Effects Of Exercise Training On Blood Pressure: Protocol For An Overview Of Systematic Reviews

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Protocol

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Abstract

Background

This overview aims to identify, appraise, and summarize the findings of all relevant systematic reviews about the benefits and harms of different exercise training modalities on blood pressure in normotensive, pre-hypertensive, and high blood pressure adults.

Methods

This overview of systematic reviews protocol was reported following the PRISMA-P Statement. We will search MEDLINE, EMBASE, and Epistemonikos to identify systematic reviews of randomized controlled trials (RCTs) in adults with or without a diagnosis of high blood pressure that compared exercise training interventions with other or no exercise interventions. Major outcomes will be blood pressure and adverse events. Pairs of reviewers will independently screen the systematic reviews for inclusion, extract data, and appraise the methodological quality. The GRADE approach will be used to evaluate the quality of the evidence.

Discussion

Findings from this study will contribute to the knowledge base in the area by providing a systematic synthesis of the certainty of the evidence for the effects of the different training modalities on blood pressure. These assessments might also assist in both the development of clinical practice guidelines and to strengthen evidence-informed decision making in healthcare. Finally, this study might serve to inform patients, caregivers, healthcare providers, researchers, and decision-makers about the benefits and adverse events related to different exercise training modalities, as well as the knowledge gaps in the body of evidence.

Protocol registration:

PROSPERO CRD42021247062

Background

Cardiovascular diseases (CVDs) represent the third leading cause of death worldwide, counting for 18 million deaths per year [1]. Around 10 million people die each year from high blood pressure (HBP), which represents more than half of the mortality attributed to CVDs [2]. The economic burden of HBP is high, and the global medical costs of HBP are estimated at 370 billion dollars per year [3,4].

Different scientific societies recommend exercise training as part of behavioral change interventions for the prevention and management of HBP [5]. Recent clinical guidelines have proposed exercise training as an effective non-pharmacological approach for reducing blood pressure (BP) values at clinically significant levels (reductions in systolic blood pressure ranging between 4 to 8 mmHg) [5]. Exercise training has proven to be a safe intervention in CVD patients, since it has been related to fewer adverse effects than either pharmacological or surgical treatments [6]. However, the evidence for safety data in patients with HBP remains unclear [6].

A recent overview of reviews conducted by researchers from the American College of Sports Medicine (ACSM) concluded that any form of physical activity reduced BP values in normotensive, pre-hypertensive, and HBP adults [7]. The authors summarized data from both exercise training and physical activity into the same analysis, which increased the heterogeneity of their results as evidenced in the analyses. This limitation in the current evidence was further reinforced by incomplete literature searches, as acknowledged recently by European experts in the field [8].

The number of systematic reviews (SRs) on the effects of exercise training for HBP has increased exponentially in recent years. Most of those reviews have serious methodological limitations, report heterogeneous effect estimates, and lack systematic assessments of the quality of the evidence [9,10]. Considering this, we propose a systematic overview of high-quality systematic reviews with a transparent approach to grade the quality of the evidence in order to facilitate the translation of research findings into practice.

Objectives

This overview of reviews aims to identify, appraise, and summarize the findings of all relevant systematic reviews about the benefits and harms of different exercise training modalities on blood pressure in normotensive, pre-hypertensive, and high blood pressure adults.

Methods

This protocol is reported according to the PRISMA for systematic review protocols (PRISMA-P) (Additional file 1) [11], and is registered in the International Prospective Register of Systematic Reviews (PROSPERO registration number: CRD42021247062). We will follow the methodological guidance provided in chapter V of the Cochrane handbook version 6.2 [12]. The final version of this overview will be reported in line with the PRISMA statement [13,14]. For quality purposes, two independent reviewers will conduct the following steps: study selection, data extraction, quality appraisal, and assess the certainty of the body of evidence. Disagreements will be resolved by consensus or by including a third reviewer if necessary.

