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FUNCIONAL

Ariany Klein Tahara

**EFEITOS DE 8 SEMANAS DE EXERCÍCIOS ISOMÉTRICOS DE
RESISTÊNCIA MUSCULAR À FADIGA NO TRATAMENTO DA DISFUNÇÃO
TEMPOROMANDIBULAR EM MULHERES POR MEIO DE BIOFEEDBACK:
ENSAIO CLÍNICO RANDOMIZADO**

Juiz de Fora

2019

Ariany Klein Tahara

Efeitos de 8 semanas de exercícios isométricos de resistência muscular à fadiga no tratamento da disfunção temporomandibular em mulheres por meio de biofeedback: ensaio clínico randomizado

Dissertação apresentada ao Programa de Pós-graduação Mestrado em Ciências da Reabilitação e Desempenho Físico-Funcional da Universidade Federal de Juiz de Fora como requisito para obtenção do título de Mestre em Ciências da Reabilitação e Desempenho Físico-

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RESUMO

INTRODUÇÃO: Alterações na articulação, na musculatura e em ossos da região temporomandibular caracterizam as chamadas desordens temporomandibulares (DTM), sendo apontada como segunda causa mais frequente de dor orofacial no mundo. Ainda desconhecida a fisiopatologia e com etiologia multifatorial (fatores funcionais, estruturais e psicológicos), acomete mais o sexo feminino e apresenta como sintomas mais comuns limitação ou assimetria mandibular, sons articulares, dores de ouvido, cabeça e na região cervical. Portadores desses sintomas possuem a extração do oxigênio muscular diminuída, fadigando precocemente e tornando menos eficiente a musculatura mastigatória. Para tratar tais desordens, exercícios eram utilizados associados a outras terapias, entretanto ainda não havia estudos que padronizassem um protocolo unicamente de exercícios de resistência à fadiga. **OBJETIVO:** Avaliar a eficácia de um protocolo de 08 semanas de exercícios de resistência muscular à fadiga referente a excitação muscular, força de resposta, dor percebida e eficiência muscular. **MÉTODOS:** Estudo clínico randomizado com 46 mulheres diagnosticadas pelo Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) com DTM miogênica que foram divididas randomicamente em grupo experimental (n=23) e grupo controle (n=23). O grupo experimental realizou protocolo de exercícios de resistência controlado por biofeedback. O grupo controle recebeu placebo via laserterapia com aparelho desligado. Foi realizada avaliação inicial, com 04 semanas e ao final da semana 08, que analisou dor por algometria de pressão e escala visual analógica de dor, atividade muscular por eletromiografia de superfície e força de mordida pela sincronização da célula de carga à eletromiografia dos músculos masseter e temporal anterior, bilateralmente. O modelo linear geral de Análise Multivariada de Variância (MANOVA) com medidas repetidas foi usado para classificar diferenças intra e entre grupos e levando em consideração múltiplas variáveis dependentes contínuas, com significância estabelecida em $p < 0,05$. **RESULTADOS:** o grupo experimental apresentou maiores tempo até a fadiga e eficiência muscular intra e entre grupos e maior excitação em temporal anterior na 8ª semana comparada a avaliação inicial, porém sem diferença entre os grupos. Força de mordida aumentou no grupo controle entre a 4ª e 8ª semanas, porém sem diferença entre os grupos. Houve diminuição de dor nos dois grupos, com menores scores no grupo experimental ao final da semana 8. Não houve diferença significativa nos valores das algometria de pressão, apesar de aumentada nos dois grupos ao longo do tempo. **CONCLUSÃO:** O protocolo de 08 semanas de exercícios de resistência aumenta o tempo até a fadiga, aprimora a eficiência muscular e alivia a dor em portadores de DTM.

Palavras-chaves: desordens temporomandibulares, dor orofacial, exercícios terapêuticos, treino de resistência, força de mordida, eletromiografia

ABSTRACT

BACKGROUND: Changes in the temporomandibular joint, muscles and bones characterize the so-called temporomandibular disorders (TMD), being pointed out as the second most frequent cause of orofacial pain in the world. The pathophysiology and multifactorial etiology (functional, structural and psychological factors) are still unknown, affecting frequently women and presenting as the most common symptoms limitation or mandibular asymmetry, joint sounds, ear, head or neck pain. Patients with these symptoms have decreased muscle oxygen extraction, early fatigue and less effective masticatory muscles. To treat such disorders, exercises were used in combination with other modalities of treatment. However there were no studies that standardized a protocol solely on fatigue resistance exercises.

OBJECTIVE: To assess the efficacy of 8-week protocol of endurance exercises on muscle excitation, force response, perceived pain and over muscle efficiency.

METHODS: Randomized clinical trial with 46 women diagnosed by RDC/TMD with TMD myogenic were divided into experimental group (n = 23) and control group (n = 23). The experimental group received a protocol of endurance exercises controlled by biofeedback. The control group received placebo by laser therapy with device turned off. Evaluations were on baseline, at 4 weeks and at the end of the eighth week, which measured the pressure pain threshold and visual analog scale of pain, muscle activity by surface electromyographic and bite force by a load cell synchronized with electromyograph of the anterior temporal and masseter muscles, bilaterally. The general linear multivariate analysis of variance (MANOVA) model with repeated measures was used to classify within- and between subjects variables, with significance set at $p < 0.05$.

RESULTS: The experimental group had longer time until fatigue, more efficiency within- and between groups and greater anterior temporal arousal at week 8 compared to the baseline evaluation, but without differences between groups. Bite force increased in control group between the 4th and 8th weeks, but no difference between groups. There was a decrease in pain for both groups, with lower scores in the experimental group at the end of week 8. There was no significant difference in pressure pain threshold, although increased in both groups over time.

CONCLUSION: An 8-week endurance exercise protocol improve time until fatigue and muscle efficiency, as well as relieving the pain in TMD subjects.

Keywords: exercise therapy; resistance training; temporomandibular joint disorders; facial pain; bite force; electromyography.

LISTA DE FIGURAS

FIGURA 1 -	Fluxograma.....	24
FIGURA 2 -	Adaptação para algometria de pressão com dispositivo puntiforme conectado à célula de carga e esta conectada ao eletromiógrafo.....	27
FIGURA 3 -	Adaptação à célula de carga para teste de mordida com as extensões de aço inox nas extremidades superior e inferior fixadas na célula de carga e posicionamento das extensões nas arcadas dentárias.....	30

LISTA DE TABELAS

TABELA 1 -	Protocolo de resistência muscular à fadiga utilizando biofeedback.....	31
TABELA 2 -	Variáveis com diferenças significativamente estatísticas.....	63

LISTA DE GRÁFICOS

GRÁFICO 1 -	Dor pela Escala Visual Analógica em função do tempo.....	64
GRÁFICO 2 -	Tempo até a fadiga em função dos momentos de avaliação...	64
GRÁFICO 3 -	Eficiência muscular ao longo do tempo.....	64

LISTA DE SIGLAS E ABREVIATURAS

Ag/AgCl – Prata / Cloreto de Prata

ATM – Articulação temporomandibular

ATP – Adenosina trifosfato

CIVM - Contração isométrica voluntária máxima

cm – Centímetro

CNS – Conselho Nacional de Saúde

dB – Decibel

DC/TMD – Diagnostic Criteria for Temporomandibular Disorders

DOF – Dor orofacial

DTM – Disfunções temporomandibulares

EVA – Escala visual analógica de dor

GC - Grupo controle

GE - Grupo experimental

Hz – Hertz

ICC – Coeficiente de correlação intraclasse

kg / cm² - Quilograma por centímetro quadrado

kg / s – Quilograma por segundo

KGF – Quilograma-força

kHz – Quilohertz

LDP – Limiar doloroso de pressão

MFIQ - Questionário e Índice de Limitação Funcional Mandibular

mRNA – Ácido ribonucleico mensageiro

ms – Milissegundos

μV – Microvolt

Ω – Ohm

RDC/TMD - Research Diagnostic Criteria for Temporomandibular Disorders

RMF – Resistência muscular à fadiga

sEMG – Eletromiografia de superfície

SENIAM - Surface EMG for Non-Invasive Assessment of Muscles

s – Segundos

SUMÁRIO

1	INTRODUÇÃO.....	15
2	OBJETIVOS.....	21
2.1	OBJETIVO PRIMÁRIO.....	21
2.2	OBJETIVO SECUNDÁRIO.....	21
3	HIPÓTESE.....	22
4	MATERIAIS E MÉTODOS.....	23
4.1	DESENHO DE ESTUDO.....	23
4.2	CÁLCULO AMOSTRAL.....	23
4.3	AMOSTRA.....	23
4.4	CRITÉRIOS DE INCLUSÃO.....	25
4.5	CRITÉRIOS DE EXCLUSÃO.....	25
4.6	INSTRUMENTOS DE AVALIAÇÃO.....	25
4.6.1	Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD).....	25
4.6.2	Escala Visual Analógica de dor (EVA).....	26
4.6.3	Limiar pressórico de dor por algometria de pressão.....	27
4.6.4	Questionário e Índice de Limitação Funcional Mandibular (MFIQ).....	28
4.6.5	Eletromiografia de superfície sincronizada à dinamometria por célula de carga.....	28
4.7	RISCOS.....	32
4.8	BENEFÍCIOS.....	32
4.9	EXTRAÇÃO DE DADOS.....	32
4.10	METODOLOGIA DE ANÁLISE DE DADOS.....	33
5	RESULTADOS.....	34
6	CONSIDERAÇÕES FINAIS.....	65
7	REFERÊNCIAS BIBLIOGRÁFICAS.....	66
	APÊNDICES.....	71
	APÊNDICE 1 – PARECER DE INFRAESTRUTURA E CONCORDÂNCIA PARA REALIZAÇÃO DA PESQUISA.....	71
	APÊNDICE 2 – TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO.....	72
	ANEXOS.....	74

ANEXO 1 – PARECER CNS.....	74
ANEXO 2 – RDC/TMD- EIXO 1.....	75
ANEXO 3 – EVA.....	78
ANEXO 4 – MFIQ.....	79
ANEXO 5 – ARTIGO PUBLICADO.....	80

1 – INTRODUÇÃO

A dor orofacial (DOF) é caracterizada pela presença de dores na cavidade oral e na face associadas a tecidos moles, dentes, articulações e pele, podendo se estender para região de pescoço e cabeça, provocando cervicalgias ou cefaléias. O diagnóstico de DOF é essencial para o manejo do tratamento, porém é complexo por apresentar diferentes etiologias como neuropatias, doenças reumatológicas ou auto-imunes, trauma tecidual, problemas odontológicos, infecções, dores psicogênicas e musculoesqueléticas. (JAFREE et al., 2018; CARRARA; CONTI; BARBOSA, 2010) A alta prevalência de DOF na população foi citada em um estudo no qual 22% dos voluntários eram portadores de algum tipo de dor na face nos 06 meses que antecederam o estudo, e dessa porcentagem, 5,3% dos voluntários apresentavam DOF causada por desordens temporomandibulares. (CARRARA; CONTI; BARBOSA, 2010)

As desordens temporomandibulares (DTM) são caracterizadas por alterações na articulação temporomandibular (ATM), na musculatura mastigatória e em estruturas ósseas que cursam com dor orofacial e acometimentos de cabeça e pescoço. (CARRARA; CONTI; BARBOSA, 2010) A fisiopatologia ainda é desconhecida e a etiologia é multifatorial, relacionando fatores funcionais, estruturais e psicológicos. (GAUER; SEMIDEY, 2015) Alguns dos sintomas mais comuns são limitação ou assimetria na movimentação mandibular, sons articulares, dores de ouvido, zumbido, desconforto na mandíbula, dores de cabeça e região cervical. (GIL-MARTÍNEZ et al., 2016)

A DTM é apontada como a segunda causa mais frequente de DOF no mundo. (CARRARA; CONTI; BARBOSA, 2010) Cerca de 60-70% da população mundial apresenta sinais da desordem, sendo a taxa de adultos sintomáticos entre 27-38%, entretanto apenas 05-12% desta população busca tratamento. (ANASTASSAKI KÖHLER; HUGOSON; MAGNUSSON, 2012; SHARMA et al., 2011) No Brasil, 37,5% da população, composta de maior parte de mulheres dos 18 aos 45 anos, apresenta sintomas de DTM. (GIL-MARTÍNEZ et al., 2016)

A faixa etária com pico de incidência é de 20-40 anos e as mulheres apresentam maior prevalência que os homens, sendo até quatro vezes mais acometidas por desordens e condições dolorosas. (RAMALHO et al., 2015; VIANA et al., 2015; WOŹNIAK et al., 2015; SHARMA et al., 2011) Não há explicação clara para essa maior proporção no sexo feminino, mas estudos em animais e humanos sugerem que as oscilações nos níveis dos hormônios sexuais, especificamente o estrógeno, podem aumentar a predisposição à DTM e potencializar sintomas dolorosos ao longo do ciclo menstrual. (BUENO et al., 2018; OMAR ABUBAKER; F. RASLAN; C. SOTEREANOS, 1993)

A classificação da DTM pode ser intra-articular e extra-articular, ou articular e não-articular, respectivamente. As desordens articulares são divididas em inflamatórias (acometimentos reumatológicos como artrite reumatoide, espondilite anquilosante, por exemplo) e não-inflamatórias, como traumas ou cirurgias na face, danos ósseos. Desordens extra-articulares se caracterizam por dor miofascial, essencialmente nos músculos mastigatórios, que cursam com espasmos, dor e limitações funcionais. (DE ROSSI et al., 2014) No presente estudo selecionamos as desordens extra-articulares, especificamente as de origem miogênica, que envolvem a musculatura mastigatória e compõem pelo menos 50% dos casos de DTM. (FARELLA et al., 2000) Há evidências de que a dor proveniente de desordens extra-articulares está relacionada com uma menor atividade elétrica da musculatura envolvida em portadores de DTM quando comparados com indivíduos não acometidos. (SANTANA-MORA et al., 2014)

Estudos indicam que existe a tendência do recrutamento variado das fibras da musculatura levantadora da mandíbula, a partir de estímulos nociceptivos devido a terminações nervosas livres em portadores de DTM de origem miogênica. A incerteza sobre a atuação de mecanismos centrais e a alteração nos disparos das unidades motoras devido a mudanças no padrão da ativação agonista-antagonista podem se correlacionar a intensidade da dor na musculatura. (PITTA et al., 2015; SANTANA-MORA et al., 2014) La Touche e colaboradores em um estudo de 2018 sugeriram a sensibilização do sistema nervoso central e periférico devido à sensibilidade da dor à pressão mecânica na região do trigêmeo e irradiações em indivíduos com DTM e ainda neste

estudo sugeriram hiperexcitabilidade central e espinhal nestes indivíduos. (LA TOUCHE et al., 2018) A sensibilização central pode amplificar a aferência do estímulo doloroso ao cérebro e desta forma reduzir o mecanismo de inibição que auxilia no equilíbrio dos centros superiores do dor. (HARRISON; THORP; RITZLINE, 2014)

A ativação dos músculos de forma desordenada sugere ainda uma menor eficiência funcional predispondo-os à fadiga precoce quando comparado a indivíduos assintomáticos. (LIU; SUN, 1999) Uma sequência de eventos leva um músculo à fadiga, sendo então observado o aumento na concentração de metabólitos teciduais e a alterações na velocidade de condução da fibra muscular e no recrutamento das unidades motoras. (ADAM, 2005) Portadores de DTM apresentam a capacidade de extração de oxigênio muscular diminuída quando comparada com indivíduos assintomáticos. A menor capacidade de extração de oxigênio muscular implica em uma maior gravidade dos sinais e sintomas apresentados na DTM. (FERREIRA et al., 2017)

O treinamento de resistência muscular pode impactar nos sistemas corporais, aprimorando o desempenho dos músculos estriados esqueléticos e minimizando o risco de lesões. Este tipo de treinamento muscular necessita de fornecimento contínuo de energia, obtido pelo armazenamento local ou por adaptações no sistema musculoesquelético como o aumento da densidade do leito capilar e da densidade, do volume e da concentração mitocondrial dos músculos para que haja produção de adenosina trifosfato (ATP) a partir dos níveis de ácido ribonucleico mensageiro (mRNA) e alterações protéicas, de acordo com a progressão do exercício de resistência. (BOOTH et al., 2015; PERRY et al., 2010; KISNER; COLBY, 2007) Além da maior concentração de mitocôndrias, a demanda energética da contração muscular também é controlada pela taxa de glicose e pelos níveis de gordura corporal. (BOOTH et al., 2015; KRAEMER et al., 2002) Portadores de DTM por serem mais susceptíveis à fadiga devido à reduzida capacidade de extração de oxigênio celular e pelo recrutamento deficitário nas unidades motoras podem ter tais adaptações prejudicadas.

