The effectiveness of mindfulness-based stress reduction (MBSR) on the mental health, HbA1C, and mindfulness of diabetes patients: A systematic review and meta-analysis of randomised controlled trials

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ABSTRACT

Background: The present study aimed to assess the effectiveness of mindfulness-based stress reduction (MBSR) on the mental health, haemoglobin A1c (HbA1C), and mindfulness of diabetes patients. **Method**: A systematic review and meta-analysis approach was employed to review randomised controlled trials published between the inception of eight databases to July 2022. Eleven articles from 10 studies, with a combined sample size of 718 participants, were included in the systematic review, and nine studies were included in the meta-analysis. In the meta-analysis, outcomes at post-intervention and follow-up were compared between the MBSR intervention and control groups with an adjustment of the baseline values. **Results**: The results showed that MBSR demonstrated effects at post-intervention and follow-up (in a period between one to 12 months with a mean length of 4.3 months) in reducing anxiety and depressive symptoms, and enhancing mindfulness, with large effect sizes. However, the effect of MBSR on reducing stress was observed at follow-up, but not at post-intervention. Effects of MBSR on HbA1C were not detected at post-intervention and follow-up. **Conclusions**: The findings suggest that MBSR appears to be an effective treatment for improving mental health conditions and mindfulness in people with diabetes. The measurement of cortisol is recommended to be used as a biological measure to evaluate the effectiveness of MBSR for diabetes patients in future research.

OBJECTIVES

Diabetes, a chronic metabolic disorder marked by high blood glucose levels, has significant negative effects on patients' health (International Diabetes Federation, 2021). Over time, poorly controlled diabetes leads to complications including coronary artery disease, neuropathy, retinopathy, nephropathy, and peripheral vascular disease (Chen et al., 2021). Diabetes is also associated with mental health problems, including stress, anxiety, and depression. Multiple factors, such as being overwhelmed by the daily burden of diabetes management activities, concerns related to the long-term complications of diabetes, and frustration with the uncontrollability and unpredictability of blood glucose levels, often lead to diabetes patients commonly having high levels of chronic stress (Ellis et al., 2019). High stress levels are in turn associated with a reduction in daily diabetes self-care activities (Ellis et al., 2018), which may lead to higher blood glucose levels (Bo et al., 2020). Research has shown that depression/anxiety and diabetes are often comorbid (Joseph & Golden, 2017). Diabetes is likely to trigger chronic stress, which increases cortisol levels. The higher levels of cortisol in turn are associated with higher levels of anxiety and depression (Joseph & Golden, 2017; Vedhara et al., 2003). Among diabetes patients, anxiety and depression are linked to impaired blood glucose management and worse health-related outcomes in diabetes. Psychotherapies, such as the clinically standardised mindfulness-based stress reduction (MBSR), that help diabetes patients manage chronic stress, anxiety, and depression are beneficial to assist in the treatment of diabetes (Ellis et al., 2018, 2019). Two research questions are proposed:

RQ1: What are the within-group effects of MBSR on mental health outcomes, HbA1C and mindfulness comparing post-tests against pre-tests and follow-up tests against pre-tests?

RQ2: What are the between-group effects of MBSR on mental health outcomes, HbA1C and mindfulness between the MBSR intervention and the control groups at post-test and follow-up timepoints in RCTs?

METHODS

Inclusion criteria: Quantitative, qualitative, and mixed method studies, published in peer-reviewed journals, which specifically focussed on MBSR interventions for diabetes patients, with mental health as a primary outcome measure, and physiological effects as secondary outcome measures. **Exclusion criteria:** Articles that did not contain the keywords of the search in the abstract or title, and were published in a language other than English, non-empirical (e.g. editorials, comments, opinion pieces and letter to editors), systematic reviews and meta-analyses, theses/dissertations, book chapters and articles with full texts unavailable.

