Study Protocol

SPIN ANALYSIS IN RANDOMIZED CLINICAL TRIALS OF PHYSIOTHERAPEUTIC TREATMENT FOR TEMPOROMANDIBULAR DISORDERS: A SYSTEMATIC REVIEW PROTOCOL.

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ABSTRACT

Objective: To investigate whether clinical trials of physiotherapeutic interventions for treating temporomandibular disorders (TMD) contained spin and whether there was consistency between the abstract and the full text.
Study design: Systematic Review Protocol. (PROSPERO ID: CRD42022369637)
Methodology: Study selection and data extraction assessments were conducted independently and in duplicate. The sample will be composed of randomized controlled clinical trials of physiotherapeutic treatment for TMD as one of the treatments, regardless of whether it is muscular, articular, or mixed; and have at least pain and mandibular range of motion as outcome measures. Without language restriction, 2010 to 2025 is the year of publication, which allows a comparative analysis between the abstract and the full text. The analysis will be performed independently and in duplicate. In case of disagreement, a third reviewer will be consulted to reach a consensus through discussion. The electronic databases used were PubMed/Medline, EMBASE, CINAHL, CENTRAL, PEDro, SPORTDiscus, and LILACS. A search strategy developed for PubMed/Medline will be adapted for each database. Two checklists will be used to analyze the studies: Consolidated Standards of Reporting Trials (CONSORT) for abstract (CONSORT-A) to evaluate the completeness of reporting of the abstracts and the spin checklist to evaluate the presence and consistency of spin in abstract. The risk of bias was assessed using the PEDro scale independently and in duplicate.
Results: The results will be presented in tables and flowcharts.
Conclusion: Inconsistencies between the abstract and full text require investigation to alert clinicians, researchers, and readers.

Keywords: temporomandibular joint dysfunction syndrome; musculoskeletal manipulations; exercise therapy; data interpretation; systematic review.

1. INTRODUCTION

Temporomandibular dysfunction (TMD) refers to a set of conditions that affect the temporomandibular joint (TMJ), masticatory muscles, or both, as well as the structures of the stomatognathic system. Therefore, it is represented by a heterogeneous group of signs and symptoms, including pain and limited jaw movements that can worsen and become (1–3).

Physiotherapeutic treatments for TMD generally have a multimodal approach (4), techniques such as myofunctional therapy, which increases muscle strength and provides stability to orofacial structures (5); the use of manual therapies and massage therapy improves patients

pain (3,6); proprioceptive exercises using hyperboloids (7); transcutaneous electrical nerve stimulation (TENS)(8); and low-power laser therapy (LLLT) have been used to treat pain and the inflammatory process with very satisfactory results (9,10). It is important to evaluate the effectiveness of physiotherapeutic interventions for TMD to support evidence-based clinical practice (11).

In some situations, due to the restricted access to the full text and the lack of complete publication of data, the abstract play an important role in clinical decision-making. Many professionals use abstracts as a primary source of information to implement new therapeutic modalities (12–14). It is essential that abstract present the results accurately, leaving no room for misinterpretation, and that they are consistent with the results presented in the full text. If there is a distortion in the description of the results, it occurs what we call spin (13,15).

The "spin" term, studied since 1995 by Horton and colleagues (16), refers to the distorted representation of results by authors, whether intentionally or not, commonly exaggerating the benefits of the intervention in question. Spin manifests itself in a variety of ways and is commonly categorized into 3 categories (17): 1) misleading reports, which are incomplete or misrepresentations of the results; 2) inadequate interpretation of the data, usually the authors overestimate the benefits of an intervention; and 3) inappropriate extrapolation of results inappropriately, when clinical recommendations based on observational data are not robust or extrapolations to populations not studied in the study in question (18)).

Another manifestation of "spin" is linguistic spin, in which language is used in a distorted way to emphasize the benefits of an intervention or minimize its risks (17,19). This distortion can compromise the validity of the data and, consequently, its results (20) and is often observed in abstract that do not directly reflect the context of the full text (16,17).

