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# Short-term effects of a Rigid Interocclusal Appliance and Hypnosis on individuals with bruxism: a feasibility study for a randomized clinical trial

Alexandre Henrique dos Reis-Prado
Doutorado sanduíche em Odontologia - (Bottino Lab - Regenerative Dentistry)
University of Michigan School of Dentistry
Michigan – Estados Unidos
http://lattes.cnpq.br/7159141245504619
E-mail: alexandreprado.cba@gmail.com

Adriana Maria Botelho
Professora de Dentística – Departamento de Odontologia/UFVJM
Universidade Federal dos Vales do Jequitinhonha e Mucuri - UFVJM
Diamantina - Minas Gerais - Brasil
http://lattes.cnpq.br/3236665545484148
E-mail: adriana.botelho@ufvjm.edu.br

Cláudia Valadares Roquete Maia
Psicóloga – PUC/MG
Pontifícia Universidade Católica de Minas Gerais - PU
Belo Horizonte - Minas Gerais - Brasil
E-mail: claudia.maia@ibhc.com.br

Ana Carolina Coelho de Oliveira
Doutoranda pelo Programa de Pós-Graduação em Fisiopatologia Clínica e Experimental - FISCLINEX
Universidade do Estado do Rio de Janeiro - UERJ
Maracanã – Rio de Janeiro - Brasil
http://lattes.cnpq.br/9159599805966263
E-mail: carolina.coelho@ufvjm.edu.br

Jane Evangelista Cordeiro
Graduada em Odontologia pela UFVJM
Universidade Federal dos Vales do Jequitinhonha e Mucuri - UFVJM
Diamantina - Minas Gerais - Brasil
http://lattes.cnpq.br/6199619385030738
E-mail: jane.evangelista@ufvjm.edu.br

Letícia Pena Botelho
Doutorado em Clínica Odontológica pela UFVJM
Universidade Federal dos Vales do Jequitinhonha e Mucuri - UFVJM
Diamantina - Minas Gerais - Brasil
http://lattes.cnpq.br/5769876911176841
E-mail: leticia.botelho@ufvjm.edu.br

Brender Leonan da Silva
Professor voluntário de Periodontia – Departamento de Odontologia/UFVJM
Mestrando em Clínica Odontológica – PPGOdonto/UFVJM
Universidade Federal dos Vales do Jequitinhonha e Mucuri - UFVJM
Diamantina - Minas Gerais - Brasil
http://lattes.cnpq.br/8785125295740339
E-mail: brender.leonan@ufvjm.edu.br

Rodrigo Galo
Professor Doutor MS-3.1 do Departamento de Materiais Dentários e Prótese/USP
Faculdade de Odontologia de Ribeirão Preto da Universidade de São Paulo – FORP/USP
Diamantina - Minas Gerais - Brasil
http://lattes.cnpq.br/9207872880367948
E-mail: atendimento.pc@usp.br

Dhelfeson Willya Douglas de Oliveira
Professor de Periodontia – Departamento de Odontologia/UFVJM
Universidade Federal dos Vales do Jequitinhonha e Mucuri - UFVJM
Diamantina - Minas Gerais - Brasil
http://lattes.cnpq.br/2860704725625323

E-mail: dhelfeson@ufvjm.edu.br

Olga Dumont Flecha
Professora de Periodontia – Departamento de Odontologia/UFVJM
Universidade Federal dos Vales do Jequitinhonha e Mucuri - UFVJM
Diamantina - Minas Gerais - Brasil
http://lattes.cnpq.br/5254763049091753
E-mail: olga.flecha@ufvjm.edu.br

Karine Taís Aguiar Tavano
Professora de Dentística – Departamento de Odontologia/UFVJM
Universidade Federal dos Vales do Jequitinhonha e Mucuri - UFVJM
Diamantina - Minas Gerais - Brasil
http://lattes.cnpq.br/2171671063408600
E-mail: karine.tavano@ufvjm.edu.br

**Abstract:** This study had the aim of evaluate the feasibility of a randomized clinical trial to compare the effects of a Rigid Interocclusal Appliance and Hypnosis on the quality of life and muscle pain in individuals with bruxism. Forty-two patients with self-report bruxism and clinical examination were randomly assigned to three groups: Rigid Interocclusal Appliance (G1), Hypnosis (G2), and a Control Group (G3). Data collection occurred at baseline and 40 days after the interventions using the Oral Health Impact Profile (OHIP-14), Lip's Inventory of Stress Symptoms (ISSL) and muscle and joint palpation. P-value < 0.05 was considered significant. The G1 showed a greater reduction in pain in the masseter's portions and in the temporalis tendon insertion (p<0.05). No significant differences were observed in the quality of life (OHIP-14). From this pilot study it was possible to verify the feasibility of a clinical trial with a larger sample size and follow-up time.

**Keywords**: Temporomandibular disorders; Bruxism; Hypnosis; Interocclusal Splints.

## Introduction

Bruxism is a condition characterized by hyperactivity of the masticatory muscles, especially the masseter muscle, which can manifest as the habit of grinding and/or clenching teeth and, when absent, repetitive mandibular movements [1]. According to the circadian cycle in which it occurs, it can be classified as Sleep Bruxism (SB) and Waking Bruxism (WB), which are considered risk and/or protective factors when observed in healthy individuals [2,3].

Despite being a condition that affects around 31% of the world's adult population [4], the epidemiology of bruxism is complex due to the difficulties involved in the validity of the diagnosis of this condition adopted by some studies based only on patients' self-report. Thus, it is not possible to identify a concrete relationship with factors such as gender and age [5,6]. From this perspective, current literature suggests that Bruxism should be assessed beyond the 'present or absent' dichotomy, since the different motor activities associated with the occurrence of Bruxism need to be assessed separately [7].

