Study protocol

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Dropout rates in controlled trials with exergames for blood pressure management: a systematic review and meta-analysis protocol

Taxas de abandono em estudos controlados com exergames para gerenciamento da pressão arterial: protocolo de uma revisão sistemática e metanálise

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ABSTRACT

Exergame, a type of enjoyable active video game that combines physical exertion and game is a technological innovation that has generated important information for the health field. In the cardiovascular area, exergames have been used to manage blood pressure in adults with some positive results. Despite this, in primary studies, it is possible to identify that participants dropout of the exergames interventions, but no synthesis of evidence has been produced so far to explore that. The aims of this review are i) to estimate the pooled rate of dropouts in controlled trials assessing the effects of exergame-based interventions on resting blood pressure in adults and older people; ii) to compare dropout rates between exergame and controls groups, and iii) to investigate the intervention characteristics associate with dropout rates. Inclusion criteria: Randomized controlled trials (RCTs) or quasi-RCTs (≥ 4 weeks) assessing the effects of exergame-based interventions on resting blood pressure in adults aged ≥ 18 years old. Without restriction to language, date of the publication, and intervention setting. Literature searches will be conducted using PubMed, Scopus, SPORTDiscus, Cumulative Index of Nursing and Allied Health Literature, Web of Science, Cochrane Central Register of Controlled Trials, and Scientific Electronic Library Online. The quality of the RCTs will be assessed using Cochrane's risk of bias tool. A descriptive narrative synthesis and a random-effects model meta-analysis of the pooled event rate (prevalence) will be provided ($p < 0.05$). This protocol is registered with PROSPERO: CRD42020199547.

Keywords: Blood pressure; Patient dropouts; Physical exercise; Motor activity; Protocols.

RESUMO

Exergame, um tipo de videogame ativo divertido que combina esforço físico e jogo virtual, é uma inovação tecnológica que tem gerado informações importantes para a área da saúde. Na área cardiovascular, os exergames têm sido usados para gerenciar a pressão arterial em adultos, com alguns resultados positivos. Apesar disso, em estudos primários, é possível identificar que os participantes abandonaram (dropout) as intervenções dos exergames, mas nenhuma síntese de evidências foi produzida até o momento para explorar isso. Os objetivos desta revisão são i) estimar a taxa combinada de dropouts em estudos controlados que avaliam os efeitos de intervenções baseadas em exergame na pressão arterial de repouso em adultos e idosos; ii) comparar as taxas de dropouts entre os grupos exergame e controles e iii) investigar as características de intervenção associadas às taxas de dropouts. Serão incluídos ensaios clínicos randomizados (ECRs) ou quase-ECRs (≥ 4 semanas) avaliando efeitos de intervenções com exergames sobre a pressão arterial em repouso em adultos (≥ 18 anos). Não haverá restrição de idioma, data de publicação e ambiente de intervenção. As buscas na literatura serão conduzidas usando PubMed, Scopus, SPORTDiscus, Cumulative Index of Nursing and Allied Health Literature, Web of Science, Cochrane Central Register of Controlled Trials e Scientific Electronic Library Online. O risco de viés dos ECRs será avaliado por meio da ferramenta da Cochrane. Uma síntese narrativa descritiva e uma metanálise de modelo de efeitos aleatórios da taxa de eventos combinados (prevalência) serão fornecidas ($p < 0,05$). Este protocolo está registrado com PROSPERO: CRD42020199547.

Palavras-chave: *Pressão arterial; Pacientes desistentes do tratamento; Exercício físico; Atividade motora; Protocolos.*

Introduction

In the last three decades, several technological innovations have gained ground in various contexts of health. Exergames, a type of active video games that integrate exertion and game[1], are considered an innovative way of exercise, offering a great opportunity to generate information and impact on health through the promotion of physical activity[2].

Newer games technologies, such as Nintendo Wii and Xbox Kinect, have allowed traditional video games

to overcome the conventional sedentary use of this technology. In the primary literature, for example, randomized controlled trials (RCT) with exergames have shown a positive effect on blood pressure management[3,4]. That is, at the end of the intervention period, people who completed the study had a significant reduction in resting blood pressure, which is particularly important against hypertension. Additionally, enjoyment can be high playing exergame[5] and even superior to other types of physical activity[6], suggesting a positive impact on adherence to these exergame programs[7]. However, despite being pleasurable and attractive to exercise and having beneficial effects on blood pressure, it seems that a substantial prevalence of dropouts also might occur in RCTs which evaluate the effects of exergaming on the resting blood pressure of adults[8–10].

