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ORIGINAL ARTICLE

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Quality of life assessment in patients with temporomandibular disorder with stabilization splints and home therapeutic exercises: a randomized clinical trial

Avaliação da qualidade de vida em pacientes com desordem temporomandibular com uso da placa estabilizadora e exercícios terapêuticos caseiros: um ensaio clínico randomizado

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ABSTRACT

Objective: The present study aimed to evaluate the quality of life in TMD patients with the use of Stabilization Splints (SSs) and Home Therapeutic Exercises (HTEs) guidance. **Material and Methods**: The study was a clinical, randomized, controlled, prospective, and interventional trial. The screening included dentate patients of both genders, diagnosed with TMD through the RDC/TMD questionnaire with no TMJ osteoarthritis and/or osteoarthrosis. To assess the quality of life, the Short-Form Health Survey (SF-36) questionnaire was applied to all patients (n=70), randomized into a test group with SS and a control group with HTE. The evaluations of both questionnaires were performed before and after the intervention of 12 weeks. **Results:** The comparisons between pre- and post-intervention intragroups were performed by the non-parametric Wilcoxon test with a 5% significance level. There was a frequency distribution of the responses to the 36 items of the SF-36 questionnaire and comparisons between times. In the test group, 49 patients received a SS and did HTEs. In the control group, 21 patients performed HTEs. In the statistical analysis, among the eight domains, three were identified with significant scores: pain, mental health, and vitality. **Conclusion:** It was found that there was an improvement in pain and quality of life after the treatment of TMD with a SS and HTE.

KEYWORDS

Clinical trial; Quality of life; Stabilization splint; Temporomandibular disorder; Therapeutic exercises.

RESUMO

Objetivo: O presente estudo teve como objetivo avaliar a qualidade de vida em pacientes com DTM com o uso de placas de estabilização (SSs) e orientação de exercícios terapêuticos domiciliares (HTEs). **Material e Métodos:** O estudo foi um ensaio clínico, randomizado, controlado, prospectivo e intervencionista. A triagem incluiu pacientes dentados de ambos os sexos, diagnosticados com DTM através do questionário RDC/TMD sem osteoartrite e/ou osteoartrose da ATM. Para avaliar a qualidade de vida, o questionário Short-Form Health Survey (SF-36) foi aplicado a todos os pacientes (n=70), randomizados em grupo teste com SS e grupo controle com HTE. As avaliações de ambos os questionários foram realizadas antes e após a intervenção de 12 semanas. **Resultados:** As comparações intragrupos pré e pós-intervenção foram realizadas pelo teste não paramétrico de Wilcoxon com nível de significância de 5%. Houve distribuição de frequência das respostas aos 36 itens do questionário SF-36 e comparações entre os tempos. No grupo controle, 21 pacientes realizaram HTEs. Na análise estatística, dentre

os oito domínios, três foram identificados com escores significativos: dor, saúde mental e vitalidade. Conclusão: Verificou-se que houve melhora da dor e da qualidade de vida após o tratamento da DTM com SS e HTE.

PALAVRAS-CHAVE

Ensaio Clínico; Qualidade de vida; Placa oclusal; Desordem temporomandibular; Exercícios terapêuticos.

INTRODUCTION

Temporomandibular disorders (TMDs) are a group of clinical conditions that affect the masticatory muscles, the temporomandibular joints, and the associated structures [1,2]. The common signs and symptoms of TMD include pain, joint sounds, limited mouth opening, and asymmetric jaw movement [3]. In addition to pain and dysfunction, TMDs have also been shown to reduce sleep quality [4,5], increase anxiety and lower the psychological stability of sufferers [6]. The etiology of TMDs is multifactorial with biomechanical, neuromuscular, biopsychosocial, and neurobiological factors contributing to the development of this disorder [7]. The 'biopsychosocial model,' which incorporates biological, psychological, social, and cultural aspects, has a role in the onset, maintenance, and exacerbation of TMDs [8], and it also supports the high occurrence of psychological distress and somatization among individuals with TMDs [9-11].

Previous studies with patient samples have pointed out that pain, functional limitations, and muscle tension associated with TMD may exacerbate physical, psychological, and social disabilities and lead to a substantial negative impact on the Oral Health-Related Quality of Life (OHRQoL) [11-21]. Hence, therapeutic TMD intervention requires an emphasis on pain management and maintaining good mental health [22,23], while targeting the improvement of quality of life assessments [20,24].

Clinicians and researchers emphasize the importance of providing conservative treatment first before introducing irreversible methods [24]. Stabilization Splints (SSs) are the most recommended non-invasive treatment method for TMD [1,25,26]. They provide an ideal centric relation occlusion which has been suggested to reduce abnormal muscle activity and contribute to the formation of so-called 'neuromuscular balance' in the masticatory system [27]. The systematic review by Fricton et al. [28], claimed that hard stabilization appliances when adjusted properly present good evidence of modest efficacy in the treatment of TMJ disorder pain when compared to non-occluding appliances and no treatment, and are, at least, equally effective in reducing TMJ disorder pain when compared to physical, behavioral therapies, and pharmacological treatments. Therefore, there is insufficient evidence either for or against the use of stabilization splint therapy over other active interventions for the treatment of temporomandibular myofascial pain [20,25,26,29], especially when analyzing RCT studies with standardized criteria for TMD assessment and intervention outcomes. Another conservative treatment option is exercise therapy, which is used to improve strength, mobility, coordination and reduce pain in the joints and muscles. Previous reviews have already analyzed the effectiveness of exercise therapy for the management of TMD due to improvements in local analgesia, muscle function, and restoration of local blood flow [30]. And yet, in the literature, there are inconclusive and controversial results regarding the effect of exercises and occlusal splint treatments on the OHRQoL perceived by the TMD patients [31]. More randomized controlled trials comparing the effects of each therapy need to be implemented [30].

For a painful condition such as TMD, the patient's point of view of well-being, known as the quality of life, is positive for the measurement of effectiveness. It has been shown that the OHRQoL provides more information regarding the impact of the oral condition or disease on a patient's everyday life and its quality when compared to clinical measures of disease or mere pain intensity. The present RCT aimed to evaluate the impact of SS therapy on the quality of life among TMD patients compared with Home Therapeutic Exercises.