Thus, a group of researchers in the study of bruxism developed the Standardized Tool for the Assessment of Bruxism (STAB), a guide with criteria that define the characteristics of the condition presented by the patient, the comorbidities involved, the probable etiological factors and their consequences [8]. According to this assessment tool, bruxism can be identified using non-instrumental and instrumental approaches. Non-instrumental criteria include self-reporting by patients and clinical examination by the dental surgeon [9], while instrumental criteria include recording with Electromyography (EMG) during wakefulness (BV) and during sleep (BS) and analyses involving polysomnography to ascertain patients' muscle activity during sleep. Based on these criteria, it is possible to classify Bruxism as possible (when based on self-report alone), probable (based on clinical inspection with or without self-report) and definitive (based on positive instrumental assessment with or without self-report and/or clinical inspection) [1,10].

Bruxism has a multifactorial aetiology [11,12], involving sleep disorders, genetic and psychological factors [13]. The primary consequences of this condition include masticatory muscle fatigue [14], fracture of restorations and teeth, temporal headaches, cheek ridging [12], and a potential reduction in the quality of life due to occlusal deterioration and emotional disturbances.

Several manage are available for bruxism, including Acupuncture [15], the application of local Botulinum Toxin [16], and the use of Interocclusal Appliances (Oclusal Splints, Nightguards) [17,18]. Additionally, Hypnosis has been explored as a potential treatment option [19,20]. Despite being one of the popular manage of bruxism, the effectiveness and specificity of Oral Appliances have been challenged by some studies [17, 21,22]. This device protects the teeth, stabilizes joint, redistributes forces, and decreases bruxism [23,24]. Another effective manage for chronic pain, which may lack negative side effects, is Hypnosis [22,25]. Hypnosis has shown promise in reducing the frequency, duration, and intensity of orofacial injuries [26,27], although only a limited number of studies have explored its effects in orofacial pain conditions [22,28].

While numerous studies have provided evidence of the effectiveness of Interocclusal Appliances for manage of bruxism [29-34], to the best of our knowledge, no previous Randomized Clinical Trials (RCTs) have compared the effects of this Interocclusal Appliances with hypnosis in individuals with bruxism. Therefore, the purpose of the present study was to evaluate the feasibility of a randomized clinical trial to compare the effects of Interocclusal Appliance and Hypnosis on the quality of life and muscle pain in individuals with bruxism. The null hypothesis to the design of the main study was adopted, suggesting no difference between both manage type.

## Materials and methods

### *Ethical considerations*

This study followed the Consolidated Standards of Reporting Trials guidelines (CONSORT) [34] and was approved by the Research Ethics Committee (Protocol 70399317.1.0000.5108) of the Federal University of Jequitinhonha and Mucuri Valleys (UFVJM), in full compliance with the Declaration of Helsinki, revised in 2013. After explanation of the research, the individuals who agreed to participate signed the

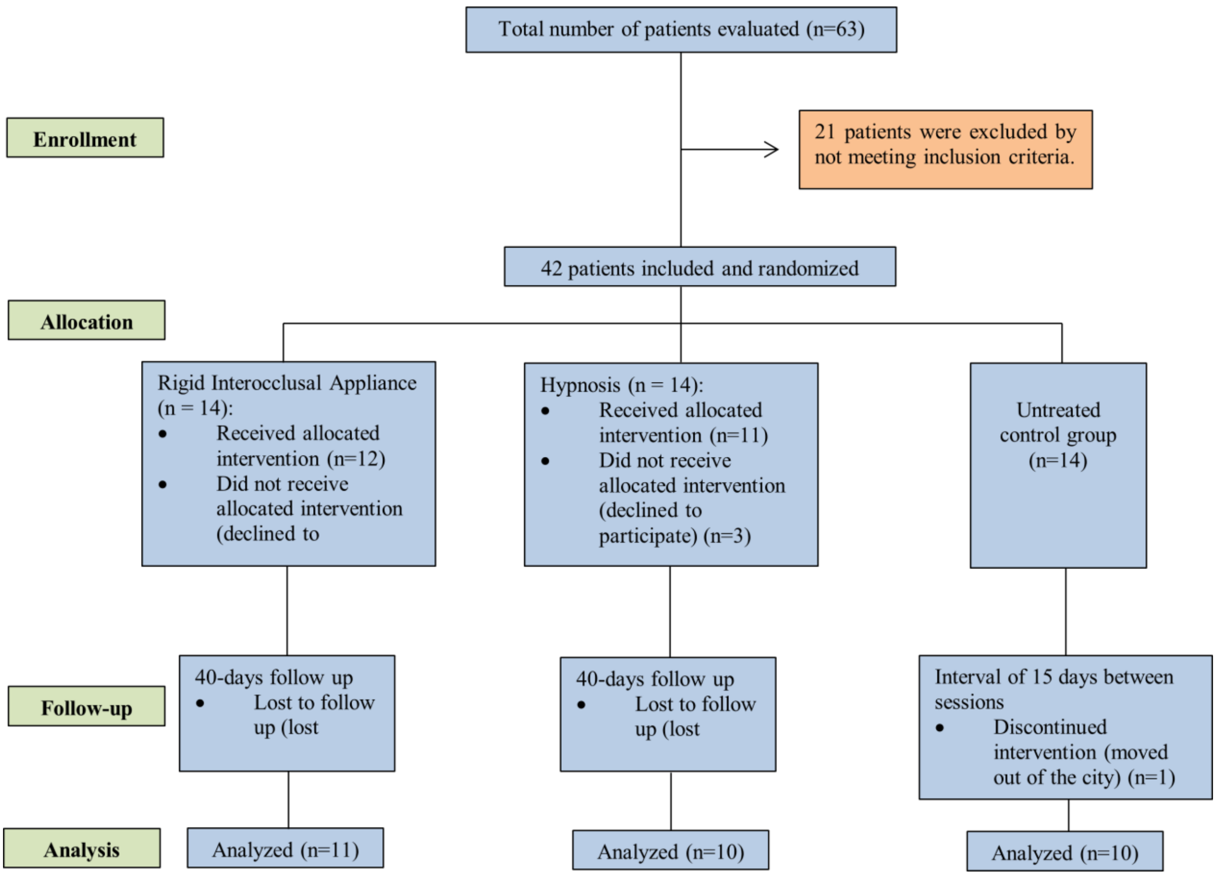
Term of Free and Informed Consent. Moreover, this study protocol was registered in the Brazilian Registry of Clinical Trials (REBEC: RBR-5s8fy4) platform.