Eligibility criteria

We will use the PICOTS acronym (P - population; I - intervention; C - comparison or control; O- outcome(s), T - Time and S - study design) to guide study selection [15], as follows:

Participants

Adults (≥ 18 years old) with normal, pre-hypertensive, and HBP values, with or without associated risk factors or comorbidities, categorized according to American Heart Association (AHA) criteria [16] and the International Society of Hypertension (ISH) [17]:

AHA

- Normal: Systolic blood pressure (SBP) <120 mm Hg and diastolic blood pressure (DBP) <80 mm Hg
- Pre-hypertensive: SBP 120–129 mm Hg and DBP<80 mm Hg
- High blood pressure: SBP 130–139 mm Hg or DBP 80-89 mm Hg.

ISH

- Normal: SBP <130 mm Hg and DBP <85 mm Hg
- Pre-hypertensive: SBP 130–139 mm Hg and/or DBP 85–89 mm Hg
- High blood pressure: SBP >140 mm Hg and/or DBP >90 mm Hg.

Interventions

We will accept for inclusion the main traditional exercise training modalities, such as dynamic resistance training (DRT), isometric resistance training (IRT), aerobic training (AET) and combined training (CT) will be considered [5]. Definitons are presented in figure 1.

We will exclude SRs summarizing evidence from PA programs. PA is defined as any movement of the body generated by the skeletal muscles which generate an energy expenditure (18). However, any PA program which is structured according to the parameters and characteristics of FITT-VP would be considered as exercise training; otherwise, these programs will be discarded. A threshold of ≥50% primary studies reporting on exercise training will be accepted for inclusion. SRs on pregnant women will be excluded.

Comparators

Standard care (e.g., pharmacological interventions, or behavioral change approaches) or any active interventions (e.g., flexibility, yoga, Qigong), waitlist, or no intervention.

Primary outcomes

Blood pressure

SBP, DBP, and mean blood pressure (MBP). BP is defined as the force exerted by the circulating blood through the arteries against the arterial wall [22]. BP includes two measurements: systolic pressure, which is measured during the heartbeat (maximum pressure moment), and diastolic pressure, which is measured during the rest between two beats (minimum pressure moment). Mean blood

pressure (MBP), the average blood pressure in the arteries is approximately one-third of the way between the diastolic and systolic pressures [22].

Secondary outcome

Adverse events

The National Institute for Health and Care Excellence (NICE) defines adverse events as any undesirable event experienced by a person while they are having a drug or any other treatment or intervention, regardless of whether or not the event is suspected to be related to or caused by the drug, treatment or intervention [23].

Time

Both primary and secondary research studies have reported both clinically and statistically significant effects of the different exercise training modalities on SBP, DBP, and MBP values over a 3-weeks follow-up [24]. Therefore, we will include SRs reporting outcome data at/over 3 weeks post-intervention follow-up.

Study design

We will only include SRs of randomized controlled trials (RCTs). Cochrane defines a “systematic review as summaries of research evidence that address a clearly formulated question using systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyses data from the studies that are included in the review” [15]. Inclusion will be restricted to SRs of high methodological quality, which will be appraised by using the Assessment of Multiple Systematic Reviews (AMSTAR) scale [25]. Besides, the list of systematic reviews on the basis of quality appraisal will be reported in the final publication.

We will use the definition of RCTs provided by National Institute for Health and Car Excellence (NICE), which understands an RCT as an experimental study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug, treatment, or other intervention. One group (the experimental group) has the intervention being tested, the other (the comparison or control group) has an alternative intervention, a dummy intervention (placebo), or no intervention at all. The groups are followed up to see how effective the experimental intervention was. Outcomes are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce bias [23]. In terms of the included studies, we will include SRs of both randomized and non-randomized studies as long as the review provides separate information for the RCTs (e.g., subgroup data).

Language: No restrictions will be set for language.

Search strategy

We will conduct a systematic literature search in MEDLINE (via Pubmed), EMBASE, and Epistemonikos. No restrictions will be applied for publication date. Additional file 2 presents the search strategy that will be used in MEDLINE, and that will be adapted to the other databases. Furthermore, one reviewer (AFL-B) will inspect the PROSPERO repository for ongoing SRs, the reference lists of the included SRs, as well as the references of clinical guidelines and scientific journals specialized in the field in order to retrieve potentially relevant SRs.

