



# Mandibular Mobilization in Individuals with Anterior Disc Displacement with Magnetic Resonance Imaging Assessment: A Study Protocol

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## **Authors' contributions**

*This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.*

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**Study Protocol**

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## ABSTRACT

**Objective:** To assess the influence of mandibular mobilization on the positioning of the articular disc using magnetic resonance imaging (MRI) in participants with anterior disc displacement, with and without reduction, immediately after treatment, and at 3 and 6 months post-treatment.

**Study Design:** Controlled, randomized clinical trial with blinded evaluators and participants.

**Methodology:** Individuals aged 18-45 years with an MRI-confirmed diagnosis of anterior disc displacement.

**Intervention:** Two groups: GA (intervention) and GB (placebo), each receiving 12 treatment sessions.

**Main Outcome Measures:** Disc positioning assessed by MRI before and after the final session, as well as at 3- and 6-month follow-ups.

**Analysis:** Statistical analysis will be conducted using linear mixed models, based on an-intention-to-treat approach. The significance level will be set at 5%.

**Results:** The intervention will be considered successful if there is a 30% improvement in MRI parameters between pre- and post-treatment measurements, along with clinical improvement in mandibular movement.

*Keywords:* Temporomandibular joint disorders; anterior disc displacement; magnetic resonance imaging; musculoskeletal manipulations.

## 1. INTRODUCTION

Temporomandibular disorder (TMD) involves changes that affect the temporomandibular joint (TMJ), masticatory muscles, and structures related to the head and neck. TMD, which has a multifactorial etiology, can be of joint, muscular, or mixed origin, and is associated with pain, jaw dysfunction, and structural changes [1,2,3,4].

Joint-related TMD refers to intra-articular disorders, including disc displacements. Anterior disc displacement describes an abnormal geometric relationship between three TMJ components (i.e., temporal bone, disc, and condyle). Anterior disc displacement with reduction (DDWR) occurs when the disc is positioned anteriorly when the mouth is closed, but is recaptured into a posterior position upon mouth opening. DDWR is the most prevalent form of internal TMJ derangement, affecting 41% of the population worldwide, with 33% being asymptomatic [5].

The literature points to anatomical, biomechanical factors, and parafunctional habits as possible etiologies [2,6]. Disc displacement without reduction (DDwoR) refers to the constant anterior position of the disc, which limits mandibular function and may present the final stage of condyle-disc dysfunction after episodes of joint noises [7,8].

Disc position is diagnosed through clinical evaluations (Diagnostic Criteria for TMD –

DC/TMD) and imaging exams, with magnetic resonance imaging (MRI) being the gold standard for identifying disc position, with high specificities (88-90%) and sensitivities (78-83.3%) [2,9]. However, treating anterior disc positioning is challenging, and raising patient awareness of their condition, as well as advising them to avoid aggravating activities, is often recommended [5]. While no standard treatment exists, conservative approaches such as manual therapy, photobiomodulation, intraoral medications, and devices are typically prioritized.

Manual therapy is a common physiotherapeutic treatment that involves manual techniques aimed at reducing pain, increasing mobility, improving the function of soft tissues and joints, and restoring muscular and skeletal balance. One commonly used conservative treatment is mandibular mobilization (MM), which involves passive, oscillatory movements designed to restore artrokinematics — the rotation, rolling, and sliding movements between articular surfaces. The joint mobilization technique proposed by Maitland [10] is based on a system that utilizes small, passive, rhythmic, and oscillatory movements, graded into four levels based on the amplitude of accessory joint movements. This technique aims not only to restore function but also to alleviate symptoms of temporomandibular dysfunction [5,11].

Invasive procedures such as TMJ arthrocentesis, arthroscopies, and surgery

should only be considered if conservative interventions fail, due to the associated risks [12]. The primary goal of treatment is to improve mandibular function and remodel the soft tissues of the joint [7,8].

Despite the extensive literature on the use of MRI for evaluating internal TMJ disorders [13,14] and treatments [15,16,17,18,19,20,21], there is a gap regarding the evaluation of imaging findings after physiotherapeutic interventions. Therefore, the present study aims to evaluate the influence of mandibular mobilization on the positioning of the articular disc, using MRI in individuals with anterior disc displacement. The study hypothesizes that joint mobilization influences the position of the anteriorly displaced joint disc.