*Study design and participants*

This study was conducted between April 2017 and February 2018. The population was determined based on the self-report bruxism and clinical examination to check for tooth wear. Considering that pilot studies are not based on hypotheses, a formal calculation of statistical power is unfeasible [36]. It has been suggested that n=12 per group is an acceptable pilot test sample for a comparative (continuous outcome) study [37,38]. To prevent losses, 10% was added to the sample. Therefore, this study was conducted with n=14 participants per group.

A detailed description of the selected patients who completed the study can be seen in the Figure 1.

**Figure 1: Flowchart of sample distribution.**



*Eligibility criteria*

Patients aged 18 with self-report bruxism and clinical examination over with tooth surface loss, cheek ridging, tongue scalloping and reporting untreated orofacial pain were eligible for the study. The exclusion criteria were: 1) patients with occlusal instability due to missing permanent teeth and/or occlusal changes; 2) patients with many indirect restorations current or using orthodontic appliances; 3) syndromic patients with motor functional neurological disorder; and 4) individuals in current use of analgesic/anti-inflammatory agents or using medication that act on the Central Nervous System, such as serotonin reuptake inhibitor antidepressants.

*Interventions*

The patients were allocated into 3 parallel groups: G1: treatment with Rigid Interocclusal Appliance (14 patients), G2: Hypnosis sessions for relaxation and induction and G3: Control group without any intervention. All participants underwent the following initial procedures: anamnesis based on a clinical form adapted from the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD), assessment of the level of pain through muscle and joint palpation carried out by a calibrated professional, application of the Oral Health Impact Profile (OHIP-14) [39] and Lipp's Inventory of Symptoms as Stress for adults (ISSL) [40].

*Treatment with Rigid Interocclusal Appliance (G1)*

The Rigid Interocclusal Appliances were made in acrylic according to laboratory routine in a clinical environment in the following sequence: a) impression of the upper and lower dental arches with alginate; b) registration with the face bow in centric relation; c) preparation of plaster models and assembly on a semi-adjustable articulator; d) wax-up and making of acrylic Rigid Interocclusal Appliance; e) installation and clinical adjustments of the Rigid Interocclusal Appliance; f) periodic monitoring.

The Rigid Interocclusal Appliances were made by a trained professional, following the protocols described in previous studies [41,42]. They were manufactured by the same technician and laboratory, using thermopolymerizable acrylic resin (JET® - Clássico, Campo Limpo Paulista, SP, Brazil). The installed Rigid Interocclusal Appliances had an average thickness of 2 mm in the posterior region, with bilateral occlusal contacts, incisal and canine orientation (anterior guide and canine guide), smooth and flat surface. Individuals were instructed to use the Rigid Interocclusal Appliances during sleep throughout the follow-up period and received guidance on hygiene and care of the appliances. When necessary, additional adjustments were made.

*Hypnosis sessions for relaxation and induction (G2)*

Five clinical hypnotherapy sessions were held every 15 days, a time suggested by some hypnotherapists. The hypnotic inductions were carried out by just one professional Hypnotherapist, where each patient was induced at a time different from that of the clinics established by the institution, to guarantee privacy, respecting ethical and biosafety principles. The participant remained seated in the dental chair, slightly lying down, to keep him well supported with his hands on his thighs, in a silent environment without external interference. Next, a progressive relaxation session and induction into a hypnotic state was carried out with hypnotic and post-hypnotic suggestions [43]. At each new session, the professional held a brief conversation about the participant's state during the period and again induced the hypnotic state.

*Control group without any intervention (G3)*

Despite initially not receiving any intervention, this group was informed of all aspects involved in the research and that at the end of the study this group would receive the treatment with the best results achieved.

*Randomization, allocation concealment and blinding*

A blinded researcher who was not involved in the treatment evaluations conducted the entire randomization procedure, ensuring that the sample size for each group was considered. The names of the patients were randomly allocated into numbers from 0 to 42 and the interventions into letters A, B and C. Patients were then randomly distributed into envelopes, along with a letter from A to C, forming groups with 14 patients each. Confidentiality was maintained through a process involving opaque envelopes. These envelopes remained sealed until the day of the interventions. Only on the day of the interventions did each operator discover what each patient would receive. The other investigator responsible for conducting assessments at baseline and during the follow-up period did not have access to allocation information until study completion.

*Statistical analysis*

Statistical analysis was performed by single calibrated operator in a blinded manner, using Statistical Package for Social Science (SPSS; version 23.0, Armonk, New York, USA) software program. Descriptive analysis was used with frequencies, and measures of central tendency and variability. Nonparametric data were analyzed by the Wilcoxon test. Parametric data were submitted to the one-way ANOVA test after normality of the data was tested for, to observe the difference among the groups over time and within groups. $P<0.05$ was considered statistically significant.