Study selection process

Two blinded and independent reviewers (AFL-B and EP-B) will select the studies at title, abstract and full-text. These steps will be carried out in Rayyan [26].

Data management and extraction

We will extract data from the included SRs into an ad-hoc standardized electronic form created in Microsoft Excel. This form will be piloted in a random sample of two SRs. We will extract the following information:

Systematic reviews characteristics:

- Author(s) and year of publication.
- Review aims and PICO components.

- Protocol registration number.
- Date of literature searches.
- Characteristics of the primary studies: number sample size, country
- Characteristics of the participants: age, sex, ethnicity, comorbidities).
- Description of interventions and comparisons (frequency, intensity, time, volume, progressions).
- Outcomes and time points assessed.
- Data synthesis approach: whether statistical or narrative.
- Certainty of the evidence assessment (if conducted in the SR)

Statistical summaries:

- Effect estimates, 95% confidence intervals (CIs) and accompanying measures of heterogeneity for the pooled estimates of intervention effects; for all relevant comparisons at all available time points (e.g., mean differences (MDs), standardized mean difference (SMDs), risk ratios (RRs), odds ratios (ORs)).
- Results from exploration of heterogeneity, including subgroup analyses/meta-regression and whether these were prespecified.
- Results from sensitivity analyses, including details of the approach taken and whether these were prespecified.
- The judgments of risk of bias in the evidence, including details of the approach used (e.g., Cochrane RoB tool [27])

If necessary, we will try to contact the corresponding author of the SRs to clarify data or obtain missing information.

Quality appraisal

Pairs of reviewers will independently appraise the methodological quality of the included SRs by using the AMSTAR scale [25]. The AMSTAR scale is the most widely used tool for critically appraising SRs of RCTs and contains 11 questions (Additional file 3). Each question of AMSTAR is rated as yes (clearly done), no (clearly not done), cannot answer, or not applicable [25]. In case that any of the reviewers participated as an author in an included SR, they should report it and assign the assessment of quality appraisal to another reviewer.

Data synthesis

In line with the methodological literature, we propose a narrative synthesis approach for this study [12]. We will present data from each SR, sorted by each primary and secondary outcome according to the certainty of the evidence (e.g., high-certainty evidence first, followed by moderate-certainty evidence, etc.). Where possible, we will present effect measures (MDs, SMDs, RRs, ORs) with 95% CIs for both continuous and dichotomized outcome measures. We plan to present the overall results in a 'Summary of findings' table (Additional file 4) [15], according to the following subgroups:

- The clinical status of the participants regarding AHA [16] or ISH [17] blood pressure values: normal, pre-hypertensive, and high blood pressure.
- Comorbidities (type 2 diabetes mellitus, dialysis chronic kidney disease, non-dialysis chronic kidney disease, coronary heart disease, heart failure, polycystic Ovary syndrome, stroke, overweight, obese, cardiometabolic diseases, peripheral artery disease, heart failure, cardiometabolic risk, cardiac patients, heart disease, transient ischemic attack, metabolic syndrome, intermittent claudication).
- Population under pharmacological antihypertensive treatment.
- Age: $\leq$ 65 years old and > 65 years old.

We will present the results of the remaining narrative analysis of primary and secondary outcomes in the "Overview of reviews" table. Based on evidence from both experimental and observational studies, reductions of 5 mm Hg on SBP and 2 mm Hg on DBP will be considered clinically significant [28,29].

Managing overlapping systematic reviews

We will investigate the degree to which the systematic reviews shared the same included studies (overlap) and the number of studies that were unique to each SR (Additional file 5). If we will find complete overlap in terms of included studies between two or more

systematic reviews, we will report the results from the most recent SR with the most detailed description. This assessment will be done on the primary studies that will provide information on the outcome of interest [30].

