

Protocol for a randomized clinical trial of Oculomotor Exercises Added to Treatment for Temporomandibular Disorders

ABSTRACT

Objective: To evaluate the effect of adding oculomotor exercises to the treatment of Temporomandibular Disorder (TMD) on pain intensity, range of mandibular movement, TMD severity, and ocular convergence insufficiency (CI), immediately, 3 months, and 6 months after treatment.

Study design: Controlled and randomized clinical trial included blinded evaluators and participants.

Methodology: Individuals aged 18–45 years diagnosed with TMD and convergence insufficiency.

Intervention: Two groups: the experimental group (EG) and the control group (CG) groups will receive 12 treatment sessions. Main outcome measures: pain intensity, range of mandibular movement, convergence insufficiency, and severity of TMD during follow-up immediately after treatment, 3 and 6 months.

Analysis: The statistical analysis will use linear mixed models based on the intention to treat. The significance level will be set at 5%.

Results: This is a preliminary protocol; results will be available once the study is completed. It is expected relevant patient clinical improvement results.

Conclusion: It will be possible to determine the effects of adding oculomotor exercises in the treatment of TMD

Implications for practice: If successful, the protocol could be integrated into clinical practice as an adjunct to conventional therapy for TMD, expanding the therapeutic options available to healthcare professionals and patients

Keywords: temporomandibular disorder, clinical trials, physical therapy, convergence insufficiency, oculomotor therapy

1. INTRODUCTION

Convergence insufficiency (CI) is a prevalent binocular vision disorder in which the eyes do not focus on a nearby object [WIDMER et. al, 2018, SCHEIMAN et. al, 2008]. This dysfunction can cause symptoms such as headache, discomfort, drowsiness, diplopia, eye fatigue, blurred vision, difficulty in concentrating, tearing, orbital discomfort, among others [ALVAREZ et. al, 2010; PICKWELL et. al, 1981; DAUM, 1984, BADE et. al, 2013]. The prevalence of this condition varies from 1.75% to 33.0%, with an average of 5% [ALETAHA et. al, 2018; PORCAR et. al, 1997; COOPER et. al, 2012].

Studies have identified different therapeutic approaches for ocular convergence insufficiency and have sought to clarify the effectiveness of these treatment approaches based on the signs and symptoms present [ALVAREZ et. al, 2010; BASTOS, 2018]. Therapeutic modalities include Brock's cord, Barriles card, and eccentric circles [SCHEIMAN et. al, 2005; CITT, 2008]. However, there is no consensus on the ideal intervention for adults [SCHEIMAN et. al, 2005].

Anatomical and physiological evidence indicates connections between the oculomotor and stomatognathic systems [DOS SANTOS et. al, 2021; MONACO et. al, 2003; MONACO et. al, 2004; PORTER, 1986; WANG et. al, 2008; NYBERG et. al, 1984]. The visual and masticatory systems are integrated by the trigeminal system, as the afferent pathways of the trigeminal nerve linked to the masticatory muscles and extraocular muscles are located in the mesencephalic and cuneate nuclei of the brain stem, where they make connections [MORQUETE et. al; 2012; PORTER, 1986; WANG et. al, 2008; NYBERG et. al, 1984].

The literature points to associations between convergence insufficiency (CI) and Temporomandibular Disorder (TMD) in the outcomes of pain and severity of TMD [DOS SANTOS et. al, 2021]. Monaco et al. [2003] found correlations between abnormalities in ocular convergence in adults with TMD and concomitant symptoms, such as restrictions in maximum mouth opening and myofascial pain.

It is important to highlight that TMD has a multifactorial etiology and is the main musculoskeletal cause of non-odontogenic orofacial pain [HERRERA-VALENCIA et. al, 2020; KALLADKA et. al, 2021; ARMIJO-OLIVO et. al, 2015], with an estimated prevalence of 31% in adults and around 11% in young children [OKESON, 2012; VALESAN et. al, 2021], and is more prevalent in women [GONÇALVES et. al, 2010; FERNÁNDEZ-DE-LAS-PENAS et. al, 2016].

The most common manifestation of TMD is myofascial pain in the masticatory muscles [MANFREDINI et. al, 2011], which can coexist with other conditions, such as headache, chronic fatigue, sleep disorders, and sensory disorders [GONALVES et. al, 2010; DAHAN et al, 2015; RENER-SITAR et. al, 2014].

Conservative and non-invasive therapeutic approaches have been prioritized for the management of TMD [FERRILO et al., 2022]. One of the most recommended therapeutic modalities is physiotherapy, especially manual therapy, which directly affects the muscular system to reduce excessive tension and pain [URBANSKI et. al, 2021].

Considering the proposed interrelationship between the oculomotor system and TMD, this study aimed to evaluate the effects of oculomotor therapy on the outcomes of perceived pain intensity, ocular convergence insufficiency, and range of mandibular movement. Considering the proposed interrelationship between the oculomotor system and TMD, this study aimed to

evaluate the effects of oculomotor therapy on the outcomes of perceived pain intensity, ocular convergence insufficiency, range of mandibular movement, and severity of TMD.

The hypothesis of the present study was to identify whether the addition of oculomotor treatment in patients with TMD interferes with the intensity of perceived pain, insufficiency of ocular convergence, range of mandibular movement, and severity of TMD.

2. METHODOLOGY

Design

This study is a randomized, double-blind clinical trial, following the recommendations of the Consolidated Standards of Reporting Trials (CONSORT), as shown in Figure 1 [BUTCHER et. al, 2022]. This protocol will follow the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [CHAN et. al, 2013].

Participants

The screening of individuals will be conducted using posters installed in corridors and at the reception of the university's school clinic, as well as publicity via social networks. The screening will continue until the target population is reached. The study participants will not participate in the design or objectives of this research.