## Results

*Characterization of the sample*

Of the 42 individuals initially recruited, 14 were randomly allocated to each group (G1, G2 and G3) (Figure 1). A total of 11 patients (26,19%) did not attend the follow-up data. Thus, the remaining 31 participants (11 from G1, 10 from G2 and 10 from G3) completed the study protocol successfully and were considered for statistical analysis. The mean age of the participants was 26.9 ± 5.97 (mean ± SD) years. Furthermore, most of the participants (64.52%) of all groups were female.

*Life quality (OHIP-14)*

The results of the quality of life assessment are summarized in the Table 1 and 2. There were no significant differences observed among the interventions before and after treatment. Additionally, no significant differences were found between the groups at the baseline and at the end of the analysis.

**Table 1. Quality of life assessment**

| | Rigid Interocclusal Appliance – G1 | | | | | Hypnosis – G2 | | | | | Control – G3 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Baseline | | Post-Treatment | | p* | Baseline | | Post-Treatment | | p* | Baseline | | Post-Treatment | | p* |
| | Mean | SD | Mean | SD | | Mean | SD | Mean | SD | | Mean | SD | Mean | SD | |
| Functional limitation | 1,00 | 1,18 | 1,00 | 1,10 | 0,999 | 0,40 | 0,97 | 0,80 | 1,48 | 0,496 | 0,60 | 0,97 | 0,40 | 0,97 | 0,157 |
| Physical pain | 3,82 | 2,75 | 4,27 | 2,72 | 0,236 | 3,50 | 2,37 | 1,90 | 1,79 | 0,085 | 3,50 | 2,32 | 2,80 | 1,87 | 0,305 |
| Psychologic discomfort | 2,73 | 2,97 | 2,64 | 2,11 | 0,932 | 2,60 | 2,32 | 1,70 | 1,83 | 0,371 | 2,30 | 1,89 | 2,50 | 1,84 | 0,722 |
| Physical disability | 1,45 | 1,63 | 1,73 | 1,42 | 0,317 | 1,10 | 1,91 | 0,60 | 1,07 | 0,465 | 1,50 | 2,07 | 0,90 | 1,37 | 0,257 |
| Psychologic disability | 1,91 | 2,02 | 2,09 | 2,07 | 0,516 | 2,50 | 2,12 | 1,00 | 1,25 | 0,089 | 2,30 | 1,77 | 2,00 | 1,70 | 0,427 |
| Social disability | 1,45 | 2,07 | 1,82 | 1,72 | 0,438 | 1,40 | 1,51 | 1,00 | 1,83 | 0,524 | 1,00 | 1,15 | 1,30 | 1,25 | 0,680 |
| Handicap | 1,64 | 2,06 | 1,64 | 1,80 | 0,999 | 1,00 | 1,33 | 0,60 | 1,35 | 0,414 | 1,00 | 1,33 | 1,20 | 1,55 | 0,680 |
| OHIP total score | 14,00 | 12,51 | 15,18 | 10,23 | 0,357 | 12,50 | 11,23 | 7,60 | 7,34 | 0,359 | 12,20 | 7,63 | 11,10 | 7,74 | 0,646 |

Font: Authors, 2023.

**Table 2. Inter-group Analysis**

| | Baseline | Post-treatment |
|---|---|---|
| | p** | p** |
| Functional limitation | 0,296 | 0,325 |
| Physical pain | 0,919 | 0,097 |
| Psychologic discomfort | 0,977 | 0,455 |
| Physical disability | 0,714 | 0,082 |
| Psychologic disability | 0,735 | 0,467 |
| Social disability | 0,824 | 0,201 |
| Handicap | 0,866 | 0,140 |
| OHIP total score | 0,985 | 0,215 |

Font: Authors, 2023.

*Stress assessment*

A decrease in the average symptom of stress post treatment is observed in Table 3 (p <0.05). At the baseline, 93.75% showed some type of symptom, with 43.75% of the sample in the resistance phase. At 40 days after interventions, most of the participants in all groups remained in the resistance phase, while no subject was found in the exhaustion and close to exhaustion stages in the G1 and G2 groups.

**Table 3. Stress level post treatment**

| | ISSL before | | | | |
|---|---|---|---|---|---|
| | Without stress | | With stress | | |
| | n | % | n | % | p |
| **ISSL after** | | | | | |
| Without stress | 7 | 77,8 | 8 | 36,4 | 0,044* |
| With stress | 2 | 22,2 | 14 | 63,6 | |

Statistical significance (p < 0.05) * provided.
The data were subjected to Spearman correlation analysis, Wilcoxon test, Kruskal-Wallis test and Fischer's exact test.
Font: Authors, 2023.

*Assessment of muscle and joint palpation*

The assessment of muscle pain on palpation before and after treatments showed significant results (p<0.05) with a predominance of the group that received the occlusal splints. These results can be seen in Table 4. The joint palpation did not present significant results (p>0.05), but the values can be viewed in the Supplementary Data with the values of the other muscles that underwent the palpation test but did not present significant values.

