Study Protocol

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 18–60 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.

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 generate symptoms that include headache, discomfort, drowsiness and 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 Tempromandibular 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

Ethical aspects

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 Informed 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).

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 60 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, BarrillesChart , 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. AxisI 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 12), 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 α = 0.05 [5% chance of type I error] and 1-β = 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 ($_p^2$) 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 $_p^2$ =0.01); moderate effect (approximately *d* =0.5 and $_{p2 =}^{0.06}$); and large effect (from: *d* =0.8 and $_p^2$ =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.

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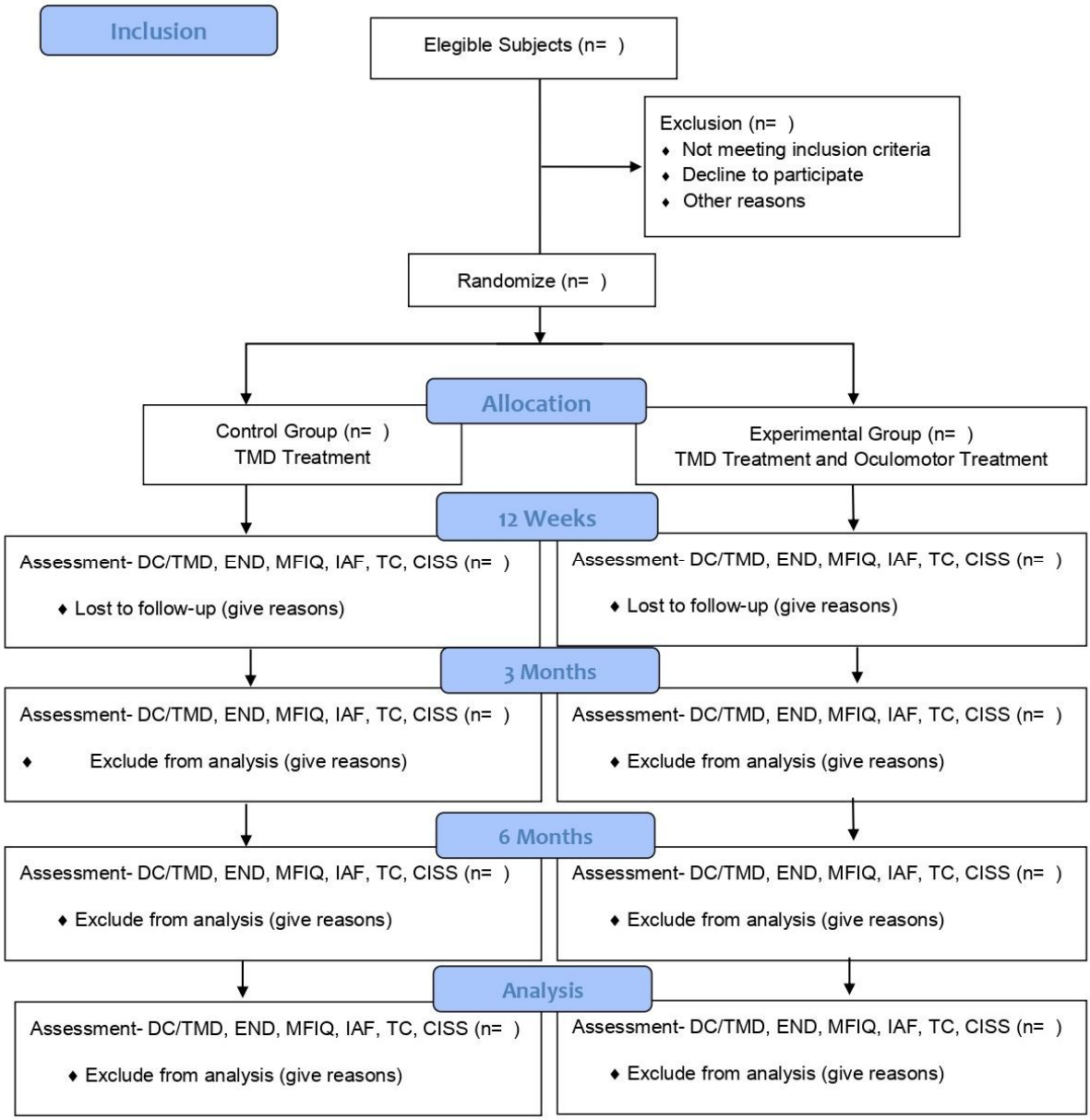