Exercícios de resistência tendem a constituir uma alternativa não invasiva e de alta aplicabilidade no tratamento da DTM, entretanto falta coerência em relação aos parâmetros de dosagem destes exercícios. De acordo com a revisão sistemática com meta-análise de 2016, a intervenção fisioterapêutica é uma opção eficaz para o tratamento da DTM, principalmente com a aplicação de exercícios, que melhoram os sintomas e a função dos indivíduos com a desordem. Contudo, os estudos reunidos nesta revisão já se encontravam desatualizados e com relevância comprometida por associarem o tratamento da DTM às patologias da extremidade superior do corpo, bem como a falta de padronização dos protocolos. (ARMIJO-OLIVO et al., 2016)

Em outra revisão sistemática com meta-análise verificou-se os efeitos do controle motor, da educação postural e do biofeedback para o tratamento de pacientes com DTM, porém as técnicas não foram analisadas de forma isolada. Foi constatada alta variabilidade nos parâmetros de dosagem utilizados nos exercícios terapêuticos empregados bem como falta de controle de co-intervenções, o que comprometeu a análise dos resultados obtidos. (DICKERSON et al., 2016)

Herpich e colaboradores em uma revisão sistemática da literatura analisaram o uso do laser de baixa intensidade e os métodos de avaliação da DTM. De acordo com os autores o laser apresenta bons resultados, mas por ser uma condição multifatorial, a DTM também apresenta outras condutas para seu manejo e tratamento como cinesioterapia, massagem terapêutica, acupuntura, mobilização articular entre outras. Entretanto sem uma padronização no que se refere a protocolos e sem citar modalidade de exercícios de resistência e sugerindo novos estudos com maior rigor metodológico. (HERPICH et al., 2015)

Desta forma, a proposição de novos estudos sobre exercícios terapêuticos e quais instrumentos deveriam ser utilizados na avaliação da DTM para identificar a periodização do exercício e seus benefícios, a taxa de adesão do paciente à terapia e elaboração de um protocolo que seja reprodutível e eficaz. A eletromiografia de superfície (sEMG) é citada como um instrumento avaliativo objetivo, e no presente estudo foi proposto seu uso não somente na

avaliação e diagnóstico, como também no tratamento. (ARMIJO-OLIVO et al., 2016; DICKERSON et al., 2016; HERPICH et al., 2015)

O uso da eletromiografia de superfície quando bem controlado, pode ser considerado uma estratégia na análise da fisiopatologia da DTM miogênica uma vez que as manifestações observadas no recrutamento dos músculos masseter e temporal de indivíduos com e sem DTM apresentam diferenças significativas. (CASTROFLORIO et al., 2012)

A sEMG na região orofacial auxilia na avaliação, no diagnóstico e no tratamento das alterações de motricidade. Grande parte dos trabalhos que utilizam a sEMG em pacientes com DTM, enfatizam apenas o diagnóstico em detrimento ao seu uso como instrumento de tratamento por meio de biofeedback. Este mesmo estudo aponta a necessidade de realização de pesquisas que enfatizem o uso da eletromiografia de superfície para auxiliar no estabelecimento de parâmetros objetivos de avaliação, diagnóstico e acompanhamento terapêutico em distintas alterações do sistema neuromuscular. (CZLUSNIAK et al., 2013) A sEMG associada com a história clínica e a avaliação física fornece dados objetivos da desordem e da condição dos músculos mastigatórios. (PIRES; RODRIGUES-BIGATON, 2018)

Conhecer a atividade muscular em função do tempo de contração e repouso auxiliará no aperfeiçoamento da prática clínica e da pesquisa dos procedimentos de diagnóstico e tratamento já existentes. Não foram encontradas informações seguras na literatura que forneçam parâmetros eletromiográficos de amplitude e frequência mediana para o estabelecimento de protocolos de contração e ou repouso dos músculos mastigatórios de portadores de DTM para realização de avaliações e intervenções terapêuticas. (RIES et al., 2016)

Os indivíduos com DTM têm um tempo de resistência significativamente menor durante atividades funcionais como mordida (bilateral ou unilateral) em comparação a não-portadores. (WÄNMAN, 2012) No entanto, a resposta dos músculos da mandíbula ao exercício de resistência permanece pouco conhecida, apesar dos benefícios dos exercícios de resistência para outros grupos de músculos esqueléticos. Estabelecer parâmetros apropriados para a

aplicação de exercícios específicos na desordem temporomandibular pode oferecer balizadores determinantes na redução da dor e melhora da função.

Como todo o sistema de prescrição de exercícios com alto índice de sucesso nas disfunções musculoesqueléticas está baseado na porcentagem de carga aplicada a partir da carga máxima obtida inicialmente, tanto a sEMG quanto a dinamometria podem fornecer dados objetivos confiáveis e válidos para o delineamento do tratamento com exercícios para DTM. A avaliação do comportamento da excitação muscular e da força exercida em contrações isométricas máximas por protocolo de exercícios isométricos para resistência muscular à fadiga (RMF) podem fornecer dados importantes para o estabelecimento de condutas mais objetivas e eficientes para o tratamento de portadores de disfunções temporomandibulares.

2 – OBJETIVOS

2.1 –OBJETIVO PRIMÁRIO

Verificar a eficácia de um protocolo de 08 semanas de exercícios isométricos de resistência muscular à fadiga nos músculos mastigatórios a partir da análise da excitação muscular, da resposta de força, da dor relatada, tempo até a fadiga e a eficiência muscular no tratamento da desordem temporomandibular por meio de biofeedback.

2.2 –OBJETIVO SECUNDÁRIO

Analisar os parâmetros eletromiográficos (excitação dos músculos masseter e temporal anterior, tempo até a fadiga, eficiência da força em função do tempo) e comportamento algico pré e pós-treinamento.

3- HIPÓTESE

O programa de treinamento de exercícios isométricos de RMF aplicado na musculatura levantadora da mandíbula por meio de biofeedback melhora a função e reduz a dor de pacientes com desordem temporomandibular miogênica.

4- MATERIAIS E MÉTODOS

4.1- DESENHO DE ESTUDO

Trata-se de um Ensaio Clínico Randomizado Placebo Controlado realizado em 46 mulheres portadoras de DTM miogênica, divididas com taxa de alocação de 1:1 em grupo controle (placebo) e grupo experimental (exercícios de RMF).

4.2- CÁLCULO AMOSTRAL

O cálculo amostral foi realizado através do programa G-Power (versão 3.1.5, Franz Faul, Universität Kiel, Germany) utilizando como parâmetros os dados obtidos em um estudo anterior, (MACHADO et al., 2016) considerando o tamanho de efeito entre as variáveis estudadas de 0.60, nível alfa de 5%, intervalo de confiança de 95% e poder do teste de 95%, retomando a uma amostra de 32 participantes.

4.3- AMOSTRA

As voluntárias foram recrutadas na comunidade local, via chamada pública com cartazes e panfletos, além de lista de contatos pessoais (os autores do estudo assumem que esta forma de recrutamento poderia ser um viés, entretanto a falta de serviço público ou privado que avalie DTM na cidade impedia que portadores da disfunção buscassem auxílio para avaliar e tratar tal condição). Os procedimentos foram realizados na Clínica Escola de Fisioterapia da UFJF-GV com ambiente privativo e adequado às regras sanitárias vigentes (APÊNDICE 1).

Após serem informadas e esclarecidas sobre a pesquisa, seus benefícios e possíveis riscos, as voluntárias assinaram o termo de consentimento informando a sua participação no estudo, previamente aprovado pelo Comitê de Ética local (APÊNDICE 2).

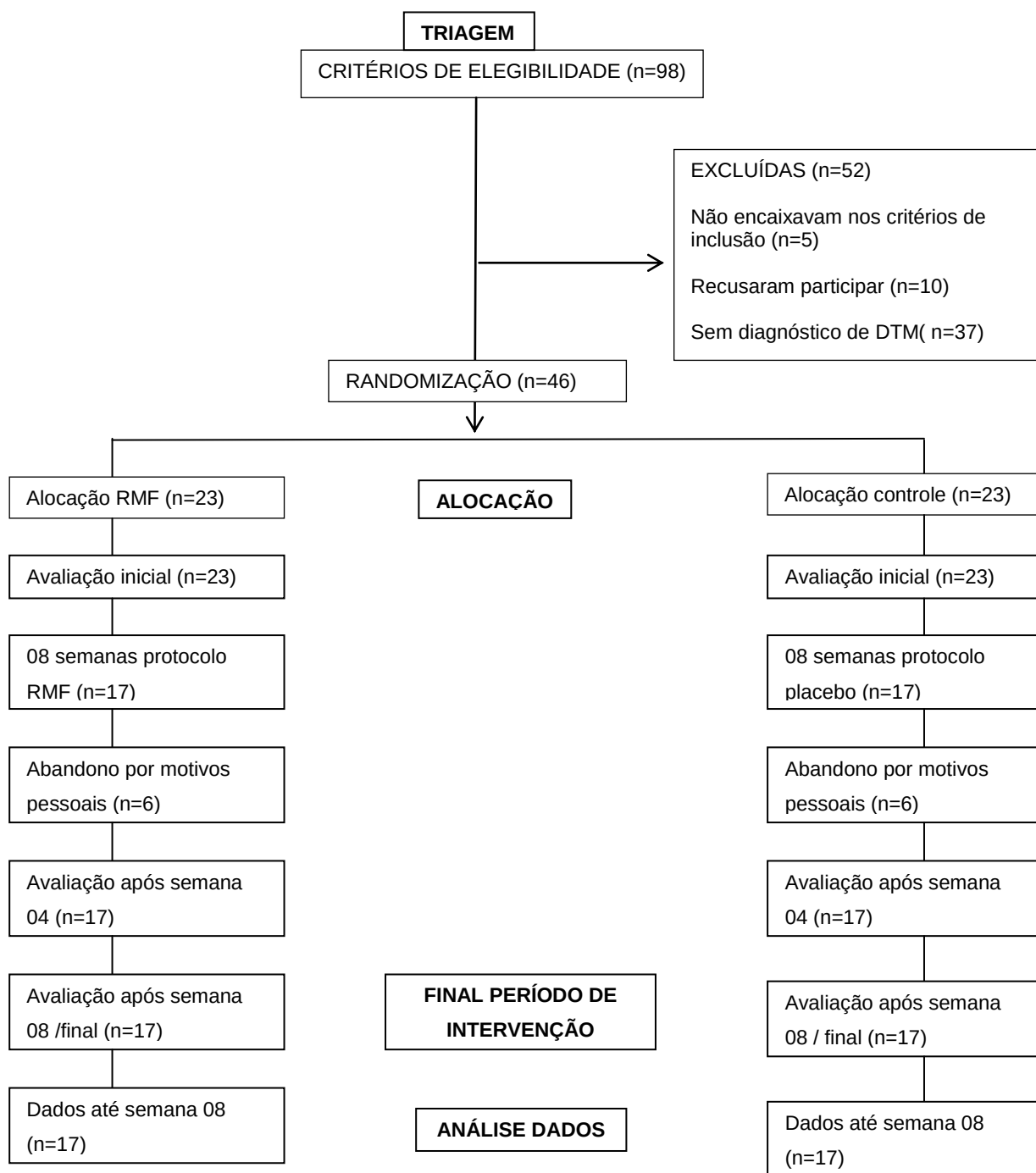


FIGURA 1 – Fluxograma

Fonte: Elaborada pela autora

Não foram realizadas co-intervenções em ambos os grupos e nenhum treino em casa foi solicitado. Não houve relato de nenhum efeito adverso por qualquer voluntária ao longo das 08 semanas de execução do protocolo.

Foi planejado um follow-up três meses após o término do protocolo. Entretanto 13 voluntárias não responderam ao nosso contato, e da amostra restante 17 se recusaram a retornar para outra avaliação. Apenas 04

voluntárias concordaram em retornar para uma nova avaliação, prejudicando a comparação prospectiva.

Os investigadores responsáveis por este trabalho estavam comprometidos com a resolução 466/12 do Conselho Nacional de Saúde (ANEXO 1).

4.4- CRITÉRIOS DE INCLUSÃO

Mulheres de 18 a 45 anos de idade com dor na região da articulação temporomandibular de longa duração (mais de 06 meses), apresentar dentição permanente completa, correspondendo ao mínimo de 28 permanentes e não apresentar problemas periodontais graves. (DE FELÍCIO; MEDEIROS; DE OLIVEIRA MELCHIOR, 2012)

4.5- CRITÉRIOS DE EXCLUSÃO

Histórico de traumas na face, na articulação temporomandibular, auto-relato de doenças sistêmicas ou reumatológicas como artrite; portadoras de aparelhos ortodônticos ou próteses, em uso de medicamentos analgésicos, anti-inflamatórios ou drogas psiquiátricas e apresentar déficit neurológico ou cognitivo que impediam a execução de comandos. (DE FELÍCIO; MEDEIROS; DE OLIVEIRA MELCHIOR, 2012)

4.6- INSTRUMENTOS DE AVALIAÇÃO

4.6.1- Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD): Para verificar quais voluntárias atendiam aos critérios de inclusão da pesquisa foi aplicado o questionário RDC/TMD Eixo 01 (ANEXO 2), para determinação da DTM miogênica.

O RDC/TMD é aceito internacionalmente como ferramenta diagnóstica padrão-ouro, sendo amplamente utilizado. Existe a última versão atualizada, o DC/TMD (Diagnostic Criteria for Temporomandibular Disorders), entretanto a ausência da versão validada para o Português do Brasil fez com que utilizássemos a versão anterior. Este questionário foi traduzido em 18 idiomas e apresentou níveis de confiabilidade aceitáveis.

É uma ferramenta biaxial, sendo o Eixo 01 voltado para achados físicos (padroniza a pesquisa sobre a etiologia das duas formas mais comuns de classificar a DTM: mio gênica e artrogênica) e o Eixo 02 analisa os status psicossociais como depressão, ansiedade e relaciona tais condições aos acometimentos físicos.

Para critérios diagnósticos, há a divisão em três grupos: (CHAVES; OLIVEIRA; GROSSI, 2008a)

- Grupo I: Diagnósticos musculares (dor miofascial e dor miofascial com limitação na abertura);
- Grupo II: Deslocamentos de disco (com redução, sem redução com abertura limitada, e sem redução, sem abertura limitada);
- Grupo III: Artralgia, artrite, artrose da articulação temporomandibular (ATM).

Após avaliação utilizando o RDC/TMD Eixo 01, foram selecionadas voluntárias que atendiam aos critérios de inclusão da amostra e com a capacidade de abertura da boca preservada em níveis normais (acima de 04 cm, medido com paquímetro ao realizar o RDC/TMD). As avaliações seguintes foram compostas por:

4.6.2- Escala Visual Analógica de Dor (EVA): cada voluntária recebeu uma EVA, que consistia de uma linha reta de 100 milímetros (mm) (ANEXO 3) onde a voluntária marcava nesta reta uma linha perpendicular entre os dois extremos o ponto que indicava seu nível de dor naquele instante, sendo os valores de zero (que significa ausência de dor e/ou desconforto) a dez (que significa o máximo de dor e/ou desconforto). (CELAKIL et al., 2017)

As propriedades psicométricas da EVA foram previamente testadas com resultados excelentes para avaliar a dor em adultos. (BIRD et al., 2016; HERR et al., 2004; CARLSSON, 1983)

A classificação da dor pela EVA aconteceu da seguinte forma: marcação $\leq 3,4$ dor leve, entre 3,5 a 7,4 dor moderada e $\geq 7,5$ dor severa. (BOONSTRA et al., 2014) Os resultados da EVA foram usados para comparações nas avaliações basal, semana 04 e semana 08.

4.6.3- Limiar Pressórico de Dor – por algometria de pressão: A algometria de pressão foi realizada com a utilização de uma adaptação à célula de carga (Miotec® Equipamentos Biomédicos, Porto Alegre, RS, Brasil. Máxima tensão-compressão = 200 quilograma-força (Kgf), precisão de 0,1 Kgf, erro máximo de medição = 0,33%) conectada a dispositivo puntiforme composto por uma cabeça com aplicação de borracha de 01 centímetro-quadrado (cm²) e as medidas foram calculadas como quilograma/centímetro-quadrado (kg / cm²).

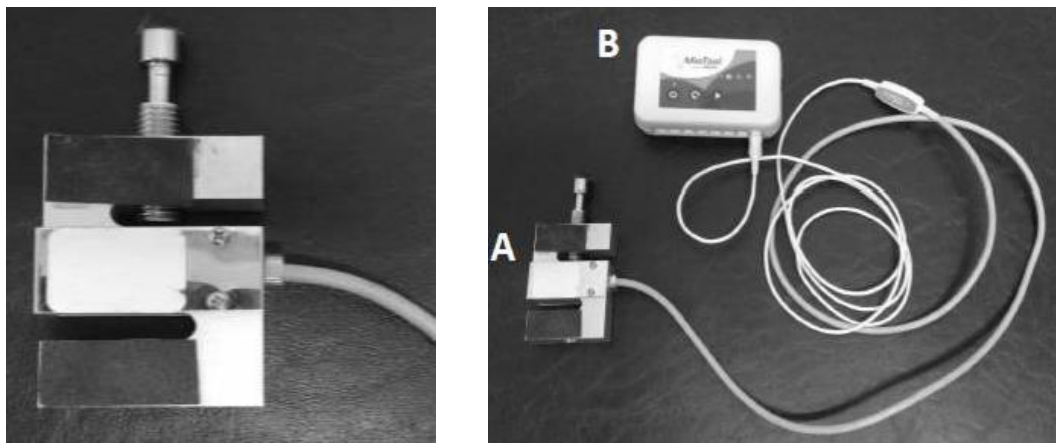


FIGURA 2- Adaptação para algometria de pressão com dispositivo puntiforme conectado à célula de carga (A) e esta conectada ao eletromiógrafo (B)

Fonte: Elaborada pela autora

Todas as medidas foram realizadas pelo mesmo examinador. A confiabilidade intra-avaliador do equipamento foi previamente testada com medidas repetidas com intervalo de uma semana entre os testes. Os resultados foram adequados, com um coeficiente de correlação intraclassa (ICC) de 0,83.

