that have not been answered by our review include whether there is a difference between method of delivery and adverse effects of MBIs. These can be addressed with subsequent trials. In addition, high rates of attrition highlights the need to explore participant engagement and sustainability of the intervention. To improve certainty of the evidence, sample size calculations are needed to ensure trials are adequately powered to detect between group differences.

MBIs may have large effects for psychological outcomes of stress and depression and moderate effects for anxiety. The reduction in HbA1c and blood pressure was modest and not clinically significant. The certainty of the evidence is very low, therefore it is difficult to make clinical recommendations on the use of MBIs in people with T2D. However, we can conclude that the evidence is promising for depression and stress. We are currently unclear if adding MBIs to standard treatments such as lifestyle advice has any benefits, due to the small number of trials and methodological limitations of the studies included. MBIs are a generally low-risk intervention, with few reported adverse events,[81] although adverse events may be under-reported in clinical trials.[82] A temporary increase in anxiety or negative emotions has been reported.[83] Despite the overall low risk, standard mindfulness-based programs such as MBSR require a substantial time commitment and may also require a significant financial commitment depending on the cost of the program. These are important considerations for clinicians and patients to bear in mind when contemplating the use of MBIs for managing T2DM.

Strengths of this study are a comprehensive search strategy and use of the GRADE approach to determine certainty of evidence. While our decision to include unpublished data from three trials[51,53,54] introduces challenges as there is incomplete data from the unpublished trials (for example, on demographic data) this decision ensures that our review is comprehensive. Similarly, the inclusion of all studies regardless of language allowed us to include a greater number of studies compared

to other published reviews. In conclusion, MBIs may have large effects for stress and depression with moderate effects for anxiety. A modest and near clinically significant reduction in HbA1c was observed. While evidence is promising for depression and stress reduction with MBIs in people with T2DM, certainty of the evidence is low to very low. Further research is needed before making clinical recommendations on the use of MBIs in people with T2DM.

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Author contributions

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Declaration of competing interest

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Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Supplementary materials

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