## 2. METHODOLOGY

**Design:** This study is a randomized, double-blind clinical trial, following the guidelines of the Consolidated Standards of Reporting Trials (CONSORT), as illustrated in Fig. 1 [22]. The protocol also adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [23].

**Participants:** Study participants were not involved in the development of the research design or objectives. The design and goals of this project were established by the research team and subsequently reviewed by ad hoc advisors from the entity funding the MRI exams.

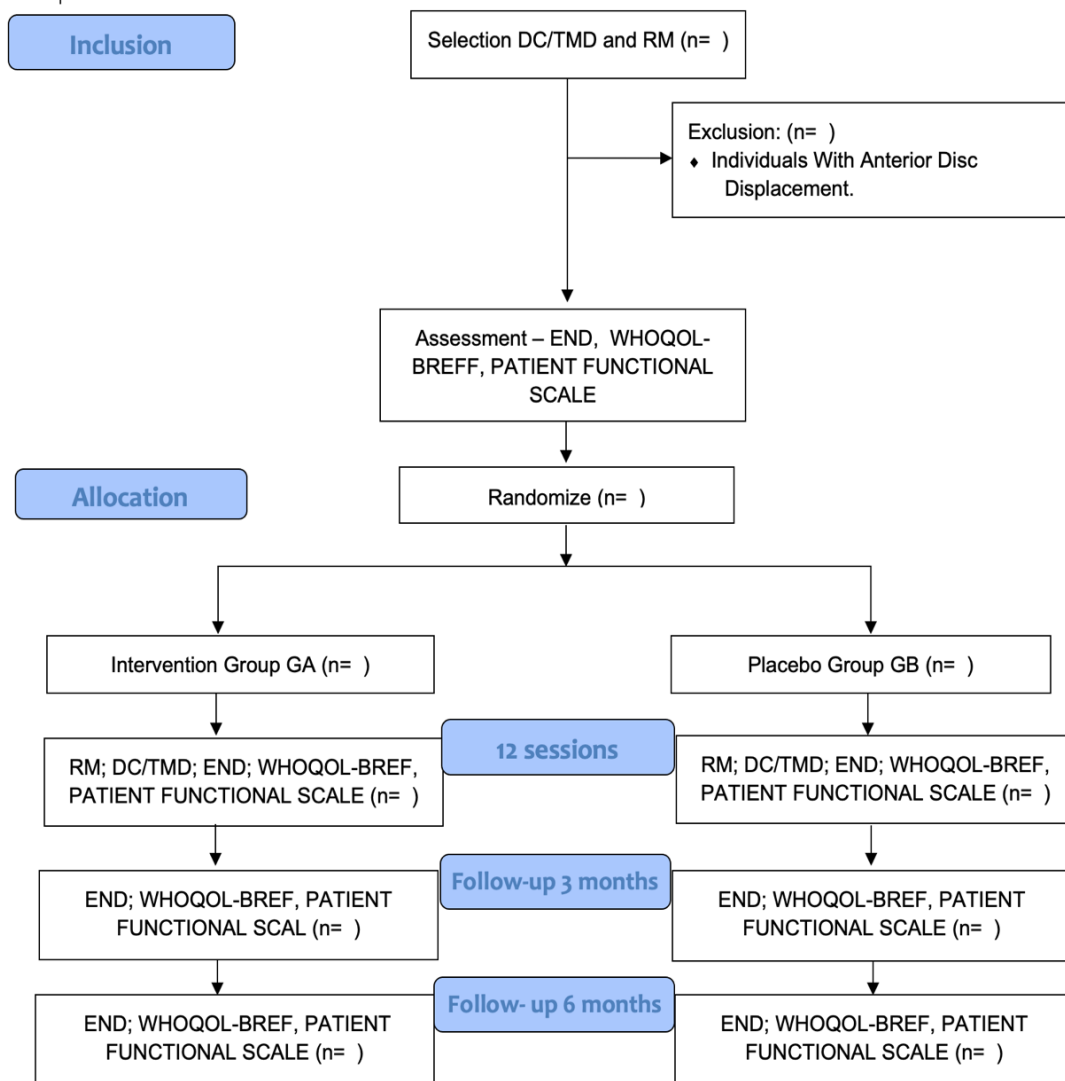


Fig. 1. Study design flowchart according to CONSORT

**Eligibility criteria:** Individuals aged between 18 and 45 years, of both genders, diagnosed with anterior disc displacement with or without reduction, will be included. Exclusion criteria include individuals with exclusively muscular TMD; those with systemic diseases affecting the joints and/or masticatory muscles; neuromuscular diseases; condylar hypo/hyperplasia; use of any type of dental prosthesis; those undergoing orthodontic and/or physiotherapeutic treatment; absence of dental elements except for third molars; neurological or behavioral disorders that prevent undergoing MRI and/or with a history of previous temporomandibular joint surgery. Participants will be instructed not to use pharmacological analgesics during the study but will be encouraged to report any use if unavoidable.