A voluntária permaneceu sentada em uma cadeira com apoio posterior com tronco ereto, pés apoiados no chão e mãos sobre as coxas. O limiar doloroso de pressão (LDP) foi medido bilateralmente sobre a ATM justamente na frente do canal auditivo, no ventre dos músculos masseteres e dos músculos temporais anteriores. (HERPICH et al., 2017) Esses locais receberam pressão progressiva de 01 quilograma por segundo (1 kg / s) até a voluntária levantar a mão, sinalizando quando o LDP foi alcançado e o estímulo foi então cessado. O teste consistiu da seguinte sequência: músculo temporal esquerdo, pólo articular esquerdo, músculo masseter esquerdo, músculo temporal direito, pólo articular direito e músculo masseter direito e em cada

local foi medido 03 vezes com intervalo de 03 segundos. Como o sinal foi coletado continuamente, a ordem da sequência foi sempre a mesma para identificar cada ponto de pressão. Foi analisado o valor médio das medidas. (BATISTA GOMES et al., 2006)

A célula de carga foi recalibrada anteriormente ao uso para cada voluntária seguindo as recomendações do fabricante.

Foi realizada a conversão analógica para digital pelo módulo de aquisição executado por uma placa A/D com resolução de 14 bits, frequência de amostragem de 02 quilohertz (kHz), módulo de rejeição comum maior que 100 decibéis (dB), relação sinal-ruído menor que raiz quadrada média de 03 microvolts (μV) e impedância de 109 ohms (Ω). O software gravou continuamente todas as medidas para comparações offline.

4.6.4- Questionário e Índice de Limitação Funcional Mandibular (MFIQ): Composto por 17 questões combinadas em duas dimensões (capacidade funcional e alimentação) que a voluntária respondeu qual o seu nível de dificuldade na execução das tarefas questionadas. (ANEXO 4)

As possibilidades de resposta compreendiam: nenhuma, um pouco, bastante, muita, muitíssima. A pontuação possibilitou classificar as voluntárias de acordo com a severidade e limitação funcional, sendo obtida por média ponderada entre o valor máximo de respostas e o maior escore obtido.

A validade e confiabilidade da versão em Português do MFIQ foram previamente avaliadas. Por medir a limitação funcional causada pela DTM, o questionário MFIQ foi útil para comparar a funcionalidade antes e depois de períodos de intervenção. (CAMPOS; CARRASCOSA; MAROCO, 2012; CHAVES; OLIVEIRA; GROSSI, 2008b)

4.6.5- Eletromiografia de superfície sincronizada à dinamometria por célula de carga: A eletromiografia de superfície (sEMG) foi utilizada para avaliar a excitação dos músculos masseter e temporal, bilateralmente, durante o teste de fadiga da mordida em ambos os grupos, controle e experimental.

Um módulo de aquisição com oito canais analógicos (Miotec™, Equipamentos Biomédicos, Porto Alegre, RS, Brasil) registrou continuamente os sinais biológicos. A conversão de sinais analógicos para digitais foi realizada

por uma placa A/D com resolução de 14 bits, frequência de amostragem de 2 kHz, módulo de rejeição comum maior que 100 dB, relação sinal-ruído menor que raiz quadrada média de 03 μ V e impedância de 109 Ω . Os dados coletados foram exibidos em janela de 125 milissegundos (ms) usando o software Miotec™ Suite. Os sinais eletromiográficos foram registrados em raiz quadrada média em μ V com eletrodos de prata/cloreto de prata (Ag/AgCl) superficiais Meditrace™ (Ludlow Technical Products, Gananoque, Canadá) com diâmetro de 1 cm e distância de centro a centro de 1 cm, aplicados em uma orientação transversal, paralelamente às fibras subjacentes nos músculos. Os sinais da sEMG foram amplificados e filtrados (Butterworth de quarta ordem, filtro passa banda de 20-450 Hz, filtro notch de 60 Hz). Todas as informações foram gravadas e processadas usando o software Miotec Suite™ (Miotec Biomedical Equipamentos, Porto Alegre, RS, Brasil).

Para a colocação de eletrodos que precedeu a realização da sEMG foi feita limpeza da pele com álcool 70% para eliminar a gordura residual, seguida de uma esfoliação com uma lixa específica para a pele e uma segunda limpeza com álcool. Os eletrodos foram posicionados no ventre dos músculos temporal anterior e masseter superficial em ambos os lados, paralelamente às fibras musculares. O eletrodo de referência foi colocado no epicôndilo lateral do úmero esquerdo, obedecendo às normas da SENIAM (Surface EMG for Non-Invasive Assessment of Muscles - <http://www.seniam.org/>).

Antes de iniciar a coleta de dados a voluntária foi instruída a manter-se relaxada, sem realizar nenhum movimento, durante 15 segundos. Após este período foi realizada em modo síncrono a sEMG e a dinamometria.

A dinamometria foi realizada com a voluntária sentada em uma cadeira com apoio posterior, os pés apoiados no chão, mãos sobre as coxas e tronco ereto. A célula de carga (Miotec® Equipamentos Biomédicos, Porto Alegre, RS, Brasil. Máxima tensão-compressão = 200 quilograma-força (Kgf), precisão de 0.1 Kgf, erro máximo de medição = 0,33%) recebeu uma adaptação que consistiu de duas extensões de aço inox fixadas nas suas extremidades superior e inferior. (BARBOSA et al., 2015) Para realização da coleta de dados, as extensões foram recobertas com uma luva de látex que foi descartada após o uso com cada voluntária. As extensões foram posicionadas entre as arcadas dentárias na direção dos incisivos centrais superiores e inferiores. A postura

anterior da cabeça foi controlada durante todos os procedimentos posicionando a célula de carga mais próximo possível das voluntárias, em um suporte de metal vertical com altura adaptável para cada voluntária, para que pudessem morder mantendo a postura natural da cabeça.

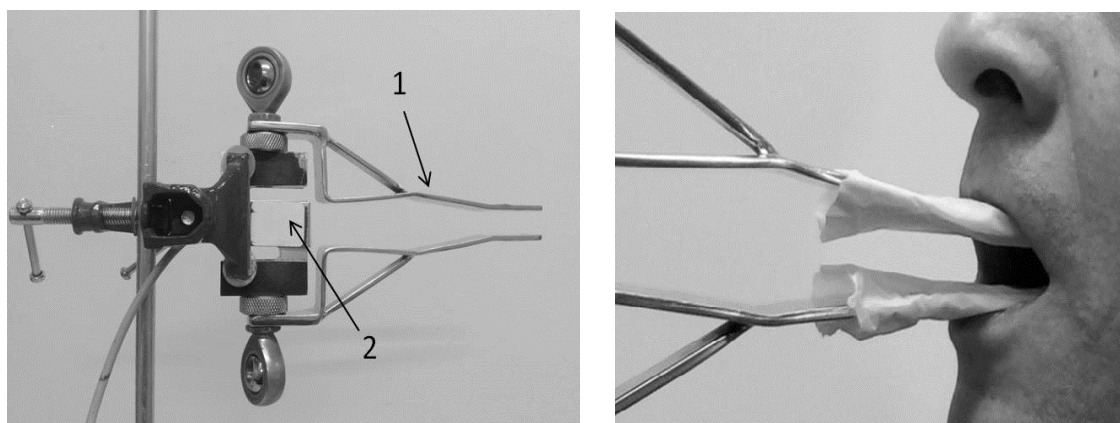


FIGURA 3 – Adaptação à célula de carga para teste de mordida com as extensões de aço inox nas extremidades superior e inferior (1) fixadas na célula de carga (2) e posicionamento das extensões nas arcadas dentárias

Fonte: Elaborada pela autora

Para coletar dados da contração isométrica voluntária máxima (CIVM) foram realizadas três repetições de 05 segundos de mordida com força máxima nas extensões adaptadas na célula de carga. Entre cada CIVM houve um período de repouso de 05 minutos. Comandos verbais padronizados (“morde”, “força, mantenha a mordida”, “pare”) foram usados pelo mesmo avaliador para todos os registros dos testes. Uma familiarização de 05 segundos foi seguida por 03 minutos de descanso antes da CIVM.

A confiabilidade intra-examinador da célula de carga adaptada foi previamente avaliada duas vezes (01 semana de intervalo entre as medidas), retornando um ICC muito bom de 0,84.

A célula de carga foi acoplada e sincronizada com o eletromiógrafo e permitiu o registro para posterior análise dos valores registrados para a CIVM da musculatura levantadora da mandíbula. A média entre as três medidas da CIVM foi utilizada para fins de normalização.

A fadiga dos músculos masseter e temporal foi avaliada durante um teste de esforço de mordida máxima. Os procedimentos de CIVM descritos anteriormente foram adotados. Entretanto, para testar a força até a fadiga durante a mordida em vez de um esforço máximo curto, cada voluntária foi

solicitada a executar uma CIVM o máximo de tempo suportado, até a falha na tarefa.

A sEMG dos músculos masseteres e temporais ocorreu sincronizada com a dinamometria, conforme procedimento já elucidado. A captação dos sinais eletromiográficos foi coletada e processada pelo MiotecSuite Software®.

Após procedimentos avaliativos, cada participante foi alocada randomicamente em Grupo Controle (GC) ou Grupo Experimental (GE). Para tal distribuição foi utilizada a plataforma online www.randomizer.org.br. O GE realizou um treinamento de resistência muscular à fadiga (RMF) por meio de biofeedback através do módulo Miotec® New Miotool® modelo 800 wireless. O protocolo consistiu de séries com repetições crescentes ao longo de 08 semanas, com carga progressiva de 20 a 50% da capacidade máxima individual. A periodização do treinamento foi de duas sessões semanais e cada sessão com duração média de 30 minutos.

O GC recebeu tratamento placebo que consistiu na aplicação de laserterapia de baixa potência em pontos na região temporomandibular (masseter, ATM e temporal), com equipamento desligado, durante 01 minuto em cada região. A periodização do tratamento foi de duas sessões semanais durante o período de oito semanas. Cada sessão teve em média 15 minutos de duração.

SEMANA	DESCANSO ANTES CONTRAÇÃO	TEMPO CONTRAÇÃO	CARGA (% CIVM)	REPETIÇÕES	INTERVALO ENTRE REPETIÇÕES	SÉRIES	INTERVALO ENTRE SÉRIES	TEMPO TOTAL SESSÃO
1	7s	5s	20%	10	2s	3	2	7min41s
2	6s	5s	20%	12	2s	4	2	11min05s
3	7s	4s	25%	15	2s	4	1,5	10min39s
4	8s	4s	30%	18	2s	4	1,5	11min51s
5	9s	3s	35%	20	1s	5	1	10min50s
6	10s	3s	40%	22	1s	5	1	11min09s
7	11s	2s	45%	25	1s	5	0,5	8min25s
8	12s	2s	50%	25	1s	5	0,5	8min25s

TABELA 1 – Protocolo de resistência muscular à fadiga utilizando biofeedback

Fonte: Elaborada pela autora

As voluntárias foram reavaliadas ao final da quarta semana de execução dos protocolos e também ao finalizar a oitava semana conforme os procedimentos descritos anteriormente. Caso o protocolo experimental se mostrasse eficaz, seria garantido o treinamento RMF por meio de biofeedback ao grupo controle após o término do experimento.

4.7- RISCOS

Havia o risco de contaminação cruzada pelo uso das extensões da célula de carga. Antes de iniciarmos cada atendimento, tais extensões eram esterilizadas com álcool a 70% e cada extensão foi coberta com luva de látex para se evitar contato direto.

Havia o risco, embora mínimo, de lesionar a pele ao aplicar e retirar os eletrodos para a coleta do sinal eletromiográfico. Este risco foi minimizado através de treinamento do avaliador que coletaria os dados sobre como realizar o procedimento com segurança.

Era improvável que os questionários utilizados nesse estudo causassem algum estresse psicológico, entretanto os participantes foram entrevistados em local privativo, resguardando o sigilo de seus dados.

4.8 – BENEFÍCIOS

O estabelecimento de parâmetros adequados do treinamento RMF no tratamento da DTM por meio de biofeedback contribui para a aplicação de um tratamento mais eficiente pelo fisioterapeuta.

Em caso de melhora em qualquer variável estudada, o participante teria o benefício do tratamento para sua desordem. Atualmente as voluntárias que participaram do grupo controle estão em sendo atendidas seguindo o protocolo de treinamento de exercícios RMF aplicado no grupo experimental.

4.9- EXTRAÇÃO DOS DADOS

Todos os dados foram extraídos offline usando o software Miotec Suite™ (Miotec Equipamentos Biomédicos, Porto Alegre, RS, Brasil). Como a célula de carga foi sincronizada com os canais de eletromiografia, o avaliador treinado estabeleceu o intervalo usando o início da força. Após três janelas de repouso de 01 segundo (s), o início foi definido por três vezes o desvio padrão

dos intervalos de repouso médio mais a média em si. O intervalo começou quando o sinal excedeu o valor do limiar de início. O final do intervalo foi definido usando o mesmo limite.

Médias de intervalo foram utilizadas para análise estatística (força, excitação muscular). O tempo total até a fadiga (do início até o final do intervalo) também foi coletado dos registros do software. Os escores da EVA e a média dos três picos de algometria foram considerados para a análise estatística. A eficiência muscular considerou a média total do tempo de força e a quantidade de tempo gasto para executar a tarefa. O resultado foi dividido por 100 para ser expresso como uma porcentagem.

4.10- METODOLOGIA DA ANÁLISE DE DADOS

Os dados foram apresentados como médias e desvio padrão. O modelo linear geral de Análise Multivariada de Variância (MANOVA) com medidas repetidas foi usado para classificar diferenças intra e entre grupos e levando em consideração múltiplas variáveis dependentes contínuas, agrupando-as em uma combinação linear ponderada ou variável composta (Hotelling's trace). O teste *post hoc* Sidak foi usado para realizar comparações pareadas. A significância foi estabelecida em $p < 0,05$. Todas as análises foram feitas usando os softwares SPSS Inc. (PASW Statistics for Windows, Versão 18.0, Chicago: SPSS Inc) e G-Power (versão 3.1.5, Franz Faul, Universität Kiel, Alemanha).

5- RESULTADOS

Os resultados estão apresentados em forma de artigo, publicado online em 13/05/2019 na Journal of Oral Rehabilitation, DOI: 10.1111/joor.12823 (Anexo 5), seguidos da tabela e dos gráficos que sinalizam as diferenças estatisticamente significativas.

A seguir, manuscrito submetido para publicação.

Original Research

Effects of 8-week of masticatory muscles focused endurance exercises on women with orofacial pain and temporomandibular disorders: a placebo randomized controlled trial

Running title: endurance exercises for TMD

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Effects of 8-week of masticatory muscles focused endurance exercises on women with orofacial pain and temporomandibular disorders: a placebo randomized controlled trial

ABSTRACT

Background: Exercises are used to treat temporomandibular disorders (TMD), but they are often assessed with other therapies. Local endurance exercises may alter the resistance to fatigue and pain.

Objective: to assess the effects of an 8-week protocol of local endurance exercises of masticatory muscles on muscle excitation, force response, perceived pain, and over muscle efficiency.

Design: randomized controlled trial.

Setting: ambulatory care.

Subjects: in a placebo randomized controlled trial, 46 women with TMD and orofacial pain were randomized into intervention group and placebo group. The intervention group received a protocol of biting endurance exercises, controlled by biofeedback. The placebo group received a placebo (simulated laser therapy).

Main Outcome Measures: the primary outcomes were collected at baseline, 4-week and 8-week. Pain was assessed through visual analogue scale (VAS) and pressure pain thresholds (PPT). Bite force was collected by a load cell synchronized with surface electromyography of masticatory muscles, bilaterally.

Results: pain scores decreased for both groups, but the intervention group showed lower values at 8-week. No differences between groups for PPT, but the results increased for both overtime. Time until fatigue and muscle efficiency were higher in the intervention group vs. placebo group in both within- and between-subject analysis. Force increased from 4 to 8-week in the PG, without differences between groups. Temporal muscle excitation was higher on 8-week compared to baseline for the intervention group, without differences between groups.

