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PROTOCOLO DE ESTUDO

Analysis of the quality of description of usual care interventions in clinical trials involving exercise for knee osteoarthritis: a systematic review protocol

Análise da qualidade da descrição das intervenções intituladas usual care em ensaios clínicos com exercício para osteoartrite de joelho: um protocolo de revisão sistemática

Lucas Henrique Caldas[1], Paula Gabrielly Oliveira Demes[1], José Ribeiro da Silva Neto[1], Nívea Renata Oliveira Monteiro[2], Ana Carolina Pereira Nunes Pinto[2], Areolino Pena Matos[1]

[1]Programa de Pós-Graduação em Ciências da Saúde (PPGCS), Universidade Federal do Amapá (UNIFAP), Macapá, AP, Brasil

[2]Centro Cochrane Iberoamericano, Instituto de Pesquisa Biomédica Sant Pau (IIB Sant Pau), Barcelona, Espanha; Cochrane Brasil, Centro de Estudos em Saúde Baseada em Evidência e Avaliação em Tecnologia em Saúde, São Paulo, SP, Brasil

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Correspondence: Areolino Pena Matos, areolino.matos@gmail.com

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Abstract

Introduction: Treatment for Osteoarthritis (OA) includes exercises, educational and self-management programs, with new therapeutic interventions often compared to “Usual Care”. *Objectives:* To investigate the quality of description of Usual Care as a comparator group in randomized clinical trials (RCTs) using exercise in the treatment of knee OA through a Systematic Review (SR). *Methods:* A search will be conducted in the MEDLINE, Embase, Cochrane Central, PEDro, CINAHL, and SPORTDiscus databases to identify RCTs that used Usual Care as a comparator in the treatment of knee OA with exercise. After selection, eligible studies will be assessed by a pair of trained researchers. The PEDro scale will be used to evaluate the risk of bias, with each study classified as “poor,” “fair,” “good,” or “excellent,” and intervention description will be assessed using the TIDieR checklist. The quality of

the intervention descriptions in each RCT will be classified as “High” if the score is equal to or greater than 50% of the total score, or “Low” if it is lower. Unpaired t-tests and the chi-square test will be used for the evaluation of numerical and categorical variables, respectively. *Expected Results:* The results of this review are expected to summarize the quality of intervention description in RCTs in OA that are often inadequately described, especially concerning the control group, making replication in RCTs and comparison between tested therapies challenging. A well-constructed SR protocol is necessary to help clarify uncertainties about interventions generically referred to as Usual Care.
Key-Words: knee osteoarthritis; patient care; exercise.

Resumo

Introdução: O tratamento para a Osteoartrite (OA) inclui exercícios, programas educacionais e de autogestão, com frequência novas intervenções terapêuticas são comparadas ao chamado “Cuidado Usual”. *Objetivos:* Investigar a qualidade da descrição do Cuidado Usual *(Usual Care*) como grupo comparador em ensaios clínicos (ECR) que utilizaram exercícios no tratamento da OA de joelho por meio de uma Revisão Sistemática (RS). *Métodos:* Será conduzida uma busca nas bases de dados MEDLINE, Embase, Cochrane Central, PEDro, CINAHL e SPORTDiscus que buscará o termo *Usual Care* como comparador em ECRs que utilizaram exercícios no tratamento da OA de joelho. Após seleção, os estudos que atenderem aos critérios de elegibilidade serão avaliados por uma dupla de pesquisadores treinados. A escala PEDro será utilizada para avaliar o risco de viés, sendo cada estudo classificado como Alto, moderado, ou baixo risco de viés e o relato de intervenções serão avaliadas pelo TIDieR *checklist*. A qualidade das descrições de cada ECR será classificada como “Alta” se a pontuação for igual ou superior a 50% do *score* total, ou “Baixa” se inferior. Para avaliação das variáveis numéricas e categóricas serão utilizados os testes *t student* não pareado e o teste qui-quadrado, respectivamente. *Resultados Esperados:* Os resultados desta revisão têm como objetivo resumir a qualidade das dos relatos de intervenções em ensaios clínicos randomizados (RCTs) em OA, que frequentemente são inadequadamente descritas, especialmente no que se refere ao grupo de controle, tornando a replicação em RCTs e a comparação entre terapias testadas desafiadoras. Um protocolo de RS bem construído é necessário para ajudar a esclarecer as incertezas em relação a intervenções geralmente referidas genericamente como “Cuidado Usual”.
Palavras-chave: osteoartrite de joelho; assistência ao paciente; exercício.