**Table 4. Assessment of muscle palpation**

| | Rigid Interocclusal Appliance – G1 | | | | | Hypnosis – G2 | | | | | Control – G3 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Baseline | | Post-Treatment | | p* | Baseline | | Post-Treatment | | p* | Baseline | | Post-Treatment | | p* |
| | Mean | SD | Mean | SD | | Mean | SD | Mean | SD | | Mean | SD | Mean | SD | |
| RSMM | 0,60 | 0,69 | 0,10 | 0,31 | 0,123 | 0,50 | 0,70 | 0,10 | 0,31 | 0,247 | 1,09 | 1,13 | 0,45 | 0,82 | 0,171 |
| LSMM | 0,80 | 0,63 | 0,10 | 0,31 | 0,019* | 0,60 | 0,69 | 0,10 | 0,31 | 0,123 | 0,81 | 1,16 | 0,18 | 0,60 | 0,171 |
| RMMM | 1,10 | 0,87 | 0,20 | 0,42 | 0,015* | 0,50 | 0,70 | 0,20 | 0,42 | 0,436 | 1,54 | 1,12 | 0,90 | 1,13 | 0,193 |
| LMMM | 1,20 | 0,78 | 0,30 | 0,48 | 0,019* | 0,90 | 0,87 | 0,30 | 0,67 | 0,143 | 1,36 | 0,80 | 0,36 | 0,67 | 0,013* |
| RIMM | 1,20 | 0,78 | 0,00 | 0,00 | 0,000* | 0,40 | 0,69 | 0,10 | 0,31 | 0,436 | 1,09 | 1,13 | 0,54 | 0,93 | 0,217 |
| LIMM | 0,90 | 0,87 | 0,10 | 0,31 | 0,043* | 0,90 | 0,87 | 0,20 | 0,63 | 0,075 | 1,09 | 0,94 | 0,81 | 0,16 | 0,438 |
| RLPM | 1,10 | 0,87 | 0,90 | 0,99 | 0,579 | 1,10 | 0,56 | 0,40 | 0,51 | 0,029* | 2,09 | 0,94 | 1,09 | 1,22 | 0,065 |
| LLPM | 1,80 | 1,31 | 0,80 | 0,78 | 0,105 | 1,30 | 0,94 | 0,60 | 0,84 | 0,123 | 1,54 | 1,36 | 0,63 | 1,02 | 0,151 |
| TRTM | 1,70 | 1,05 | 0,50 | 0,97 | 0,029* | 1,60 | 1,07 | 0,70 | 0,94 | 0,075 | 2,09 | 1,04 | 1,36 | 1,20 | 0,171 |
| TLTM | 1,70 | 1,33 | 0,60 | 0,96 | 0,049* | 1,20 | 0,63 | 1,10 | 1,37 | 0,481 | 1,90 | 1,22 | 1,18 | 1,25 | 0,193 |
| RSM | 1,30 | 0,94 | 0,10 | 0,31 | 0,004* | 1,70 | 0,94 | 0,00 | 0,00 | 0,000* | 2,09 | 1,13 | 0,18 | 0,60 | 0,001* |
| LSM | 1,00 | 0,94 | 0,10 | 0,31 | 0,043* | 1,70 | 1,25 | 0,00 | 0,00 | 0,002* | 1,90 | 1,13 | 0,18 | 0,60 | 0,002* |

Mean values and statistical significance (p < 0.05)* before and after the treatments provided.
Abbreviations: RSMM/LSMM – Right/Left Superior Masseter Muscle, RMMM/LMMM – Right/Left Middle Masseter Muscle, RIMM/LIMM – Right/Left Inferior Masseter Muscle, RLPM/LLPM – Right/Left Lateral Pterygoid Muscle, TRTM/TLTM – Tension of the Right/Left Temporal Muscle, RSM/LSM – Right/Left Sternocleidomastoid Muscle.

## Discussion

Bruxism is a multifactorial condition influenced by various risk factors such as facial morphology, occlusal discrepancies, sleep disorders and influences from somatic, social, hereditary and psychological factors [13]. Clinically, bruxism is also a risk factor for dental damage, temporomandibular joint (TMJ) pain, headaches, muscle pain and fatigue [44]. In addition, it can lead to tooth sensitivity and changes in the contact areas between antagonist teeth, with a reduction in masticatory performance, reducing individuals' quality of life [30,45,46]. This study sought to determine the feasibility of a clinical trial to assess the quality of life and muscle pain in individuals with bruxism manage with Rigid Interocclusal Appliances (G1) and Hypnosis (G2). Evaluations were carried out at the start of manage (baseline) and 40 days after the interventions with muscle palpation according to RDC/TMD and questionnaires validated for research.

Regarding the questionnaires used for research involving patients with bruxism, the ISSL and OHIP-14 are important tools for assessing patients' quality of life before and after treatment [39,40]. This is because bruxism is a common condition in patients who have been exposed to traumatic events that influence the psychological factors that predispose and modulate the experience of pain [47]. However, despite the validity of these questionnaires, this study showed no statistically significant difference in terms of quality of life using the OHIP-14, with only the level of stress recorded using the ISSL being significant. These results may be associated with the short-term follow-up, since for this type of assessment the ideal would be a period of approximately 12 months for more expressive results [48]. Even so, the greater reduction in stress levels observed in the group that received Rigid Interocclusal Appliances corroborates with other studies with a longer-term follow-up [49,50]. In the group that received the Hypnosis sessions, the reduction in stress may be associated with greater relaxation and tranquillity after the inductions and therapeutic suggestions [20,43].

The predominant action of the masseter muscle during situations requiring a greater bite force explains the intense pain reported by the patients, as observed in other studies [51,52]. As for the reports of pain after the 40-days follow-up, 5 participants in Rigid Interocclusal Appliances group (50%) reported no more muscle pain or headaches, while the other 5 (50%) reported only a reduction in the intensity and reduction of pain. The use of Rigid Interocclusal Appliances, despite not having a clear working mechanism, has shown good results in controlling pain in patients with chronic conditions associated with bruxism [50]. With Hypnosis, the number of patients who reported that they no longer felt pain was the same as the Rigid Interocclusal Appliances group (50%), in addition to greater control over the habit of grinding and clenching their teeth. However, 4 (40%) reported a reduction in intensity and frequency and 1 (10%) reported that the pain remained. The literature attributes the hypnotic action to a mechanism of descending antinociception whereby, based on hypnotic suggestions and inductions, the patient stops or reduces the practice of clenching and grinding their teeth [22,27].