Conclusion: Eight-week exercise protocol of muscle endurance alleviate the pain and improve the resistance to fatigue and muscle efficiency in TMD subjects.

Keywords: exercise therapy; resistance training; temporomandibular joint disorders; facial pain; bite force; electromyography.

INTRODUCTION

The prevalence of temporomandibular disorder (TMD) is 27–38% of the examined adult population.¹ Women showed higher prevalence of painful conditions than men, including both orofacial pain and other TMD symptoms.^{2–4} Subjects with TMD present more easily fatigued and less efficient masticatory muscles, with lower oxygen extraction capacity during mastication than healthy control subjects.⁵ Such condition leads to reduced supply of oxygen to the muscle that interfere with the contractile function.⁶ Additionally, the severity of TMD and orofacial myofunctional disorders are related to the oxygen extraction capacity percentage⁶.

Conservative interventions for subjects with TMD, including exercises, joint mobilization, splints and combinations of some of these techniques are often applied as primary choice for care.^{7,8} Low to moderate level of evidence shows positive effects for improving symptoms of muscular TMD when using posture correction exercises for patients with myofascial pain.⁹ There was also a trend to favor exercise therapy (general jaw exercises alone or combined with neck exercises in myogenous TMD) for pain free maximum opening and pain intensity when compared with a control group, with a moderate pooled effect size.⁹ However, the exercise programs were not often assessed alone, but in association to other therapies as part of a conservative treatment protocol.^{7,9} A review with meta-analysis analyzed the effectiveness of manual therapy and therapeutic exercise for TMD.⁹ The authors suggested that more trials isolating the type of exercise are necessary, mentioning that further research is required to assess the usefulness of aerobic exercise as well as focused muscular training. Exercise therapy also shows inconsistent results due to the lack of

appropriate dosage parameters, and the consequent failure to identify the effectiveness of exercise prescription.^{7,9}

Lengthy duration of submaximal contractile activity during endurance exercises requires a continuous supply of energy, provided by the local storage and through increased blood flow to skeletal muscles.¹⁰ The muscle ability to produce ATP for movement occurs by adapting the mRNA levels and protein changes to increase mitochondrial concentrations as the endurance exercise progresses.^{10,11} The increased mitochondrial concentrations are not all adaptations to endurance training. Energetic demands of muscle contraction due to such exercise are also controllers of glucose ratio and whole-body fat levels.^{10,12,13} TMD subjects have significantly lower endurance time during functional biting activities (such as bilateral or unilateral chewing) compared to controls.¹⁴ However, the response of the jaw muscles to local endurance exercise remains poorly known despite the benefits of endurance exercises for other skeletal muscles.

The present study aimed to assess the effects of an 8-week protocol of local endurance exercises. The hypothesis is that the 8-week protocol of local endurance exercises would change the biomechanical parameters (time until fatigue, electromyographic excitation, force response, and muscle efficiency considering the force-time parameters) of the masseter and temporal muscles during maximal biting until fatigue and the perceived pain (algometry and visual analogue scale) on masticatory muscles.

METHODS

Material

The subjects (figure 1) were recruited by public invitation through folders and personal contacts, the authors assume that this could represent a selection bias. However, there is no public or private service in the city to perform any TMD assessment, which impairs the voluntary seek for treatment. A sample of 98 women voluntarily presented themselves for the study. The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD-Axis I) was used for the diagnosis of TMD. The RDC/TMD is the internationally accepted gold standard, and its last version is the DC/TMD. However, the lack of a validated Portuguese version of DC/TMD leaded the authors to use the validated Portuguese version of RDC/TMD for diagnostic purposes. Only those with chronic TMD (more than 6 months of complaints) were included. The jaw opening capacity was preserved at normal levels for all patients (above 4 cm), measured with a caliper, during RDC/TMD assessment. All subjects were diagnosed as myalgia, also according to RDC/TMD. The inclusion criteria for both groups were to have a minimum of 28 permanent teeth, and age between 18 and 45 years old. All subjects reported no periodontal issues. Exclusion criteria for both groups were history of trauma on the face and on the temporomandibular joint, systemic diseases such as arthritis, pain attributable to confirmed migraine, head, or neck pain condition, chronic use (more than 6 months) of any analgesic, anti-inflammatory or psychiatric drugs, acute infection or other significant disease of the teeth, ears, eyes, nose, or throat, and to present neurological or cognitive deficit. After the first screening, only 46 subjects with TMD associated with muscular orofacial pain were included and

randomly divided by an independent rater into 2 groups: Placebo group (n=23), and Intervention group (n=23). The randomization was carried out by an independent rater considering the 1:1 allocation ratio. Before the study begins, a random allocation sequence was automatically generated using the Research Randomizer website (www.randomizer.org), by using 1 set of numbers, with a total of 46 numbers per set, and the established number range as 1 to 2, representing the placebo and the intervention group, respectively. The random sequence was delivered by the Research Randomizer, and the independent rater kept the sequence. The sequence order was continuously given to the examiner who performed the assessments when a new participant was allocated for treatment. The rater who performed the randomization was blinded to the statistical analysis. The RDC/TMD assessments, the physical examination, comprising muscle and TMJ palpation, measurement of active mandibular movements and joint noise analysis were performed by well-trained professionals. The random allocation list was not accessible to the recruiting staff or to the physiotherapists who implemented the treatment at any time. The group allocation and the allocation concealment were preserved. Personal reasons (travel during more than a week, and lack of time for treatment) lead 6 subjects from each group to discontinue the protocol. Thirty-four were analyzed at 8-week assessments. The Mandibular Function Impairment Questionnaire was used to classify the subjects in relation to the severity of the functional limitation related to TMD (table 1).^{15,16} The baseline participant's characteristics were reported in table 1. The ethics committee for human investigation of the Federal University of Juiz de Fora approved the procedures employed in the study (protocol number 68457617.6.0000.5147). The objectives of the study

were explained to the subjects, and they were notified of the benefits and potential risks involved before signing an informed consent form prior to participation. This study was registered in the Brazilian clinical trials registry (ensaiosclinicos.gov.br): protocol number RBR-6kyh2g.

The subjects were assessed before (baseline), at 4-week and at 8-week after the protocol begins. The *a priori* sample size calculation was based on a previous study,¹⁷ considering the effect size of 0.60, the alpha level of 5%, and a 95% power, returning a total of 32 individuals.

FIGURE 1

TABLE 1

Instruments

Surface electromyography was used to evaluate the muscle excitation of the temporal and masseter muscles during a fatigue biting task for both Placebo and Intervention groups. The continuous biting task lead to extreme fatigue, and it was performed only once. An acquisition module with eight analog channels (Miotec™, Biomedical Equipments, Porto Alegre, RS, Brazil) continuously recorded the biological signals. The conversion from analog to digital signals was performed by an A/D board with 14-bit resolution input range, the sampling frequency of 2 kHz, common rejection module greater than 100 dB, signal–noise ratio less than 03 µV Root Mean Square and impedance of 109 Ω. The collected data was windowed at 125 ms using the Miotec™ Suite Software. The sEMG signals were recorded in root mean square in µV with surface Meditrace™ (Ludlow Technical Products, Gananoque, Canada) Ag/AgCl electrodes with a diameter of 1 cm and centre-to-centre distance of 1 cm,

applied in a transverse orientation parallel to the underlying fibers on a muscle site. A reference electrode was placed on the left lateral humeral epicondyle. sEMG signals were amplified and filtered (Butterworth fourth-order, 20-450 Hz bandpass filter, 60 Hz notch filter). All pieces of information were recorded and processed using the software Miotec Suite™ (Miotec Biomedical Equipments, Porto Alegre, RS, Brazil). Prior to sEMG electrode placement, the skin was cleaned with 70% alcohol to eliminate residual fat, followed by an exfoliation using a specific sandpaper for skin and a second cleaning with alcohol. The electrodes were positioned on the anterior temporal muscles and the superficial masseter on both left and right sides parallel to the muscle fibres.³

Maximal Voluntary Isometric Contraction

Three 5-second maximum isometric contraction (MVIC) were performed by each participant while biting on an adapted load cell (Miotec™, Biomedical Equipments, Porto Alegre, RS, Brazil; maximum tension-compression = 200 Kgf, precision of 0.1 Kgf, maximum error of measurement = 0.33%). Each MVIC was followed by 5 minutes of rest. Subjects were asked to seat comfortably (the volunteer remained seated with the trunk erect, feet on the floor, and hands resting on the thighs) while the load cells arms were positioned on the incisors (figure S1 - Supporting information). A disposable material was used to cover the arms for each subject. The forward head posture was controlled during all procedures by positioning the load cell closer to the participant, so the subjects could bite in their natural head posture. Standardized verbal commands (“start”, “keep biting”, “stop”) were used by the same rater for all tests’ recordings. A 5-second familiarization was followed by 3 minutes of rest before the MVIC. The intra-rater reliability of the adapted load cell was previously assessed twice (1-

week apart measures), returning a very good ICC of 0.84. The load cell was coupled and synchronized with the electromyographer. The mean among the MVIC trials was used for normalization purposes.

Fatiguing biting test

The fatigue of the masseter and temporalis muscles was assessed during a single maximal biting effort test. The previously described MVIC procedures were adopted. However, instead of an immediate short maximal effort, each participant was asked to perform a MVIC for the maximal supported time.

Pain assessments

A visual analog scale (VAS) of 0 to 100 mm, which was designed as 0 being no pain and 100 being the worst pain ever experienced, was given to subjects in this study to mark a perpendicular line between the 2 extremes to represent their pain intensity at the time of evaluation with provoked pain through temporal palpation.¹⁸ Psychometric properties of VAS were previously tested with excellent results to evaluate pain.^{19–21} All VAS scores were collected by the same rater. VAS scores ≤ 3.4 represent mild pain, 3.5 to 7.4 moderate pain, and ≥ 7.5 severe pain.²² The VAS results were used for comparisons.

The pressure pain threshold (PPT) was measured with the described load cell adapted as an algometer (figure S2 - Supporting information). The equipment's intra-rater reliability was previously tested with 1-week apart repeated measures. The results were adequate, with an ICC of 0.83. The load cell was recalibrated for each participant following the manufacturer recommendations. All PPT measurements were performed by the same

investigator in the following order: left temporal, left TMJ, left masseter, right temporal, right TMJ, and right masseter. As the signal was collected continuously, the previous order was always the same to identify each PPT. The volunteer remained seated with the trunk erect, feet on the floor, and hands resting on the thighs. The device has a 1-cm² rubber application head, and measurements were calculated as kg/cm². Analog to digital conversion was performed by the previously described acquisition module. The PPT was measured bilaterally over the temporomandibular joint (TMJ, precisely in front of the ear canal), the belly of the masseter muscles, and the belly of the anterior temporal muscles.²³ These sites received progressive 1 kg/s pressure until the participant experienced pain. The participant lifted a hand when the PPT was achieved. The software continuously recorded all measures for offline comparisons. The PPT was measured 3 times at each site with 3 seconds interval. All assessments were collected in a separate session from the exercise session.

Intervention

The protocol consisted of resistance exercises twice a week for 8 weeks (16 sessions). Table 2 shows the progressive protocol developed to respect the principle of low external load, allowing more series and repetitions. The external load ranged from 20% to 50% of the MVIC, and it was controlled using the Biotrainer™ visual biofeedback software (Miotec™, Biomedical Equipments, Porto Alegre, RS, Brazil - Figure 2). The protocol was previously set by a trained rater, using the same instructions, but no verbal encouragement was given. The participant was instructed to perform short bites on the adapted load cell, and an additional familiarization session was allowed at the 1st week. The

external load, the repetitions, the rest before contraction and the series were progressively increased, while the time of contraction, the interval between repetitions, and the rest between series were progressively decreased.

The other group received placebo via simulated low intensity laser therapy (off mode) for the same time of session as the intervention group protocol (the off mode enabled the equipment to emit beep sounds, but without laser application). The simulated laser therapy followed all phases of eye protection (special glasses for the patient and for the therapist), and equipment's positioning. The sites of positioning were: the temporomandibular joint, the anterior temporal muscle, and the masseter muscle, bilaterally.

FIGURE 2

TABLE 2

Raters

An independent rater (rater 1) performed the randomization procedure, as explained. Three raters (raters 2, 3 and 4) were exhaustively trained for 6 months before the study to perform the assessments (muscle palpation, pain assessments, and how to perform the RDC/TMD) and to apply both treatments. The raters were not allowed to perform both (assessments and treatments). The long term training was necessary to ensure the procedures' reliability, and included how to behave near the subjects to minimize bias of subjects' perceptions. The calibration was first performed by one with prior experience with the RDC/TMD (gold standard examiner – rater 2). Two remaining examiners (trained examiners – raters 3 and 4) were trained and calibrated by the first, in addition to watching the RDC/TMD exam training video (available at

<http://www.rdc-tmdinternational.org>). Data extraction and the statistical analysis were performed by the independent rater (rater 1).

Primary and secondary outcomes

The primary outcome was the time until fatigue during the fatiguing biting test, as the main goal of the protocol was improve the muscle endurance. Secondary outcomes were: 1. Effects on muscle efficiency, representing a ratio between the time until fatigue and the generated force during the biting task; 2. Effects on muscle excitation, as the exercise may affect the motor unit recruitment before structural tissues changes; 3. Pain perception (VAS scores and PPT).

Data extraction

All data were offline extracted using the Miotec Suite™ Software (Miotec™, Biomedical Equipments, Porto Alegre, RS, Brazil). As the load cell was synchronized with the electromyography channels, the trained rater set the interval using the force onset. After three 1-s windows of rest were collected, the onset was defined by three times the standard deviation from the averaged rest intervals plus the mean itself. The interval started when the signal exceeded the onset threshold value. Conversely, the end of the interval was set using the same threshold. Interval means were used for statistical analysis (force, muscle excitation). The total time until fatigue (from the onset until the end of the interval) was also collected from the software recordings. The VAS scores and the mean from the three peaks of algometry were considered for the statistical analysis. The muscle efficiency considered the mean total of force

times the amount of time spent to perform the task. The result was divided by 100 to be expressed as a percentage.

Statistical analysis

Data were presented as means and standard deviation. The Multivariate Analysis of Variance General Linear Model with repeated measures was used to rate differences within and between group and to extend the analysis by taking into account multiple continuous dependent variables, bundling them together into a weighted linear combination or composite variable (Hotelling's trace). The Sidak's *post hoc* test was used to perform pairwise comparisons. The significance was set at $p < 0.05$. All analysis were done using the SPSS Inc. (PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc) and G-Power softwares (version 3.1.5, Franz Faul, Universität Kiel, Germany).

RESULTS

Table 3 summarizes the descriptive and inferential data from variables with significant differences. The descriptive data of variables without significant differences are summarized at supplementary table S1. The subjects were treated in the school clinic of Governador Valadares (Minas Gerais, Brazil) between January, 2018 and December, 2018. All treatments were provided onsite. No practice at home was asked. Attendance at sessions was, therefore, taken as compliance with the treatment protocol. No co- interventions were performed in either group, and no adverse effects were reported by any participant during the 8-week protocol. Thirty-four subjects finished the protocol.

Composite variable comparisons

Significant differences were noted between groups ($F=2.4$; $p=0.04$), and within-subjects analysis showed significant differences for time effect ($F=3.7$; $p=0.0001$) on the composite variable. However, no differences were noted considering the interaction time-by-group when all variables were bundle together into a composite ($F=1.5$; $p=0.08$).

Between-group comparisons

The between-group pairwise comparisons showed differences for the VAS ($F=4.05$; $p=0.04$) at 8-week. The intervention group showed lower value compared to the placebo group. Differences were observed between placebo and intervention group for efficiency at 4-week and 8-week assessments ($F=11.15$; $p=0.002$), with progressive higher values of efficiency on the intervention group. The time until fatigue also showed significant differences at 8-week ($F=8.25$; $p=0.007$). The intervention group performed the biting task for much more time than the placebo group.

Within-group comparisons

Considering the time factor, within-group comparisons for VAS showed a progressive decrease on perceived pain for both groups. Significant differences on the placebo group occurred between the baseline and the 8-week evaluations, with lower values at the final assessment. Variations were also observed on the intervention group for VAS between the baseline and 8 weeks, and between the 4 and 8-week assessments, with progressive lower values of VAS. No discrepancy were noted overtime for placebo group on efficiency or time until fatigue. Higher time until fatigue and muscle efficiency were progressively observed at 4 and 8-week ratings for the intervention group. No

within-group differences were observed for the force response, the algometry and the muscle excitation.