MATERIAL AND METHODS

A single-blind, two parallel arms, randomized controlled clinical trial study was performed. The present research was approved by the

FOUSP Ethics Committee (protocol 200/10) and registered on ClinicalTrials.gov under the identifier NCT02251015 according to the Consort Extension Checklist for Non-Pharmacologic Treatments (Yap, Tan, Chua, & Tan, 2002).

Study population

The present study was performed at the Occlusion and TMJ Clinic and "Envelhecer Sorrindo" (Aging with a Smile) Program of the Department of Prosthodontics of the University of São Paulo Dental School.

Eligibility criteria

To be eligible for the study, patients should be dentate and have TMD, of both genders, 18 years of age and older. The criteria included TMD diagnosed through the RDC/TMD (Research Diagnostic Criteria/Temporomandibular Disorders) questionnaire, defined as Axis I diagnoses of myofascial pain, myofascial pain with limited opening, disk displacement with reduction, disk displacement without reduction with limited opening, disk displacement without reduction without limited opening, and arthralgia. The patient, to participate in the research, presented a recent (6 months) Magnetic Resonance Imaging (MRI) image exam of the TMJ to verify the type of alteration and complement the diagnosis of TMD and Orofacial Pain according to the RDC/TMD questionnaire. The RDC/TMD questionnaire was applied by a single trained and calibrated examiner. Excluded were those patients diagnosed with osteoarthritis and osteoarthrosis on the RDC/TMD; patients on continuous use of medications that could affect balance; patients with visual impairment (without corrections); neurological problems; diabetes accompanied by sensory neuropathies; labyrinthitis; history of TMJ surgery; and pregnancy.

Procedures

The first part of the study consisted of the screening period and anamnesis procedure which contained questions related to general health and medical-dental history. All participants brought their MRI of the TMJ and completed the RDC/TMD. According to the eligibility criteria, included patients diagnosed with TMD and Orofacial pain filled the quality of life questionnaire (SF-36). Subsequently, patients were randomized into a splint group and a control group to begin the intervention stage. The clinical intervention period involved the confection, fitting, and subsequent monitoring for adaptation of the occlusal splint. After 12 weeks, re-evaluation was performed using the SF-36 and RDC/TMD questionnaires.

The test group received a stabilizing occlusal splint and home therapeutic exercise guidelines. The patients wore the acetate and acrylic resin stabilizing occlusal splint according to the occlusal stability criteria. The occlusal appliance was made using a mixed technique under a 1.5 mm thick crystal acetate plate (Bioart®), made by vacuum in a plasticizer (Bioart®), and adapted in the patient's mouth after passive insertion of the plate over the upper arch. Next, the colorless acrylic resin was added to create a stability criteria in a physiologic maxillomandibular position of centric relation, simultaneous and punctiform bilateral contacts, lateral disocclusion guide by the canine on both sides and an anterior disocclusion guide by the anterior teeth. The occlusal splint was used throughout the night plus 4 hours during the day, mainly at times of teeth-clenching wakefulness bruxism [32]. The occlusal splint was adjusted until the patient felt it adapted, and it was used for 12 weeks [32-35].

The orientation of the Home Therapeutic Exercises was to encourage patients to place their jaw in a resting position for as long as possible during the day. At this position, the teeth are unclenched, approximately 2 mm apart, and the tip of the tongue is placed over the incisor papilla on the hard palate with the lips sealed. The patients were also instructed to perform 15 repetitions of opening and closing movements three times a day for 12 weeks, keeping their tongue on the instructed location during the exercises.

Questionnaires

RDC/TDM

The RDC/TMD (Research Diagnostic Criteria / Temporomandibular Disorders) questionnaire consists of a biaxial questionnaire, with Axis I represented by the clinical examination and Axis II corresponding to the psychosomatic evaluation [3,36]. For joint and muscle palpation, the examiner was calibrated to perform digital pressure according to the RDC/TMD guidelines

at 12 bilateral sites. The 1.0 kg pressure was applied to the temporalis muscle (anterior, medial, and posterior), and the masseter muscle (origin, body, and insertion) regions. The 0.5 kg pressure was applied to the submandibular region (medial pterygoid, suprahyoid, and anterior digastric region), the posterior mandibular region (stylohyoid and posterior digastric region), the TMJ lateral pole region, posterior ligament, lateral pterygoid muscle, and temporal muscle tendon.

SF-36

Quality of life was assessed by the Medical Outcome Study Short-Form 36 Health Survey (SF-36) [37] validated in Portuguese [38]. This questionnaire consists of 36 items, stratified into eight domains: Functional Capacity (10 items), Physical Aspects (4 items), Pain (2 items), General Health Status (5 items), Vitality (4 items), Social Aspects (2 items), Emotional Aspects (3 items) and Mental Health (5 items). The quantitative measures obtained according to the items generated the domain scores [39], which were calculated according to the functions proposed by the author of the questionnaire. The values vary from 0 to 100 and the higher the score, the better the quality of life indicator.

Sample calculation and statistical method

The sample size was based on a difference between groups of 0.5 for the primary outcome, with an estimated standard deviation of 0.7, power of 80%, and alpha of 5%. Considering these estimates, 25 subjects per group would be needed (total: 50 subjects). Considering the losses to follow-up, the inclusion of 70 subjects was planned.

Comparisons between pre- and post-intervention intra-groups were performed using the Wilcoxon's non-parametric test with a significance level of 5%. There was a distribution of frequencies of responses to the 36 items of the SF-36 questionnaire and comparisons between times. Categorical data were described by absolute (n) and relative (%) frequencies and continuous data by statistics of mean, standard deviation (SD), median, minimum (min), and maximum (max) values. The SPSS software (IBM SPSS Statistics for Windows, release 19.0. Armonk, NY: IBM Group), was used for the analyses.

