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Pressure release technique versus placebo applied to cervical and masticatory muscles in patients with chronic painful myofascial temporomandibular disorder: A randomised clinical trial

Gema Serrano-Hernanz[1,2] | Teresa Angulo-Carrere[1] | Ignacio Ardizone-García[2] | Peter Svensson[3,4] | Ana M. Álvarez-Méndez[1]

[1]Department of Nursing, Faculty of Nursing, Physiotherapy and Podiatry, Complutense University of Madrid, Madrid, Spain

[2]Department of Stomatology, Faculty of Odontology, Complutense University of Madrid, Madrid, Spain

[3]Section for Orofacial Pain and Jaw Function, Department of Dentistry and Oral Health, Aarhus University, Aarhus, Denmark

[4]Faculty of Odontology, Scandinavian Center for Orofacial Neurosciences (SCON), Malmø University, Malmø, Sweden

Correspondence
Gema Serrano-Hernanz, Department of Nursing, Faculty of Nursing, Physiotherapy and Podiatry, Complutense University of Madrid, Madrid, Spain and Department of Stomatology, Faculty of Odontology, Complutense University of Madrid, Plaza de Ramón y Cajal s/n, 28040 Madrid, Spain.
Email: gema.serrano.hernanz@gmail.com and gemase01@ucm.es

Abstract

Background: The therapeutic approach to myofascial TMD should focus on pain relief and rehabilitation of function.

Objective: This study investigated whether pressure release technique (PRT) is effective for reducing pain in people with chronic myofascial temporomandibular disorders (TMD).

Methods: A single-blinded randomised parallel-group trial, with 3 months follow-up was conducted. A total of 72 patients were randomly allocated to receive PRT or sham PRT. Primary outcome was pain assessed with a visual analogue scale (VAS). Secondary outcomes included pressure pain thresholds (PPTs), range of opening of the mouth (ROM), Neck Disability Index (NDI), Pain Catastrophizing Scale (PCS), Tampa Scale for Kinesiophobia (TSK-11), State–Trait Anxiety Index (STAI) and State–Trait Depression Index (ST-DEP). All parameters were assessed at baseline, at the end of the treatment and at 3 months follow-up. Statistical analysis was performed by ANOVA.

Results: There were significant main effects of time, group and interaction between time and group ($F \geq 21.92$; $p < .001$) on VAS pain. Post hoc tests showed a significant reduction in VAS pain scores in the PRT group (≥31.9%; $p < .001$). Effect sizes were moderate in the PRT group at all follow-up periods (≥1.25 Cohen's d). Also, there were significant effects of time in secondary outcomes ($F \geq 9.65$; $p < .001$), and there were also interactions between time and group ($F \geq 3.82$; $p < .002$) with better effects in the PRT group.

Conclusions: The inclusion of PRT to conventional management with occlusal splints and self-care management appears to be effective to improve self-reported levels of pain in patients with chronic myofascial TMD pain. Retrospectively registered (ClinicalTrials.gov: NCT03619889).

KEYWORDS
chronic pain, myofascial pain syndromes, pain threshold, physical therapy modalities, temporomandibular disorders

1 | BACKGROUND

Temporomandibular disorders (TMD) are a collection of complex conditions affecting masticatory muscles, temporomandibular joint (TMJ) and other associated structures and tissues,[1] which can lead to pain, TMJ sounds or noises and dysfunction of jaw movements. Prevalence rates range between 3% and 15% in the general population, and the incidence rates are between 2% and 4%.[2]

Myofascial TMD is one of the most common pain-related TMD conditions (42%), in patients with oro-facial pain, followed by disc displacement with reduction (32.1%) and arthralgia (30%).[2] According to the American Academy of Oro-facial Pain, myofascial TMD pain is defined as the pain of muscular origin affected by movement, function or parafunction of the jaw and the reproduction of this pain with the provocation test of the masseter or temporal muscles.[3] Clinical features of TMD include spontaneous face pain on mandibular motion in the oro-facial region.[4] A typical clinical sign of myofascial TMD is the tenderness or pain on palpation of muscle structures, with standardised areas that should be explored.[1,5,6] The most commonly accepted and worldwide used diagnostic protocol criteria for TMD in Spanish are The Diagnostic Criteria for Temporomandibular disorders (DC/TMD).[1]