TABLE 3

DISCUSSION

This study assessed the effects of an 8-week protocol of local endurance exercises on masticatory muscles in women with TMD. The prevalence of TMD symptoms ranges from 15 to 35%.^{24,25} However, as the sample was stimulated to seek assessment and treatment, this study screened 98 subjects finding 61% of those with positive diagnosis of TMD. Additionally, TMD symptoms tend to be underdiagnosed due to similar complaints of other disorders, such as headaches, fibromyalgia, and painful cervical and shoulder.^{26,27} The present study also had 26% dropout rate, while another randomized controlled study with combined therapy (laser + exercises) had 20%.²⁸ A study with the same design using stabilization splints in TMD subjects had 33% dropout rate.²⁹ TMD subjects are used to receive a multimodal conservative approach. As the exercise was applied alone, the present dropout rate was probably due to a single type of therapy. The choice to use the exercise without other types of treatment was to ensure the internal validity. Perceived pain scores decreased overtime for both groups, but the intervention group showed lower values at 8 weeks compared to the placebo group. The time until fatigue and the muscle efficiency were higher on the intervention group in both within and between-group comparisons. Temporal muscle excitation was higher on 8-week evaluation compared to baseline on the intervention group, but no between-group divergences were observed.

Lower values of VAS on the placebo group were expected, as this effect is derived from the participants' perception and experience of receiving a pain-reducing treatment as well as the integration of this sensory information with memories of previous experiences and current expectations.^{30,31} Placebo effects are also associated with the expected pain levels and emotional feelings, such as reduced anxiety and the previous experience of relief.^{31,32} The current study used a simulated low intensity laser therapy with the equipment emitting beep sounds, but without the actual laser application. The equipment is widely used by physical therapists to treat pain and inflammatory musculoskeletal conditions. As the simulated laser therapy followed all phases of eye protection and equipment's positioning on the sites of pain, the subject's experience and possible expectations of relief were possibly affected, inducing a lower pain perception. However, the effect was lower than the exercise at the end of the protocol, and limited to a certain level without differences between 4 and 8-week assessments.

There are many different exercises protocols and the outcome may vary with the prescription, especially for TMD.^{7,9} The external load, the number of series and repetitions, the rest between series and the training frequency are the main factors controlled by the physical therapist.³³ Also, the many possible combinations of these factors and individual metabolic response could influence some of the results associated with a specific exercise protocol. The authors acknowledge that there are several difficulties to control exercise variables in clinical and laboratory settings. Equipment with biofeedback to control external load exercises are usually expensive, not adaptable for biting, and the software are not always friendly user. However, without controlling the exercise

parameters, all inferences would be biased. The choice of adapting the load cell allowed both assessment and training.

Individualized, supervised exercise based on patient presentation and preferences is essential for controlling chronic pain.^{34,35} Though, despite such individual variety, the overall response among subjects to an exercise protocol tend to remain similar into a group when more physical and even psychological similarities occur.^{33,36,37} The present study particularly focused on women with orofacial pain and TMD during the most prevalent phase of life for these conditions. Relevant variables changed overtime due to the exercise protocol, partially confirming the hypothesis. At the end of the protocol, the VAS scores were lower for the intervention compared to placebo group. Other studies already have shown dissimilarity in pain due to exercises in TMD subjects. A prospective study included coordination, endurance, and strengthening exercises for the jaw-neck-shoulder region in an individualized 10-24 weeks protocol. All subjects reported a reduction in jaw pain after the exercise program, classified through a numerical rating scale.³⁸ Another study consisted of 10 sessions of muscle-conditioning techniques, manual therapy, and stretching over 5-week in 12 women with mixed TMD (combining myofascial pain either with joint impairment or disc displacement).¹⁶ The results showed significant mandibular function improvement and decreased self reported pain score. Although systematic reviews and meta-analysis observed 2 major issues on the majority of studies involving exercises.^{7,9} They did not report interventions sufficiently to be reproducible and co-interventions were also not controlled. The current study isolated the exercise intervention and controlled all parameters involved in the prescription, with relevant changes in pain. A recent

review suggested peripheral and central nervous system sensitization due to mechanical pressure pain sensitivity in the trigeminal region and remote regions in subjects with TMD.³⁹ The same study suggested spinal and central hyperexcitability in TMD subjects. The central sensitization process may amplify the pain information in the brain, resulting in a reduction in the normal central inhibitory mechanisms that help to balance activation of pain centers.⁴³ The TMJ pain is an usual complaint in subjects with TMD, and it can be a referred pain from the myalgia due to central or even peripheral sensitization.^{23,41,42} The PPT increased overtime for both groups, but no differences were observed within or between-group anytime. Objectively, the placebo was as good as the exercise protocol. A possible explanation is that the present exercise approach and assessments to TMD pain did not take into account for the psychosocial sphere, mainly due to excessive number of variables and time consumed to evaluate during the sessions. The psychosocial factors have relevant role in both classifying and treating TMD subjects.⁴⁰ Subjects with emotional profile with low disability, high intensity pain-related impairment, and high to moderate levels of somatization and depression would be important split factors or a co-variables to include in future assessments.⁴⁰

The higher time until fatigue in the intervention group compared to placebo was the main factor to change the muscle efficiency as the force remained the same between groups across time. The unchanged biting force was expected due to the characteristics of the exercise protocol. High external load (>60% of MVIC), and low repetitions (6-12) are essential to strength changes.¹³ But for local muscular endurance training, it is recommended that light to moderate loads (40-60% of MVIC) be performed for high repetitions

(>15) using short rest periods (<90 s).¹³ Previous studies observed a relationship among fatigue, masticatory muscles efficiency and TMD.^{6,44} Subjects with TMD showed reduced endurance to jaw motor tasks with lower oxygen extraction capacity compared to healthy subjects.^{5,6,44} Individuals with impaired functional capacity with regard to endurance may have increased risk for developing pain and dysfunction.^{14,38} Nevertheless, general aerobic exercises have shown to improve muscle strength, flexibility, and functional capacity and could induce analgesia.⁴⁵ The current results showed that the level of perceived pain decreased as the time until fatigue increased, and consequently, the muscle efficiency was improved without changes in force response. These novel findings highlight the local muscle endurance exercises as an alternative to treat TMD subjects with orofacial pain.

Study Limitations

Further studies comparing combinations among other successful therapies are needed to provide the best care for TMD subjects. The present study also focused on women at limited range of age. Those presenting other levels of functional limitations and other age groups may show distinct patterns, as their male counterpart. The placebo procedure may also influence pain results, as inferred from the results of this study. The sample were not subjects seeking treatment, and this could represent a selection bias. The pain was provoked by palpation without report of familiar or spontaneous pain. Psychosocial assessments may influence the group split. Despite sample size calculation, the number of subjects who met the eligibility criteria was relatively restricted.

CONCLUSIONS

Physical rehabilitation with exercise protocol focusing in local muscle endurance training alleviate the perceived orofacial pain and improve the fatigue and the muscle efficiency in TMD subjects. The control of exercise parameters with a biofeedback system was important to establish an objective clinical progression. The local endurance training was clinically relevant to treat TMD, improving the fatigue threshold. Further research might focus on affordable equipment to control external loads during exercises for TMD.

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Table 1. Subjects' characteristics.

Characteristic		Control	Intervention	P
N		17	17	-
Age (years)		26±8	30±7	0.13 [†]
Weight (Kg)		58±9	64±14	0.14 [†]
Height (cm)		162±5	164±7	0.44 [†]
BMI (Kg/m ²)		22±4	24±4	0.17 [†]
Severity Index*	Low	11 (64.7%)	9 (52.9%)	0.39 [‡]
	Moderate	6 (35.3%)	8 (47.1%)	

[†]Independent t test; [‡]Chi-square binomial test

*The severity index was obtained using the Mandibular Function Impairment
Questionnaire

1 **Table 2.** Intervention protocol.

Week	Rest before Contraction	Time of Contraction	Load % of MVIC	Repetitions	Interval between Repetitions	Series	Rest between Series	Total Time of Execution/Session
1	7 s	5 s	20%	10	2 s	3	2 min	7 min 41 s
2	6 s	5 s	20%	12	2 s	4	2 min	11 min 5 s
3	7 s	4 s	25%	15	2 s	4	1.5 min	10 min 39 s
4	8 s	4 s	30%	18	2 s	4	1.5 min	11 min 51 s
5	9 s	3 s	35%	20	1 s	5	1 min	10 min 50 s
6	10 s	3 s	40%	22	1 s	5	1 min	11 min 9 s
7	11 s	2 s	45%	25	1 s	5	0.5 min	8 min 25 s
8	12 s	2 s	50%	25	1 s	5	0.5 min	8 min 25 s

2
3
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7 **Table 3.** Variables with significant differences. Descriptive data in mean and SD. Within and between-subjects post hoc
8 comparisons.

Outcomes	Groups	Baseline Mean (SD)	4-week Mean (SD)	8-week Mean (SD)	Post hoc within- group p (95% CI)	Post hoc between- group p (95% CI); Moment
VAS (cm)*	Intervention	3.7 (2.2)	2.6 (2)	1.1 (1.3)	0.003 (0.8; 4) 8-wk < Baseline 0.001 (0.7; 2) 8-wk < 4-wk	0.01 (0.4; 3.3); 8-wk
	Placebo	4.9 (3.4)	3.6 (2.5)	3.0 (2.6)	0.03 (0.3; 4) 8-wk < Baseline	
EFICIENCY**	Intervention	37 (23)	56 (31)	68 (36)	0.02 (2; 34) 4-wk > Baseline 0.03 (1; 24) 8-wk > 4-wk 0.0001 (16; 47) 8-wk > Baseline	0.01 (6; 43); 4-wk 0.001 (14; 53); 8-wk
	Placebo	26 (13)	32 (21)	35 (14)	NS	

TIME UNTIL FATIGUE (s)***	Intervention	42 (21)	65 (40)	74 (36)	0.02 (2; 43) 4-wk > Baseline	
					0.001 (11; 52) 8-wk > Baseline	0.003 (12; 54); 8-wk
	Placebo	35 (18)	41 (23)	40 (22)	NS	
EMG TEMP-R (%)****	Intervention	75 (21)	83 (37)	113 (51)	0.007 (9; 67) 8-wk > Baseline	-
	Placebo	86 (39)	81 (35)	76 (49)		-

9 Significant within-group differences:

10 *F=7.2; p=0.001 at 8-week;

11 **F=7.4; p=0.01 at 4-week, and F=12.8; p=0.001 at 8-week;

12 ***F=4.5; p=0.04 at 4-week, and F=10.6; p=0.003 at 8-week;

13 ****F=4.7; p=0.04 at 8-week.

14

RESULTADOS	GRUPOS	BASAL MEDIA (DP)	SEMANA 04 MÉDIA (DP)	SEMANA 08 MÉDIA (DP)	POST HOC INTRA GRUPO P(95%IC)	POST HOC ENTRE GRUPOS P(95%IC) MOMENTOS
EVA (cm)*	GE	3.7 (2.2)	2.6 (2)	1.1 (1.3)	0,003 (0,8;4) Sem8<Basal 0,001 (0,7;2) Sem8<Sem4	0,01 (0,4;3,3) Sem8
	GC	4.9 (3.4)	3.6 (2.5)	3.0 (2.6)	0,03 (0,3;4) Sem8<Basal	
EFICIÊNCIA**	GE	37 (23)	56 (31)	68 (36)	0,02 (2;34) Sem4>Basal 0,03 (1;24) Sem8>Sem4 0,0001(16;47) Sem8>Basal	0,01 (6;43) Sem4 0,001 (14;53) Sem8
	GC	26 (13)	32 (21)	35 (14)	NS	
TEMPO ATÉ FADIGA (s)***	GE	42 (21)	65 (40)	74 (36)	0,02 (2;43) Sem4>Basal 0,001 (11;52) Sem8>Basal	0,003 (12;54) Sem8
	GC	35 (18)	41 (23)	40 (22)	NS	
EMG TEMP. D (%)****	GE	75 (21)	83 (37)	113 (51)	0,007 (9;67) Sem8>Basal	
	GC	86 (39)	81 (35)	76 (49)		

TABELA 2 – Variáveis com diferenças estatisticamente significativas

Dados descritivos em média e desvio-padrão. Comparações de *Post-hoc* intra e entre sujeitos. Diferenças significativas intra-grupo

*F= 7,2; p=0,001 na semana 8

**F= 7,4; p=0,01 na semana 4 e F= 12,8; p=0,001 na semana 8

***F= 4,5; p=0,04 na semana 4 e F= 10,6; p=0,003 na semana 8

****F= 4,7; p=0,04 na semana 8

Fonte: Elaborada pela autora

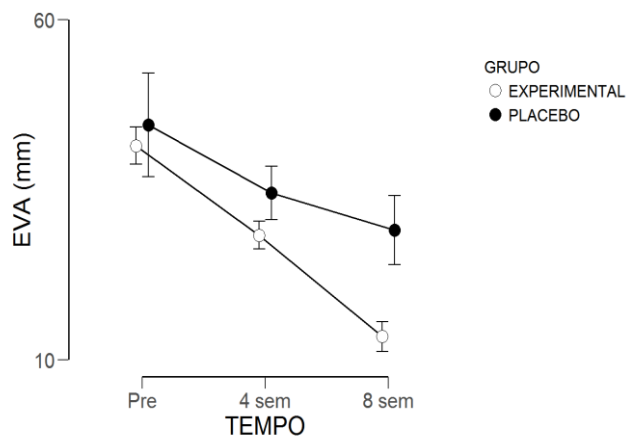


GRÁFICO 1 – Dor pela Escala Visual Analógica em

função do tempo

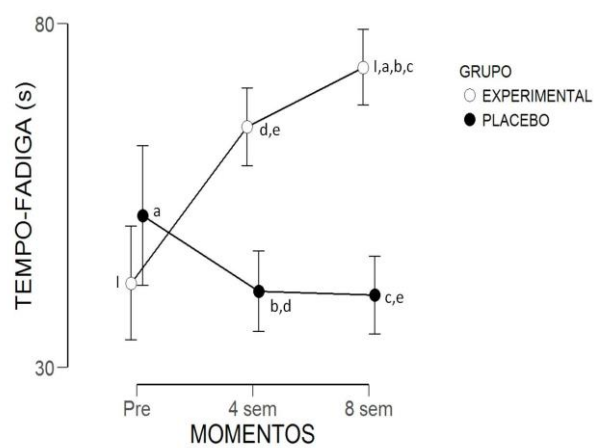


GRÁFICO 2 – Tempo até a fadiga em função dos

momentos de avaliação

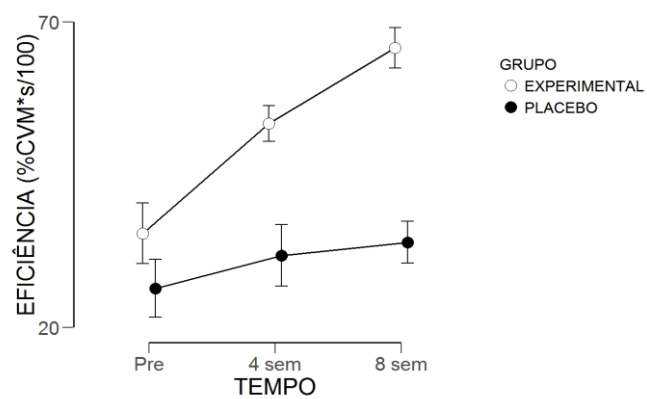


GRÁFICO 3 - Eficiência muscular ao longo do

tempo

Fonte: Elaborados pela autora

6- CONSIDERAÇÕES FINAIS

Concluimos que o protocolo estabelecido de exercícios de treinamento de resistência muscular à fadiga da musculatura levantadora da mandíbula por meio de biofeedback pode ser uma alternativa eficaz para aliviar a dor orofacial, ampliar o tempo até a fadiga e a eficiência muscular em pacientes com DTM.

Houve diminuição da dor em ambos os grupos, tanto na avaliação da 4ª semana como na da 8ª semana. O tempo até a fadiga e eficiência muscular apresentaram melhores e significativas pontuações ao final do protocolo de 08 semanas para o grupo experimental.

Mais estudos são necessários comparando combinações entre outras terapias bem-sucedidas ou analisando o comportamento da DTM em outras faixas etárias, ou de acordo com aspectos psicossociais e ainda na população masculina, para fornecer o melhor atendimento e resultados para portadores de DTM.

O follow-up após 03 meses não foi possível devido à indisponibilidade das participantes.

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APÊNDICE 1 – Parecer infraestrutura e concordância para realização de pesquisa



DEPARTAMENTO DE FISIOTERAPIA – UNIVERSIDADE FEDERAL DE JUIZ DE FORA – CAMPUS GV
RUA ISRAEL PINHEIRO, 2000, BL.D9, BAIRRO UNIVERSITÁRIO, GOVERNADOR VALADARES – MG

DECLARAÇÃO DE INFRAESTRUTURA E CONCORDÂNCIA PARA REALIZAÇÃO DE PESQUISA

Eu, Prof^ª. Dr^ª. Alessa Sin Singer Brugiolo, Chefe do Departamento de Fisioterapia, na qualidade de responsável pela Clínica Escola de Fisioterapia da Universidade Federal de Juiz de Fora - Campus Governador Valadares, autorizo a realização da pesquisa intitulada “Exercícios isométricos de resistência muscular à fadiga no tratamento da disfunção temporomandibular por meio de biofeedback”, a ser conduzida sob a responsabilidade do pesquisador Prof. Dr. Alexandre C. Barbosa e DECLARO que esta instituição apresenta infraestrutura necessária à realização da referida pesquisa, contando com salas devidamente preparadas para as avaliações constantes no projeto, garantindo a segurança e a privacidade dos participantes. A mesma se encontra à disposição, conforme cronograma apresentado e devidamente autorizado o uso das instalações pelo pesquisador e sua equipe. Esta declaração é válida apenas no caso de haver parecer favorável do Comitê de Ética da UFJF para a referida pesquisa.