As this is a feasibility study, also known as a pilot study, the results should be interpreted with caution, as they should not be used to estimate manage due to the limited sample number and evaluation time, which confer a high risk of bias [53]. The fact is that pilot studies are developed to establish strategies that will be improved in the main study, as well as being an important tool in defining the most appropriate sample size for a clinical trial [54].

From this pilot study, the assessment instruments and manages addressed are feasible but need to be altered in view of the assessment time and sample size in each group. In this case, it is advisable to adopt an evaluation period of at least 12 months to obtain more realistic results, especially in the case of chronic conditions [48]. As for the appropriate sample calculation for a clinical trial evaluating the same variables as this pilot, the research team must meet to define which variables will be considered, in what order and potentially with what weights [55]. This information will determine how the calculation will be carried out, ensuring that the results are compatible with the study design.

## Conclusion

From this pilot study, it was possible to confirm the feasibility of a randomized clinical trial to evaluate the effectiveness of Rigid Interocclusal Appliances compared to Hypnosis for the manage of bruxism. Despite the limitations involved in the study design, in a short-term follow-up, both manages were shown to be effective in reducing stress levels and pain on muscle palpation, with the Rigid Interocclusal Appliances standing out.

## References

[1] Lobbezoo F, Ahlberg J, Raphael KG, Wetselaar P, Glaros AG, Kato T, Santiago V, Winocur E, De Laat A, De Leeuw R, Koyano K, Lavigne GJ, Svensson P, Manfredini D. International consensus on the assessment of bruxism: Report of a work in progress. J Oral Rehabil. 2018 Nov;45(11):837-844. DOI: 10.1111/joor.12663.

[2] Bracci A, Djukic G, Favero L, Salmaso L, Guarda-Nardini L, Manfredini D. Frequency of awake bruxism behaviours in the natural environment. A 7-day, multiple-point observation of real-time report in healthy young adults. J Oral Rehabil. 2018 Jun;45(6):423-429. DOI: 10.1111/joor.12627.

[3] Bracci A, Lobbezoo F, Colonna A, Bender S, Conti PCR, Emodi-Perlman A, Häggman-Henrikson B, Klasser GD, Michelotti A, Lavigne GJ, Svensson P, Ahlberg J, Manfredini D. Research routes on awake bruxism metrics: Implications of the updated bruxism definition and evaluation strategies. J Oral Rehabil. 2024 Jan;51(1):150-161. DOI: 10.1111/joor.13514.

[4] Mesko ME, Hutton B, Skupien JA, Sarkis-Onofre R, Moher D, Pereira-Cenci T. Therapies for bruxism: a systematic review and network meta-analysis (protocol). Syst Rev. 2017 Jan 13;6(1):4. DOI: 10.1186/s13643-016-0397-z.

[5] Manfredini D, Winocur E, Guarda-Nardini L, Paesani D, Lobbezoo F. Epidemiology of bruxism in adults: a systematic review of the literature. J Orofac Pain. 2013 Spring;27(2):99-110. DOI: 10.11607/jop.921.

[6] Manfredini D, Restrepo C, Diaz-Serrano K, Winocur E, Lobbezoo F. Prevalence of sleep bruxism in children: a systematic review of the literature. J Oral Rehabil. 2013 Aug;40(8):631-42. DOI: 10.1111/joor.12069.

[7] Manfredini D, Ahlberg J, Wetselaar P, Svensson P, Lobbezoo F. The bruxism construct: from cut-off points to a continuum spectrum. J Oral Rehabil. 2019; 46:991-997. DOI: https://doi.org/10.1111/joor.12833.

[8] Manfredini D, Ahlberg J, Aarab G, Bracci A, Durham J, Emodi-Perlman A, Ettlin D, Gallo LM, Häggman-Henrikson B, Koutris M, Peroz I, Svensson P, Wetselaar P, Lobbezoo F. The development of the Standardised Tool for the Assessment of Bruxism (STAB): An international road map. J Oral Rehabil. 2024 Jan;51(1):15-28. doi: 10.1111/joor.13380.

[9] Svensson P, Arima T, Lavigne G, Castrillon E. Sleep bruxism: definition, prevalence, classification, etiology and consequences. In: Kryger MH, Roth T,

Dement WC, eds. Principles and Practice of Sleep Medicine, 6th ed. Philadelphia, PA: Elsevier; 2016:1423-1426.

[10] Lobbezoo F, Ahlberg J, Glaros AG, Kato T, Koyano K, Lavigne GJ, de Leeuw R, Manfredini D, Svensson P, Winocur E. Bruxism defined and graded: an international consensus. J Oral Rehabil. 2013 Jan;40(1):2-4. DOI: 10.1111/joor.12011.

[11] Johansson A, Omar R, Carlsson GE. Bruxism and prosthetic treatment: a critical review. J Prosthodont Res. 2011 Jul;55(3):127-36. DOI: 10.1016/j.jpor.2011.02.004.

[12] Needham R, Davies SJ. Use of the Grindcare® device in the management of nocturnal bruxism: a pilot study. Br Dent J. 2013 Jul;215(1):E1. DOI: 10.1038/sj.bdj.2013.653.

[13] Soares LG, Costa IR, Brum Júnior JDS, et al. Prevalence of bruxism in undergraduate students. Cranio. 2017 Sep;35(5):298-303. DOI: 10.1080/08869634.2016.1218671.

