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Mindfulness-based Intervention (MBI) for blood pressure reduction and other health benefits in patients with hypertension: An umbrella review of meta-analyses of randomized clinical trials

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202410006

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 January 2024 and was last updated on 03 January 2024.

INTRODUCTION

Review question / Objective The objective of this umbrella review is to systematically locate relevant meta-analyses of RCTs investigating the efficacy of mindfulness as a means to reduce blood pressure in individuals with hypertension. The intention is to concisely outline the findings from these meta-analyses and appraise the strength of evidence, providing a comprehensive understanding of the influence of MBI on health outcomes associated with blood pressure reduction.

Condition being studied In recent years, there has been a significant surge in the exploration of mindfulness-based interventions (MBIs), encompassing both the science and practical application of these approaches.(1) Among the various MBIs, the mindfulness-based stress reduction program (MBSR) stands out as a widely employed and well-structured clinical intervention. MBSR is an 8–10 week program involving weekly 2.5-hour group sessions with 10-40 participants. The sessions cover meditation, yoga, and stress management. Participants commit to 45 minutes of daily homework, applying mindfulness in their daily lives.(2) The increasing popularity of MBIs is indicative of a growing recognition of their potential therapeutic benefits. In a clinical context, mindfulness-based interventions have demonstrated promise as a novel and non-pharmacological treatment for controlling blood pressure in individuals with hypertension.(3) This suggests a shift towards considering mindfulness practices as valuable tools in addressing health concerns, particularly in conditions such as hypertension.

In recent years, few systematic reviews and meta-analyses of randomized clinical trials have highlighted mindfulness as an effective adjunct therapy for lowering blood pressure and other health outcomes among individuals diagnosed with hypertension.(4) To the best of our knowledge, there have been no studies conducted this far that aim to assess the reliability or validity of existing

meta-analyses or randomized controlled trials on this subject. The objective of this review is to undertake an umbrella review of meta-analyses, aiming to grade the available evidence systematically and comprehensively from randomized controlled trials.

METHODS

Participant or population The study population comprises patients with underlying hypertension.

Intervention MBI programme with and without other interventions.

Comparator Usual care for patient with hypertension.

Study designs to be included Randomized controlled trials that evaluate the efficacy of MBSR programmes on the following outcomes: blood pressure reduction in patients with hypertension, other health benefits in patients with hypertension.

Eligibility criteria Inclusion criteria : patient with hypertension Exclusion criteria: Intervention study, Animal research, Non-peer review study.

Information sources We will identify relevant randomized controlled trials (RCTs), by a systematic search of PubMed, Epistemonikos and Cochrane CENTRAL Register of Controlled Trials from inception to February 2024. To identify studies not captured by database searches, we will manually check the reference lists of published systematic reviews and articles retrieved after title and abstract exclusion. A search of human studies in these databases will be performed by using subject headings and free text terms. Articles written in English will be recruited in this review. The search criteria for this review include terms such as MBSR, mindfulness, mind-body therapies, combined with hypertension or prehypertension.

Main outcome(s) Level of blood pressure reduction.

Additional outcome(s) Other documented health benefits (glucose levels, lipid profile, skin diseases, pain, immune disorders stress level, depression, anxiety & burnout, quality of life).

Data management Two independent reviewers will conduct data extraction, and any disparities will be resolved through consultation with a third reviewer. Meta-analyses examining multiple outcomes will be documented separately. For each eligible meta-analysis, we will extract information including the first author, publication year, study design, definition of the underlying condition, number of cases and participants in each arm, total number of cases and participants, treatment regimen details, control conditions, follow-up period (mean or median), adverse outcomes (as defined by authors), reported summary meta-analytic estimates with corresponding 95% confidence intervals (95% CI), evidence grading (if available), and quality score based on AMSTAR 2.

Quality assessment / Risk of bias analysis The risk of bias of the included studies will be assessed using Revised Cochrane Risk of Bias Tool (RoB 2.0). We intend to evaluate the evidence quality in each meta-analysis utilizing the GRADE criteria (Grading of Recommendations, Assessment, Development, and Evaluations) across five domains: risk of bias, inconsistency, indirectness, imprecision, and publication bias. The strength of evidence will be categorized as high, moderate, low, or very low using GRADEpro version 3.6.1 from McMaster University.

Strategy of data synthesis We will employ the random-effects model by DerSimonian and Laird to recalculate adjusted summary estimates, along with corresponding 95% confidence intervals (CI) and p-values, for each association. This model, which considers heterogeneity both within and between studies, will also generate the 95% prediction interval (PrI). Within each meta-analysis, heterogeneity will be assessed using the I^2 statistic. Evaluation for small study effects will involve the regression asymmetry test, specifically Egger's test, and the excess significance test.
For the assessment of evidence from randomized controlled trial (RCT) meta-analyses, considerations will include the amount of evidence, statistical significance, PrI, heterogeneity, small-study effect, and excess significance, as detailed previously. Conclusions for RCT meta-analyses with sufficient evidence will be reevaluated in the presence of overlapping meta-analyses. Furthermore, the GRADE framework will be applied to ascertain the certainty of evidence from RCTs, and a comparative analysis will be conducted with the credibility of evidence determined through the aforementioned methods.

Subgroup analysis Subgroup analyses will be performed based on: Age group (young vs old) ; Severity of hypertension (mild, moderate, severe) ; duration of the disease (newly diagnosed vs longstanding) ; other comorbidities ; type of interventions (MBSR, MBI, other technique).

Sensitivity analysis We performed sensitivity analysis by using leave-one-out meta-analysis to examine how each particular study alters the overall performance of the rest of the studies especially the pooled prevalence estimates and heterogeneity.

Language restriction English.

Country(ies) involved Malaysia.

Keywords MINDFULNESS; BLOOD PRESSURE REDUCTION; HYPERTENSION; INTERVENTION STUDIES; HEALTH PROMOTION; MIND-BODY THERAPIES; COMPLEMENTARY THERAPIES; INTEGRATIVE MEDICINE; CARDIOVASCULAR HEALTH; SYSTEMATIC REVIEW; UMBRELLA.

Contributions of each author

Author 1 - Siew Mooi Ching - SM conceived, designed and will curate the data and supervise the writing.
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Author 2 - Chao Jie Liew - CJ write the protocol and will do formal analysis and write the review.
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Author 5 - Yit Siew Chin - YS provide the resources and methodology.
Author 6 - Kamal Tahir - Kamal provide ideas in the domain of being studied and will do the writing.
Author 7 - Roovam Balasubramaniam - Roovam will handle the software and do the writing.
Author 8 - Dhashani Sivaratnam - Dhashani conceptualize the review and provides supervision for the software handling.
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