Introduction

Among the various therapeutic approaches explored for knee osteoarthritis (KOA) treatment, clinical trials involving physical exercise have demonstrated that such practices have emerged as an effective non-pharmacological intervention for symptom relief, functional improvement, and disease progression attenuation [1,2]. Nevertheless, the quality of clinical trials and the interpretation of their results depend fundamentally on the detailed and precise description of intervention and control groups [3].

The presence of a well-defined control group is essential for determining the actual efficacy of an intervention as it enables comparisons with an established standard. In this context, the control group, often denoted as 'Usual Care,' plays a pivotal role [3,4].

The term "Usual Care" is commonly employed to delineate the standard of care provided to knee OA patients in clinical trials [5–7]. However, this terminology is ambiguous [8] due to the diversity in routine clinical practices among medical specialties and even within professionals of the same specialty. This challenge hinders the comprehension and contextualization of what genuinely constitutes 'Usual Care.' The lack of uniformity in this definition directly jeopardizes the validity, applicability, and reproducibility of clinical trial results, impacting clinical decision-making and the implementation of effective interventions in daily practice [9].

Hence, it is imperative to systematically assess the quality of 'Usual Care' intervention descriptions in clinical trials involving knee osteoarthritis and exercises. An invaluable approach to conduct this analysis involves the utilization of the Template for Intervention Description and Replication (TIDieR) tool, specifically designed to enhance transparency and standardization in intervention descriptions [10], in conjunction with the methodological evaluation of clinical trials using the Physiotherapy Evidence Database (PEDro) scale [11]. This approach will help identify potential methodological gaps, inconsistencies, or inadequacies in the intervention descriptions in the analyzed studies."Parte superior do formulário

Objective

The aim of this study is to investigate the quality of description of Usual Care as a comparator group in randomized clinical trials (RCTs) employing exercises in the treatment of knee osteoarthritis through a Systematic Review (SR).

Methods

Study Design

This is a systematic review protocol that will include RCTs published up to May 2023. The study will be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol (PRISMA-P) [12,13] guidelines. This research is characterized as a systematic review following the methodological recommendations of Cochrane Handbook [14] and reported following the recommendations of PRISMA [12].

Ethical Aspects and Protocol Registration

The research will use anonymous and publicly accessible secondary data and will undergo an analysis by the Research Ethics Committee of the Federal University of Amapá. The review protocol will be registered on the Open Science Framework (OSF).

Eligibility Criteria

Types of Studies included

Only full-text RCT articles will be considered for data analysis.

Types of Studies excluded

Incomplete texts, non-randomized studies, or partially randomized studies will be excluded from the analysis.

Participants

Individuals with a clinical diagnosis of KOA or through any other valid diagnostic method.

Intervention and Comparator

Randomized Clinical Trials that investigated exercises in the treatment of KOA as the intervention group, and "Usual Care" or equivalent terms such as "standard," "routine," "conventional," or any other generic term to describe usual/habitual care (e.g., social education, phone calls, social attention, exercises, or no treatment) in the control group will be included.

Outcomes

Primary Outcome

Quality of description in the intervention and comparator groups in RCTs will be performed using the TIDieR, a tool designed to improve the description of interventions in RCTs.

Secondary Outcomes

a) Analyze the main gaps in the quality of the description of "Usual Care" as a comparator in RCTs investigating exercises for knee OA; b) Correlate the degree of agreement and consistency between the methodological quality assessment tools (PEDro) and reporting quality assessment (TIDieR); c) Compare the average scores obtained with TIDieR before and after its publication year (2014).

Literature Search

The search sources will include the following databases: Medical Literature Analysis and Retrieval System Online (MEDLINE) via PubMed, Excerpta Medica database (Embase) via Elsevier, Cochrane Central Register of Controlled Trials (CENTRAL) via Cochrane Library, Physiotherapy Evidence Database (PEDro), SPORTDiscus, and CINAHL, with no language or publication date restrictions. The strategy described below (Table I) will be applied to Medline via PubMed and will be adapted with the respective specifications for other databases.