**Randomization and blinding:** After participants sign the informed consent, a physical therapist will assess their eligibility. Participants will then be randomized into two groups: Group A (intervention) and Group B (placebo), using the randomization.com program. Three physical therapists will be involved in the protocol. One will be responsible for pre- and post-intervention assessments and will be blinded to the type of intervention. The second physical therapist will administer the intervention to Group A (GA) and will be blinded to the assessments. The third physical therapist will administer the placebo

intervention to Group B (GB) and will also be blinded to the evaluations. A radiology technician will perform the MRI examinations, a laboratory radiologist will provide the reports, and three dentists specialized in radiology will analyze the disc positioning before and after the intervention, all of whom will be blinded to the type of intervention received by the participants. A tenth collaborator will process and analyze the collected data, remaining blinded to the type of intervention received by the participants.

**Intervention:** Group A (GA): With the participant in a supine position on the stretcher, non-specific mandibular mobilization will be performed by an experienced and previously trained therapist wearing disposable gloves. The therapist will position their thumb on the participant's last molar, the participant will lightly press the therapist's thumb with both the upper and lower dental arches during Grade III mobilization. Five repetitions of 1 minute each will be performed [10]. Between repetitions, the participant will perform mouth-opening exercises fifteen times with their tongue positioned on the incisive papilla [24]. The mandible will be mobilized bilaterally. The therapist will stand on the opposite side of the mandibular mobilization, performing millimeter oscillatory movements. The treatment will last 6 weeks, with two sessions per week, for a total of 12 sessions.

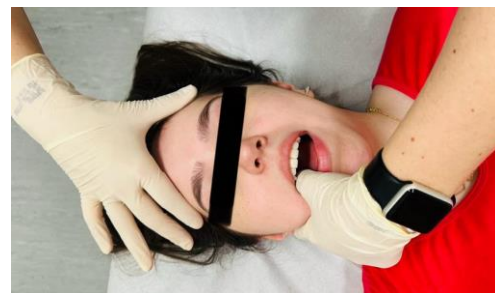
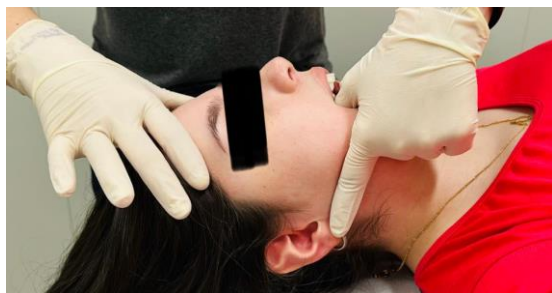


Fig. 2. Nonspecific mandibular mobilization technique



Fig. 3. Mouth opening exercise with tongue on the incisive papilla

Group B (GB): The positioning for both the therapist and the patient will be identical to that of Group A. However, no mobilization will be performed. The therapist will place their thumb on the patient's last molar and will slightly flex and extend the interphalangeal joint for 1 minute, without generating any movements in the TMJ. Five repetitions will be performed. The treatment duration will be the same as for GA.

**Treatment Protocol for TMD:** Physiotherapy is considered a conservative and effective approach for treating temporomandibular disorders (TMDs), with significant efficacy in reducing symptoms, along with lower costs and risks for patients [25,26,27]. Through interventions such as therapeutic exercises and manual therapy, physiotherapy can manage symptoms and improve function in patients with TMD [27,28,29]. TMJ mobilization is often combined with other interventions. However, evidence on the immediate effects of TMJ mobilization is limited, and support for its use remains inconclusive [30,31]. Therefore, evaluating the effects of a single technique can help minimize bias from other factors influencing the outcomes being studied.

