

Content, Structure, and Delivery Characteristics of Yoga Interventions for Managing Hypertension: A Systematic Review Protocol

Abstract

Aims: This systematic review aims to summarize the content, structure, and delivery characteristics of yoga interventions used for managing hypertension. **Introduction:** Globally, hypertension-related morbidity and mortality are high. Yoga might be a potential solution for managing hypertension. Several systematic reviews have evaluated the effectiveness of yoga interventions for managing hypertension. There is a need to summarize the content, structure, and delivery characteristics of yoga interventions used for managing hypertension. **Inclusion Criteria:** Randomized controlled trials assessing the effectiveness of yoga interventions for managing hypertension in adults and reporting either the content, structure, or delivery characteristics will be included in this systematic review. **Methods:** The Joanna Briggs Institute systematic review methodology will be followed to conduct the review. We aim to search for a wide range of sources to find both published and unpublished studies. The following databases will be searched: MEDLINE, Embase, CINAHL, PsycINFO, Allied and Complementary Medicine (AMED), Web of Science, Cochrane Central Register of Controlled Trials (CENTRAL), Turning Research Into Practice (TRIP), AYUSH Research Portal, A Bibliography of Indian Medicine (ABIM), Digital Helpline for Ayurveda Research Articles (DHARA), CAM-QUEST, and Directory of Open Access Journals (DOAJ). The search for unpublished studies will include OpenGrey, ETHOS, and ProQuest Dissertations and Theses. Databases will be searched from their inception dates, and no language restrictions will be applied. A narrative description of the findings will be written, structured around the aims of this systematic review. **Systematic review registration number:** CRD42019139404

Keywords: Hypertension, management, yoga

Introduction

Importance of managing hypertension

Hypertension is a significant global threat because of its high prevalence and close links with serious health problems, such as cardiovascular disease, cerebrovascular disease, and kidney failure.^[1] It is characterized by consistently high arterial blood pressure where systolic blood pressure (SBP) is ≥ 140 mmHg and diastolic blood pressure (DBP) is ≥ 90 mmHg.^[2] Globally, hypertension accounts for approximately 9.4 million deaths every year.^[3] According to the World Health Organization, at least 45% of deaths owing to cardiovascular disease and 51% of deaths due to stroke are attributable to hypertension.^[1] Although it is difficult to calculate the global prevalence of hypertension-induced renal failure due to the absence of standard criteria to make

a diagnosis of hypertensive nephropathy, it is estimated that hypertension is accountable for around 10% of chronic kidney disease.^[4] Thus, the management of hypertension is crucial in reducing morbidity and mortality caused by cardiovascular events, cerebrovascular events, and renal failure.

The current strategy for managing hypertension and its limitations

The increasing prevalence of hypertension is ascribed to the aging population and behavioral risk factors, such as unhealthy diet, tobacco use, lack of physical activity, harmful use of alcohol, overweight, and exposure to persistent stress.^[1] Currently, hypertension cannot be completely cured but is usually managed through pharmacotherapy.^[5] In addition to pharmacotherapy, the management of

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behavioral risk factors is highly recommended for better outcomes.^[1] Systematic reviews and meta-analyses have reported the positive effects of behavior modification on hypertension management.^[6,7]

The reluctance of patients to use medicines due to their interactions, side effects, and high costs is seen as a contributor to uncontrolled hypertension.^[8] In addition, the interest of patients in alternative therapies to manage hypertension highlights the importance of and the need for alternative cost-effective approaches.^[9] Another reason for the unsuccessful management of hypertension is poor stress management. Stress is generally accompanied by unhealthy choices that trigger hypertension, such as unhealthy diet, tobacco use, and harmful use of alcohol.^[10] Due to the subjective nature of stress and the unavailability of a standard pharmacotherapy to treat it, it is difficult to develop an across the board strategy for stress management. In this regard, yoga might be a potential solution for hypertension management.