The aetiology of myofascial TMD is believed to be multifactorial.[7] Studies have suggested that TMD pain may be the result of an interaction between environmental, emotional, behavioural and physical factors,[7] that can sensitise the central and peripheral nervous system (CNS/PNS).[8,9]

Nevertheless, the main reason for clinical consultation is chronic and persistent oro-facial pain.[10] A common clinical finding is that TMD pain can originate in so-called trigger points (TrPs) of the masticatory and cervical muscles, which refer pain to the oro-facial and temporomandibular regions.[1,11] TrPs are however enigmatic as the underlying pathophysiology remains unclear and discussed.[12,13]

The therapeutic approach to myofascial TMD should focus on pain relief and rehabilitation of function and to prevent or remove predisposing and/or perpetuating factors, by non-invasive, simple and reversible therapies that adhere to the biopsychosocial approach such as conservative dentistry, physiotherapy and psychology.[14] There is a disparity of criteria regarding treatment, while Kakudate et al.[15] showed the occlusal splint and self-care management are the most commonly recommended, Fernández de la Peñas et al.[8] have provided good evidence at level Ia in terms of the effectiveness of manual therapy in painful TMDs. However, there is no scientific evidence in TMD pain to support the recommendation of treatment using a Pressure Releasing Technique (PRT).[16] The PRT is a neuromuscular technique used by physiotherapists to reduce referred or local muscle pain.[17] However, no study has so far investigated effects of PRT in patients with chronic myofascial TMD pain.

The objective of the present study was to conduct a randomised clinical trial to compare the immediate and short-term effectiveness on self-reported pain and biopsychosocial disability of the inclusion of PRT into a conventional treatment with an occlusal splint and self-care management for patients with chronic myofascial TMD pain.

2 | METHODS

2.1 | Study design

A randomised controlled clinical trial was designed to evaluate a physiotherapy treatment for chronic myofascial TMD pain. The intervention group was treated with conventional treatment (occlusal splint and self-care management) and PRT and the control group with conventional treatment and sham PRT. The primary endpoint was self-reported pain at post-treatment (T1) and 3 months follow-up (T2) compared with baseline (T0). Secondary outcomes included pressure pain thresholds (PPTs), range of opening of the mouth (ROM), Neck Disability Index (NDI), and measures of biopsychosocial disabilities like pain catastrophizing (PCS), Tampa Scale for Kinesiophobia (TSK-11), State–Trait anxiety Index (STAI) and State–Trait depression Index (ST-DEP). All the tools have been validated in the TMD population. The current report follows the CONSORT (consolidated standards of reporting trials) guidelines for clinical trials.[18] The study was approved by the Ethic and Clinical Research Committee of the Hospital Clínico San Carlos with protocol number C.P.-C.I. 15/105-E, on the 16th of march, 2015, in accordance with the Helsinki Declaration, and the clinical trial was retrospectively registered but adhered to the original protocol (ClinicalTrials.gov: NCT03619889).

2.2 | Participants

Ninety-one mixed sex patients tentatively diagnosed with chronic myofascial TMD pain from the clinic at Faculty of Dentistry (Universidad Complutense de Madrid, Spain) were screened for eligibility criteria. Participants were invited to participate in the study during the routine medical visit. Inclusion criteria were: (1) over 18 years of age; (2) the population was composed of myofascial and mixed TMD pain according to the DC/TMD with or without referred pain; (3) the primary reason for consultation was the pain of more than 6 months duration; (4) if already treated with an occlusal splint that this had not been adjusted in the past 6 months; and (5) self-care therapy for at least the last 6 months. Patients were excluded if they exhibited: (1) systemic, neurological or muscle pathology; (2) psychiatric or psychological pathology; and (3) cervical pathology.