Table I - *Search strategy of systematic review*

	Combining terms	Terms
1	Population	#1 "Osteoarthritis, Knee"[Mesh] OR (Knee Osteoarthritides) OR (Knee Osteoarthritis) OR (Osteoarthritis of Knee) OR (Osteoarthritis of the Knee)
2	**Intervention**	#2 "Exercise"[Mesh] OR Exercise (Physical Activity) OR (Activities, Physical) OR (Activity, Physical) OR (Physical Activities) OR (Exercise, Physical) OR (Exercises, Physical) OR (Exercises, Physical) OR (Physical Exercise) OR (Physical Exercises) OR (Acute Exercise) OR (Acute Exercises) OR (Exercise, Acute) OR (Exercises, Acute) OR (Exercise, Isometric) OR (Exercises, Isometric) OR (Isometric Exercises) OR (Isometric Exercise) OR (Exercise, Aerobic) OR (Aerobic Exercise) OR (Aerobic Exercises) OR (Exercises, Aerobic) OR (Exercise Training) OR (Exercise Trainings) OR (Training, Exercise) OR (Trainings, Exercise) OR "Exercise Therapy"[Mesh] OR (Remedial Exercise) OR (Exercise, Remedial) OR (Exercises, Remedial) OR (Remedial Exercises) OR (Therapy, Exercise) OR (Exercise Therapies) OR (Therapies, Exercise) OR (Rehabilitation Exercise) OR (Exercise, Rehabilitation) OR (Exercises, Rehabilitation) OR (Rehabilitation Exercises)
3	**Comparator**	#3 "Standard of Care"[Mesh] OR (Usual care) OR (Care Standard) OR (Care Standards) OR (Standards of Care) OR (Usual standard care) OR (Standard conservative therapy) OR (Care-as-usual) OR (Non-standardized care) OR (Routine treatment) OR (Treatment-as-usual)
4	**Type of study**	#4 ((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials as topic[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading])
5		#1 AND #2 AND #3 AND #4

Study Selection Strategy

Starting in August 2023, studies will be selected by two independent reviewers (J.R.N and L.H.C) will independently search for "Usual Care" as a comparator in RCTs that used exercises in the treatment of knee OA. In case of discrepancies between the reviewers during the study selection, a third independent researcher will serve as a tiebreaker (A.P.M). The entire process of study selection will be conducted through Rayyan (https://www.rayyan.ai/), a website that assists researchers in the systematic review study selection process. The results related to the process of selection of studies will be presented in a flowchart, as recommended by PRISMA (Figure I).

The methodological quality and risk of bias of the included studies will be assessed according to the PEDro Scale [11], and the scores can be found in the Physiotherapy Evidence Database (https://pedro.org.au/).