For instance, in an 8-week RCT, the number of dropouts in the Wii group was higher than in the cycle ergometer exercise group, resulting in a low number of participants in each intervention group[8]. In another RCT, the proportion of dropouts in the Wii group was 22.5% against 17% in the routine care group[9]. In an Xbox Kinect intervention, the number of dropouts was also higher in the exergame group compared to conventional aerobic exercise group[10]. Regardless of research fields, dropouts usually occur to some extent and can cause methodological problems for experimental studies. The attrition bias is the most common problem caused by dropouts, as it introduces systematic differences between the study groups in the quantitative and qualitative characteristics of the processes of loss of their participants during study conduct[11]. Furthermore, participants who dropout of the intervention may not benefit from the possible positive effect of exergames on blood pressure[3,4].

The synthesis of evidence on the dropout rate can anticipate the overall dropout rate and the characteristics of the participants and/or intervention components associated with dropout. For example, meta-analysis of exercise RCTs among people with anxiety and stress-related disorders showed that the dropout rate was ~22% and supervision during all sessions and by an expert in exercise prescription and application of autonomous motivation strategies predicted lower dropout[12]. This information can be incorporated into the proposed new RCT protocols in order to mitigate attrition bias. Despite the topic's methodological relevance[11], no review explored the overall dropout rate in studies that looked at the effect of exergame-based interventions on blood pressure. To illustrate this, a search for "blood pressure" OR "hypotension" AND "exergame" OR "active video games" conducted on different databases (PubMed, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Joanna Briggs Institute Database of Systematic Reviews and Implementation Reports, Scientific Electronic Library Online (SciELO), Cochrane Database of Systematic Reviews, PROSPERO and Web of Science) indicated no prior review about this subject in progress or completed.

Thus, this systematic review study with meta-analysis is justified in order to answer the following review questions (1): what is the pooled estimate of dropout across controlled trials using exergame-based interventions for effects on resting blood pressure in adults and older people? (2): are dropout rates significantly different between intervention groups (exergame vs. control groups) across controlled trials using exergame-based interventions for effects on resting blood pressure in adults and older people? (3) do the study, e.g., subjects characteristics (e.g., age, sex, the clinical status of blood pressure) and/or intervention components (e.g., duration, intensity, used technology), explain the dropout rate in exergame interventions focused on blood pressure management? We will collect and describe the secondary outcomes in this review (adherence rates, reasons for dropout and adverse events), insofar as these have been reported.

Method

This study protocol was prepared and written according to the Preferred Reporting Items Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) guidelines[13]. Considering principles of transparency and reproducibility in research for systematic review[14], the policy of data sharing was adopted. In this way, the PRISMA-P was changed by adding an item (#18) about data sharing (see Appendix I: PRISMA Protocol). The PRISMA guidelines will guide the report of this review[15] (we will provide a checklist in the final document). This protocol is registered with PROSPERO: CRD42020199547 (date of registration: August 17, 2020). Protocol amendments will be recorded in PROSPERO. In the design of the review methods, we will follow the Cochrane Collaboration guidelines for intervention reviews[16]. We will provide a checklist based on the measurement tool to assess systematic reviews (AMSTAR)[17] in the final document.

Studies will be selected according to the criteria of

Participants, Intervention, Comparators, Outcomes and Types of Studies (PICOT) described below. Studies with adults aged ≥18 years old, with any clinical status of blood pressure at baseline (normotensive, elevated blood pressure, and hypertensive), will be included. No limitations for participant health status (e.g., obesity, diabetes) were adopted. Studies with participants from different age groups will only be included if results are presented according to age of interest in this review (adults [>19 years old] and elderly [>65 years old]).

It will be included studies that investigate the effects of exergame-based interventions on resting blood pressure. Exergame is an active video game that requires physical exertion and interaction with the game system through body movements[1]. There will be no restriction on other characteristics of the intervention (e.g., session length and frequency, exergame platform (e.g., Dance Dance Revolution, GameBike, Nintendo Wii, PlayStation EyeToy, Xbox Kinect, XAviX etc.). Interventions combining exergames and a co-intervention (e.g., exergame + strength training or exergame + usual care) will not be included. The comparison group can include usual care (e.g., health counseling), active (e.g., strength or endurance training) or passive control groups (e.g., waiting list).