All participants signed an informed consent prior to their inclusion in the study in accordance with the Helsinki declaration.

2.3 | Sample size determination

The sample size calculations were based on detection of between-group differences of 1.2 cm of self-reported pain (0–10 cm VAS) as the main outcome measure, assuming a standard deviation of 1.5, a two-tailed test, an alpha level (α) of 0.05 and desired power (β) of 98.4% for dependent samples and 81.1% for independent samples. The estimated desired sample size was calculated to be at least 35 patients per group. A 10% dropout rate was expected.

2.4 | Randomisation and masking

A block randomisation method was designed to randomise patients into groups to ensure a balance in sample size. Patients were randomly assigned to receive PRT or sham PRT. Concealed allocation was done using a computer-generated randomised table of numbers created by a statistician who did not participate in the main trial. Individual and sequentially numbered index cards with the random assignment were prepared, folded and placed in sealed opaque envelopes. A second external researcher opened the envelope and proceeded with allocation. Participants were blinded to the hypothesis of the study. Another independent statistician carried out the final statistical analysis without knowing which patients had received PRT or sham PRT (Table 1, Figure 1).

TABLE 1 Baseline characteristics by treatment assignment.

	Sham PRT group	PRT group
Gender (male/female)	4/31	8/29
Age (years)	36.6 ± 13.2	46.9 ± 14.0
VAS (0–10 cm)	7.4 ± 0.9	7.2 ± 0.2
PPT-UT (kgf/cm^2)	1.9 ± 0.8	2.0 ± 0.8
PPT-SS (kgf/cm^2)	1.3 ± 0.6	1.1 ± 0.6
PPT-SM (kgf/cm^2)	1.4 ± 0.5	1.3 ± 0.7
PPT-AT (kgf/cm^2)	1.7 ± 0.7	1.5 ± 0.7
ROM (mm)	38.5 ± 8.9	36.1 ± 10.2
NDI (0–50)	9.6 ± 5.4	14.0 ± 7.4
TSK-11 (0–44)	22.7 ± 6.5	25.1 ± 6.2
PCS (0–52)	15.7 ± 8.8	20.4 ± 10.7
S-ST-DEP (standardised)	0.3 ± 1.0	0.8 ± 1.1
S-STAI (standardised)	0.3 ± 1.6	1.1 ± 2.0

Note: Mean ± standard deviation.

Abbreviations: NDI, neck disability index; PCS, Pain Catastrophizing Scale; PPT-AT, pressure pain threshold of anterior temporalis; PPT-SM, pressure pain threshold of superficial masseter; PPT-SS, pressure pain threshold of sternal portion of sternocleidomastoid; PPT-UP, pressure pain threshold of upper trapezius; ROM, range of the opening of the mouth; S-STAI (standardised), Standardised State Anxiety Index; S-ST-DEP (standardised), Standardised State Depression Index; TSK-11, Tampa Scale for Kinesiophobia; VAS, visual analogue scale.

2.5 | Interventions

The study was conducted at the Dentistry Faculty of the Complutense University of Madrid, where participants were recruited and treated. The two groups received the same conventional treatment, a check of the adjustment of the splint and self-care (previously, all patients had an occlusal splint fabricated and used self-care for at least the past 6 months) by trained and experienced dentists.