RESULTS

The study began in July 2011, and the primary completion date was December 2011. A total of 70 patients diagnosed with TMD met the inclusion criteria of the present research. The final analysis of the SF-36 questionnaire, after the intervention, was performed for a total of 70 patients. Of this number, 49 were from the test group and 21 from the control group. The total number of patients who completed the survey had a female prevalence, with 77% of women and a mean age of 42.5 years.

The 36 items of the quality of life questionnaire led to the construction of 8 domain scores, which included: functional capacity, physical aspects, pain, general health status, vitality, social aspects, emotional aspects, and mental health. For the test group, among the eight domains, three of them (pain, vitality, and mental health domains), indicated improvement in quality of life after treatment, with a significant increase in their values. Table I describes the statistically significant measures of the quality of life domain scores and comparisons between the times, and Table II presents the results of frequency distribution for the statistically significant responses on the SF-36 and comparisons between times. Table II table shows the *p-value* for the comparisons before and after the intervention.

The items of the quality of life instrument that showed significant differences after treatment and contributed to the increase in the scores of the domains were: QV4 (Does your health now limit you in these activities? Moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf. If so, how much?), QV21 (How much bodily pain have you had during the past 4 weeks?), QV22 (During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework?), QV23 (How much of the time during the past 4 weeks did you feel energized?), and QV26 (How much of the time during the past 4 weeks have you felt calm and peaceful?). It was observed that the differences in items QV4, QV21, QV23, and QV26 occurred only in the test group. Meanwhile, item QV22 was observed in the total number of patients.

Table III showed that there was a significant difference between the times that indicated improvement after treatment according to the RDC/TMD diagnosis. A statistically significant

Table I - Descriptive statistics of scores and p-values of tests for comparison before (pre) and after (post) treatment of QOL scores

	Total							Control Group							Test Group					
	M	SD	Mdn	Q1	Q3	Min	Max	M	SD	Mdn	Q1	Q3	Min	Max	M	Mdn	Q1	Q3	Min	Max
V. Pre I. (%)	58.6	18.5	60	50	75	10	90	56.4	17.3	50	50	70	30	90	59.6	60	47.5	75	10	90
V. Post I(%)	62.7	19.2	65	50	76.3	20	100	59	15.4	60	50	67.5	35	95	64.3	70	47.5	80	20	100
p-value (between times):				***0.006***							0.176						***0.018***			
MH Pre I. **(%)**	66	17.9	68	55	81	16	100	65.9	17.7	68	48	80	36	92	66	64	56	82	16	100
MH Post I.(%)	69.3	17.9	72	60	84	20	100	68	15.8	68	56	80	36	96	69.8	72	62	86	20	100
p-value (between times):				***0.017***							0.258						***0.034***			
P. Pre I. **(%)**	62.8	24.3	61.5	41	84	10	100	64.1	25.1	72	46	84	22	100	62.2	61	41	84	10	100
P. Post I. **(%)**	69.4	24.7	72	51	100	22	100	66	20.8	72	51	79	31	100	70.9	74	46	100	22	100
p-value (between times):				***0.006***							0.959						***0.004***			

V: Vitality; MH: Mental Health; P: Pain; M: Mean; SD: Standard Deviation; Med: Median; Q1: 25th percentile; Q3: 75th percentile; Pre-I.: Pre-Intervention; Post I.: Post-Intervention; p-value (between times): Wilcoxon test.

difference was shown for myofascial pain in both groups and only for the test group in the diagnoses of disc displacement and arthralgia.

There was an improvement in the test group in relation to the opening pattern and the Range Of Movement (ROM), regarding the values in "mm" during the opening. There was an improvement in muscle and joint pain in maximum opening with and without assistance (Table IV).

DISCUSSION

In the literature, there is a consensus that temporomandibular disorder is a condition that compromises quality of life. Former analyses with patient samples have pointed out the negative impact of TMD on the quality of life (QoL) [13, 14,16, 17, 40, 41]. A recent study has claimed that the presence of TMJ pain appeared to impair the OHRQoL more than the severity of TMJ DJD (Degenerative Joint Disease) [18]. This is best explained by the biopsychosocial model of etiopathogenesis, whether TMD risk factors include alterations of mood, anxiety, depression, somatization, emotional stress, or catastrophizing, which go along with a genetic character (i.e., serotonin and dopamine receptors and monoamine oxidase expression), social functions (affective and cognitive equilibrium, sleep, and physical activities), and environmental aspects (everyday stress, lifestyle, cultural beliefs, and demographics). These may manifest with the OHRQoL in multiple ways.

It is noted that for the management of TMD, conservative methods are preferred since success rates from invasive treatment are not better [19,42]. An invasive approach - TMJ surgeries - varying from arthrocentesis to complex total joint replacements is considered only if patients fail to respond to conservative therapy [18]. In 2010, a systematic review [43] concluded that conservative treatment including exercise therapy, postural training, and occlusal appliances could effectively relieve TMD pain and increase jaw opening. Yet, there is a lack of agreement in studies regarding the efficacy of stabilization splint therapy and therapeutic exercises. Previous studies have provided inconclusive and controversial results. [41,44] These findings corroborate with two recent reviews [30,45], which proposed an analysis of the effectiveness of exercise therapy versus occlusal splint therapy for the treatment of painful temporomandibular disorders. It's been settled that there is a small number of reproducible and clear protocols in well-designed RCT studies, with overall standardized and validated measurements of clinical outcomes and high-quality evidence.