[14] Hara ES, Witzel AL, Minakuchi H, de Pitta CE, Gallo RT, Okada M, Matsumoto T, Kuboki T, Bolzan MC. Vibratory splint therapy for decreasing sleep clenching: A pilot study. Cranio. 2020 Jan;38(1):15-21. DOI: 10.1080/08869634.2018.1488652.

[15] Garbelotti TO, Turci AM, Serigato JMVA, Pizzol KEDC, Franco-Micheloni AL. Effectiveness of acupuncture for temporomandibular disorders and associated symptoms. Rev. dor. 2016;17(3):223-7.

[16] Connelly ST, Myung J, Gupta R, Tartaglia GM, Gizdulich A, Yang J, Silva R. Clinical outcomes of Botox injections for chronic temporomandibular disorders: do we understand how Botox works on muscle, pain, and the brain? Int J Oral Maxillofac Surg. 2017 Mar;46(3):322-327. DOI: 10.1016/j.ijom.2016.11.004.

[17] Johansson A, Omar R, Carlsson GE. Bruxism and prosthetic treatment: a critical review. J Prosthodont Res. 2011 Jul;55(3):127-36. DOI: 10.1016/j.jpor.2011.02.004.

[18] Ainoosah S, Farghal AE, Alzemei MS, et al. Comparative analysis of different types of occlusal splints for the management of sleep bruxism: a systematic review. BMC Oral Health. 2024 Jan 5;24(1):29. DOI: 10.1186/s12903-023-03782-6.

[19] Dowd ET. Nocturnal bruxism and hypnotherapy: a case study. Int J Clin Exp Hypn. 2013;61(2):205-18. DOI: 10.1080/00207144.2013.753832.

[20] Griffiths MJ. The role of hypnotherapy in evidence-based clinical practice. Oral Dis. 2017 May;23(4):420-423. DOI: 10.1111/odi.12532.

[21] Truelove E, Huggins KH, Mancl L, Dworkin SF. The efficacy of traditional, low-cost and nonsplint therapies for temporomandibular disorder: a randomized controlled trial. J Am Dent Assoc. 2006 Aug;137(8):1099-107; quiz 1169. DOI: 10.14219/jada.archive.2006.0348.

[22] Abrahamsen R, Zachariae R, Svensson P. Effect of hypnosis on oral function and psychological factors in temporomandibular disorders patients. J Oral Rehabil. 2009 Aug;36(8):556-70. DOI: 10.1111/j.1365-2842.2009.01974.x.

[23] Roark AL, Glaros AG, O'Mahony AM. Effects of interocclusal appliances on EMG activity during parafunctional tooth contact. J Oral Rehabil. 2003 Jun;30(6):573-7. DOI: 10.1046/j.1365-2842.2003.01139.x.

[24] Ram HK, Shah DN. Comparative evaluation of occlusal splint therapy and muscle energy technique in the management of temporomandibular disorders: A randomized controlled clinical trial. J Indian Prosthodont Soc. 2021 Oct-Dec;21(4):356-365. DOI: 10.4103/jips.jips_332_21.

[25] Silva JJ, Da Silva J, Souza LF, Sá-Caputo D, Cortez CM, Paineiras-Domingos LL, Bernardo-Filho M. Effectiveness of hypnosis on pain and anxiety in dentistry: Narrative review. Am J Clin Hypn. 2022 Oct;65(2):87-98. doi: 10.1080/00029157.2021.2005528.

[26] Simon EP, Lewis DM. Medical hypnosis for temporomandibular disorders: treatment efficacy and medical utilization outcome. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2000 Jul;90(1):54-63. DOI: 10.1067/moe.2000.106692.

[27] Dillworth T, Mendoza ME, Jensen MP. Neurophysiology of pain and hypnosis for chronic pain. Transl Behav Med. 2012 Mar;2(1):65-72. DOI: 10.1007/s13142-011-0084-5.

[28] Venkiteswaran A, Tandon S. Role of Hypnosis in Dental Treatment: A Narrative Review. J Int Soc Prev Community Dent. 2021 Apr 15;11(2):115-124. DOI: 10.4103/jispcd.JISPCD_320_20.

[29] Ommerborn MA, Schneider C, Giraki M, Schäfer R, Handschel J, Franz M, Raab WH. Effects of an occlusal splint compared with cognitive-behavioral treatment on sleep bruxism activity. Eur J Oral Sci. 2007 Feb;115(1):7-14. DOI: 10.1111/j.1600-0722.2007.00417.x.

[30] Rodrigues Garcia RC, Faot F, Cury AA. Effect of interocclusal appliance on masticatory performance of patients with bruxism. Cranio. 2005 Oct;23(4):264-8. DOI: 10.1179/crn.2005.037.

[31] Karakis D, Dogan A, Bek B. Evaluation of the effect of two different occlusal splints on maximum occlusal force in patients with sleep bruxism: a pilot study. J Adv Prosthodont. 2014 Apr;6(2):103-8. DOI: 10.4047/jap.2014.6.2.103.

[32] Gomes CAFP, El-Hage Y, Amaral AP, et al. Effects of Massage Therapy and Occlusal Splint Usage on Quality of Life and Pain in Individuals with Sleep Bruxism: A Randomized Controlled Trial. J Jpn Phys Ther Assoc. 2015;18(1):1-6. DOI: 10.1298/jjpta.Vol18_001.

[33] Amin A, Meshramkar R, Lekha K. Comparative evaluation of clinical performance of different kind of occlusal splint in management of myofascial pain. J Indian Prosthodont Soc. 2016 Apr-Jun;16(2):176-81. DOI: 10.4103/0972-4052.176521.