The database search was conducted between the 27th of February and the 25th of July 2022 in eight electronic databases (MEDLINE (Ovid), EMCARE(Ovid), CINAHL, PsycInfo (ProQuest), PubMed, SCOPUS, EMBASE and Cochrane). The titles and abstracts of identified articles were screened by two authors independently, and rated with a 'yes', 'no' or 'maybe' depending on if they satisfied the inclusion criteria. Studies that received 'maybe' ratings or non-unanimous ratings were discussed between raters until an agreement was made (Li et al., 2021). The next stage of screening involved assessing the full texts of qualified articles to determine the methodological quality, with the use of the modified Mixed Methods Appraisal Tool (MMAT) Version 2018 (Hong et al., 2019). Fleiss' kappa (*k*) was used to determine the inter-rater agreement indexes, $k < .20$, .20 -.39, .40 -.59, .60 -.79 and .80 - 1.00 indicating poor, fair, moderate, substantial, and perfect agreements, respectively (Fleiss, 1971). All articles with $k < .40$ were discussed and a post-discussion rating was conducted with *k*s all over .40. Data was extracted from the eligible studies and was independently assessed by the three authors to evaluate the evidence supporting the findings in each study, using codes of 'unequivocal', 'credible', or 'unsupported'. All articles met the inclusion criterion of rater agreement index = $((N_{unequivocal} + N_{credible}) / N_{reviewers}) > .80$ (Li et al., 2021). Comprehensive Meta-Analysis V3 (Borenstein et al., n.d.) software was used to conduct the meta-analysis, and the random-effects model was used. For the within-group and between-group comparison on anxiety, depression, diabetes-related stress, and general stress, effect sizes were entered using the multiple outcome analysis that generated a pooled effect size for the composite mental distress that included the four outcomes, in addition to the individual effect sizes for each outcome. Separate meta-analyses were conducted for HbA1C levels and mindfulness.

RESULTS

11 articles from 10 studies were included in the systematic review, with a combined sample size of 718 participants, and nine studies were included in the meta-analysis.

Test of RQ1: As presented in Fig 1., the forest plot, the pooled effect sizes comparing the MBSR and control group post-test scores demonstrated that anxiety and depression in the MBSR group were significantly lower by 2.407 and 1.110 standard deviations, respectively, compared to the control group, and that mindfulness was significantly higher by 1.834 standard deviations. However, MBSR did not have a significant effect on stress, or HbA1C.

Study name	Group by Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	p-Value
Chen et al. 2021	Anxiety	-2.701	0.203	0.041	-3.099	-2.303	0.000
Hamidi et al. 2020	Anxiety	-4.339	0.275	0.076	-4.878	-3.800	0.000
Ravari et al. 2020	Anxiety	-0.240	0.198	0.039	-0.629	0.149	0.226
	Anxiety	-2.407	0.625	0.390	-3.631	-1.183	0.000
Chen et al. 2021	Depression	-2.191	0.260	0.067	-2.700	-1.682	0.000
Ravari et al. 2020	Depression	-0.106	0.198	0.039	-0.493	0.282	0.592
Ellis et al. 2019	Depression	-0.788	0.358	0.128	-1.491	-0.086	0.028
Hartmann et al. 2012	Depression	-0.060	0.142	0.020	-0.338	0.218	0.673
Latheef & Latheef 2017	Depression	-2.881	0.459	0.210	-3.780	-1.982	0.000
Nathan et al. 2017	Depression	-0.878	0.263	0.069	-1.394	-0.363	0.001
	Depression	-1.110	0.448	0.201	-1.988	-0.232	0.013
Ravari et al. 2020	HbA1C	-0.527	0.201	0.040	-0.921	-0.133	0.009
Ellis et al. 2019	HbA1C	0.054	0.345	0.119	-0.622	0.729	0.876
Hartmann et al. 2012	HbA1C	0.126	0.142	0.020	-0.152	0.404	0.375
	HbA1C	-0.118	0.626	0.392	-1.345	1.110	0.851
Latheef & Latheef 2017	Mindfulness	3.097	0.477	0.227	2.163	4.032	0.000
Rozworska et al. 2020	Mindfulness	0.722	0.259	0.067	0.214	1.230	0.005
	Mindfulness	1.834	0.794	0.630	0.278	3.391	0.021
Ravari et al. 2020	Stress	-0.166	0.198	0.039	-0.554	0.222	0.401
Ellis et al. 2019	Stress	-0.183	0.345	0.119	-0.860	0.494	0.597
Hartmann et al. 2012	Stress	-0.065	0.142	0.020	-0.343	0.213	0.647
Latheef & Latheef 2017	Stress	-2.221	0.407	0.166	-3.019	-1.422	0.000
Nathan et al. 2017	Stress	-0.552	0.256	0.065	-1.054	-0.051	0.031
Jung et al. 2015	Stress	0.616	0.327	0.107	-0.025	1.257	0.060
	Stress	-0.409	0.448	0.200	-1.287	0.469	0.361