In the present study, the Stabilization Splint (SS) combined with Home Therapeutic Exercises (HTEs) guidance has been appointed as a significant therapeutic option for the improvement of life quality in TMD patients. The reflection on the quality of life (QoL) is a great measurement of assessing how a condition or disease affects the patient`s everyday life [46, 47], especially considering a scenario of chronic pain and with a fluctuant condition such as TMD, this is a

Table II - Frequency distribution of significant statistical responses on SF-36 items and comparisons between times

	Total (n=70)					Control Group (n=21)					Test Group (n=49)				
	Pre I.		Post I.			Pre I.		Post I.			Pre I.		Post I.		
	n	%	n	%	p- value*	n	%	n	%	p- value*	n	%	n	%	p value*
QV4					***0.02***					0.317					***0.033***
Yes, limited a lot	6	8.6	2	2.9		2	9.5	2	9.5		4	8.2	0	0.0	
Yes, limited a little	18	25.7	17	243		6	28.6	5	23.8		12	24.5	12	24.5	
No, not limited at all	46	65.7	51	72.9		13	61.9	14	66.7		33	67.3	37	75.5	
QV21					***<0.001***					0.942					***< 0.001***
None	12	17.1	22	31.4		4	19	4	19		8	16.3	18	36.7	
Very mild	12	17.1	15	21.4		4	19	4	19		8	16.3	11	22.4	
Mild	15	21.4	12	17.1		6	28.6	6	28.6		9	18.4	6	12.2	
Moderate	23	32.9	19	271		5	23.8	7	33.3		18	36.7	12	24.5	
Severe	7	10	2	2.9		2	9.5	0	0.0		5	10.2	2	4.1	
Vere severe	1	1.4	0	0		0	0.0	0	0.0		1	2	0	0,0	
QV22					***0.032***					0.068					0.162
Not at all	30	42.9	36	52.2		9	42.9	10	47.6		21	42.9	26	54.2	
A little bit	16	22.9	18	26.1		4	19	7	33.3		12	24.5	11	22,9	
Moderately	18	25.7	10	14.5		5	23.8	3	14.3		13	26.5	7	14.6	
Extremely	6	8.6	5	7.2		3	14.3	1	4.8		3	6.1	4	8.3	
QV23					***0.004***					1					***0.002***
All of the time	3	4.3	8	11.4		1	4.8	2	9.5		2	4.1	6	12.2	
Most of the time	23	32.9	24	34.3		9	42.9	7	33.3		14	28.6	17	34.7	
A good bit of the time	17	24.3	19	27.1		3	14.3	5	23.8		14	28.6	14	28.6	
Some of the time	17	24,3	12	17.1		6	28.6	4	19		11	22.4	8	16.3	
A little of the time	9	12.9	6	8.6		2	9.5	3	14.3		7	14.3	3	6.1	
None of the time	1	1.4	1	1.4		0	0.0	0	0.0		1	2	1	2	
QV26					***0.002***					0.129					***0.005***
All of the time	4	5.7	9	12.9		2	9.5	2	9.5		2	4.1	7	14.3	
Most of the time	17	24.3	19	27.1		4	19	4	19		13	26.5	15	30.6	
A good bit of the time	18	25.7	20	28.6		4	19	7	33.3		14	28.6	13	26.5	
Some of the time	16	22.9	15	21.4		9	42.9	8	38.1		7	14.3	7	14.3	
A little of the time	12	17.1	6	8.6		2	9.5	0	0.0		10	20.4	6	12.2	
None of the time	3	4.3	1	1.4		0	0.0	0	0.0		3	6.1	1	2	

Pre I.: Pre-Intervention; Post I.: Post-Intervention; p-value* (between times): Wilcoxon test.

Table III - P-values for between-time and between-group comparisons of TMD diagnostic measures

	Between times (W)			Between groups (MN)	
	Total	Control	Test	Pre I.	Post I.
Myofacial pain	***<0.001***	***0.046***	***<0.001***	0.147	***<0.001***
Right Side Disc Displacement	0.445	0.257	***0.007***	0.539	***0.004***
Left Side Disc Displacement	0.403	0.564	***0.058***	0.296	0.423
Right Side Arthralgia	***0.002***	1	***0.002***	0.992	***0.005***
Left Side Arthralgia	***0.004***	0.317	***<0.001***	0.243	***0.025***

W: Wilcoxon test; MN: Mann-Whitney test; Pre I.: Pre-Intervention; Post I.: Post-Intervention.

Table IV - P-values for between-time and between-group comparisons of TMD sign and symptom measures

	Between times (W)			Between groups (MN)	
	Total	Control	Test	Pre I.	Post I.
Opening pattern	***<0.001***	0.063	***<0.001***	0.568	***0.002***
Pain Free Opening (mm)	***<0.001***	0.095	***<0.001***	0.764	***<0.001***
Maximum Unassisted Opening	***<0.001***	0.082	***<0.001***	0.099	***0.,036***
Muscle Pain	***<0.001***	0.109	***0.002***	0.616	***0.001***
Joint Pain	***0.039***	0.066	***0.002***	0.155	***<0.001***
Maximum Assisted Opening (mm)	***<0.001***	0.106	***<0.001***	0.266	***0.009***
Muscular Pain	***<0.001***	0.317	***0.001***	0.986	***0.004***
Articular Pain	***0.003***	0.655	***0.003***	0.141	***0.269***

W: Wilcoxon test; MN: Mann-Whitney test; Pre I.: Pre-Intervention; Post I.: Post-Intervention.

relevant clinical measure to conclude the efficacy of SS+HTE intervention.

A similar RCT study was conducted by Kokkola et al. [31], and the results showed that SS+HTE treatment compared to HTE alone, was not more beneficial to self-perceived oral health-related quality of life among TMD patients over a 1-year follow-up. It is hypothesized that the result differences were mainly due to the SS time usage orientation. In the test group, patients were instructed to use the SS only during the night. In contrast to the present study, usage was orientated during nighttime and daytime (2 hours in the morning and 2 hours in the afternoon), according to Oliveira et al. [32]. It is believed that the instructional use of the SS therapy during the day is associated with changes in oral behaviors of teeth clenching in patients with waking bruxism, for example, in stressful situations or during physical activity. The stabilization splint provides benefits not only in protecting teeth clenching but it reproduces a position of neuromuscular balance and reorganization of motor unit recruitment. Furthermore, a sample controlled study [48] showed reduction of sleep bruxism by the use of a stabilizing plate in a short period, revealing that peripheral oral sensory input temporarily reduces sleep bruxism associated with cortical plasticity by adaptation of the oral condition in a short term. It is important to highlight the need for periodical adjustments of the appliance during the period of adaptation of the individual for a new splint because the intensity of contraction of the masseter muscle differs for everyone. Attention should also be paid to the period of re-evaluation of the use of the plate by patients in relation to the pre-established criteria [49].