Figure 1: Study design flowchart according to CONSORT.

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 Pompage ; [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.

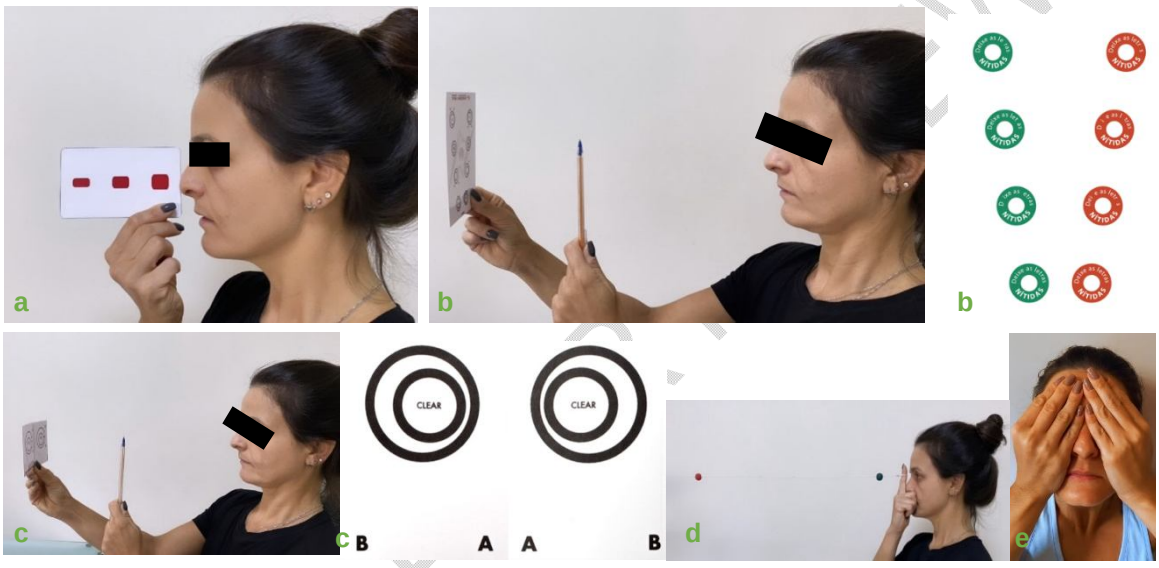

Figure 5: [a] Barrile Chart; [b] Life Saving Letter; [c] Eccentric Circles; [d] Brock cord [e] Eye relaxation.

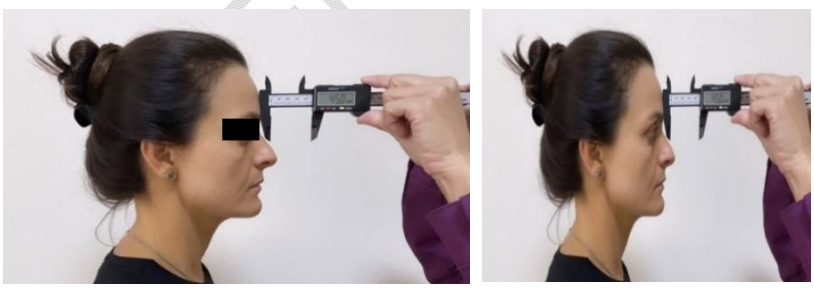

Figure 6: Convergence Test