Treatment needed to be given by the physiotherapist staff. Patients allocated to the PRT group received PRT applied to the TrPs of both sides of the masticatory and cervical muscles systematically independently if TrPs reproduced referred sensations or pain, during 45 min, once per week, for 5 weeks. The muscles included in the experimental treatment were: upper trapezius, sternocleidomastoid sternal and clavicular portions, superficial and deep masseters and anterior, medium and posterior temporalis, both sides. The selection of these muscles was partly based on the Diagnostic Criteria for TMD (DC/TMD).[1] Since some muscles can exhibit multiple TrPs[11] a clinically pragmatic approach was applied. Therefore, if multiple active TrPs were found, the clinician selected the most painful TrP for receiving PRT. Participants received PRT on all the selected muscles, on both sides. In this study, the PRT described by Lewit[17] and extended by Simons[19] was applied. PRT consisted of application of sustained pressure on the TrP below the pain threshold and gradually increases up to the ceiling of tissue resistance (isquemic compression technique is a more painful technique, consists of application of sustained pressure checking to ensure that in staying within the limits of tolerance pain threshold). Once the TrPs were located, pressure was applied with the finger for 90 s until the resistance of the muscle tissue was felt, the operation was repeated increasing the pressure if the tissue resistance was not reduced (example of PRT applied on superficial masseter TrP; Figure 2). By convention, a decrease in tissue resistance and painful sensitivity suggest an adequate and successful technique. PRT was applied by a physical therapist with 20 years of clinical experience in this therapeutic approach. Patients allocated to the sham group received a similar treatment but applying only a superficial and non-specific pressure. The application of this pressure was trained using a scale and a target below 2 N/cm^2 during 90 s in accordance with Fryer and Hodgson[20] on the same muscles and in the same sequence as in the PRT group.

2.6 | Outcome measures

Compliance was evaluated by direct observation. At each visit made to receive the treatment, the participants completed the questionnaires. Clinical records of all patients included questions regarding the intensity of the symptoms, range of motion and questionnaires.

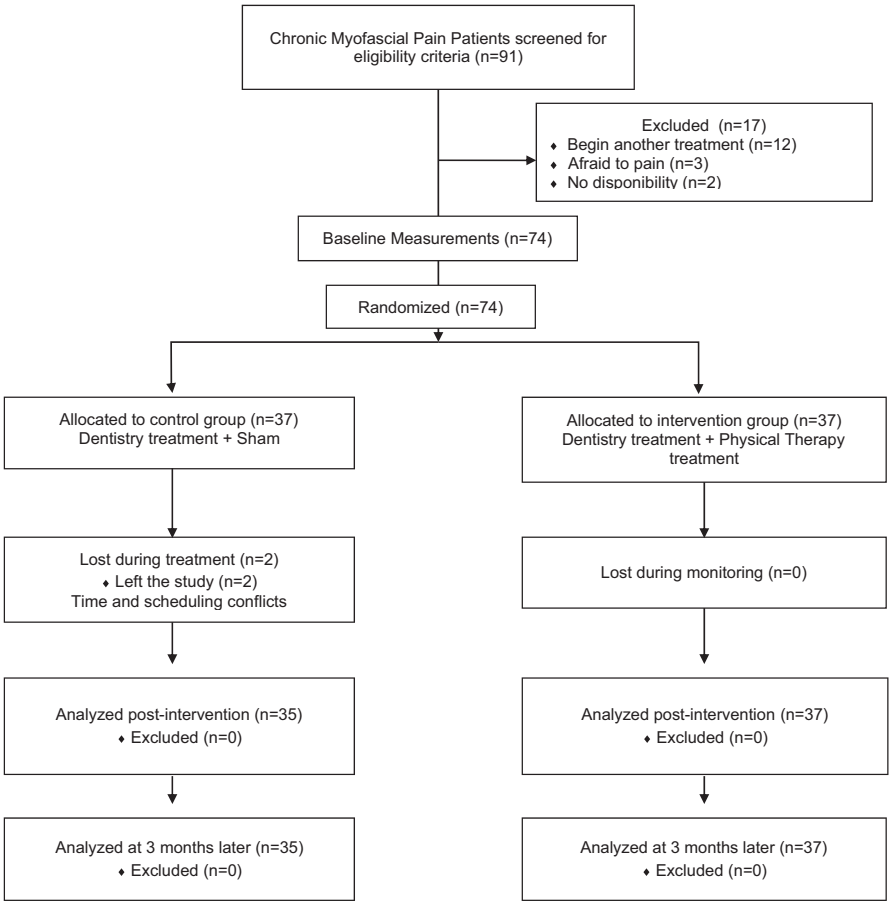

FIGURE 1 Flow diagram of patients throughout the course of the study.