It's recognized that while sleep bruxism is centrally mediated with a complex interaction of autonomic system function during sleep, awake bruxism is mainly related to psychosocial factors [50]. Another difference between both studies was the means of assessment of the Oral Health Impact Profile-14 (OHIP-14) questionnaire. According to a systematic review (Bitiniene et al. [40]), the two most utilized methods of assessment of the quality of life in TMD patients were the SF-36 and OHIP-14, which are short-form questionnaires, which are, therefore, very comfortable to use in everyday practice. The time evaluation period was successful in the Kokkola et al. [31] study. In assessing a complex context such as the quality of life, longer follow-up analyses would provide a more accurate measure

of how the intervention affects the patient's life. However, it's worth noticing that, over a longer period, more variables could interfere with the patient treatment context. Few long-term studies in the literature conducted the efficacy of a SS and, to our knowledge, just one of them analyze the quality of life outcome.

A strength of the present study was the standardization protocol confection of the stabilization splint parameters. In our perspective, the absence of well-designed stabilization splints, according to the ideal occlusal criteria, is the main reason for failures in splint intervention patients. This idea agrees with other authors' statements [25,29]. Likewise, other researchers have discussed the need for an appliance that provides a centric relation position (or as close as it can get, depending on the patient TMD stage), which has been suggested to reduce abnormal muscle activity and contribute to the formation of so-called 'neuromuscular balance' in the stomatognathic system [26,51]. Other potential factors that have been suggested are the increase of cognitive awareness or a peripheral input to the central nervous system [20]. In the present study, the splints were made by an experienced professional through the mixed technique, under a 1.5 mm thick crystal acetate plate frame. A transparent acrylic resin was added to create the stability criteria of a physiologic maxillomandibular position in centric relation, simultaneous bilateral and punctiform contacts, canine disocclusion guide on both sides, and anterior disocclusion guide by the anterior teeth. A key element of the present research was that the occlusal appliance needed to be adjusted until the patient felt it adapted. This could occur over several visits as the masticatory muscles relaxed into a consistent jaw relationship [28]. In the present study, starting from this maxillomandibular position, the patient was oriented to use the appliance for 12 weeks. Well designed and adjusted splints are the bottom line of clinical outcome success.

In the present research, the isolated Home Therapeutic Exercise (HTE) intervention did not show any improvement in the quality of life domains. However, the HTE therapy alone showed significant improvement on the diagnosis of myofascial pain by RDC/TMD. Previous reviews have investigated the effectiveness of exercise therapy for the treatment of TMD and emphasized the lack of high-quality evidence due to the divergence of nomenclature and well-established exercises protocols [44,45,52]. Herein, HTE aimed to make patients aware of the need to position their jaws rested for as long as possible during the day. In this position, the teeth are unclenched, approximately 2 mm apart, and the tip of the tongue should be placed over the incisor papilla with the lips sealed. In addition, patients were instructed to perform 15 repetitions three times a day for 12 weeks of repeated opening and closing movements, while keeping the tongue in the position instructed during the exercises. It is hypothesized that exercise programs are designed to improve muscular coordination, relax tense muscles, and increase Range of Motion (ROM), and muscular strength. In addition, it reduces the mechanical stress on the TMJ and the contraction of the facial muscles. When considering a highly complex and connected device such as the Stomatognathic System, when something is out of range, the system tries to adapt and, sometimes, the muscles are over-required. For this reason, especially when a collapse situation on the TMJ complex is evident, techniques for re-education and rehabilitation of the masticatory muscles are useful. Clinical and study-based outcomes have confirmed the effectiveness of therapeutic exercise modalities for the management of TMD due to improvements in local analgesia, muscle function, and restoration of local blood flow [53]. McNeely et al. [54] have pointed out that passive and active stretching of muscles or range-of-motion exercises are performed to increase oral opening and decrease pain. In addition, postural exercises are also recommended to restore or optimize the alignment of the craniomandibular system. Following the same path, Armijo-Olivo et al. [44], realized that manual therapy has been used to restore normal ROM, reduce local ischemia, stimulate proprioception, break fibrous adhesions, stimulate synovial fluid production, and reduce pain. In the present study, statistically significant difference was shown only when the Home Therapeutic Exercise Therapy was associated with the Stabilization Splint. Whereas an improvement in ROM measures was demonstrated: "mm" during opening, opening pattern, muscle, and joint pain in maximum opening with and without assistance.

For the TMD diagnosis, the RDC/TMD questionnaires were applied. In TMD studies, RDC/TMD and DC/TMD are the most contemporary

gold-standard instruments of evaluation. By the time the present study was projected, the DC/TMD wasn't available in Brazilian Portuguese, which excluded the possibility of using the most recent diagnostic criteria tool available in the present research. The usage of contemporary diagnostic criteria tools is fundamental in research to allow classification, taxonomy, and nomenclature, especially for further validation by analysis reviews. [2,14]. Likewise, to assess the quality of life, the validated Brazilian Portuguese translated SF-36 questionnaire was applied. For the present study, the authors have chosen the non-disease-specific SF-36 due to the mental and psychological health approach [16] on a pain perspective due to the importance of the biopsychosocial model on TMD etiopathogenesis. TMD is a painful condition that can be acute or chronic. The association with related comorbidities can further disturb the biopsychosocial aspect. Intervention reflection on the quality of life is an important measure of the treatment evolution process. Therefore, the use of these two validated tools (SF-36 and RDC/TMD), were strengths for the present research.

A possible limitation in most of the TMD intervention RCT studies observed in the literature is probably due to the lack of multidisciplinary treatment, excluding the biopsychosocial character of TMD [8-11]. Since the psychological domains were featured prominently in the TMD etiopathogeneses, a careful psychosocial approach would be necessary for the management of patients with TMD. This could include supportive psychotherapy, cognitive behavioral therapy, interpersonal therapy, counseling, and wellness programs. Psychosocial interventions have been shown to reduce both psychological and physical symptoms, increase coping, enhance the quality of life and improve function [18]. Likewise, in the present study, associated comorbidities were not identified. Temporomandibular disorder, when in a chronic condition, is often embedded in a bigger scenario of central sensitization. Thus, there is a high chance of the existence of associated comorbidities, and if not well treated and identified, could potentially worsen the TMD condition. This knowledge substantiates recent findings [52], which noted that the presence of widespread pain, before treatment initiation in TMD patients was related to a worse response to conventional TMD treatment.