The primary outcome will be the treatment dropout rate in exergame-based intervention studies. The dropout rate is the proportion of participants enrolled in each intervention that does not complete the study. For each study, we will calculate the dropout rate by extracting the baseline sample and the number of completers or dropouts. Participants who were lost before randomization will not be considered dropouts. For comparison purposes, we also will collect overall dropout rates in all control conditions. Two independent reviewers will complete this step (CLML and VM), and a third reviewer can be consulted, if necessary (ARB). The authors will be consulted in case of missing data.

As for secondaries outcomes, we will collect adherence rates (percentage of the exercise sessions completed), reasons for dropout, and adverse events in each study.

This review will include randomized controlled trials (RCTs - trial in which people are allocated at random [by chance alone, e.g., computer generated numbers]) and quasi-RCTs (trials in which participants are allocated to different arms of the trial using a method of allocation that is not truly random, e.g., allocation by date of birth). Studies will be included if they have a period of at least four weeks – this is an attempt to include studies with exercise programs that were chronic in nature rather than studies examining acute exercise episodes and ensure comparability with meta-analysis of conventional exercise dropouts[18]. No limitations are placed on the setting of the interventions (i.e., home- or laboratory-based). In crossover studies, we will only consider the first period.

Search strategies will be created by a member of the review team (CLML) and evaluated by a librarian (SP). It will be initially created to PubMed and adapted for the other electronic databases. The searches will be based on the PICO strategy and will include controlled (e.g., MeSH) and not controlled (key concepts) terms related to exergames (e.g., "Video Games [MeSH]", "Virtual Reality Exposure Therapy [MeSH]", "Active video" , "Exergame") and blood pressure (e.g., "Blood Pressure [MeSH]","Hypotension [MeSH]","Hypertension [MeSH]","Post-Exercise Hypotension"), without delimitation of date and language of publication. We have not included the terms Population and Comparators to maximize searches. During the searches, the terms will consider the availability of the database (e.g., in PubMed by "text word") (see Appendix 1).

The following databases will be consulted for papers in any language: PubMed (including MEDLINE), Scopus, SPORTDiscus (via EBSCOhost), CINAHL (via EBSCOhost - excluding MEDLINE), Web of Science, Cochrane Central Register of Controlled Trials (CENTRAL) and SciELO. We will check the reference lists of all articles included (cross-reference) and potential reviews and meta-analyses retrieved by searches in the databases. The list of excluded articles will be available for readers. We will only include by published and peer-reviewed studies, therefore grey literature (theses, proceedings papers, abstracts, and congress annals, books, reports) will be excluded.

The search in the electronic databases will be inserted into reference management software (EndNote® X7, Thompson Reuters) for the removal of duplicates. Manual duplicate checking will also be performed in the software. We will use the Covidence web-based systematic review software to manage our review (www.covidence.org). The selection flow will follow three steps, described below:

- Step 1: The initial screening for potential studies will be performed independently by two review team members (CLML and VM). After the exclusion of duplicates, these reviewers will read the

titles and abstracts, responding to a previously constructed form as "accepted" or "refused" (the reason for refusal must be presented).

- Step 2: Two independent reviewers will read the full articles accepted in the previous stage, applying the eligibility criteria and, again, responding to the form (accepted or refused). In case of refusal, the reasons must be presented.

  In both steps, the disagreements will be debated between the reviewers for consensus; if the agreement could not be reached, a third review team member (ARB) will be contacted. At each step of the selection procedure, a random sample of the studies (10%) will be extracted to verify the agreement between the reviewers (Cohen's Kappa - scale: 0.40 to 0.59 = reasonable agreement, 0.60 to 0.74 = good agreement, ≥ 0.75 = excellent agreement)[19]. In the case of low agreement (Kappa ≤ 0.39), another training might be provided to the reviewers.
- Step 3: Manual searches will be carried out in the references lists of the articles accepted in step 2 and other sources of information (potential systematic review with meta-analysis, journals, contact with authors).

We will present the results of the search and main reasons for excluding studies in a PRISMA flow diagram[15].