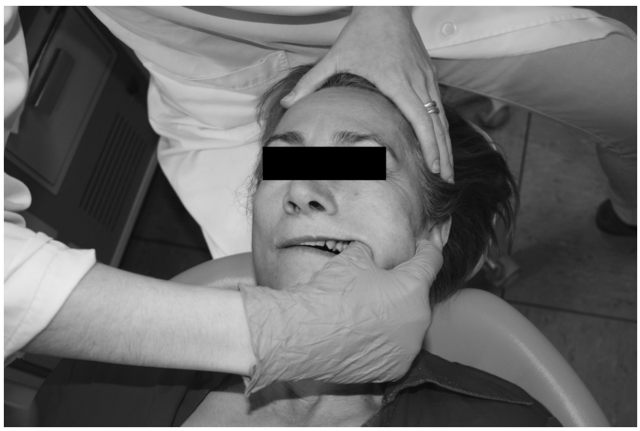

FIGURE 2 Pressure release technique applied on superficial masseter trigger point, with interdigital contact, while, the cranial hand stabilised the head.

Self-reported pain, PPT, ROM, NDI, PCS, TSK-11, STAI and ST-DEP were assessed at baseline (T0), immediately after the treatment (T1) and at 3 months follow-up (T2).

It has been found that the self-reported oro-facial pain is the most frequent symptom for TMD[1] and the principal motive for consultation.[10] Therefore, we decided self-reported pain as the primary outcome. Self-reported pain was assessed with a 10 cm visual analogue scale (VAS) and 0 defined as 'no pain at all' and 10 as 'the worst imaginable pain'.

The secondary outcomes were the PPTs at the TrPs[21] of upper trapezius, clavicular and sternal sternocleidomastoid, deep and superficial masseter and anterior, medium and posterior temporalis; the ROM (mm),[21] that is an important parameter for assessment and evaluation of the TMD at follow-up; NDI,[22] a 50-points NDI (0: no disability; 50: maximum disability) was used. It is described that neck disability is frequently associated to TMD[1]; the TSK-11,[23] an 11–44 points TSK-11 (11: low fear to movement and pain, 44: high fear to movement and pain); PCS,[23] 0–52 points PCS (0: no catastrophizing level, 52: highest catastrophizing level); STAI,[24] a 0–60 points STAI subscale (0: no state anxiety and 60: highest state anxiety level), and ST-DEP,[24] a 20–80 points ST-DEP (20: lowest state depression and 80: highest state depression).

We also defined a successful outcome when patients reported, at least, 1.2 cm[25] improvement from baseline (T0) on the VAS at the end of the treatment (T1) and 3 months follow-up period (T2).

2.7 | Statistical analysis

Statistical analysis was performed using SPSS software, version 21.0 and SAS® 9.4 (TS1M4). It was conducted by an independent statistical technician as described above. Q-Q plots indicated normal distribution of the primary and secondary outcome parameters. Our primary and secondary evaluations included ANOVA of repeated measurements for three related samples (T0, T1, T2), and adjusted

for baseline outcomes for evaluating between-group differences in all the outcomes. To avoid limitations inherent to the test of significance of the null hypothesis and the interpretation of the results, the presence of the phenomenon analysed was quantified by calculating the effect size. The choice of the magnitude of the effect was made based on the study conducted by Dominguez-Lara.[26] $p < .05$ was considered statistically significant.

3 | RESULTS

Ninety-one mixed sex patients with chronic myofascial or mixed TMD pain were screened for eligibility criteria, between October 2015 and October 2017, at the clinic in Faculty of Dentistry, Complutense University, Madrid. Seventy-four patients (81%) satisfied all criteria, and agreed to participate. They were randomly allocated into a sham PRT group ($n = 37$) or a PRT group ($n = 37$) (Table 1). Drop-out in the sham group was due to time and scheduling conflicts. The flow diagram of patient recruitment and retention can be found in Figure 1. Compliance rate was 97%. None of the participants in either group reported any other therapeutic interventions during the study period. The study did not involve testing medications and a person's regular medications was not changed.