According to Chan and Altman (2005)(21), positive findings are more likely to be published in higher impact journals, which naturally generates a tendency to accentuate a positive approach to their results (22). Another important issue is that the interpretation of non-significant negative results requires caution. In clinical trials, this type of results is common, leading to potential bias (23).

To the best of our knowledge, there is no study investigating the presence of spin and the consistency between the abstract and the full text of clinical trials investigating physiotherapeutic interventions for treating TMD; therefore, this protocol would aid in investigating this.

2. METHODOLOGY

First, a search was carried out in the databases PubMed/Medline, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Central Register of Controlled Trials (CENTRAL), Physiotherapy Evidence Database (PEDro), SPORTDiscus and Latin American and Caribbean Health Sciences Literature (LILACS) to identify possible similar or identical studies. No studies were found. Therefore, this systematic review protocol was previously submitted and accepted by PROSPERO with registration number CRD42022369637 and is registered and will be conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) (24).

To formulate the research question, the anagram PCC (population, concept, and context) was used to guide the study: a) population: randomized controlled clinical trials that address physiotherapeutic treatments for TMD; b) concept: evaluation of the presence of SPIN

between the abstract and the full text; c) context: report of the data found. Based on these definitions, the alternative hypothesis was established: do abstract of clinical trials involving physiotherapy in TMD clients contain spin and are they associated with the type of conclusion (positive, negative, neutral, or indeterminate)?

2.1 Eligibility criteria

The eligibility criteria for the randomized controlled clinical trials will be full publications (abstract and full text),without language restriction (we will use artificial intelligence to read the articles in different languages), published between 2010 and 2025. The 2010-2025 period was chosen because the last update of CONSORT(Consolidated Standards of Reporting Trials) was published in 2010, which raised the standards of the randomized clinical trials compared with those previously published.

The sample will be composed of randomized controlled clinical trials of physiotherapeutic treatment for TMD as one of the treatments, regardless of whether it is muscular, articular, or mixed; and have at least pain and mandibular range of motion as outcome measures.

2.2 Search strategy

The electronic databases searched were PubMed/Medline, EMBASE, CINAHL, CENTRAL, PEDro, SPORTDiscus, and LILACS.

Table 1 shows the search strategy initially used for the PubMed/Medline search, which will be adapted for each database. The terms validated in the Medical Subject Headings-MeSH" were selected following the research question and were relevant to the topic addressed.

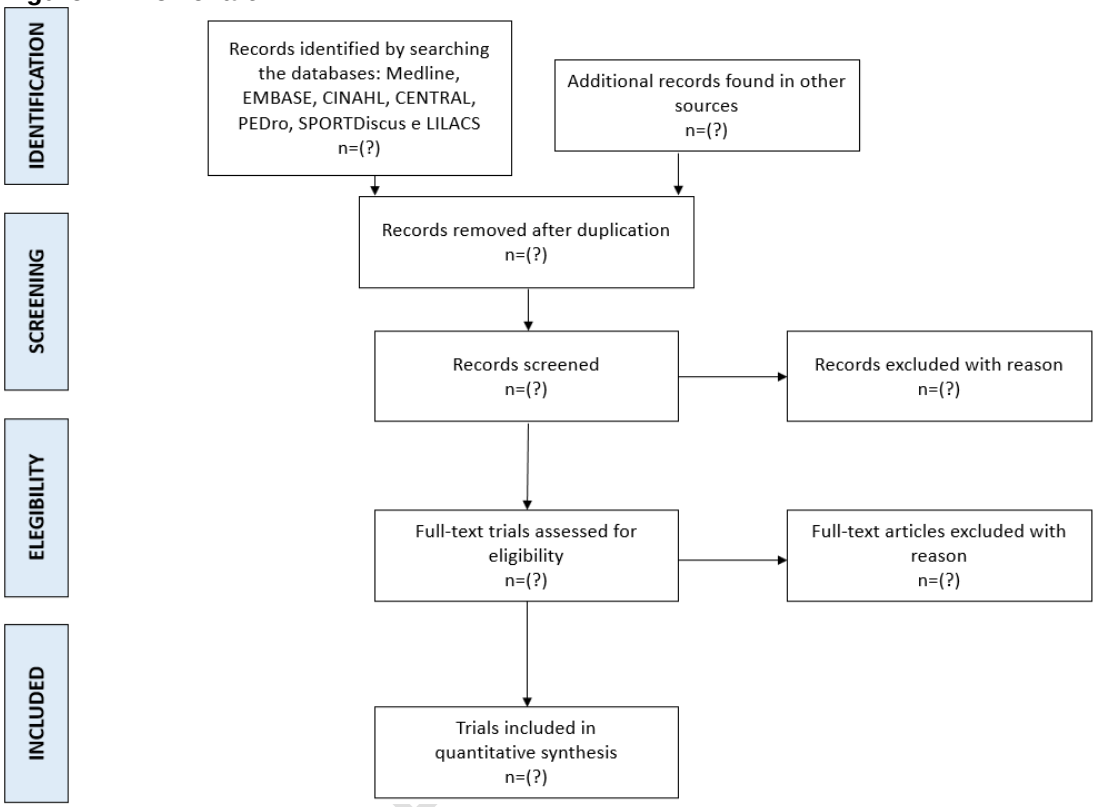
Table 1 - Search strategy - PubMed/Medline (search conducted on September 26, 2023).