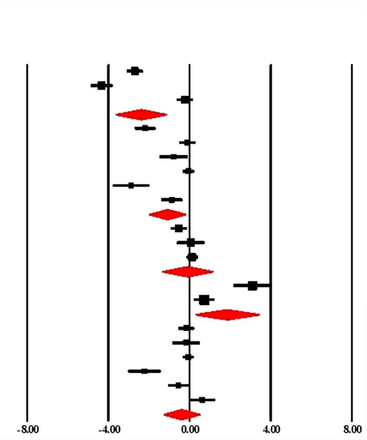

Fig 1. The forest plot of the between-group compariso n at the post-test timepoint

Test of RQ2: As presented in Fig 2., the pooled effect sizes comparing the MBSR and control group follow-up test scores showed that depression and stress were significantly lower by 2.717 and 1.876 standard deviations, respectively, and that mindfulness was significantly higher by 2.683 standard deviations, in the MBSR group compared to the control group. MBSR did not have a significant effect on HbA1C, and data of the effect sizes on anxiety at follow-up were unavailable.

Study name	Group by Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	p-Value
Ellis et al. 2019	Depression	-0.143	0.345	0.119	-0.819	0.534	0.679
Hartmann et al. 2012	Depression	-3.926	0.243	0.059	-4.402	-3.450	0.000
Latheef & Latheef 2017	Depression	-6.112	0.770	0.593	-7.621	-4.603	0.000
Nathan et al. 2017	Depression	-1.120	0.270	0.073	-1.650	-0.590	0.000
	Depression	-2.717	0.912	0.831	-4.504	-0.930	0.003
Ellis et al. 2019	HbA1C	-0.157	0.380	0.145	-0.902	0.589	0.681
Hartmann et al. 2012	HbA1C	-2.139	0.178	0.032	-2.488	-1.790	0.000
	HbA1C	-1.165	1.268	1.607	-3.650	1.320	0.358
Latheef & Latheef 2017	Mindfulness	4.514	0.608	0.369	3.323	5.705	0.000
Rozworska et al. 2020	Mindfulness	1.008	0.267	0.071	0.485	1.531	0.000
	Mindfulness	2.683	1.292	1.671	0.149	5.216	0.038
Ellis et al. 2019	Stress	-0.114	0.345	0.119	-0.790	0.562	0.741
Hartmann et al. 2012	Stress	-2.791	0.200	0.040	-3.183	-2.399	0.000
Latheef & Latheef 2017	Stress	-3.678	0.528	0.279	-4.714	-2.643	0.000
Nathan et al. 2017	Stress	-0.996	0.266	0.071	-1.519	-0.474	0.000
	Stress	-1.876	0.902	0.813	-3.643	-0.109	0.037

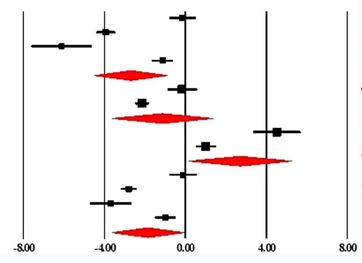

Fig 2. The forest plot of the between-group comparison at the follow-up test timepoint

CONCLUSIONS

Our meta-analysis results show that MBSR demonstrated large and clinically significant effects in reducing anxiety and depression symptoms at post-intervention, and the reductions were maintained at follow-up (in a period between one to 12 months with a mean length of 4.3 months). Our findings also show that participants in the MBSR group were more mindful at post-intervention compared to the control group and that the gains were maintained at the follow-up.

Our findings show that the effects of MBSR on reducing stress are less conclusive. The reduction of stress was observed at follow-up, but not at post-intervention. The findings are interesting because MBSR is designed to reduce stress as indicated in its name. The sensitivity analysis suggests that effects on stress at follow-up disappeared after removing the study with a follow-up period of 12 months. This result suggests that the effects of MBSR on stress may emerge over time.

The results of our study show that effects of MBSR on HbA1C levels were not observed at both post-intervention and follow-up.

Analyses of the heterogeneity in the effect sizes suggest that substantial heterogeneity was present. This indicates that the effect sizes of MBSR on mental health outcomes, HbA1C, and mindfulness are high in some populations of diabetes patients and low in others (Borenstein, 2019). Therefore, it is necessary to exercise caution in generalising the results of the present study to all populations of diabetes patients.

The meta-regression analysis in our study suggests that the diabetes types of the participants and publishing year of the studies moderated the effectiveness of MBSR, suggesting that the heterogeneity may be further explained by differences in characteristics of the studies.

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