Eligibility Criteria

Individuals aged between 18 and 45 years will be included; pain intensity greater than or equal to 3 in the Temporomandibular Joint (TMJ) or masticatory muscles; diagnosis of myogenic TMD; Moderate or severe TMD; and insufficiency of convergence. Individuals with persistent strabismus will be excluded; previous surgeries for strabismus; trauma or surgery in the cervical/craniofacial region; injuries to ocular innervation; neurological pathologies; systemic diseases; diagnosis of fibromyalgia; treatment for TMD in the last 3 months; recent oculomotor therapies for convergence insufficiency; continuous occlusal treatment; use of medications that affect accommodation or vergence; conditions that compromise ocular accommodation and motility, such as multiple sclerosis, diabetes, Graves' disease, myasthenia gravis; and confirmed pregnancy.

Randomization and blinding

A physical therapist will screen the participants to determine their eligibility. Participants will be stratified according to gender, severity, and pain into two groups: The experimental group (EG) and the Control group (CG), using the randomization.com program. A second researcher will be responsible for evaluating eligible participants. Participants will remain blinded to the treatment modality prescribed. A third researcher will be responsible for the treatment and will not know the evaluations. Unmasking will only be available to the researcher conducting the assessments after the last session.

The researcher responsible for evaluating the results will remain blind to the type of treatment assigned, aiming to minimize any detection bias inherent to the study. Likewise, the statistician responsible for analyzing the data will be unaware of the specificity of group allocation, ensuring an objective interpretation devoid of predispositions.

Intervention

EG will undergo the clinical protocol for TMD added to the oculomotor intervention. The GC will receive the clinical protocol for TMD. Both groups will receive individual care provided by a trained physiotherapist with 10 years of experience. The duration of the therapeutic protocol for both groups will be 12 sessions of 50 min per week. The number of sessions

may be at least 6, if the participant presents no pain, as assessed by the END. After each session, the Patient Global Impression Instrument [PGIS] will be applied to capture the subject's global perception of the therapy [HURST et. al, 2004; DOMINGUES et. al, 2011]. A reassessment will be performed after the 12th session, as well as after 3 and 6 months, by the same evaluator responsible for the initial measurement, considering the same clinical parameters obtained in the initial assessment. It is worth noting that patients will be instructed, from the moment they accept to participate, not to miss and be aware of the importance of their adherence to benefit science and future therapeutic protocols for TMD. If a group has a better result, patients in the opposite group will receive the best treatment after the study is completed.

Treatment Protocol for TMD: The proposed treatment is in accordance with the current guidelines for TMD [BUSSE et al., 2023]. Standardized techniques will be used, such as intra- and extraoral massages [DE MELO et. al, 2020; MIERNIK et. Al, 2012]; myofascial release of the masseter, temporalis, and sternocleidomastoid muscles [URBANSKI et. al, 2021]; release of cervical soft tissues [GHODRATI et. al, 2020]; cervical pumpage [SILVA et. al, 2022]; suboccipital inhibition and passive anteroposterior mobilization of the upper cervical [CALIXTRE et. al, 2019; [MAITLAND et. al, 2005][Figure 2]; cervical exercises [GHODRATI et. al, 2020] [Figure 3]; and exercises targeting the TMJ, including the opening exercise with the tongue on the palate and proprioceptive exercises [GHODRATI et. al, 2020; SHAFFER et. al, 2014; LINDFORS et. al, 2019][Figure 4].

Oculomotor Therapeutic Protocol: Oculomotor intervention will be guided and adapted on the basis of the CITT protocol to treat convergence insufficiency [CITT, 2008]. The modalities will be introduced progressively, from the least to the most complex degree, covering techniques such as Brock's Cord, Barrilles Chart , Lifeguard Chart, Eccentric Circles, and Eye Relaxation [Figure 5].

It is worth noting that in both therapeutic protocols, if the patient needs to be interrupted for any reason, it will be interrupted.

Primary outcome measures

Diagnostic Criteria for Research on Temporomandibular Disorders (CD/TMD): A biaxial instrument for diagnosing TMD. Axis I comprises demographic data, two questionnaires, and clinical examination. Axis II consists of pain drawing and eight other questionnaires. The diagnostic decision diagram offers nine diagnostic possibilities, with more than one diagnosis possible for each joint [AHMAD et. al, 2009]. Axis 1 physical examination will be conducted by a single examiner [physiotherapist] previously trained with 6 years of experience.

Numerical Pain Scale (END): This is an easy-to-apply scale, where the individual will be asked to respond, in a numerical sequence from 0 (o pain) to 10 (worst pain), how intense their pain is [FERRERA-VALENTE et.al, 2011].

Convergence Test (CT): This instrument will be used to diagnose IC and evaluate the balance of the extrinsic ocular muscles. The operator will move a digital caliper (150mm/6"), from Starrett[®] Ind. e Com. LTDA, toward the nose at eye level (Figure 6), allowing the estimation of the distance by which the two eyes diverge; less than 4.0 cm will be considered normal, 4.1–6.9 cm will be considered sufficient, and greater than or equal to 7 will be considered insufficient [CUCCIA et. al, 2008].

Convergence Insufficiency Symptom Questionnaire (CISS): Developed by the Convergence Insufficiency Treatment Trial, the CISS is a validated and reliable instrument composed of 15

items, which quantifies the frequency and type of symptoms related to convergence insufficiency or other binocular or accommodative disorders 6. It is classified from 0 to 10 points: normal binocular vision; 11 to 36 points: suspected IC, and 37 to 60 points: IC [TAVARES et. al, 2013].

Secondary outcome measures

Mandibular Function Impairment Questionnaire (MFIQ): This is a validated tool for the Portuguese language and is reliable for evaluating mandibular function in individuals with TMD [CAMPOS et. al, 2012]. It has two domains: functional capacity and nutrition. The higher the score, the greater the functional limitation.