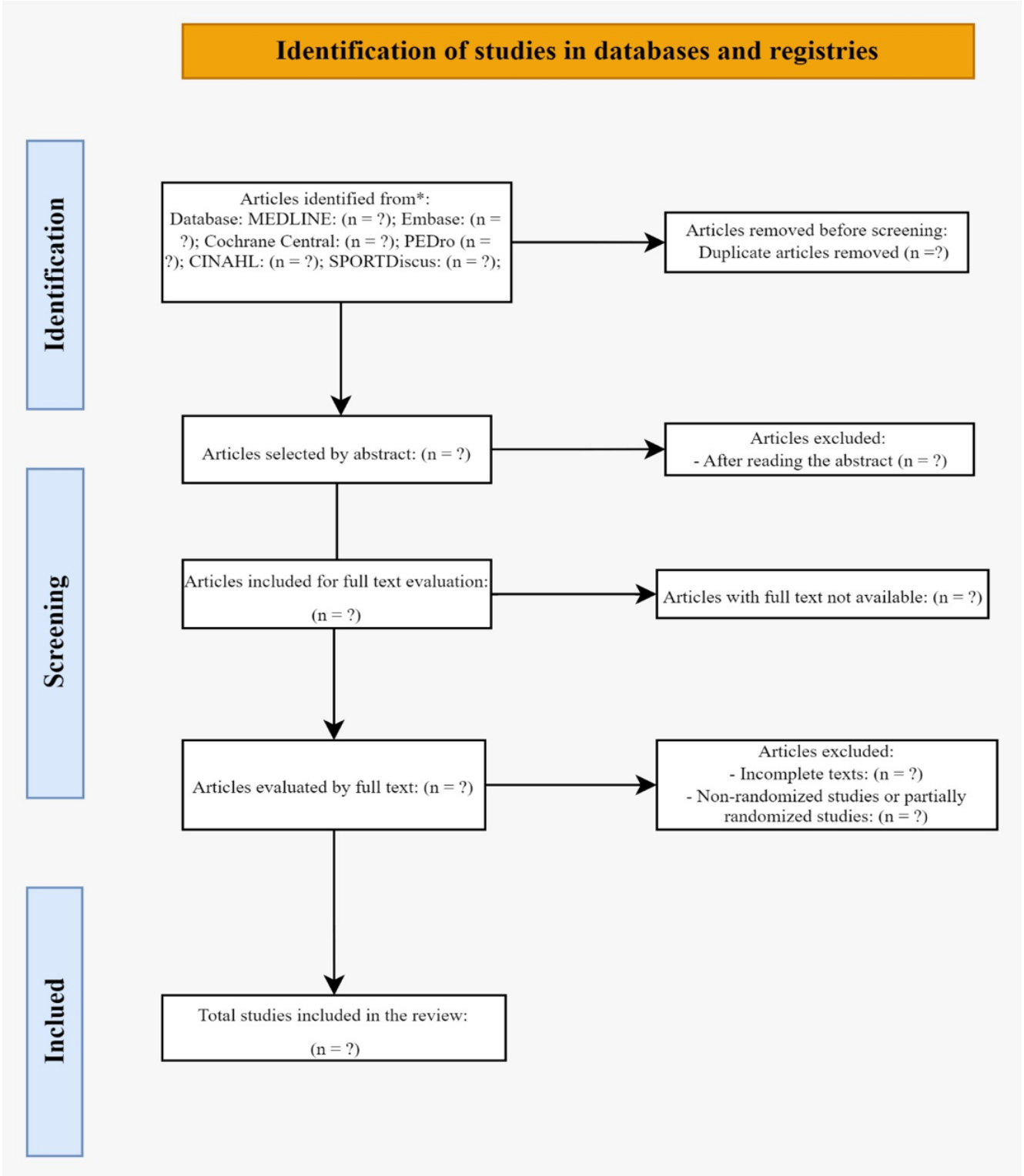

Figure I - *Flowchart of systematic review.*

For RCTs where scores are not available in the PEDro database, an independent review will be conducted by two researchers (J.R.N and L.H.C), and after a full-text review, they will reach a consensus on the final score. Similarly, the studies will also be assessed using the TIDieR checklist, and

the quality of the descriptions for each clinical trial will be categorized as “High” if the score is equal to or greater than 50% or “Low” if it falls below 50% of the total score [16,17].

Additionally, researchers will be trained in the use of evaluation tools, which will be conducted by a more experienced and trained researcher (A.C.N.P). To familiarize each researcher with the use of the tools, they will be guided on the purpose and content of each evaluation instrument. In the second stage, each researcher will independently evaluate a separate article that will not be included in the sample. Subsequently, an online meeting will be held to discuss the findings and address any questions or uncertainties.

Evaluation of methodological quality

To assess the methodological quality of the included clinical trials, the Brazilian Portuguese version of the PEDro scale will be used. The scale consists of a total of 11 items, divided into three categories: External validity (item 1), Risk of bias analysis (items 2 to 9), and Statistical description (items 10 and 11). The scale results in a score ranging from 0 to 10, where a higher score indicates better methodological quality. To assign a score to each of the items, they must have been reported clearly and appropriately. Item 1 is not counted towards the final score as it assesses the external validity of the study. Based on the final score, the methodological quality of the clinical trial is categorized as “Poor” (< 4), “Fair” (4-5), “Good” (6-8), or “Excellent” (9-10).

The scores on this scale are available for all clinical trials indexed in the PEDro database, allowing clinicians to guide their practice based on studies of high methodological quality [11]. The scale has been translated into Brazilian Portuguese and has acceptable reliability and reproducibility, similar to the original English version [17]. For clinical trials where scores are not available in the PEDro database, an independent review will be conducted by two researchers and after a full-text review, they will reach a consensus on the final score.