A reviewer will independently assess the risk of bias in each study. To assess the risk of bias in non-randomized studies, the Cochrane Risk Of Bias In Non-randomised Studies - of Interventions will be used[20]. This tool is divided into seven domains: selection bias (selection and confounding), misclassification bias, performance bias, detection bias, attrition bias, reporting bias. For each section within a domain, the reviewer will assign a rating of high, low, or unclear risk. RobotReviewer will be used for automated risk of bias assessment[21]. Authors of papers will be contacted to provide missing or additional data for clarification, where required. Discordant items will be collected and discussed for resolution with a third reviewer (ARB). The results of critical appraisal will be reported in a table with accompanying narrative.

Two independent reviewers (CLML and VM) will extract the data using a standardized form, as proposed by the Data Extraction for Complex Meta-Analysis guide (DECiMAL)[22].

Detailed instructions and a training session will be provided to all authors involved in data extraction. The reliability data will be evaluated according to the nature of the variables: categorical (Cohen's Kappa) and continuous (intraclass correlation coefficient)[19]. The extraction will follow the Center for Reviews and Dissemination[23] form and includes, but not limited to:

- General information - identification (e.g., author, year, country);
- Study characteristics - study design, recruitment procedure;
- Participants characteristics - sample size, sex, age group, ethnicity, stage of the disease, and medications;
- Intervention - exergame console/platform, supervision level, site of delivery, setting, intervention and sessions length and frequency, type of analysis used (intention to treat or complete case analysis);
- Outcome data – dropout rates (by group), adherence rates, reasons for dropout and adverse events.

Authors of papers will be contacted to provide missing data.

The data extracted from the characteristics of each study will be reported as a narrative synthesis and in a tabular format. If available, specific reasons for dropouts will be counted and reported (e.g., personal reasons [loss of interest, lack of time, etc.], discontinued participation due to injuries/orthopedic complaints); the same procedure will be adopted for adverse events reported in the RCTs. Physical exercise trials always show a slight variation in characteristics, so we will use a random-effects model for the meta-analysis in anticipation of heterogeneity[24].

A randomized participant will be considered the unit of analysis. In quasi-RCTs, the number of participants in each group will be considered. In the case of studies with more than two intervention groups, similar groups will be pooled, or only two groups will be chosen to make a single peer comparison[16].

We will conduct a random-effects model meta-analysis using a pooled event rate (prevalence) as the effect size, with a two-sided 95% confidence interval. We will calculate: a) the prediction intervals for pooled prevalence; b) Event rates will be calculated and reported for dropout from exergame groups compared to other groups; c) Odds ratio to compare exergame versus control groups. The pooled event rate from studies will be weighted according to the inverse variance method and combined according to the random-ef-

fects model[24]. For all analyses, we will use the Comprehensive Meta-Analysis software version 2.0 (CMA V2, Biostat, Englewood, USA).

The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach for grading the certainty of evidence will not be applied because the systematic review and meta-analysis is not centered on the effects of intervention on the participant.

The heterogeneity will be assessed visually through the forest plot, and the I^2 will be reported[25]. Confidence intervals of 95% (95%CI) will be calculated for I^2, and the hypothesis of statistical heterogeneity will be rejected when the lower limit of 95%CI include the value of 0%[26].

We will produce and examine the funnel plot and address any possible causes for asymmetry. In addition, the Egger's test[27] will be applied to test the hypothesis of bias abstinence ($p < 0.10$). This test is based on the linear regression method of estimating the effect of the intervention against its standard error, weighted by the inverse of the variance[28]. In an attempt to obtain the best estimate of non-skewed grouped effect, the effect estimate will be recalculated using the Trim and Fill method[29] (trimming the studies that cause the asymmetry from the funnel plot and then filling in the missing imputed studies into the funnel plot based on corrected bias).

A sensitivity analysis will be conducted based on how the studies differed on the risk of bias assessment. However, since the blinding of the participants is not feasible for the physical exercise trials, the performance bias will not be included in this analysis. If participant's data is available to the personnel carrying out the interventions, this will be considered. According to Cochrane guidelines, the results may be presented in a multiple (stratified) analyses on forest plot[16].

If possible, we will perform subgroup analyses to determine the dropout rates according to exergame platforms, study setting (laboratory- vs. home-based), supervision level (yes vs. no), reasons for dropouts (e.g., personal reasons vs. discontinued participation due to injuries/orthopedic complaints), age group, gender, duration of the intervention (short vs. long-term). We will conduct a meta-regression analysis to assess the association between potential predictors and dropout rates among the included studies.