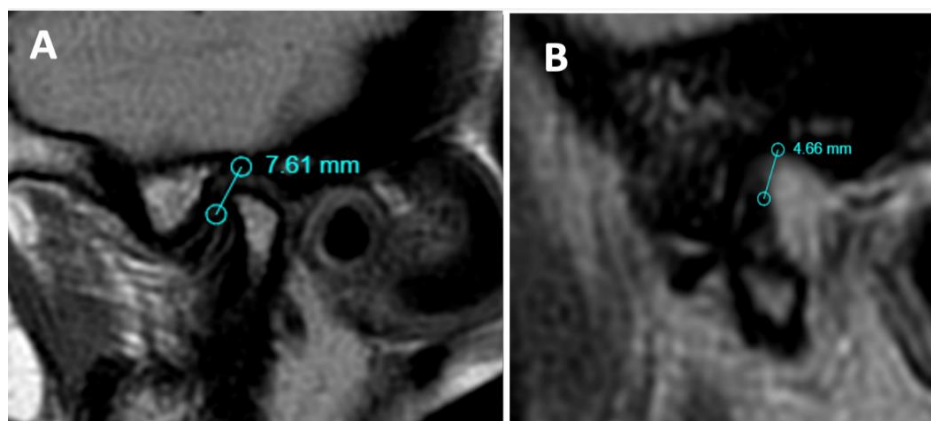
**Primary outcome measures:** Diagnostic Criteria for Temporomandibular Dysfunction (DC/TMD): This is a biaxial diagnostic instrument. Axis I consists of two questionnaires, demographic data collection, and a clinical examination, which includes palpation of structures, measurement of mandibular range of motion, and assessment for joint noises, among others. Axis II comprises a pain drawing tool and eight questionnaires, each with its own interpretation. The diagnostic decision diagram provides nine diagnostic possibilities, with the

potential for multiple diagnoses for each joint. Imaging examinations are required to confirm diagnoses of intra-articular and degenerative joint disorders [32].

**Magnetic Resonance Imaging (MRI):** The magnetic resonance machine to be used will be the Philips Multiva, 1.5 tesla, manufactured in 2019. The distance between the chin and the sternal notch will be measured in the first examination and maintained in the final examination to ensure consistent conditions (pre- and post-intervention).

TMJ image acquisition will occur in two positions: 1) mouth closed, with the tongue resting on the incisive papilla and without tooth contact, and 2) mouth open, at 80% of the maximum opening (submaximal), previously measured. During the open-mouth examination, overlapping toothpicks will be placed between the right and left premolars to maintain the submaximal opening. Images will be captured in T1, T2, and DP sequences, in sagittal and coronal sections, by a single radiological technician to ensure consistency in scanning methods and parameters.

**Magnetic Resonance Analysis:** The MRI exams will be analyzed by three independent dental radiologists, based on parameters established in a prior meeting. Two mandibular positions will be considered: closed mouth and open mouth. For a precise and quantitative assessment, a tracing will be made from the most central and superior region of the mandibular fossa to the most posterior portion of the articular disc band (Fig. 4). These parameters will be compared pre- and post-treatment for both groups.



**Fig. 4. Protocol for measuring the articular disc on magnetic resonance imaging, (A) closed mouth, (B) open mouth**

**Secondary outcome measures:** World Health Organization Quality of Life Abbreviated (WHOQOL-BREF): The WHOQOL-BREF will be used to assess the quality of life. It is an abbreviated version of the WHOQOL-100, consisting of 26 questions, 2 related to global and general health, and the rest divided into four domains: physical health, psychological health, social relationships, and environment. Scores close to 0 indicate an unfavorable quality of life, while scores close to or equal to 100 indicate a favorable quality of life [33].

**Patient-specific functional scale:** This global scale can be applied to any region of the body. Patients will be asked to identify up to three activities they are unable to perform or have difficulty with. The higher the average score (0-10), the better the patient's ability to perform these activities [34].

**Numerical Pain Scale (NPS):** This simple scale, asks participants to rate their pain intensity on a scale from 0 (no pain) to 10 (worst pain) [35].

**Sample size:** The sample size was calculated based on data from Emara, et al. [16], which reported a mean difference ( $0.62 \pm 0.27$ ) in disc displacement before and after intervention with botulinum toxin. Using the mean and standard deviation of the pre- and post-intervention conditions for each primary clinical outcome, and assuming  $\alpha = 0.05$  (5% chance of type I error) and  $1-\beta = 0.95$  (95% sample power), it was determined that 6 participants per group would be needed to evaluate disc position after treatment with nonspecific mandibular mobilization. The sample size was calculated using the G\*POWER software [36].