Certainty of the evidence: GRADE approach

We will follow the GRADE approach (Grading of Recommendations, Assessment, Development, and Evaluation) to assess the certainty of the evidence supporting the effects of each exercise training modality on blood pressure [31]. According to the GRADE approach, five factors reduce the certainty of the evidence, these are: 1) limitations in study design; 2) inconsistency in results; 3) indirectness of evidence; 4) imprecision; 5) publication bias. The certainty of the evidence will be rated as high, moderate, low, or very low [31]. If available, we will use GRADE assessments reported in the included SRs and will supply those with our assessment for the SRs that did not provide any GRADE assessment. We will follow the guidance provided by Meader et al. (2014) on assessing GRADE in SRs [32].

Discussion

This overview of reviews aims to identify, appraise, and summarize the findings of all relevant systematic reviews about the benefits and harms of different exercise training modalities on blood pressure in normotensive, pre-hypertensive, and high blood pressure adults. We will adhere to the most widely used criteria for the diagnosis of HBP [16, 17] and will follow the highest methodological standards for conducting overviews of reviews. The potential of the current body of evidence to draw solid conclusions about the effects of exercise training in HBP is mainly constrained due to the lack of a systematic assessment of the quality of the evidence [9, 10]. We plan to tackle this gap by following the GRADE approach, whose results will serve to inform stakeholders about the certainty of the evidence pertaining evidence-informed decision making. In a national context, our findings will assist in the development of the next Public Health Plan in Colombia [33, 34]. Finally, our results will enable patients, caregivers, healthcare providers, researchers, and decision-makers when implementing findings from this overview into practice.

Abbreviations

AET
Aerobic Training; AMSTAR:the Assessment of Multiple Systematic Reviews; BP:Blood Pressure; CT:Combined Training; DBP:Diastolic Blood Pressure; DRT:Dynamic Resistance Training; GRADE:Grading of Recommendations, Assessments, Development and Evaluation; MBP:Mean Blood Pressure; IRT:Isometric Resistance Training; MD:Mean difference; NICE:National Institute for Health and Care Excellence; OR:odds ratios ORs; PA:Physical activity; PRISMA-P:Preferred Reporting Items for Systematic Review and Meta-Analyses Protocol; PROSPERO:Prospective Register of Systematic Reviews; SMD:Standardized mean difference; RR:risk ratios, SBP:Systolic Blood Pressure.

Declarations

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Authors' contributions

AFL-B and JFM-E conceptualized the idea for this overview. All authors will contribute to the development of the selection criteria, study selection, data extraction, quality appraisal, and assessment of the certainty of the evidence. AFL-B and JFM-E are the guarantors and drafted the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

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Ethics approval and consent to participate.

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Figures

Exercise training: Exercise is defined as a planned, structured, repetitive physical activity (PA), which aims to improve or maintain one or more components of physical fitness (i.e., cardiorespiratory fitness and/or muscular fitness) [18]. Thus, any PA program which is structured according to parameters and characteristics of FITT-VP (Frequency, Intensity, Time, Type, Volume, and Progression) would be considered as exercise training; otherwise, these programs will be discarded.
Dynamic resistance training (DRT): This can be performed in water or on land. DRT involves an exercise movement using a constant load or a uniform weight regardless of the training program. There are many types of resistance training equipment, including free weight, machines with pneumatic resistance, and elastic bands [19].
Isometric resistance training (IRT): IRT is understood as any muscular contraction in which the tension of both the joint and the contractile elements does not vary on the movement range (holding a position or weight without moving against it) [20].
Aerobic training (AET): This training can be performed in water or on land. Cyclic exercises involve a large amount of muscle mass for different time units, where the cardiovascular and respiratory systems predominate (e.g., jogging, swimming, running, cycling, dancing) [19].
Combined training (CT): This training modality represents the systematic integration of both resistance and aerobic exercise within a coherent training plan [21].

Figure 1

Definitions of the different exercise training modalities.

Supplementary Files

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- Additionalfile1.PRISMAP.docx
- Additionalfile2.Searchstrategy.docx
- Additionalfile3.AMSTAR.docx
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