The systematic review with meta-analysis will follow principles of research transparency and reproducibility. In this way, we will adopt a data sharing policy[14], as follows:

- The complete search strategies for each database will be available;
- The list of included and excluded articles will be available;
- The datasheet will be available;
- The data listed should be available in repositories on the Open Science Framework platform (repository DOI 10.17605/OSF.IO/YAQM3). Additionally, the results of this review must be included in a scientific report to be published in a scientific journal.

Conflict of interest

The authors declare no conflict of interest.

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Authors' contributions

Lourenço CLM, Barbosa AR, Meneghini V, Gerage AM Lourenço CLM, participated in the conceptualization, methodology, formal analysis, investigation, writing original draft, writing - reviewing, and editing. Barbosa AR and Gerage AM, participated in the supervision, writing (reviewing, and editing). Meneghini V, participated in the investigation, writing (reviewing, and editing).

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Appendix I: Draft of search strategy (PubMed)

Database	**PubMed (including MEDLINE)** Hits: XX (update: XX)	Search date mm dd, yyyy (update: mm dd, yyyy)
Description	Search performed considering terms by "**text word**" and terms not controlled and controlled Medical Subject Headings (MeSH).	
Strategy		
#1	("Video Games"[Mesh] OR "Video Games" OR "Video Game" OR "Video gaming" OR "Computer Games" OR "Computer Game" OR "Virtual Reality Exposure Therapy"[Mesh] OR "Virtual Reality Exposure Therapy" OR "Virtual reality" OR "virtual realities" OR Exergame OR Exergames OR Exergaming OR "Active video" OR "Serious Game" OR "Xbox Kinect" OR "Kinect games" OR "Nintendo wii" OR Wii OR "Wii fit" OR wiifit OR "Playstation eyetoy" OR Eyetoy OR "dance dance revolution")	
AND		
#2	("Blood Pressure"[Mesh] OR "Blood Pressure" OR "Blood Pressures" OR "Post-Exercise Hypotension"[Mesh] OR "Post-Exercise Hypotension" OR "Hypotension"[Mesh] OR "Hypotension" OR "Hypotensions" OR "Hypertension"[Mesh] OR "Hypertension" OR "Hypertensions" OR "Prehypertension"[Mesh] OR "Prehypertension" OR "Pre-hypertension" OR "Pre hypertension" OR "mean arterial" OR "arterial pressure" OR "arterial pressures" OR normotension OR normotensive OR hypertensive OR antihypertensive OR hypotensive OR "systolic pressure" OR "systolic pressures" OR "diastolic pressure" OR "diastolic pressures" OR "pulse pressure" OR "pulse pressures" OR "venous pressure" OR "venous pressures" OR "pressure monitor" OR "pressure monitors" OR "bp response" OR "bp responses" OR "bp decrease" OR "bp reduction" OR "bp monitor" OR "bp monitors" OR "bp measurement" OR "bp measurements" OR "Hemodynamics"[Mesh] OR Hemodynamics OR "Vascular Stiffness"[Mesh] OR "Vascular Stiffness" OR "arterial stiffness" OR "Cardiovascular Agents"[Mesh] OR "Cardiovascular Agents" OR "Heart Rate"[Mesh] OR "Heart Rate" OR "Heart Rates" OR "endothelial function" OR "endothelial functions")	
NOT		
#3	Adolescent[Text Word]) OR "Adolescent behavior"[Text Word]) OR Child[Text Word]	

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	p.
		ADMINISTRATIVE INFORMATION	
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	01
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	02
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	01
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	05
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	02
Support:			
Sources	5a	Indicate sources of financial or other support for the review	05
Sponsor	5b	Provide name for the review funder and/or sponsor	NA
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	NA
		INTRODUCTION	
Rationale	6	Describe the rationale for the review in the context of what is already known	01
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	03
		METHODS	
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	03
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	03
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	03 Appendix I
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	03

Section and topic	Item No	Checklist item	p.
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	03
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	04
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	04
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	04
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	04
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	04
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	05
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	05
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	05
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	05
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	05
Data sharing	18*	Data sharing policy details.	05

NR = not reported; NA = not applicable; * = item added by the authors