Fonseca Anamnestic Index (IAF): This instrument classifies TMD according to severity [MIERNIK et al., 2012]. The sum of the points is classified as no TMD (0-15 points), mild TMD (20-40 points), moderate TMD [45-65 points], and severe TMD [70-100 points] [BEVILAQUA-GROSSI et. al, 2006].

Sample size

The sample size was calculated from a pilot study with eight individuals with TMD and CI, aged between 18 and 60 years, considering the mean and standard deviation of the pre- and post-intervention conditions for each clinical outcome [primary]. For the calculation, the values $\alpha = 0.05$ [5% chance of type I error] and $1-\beta = 0.95$ [% of sample power] were considered. The number of individuals was estimated for each outcome studied to compose the sample. The possibility of a sample loss of 20% was also considered and added to the estimated calculation (Table 1). Calculations were performed using G*Power software [FAUL et. al, 2007].

Statistical analysis

The normality of data related to outcome measures will be verified using the Shapiro-Wilk test. Participant characteristics will be verified using descriptive statistics (test *t* independent), and possible differences between groups will be tested using linear mixed models, considering the moments before, after 12 treatment sessions, after 3 months of treatment, and after 6 months of treatment. The differences between the groups [treatment effects] and their respective confidence intervals (95%CI) will be calculated through the construction of linear mixed models [TWISK et. al, 2003] using interaction terms of treatment groups versus time, with all models adjusted to initial estimates. If the data do not present a normal distribution, Friedman's ANOVA with Dunn's post hoc test will be used. The statistical significance considered will be $p < 0.05$.

Cohen *d* and the partial eta squared (η^2) will be used to calculate the effect size of the results [COHEN et. al, 1998], and the interpretation will be based on the values established by Cohen: low effect ($d=0.2$ and $\eta^2=0.01$); moderate effect (approximately $d=0.5$ and $\eta^2=0.06$); and large effect (from: $d=0.8$ and $\eta^2=0.14$).

For data analysis, a value of $p < 0.05$ will be considered. These analyses were performed using SPSS 20.0 software [SPSS Inc., Chicago, USA].

3. Results

The protocol of the present study is innovative because in a pilot study conducted in our laboratory, before the development of this protocol, we observed that patients who received treatment for TMD with the addition of oculomotor therapy benefited with results for the outcome pain, range of motion, and ocular convergence. To determine the success of the intervention protocol, a minimum clinically important difference (DMCI) will be considered,

i.e., a 30% decrease in pain intensity and an increase in range of motion between 3 and 9 mm [CALIXTE et. al, 2020]. In addition, there was a change in the severity of TMD. For the convergence test, values smaller than 4.0 cm will be considered normal, and 4.1–6.9 cm will be considered sufficient convergence [CUCCIA et. al, 2008].

4. DISCUSSION

The study protocol will be the first randomized, blind, and controlled clinical trial that describes a methodology to evaluate the additional effect of an oculomotor rehabilitation protocol on the treatment for TMD, which aims to evaluate the intensity of perceived pain, range of mandibular movement, ocular convergence insufficiency, and severity of TMD in individuals with TMD.

This study highlights the importance of therapeutic exercises and manual therapy, supported by existing evidence [DE MELO et al., 2020; BUSSE et al., 2023], to promote strength, coordination, mobility, and pain relief in the management of TMD. Furthermore, to the best of our knowledge, no previous study has investigated the additional effect of an oculomotor rehabilitation protocol on a rehabilitation program for TMD. We believe that this study will help to better understand whether eye exercises contribute to the chosen outcomes when compared before, after 12 sessions, and at follow-up.

In the clinical practice of physiotherapy, it is common to include global mandibular exercises and manual therapy for treating patients with TMD. However, the literature is inconsistent regarding the best therapeutic practices for HF in adults. A systematic review with meta-analysis showed the use of different therapeutic strategies to improve ocular convergence and its symptoms. The resources used were compared with those of other therapies and placebo.

This study suggests that accommodative vergence therapy with home reinforcement can significantly increase the chances of therapeutic success compared with placebo therapy [SCHEIMAN et. al, 2020].

However, the body of therapeutic evidence becomes limited when we combine CI in patients with TMD. To date, no studies have shown the effect of oculomotor interventions in improving the symptoms of this dysfunction and CI in this population. There is a possibility of a connection between the oculomotor system and the stomatognathic system [DOS SANTOS et. al, 2021; MONACO et. al, 2003; MONACO et. al, 2004; PORTER, 1986; WANG et. al, 2008; NYBERG et. al, 1984], as well as significant relationships between HF and TMD [DOS SANTOS et. al, 2021; MONACO et. al, 2003], this protocol can add evidence to clinical practice. However, as TMD is multifactorial, the need for multimodal approaches to managing symptoms has been shown to be effective in reducing pain intensity and improving muscle function [LÓPEZ-DE-URALDE-VILLANUEVA et. al, 2020], justifying the use of oculomotor therapy added to other interventions already used to treat TMD in this protocol.

The lack of standardization in interventions for this population makes it important to develop targeted studies to identify effective therapeutic approaches [LÓPEZ-DE-URALDE-VILLANUEVA et. al, 2020; VALESAN et. al, 2021; MELIS et. al, 2022]. In summary, this study seeks to fill gaps in the scientific literature by providing useful findings to optimize the treatment of individuals with TMD and IC through a multimodal approach, which can help physiotherapists and patients select the most appropriate treatments for convergence insufficiency in patients who present with this dysfunction and TMD.