Yoga: A potential solution

Yoga, an ancient system of health and way of life, originated in the Indian subcontinent around 5000 years ago.^[8] It is based on the unity of body, mind, and spirit.^[11] The origin of yoga is based on philosophy and spirituality, but today, it is mainly performed as a health practice and as an exercise and relaxation method.^[11] Yoga integrates highly sophisticated mind-body practices, such as asana (yogic poses), pranayama (breathing practices), dhyana (meditation), and relaxation practices.^[12] There are divergent types of yoga practiced, and these vary in intensity from gentle to vigorous, in how much they emphasize spirituality and in the type of postures and how long they may be held.^[13]

Of the benefits attributed to yoga practice, blood pressure management is among the most studied.^[8] The beneficial effects of yoga on hypertension appear to occur by altering markers of sympathetic and parasympathetic activity. Physiological research on the effects of yoga on the body indicates that yoga is associated with a decrease in sympathetic nervous system tone and an increase in parasympathetic (vagal) activity, both of which are related to a reduction in stress-related responses.^[14] It has also been proposed that yoga has a beneficial effect on age-related arterial stiffness and encourages improvements in functional capacity.^[14] The positive effects of yoga on stress reduction and functional capacity, which are closely related to hypertension, can make yoga an effective approach in hypertension management.^[8,12]

Several systematic reviews have evaluated the effectiveness of yoga interventions for managing hypertension.^[5,8,9,12,15,16] Some of these have included both observational and experimental studies,^[8,12,16] whereas others have included only randomized controlled trials (RCTs).^[5,9,15] These systematic reviews have suggested beneficial effects

of yoga in managing blood pressure. Yoga was found to be more effective in reducing SBP than DBP. No major safety issues were reported. However, most of the included studies were short term and were often associated with considerable methodological limitations, such as small sample sizes in treatment groups resulting in a lack of statistical power for outcome assessment, and poor concealment of treatment allocation leading to potential analysis bias. Two such systematic reviews conducted a meta-analysis.^[8,15] Yoga was found to have a modest but significant effect on SBP and DBP compared to no treatment but did not have a significant effect when compared to exercise or other types of interventions (SBP: mean difference (MD) = -4.17 mmHg, 95% confidence interval (CI) = -6.35 to -1.99, $P < 0.001$; DBP: MD = -3.76 mmHg, 95% CI = -6.09 to -1.43, $P < 0.001$).^[8] A low evidence of short-term effects of yoga interventions on SBP and DBP was found (SBP: MD = -9.65 mmHg, 95% CI = -17.23 to -2.06, $P = 0.01$; DBP: MD = -7.22 mmHg, 95% CI = -12.83 to -1.62, $P = 0.01$).^[15]

The rationale for this systematic review

Several systematic reviews have evaluated the effectiveness of yoga interventions for managing hypertension.^[5,8,9,12,15,16] However, it is hard to select one yoga intervention over the other because of their heterogeneous content, structure, and delivery characteristics, which are important aspects of yoga interventions.^[13] There is a need to summarize the content, structure, and delivery characteristics and, perhaps, develop a single intervention for hypertension management and evaluate it in a robustly designed RCT. Only one systematic review, published by Posadzki *et al.* in 2014, has summarized the content and structure of yoga interventions used for managing hypertension.^[5] However, they have not summarized the delivery characteristics, which will be new in our systematic review. In addition, since the publication of this systematic review, the evidence base has substantially grown up. For example, a preliminary search showed that at least 21 new RCTs have been published between 2014 and 2019. Thus, there is a need for an updated and comprehensive systematic review. In addition, effective and ineffective yoga interventions will be included in our systematic review, which will help to understand what types of yoga interventions have been used and which yoga interventions have been more effective in managing hypertension. The inclusion of ineffective yoga interventions will avoid selecting studies based on the subjective criteria about effectiveness. For example, it will avoid excluding smaller studies which may have had some limitations that may cause misinterpretation about the effectiveness of the yoga intervention.

Aims

This systematic review will summarize the content, structure, and delivery characteristics of yoga interventions used for managing hypertension.

Inclusion criteria

Population

This systematic review will include studies conducted among adults (≥ 18 years) diagnosed with hypertension. The International Society of Hypertension and the American Society of Hypertension (ISH/ASH) classifies hypertension into three stages as prehypertension (SBP: 120–139 mmHg, DBP: 80–89 mmHg), stage 1 hypertension (SBP: 140–59 mmHg, DBP: 90–99 mmHg) and stage 2 hypertension (SBP ≥ 160 , DBP ≥ 100 mmHg).^[2] Studies that are in line with the classification of hypertension by ISH/ASH will be regarded as eligible. If a study includes children, adolescents, and adults, it will be included if the mean age of the study participants is ≥ 18 years. Furthermore, if the study findings are stratified by age, yoga interventions used in adults for managing hypertension will be extracted. If it is not possible to extract these findings, the study will be excluded.

Intervention

Studies reporting at least one of the major components of yoga (i.e., yogic poses, breathing practices, and meditation and relaxation practices) will be included. Studies on multimodal interventions that include yoga among others will be excluded if the specific data are not possible to extract.