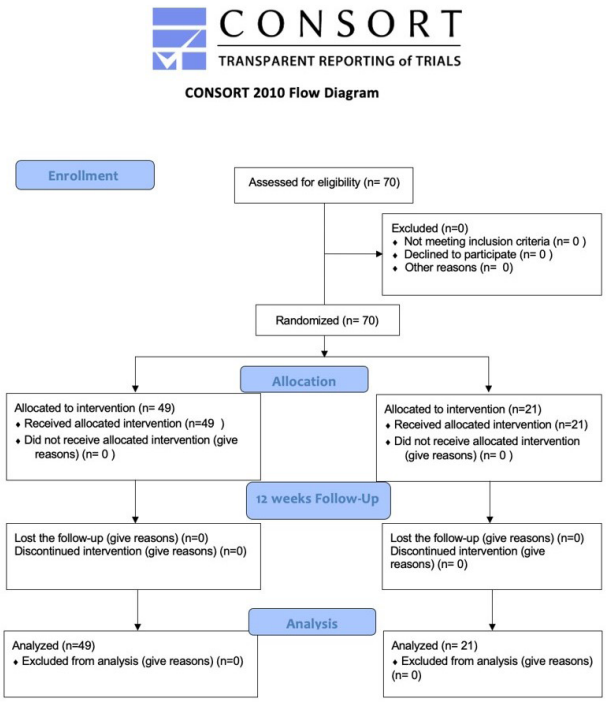

Figure 1 - CONSORT flow diagram.

A suggestion for future studies, in the absence of a multimodal treatment approach, is at least tracking the possible associated comorbidities.

CONCLUSION

It was concluded that there was an improvement in pain and quality of life after treatment of temporomandibular disorder with a stabilization splint and home therapeutic exercises.

Author's Contributions

SSIO: Investigation and writing and reading. JIO: Writing and reading. MLMAF: Research advisor and methodology. DCL: Research advisor and methodology.

Conflict of Interest

The authors declare that there is no affiliation or any other conflict of interest. Implementation of the present study happened without any financial industrial support. There were no financial relationships between any of the authors and the manufacturers of products involved in the study.

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Regulatory Statement

The manuscript was prepared according to the Consort Extension Checklist for Non-Pharmacologic Treatments. This research was approved by the ethics committee of FOUSP (protocol 200/10) and registered at **ClinicalTrials.gov** under identifier NCT2251015.

Clinical Trials

The present study is available at https://clinicaltrials.gov/, registered under ClinicalTrials.gov Identifier NCT 02251015. CONSORT transparent reporting of trials by CONSORT flow diagram in Figure 1.

REFERENCES

1. Okeson JP. Management of temporomandibular disorders and occlusion. USA: Elsevier Health Sciences; 2019.
2. Yap AU, Cao Y, Zhang MJ, Lei J, Fu KY. Number and type of temporomandibular disorder symptoms: their associations with psychological distress and oral health-related quality of life. Oral Surg Oral Med Oral Pathol Oral Radiol. 2021;132(3):288-96. http://dx.doi.org/10.1016/j.oooo.2021.04.059. PMid:34144943.
3. Dworkin SF, LeResche L. Research diagnostic criteria for temporomandibular disorders: review, criteria, examinations and specifications, critique. J Craniomandib Disord. 1992;6(4):301-55. PMid:1298767.
4. Oliveira LK, Almeida GA, Lelis ÉR, Tavares M, Fernandes Neto AJ. Temporomandibular disorder and anxiety, quality of sleep, and quality of life in nursing professionals. Braz Oral Res. 2015;29(1):29. http://dx.doi.org/10.1590/1807-3107BOR-2015.vol29.0070. PMid:26039910.
5. Lei J, Liu MQ, Yap AU, Fu KY. Sleep disturbance and psychologic distress: prevalence and risk indicators for temporomandibular disorders in a Chinese population. J Oral Facial Pain Headache. 2015;29(1):24-30. http://dx.doi.org/10.11607/ofph.1301. PMid:25635957.
6. Panteleev VD, Zagorko MV, Filippchenkova SI, Vlasenko N I.u. Psychological status assessment in patients with TMJ malfunctions]. Stomatologia (Mosk). 2014;93(1):34-6.
7. Chisnoiu AM, Picos AM, Popa S, Chisnoiu PD, Lascu L, Picos A, et al. Factors involved in the etiology of temporomandibular disorders - a literature review. Clujul Med. 2015;88(4):473-8. PMid:26732121.
8. Fillingim RB, Ohrbach R, Greenspan JD, Knott C, Diatchenko L, Dubner R, et al. Psychological factors associated with development of TMD: the OPPERA prospective cohort study. J Pain. 2013;14(12, Suppl):T75-90. http://dx.doi.org/10.1016/j.jpain.2013.06.009. PMid:24275225.
9. De La Torre Canales G, Câmara-Souza MB, Muñoz Lora VRM, Guarda-Nardini L, Conti PCR, Rodrigues Garcia RM, et al. Prevalence of psychosocial impairment in temporomandibular disorder patients: A systematic review. J Oral Rehabil. 2018;45(11):881-9. http://dx.doi.org/10.1111/joor.12685. PMid:29972707.
10. Florjański W, Orzeszek S. Role of mental state in temporomandibular disorders: a review of the literature. Dent Med Probl. 2021;58(1):127-33. http://dx.doi.org/10.17219/dmp/132978. PMid:33754501.
11. Lei J, Yap AU, Zhang M, Fu KY. Temporomandibular disorder subtypes, emotional distress, impaired sleep, and oral health-related quality of life in Asian patients. Community Dent Oral Epidemiol. 2021;49(6):543-9. http://dx.doi.org/10.1111/cdoe.12643. PMid:33829540.
12. Song YL, Yap AU. Impact of pain-related temporomandibular disorders on jaw functional limitation, psychological distress and quality of life in postoperative class III East Asian patients. Clin Oral Investig. 2020;24(2):953-61. http://dx.doi.org/10.1007/s00784-019-02994-x. PMid:31273526.
13. Almoznino G, Zini A, Zakuto A, Sharav Y, Haviv Y, Hadad A, et al. Oral health-related quality of life in patients with temporomandibular disorders. J Oral Facial Pain Headache. 2015;29(3):231-41. http://dx.doi.org/10.11607/ofph.1413. PMid:26244431.
14. Dahlström L, Carlsson GE. Temporomandibular disorders and oral health-related quality of life. A systematic review. Acta Odontol Scand. 2010;68(2):80-5. http://dx.doi.org/10.3109/00016350903431118. PMid:20141363.
15. Schiffman E, Ohrbach R, Truelove E, Look J, Anderson G, Goulet JP, et al. Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) for Clinical and Research Applications: recommendations of the International RDC/TMD Consortium Network* and Orofacial Pain Special Interest Group†. J Oral Facial Pain Headache. 2014;28(1):6-27. http://dx.doi.org/10.11607/jop.1151. PMid:24482784.
16. Pigozzi LB, Pereira DD, Pattussi MP, Moret-Tatay C, Irigaray TQ, Weber JBB, et al. Quality of life in young and middle age adult temporomandibular disorders patients and asymptomatic subjects: a systematic review and meta-analysis. Health Qual Life Outcomes. 2021;19(1):83. http://dx.doi.org/10.1186/s12955-021-01727-7. PMid:33691709.
17. Bayat M, Abbasi AJ, Noorbala AA, Mohebbi SZ, Moharrami M, Yekaninejad MS. Oral health-related quality of life in patients with temporomandibular disorders: A case-control study considering psychological aspects. Int J Dent Hyg. 2018;16(1):165-70. http://dx.doi.org/10.1111/idh.12266. PMid:28116859.
18. Yap AU, Zhang XH, Cao Y, Fu KY. Functional, physical and psychosocial impact of degenerative temporomandibular joint disease. J Oral Rehabil. 2022;49(3):301-8. http://dx.doi.org/10.1111/joor.13288. PMid:34862971.
19. Derwich M, Gottesman L, Urbanska K, Pawlowska E. Craniovertebral and craniomandibular changes in patients with temporomandibular joint disorders after physiotherapy combined with occlusal splint therapy: a prospective case control study. Medicina (Kaunas). 2022;58(5) PMid:35630101.
20. Alajbeg IZ, Gikić M, Valentić-Peruzović M. Changes in pain intensity and oral health-related quality of life in patients with temporomandibular disorders during stabilization splint therapy--a pilot study. Acta Clin Croat. 2014;53(1):7-16. PMid:24974661.
21. de Lima CO, Miranda JS, Caetano PL, Malta NV, Leite IG, Leite FPP. Evaluation of the life quality in patients with Temporomandibular Disorders. Braz Dent Sci. 2015;18(3):77-83. http://dx.doi.org/10.14295/bds.2015.v18i3.1144.