3.1 | Primary outcome

Within patients allocated to the sham PRT group, two were lost during the treatment period; however, none left the PRT group. Adjusting the baseline VAS pain scores, the ANOVA model for self-reported pain showed that there were main effects of time and group ($F = 81.30$ and $F = 33.98$, respectively; $p < .001$). There were also a significant interaction between time and group ($F = 21.92$; $p < .001$). Treatment with PRT resulted in lower self-reported VAS pain scores than the sham at T1 and T2 ($p < .001$) (Table 2). Furthermore, post hoc tests for time showed that the participants reported significantly lower VAS pain scores at T2 than at T0 and T1 ($p < .001$), and T1 lower than VAS pain scores at T0 ($p < .001$). Post hoc test for interaction showed that the participants reported significantly lower self-reported pain scores at T2 compared to T0 and at T1 compared to T0 for both groups ($p < .001$). There was also a significant difference between the T1 and T2 for the PRT group ($p < .015$). The PRT group reported significantly lower VAS pain scores compared to the sham PRT group at both T1 and T2 ($p < .001$); however, the sham PRT group reported significantly lower VAS pain scores at T1 and T2 ($p < .001$) but the mean self-reported VAS pain score was smaller than the a priori defined 1.2 cm clinically significant decrease. The proportion of participants with a change in self-reported VAS pain greater than the 1.2 cm threshold for the PRT and the sham PRT groups at follow-up were: PRT at T1 = 78.4%, T2 = 81.1%; sham PRT at T1 = 28.6%, T2 = 17.4%, respectively. Effect sizes were moderate in the PRT group at all follow-up periods [T1 1.25 Cohen's d (0.75, 1.76); and T2 1.36 Cohen's d (0.85, 1.87)] (Table 3), with an efficacy percentage in VAS pain reduction by 31.9% at T1 and 39.3% at T2.

3.2 | Secondary outcomes

For the evaluation of PPTs we found no significant differences between sides or within the same muscle ($p < .05$). The PPT of the upper trapezius, the sternal sternocleidomastoid, the superficial masseter and the anterior temporalis of the right side were used for inferential analysis. Adjusting for baseline outcomes, the ANOVA model indicated only significant effects of time for PPTs at the upper trapezius ($F = 6.20$; $p = .003$) at T1 ($p = .002$) compared with T0; sternal sternocleidomastoid ($F = 7.79$; $p = .001$) at T1 ($p = .001$) and T2 ($p = .013$) compared with T0; superficial masseter ($F = 15.68$; $p < .001$) at T1 ($p < .001$) and T2 ($p < .001$) compared with T0; and anterior temporalis ($F = 14.31$; $p < .001$) at T1 ($p < .001$) and T2 ($p < .001$) compared with T0. (Table 2).

For the ROM, and adjusting for baseline outcomes, the ANOVA model showed significant effects of time ($F = 9.65$; $p < .001$). There was also an interaction between time and group ($F = 3.82$; $p < .001$). Post hoc tests showed that the participants presented significantly higher ROM scores at T2 compared to T0 ($p < .001$) and compared to T1 ($p = .005$), and at T1 compared to T0 ($p = .007$). Post hoc test for interaction showed that the participants reported significantly higher ROM scores at T2 compared to T0 and T1 compared to T0 for the PRT group ($p < .001$) (Table 2).

For the NDI, and adjusting for baseline outcomes, the ANOVA model showed significant effects of time ($F = 24.89$; $p < .001$). There was also an interaction between time and group ($F = 15.02$; $p < .001$). Post hoc tests showed that the participants reported significantly lower NDI scores at T2 compared to T0 ($p < .001$) and a T1 compared to T0 ($p < .001$). Post hoc test for interaction showed that the participants reported significantly lower NDI scores at T2 compared to T0 and at T1 compared to T0 for the PRT group ($p < .001$) (Table 2).