Search	MeSH Terms	Found records
#1	'Disorder Temporomandibular Joint' OR 'Disorders Temporomandibular Joint' OR 'Joint Disorder Temporomandibular' OR 'Joint Disorders, Temporomandibular' OR 'Temporomandibular Joint Disorder' OR 'TMJ Disorders' OR 'Disorder TMJ' OR 'Disorders TMJ' OR 'TMJ Disorder' OR 'Temporomandibular Disorders' OR 'Disorder Temporomandibular' OR 'Disorders Temporomandibular' OR 'Temporomandibular Disorder' OR 'Temporomandibular Joint Diseases' OR 'Disease Temporomandibular Joint' OR 'Diseases	24,419

	Temporomandibular Joint' OR 'Joint Disease Temporomandibular' OR 'Joint Diseases Temporomandibular' OR 'Temporomandibular Joint Disease' OR 'TMJ Diseases' OR 'Disease TMJ' OR 'Diseases TMJ' OR 'TMJ Disease' OR 'Temporomandibular Joint Dysfunction Syndrome' OR 'Temporomandibular Joint Disorders'	
#2	'Manipulations Musculoskeletal' OR 'Manipulation Therapy' OR 'Manipulative Therapies' OR 'Manipulative Therapy' OR 'Therapies Manipulative' OR 'Therapy Manipulative' OR 'Therapy Manipulation' OR 'Manipulation Therapies' OR 'Therapies Manipulation' OR 'Reflexology' OR 'Bodywork' OR 'Bodyworks' OR 'Rolfing' OR 'Craniosacral Massage' OR 'Massage Craniosacral' OR 'Manual Therapies' OR 'Manual Therapy' OR 'Therapies Manual' OR 'Therapy Manual' OR 'Musculoskeletal Manipulations'	69,376
#3	'Modalities Physical Therapy' OR 'Modality Physical Therapy' OR 'Physical Therapy Modality' OR 'Physical Therapy Techniques' OR 'Physical Therapy Technique' OR 'Techniques Physical Therapy' OR 'Group Physiotherapy' OR 'Group Physiotherapies' OR 'Physiotherapies Group' OR 'Physiotherapy Group' OR 'Physical Therapy' OR 'Physical Therapies' OR 'Therapy Physical' OR 'Specialty Physical Therapy' OR 'Therapy Specialty Physical' OR 'Physiotherapy Specialty' OR 'Specialty Physiotherapy' OR 'Physical Therapy	433,040