22. Dos Santos Aguiar A, Bataglion C, Felício LR, Azevedo B, Chaves TC. Additional effect of pain neuroscience education to craniocervical manual therapy and exercises for pain intensity and disability in temporomandibular disorders: a study protocol for a randomized controlled trial. Trials. 2021;22(1):596. http://dx.doi.org/10.1186/s13063-021-05532-x. PMid:34488856.

23. Oliveira SSI, Gonçalves SLM, Weig KM, Magalhães TR Fo, Martinez OER, Cunha Kalil MTA, et al.,Temporomandibular disorders:Guidelines and Self-Care for Patients During COVID-19 Pandemic. Braz Dent Sci,2020;23(2, suppl 2):1-8.

24. Song YL, Yap AU. Outcomes of therapeutic TMD interventions on oral health related quality of life: A qualitative systematic review. Quintessence Int. 2018;49(6):487-96. PMid:29700502.

25. Vrbanović E, Alajbeg IZ. Long-term effectiveness of occlusal splint therapy compared to placebo in patients with chronic temporomandibular disorders. Acta Stomatol Croat. 2019;53(3):195-206. http://dx.doi.org/10.15644/asc53/3/1. PMid:31749451.

26. Al-Ani Z, Gray RJ, Davies SJ, Sloan P, Glenny AM. Stabilization splint therapy for the treatment of temporomandibular myofascial pain: a systematic review. J Dent Educ. 2005;69(11):1242-50. http://dx.doi.org/10.1002/j.0022-0337.2005.69.11.tb04023.x. PMid:16275687.

27. Niemelä K, Korpela M, Raustia A, Ylöstalo P, Sipilä K. Efficacy of stabilisation splint treatment on temporomandibular disorders. J Oral Rehabil. 2012;39(11):799-804. http://dx.doi.org/10.1111/j.1365-2842.2012.02335.x. PMid:22809314.

28. Fricton J, Look JO, Wright E, Alencar FG Jr, Chen H, Lang M, et al. Systematic review and meta-analysis of randomized controlled trials evaluating intraoral orthopedic appliances for temporomandibular disorders. J Orofac Pain. 2010;24(3):237-54. PMid:20664825.

29. Ebrahim S, Montoya L, Busse JW, Carrasco-Labra A, Guyatt GH, Medically Unexplained Syndromes Research Group. The effectiveness of splint therapy in patients with temporomandibular disorders: a systematic review and meta-analysis. J Am Dent Assoc. 2012;143(8):847-57. http://dx.doi.org/10.14219/jada.archive.2012.0289. PMid:22855899.

30. Zhang Y, Lu JF, Zhang QB. Clinical study of modified posterior dental splint in the treatment of anterior disk displacement without reduction of the temporomandibular joint. Shanghai Kou Qiang Yi Xue. 2021;30(2):210-3. PMid:34109365.

31. Kokkola O, Suominen AL, Qvintus V, Myllykangas R, Lahti S, Tolvanen M, et al. Efficacy of stabilisation splint treatment on the oral health-related quality of life-A randomised controlled one-year follow-up trial. J Oral Rehabil. 2018;45(5):355-62. http://dx.doi.org/10.1111/joor.12622. PMid:29512838.