Atenciosamente,

Governador Valadares, 12 de maio de 2017.

APÊNDICE 2 – Termo de consentimento livre e esclarecido

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

O Sr. (a) está sendo convidado (a) como voluntário (a) a participar da pesquisa **EXERCÍCIOS ISOMÉTRICOS DE RESISTÊNCIA MUSCULAR À FADIGA NO TRATAMENTO DA DISFUNÇÃO TEMPOROMANDIBULAR POR MEIO DE BIOFEEDBACK**. Nesta pesquisa pretendemos analisar a eficácia de um treinamento com exercícios para o tratamento da disfunção temporomandibular por meio de biofeedback, identificar parâmetros eletromiográficos de força pré- e pós-treinamento e verificar o comportamento da dor com a utilização do treinamento com exercícios para o tratamento da sua disfunção temporomandibular (dor na mandíbula) com o equipamento para monitorar a atividade muscular. O motivo que nos leva a estudar não há na literatura parâmetros determinados para emprego deste recurso, nem clareza de que tipo de exercício deve ser empregado no tratamento da disfunção. Para esta pesquisa adotaremos os seguintes procedimentos: O Sr. (a) passará por uma avaliação funcional que compreenderá a aplicação de questionários, avaliação da dor, avaliação da atividade muscular e força muscular da musculatura levantadora da mandíbula e limite de dor por pressão.

Há o risco de contaminação bucal pelo uso dos equipamentos, mas antes de iniciarmos cada atendimento, tais equipamentos serão esterilizados com álcool a 70% e cada um terá uma cobertura de látex para se evitar contato direto. Há o risco, embora mínimo, de corte ao realizar a retirada de pelos faciais para melhor aderência dos eletrodos para a coleta da atividade muscular. Minimizaremos este risco através de treinamento para o terapeuta a coletar os dados sobre como realizar o procedimento com segurança. Além disso, os instrumentos utilizados para o procedimento serão todos descartáveis. É improvável que os questionários utilizados nesse estudo causem algum estresse psicológico, entretanto o Sr. (a) será entrevistado em local privativo, resguardando o sigilo de seus dados. Estabelecer parâmetros adequados do treinamento muscular no tratamento da disfunção temporomandibular contribui para a aplicação de um tratamento mais eficiente pelo fisioterapeuta. Em caso de melhora em qualquer variável estudada, o voluntário terá o benefício do tratamento para sua disfunção. Para participar deste estudo o Sr (a) não terá nenhum custo, nem receberá qualquer vantagem financeira. Apesar disso, caso sejam identificados e comprovados danos provenientes desta pesquisa, o Sr.(a) tem assegurado o direito a indenização.

O Sr. (a) terá o esclarecimento sobre o estudo em qualquer aspecto que desejar e estará livre para participar ou recusar-se a participar. Poderá retirar seu consentimento ou interromper a participação a qualquer momento. A sua participação é voluntária e a recusa em participar não acarretará qualquer penalidade ou modificação na forma em que o Sr. (a) é atendido (a). O pesquisador tratará a sua identidade com padrões profissionais de sigilo. Os resultados da pesquisa estarão à sua disposição quando finalizada. Seu nome ou o material que indique sua participação não será liberado sem a sua permissão. O (A) Sr (a) não será identificado (a) em nenhuma publicação que possa resultar.

Este termo de consentimento encontra-se impresso em duas vias originais, sendo que uma será arquivada pelo pesquisador responsável, na clínica escola de fisioterapia da UFJF campus Governador Valadares e a outra será fornecida ao Sr. (a). Os dados e instrumentos utilizados na pesquisa ficarão arquivados com o pesquisador responsável por um período de 5 (cinco) anos, e após esse tempo serão destruídos. Os pesquisadores tratarão a sua identidade com padrões profissionais de sigilo, atendendo a

legislação brasileira (Resolução Nº 466/12 do Conselho Nacional de Saúde), utilizando as informações somente para os fins acadêmicos e científicos.

Eu, _____, portador do documento de Identidade _____ fui informado (a) dos objetivos da pesquisa **EXERCÍCIOS ISOMÉTRICOS DE RESISTÊNCIA MUSCULAR À FADIGA NO TRATAMENTO DA DISFUNÇÃO TEMPOROMANDIBULAR POR MEIO DE BIOFEEDBACK**, de maneira clara e detalhada e esclareci minhas dúvidas. Sei que a qualquer momento poderei solicitar novas informações e modificar minha decisão de participar se assim o desejar.

Declaro que concordo em participar. Recebi uma via original deste termo de consentimento livre e esclarecido e me foi dada à oportunidade de ler e esclarecer as minhas dúvidas.

Governador Valadares, _____ de _____ de _____.

Assinatura do Participante

Assinatura do (a) Pesquisador (a)

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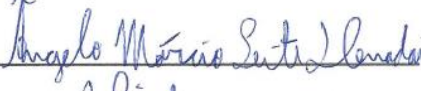
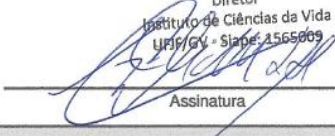
mail: alexwbarbosa@hotmail.com

ANEXO 1 – Parecer CNS



MINISTÉRIO DA SAÚDE - Conselho Nacional de Saúde - Comissão Nacional de Ética em Pesquisa – CONEP

FOLHA DE ROSTO PARA PESQUISA ENVOLVENDO SERES HUMANOS

1. Projeto de Pesquisa: Exercícios isométricos de resistência muscular à fadiga no tratamento da disfunção temporomandibular por meio de biofeedback: estudo controle randomizado			
2. Número de Participantes da Pesquisa: 40			
3. Área Temática: Ciências da Saúde/Educação Física/Fisioterapia e Terapia Ocupacional			
4. Área do Conhecimento: Grande Área 4. Ciências da Saúde			
PESQUISADOR RESPONSÁVEL			
5. Nome: Alexandre Wesley Carvalho Barbosa			
6. CPF: 035.429.666-30		7. Endereço (Rua, n.º): Rua Joaquim Faria Salgado Morada do Vale 378 A GOVERNADOR VALADARES MINAS GERAIS 35065100	
8. Nacionalidade: BRASILEIRO	9. Telefone: 33991541851	10. Outro Telefone:	11. Email: alexwbarbosa@hotmail.com
Termo de Compromisso: Declaro que conheço e cumprirei os requisitos da Resolução CNS 466/12 e suas complementares. Comprometo-me a utilizar os materiais e dados coletados exclusivamente para os fins previstos no protocolo e a publicar os resultados sejam eles favoráveis ou não. Aceito as responsabilidades pela condução científica do projeto acima. Tenho ciência que essa folha será anexada ao projeto devidamente assinada por todos os responsáveis e fará parte integrante da documentação do mesmo.			
Data: 12 / 05 / 2017		 Prof. Dr. Alexandre C. Barbosa Professor Adjunto I - SIAPE 1815061 Universidade de Juiz de Fora/UJF Departamento de Fisioterapia Assinatura	
INSTITUIÇÃO PROPONENTE			
12. Nome: UNIVERSIDADE FEDERAL DE JUIZ DE FORA UFJF		13. CNPJ: 21.195.755/0003-20	
14. Unidade/Órgão: Campus Governador Valadares		15. Telefone: (32) 2102-3950	
16. Outro Telefone:			
Termo de Compromisso (do responsável pela instituição): Declaro que conheço e cumprirei os requisitos da Resolução CNS 466/12 e suas Complementares e como esta instituição tem condições para o desenvolvimento deste projeto, autorizo sua execução.			
Responsável: 		CPF: 034.833.596-21	
Cargo/Função: Diretor		Prof. Dr. Ângelo Márcio Leite Denadai Diretor Instituto de Ciências da Vida UJF/GV - SIAPE 1565009	
Data: 12 / 05 / 17		 Assinatura	
PATROCINADOR PRINCIPAL			
Não se aplica.			

ANEXO 2- Research Diagnostic Criteria for Temporomandibular Disorders (Eixo 01)

EXAME CLÍNICO	
1. Você tem dor no lado direito da sua face, lado esquerdo ou ambos os lados?	
☐ 0	Nenhum
☐ 1	Direito
☐ 2	Esquerdo
☐ 3	Ambos
2. Você poderia apontar as áreas aonde você sente dor ?	
Direito	Esquerdo
☐ 0	☐ 0
Nenhuma	Nenhuma
☐ 1	☐ 1
Articulação	Articulação
☐ 2	☐ 2
Músculos	Músculos
☐ 3	☐ 3
Ambos	Ambos
3. Padrão de abertura:	
☐ 0	Reto
☐ 1	Desvio lateral direito (não corrigido)
☐ 2	Desvio lateral direito corrigido ("S")
☐ 3	Desvio lateral esquerdo (não corrigido)
☐ 4	Desvio lateral esquerdo corrigido ("S")
☐ 5	Outro tipo _____ (Especifique)
4. Extensão de movimento vertical	
<i>Incisivo superior utilizado</i> 11 21 	
a. Abertura sem auxílio sem dor mm	
b. Abertura máxima sem auxílio mm	
Dor Muscular	Dor Articular
☐ 0	☐ 0
Nenhuma	Nenhuma
☐ 1	☐ 1
Direito	Direito
☐ 2	☐ 2
Esquerdo	Esquerdo
☐ 3	☐ 3
Ambos	Ambos
c. Abertura máxima com auxílio mm	
Dor Muscular	Dor Articular
☐ 0	☐ 0
Nenhuma	Nenhuma
☐ 1	☐ 1
Direito	Direito
☐ 2	☐ 2
Esquerdo	Esquerdo
☐ 3	☐ 3
Ambos	Ambos
d. Trespasse incisal vertical mm	

5. Ruídos articulares (palpação)

a. abertura

Direito		Esquerdo	
☐ 0	Nenhum	☐ 0	Nenhum
☐ 1	Estalido	☐ 1	Estalido
☐ 2	Crepitação grosseira	☐ 2	Crepitação grosseira
☐ 3	Crepitação fina	☐ 3	Crepitação fina
mm		mm	
(Medida do estalido na abertura)			

b. Fechamento

Direito		Esquerdo	
☐ 0	Nenhum	☐ 0	Nenhum
☐ 1	Estalido	☐ 1	Estalido
☐ 2	Crepitação grosseira	☐ 2	Crepitação grosseira
☐ 3	Crepitação fina	☐ 3	Crepitação fina
mm		mm	
(Medida do estalido no fechamento)			

c. Estalido recíproco eliminado durante abertura protrusiva

Direito		Esquerdo	
☐ 0	Não	☐ 0	Não
☐ 1	Sim	☐ 1	Sim
☐ 8	NA	☐ 8	NA
(NA: Nenhuma das opções acima)			

6. Excursões

a. Excursão lateral direita mm

Dor Muscular		Dor Articular	
☐ 0	Nenhuma	☐ 0	Nenhuma
☐ 1	Direito	☐ 1	Direito
☐ 2	Esquerdo	☐ 2	Esquerdo
☐ 3	Ambos	☐ 3	Ambos

b. Excursão lateral esquerda mm

Dor Muscular		Dor Articular	
☐ 0	Nenhuma	☐ 0	Nenhuma
☐ 1	Direito	☐ 1	Direito
☐ 2	Esquerdo	☐ 2	Esquerdo
☐ 3	Ambos	☐ 3	Ambos

c. Protrusão mm

Dor Muscular		Dor Articular	
☐ 0	Nenhuma	☐ 0	Nenhuma
☐ 1	Direito	☐ 1	Direito
☐ 2	Esquerdo	☐ 2	Esquerdo
☐ 3	Ambos	☐ 3	Ambos

d. Desvio de linha média mm

☐ 1 Direito

☐ 2 Esquerdo

☐ 8 NA

(NA: Nenhuma das opções acima)

7. Ruídos articulares nas excursões

Ruídos direito

	Nenhum	Estalido	Crepitação grosseira	Crepitação fina
7.a Excursão Direita	0	1	2	3
7.b Excursão Esquerda	0	1	2	3
7.c Protrusão	0	1	2	3

Ruídos esquerdo

	Nenhum	Estalido	Crepitação grosseira	Crepitação fina
7.d Excursão Direita	0	1	2	3
7.e Excursão Esquerda	0	1	2	3
7.f Protrusão	0	1	2	3

INSTRUÇÕES, ÍTENS 8-10

O examinador irá palpar (tocando) diferentes áreas da sua face, cabeça e pescoço. Nós gostaríamos que você indicasse se você não sente dor ou apenas sente pressão (0), ou dor (1-3). Por favor, classifique o quanto de dor você sente para cada uma das palpações de acordo com a escala abaixo. Marque o número que corresponde a quantidade de dor que você sente. Nós gostaríamos que você fizesse uma classificação separada para as palpações direita e esquerda.

0 = Somente pressão (sem dor)
 1 = dor leve
 2 = dor moderada
 3 = dor severa

8. Dor muscular extraoral com palpação	Direita				Esquerda			
a. Temporal posterior (1,0 Kg.) "Parte de trás da têmpora (atrás e imediatamente acima das orelhas)."	0	1	2	3	0	1	2	3
b. Temporal médio (1,0 Kg.) "Meio da têmpora (4 a 5 cm lateral à margem lateral das sobrancelhas)."	0	1	2	3	0	1	2	3
c. Temporal anterior (1,0 Kg.) "Parte anterior da têmpora (superior a fossa infratemporal e imediatamente acima do processo zigomático)."	0	1	2	3	0	1	2	3
d. Masseter superior (1,0 Kg.) "Bochecha/ abaixo do zigoma (comece 1 cm a frente da ATM e imediatamente abaixo do arco zigomático, palpando o músculo anteriormente)."	0	1	2	3	0	1	2	3
e. Masseter médio (1,0 Kg.) "Bochecha/ lado da face (palpe da borda anterior descendo até o ângulo da mandíbula)."	0	1	2	3	0	1	2	3
f. Masseter inferior (1,0 Kg.) "Bochecha/ linha da mandíbula (1 cm superior e anterior ao ângulo da mandíbula)."	0	1	2	3	0	1	2	3
g. Região mandibular posterior (estilo-hióideo/ região posterior do digástrico) (0,5 Kg.) "Mandíbula/ região da garganta (área entre a inserção do esternocleidomastóideo e borda posterior da mandíbula. Palpe imediatamente medial e posterior ao ângulo da mandíbula)."	0	1	2	3	0	1	2	3
h. Região submandibular (pterigóideo medial/ supra-hióideo/ região anterior do digástrico) (0,5 Kg.) "abaixo da mandíbula (2 cm a frente do ângulo da mandíbula)."	0	1	2	3	0	1	2	3

9. Dor articular com palpação	Direita				Esquerda			
a. Polo lateral (0,5 Kg.) "Por fora (anterior ao trago e sobre a ATM)."	0	1	2	3	0	1	2	3
b. Ligamento posterior (0,5 Kg.) "Dentro do ouvido (pressione o dedo na direção anterior e medial enquanto o paciente está com a boca fechada)."	0	1	2	3	0	1	2	3

10. Dor muscular intraoral com palpação	Direita				Esquerda			
a. Área do pterigóideo lateral (0,5 Kg.) "Atrás dos molares superiores (coloque o dedo mínimo na margem alveolar acima do último molar superior. Mova o dedo para distal, para cima e em seguida para medial para palpar)."	0	1	2	3	0	1	2	3
b. Tendão do temporal (0,5 Kg.) "Tendão (com o dedo sobre a borda anterior do processo coronoide, mova-o para cima. Palpe a área mais superior do processo)."	0	1	2	3	0	1	2	3

ANEXO 3 – Escala visual analógica da dor

Nome: _____

Imagine que a ausência de dor seja o valor 0 e a maior dor que possa existir seja o valor 10, marque na reta abaixo aonde estaria a sua dor.