Comparator

Studies comparing yoga interventions with no intervention or any intervention (such as pharmacotherapy and behavior modification) will be included in this systematic review. Studies allowing individual co-interventions will be included (i.e., studies allowing participants to continue their individual treatment will not be excluded as long as all the study groups were allowed to do so).

Outcome

Studies that measure changes in SBP and DBP at follow-ups will be included in this systematic review.

Study design

This systematic review will include only RCTs.

Methods

The systematic review process will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses and Joanna Briggs Institute (JBI) systematic review methodology guidelines.^[17,18]

Search strategy

An initial limited search was conducted in MEDLINE database using keywords such as yoga, hypertension, and RCT. The search results were inspected to ensure that the relevant articles were identified. The text words contained in the titles and abstracts of relevant articles and the index

terms used to describe the articles were used to develop a search strategy for MEDLINE. The search strategy will be adapted for other databases in consultation with an information specialist/librarian.

We aim to search for a wide range of sources to find both published and unpublished studies. The following databases will be searched: MEDLINE (1946-present), Embase (1974-present), CINAHL (1937-present), PsycINFO (1806-present), Allied and Complementary Medicine (AMED) (1985-present), Web of Science (1900-present), Cochrane Central Register of Controlled Trials (CENTRAL) (1996-present), Turning Research Into Practice (TRIP) (1997-present), AYUSH Research Portal, A Bibliography of Indian Medicine (ABIM), Digital Helpline for Ayurveda Research Articles (DHARA), CAM-QUEST, and Directory of Open Access Journals (DOAJ). The search for unpublished studies will include OpenGrey, EThOS, and ProQuest Dissertations and Theses. The reference list of all the identified reviews and studies included in the systematic review will be screened for additional studies. No language restrictions will be applied, and translations will be sought where necessary.

Screening and full-text reading

Following the search, all identified citations will be collated and imported into Endnote X8.2 (Clarivate Analytics, PA, USA), a reference management software.^[19] Subsequently, all the duplicate citations will be removed. Titles and abstracts of studies will be screened for eligibility using the inclusion criteria by two reviewers (GN and SL/KC) independently. Studies identified as potentially eligible or those without an abstract will have their full-text retrieved and will be assessed in detail against the inclusion criteria by the two reviewers. Full-text studies that do not meet the inclusion criteria will be excluded, and the reasons for exclusion will be reported. Any disagreements that arise between the two reviewers will be resolved through discussion. If consensus is not reached, then a third reviewer (SL/KC) will be involved.

Assessment of methodological quality

Included studies will be critically assessed by two independent reviewers (GN and SL/KC) using the standardized critical appraisal tool developed by JBI for RCTs.^[18] This tool uses a series of criteria that can be scored as being met (yes), not met (no), unclear, or not applicable (n/a). The two reviewers will independently assess each criterion and comment on it. Any disagreements that arise between the two reviewers will be resolved through discussion. If consensus is not reached, then a third reviewer (SL/KC) will be involved. The critical appraisal results will be presented in a table and narrated. All studies, regardless of their methodological quality, will undergo data extraction and synthesis, where possible.

Data extraction

The two reviewers (GN and SL/KC) will independently extract data using a data extraction form, specifically developed for this purpose. Any disagreements that arise between the two reviewers will be resolved through discussion. If consensus is not reached, then a third reviewer will be involved (SL/KC). If required, the corresponding author of the included study will be contacted by e-mail (two times per author) to clarify existing data or to request additional data. The following data will be extracted: authors, year of publication, country, study period, study design, inclusion and exclusion criteria, recruitment and randomization methods, sample size, comparator, data collection procedures and tools, data analysis techniques, dropout rates and reasons for dropping out, participant characteristics (such as age, sex, and comorbidities), and study outcomes (such as blood pressure, secondary outcomes, and adverse effects). In addition, the following aspects of yoga interventions used for managing hypertension will be extracted: content (such as yogic poses, breathing practices, and meditation and relaxation practices), structure (such as frequency and duration of yoga sessions), and delivery characteristics (such as context of the intervention, strategies used to enhance intervention uptake and adherence, and characteristics of yoga instructors).

Data synthesis

We will write a narrative description of the findings, with the aid of tables and text, structured around the aims of this systematic review. In addition, effective and ineffective yoga interventions will be presented separately to uncover any similarities and differences. Statistical significance ($P < 0.05$) will be used to determine the effectiveness of the intervention. A funnel plot will be generated to assess publication bias if there are 10 or more studies included in the systematic review.

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Conflicts of interest

There are no conflicts of interest.

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