[34] Rosar JV, Barbosa TS, Dias IOV, Kobayashi FY, Costa YM, Gavião MBD, Bonjardim LR, Castelo PM. Effect of interocclusal appliance on bite force, sleep quality, salivary cortisol levels and signs and symptoms of temporomandibular dysfunction in adults with sleep bruxism. Arch Oral Biol. 2017 Oct;82:62-70. DOI: 10.1016/j.archoralbio.2017.05.018.

[35] Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ. 2010 Mar 23;340:c332. DOI: 10.1136/bmj.c332.

[36] Kunselman AR. A brief overview of pilot studies and their sample size justification. Fertil Steril. 2024 Jun;121(6):899-901. DOI: 10.1016/j.fertnstert.2024.01.040.

[37] Moore CG, Carter RE, Nietert PJ, Stewart PW. Recommendations for planning pilot studies in clinical and translational research. Clin Transl Sci. 2011 Oct;4(5):332-7. DOI: 10.1111/j.1752-8062.2011.00347.x.

[38] Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharmaceut. Statist. 2005; 4: 287-291. DOI: https://doi.org/10.1002/pst.185.

[39] Hyde S, Satariano WA, Weintraub JA. Welfare dental intervention improves employment and quality of life. J Dent Res. 2006 Jan;85(1):79-84. DOI: 10.1177/154405910608500114.

[40] Lipp MN, Lipp LMN. Proposal for a Four- Phase Stress Model. Psychology; 2019; 10:1435-1443.

[41] Okeson JP. Management of temporomandibular disorders and occlusion. 6th ed. St. Louis, MO: Elsevier/ Mosby; 2008. p. 468–497.

[42] Lima DG, Oliveira DWD, Oliveira ES, Gonçalves PF, Flecha OD. Stabilization splints in patients with Temporomandibular Disorders: report of two cases. Rev. Bras. Odontol. 2016; 73(3): 261-264. LINK: http://revodonto.bvsalud.org/pdf/rbo/v73n3/a16v73n3.pdf.

[43] Simon EP, Lewis DM. Medical hypnosis for temporomandibular disorders: treatment efficacy and medical utilization outcome. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2000 Jul;90(1):54-63. doi: 10.1067/moe.2000.106692.

[44] Manfredini D, Ahlberg J, Lobbezoo F. Bruxism definition: Past, present, and future - What should a prosthodontist know? J Prosthet Dent. 2022 Nov;128(5):905-912. DOI: 10.1016/j.prosdent.2021.01.026.

[45] McGuire MK, Nunn ME. Prognosis versus actual outcome. III. The effectiveness of clinical parameters in accurately predicting tooth survival. J Periodontol. 1996 Jul;67(7):666-74. DOI: 10.1902/jop.1996.67.7.666.

[46] Jiménez-Silva A, Peña-Durán C, Tobar-Reyes J, Frugone-Zambra R. Sleep and awake bruxism in adults and its relationship with temporomandibular disorders: A systematic review from 2003 to 2014. Acta Odontol Scand. 2017 Jan;75(1):36-58. DOI: 10.1080/00016357.2016.1247465.

[47] Solis ACO, Corchs F, Duran ÉP, Silva C, Del Real N, Araújo ÁC, Wang YP, Lotufo-Neto F. Self-reported bruxism in patients with post-traumatic stress disorder. Clin Oral Investig. 2024 Feb 16;28(2):152. DOI: 10.1007/s00784-024-05534-4.

[48] Sutinen S, Lahti S, Nuttall NM, et al. Effect of a 1-month vs. a 12-month reference period on responses to the 14-item Oral Health Impact Profile. Eur J Oral Sci. 2007 Jun;115(3):246-9. DOI: 10.1111/j.1600-0722.2007.00442.x.

[49] Zhang SH, He KX, Lin CJ, et al. Efficacy of occlusal splints in the treatment of temporomandibular disorders: a systematic review of randomized controlled trials. Acta Odontol Scand. 2020 Nov;78(8):580-589. DOI: 10.1080/00016357.2020.1759818.

[50] Al-Moraissi EA, Farea R, Qasem KA, Al-Wadeai MS, Al-Sabahi ME, Al-Iryani GM. Effectiveness of occlusal splint therapy in the management of temporomandibular disorders: network meta-analysis of randomized controlled trials. Int J Oral Maxillofac Surg. 2020 Aug;49(8):1042-1056. DOI: 10.1016/j.ijom.2020.01.004.

[51] Lobbezoo F, van der Glas HW, van Kampen FM, Bosman F. The effect of an occlusal stabilization splint and the mode of visual feedback on the activity balance between jaw-elevator muscles during isometric contraction. J Dent Res. 1993 May;72(5):876-82. DOI: 10.1177/00220345930720050801.

[52] Almeida FL, Silva AMT, Correa ECR, Busanello AR. Relation between pain and electric activity in the presence of bruxism. Rev. Cefac. 2011;13:399-406.

[53] Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA. Caution regarding the use of pilot studies to guide power calculations for study proposals. Arch Gen Psychiatry. 2006 May;63(5):484-9. DOI: 10.1001/archpsyc.63.5.484.

[54] Thabane L, Ma J, Chu R, Cheng J, et al. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010 Jan 6;10:1. DOI: 10.1186/1471-2288-10-1. Erratum in: BMC Med Res Methodol. 2023 Mar 11;23(1):59. DOI: 10.1186/s12874-023-01880-1.

[55] Wang P, Chow SC. Sample size re-estimation in clinical trials. Stat Med. 2021 Nov 30;40(27):6133-6149. DOI: 10.1002/sim.9175.

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