32. Oliveira SSI, Pannuti CM, Paranhos KS, Tanganeli JPC, Laganá DC, Sesma N, et al. Effect of occlusal splint and therapeutic exercises on postural balance of patients with signs and symptoms of temporomandibular disorder. Clin Exp Dent Res. 2019;5(2):109-15. http://dx.doi.org/10.1002/cre2.136. PMid:31049212.

33. De Nordenflycht D, Salinas J, Armstrong L. Thermoformed occlusal splints for the treatment of masticatory muscle pain: a clinical trial. Braz Dent Sci. 2022;25(3):e3401. http://dx.doi.org/10.4322/bds.2022.e3401.

34. 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;137(8):1099-107, quiz 1169. http://dx.doi.org/10.14219/jada.archive.2006.0348. PMid:16873325.

35. Ekberg E, Vallon D, Nilner M. The efficacy of appliance therapy in patients with temporomandibular disorders of mainly myogenous origin. A randomized, controlled, short-term trial. J Orofac Pain. 2003;17(2):133-9. PMid:12836501.

36. Schiffman EL, Truelove EL, Ohrbach R, Anderson GC, John MT, List T, et al. The Research Diagnostic Criteria for Temporomandibular Disorders. I: overview and methodology for assessment of validity. J Orofac Pain. 2010;24(1):7-24. PMid:20213028.

37. Eshaghi S-R, Arash Rame M, Shahsanaee A, Pooya A. Validity and reliability of the Short Form-36 Items questionnaire as a measure of quality of life in elderly Iranian population. Am J Appl Sci. 2006;3(3):1763-6. http://dx.doi.org/10.3844/ajassp.2006.1763.1766.

38. Ciconelli R, et al. Brazilian-Portuguese version of the SF-36. A reliable and valid quality of life outcome measure. Rev Bras Reumatol. 1999;39:143-50.

39. Pereira JCR. Análise de dados qualitativos: estratégias metodológicas para as ciências da saúde humanas e sociais. São Paulo: Edusp; 1999.

40. Bitiniene D, Zamaliauskiene R, Kubilius R, Leketas M, Gailius T, Smirnovaite K. Quality of life in patients with temporomandibular disorders. A systematic review. Stomatologija. 2018;20(1):3-9. PMid:29806652.

41. Inglehart MR, Widmalm SE, Syriac PJ. Occlusal splints and quality of life - does the patient-provider relationship matter? Oral Health Prev Dent. 2014;12(3):249-58. PMid:24914428.

42. Stohler CS, Zarb GA. On the management of temporomandibular disorders: a plea for a low-tech, high-prudence therapeutic approach. J Orofac Pain. 1999;13(4):255-61. PMid:10823039.

43. List T, Axelsson S. Management of TMD: evidence from systematic reviews and meta-analyses. J Oral Rehabil. 2010;37(6):430-51. http://dx.doi.org/10.1111/j.1365-2842.2010.02089.x. PMid:20438615.

44. 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;96(1):9-25. http://dx.doi.org/10.2522/ptj.20140548. PMid:26294683.

45. Eliassen M, Hjortsjö C, Olsen-Bergem H, Bjørnland T. Self-exercise programmes and occlusal splints in the treatment of TMD-related myalgia-Evidence-based medicine? J Oral Rehabil. 2019;46(11):1088-94. http://dx.doi.org/10.1111/joor.12856. PMid:31286551.

46. Moufti MA, Wassell RW, Meechan JG, Allen PF, John MT, Steele JG. The Oral Health Impact Profile: ranking of items for temporomandibular disorders. Eur J Oral Sci. 2011;119(2):169-74. http://dx.doi.org/10.1111/j.1600-0722.2011.00809.x. PMid:21410558.

47. Allen PF. Assessment of oral health related quality of life. Health Qual Life Outcomes. 2003;1(1):40. http://dx.doi.org/10.1186/1477-7525-1-40. PMid:14514355.

48. Harada T, Ichiki R, Tsukiyama Y, Koyano K. The effect of oral splint devices on sleep bruxism: a 6-week observation with an ambulatory electromyographic recording device. J Oral Rehabil. 2006;33(7):482-8. http://dx.doi.org/10.1111/j.1365-2842.2005.01576.x. PMid:16774505.

49. Abe S, Huynh NT, Kato T, Rompré PH, Landry-Schönbeck A, Landry ML, et al. Oral appliances reduce masticatory muscle activity-sleep bruxism metrics independently of changes in heart rate variability. Clin Oral Investig. 2022;26(9): 5653-62. http://dx.doi.org/10.1007/s00784-022-04520-y. PMid:35538329.

50. Manfredini D, Colonna A, Bracci A, Lobbezoo F. Bruxism: a summary of current knowledge on aetiology, assessment and management. Oral Surg. 2020;13(4):358-70. http://dx.doi.org/10.1111/ors.12454.

51. Gray RJ, Davies SJ. Occlusal splints and temporomandibular disorders: why, when, how? Dent Update. 2001;28(4):194-9. http://dx.doi.org/10.12968/denu.2001.28.4.194. PMid:11476035.

52. La Touche R, Boo-Mallo T, Zarzosa-Rodríguez J, Paris-Alemany A, Cuenca-Martínez F, Suso-Martí L. Manual therapy and exercise in temporomandibular joint disc displacement without reduction. A systematic review. Cranio. 2022;40(5):440-50. http://dx.doi.org/10.1080/08869634.2020.1776529. PMid:32589520.

53. Dostalová T, Hlinakova P, Kasparova M, Rehacek A, Vavrickova L, Navrátil L. Effectiveness of physiotherapy and GaAlAs laser in the management of temporomandibular joint disorders. Photomed Laser Surg. 2012;30(5):275-80. http://dx.doi.org/10.1089/pho.2011.3171. PMid:22551049.

54. McNeely ML, Armijo Olivo S, Magee DJ. A systematic review of the effectiveness of physical therapy interventions for temporomandibular disorders. Phys Ther. 2006;86(5):710-25. http://dx.doi.org/10.1093/ptj/86.5.710. PMid:16649894.

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