	Specialty' OR 'Physiotherapy Specialty' OR 'Specialty Physical Therapy' OR 'Specialty Physiotherapy' OR 'Therapy Specialty Physical' OR 'Physical Therapy Modalities' OR 'Group Physiotherapies' OR 'Group Physiotherapy' OR 'Modalities Physical Therapy' OR 'Modality Physical Therapy' OR 'Physical Therapies' OR 'Physical Therapy' OR 'Physical Therapy Modality' OR 'Physical Therapy Technique' OR 'Physical Therapy Techniques' OR 'Physiotherapies (Techniques)' OR 'Physiotherapies Group' OR 'Physiotherapy (Techniques)' OR 'Physiotherapy Group' OR 'Techniques Physical Therapy' OR 'Therapy Physical'	
#4	'Remedial Exercise' OR 'Exercise Remedia' OR 'Exercise Remedia'l OR 'Remedial Exercises' OR 'Therapy Exercise' OR 'Exercise Therapies' OR 'Therapies Exercise' OR 'Rehabilitation Exercise' OR 'Exercise Rehabilitation' OR 'Exercises Rehabilitation' OR 'Rehabilitation Exercises' OR 'Exercise Therapy'	188,665
#5	'Clinical Trial Randomized' OR 'Trial Randomized Clinical' OR 'Controlled Clinical Trial Randomized' OR 'Randomized' OR 'Comparative study' OR 'Placebo' OR 'Drug therapy' OR 'Randomly' OR 'Trial' OR 'Groups' OR 'Clinical Trial' OR 'Controlled Clinical Trial' OR 'Randomized Controlled Trial'	10,722,148
#6	#1 AND #2 AND #3 AND #4 AND #5	65

Figure 1 - Flowchart



2.3 Data selection

Two checklists will be used to analyze the studies.

Table 2 shows the CONSORT-A (Consolidated Standards of Reporting Trials (CONSORT) for abstract) checklist with 17 items, which was used to evaluate the completeness of reporting of the abstract and the full text of the included trials (25,26). For this study, we will remove two items from our data analysis because they are not relevant: "authors" (related to the reporting of the corresponding author's contact details in conference proceedings) and "recruitment" (indicates the recruitment phase or in progress). Each item will be classified as "fully reported" (if all the specified information was reported) and "not reported" (if the specified information was partially reported, if no information specified in the item was reported or when the primary outcomes were not specified) for each study. We also generated a summary score (CONSORT-A score) for each study, counting the number of items that were "fully reported". The summary score can range from 0 (low level of completeness of reporting) to 15 (high level of completeness of reporting).

The analysis will be carried out by two reviewers. In case of disagreement, a third reviewer will be consulted to reach a consensus through discussion.

Table 2: CONSORT-A Checklist

Item	Description
1.Title	Identification of the study as a randomized
2.Trial design	Description of the trial design
Methods	
3. Participants	Eligibility criteria for participants and the settings where the data were collected
4.Interventions	Interventions intended for each group
5.Objective	Specific objective or hypothesis
6.Outcome	Clearly defined primary outcome for this report
7.Randomization	How participants were allocated to interventios
8. Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were bilnded to group assignment
Results	
9.Numbers randomized	Number of participants randomized to each group
10.Numbers analysed	Number of participants analysed in each group
11.Outcome	For the primary outcome, a result for each group and the estimated effect size and precision
12.Harms	Important adverse events or side effects
13.Conclusions	General interpretation of the results
14.Trial registration	Registration number and name of trial

	register
15.Funding	Source of funding

We will use a 7-item spin checklist (Table 3) to evaluate the presence and consistency of spin in the abstract and in the full text. This checklist has been previously used to measure spin in abstract of randomized controlled trials in the field of oncology and in an overview study of the completeness of reporting of abstract in the field of low back pain (17,25).

To analyze thesedatas, we will use the same strategy as that of the study of Nascimento et al., 2019 (25). Each item will be classified as “yes” (ie, the spin is clearly present, the primary outcome results are not reported, or the primary outcome results are omitted, all of which represented that the spin is also present) or “no” (ie, the spin it is not present). The score could range from 0 (low levels of spin) to 7 (high levels of spin). The analysis will be carried out by two reviewers. In case of disagreement, a third reviewer will be consulted to reach a consensus through discussion.

Table 3 - *Spin* identification checklist

Description of each item
1.Omission of primary results
2. Do not mention adverse events from the interventions
3.Selective reporting of positive results and omission of negative results from primary results
4. Do not report statistically non-significant primary results
5. Focus on statistically significant results that are not the primary ones
6. Over-enthusiastic interpretation of statistically non-significant primary results as effective
7. Recommending a treatment without a clinically important effect on the primary results

2.4 Data extraction and synthesis

Data extraction will be divided into 2, to answer our research question: (1) consistency between the abstract and the full text and (2) presence of spin in the abstract and full text. To investigate the consistency between the abstract and the full text of the studies included, using CONSORT-A, we will tabulatethe data. To investigate the presence of spin using the spin checklist, we will also tabulate the datas and do a descriptively analysis.