0 10

Ausência de Dor

Maior dor existente

ANEXO 4 – Questionário e Índice de Limitação Funcional Mandibular

Quadro 5 Questionário e Índice de Limitação Funcional Mandibular (MFIQ)²⁹ [Tradução não-oficial]

Item	Pontuação	Nível de dificuldade				
		Nenhuma (0)	Um pouco (1)	Bastante (2)	Muita (3)	Muitíssima*
Com relação a queixas de dores na mandíbula, quanto de dificuldade você apresenta para realizar as seguintes atividades:						
1 Atividades sociais						
2 Falar						
3 Dar uma boa mordida						
4 Mastigar comida dura						
5 Mastigar comida mole						
6 Trabalhar ou realizar atividades de vida diária						
7 Beber						
8 Rir						
9 Mastigar comida dura						
10 Bocejar						
11 Beijar						
Comer inclui morder, mastigar e deglutir. Quanto de dificuldade você tem para comer os seguintes alimentos:						
1 Uma bolacha dura						
2 Um bife						
3 Uma cenoura crua						
4 Um pão francês						
5 Amendoim						
6 Uma maçã						

Soma das pontuações S = _____ = _____ + _____ + _____ + _____ + _____

Cálculo do índice: $C = S/N.4$, onde S = soma das pontuações obtidas e N = número de itens respondidos (divida a soma S encontrada pelo número de itens respondidos vezes 4)

Para chegar ao grau de acometimento funcional, calcule C e siga as regras da 1ª coluna:

Regras (R = resposta/s)	Faixas de variação do índice C	Grau de acometimento funcional
Todas as R com pontuação < 2	$C \leq 0,3$	0
Pelo menos uma R ≥ 2	$C \leq 0,3$	1
Todas as R com pontuação < 3	$0,3 < C \leq 0,6$	2
Pelo menos uma R ≥ 3	$0,3 < C \leq 0,6$	3
Todas as R $\neq 4$	$C > 0,6$	4
Todas as R = 4	$C > 0,6$	5
Graduação da severidade	I baixo	0 ou 1
	II moderado	2 ou 3
	III severo	4 ou 5

* Pontuação (4): no original, “é muito difícil OU é impossível sem ajuda”

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ORIGINAL ARTICLE

JOURNAL OF ORAL
REHABILITATION

WILEY

Effects of 8 weeks of masticatory muscles focused endurance exercises on women with oro-facial pain and temporomandibular disorders: A placebo randomised controlled trial

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Superior

Abstract

Background: Exercises are used to treat temporomandibular disorders (TMD), but they are often assessed with other therapies. Local endurance exercises may alter the resistance to fatigue and pain.

Objective: To assess the effects of an 8-week protocol of local endurance exercises of masticatory muscles on muscle excitation, force response, perceived pain and over muscle efficiency.

Design: Randomised controlled trial.

Setting: Ambulatory care.

Subjects: In a placebo randomised controlled trial, 46 women with TMD and oro-facial pain were randomised into intervention group and placebo group. The intervention group received a protocol of biting endurance exercises, controlled by biofeedback. The placebo group received a placebo (simulated laser therapy).

Main Outcome Measures: The primary outcomes were collected at baseline, 4 weeks and 8 weeks. Pain was assessed through visual analogue scale (VAS) and pressure pain thresholds (PPT). Bite force was collected by a load cell synchronised with surface electromyography of masticatory muscles, bilaterally.

Results: Pain scores decreased for both groups, but the intervention group showed lower values at 8 weeks. No differences were noted between groups for PPT, but the results increased for both overtime. Time until fatigue and muscle efficiency were higher in the intervention group vs placebo group in both within- and between-subject analysis. Force increased from 4 to 8 weeks in the PG, without differences between groups. Temporal muscle excitation was higher on 8 weeks compared with baseline for the intervention group, without differences between groups.

Conclusion: Eight-week exercise protocol of muscle endurance alleviates the pain and improves the resistance to fatigue and muscle efficiency in TMD subjects.

KEYWORDS

bite force, electromyography, exercise therapy, facial pain, resistance training, temporomandibular joint disorders

1 | INTRODUCTION

The prevalence of temporomandibular disorder (TMD) is 27%-38% of the examined adult population.¹ Women showed higher prevalence of painful conditions than men, including both oro-facial pain and other TMD symptoms.²⁻⁴ Subjects with TMD present more easily fatigued and less efficient masticatory muscles, with lower oxygen extraction capacity during mastication than healthy control subjects.⁵ Such condition leads to reduced supply of oxygen to the muscle that interferes with the contractile function.⁶ Additionally, the severity of TMD and oro-facial myofunctional disorders is related to the oxygen extraction capacity percentage.⁶

Conservative interventions for subjects with TMD including exercises, joint mobilisation, splints and combinations of some of these techniques are often applied as primary choice for care.^{7,8} Low to moderate level of evidence shows positive effects for improving symptoms of muscular TMD when using posture correction exercises for patients with myofascial pain.⁹ There was also a trend to favour exercise therapy (general jaw exercises alone or combined with neck exercises in myogenous TMD) for pain free maximum opening and pain intensity when compared with a control group, with a moderate pooled effect size.⁹ However, the exercise programmes were not often assessed alone, but in association to other therapies as part of a conservative treatment protocol.^{7,9} A review with meta-analysis analysed the effectiveness of manual therapy and therapeutic exercise for TMD.⁹ The authors suggested that more trials isolating the type of exercise are necessary, mentioning that further research is required to assess the usefulness of aerobic exercise as well as focused muscular training. Exercise therapy also shows inconsistent results due to the lack of appropriate dosage parameters and the consequent failure to identify the effectiveness of exercise prescription.^{7,9}

Lengthy duration of submaximal contractile activity during endurance exercises requires a continuous supply of energy, provided by the local storage and through increased blood flow to skeletal muscles.¹⁰ The muscle ability to produce ATP for movement occurs by adapting the mRNA levels and protein changes to increase mitochondrial concentrations as the endurance exercise progresses.^{10,11} The increased mitochondrial concentrations are not the only adaptations to endurance training. Energetic demands of muscle contraction due to such exercise are also controllers of glucose ratio and whole-body fat levels.^{10,12,13} TMD subjects have significantly lower endurance time during functional biting activities (such as bilateral or unilateral chewing) compared with controls.¹⁴ However, the response of the jaw muscles to local endurance exercise remains poorly known despite the benefits of endurance exercises for other skeletal muscles.

The present study aimed to assess the effects of an 8-week protocol of local endurance exercises. The hypothesis is that the 8-week protocol of local endurance exercises would change the biomechanical parameters (time until fatigue, electromyographic excitation, force response and muscle efficiency considering the force-time parameters) of the masseter and temporal muscles during maximal biting

until fatigue and the perceived pain (algometry and visual analogue scale) on masticatory muscles.

2 | METHODS

2.1 | Material

The subjects (Figure 1) were recruited by public invitation through folders and personal contacts; the authors assume that this could represent a selection bias. However, there is no public or private service in the city to perform any TMD assessment, which impairs the voluntary seek for treatment. A sample of 98 women voluntarily presented themselves for the study. The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD-Axis I) was used for the diagnosis of TMD. The RDC/TMD is the internationally accepted gold standard, and its last version is the DC/TMD. However, the lack of a validated Portuguese version of DC/TMD led the authors to use the validated Portuguese version of RDC/TMD for diagnostic purposes. Only those with chronic TMD (more than 6 months of complaints) were included. The jaw opening capacity was preserved at normal levels for all patients (above 4 cm), measured with a caliper, during RDC/TMD assessment. All subjects were diagnosed as myalgia, also according to RDC/TMD. The inclusion criteria for both groups were to have a minimum of 28 permanent teeth and age between 18 and 45 years old. All subjects reported no periodontal issues. Exclusion criteria for both groups were history of trauma on the face and on the temporomandibular joint (TMJ), systemic diseases such as arthritis, pain attributable to confirmed migraine, head, or neck pain condition, chronic use (more than 6 months) of any analgesic, anti-inflammatory or psychiatric drugs, acute infection or other significant disease of the teeth, ears, eyes, nose, or throat, and to present neurological or cognitive deficit. After the first screening, only 46 subjects with TMD associated with muscular oro-facial pain were included and randomly divided by an independent rater into two groups: placebo group ($n = 23$), and intervention group ($n = 23$). The randomisation was carried out by an independent rater considering the 1:1 allocation ratio. Before the study begins, a random allocation sequence was automatically generated using the Research Randomizer website (www.randomizer.org), by using 1 set of numbers, with a total of 46 numbers per set, and the established number range as 1-2, representing the placebo and the intervention group, respectively. The random sequence was delivered by the Research Randomizer, and the independent rater kept the sequence. The sequence order was continuously given to the examiner who performed the assessments when a new participant was allocated for treatment. The rater who performed the randomisation was blinded to the statistical analysis. The RDC/TMD assessments, the physical examination, comprising muscle and TMJ palpation, measurement of active mandibular movements and joint noise analysis were performed by well-trained professionals. The random allocation list was not accessible to the recruiting staff or

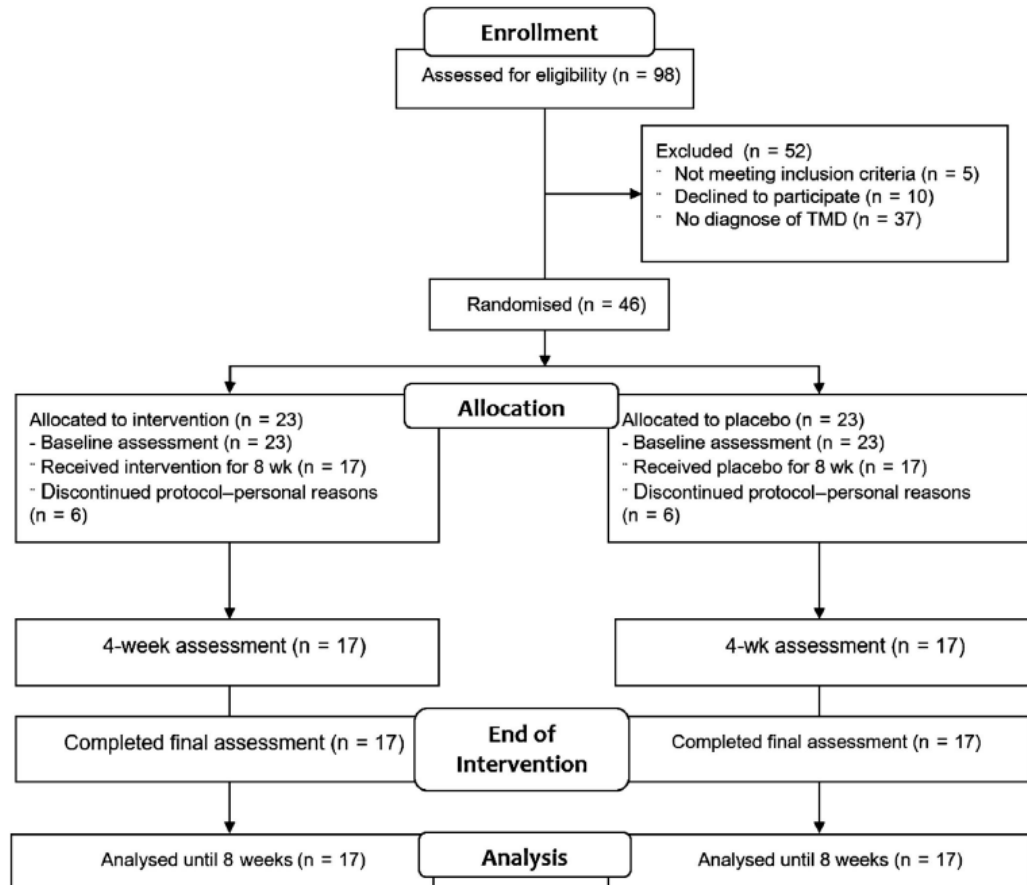


FIGURE 1 Flow diagram

to the physiotherapists who implemented the treatment at any time. The group allocation and the allocation concealment were preserved. Personal reasons (travel during more than a week and lack of time for treatment) lead six subjects from each group to discontinue the protocol. Thirty-four were analysed at 8-week assessments. The Mandibular Function Impairment Questionnaire was used to classify the subjects in relation to the severity of the functional limitation related to TMD (Table 1).^{15,16} The baseline participant's characteristics were reported in Table 1. The ethics committee for human investigation of the Federal University of Juiz de Fora approved the procedures employed in the study (protocol number 68457617.6.0000.5147). The objectives of the study were explained to the subjects, and they were notified of the benefits and potential risks involved before signing an informed consent form prior to the participation. This study was registered in the Brazilian clinical trials registry (ensaiosclinicos.gov.br): protocol number RBR-6kyh2g.

The subjects were assessed before (baseline), at 4 weeks and at 8 weeks after the protocol begins. The a priori sample size calculation was based on a previous study,¹⁷ considering the effect size of 0.60, the alpha level of 5% and a 95% power, returning a total of 32 individuals.

2.2 | Instruments

Surface electromyography was used to evaluate the muscle excitation of the temporal and masseter muscles during a fatigue biting task for both Placebo and Intervention groups. The continuous biting task leads to extreme fatigue, and it was performed only once. An acquisition module with eight analog channels (Miotec™, Biomedical Equipments) continuously recorded the biological signals. The conversion from analog to digital signals was performed by an A/D board with 14-bit resolution input range, the sampling frequency of 2 kHz, common rejection module greater than 100 dB, signal-noise ratio less than 03 μ V Root Mean Square and impedance of 109 Ω . The

TABLE 1 Subjects' characteristics

Characteristic	Control	Intervention	P
n	17	17	-
Age (y)	26 ± 8	30 ± 7	0.13 ^a
Weight (kg)	58 ± 9	64 ± 14	0.14 ^a
Height (cm)	162 ± 5	164 ± 7	0.44 ^a
BMI (kg/m ²)	22 ± 4	24 ± 4	0.17 ^a
Severity index ^c			
Low	11 (64.7%)	9 (52.9%)	0.39 ^b
Moderate	6 (35.3%)	8 (47.1%)	

^aIndependent t test.^bChi-square binomial test.^cThe severity index was obtained using the Mandibular Function Impairment Questionnaire.

collected data were windowed at 125 ms using the Miotec™ Suite Software. The sEMG signals were recorded in root mean square in μ V with surface Meditrace™ (Ludlow Technical Products) Ag/AgCl electrodes with a diameter of 1 cm and centre-to-centre distance of 1 cm, applied in a transverse orientation parallel to the underlying fibres on a muscle site. A reference electrode was placed on the left lateral humeral epicondyle. sEMG signals were amplified and filtered (Butterworth fourth-order, 20–450 Hz bandpass filter, 60 Hz notch filter). All pieces of information were recorded and processed using the software Miotec Suite™ (Miotec Biomedical Equipments). Prior to the sEMG electrode placement, the skin was cleaned with 70% alcohol to eliminate residual fat, followed by an exfoliation using a specific sandpaper for skin and a second cleaning with alcohol. The electrodes were positioned on the anterior temporal muscles and the superficial masseter on both left and right sides parallel to the muscle fibres.³

2.3 | Maximal voluntary isometric contraction

Three 5-second maximum isometric contraction (MVIC) were performed by each participant while biting on an adapted load cell (Miotec™, Biomedical Equipments; maximum tension-compression = 200 kgf, precision of 0.1 kgf, maximum error of measurement = 0.33%). Each MVIC was followed by 5 minutes of rest. Subjects were asked to sit comfortably (the volunteer remained seated with the trunk erect, feet on the floor and hands resting on the thighs) while the load cell arms were positioned on the incisors (Figure S1). A disposable material was used to cover the arms for each subject. The forward head posture was controlled during all procedures by positioning the load cell closer to the participant, so the subjects could bite in their natural head posture. Standardised verbal commands ("start," "keep biting," "stop") were used by the same rater for all tests' recordings. A 5-second familiarisation was followed by 3 minutes of rest before the MVIC. The intra-rater reliability of the adapted load cell was previously assessed twice (1 week apart measures), returning a very good ICC of 0.84. The load cell was coupled and synchronised with the electromyography. The mean among the MVIC trials was used for normalisation purposes.

2.4 | Fatiguing biting test

The fatigue of the masseter and temporalis muscles was assessed during a single maximal biting effort test. The previously described MVIC procedures were adopted. However, instead of an immediate short maximal effort, each participant was asked to perform a MVIC for the maximal supported time.

2.5 | Pain assessments

A visual analog scale (VAS) of 0–100 mm, which was designed as 0 being no pain and 100 being the worst pain ever experienced, was given to subjects in this study to mark a perpendicular line between the 2 extremes to represent their pain intensity at the time of evaluation with provoked pain through temporal palpation.¹⁸ Psychometric properties of VAS were previously tested with excellent results to evaluate pain.^{19–21} All VAS scores were collected by the same rater. Visual analog scale scores ≤ 3.4 represent mild pain, 3.5–7.4 moderate pain and ≥ 7.5 severe pain.²² The VAS results were used for comparisons.

The pressure pain threshold (PPT) was measured with the described load cell adapted as an algometer (Figure S2). The equipment's intra-rater reliability was previously tested with 1 week apart repeated measures. The results were adequate, with an ICC of 0.83. The load cell was recalibrated for each participant following the manufacturer recommendations. All PPT measurements were performed by the same investigator in the following order: left temporal, left TMJ, left masseter, right temporal, right TMJ and right masseter. As the signal was collected continuously, the previous order was always the same to identify each PPT. The volunteer remained seated with the trunk erect, feet on the floor and hands resting on the thighs. The device has a 1-cm² rubber application head, and measurements were calculated as kg/cm². Analog to digital conversion was performed by the previously described acquisition module. The PPT was measured bilaterally over the TMJ (precisely in front of the ear canal), the belly of the masseter muscles and the belly of the anterior temporal muscles.²³ These sites received progressive 1 kg/s pressure until the participant experienced pain. The participant lifted a hand when the PPT was achieved. The software continuously recorded all measures for offline comparisons. The PPT was measured three times at each site with 3-second interval. All assessments were collected in a separate session from the exercise session.