Evaluation of report quality

The texts included in the study will also undergo analysis using the TIDieR checklist, that describes interventions with sufficient detail for replication in research and clinical practice. TIDieR was developed as an extension of the CONSORT 2010 guidelines (item 5) [18] and the SPIRIT 2013 statement (item 11) [19] and was created to address deficiencies identified in the reporting of non-pharmacological interventions, which are thought to reduce the potential impact of research on clinical practice. TIDieR consists of 12 items: intervention name; rationale for intervention for essential elements; intervention materials and details on how to access them; intervention procedure description; details of intervention providers; mode of intervention delivery; location of intervention provision and essential infrastructure; details on the number, duration, intensity, and dose of intervention sessions; details of any intervention adaptations; any intervention modifications during the study; and details of intervention fidelity assessment, monitoring, and level achieved. Higher scores indicate better quality of textual intervention reporting [10]. One point will be assigned if an item is reported completely, and zero points will be assigned for partial or unreported items.

Statistical Analysis

Descriptive analysis will be presented using mean, standard deviation, and percentage or median and interquartile range. Normality of the data will be assessed using the Kolmogorov–Smirnov test. The unpaired t-test or Mann-Whitney test will be employed to analyze numerical variables

obtained in the TIDieR before and after its publication (2014), and the chi-square test will be used to evaluate categorical data such as absolute and relative frequencies and comparison of proportions.

According to the final score, the PEDro scale will classify the methodological quality of RCTs as follows: "Poor" (< 4); "Fair" (4-5); "Good" (6-8); or "Excellent" (9-10). In the TIDieR, one (1) point will be assigned if an item is reported completely, and zero (0) for partial or unreported items. In this study, following the methodology used by [16], to correlate different evaluation instruments, the final score will determine the quality of the descriptions and will be calculated using the following formula: "Score obtained in the evaluation X 100/total points of the scale". The quality of the description of interventions in each clinical trial will then be classified as "High" if the score is equal to or greater than 50%, or "Low" if it is less than 50%.

The intraclass correlation coefficient (ICC) will be employed to assess the correlation between the TIDieR and PEDro scales, analyzing the reliability or consistency between the evaluation instruments. The statistical analysis will be performed using SPSS Statistics 25, and the adopted significance level will be 5% ($p < 0.05$).

Expected results and clinical relevance

Detailed analysis using the TIDieR tool will reveal gaps in the quality of descriptions of the "Usual Care" group in RCTs investigating exercises for knee osteoarthritis (OA). It is expected to identify specific areas where descriptions can be improved. Most studies are likely to have scores below the ideal, emphasizing the need to enhance transparency and standardization in "Usual Care" descriptions.

An improvement in average TIDieR scores is expected in studies published after 2014 compared to earlier studies. This will reflect a greater application of TIDieR guidelines after its creation, indicating a more comprehensive and transparent description of "Usual Care" in more recent RCTs.

A positive correlation is possible between TIDieR scores and PEDro scale scores in the analyzed studies. This correlation may will indicate whether studies with a more detailed description of "Usual Care" also tend to have higher methodological quality.

Highlighting gaps in the description of "Usual Care," the results will have clinical relevance by emphasizing the need for stricter standards in RCT interventions. This improvement in the quality of descriptions can directly impact clinical practice, facilitating the replication of interventions and providing reliable information for healthcare professionals in decision-making regarding knee OA treatments.

Conflict of Interest

The authors declare no conflicts of interest.

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There was no external funding for the development of the research.

Authors' Contributions

Conception and study design: Silva Neto, JR; Caldas, LH; Demes, PGO; Pinto, ACPN; Monteiro, NRO; Matos, AP; Data collection and organization: Silva Neto, JR, Caldas, LH; Demes, PGO; Matos, AP; Analysis and interpretation of data: Matos, AP; Silva Neto, JR; Caldas, LH; Monteiro, NRO; Pinto, ACPN; Manuscript writing: Silva Neto, JR; Caldas, LH; Matos, AP; Critical revision of the manuscript for important intellectual content: Silva Neto, JR; Pinto, ACPN; Matos, AP.

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