5. CONCLUSION

This study will evaluate whether the addition of oculomotor exercises decreases perceived pain intensity and improves mandibular range of motion and ocular convergence and its symptoms (headache, discomfort, drowsiness and diplopia, eye fatigue, blurred vision, difficulty concentrating, tearing, orbital discomfort, among others) in patients with TMD who have CI. This protocol seeks to determine whether the addition of oculomotor exercises can guarantee the success of rehabilitation and thus be included in therapeutic planning for patients with TMD.

Limitations: The strengths of this study include the combination of exercises that are easy to perform for eligible patients. However, this study has some limitations, such as loss of participants during the study and follow-up, in addition to possible biases or challenges in blinding.

Future Research: This protocol may contribute to new research possibilities, including oculomotor exercises combined with other therapeutic techniques and isolation in patients with TMD and headaches. Opening a new field of investigation. The approach can also be integrated into clinical practice as a complement to conventional TMD therapy, expanding the therapeutic options available to healthcare professionals and patients.

Ethical Approval and Consent :

This protocol follows specific research guidelines for human subjects and was approved by the University's Research Ethics Committee (CAAE: 56799322.9.0000.5511; document number: 5.453.957). Individuals who agree to participate in the research will sign the written Consent Form. The protocol will be developed and registered at ClinicalTrials.gov (NCT05761106) This study will be carried out at the University's Musculoskeletal Research Center (NUPEM).

Disclaimer (Artificial intelligence)

Author(s) hereby declares that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of manuscripts.

REFERENCES

- [1] Ahmad M, Hollender L, Anderson Q, Kartha K, Ohrbach R, Truelove EL, John MT, Schiffman EL. Research diagnostic criteria for temporomandibular disorders (RDC/TMD): development of image analysis criteria and examiner reliability for image analysis. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* . 2009 Jun; 107(6):844-60. doi 10.1016/j.tripleo.2009.02.023. PMID: 19464658; PMCID: PMC3139469.
- [2] Aletaha M, Daneshvar F, Mosallaei M, Bagheri A, Khalili MR. Comparison of Three Vision Therapy Approaches for Convergence Insufficiency. *J Ophthalmic Vis Res* 2018 Jul-Sep;13(3):307-314. doi : 10.4103/jovr.jovr_99_17. PMID: 30090188; PMCID: PMC6058546.
- [3] Alvarez TL, Vicci VR, Alkan Y, Kim EH, Gohel S, Barrett AM, et al. Vision therapy in adults with convergence insufficiency: clinical and functional magnetic resonance imaging measures. *Optom Vis Sci* . 2010 Dec;87(12): E985-1002. doi : 10.1097/OPX.0b013e3181fef1aa. PMID: 21057347; PMCID: PMC3134155.

- [4] Armijo-Olivo S, Pitance L, Singh V, Neto F, Thie N, Michelotti A. Effectiveness of Manual Therapy and Therapeutic Exercise for Temporomandibular Disorders: Systematic Review and Meta-Analysis. *Phys Ther* . 2016 Jan; 96(1):9-25. doi : 10.2522/ptj.20140548. Epub 2015 Aug 20. PMID: 26294683; PMCID: PMC4706597.
- [5] Bade A, Boas M, Gallaway M, Mitchell GL, Scheiman M, Kulp MT, Cotter SA, Rouse M; CITT Study Group. Relationship between clinical signs and symptoms of convergence insufficiency. *Optom Vis Sci*. 2013 Sep;90(9):988-95. doi : 10.1097/OPX.000000000000012. PMID: 23958713; PMCID: PMC3929100.
- [6] Bastos A. Assessment and types of intervention in Convergence Insufficiency: a systematic review. 2018.
- [7] Bevilaqua-Grossi D, Chaves TC, de Oliveira AS, Monteiro-Pedro V. Anamnestic index severity and signs and symptoms of TMD. *Skull*. 2006 Apr;24(2):112-8. doi : 10.1179/crn.2006.018. PMID: 16711273. , 2006.
- [8] Busse JW, Casassus R, Carrasco-Labra A, Durham J, Mock D, Zakrzewska JM, Palmer C, Samer CF, Coen M, Guevremont B, Hoppe T, Guyatt GH, Crandon HN, Yao L, Sadeghirad B, Vandvik PO, Siemieniuk RAC, Lytvyn L, Hunskar BS, Agoritsas T. Management of chronic pain associated with temporomandibular disorders: a clinical practice guideline. *BMJ*. 2023 Dec 15;383:e076227. doi : 10.1136/bmj-2023-076227. PMID: 38101929.
- [9] Butcher NJ, Monsour A, Mew EJ, Chan AW, Moher D, Mayo-Wilson E, Terwee CB, Chee-A-Tow A, Baba A, Gavin F, Grimshaw JM, Kelly LE, Saeed L, Thabane L , Askie L, Smith M, Farid-Kapadia M, Williamson PR, Szatmari P, Tugwell P, Golub RM, Monga S, Vohra S, Marlin S, Ungar WJ, Offringa M. Guidelines for Reporting Outcomes in Trial Reports: The CONSORT- Outcomes 2022 Extension. *JAMA*. 2022 Dec 13;328(22):2252-2264. doi : 10.1001/jama.2022.21022. PMID: 36511921.
- [10] Calixtre LB, Oliveira AB, Albuquerque-Sendín F, Armijo-Olivo S. What is the minimal important difference of pain intensity, mandibular function, and headache impact in patients with temporomandibular disorders? Clinical significance analysis of a randomized controlled trial. *Musculoskelet Sci Pract* . 2020 Apr;46:102108 . doi : 10.1016/j.msksp.2020.102108. Epub 2020 Jan 11. PMID: 31999615.
- [11] Calixtre LB, Oliveira AB, de Sena Rosa LR, Armijo-Olivo S, Visscher CM, Albuquerque-Sendín F. Effectiveness of mobilization of the upper cervical region and craniocervical flexor training on orofacial pain, mandibular function and headache in women with TMD. A randomized, controlled trial. *J Oral Rehabil* . 2019 Feb; 46(2):109-119. doi: 10.1111/joor.12733. Epub 2018 Oct 26. PMID: 30307636.
- [12] Campos JA, Carrascosa AC, Maroco J. Validity and reliability of the Portuguese version of Mandibular Function Impairment Questionnaire. *J Oral Rehabil* . 2012 May; 39(5):377-83. doi : 10.1111/j.1365-2842.2011. 02276.x. Epub 2012 Jan 17. PMID: 22251134. Pereira LJ, Steenks MH, de Wijer A, Speksnijder CM, van der Bilt A. Masticatory function in subacute TMD patients before and after treatment. *J Oral Rehabil* . 2009 Jun; 36(6):391-402. doi : 10.1111/j.1365-2842.2008. 01920.x. Epub 2009 Feb 6. PMID: 19210681.
- [13] Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin JA, Doré CJ, Parulekar WR, Summerskill WS, Groves T, Schulz KF, Sox HC, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 statement:

defining standard protocol items for clinical trials. *Ann Intern Med.* 2013 Feb 5; 158(3):200-7. doi: 10.7326/0003-4819-158-3-201302050-00583. PMID: 23295957; PMCID: PMC5114123.

[14] Cohen J. *Statistical Power Analysis for the Behavioral Sciences*, 2 edition. Routledge, Hillsdale, NJ, 1998.

[15] Convergence Insufficiency Treatment Trial (CITT) Study Group. The convergence insufficiency treatment trial: design, methods, and baseline data. *Ophthalmic Epidemiol.* 2008 Jan-Feb; 15(1):24-36. doi : 10.1080/09286580701772037. PMID: 18300086; PMCID: PMC2782898.

[16] Cooper J, Jamal N. Convergence insufficiency-a major review. *Optometry.* 2012 Apr 30;83(4):137-58. PMID: 23231437.

[17] Cuccia AM, Caradonna C. Binocular motility system and temporomandibular joint internal derangement: a study in adults. *Am J Orthod Dentofacial Orthop .* 2008 May;133(5):640.e 15-20. doi : 10.1016/j.ajodo.2007.10.034. PMID: 18456134.

[18] Dahan H, Shir Y, Velly A, Allison P. Specific and number of comorbidities are associated with increased levels of temporomandibular pain intensity and duration. *J Headache Pain.* 2015;16:528 . doi : 10.1186/s10194-015-0528-2. Epub 2015 May 20. PMID: 26002637; PMCID: PMC4441879.

[19] Daum KM. Convergence insufficiency. *Am J Optom Physiol Opt.* 1984 Jan;61(1):16-22. doi : 10.1097/00006324-198401000-00003. PMID: 6702996.

[20] de Melo LA, Bezerra de Medeiros AK, Campos MFTP, Bastos Machado de Resende CM, Barbosa GAS, de Almeida EO. Manual Therapy in the Treatment of Myofascial Pain Related to Temporomandibular Disorders: A Systematic Review. *J Oral Facial Pain Headache.* 2020 Spring. 34(2):141-148. doi : 10.11607/ofph.2530. PMID: 32255579.

[21] Domingues L, Cruz E. Cultural Adaptation and Contribution to the Validation of the Patient Global Impression Scale of Change. *Escola Sup de Saúde do Inst Politécnico de Setúbal ,* 2011.2(1):31-37.

[22] Dos Santos DM, Politti F, de Azevedo LMA, de Cassia das Neves Martins R, Ricci FC, Masuda KSY, et al. Association between convergence insufficiency and temporomandibular disorder cross-sectional study. *Clin Oral Investig .* 2021 Mar;25(3):851-858. doi : 10.1007/s00784-020-03372-8. Epub 2020 Jun 4. PMID: 32500402.

[23] Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods.* 2007 May; 39(2):175-91. doi : 10.3758/bf03193146. PMID: 17695343.

[24] Fernández-de- las -Penas C, Svensson P. Myofascial Temporomandibular Disorder . *Curr Rheumatol Rev.* 2016;12(1):40-54. doi : 10.2174/1573397112666151231110947. PMID: 26717949.

[25] Ferreira-Valente MA, Pais-Ribeiro JL, Jensen MP. Validity of four pain intensity rating scales. *Pain.* 2011 Oct; 152(10):2399-2404. doi : 10.1016/j.pain.2011.07.005. PMID: 21856077.