The mean and SD will be use to describe the quantitative variables for each checklist. Analysis of the abstract and full text for both CONSORT-A and the spin analysis checklist will be calculated using kappa coefficients. Kappa values greater than 0.61 (i.e. "substantial" to "almost perfect agreement") will be the criterion for "acceptable" agreement between abstract and full text

2.5 Analysis of the risk of bias

The methodological quality of eligible studies will be assessed using the PEDro scale (27), a valid tool for measuring the risk of bias, and the statistical description of clinical trials (28)for which the reproducibility of the Portuguese version is adequate (intraclass correlation coefficient-ICC of 0.82) and similar to the English version (ICC of 0.78) (29). The scale has 11 criteria (higher scores=lower risk of bias), 8 of which are related to methodological quality (i.e. random allocation, secret allocation, proven baseline, blinded subjects, blinded therapist, blinded evaluator, adequate follow-up, and intention-to-treat analysis) and 2 criteria relating to statistical description (intergroup statistical comparisons and measures of precision and variability). The first criterion (eligibility criteria) is not considered when adding up the total score because it relates to external validity.

The score for each study will be taken from the PEDro database itself (www.pedro.org.au) whenever the study is indexed there, which guarantees the most reliable score. If the study is not availbale in the PEDro database, the two reviewers will use the PEDro scale to determinate the score.The analysis will be carried out by two reviewers. In case of disagreement, a third reviewer will be consulted to reach a consensus through discussion.

3. DISCUSSION

The primary basis of science is for its results to be reliable so that professionals can safely replicate its methods based on the best evidence (15).

Abstract of scientific articles play a fundamental role in the dissemination of results because they are widely disseminated and, in many cases, made freely available to the public (17). Since readers constantly rely on the information contained in abstracts, most of which are freely accessible, how this data is implied often does or does not arouse the reader's interest in reading the full text. A worrying fact is that in situations where access to the full text of the article is restricted, the abstract may be the only reference used for clinical decisions; however, if this information is presented in a distorted way, there is a risk of inaccurate data being spread (25,30,31).

The analysis of spin in studies in the field of medicine and clinical research is relatively recent. Research has shown that journals with a high impact factor can often publish studies with misinterpretations or inaccurate reports of results, which can lead to harmful risks for patients (17,32). Evidence-based clinical practice is most often based on systematic reviews with or without meta-analyses, which are currently recognized as the most reliable sources in the field of scientific research (15).

4. CONCLUSION

Inconsistency between abstract and full text required to be investigated to alert clinicians, researchers, and readers so that they can identify it.To protect clinicians, researchers, and readers, it is essential to investigate whether clinical trials that address physiotherapeutic conduct for treating TMD present any kind of spin between abstract and full texts.

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This is not an Annexure. This is the guideline we followed to conduct this protocol. It's not necessary to published.

Anexo I

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	Reported on Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	**1a**	**Identify the report as a protocol of a systematic review**	**1**
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**	**2**
Authors:			
Contact	**3a**	**Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author**	**1**
Contributions	**3b**	**Describe contributions of protocol authors and identify the guarantor of the review**	**8-9**
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	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	8
Sponsor	5b	Provide name for the review funder and/or sponsor	8
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	8
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	2
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	2
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	2
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	3
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	3
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	2-7
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)	2-7
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	2-7
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	2-7
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	7
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	7

Data synthesis	**15a**	**Describe criteria under which study data will be quantitatively synthesised**	**7**
	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)**	**7**
	15c	**Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)**	**7**
	15d	**If quantitative synthesis is not appropriate, describe the type of summary planned**	**7**
Meta-bias(es)	**16**	**Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)**	**NA**
Confidence in cumulative evidence	**17**	**Describe how the strength of the body of evidence will be assessed (such as GRADE)**	**-**

***It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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