Study Protocol

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

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ABSTRACT

Aims: To identify through this protocol whether clinical trials of physiotherapeutic interventions for treating TMD (temporomandibular disorders) show consistency between the abstract and the full text.
Study design: Systematic Review Protocol.
Methodology: The PRISMA-P guidelines will be followed, using as a source randomized controlled clinical trials of TMD treatments that allow a comparative analysis between the abstract and the full text, produced between 1990 and 2025, without language restriction and collected in electronic databases: PubMed/Medline, EMBASE, CINAHL, CENTRAL, PEDro, SPORTDiscus, and LILACS. A search strategy developed for PubMed/Medline will be adapted for each database. Two independent reviewers will check the quality of the studies using a scored checklist.
Results: The results will be presented in tables and flowcharts.
Conclusion: Inconsistency between abstract and full text is common and it is necessary to alert clinicians, researchers, and readers so that they can identify it.

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), the masticatory muscles or both, as well as structures of the stomatognathic system. Itis therefore represented by a heterogeneous group of signs and symptoms, including pain and limited jaw movements that can worsen and become unsustainable [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]; electrothermophototherapy devices such as 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 lack of complete publication of data, many professionals'resort to summaries as a primary source of information for implementing new therapeutic modalities [12-14]. It is essential that abstracts 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, occurs what we call spin [13,15].

The "spin" term, studied since 1995 by Horton and colleagues [9], 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 [16]: 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) extrapolating results inappropriately, when clinical recommendations based on observational data are not robust or extrapolations to populations not studied in the study in question [17]).

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 [16,18]. This distortion can compromise the validity of the data and, consequently, its results [19] and is often observed in abstracts, which do not directly reflect the context of the full text [16,20]. Therefore, this protocol seeks to identify the consistency between the abstracts and the full text of clinical trials investigating physiotherapeutic interventions in the treatment of TMD.

2. METHODOLOGY

Firstly, a search was carried out in the databases to identify possible similar or identical studies and no studies were found. This systematic review protocol was therefore previously submitted and accepted by PROSPERO and is registered and will be conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) [21] (Anexo I).

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 hypothesis was established: do abstracts of clinical trials involving physiotherapy in TMD patients contain spin and are they associated with the type of conclusion (positive, negative, neutral, or indeterminate)?

2.1 Eligibility criteria

The sample will be composed of randomized controlled clinical trials that address physiotherapeutic treatments for TMD, whatever it may be, and that allow a comparative analysis between the abstract and the text, published between 1970 and 2025.

Only articles will be included that are fully published, with abstract and full text; that are randomized controlled clinical trials that address physiotherapeutic treatment for TMD as one of the treatments, regardless of whether it is muscular, articular, or mixed; and that have at least pain and mandibular range of motion as outcome measures.

2.2 Search strategy

The electronic databases searched will be 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).

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 which are 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 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	24,419
#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	69,376

	Rolfing OR Craniosacral Massage OR Massage Craniosacral OR Manual Therapies OR Manual Therapy OR Therapies Manual OR Therapy Manual OR Musculoskeletal Manipulations	
#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 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	433,040
#4	Remedial Exercise OR Exercise Remedia OR Exercise Remedial OR Remedial Exercises OR Therapy Exercise OR	188,665

	Exercise Therapies OR Therapies Exercise OR Rehabilitation Exercise OR Exercise Rehabilitation OR Exercises Rehabilitation OR Rehabilitation Exercises OR Exercise Therapy	
#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

2.3 Data selection and extraction

Two checklists will be used to analyze the studies. Table 2 shows the CONSORT-A (Consolidated Standards of Reporting Trials (CONSORT) for abstracts) checklist with 17 items, which will be used to assess the integrity of the abstracts of the selected studies and the full text of the selected studies [22,23].

Table 2: CONSORT-A Checklist

Item	Description
1.Title	Identification of the study as a randomised
2.Authors	Contact details for the corresponding author
3.Trial design	Description of the trial design
Methods	
4. Participants	Eligibility criteria for participants and the settings where the data were collected
5.Interventions	Interventions intended for each group
6.Objective	Specific objective or hypothesis
7.Outcome	Clearly defined primary outcome for this

	report
8.Randomization	How participants were allocated to interventios
9. Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were bilnded to group assignment
Results	
10.Numbers randomized	Number of participants randomized to each group
11.Recruitment	Trial status
12.Numbers analysed	Number of participants analysed in each group
13.Outcome	For the primary outcome, a result for each group and the estimated effect size and precision
14.Harms	Important adverse events or side effects
15.Conclusions	General interpretation of the results
16.Trial registration	Registration number and name of trial register
17.Funding	Source of funding

Table 3 highlights the checklist that will be used to identify the presence and consistency of spin in the abstracts and full text of the selected studies (16,22). The analysis of spin will be carried out by two reviewers who will assess the level of spin present in the abstracts. A low level of spin will be defined as spin reported with uncertainty in the framework and recommendations for further trials; a moderate level as spin reported with some uncertainty in the framework or recommendations for further trials; and a high level as spin reported without any uncertainty or recommendations for further trials. 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 synthesis

To investigate the completeness of the abstracts and the spin in the description of the results in the abstracts, the percentage of articles fulfilling each CONSORT-A item and the spin analysis checklist will be tabulated. Averages and standard deviations will be used to describe these quantitative variables. The 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 [24], a valid tool for measuring the risk of bias and the statistical description of clinical trials [25] of which the reproducibility of the Portuguese version is adequate (intraclass correlation coefficient - ICC of 0.82) and like the English version (ICC of 0.78) (26). 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, as 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.

3. DISCUSSION

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

Abstracts of scientific articles play a fundamental role in the dissemination of results, since they are widely disseminated and, in many cases, made freely available to the public [16].

Since readers constantly rely on the information contained in abstracts, most of which are freely accessible, the way in which 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 [23,28,29].

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 [16,30]. 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

Abstracts play an important role in clinical decision-making, particularly when access to the full text is restricted. An interpretation based on ineffective results can result in inappropriate therapeutic recommendations, compromising the clinical judgment of health professionals and consequently affecting patients. To protect clinicians, researchers, and readers, it is essential to investigate whether clinical trials that address physiotherapeutic conduct in the treatment of TMD present any kind of spin between abstracts and full texts.

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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**	**2-7**

		in meta-analysis)	
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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