2.6 | Intervention

The protocol consisted of resistance exercises twice a week for 8 weeks (16 sessions). Table 2 shows the progressive protocol developed to respect the principle of low external load, allowing more series and repetitions. The external load ranged from 20% to 50% of the MVIC, and it was controlled using the Biotrainer™ visual bio-feedback software (Miotec™, Biomedical Equipments – Figure 2). The protocol was previously set by a trained rater, using the same instructions, but no verbal encouragement was given. The participant was instructed to perform short bites on the adapted load cell, and

TABLE 2 Intervention protocol

Week	Rest before contraction	Time of contraction	Load % of MVIC	Repetitions	Interval between repetitions	Series	Rest between series	Total time of execution/session
1	7 s	5 s	20%	10	2 s	3	2 min	7 min 41 s
2	6 s	5 s	20%	12	2 s	4	2 min	11 min 5 s
3	7 s	4 s	25%	15	2 s	4	1.5 min	10 min 39 s
4	8 s	4 s	30%	18	2 s	4	1.5 min	11 min 51 s
5	9 s	3 s	35%	20	1 s	5	1 min	10 min 50 s
6	10 s	3 s	40%	22	1 s	5	1 min	11 min 9 s
7	11 s	2 s	45%	25	1 s	5	0.5 min	8 min 25 s
8	12 s	2 s	50%	25	1 s	5	0.5 min	8 min 25 s

an additional familiarisation session was allowed at the 1st week. The external load, the repetitions, the rest before contraction and the series were progressively increased, while the time of contraction, the interval between repetitions and the rest between series were progressively decreased.

The other group received placebo via simulated low intensity laser therapy (off mode) for the same time of session as the intervention group protocol (the off mode enabled the equipment to emit beep sounds, but without laser application). The simulated laser therapy followed all phases of eye protection (special glasses for the patient and for the therapist) and equipment's positioning. The sites of positioning were as follows: the TMJ, the anterior temporal muscle and the masseter muscle, bilaterally.

2.6.1 | Raters

An independent rater (rater 1) performed the randomisation procedure, as explained. Three raters (raters 2, 3 and 4) were exhaustively trained for 6 months before the study to perform the assessments (muscle palpation, pain assessments and how to perform the RDC/TMD) and to apply both treatments. The raters were not allowed to perform both (assessments and treatments). The long-term training was necessary to ensure the procedures' reliability and included how to behave near the subjects to minimise bias of subjects' perceptions. The calibration was first performed by one with prior experience with the RDC/TMD (gold standard examiner—rater 2). Two remaining examiners (trained examiners—raters 3 and 4) were trained and calibrated by the first, in addition to watching the RDC/TMD exam training video (available at <http://www.rdc-tmdinternational.org>). Data extraction and the statistical analysis were performed by the independent rater (rater 1).

2.7 | Primary and secondary outcomes

The primary outcome was the time until fatigue during the fatiguing biting test, as the main goal of the protocol was to improve the muscle endurance. Secondary outcomes were as follows: (a) effects on muscle efficiency, representing a ratio between the time until fatigue and the generated force during the biting task; (b) effects on

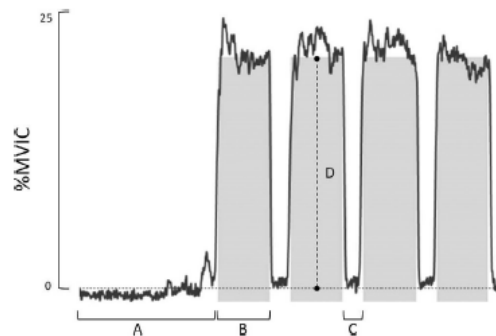


FIGURE 2 Electromyographic signal obtained from the Biotrainer™ biofeedback interface by using the load cell to control the amplitude of the contraction. A, Rest period; B, contraction period; C, inter-contraction rest period; D, the grey rectangle corresponds to the amplitude of contraction preset by the therapist. The subject was instructed to sustain the level of contraction by reaching the superior level of the rectangle and then rest during the interval between rectangles

muscle excitation, as the exercise may affect the motor unit recruitment before structural tissues changes; and (c) pain perception (VAS scores and PPT).

2.8 | Data extraction

All data were offline extracted using the Miotec Suite™ Software (Miotec™, Biomedical Equipments). As the load cell was synchronised with the electromyography channels, the trained rater set the interval using the force onset. After three 1-second windows of rest were collected, the onset was defined by three times the standard deviation from the averaged rest intervals plus the mean itself. The interval started when the signal exceeded the onset threshold value. Conversely, the end of the interval was set using the same threshold. Interval means were used for statistical analysis (force, muscle excitation). The total time until fatigue (from the onset until the end of the interval) was also collected from the software recordings. The VAS scores and the mean from the three peaks of algometry

were considered for the statistical analysis. The muscle efficiency considered the mean total of force times the amount of time spent to perform the task. The result was divided by 100 to be expressed as a percentage.

2.9 | Statistical analysis

Data were presented as means and standard deviation. The multivariate analysis of variance general linear model with repeated measures was used to rate differences within and between groups and to extend the analysis by taking into account multiple continuous dependent variables, bundling them together into a weighted linear combination or composite variable (Hotelling's trace). Sidak's *post hoc* test was used to perform pairwise comparisons. The significance was set at $P < 0.05$. All analysis was done using the SPSS Inc (PASW Statistics for Windows, version 18.0. Chicago: SPSS Inc) and G-Power software (version 3.1.5, Franz Faul, Universität Kiel, Germany).

3 | RESULTS

Table 3 summarises the descriptive and inferential data from variables with significant differences. The descriptive data of variables

without significant differences are summarised at Table S1. The subjects were treated in the school clinic of Governador Valadares (Minas Gerais, Brazil) between January 2018 and December 2018. All treatments were provided onsite. No practice at home was asked. Attendance at sessions was, therefore, taken as compliance with the treatment protocol. No co-interventions were performed in either group, and no adverse effects were reported by any participant during the 8-week protocol. Thirty-four subjects finished the protocol.

3.1 | Composite variable comparisons

Significant differences were noted between groups ($F = 2.4$; $P = 0.04$), and within-subjects analysis showed significant differences for time effect ($F = 3.7$; $P = 0.0001$) on the composite variable. However, no differences were noted considering the interaction time-by-group when all variables were bundled together into a composite ($F = 1.5$; $P = 0.08$).

3.2 | Between-group comparisons

The between-group pairwise comparisons showed differences for the VAS ($F = 4.05$; $P = 0.04$) at 8 weeks. The intervention group showed lower value compared with the placebo group. Differences

TABLE 3 Variables with significant differences

Outcomes	Groups	Baseline Mean (SD)	4 wk Mean (SD)	8 wk Mean (SD)	Post hoc within-group P (95% CI)	Post hoc between-group P (95% CI); Moment
VAS (cm)*	Intervention	3.7 (2.2)	2.6 (2)	1.1 (1.3)	0.003 (0.8; 4) 8 wk < Baseline 0.001 (0.7; 2) 8 wk < 4 wk	0.01 (0.4; 3.3); 8 wk
	Placebo	4.9 (3.4)	3.6 (2.5)	3.0 (2.6)	0.03 (0.3; 4) 8 wk < Baseline	
Efficiency**	Intervention	37 (23)	56 (31)	68 (36)	0.02 (2; 34) 4 wk > Baseline 0.03 (1; 24) 8 wk > 4 wk 0.0001 (16; 47) 8 wk > Baseline	0.01 (6; 43); 4 wk 0.001 (14; 53); 8 wk
	Placebo	26 (13)	32 (21)	35 (14)	NS	
Time until fatigue (s)***	Intervention	42 (21)	65 (40)	74 (36)	0.02 (2; 43) 4 wk > Baseline 0.001 (11; 52) 8 wk > Baseline	0.003 (12; 54); 8 wk
	Placebo	35 (18)	41 (23)	40 (22)	NS	
EMG TEMP-R (%)****	Intervention	75 (21)	83 (37)	113 (51)	0.007 (9; 67) 8 wk > Baseline	-
	Placebo	86 (39)	81 (35)	76 (49)		-

Note: Descriptive data in mean and SD. Within- and between-subject post hoc comparisons.

Significant within-group differences:

* $F = 7.2$; $P = 0.001$ at 8 wk;

** $F = 7.4$; $P = 0.01$ at 4 wk and $F = 12.8$; $P = 0.001$ at 8 wk;

*** $F = 4.5$; $P = 0.04$ at 4 wk and $F = 10.6$; $P = 0.003$ at 8 wk;

**** $F = 4.7$; $P = 0.04$ at 8 wk.

were observed between placebo and intervention group for efficiency at 4-week and 8-week assessments ($F = 11.15$; $P = 0.002$), with progressive higher values of efficiency on the intervention group. The time until fatigue also showed significant differences at 8 weeks ($F = 8.25$; $P = 0.007$). The intervention group performed the biting task for much more time than the placebo group.

3.3 | Within-group comparisons

Considering the time factor, within-group comparisons for VAS showed a progressive decrease in perceived pain for both groups. Significant differences in the placebo group occurred between the baseline and the 8-week evaluations, with lower values at the final assessment. Variations were also observed on the intervention group for VAS between the baseline and 8 weeks, and between the 4- and 8-week assessments, with progressive lower values of VAS. No discrepancy was noted overtime for placebo group on efficiency or time until fatigue. Higher time until fatigue and muscle efficiency were progressively observed at 4- and 8-week ratings for the intervention group. No within-group differences were observed for the force response, the algometry and the muscle excitation.

4 | DISCUSSION

This study assessed the effects of an 8-week protocol of local endurance exercises on masticatory muscles in women with TMD. The prevalence of TMD symptoms ranges from 15% to 35%.^{24,25} However, as the sample was stimulated to seek assessment and treatment, this study screened 98 subjects finding 61% of those with positive diagnosis of TMD. Additionally, TMD symptoms tend to be underdiagnosed due to similar complaints of other disorders, such as headaches, fibromyalgia, and painful cervical and shoulder.^{26,27} The present study also had 26% dropout rate, while another randomised controlled study with combined therapy (laser + exercises) had 20%.²⁸ A study with the same design using stabilisation splints in TMD subjects had 33% dropout rate.²⁹ TMD subjects are used to receive a multimodal conservative approach. As the exercise was applied alone, the present dropout rate was probably due to a single type of therapy. The choice to use the exercise without other types of treatment was to ensure the internal validity. Perceived pain scores decreased overtime for both groups, but the intervention group showed lower values at 8 weeks compared with the placebo group. The time until fatigue and the muscle efficiency were higher on the intervention group in both within- and between-group comparisons. Temporal muscle excitation was higher on 8-week evaluation compared with baseline on the intervention group, but no between-group divergences were observed.

Lower values of VAS on the placebo group were expected, as this effect is derived from the participants' perception and experience of receiving a pain-reducing treatment as well as the integration of this sensory information with memories of previous experiences and current expectations.^{30,31} Placebo effects are also associated with

the expected pain levels and emotional feelings, such as reduced anxiety and the previous experience of relief.^{31,32} The current study used a simulated low intensity laser therapy with the equipment emitting beep sounds, but without the actual laser application. The equipment is widely used by physical therapists to treat pain and inflammatory musculoskeletal conditions. As the simulated laser therapy followed all phases of eye protection and equipment's positioning on the sites of pain, the subject's experience and possible expectations of relief were possible affected, inducing a lower pain perception. However, the effect was lower than the exercise at the end of the protocol and limited to a certain level without differences between 4- and 8-week assessments.

There are many different exercises protocols and the outcome may vary with the prescription, especially for TMD.^{7,9} The external load, the number of series and repetitions, and the rest between series and the training frequency are the main factors controlled by the physical therapist.³³ Also, the many possible combinations of these factors and individual metabolic response could influence some of the results associated with a specific exercise protocol. The authors acknowledge that there are several difficulties to control exercise variables in clinical and laboratory settings. Equipment with bio-feedback to control external load exercises is usually expensive, not adaptable for biting, and the software are not always friendly user. However, without controlling the exercise parameters, all inferences would be biased. The choice of adapting the load cell allowed both assessment and training.

Individualised, supervised exercise based on patient presentation and preferences is essential for controlling chronic pain.^{34,35} Though, despite such individual variety, the overall response among subjects to an exercise protocol tends to remain similar to a group when more physical and even psychological similarities occur.^{33,36,37} The present study particularly focused on women with oro-facial pain and TMD during the most prevalent phase of life for these conditions. Relevant variables changed overtime due to the exercise protocol, partially confirming the hypothesis. At the end of the protocol, the VAS scores were lower for the intervention compared with placebo group. Other studies already have shown dissimilarity in pain due to exercises in TMD subjects. A prospective study included coordination, endurance and strengthening exercises for the jaw-neck-shoulder region in an individualised 10- to 24-week protocol. All subjects reported a reduction in jaw pain after the exercise programme, classified through a numerical rating scale.³⁸ Another study consisted of 10 sessions of muscle-conditioning techniques, manual therapy and stretching over 5 weeks in 12 women with mixed TMD (combining myofascial pain either with joint impairment or disc displacement).¹⁶ The results showed significant mandibular function improvement and decreased self-reported pain score. Although systematic reviews and meta-analysis observed two major issues on the majority of studies involving exercises, they did not report interventions sufficiently to be reproducible, and co-interventions were also not controlled.^{7,9} The current study isolated the exercise intervention and controlled all parameters involved in the prescription, with relevant changes in pain. A recent

review suggested peripheral and central nervous system sensitisation due to mechanical pressure pain sensitivity in the trigeminal region and remote regions in subjects with TMD.³⁹ The same study suggested spinal and central hyperexcitability in TMD subjects. The central sensitisation process may amplify the pain information in the brain, resulting in a reduction in the normal central inhibitory mechanisms that help to balance activation of pain centres.⁴⁰ The TMJ pain is an usual complaint in subjects with TMD, and it can be a referred pain from the myalgia due to central or even peripheral sensitisation.^{23,41,42} The PPT increased overtime for both groups, but no differences were observed within or between groups any-time. Objectively, the placebo was as good as the exercise protocol. A possible explanation is that the present exercise approach and assessments to TMD pain did not take into account for the psychosocial sphere, mainly due to excessive number of variables and time consumed to evaluate during the sessions. The psychosocial factors have relevant role in both classifying and treating TMD subjects.⁴³ Subjects with emotional profile with low disability, high intensity pain-related impairment, and high to moderate levels of somatisation and depression would be important split factors or a co-variables to include in future assessments.⁴³

The higher time until fatigue in the intervention group compared with placebo was the main factor to change the muscle efficiency as the force remained the same between groups across time. The unchanged biting force was expected due to the characteristics of the exercise protocol. High external load (>60% of MVIC) and low repetitions (6–12) are essential to strength changes.¹³ But for local muscular endurance training, it is recommended that light to moderate loads (40%–60% of MVIC) be performed for high repetitions (>15) using short rest periods (<90 seconds).¹³ The previous studies observed a relationship among fatigue, masticatory muscles efficiency and TMD.^{6,44} Subjects with TMD showed reduced endurance to jaw motor tasks with lower oxygen extraction capacity compared with healthy subjects.^{5,6,44} Individuals with impaired functional capacity with regard to endurance may have increased risk for developing pain and dysfunction.^{14,38} Nevertheless, general aerobic exercises have shown to improve muscle strength, flexibility, and functional capacity and could induce analgesia.⁴⁵ The current results showed that the level of perceived pain decreased as the time until fatigue increased, and consequently, the muscle efficiency was improved without changes in force response. These novel findings highlight the local muscle endurance exercises as an alternative to treat TMD subjects with oro-facial pain.

4.1 | Study limitations

Further studies comparing combinations among other successful therapies are needed to provide the best care for TMD subjects. The present study also focused on women at limited range of age. Those presenting other levels of functional limitations and other age groups may show distinct patterns, as their male counterpart. The placebo procedure may also influence pain results, as inferred

from the results of this study. The sample were not subjects seeking treatment, and this could represent a selection bias. The pain was provoked by palpation without report of familiar or spontaneous pain. Psychosocial assessments may influence the group split. Despite sample size calculation, the number of subjects who met the eligibility criteria was relatively restricted.

5 | CONCLUSIONS

Physical rehabilitation with exercise protocol focusing in local muscle endurance training alleviates the perceived oro-facial pain and improves the fatigue and the muscle efficiency in TMD subjects. The control of exercise parameters with a biofeedback system was important to establish an objective clinical progression. The local endurance training was clinically relevant to treat TMD, improving the fatigue threshold. Further research might focus on affordable equipment to control external loads during exercises for TMD.

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