- [26] Ferrillo M, Ammendolia A, Paduano S, et al. Efficacy of rehabilitation on reducing pain in muscle-related temporomandibular disorders: A systematic review and meta-analysis of randomized controlled trials. *J Back Musculoskelet Rehabil* . 2022;35(5):921-936. doi : 10.3233/BMR-210236. PMID: 35213347.
- [27] Ghodrati M, Mosallanezhad Z, Shati M. Adding Temporomandibular joint treatments to routine physiotherapy for patients with non-specific chronic neck pain: A randomized clinical study. *J Bodyw Mov Ther* . 2020 Apr; 24(2):202-212. doi : 10.1016/j.jbmt.2019.11.004. Epub 2019 Nov 22. PMID: 32507146.
- [28] Gonçalves DA, Dal Fabbro AL, Campos JA, Bigal ME, Speciali JG. Symptoms of temporomandibular disorders in the population: an epidemiological study. *J Orofac Pain*. 2010 Summer;24(3):270-8. PMID: 20664828.
- [29] Herrera-Valencia A, Ruiz-Muñoz M, Martín-Martín J, Cuesta-Vargas A, González-Sánchez M. Efficacy of Manual Therapy in Temporomandibular Joint Disorders and Its Medium- and Long-term Effects on Pain and Maximum Mouth Opening: A Systematic Review and Meta-Analysis. *J Clin Med* 2020 Oct 23;9(11):3404. doi : 10.3390/jcm9113404. PMID: 33114236; PMCID: PMC7690916.
- [30] Hurst H, Bolton J. Assessing the clinical significance of change scores recorded on subjective outcome measures. *J Manipulative Physiol Ther* ., 2004 Jan; 27(1):26-35. doi : 10.1016/j.jmpt.2003.11.003. PMID: 14739871.
- [31] Kalladka M, Young A, Khan J. Myofascial pain in temporomandibular disorders: Updates on etiopathogenesis and management. *J Bodyw Mov Ther* ., 2021 Oct; 28:104 -113. doi : 10.1016/j.jbmt.2021.07.015. Epub 2021 Aug 8. PMID: 34776126.
- [32] Lindfors E, Arima T, Baad -Hansen L. Jaw Exercises in the Treatment of Temporomandibular Disorders-An International Modified Delphi Study. *J Oral Facial Pain Headache*. 2019 Fall; 33(4):389–398. doi : 10.11607/ofph.2359. Epub 2019 Jun 24. PMID: 31247061.
- [33] López-de- Uralde -Villanueva I, Beltran- Alacreu H, Fernández- Carnero J, La Touche R. Pain management using a multimodal physiotherapy program including a biobehavioral approach for chronic nonspecific neck pain: a randomized controlled trial. *Physiother Theory Practice*. 2020; 36:45 –62. <https://doi.org/10.1080/09593985.2018.1480678>
- [34] Maitland G, Hengeveld E, et al. *Maitland's Vertebral Manipulation*. 7th Edition. 2005.
- [35] Manfredini D, Guarda-Nardini L, Winocur E, Piccotti F, Ahlberg J, Lobbezoo F. Research diagnostic criteria for temporomandibular disorders: a systematic review of axis I epidemiological findings. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* . 2011 Oct;112(4):453-62. doi : 10.1016/j.tripleo.2011.04.021. Epub 2011 Aug 11. PMID: 21835653.
- [36] Melis M, Di Giosia M, Zawawi KH. Oral myofunctional therapy for the treatment of temporomandibular disorders: A systematic review. *Skull*. 2022 Jan; 40(1):41-47. doi : 10.1080/08869634.2019.1668996. Epub 2019 Sep 17. PMID: 31530110.
- [37] Miernik M, Wieckiewicz M, Paradowska A, Wieckiewicz W. Massage therapy in myofascial TMD pain management. *Adv Clin Exp Med*. 2012 Sep-Oct;21(5):681-5. PMID: 23356206.

- [38] Monaco A, Streni O, Marci MC, Sabetti L, Giannoni M. Convergence defects in patients with temporomandibular disorders. *Skull*. 2003 Jul; 21(3):190-5. doi : 10.1080/08869634.2003.11746250. PMID: 12889675.
- [39] Monaco A, Streni O, Marci MC, Sabetti L, Marzo G, Giannoni M. Relationship between mandibular deviation and ocular convergence. *J Clin Pediatr Dent*. 2004 Winter;28(2):135-8. doi : 10.17796/jcpd.28.2.mj 731103m257134. PMID: 14969372.
- [40] Morquette P, Lavoie R, Fhima MD, Lamoureux X, Verdier D, Kolta A. Generation of the masticatory central pattern and its modulation by sensory feedback. *Program Neurobiol* . 2012 Mar;96(3):340-55. It hurts 10.1016/j.pneurobio.2012.01.011. Epub 2012 Feb 9. PMID: 22342735.
- [41] Nyberg G, Blomqvist A. The central projection of muscle afferent fibers to the lower medulla and upper spinal cord: an anatomical study in the cat with the transganglionic transport method. *J Comp Neurol*. 1984 Nov 20;230(1):99-109. doi : 10.1002/cne.902300109. PMID: 6096417.
- [42] Okeson JP. *Management of Temporomandibular Disorders and Occlusion*, Missouri Elsevier Mosby, St. Louis, MI, USA, 7th; edition, 2012.
- [43] Park JW, Clark GT, Kim YK, Chung JW. Analysis of thermal pain sensitivity and psychological profiles in different subgroups of TMD patients. *Int J Oral Maxillofac Surg*. 2010 Oct;39(10):968-74. doi : 10.1016/j.ijom.2010.06.003. Epub 2010 Jul 6. PMID: 20609564.
- [44] Pickwell LD, Hampshire R. The significance of inadequate convergence. *Ophthalmic Physiol Opt* . 1981;1(1):13-8. PMID: 7339524.
- [45] Porcar E, Martinez-Palomera A. Prevalence of general binocular dysfunctions in a population of university students. *Optom Vis Sci* . 1997 Feb;74(2):111-3. doi : 10.1097/00006324-199702000-00023. PMID: 9097328.
- [46] Renner -Sitar K, John MT, Bandyopadhyay D, Howell MJ, Schiffman EL. Exploration of dimensionality and psychometric properties of the Pittsburgh Sleep Quality Index in cases with temporomandibular disorders. *Health Qual Life Outcomes*. 2014 Jan 21;12:10 . doi : 10.1186/1477-7525-12-10. PMID: 24443942; PMCID: PMC3902412.
- [47] Scheiman M, Kulp MT, Cotter SA, Lawrenson JG, Wang L, Li T. Interventions for convergence insufficiency: a network meta-analysis. *Cochrane Database Syst Rev*. 2020 Dec 2;12(12):CD006768. doi : 10.1002/14651858.CD006768.pub3. PMID: 33263359; PMCID: PMC8092638.
- [48] Scheiman M, Mitchell GL, Cotter S, Kulp MT, Cooper J, Rouse M. A randomized clinical trial of vision therapy/orthoptics versus pencil pushups for the treatment of convergence insufficiency in young adults. *Optom Vis Sci.*, 2005 Jul;82(7):583-95. doi : 10.1097/01.opx.0000171331.36871.2f. PMID: 16044063.
- [49] Scheiman M, Wick B. *Clinical Management of Binocular Vision: Heterophoric , Accommodative, and Eye Movement Disorders*. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2008.