**Statistical analysis:** The normality of data for outcome measures will be assessed using the Shapiro-Wilk test. Descriptive statistics will be used to characterize the participants, and comparisons between the groups (GA and GB) will be made using either the independent t-test or the Mann-Whitney test. Differences between groups over time will be tested using linear mixed models, accounting for pre-treatment, post-treatment (after 12 sessions), 3 months post-treatment, and 6 months post-treatment. Differences between groups (treatment effects) and their respective 95% confidence intervals (CI) will be calculated using linear mixed models [37], incorporating interaction terms for treatment groups and time. All models will be adjusted for initial estimates. If the data do not follow a

normal distribution, Friedman's ANOVA with Dunn's post hoc test will be used. Statistical significance will be set at  $p < 0.05$ .

Cohen's  $d$  and partial eta squared ( $\eta^2$ ) will be used to calculate effect sizes [38], interpreted according to Cohen's guidelines: small effect ( $d = 0.2$ ,  $\eta^2 = 0.01$ ); moderate effect (approximately  $d = 0.5$ ,  $\eta^2 = 0.06$ ); and large effect ( $d = 0.8$ ,  $\eta^2 = 0.14$ ). All analyses will be conducted using SPSS 20.0 software [39].

### 3. RESULTS

The protocol of the current study is innovative and unprecedented, as it will assess the behavior of the anterior disc displacement through MRI following mandibular mobilization. To determine the success of the intervention protocol, a 30% improvement in the difference between the parameters measured by MRI at pre- and post-treatment moments will be considered. Additionally, the mean differences between the coordinates of the anterior and posterior points of the disc pre- and post-mobilization will be assessed, with expected values between 0.62 and 0.83 [16]. Clinical improvement in mandibular movement will also be taken into account.

### 4. DISCUSSION

In the present study, we will specifically address anterior disc displacements with or without reduction, focusing on disc positioning after joint mobilization.

Conservative approaches are generally the first therapeutic option for individuals with disc displacements. These strategies include medication, intra-oral devices, joint infiltrations, jaw exercises, and manual therapy, such as joint mobilizations, to improve disc positioning in the joint [2,6,10,40,41]. However, despite these established approaches, the literature lacks robust investigations evaluating the direct impact of joint mobilizations on disc positioning.

An important contribution of this research is to encourage further clinical trials that explore interventions for disc displacement. This study is the first to explicitly aim at demonstrating possible changes in the positioning of the articular disc in individuals with anterior disc displacement. The results will be measured using MRI, which is the reference standard for evaluating this specific joint.

## 5. CONCLUSION

This study will evaluate how the anteriorly displaced disc behaves after mandibular mobilization, using MRI to determine the effects of the intervention. This protocol seeks to assess whether mandibular mobilization can aid in rehabilitating the anteriorly displaced disc in the TMJ and potentially be included in therapeutic planning.

### DISCLAIMER (ARTIFICIAL INTELLIGENCE)

The author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during the writing or editing of this manuscript.

### ETHICAL APPROVAL AND CONSENT

This protocol follows specific research guidelines for human subjects and was approved by the University's Research Ethics Committee (CAAE: 36854714.7.0000.5511). Individuals who agree to participate in the research will sign the Informed Consent Form. The protocol will be developed, and it was registered at ClinicalTrials.gov (NCT02294799) This study will be carried out at the University's Musculoskeletal Research Center (NUPEM).

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The protocol was produced and will be developed at the Musculoskeletal Research Support Center (NUPEM) of the Universidade Nove de Julho and was previously submitted and approved by the University's Research Ethics Committee (CAAE: 36854714.7.0000.5511). It is registered at ClinicalTrials.gov under the (NCT02294799). The authors would like to thank the Universidade Nove de Julho, represented by the Rector Prof. José Eduardo Storopoli, the Director João Carlos Ferrari of Rehabilitation Sciences, and all those who will participate in the study. This work will be partially funded by the Coordination for the Improvement of Higher Education Personnel (CAPES), financial code 001. This funding source had no role in the design of this study and will have no role during its execution, analysis, interpretation of data, or decision to present results.

### COMPETING INTERESTS

The authors declare that no competing interests exist.

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