[50] Silva M, Bustamante B. Physiotherapeutic approaches in cervicocraniomandibular disorders. Publishing company Total , 2022.

[51] Shaffer SM, Brismée JM, Sizer PS, Courtney CA. Temporomandibular disorders. Part 2: conservative management. *J Man Manip The R* . 2014 Feb; 22(1):13-23. doi : 10.1179/2042618613Y.0000000061. PMID: 24976744; PMCID: PMC4062348.

[52] Tavares C, Nunes AM, Nunes AJ, Pato MV, Monteiro PM. Translation and validation of Convergence Insufficiency Symptom Survey (CISS) to Portuguese - psychometric results. *Arq Bras Oftalmol* . 2014 Jan-Feb; 77(1):21-4. doi : 10.5935/0004-2749.20140007. PMID: 25076368.

[53] Twisk , Jos WR Applied Longitudinal Data Analysis for Epidemiology: a practical guide. Cambridge, USA: Cambridge University Press, 2003.

[54] Urbański P, Trybulec B, Pihut M. The Application of Manual Techniques in Masticatory Muscles Relaxation as Adjunctive Therapy in the Treatment of Temporomandibular Joint Disorders. *Int J Environ Res Public Health*. 2021 Dec 8; 18(24):12970. doi : 10.3390/ijerph182412970. PMID: 34948580; PMCID: PMC8700844.

[55] Valesan LF, Da-Cas CD, Defendants JC, Denardin ACS, Garanhani RR, Bonotto D, Januzzi E, de Souza BDM. Prevalence of temporomandibular joint disorders: a systematic review and meta-analysis. *Clin Oral Investig* . 2021 Feb; 25(2):441-453. doi : 10.1007/s00784-020-03710-w. Epub 2021 Jan 6. PMID: 33409693.

[56] Wang N, May PJ. Peripheral muscle targets and central projections of the mesencephalic trigeminal nucleus in macaque monkeys. *Anat Rec (Hoboken)*. 2008 Aug;291(8):974-87. doi : 10.1002/ar.20712. PMID: 18461596; PMCID: PMC2859174.

[57] Widmer DE, Oechslin TS, Limbachia C, Kulp MT, Toole AJ, Kashou NH, et al. Post-therapy Functional Magnetic Resonance Imaging in Adults with Symptomatic Convergence Insufficiency. *Optom Vis Sci*. 2018 Jun; 95(6):505-514. doi : 10.1097/OPX.0000000000001221. PMID: 29787484.

58 Oliveira SS, Pannuti CM, Paranhos KS, Tanganeli JP, Laganá DC, Sesma N, Duarte M, Frigerio ML, Cho SC. Effect of occlusal splint and therapeutic exercises on postural balance of patients with signs and symptoms of temporomandibular disorder. *Clinical and experimental dental research*. 2019 Apr;5(2):109-15.

59Raja G P, Bhat N S, Fernández-de-las-Peñas C, Gangavelli R, Davis F, Shankar R, Prabhu A. Effectiveness of deep cervical fascial manipulation and yoga postures on pain, function, and oculomotor control in patients with mechanical neck pain: study protocol of a pragmatic, parallel-group, randomized, controlled trial. *Trials*. 2021 Aug 28;22(1):574.

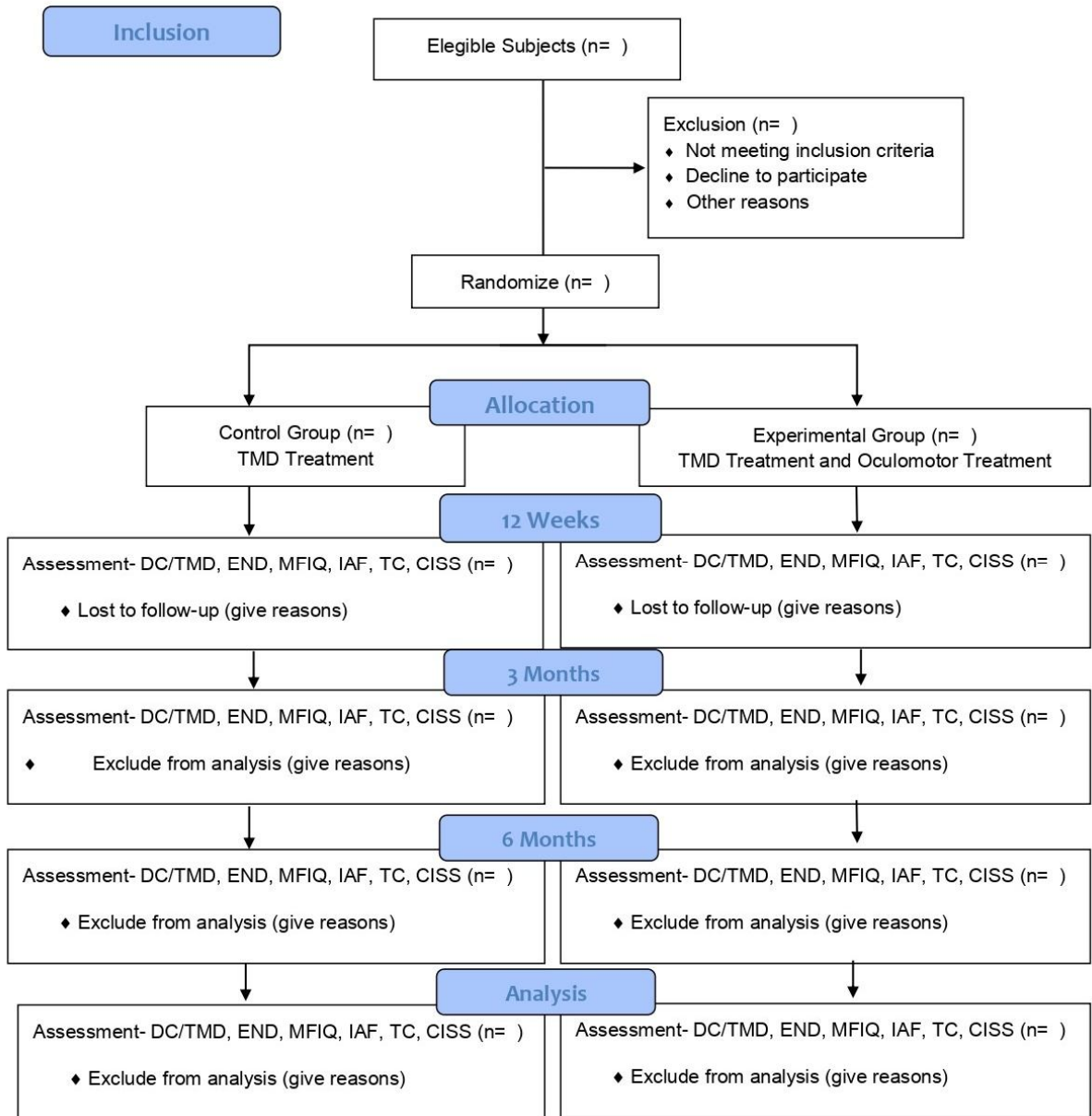


Figure 1: Study design flowchart according to CONSORT.



Figure 2: [a] Extraoral massage on the masticatory muscles; [b] Intraoral massage on the masticatory muscles; [c] Myofascial Release Massage: [c1] Masseter; [c2] Sternocleidomastoid; [c 3] Temporals ; [d1] Cervical Pumpage ; [d1] Suboccipital Inhibition; [d2] Passive Anteroposterior Mobilization of the Upper Cervical.



Figure 3: Cervical Exercises: [a] Flexion; [b] Extension; [c] Left Rotation; [d] Right Rotation; [e] Right lateral inclination; [f] Left lateral tilt



Figure 4: Exercises for the TMJ: [a] Opening the mouth with the tongue on the palate; [b] Right Lateralization; [c] Left Lateralization; [d] Protrusion.

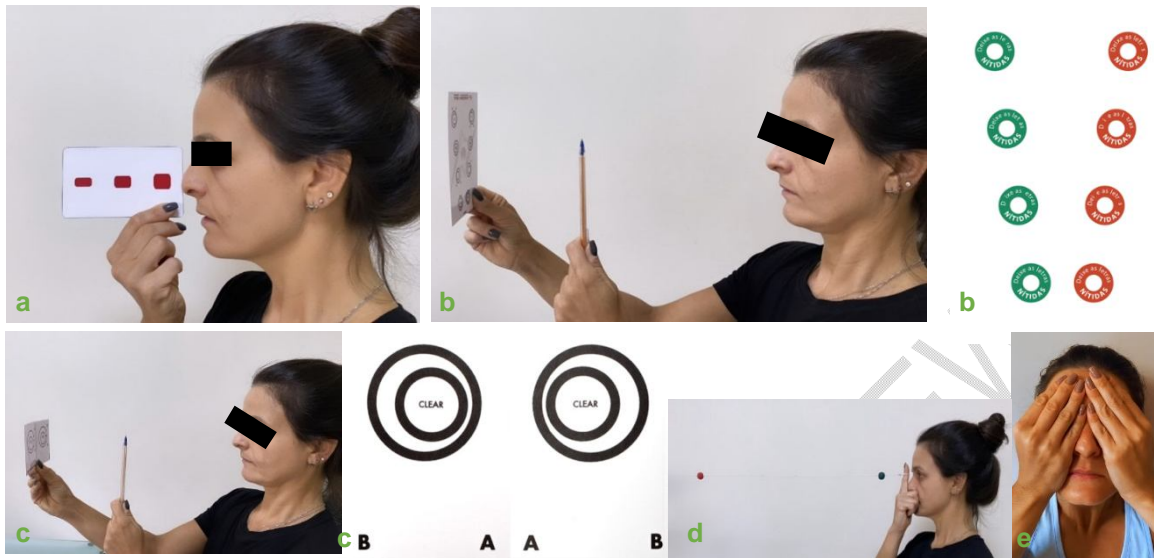


Figure 5: [a] Barrile Chart; [b] Life Saving Letter; [c] Eccentric Circles; [d] Brock cord [e] Eye relaxation.

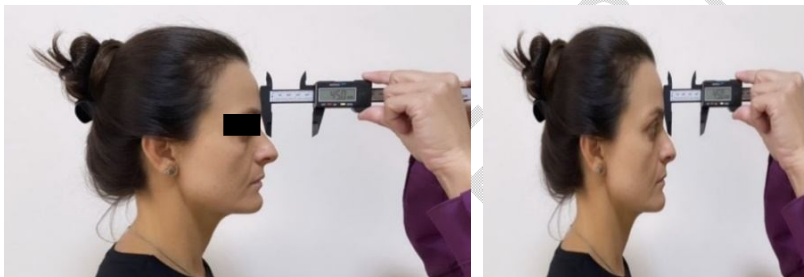


Figure 6: Convergence Test

Table 1. Sample for each clinical outcome, with a 20% increase

PRIMARY OUTCOME	Sample	20%
Pain Intensity	09	11

Ocular Convergence	25	30
Symptoms of Ocular Convergence	42	50

UNDER PEER REVIEW