For PCS and adjusting for baseline outcomes, the ANOVA model showed significant effects of time ($F = 37.21$; $p < .001$). There was also an interaction between time and group ($F = 21.03$; $p < .001$) and post hoc tests showed that the participants reported significantly lower PCS scores at T2 compared to T0 ($p < .001$) and at T1 compared to T0 ($p < .001$). Post hoc test for interaction showed that the participants reported significantly lower PCS scores at T2 compared to T0 and at T1 compared to T0 for the PRT group ($p < .001$) (Table 2).

For TSK-11 and adjusting for baseline outcomes, the ANOVA model showed significant effects time ($F = 34.31$; $p < .001$). There was also an interaction between time and group ($F = 8.87$; $p < .001$). Post hoc test showed that the participants reported significantly lower TSK-11 scores at T2 compared to T0 ($p < .001$) and at T1 compared to T0 ($p < .001$). Post hoc test for interaction showed that the participants reported significantly lower TSK-11 scores at T2 compared to T0 and at T1 compared to T0 for the PRT group ($p < .001$) (Table 2).

For ST-STAI and adjusting for baseline outcomes, the ANOVA model showed significant effects time ($F = 23.22$; $p < .001$). There

TABLE 2 Primary and secondary outcomes at T0, T1 and T2.

	T0	T1	T2
VAS (0–10)			
Sham PRT group	7.4 ± 0.9	6.3 ± 1.0	6.6 ± 1.0
PRT group	7.2 ± 0.9	4.9 ± 1.2	4.4 ± 1.8
PPT-UT			
Sham PRT group	1.9 ± 0.8	2.2 ± 0.9	2.1 ± 0.8
PRT group	2.0 ± 0.8	2.5 ± 1.1	2.4 ± 0.9
PPT-SS			
Sham PRT group	1.3 ± 0.6	1.4 ± 0.6	1.4 ± 0.6
PRT group	1.1 ± 0.6	1.3 ± 0.5	1.4 ± 0.9
PPT-SM			
Sham PRT group	1.4 ± 0.5	1.6 ± 0.7	1.59 ± 0.7
PRT group	1.3 ± 0.7	1.59 ± 0.8	1.68 ± 0.8
PPT-AT			
Sham PRT group	1.7 ± 0.7	1.9 ± 0.7	1.91 ± 0.7
PRT group	1.5 ± 0.7	2.0 ± 0.8	1.96 ± 0.8
ROM (mm)			
Sham PRT group	38.5 ± 8.9	38.74 ± 7.8	39.57 ± 7.6
PRT group	36.1 ± 10.2	40.38 ± 7.3	41.32 ± 6.1
NDI			
Sham PRT group	9.6 ± 5.4	8.5 ± 4.9	9.2 ± 5.2
PRT group	14.0 ± 7.4	8.2 ± 4.8	8.5 ± 5.1
PCS			
Sham PRT group	14.7 ± 8.8	13.60 ± 7.6	14.94 ± 7.4
PRT group	20.4 ± 10.7	10.43 ± 6.8	10.51 ± 8.1
TSK-11			
Sham PRT group	22.7 ± 6.5	20.89 ± 6.3	20.86 ± 6.7
PRT group	25.1 ± 6.2	19.89 ± 4.1	19.22 ± 4.4
DEP-S (standardised)			
Sham PRT group	0.3 ± 1.0	0.1 ± 0.9	0.2 ± 1.0
PRT group	0.8 ± 1.1	0.0 ± 0.9	0.0 ± 0.9
STAI-S (standardised)			
Sham PRT group	0.3 ± 1.6	0.0 ± 1.4	0.1 ± 1.4
PRT group	1.1 ± 1.9	−0.5 ± 1.2	0.4 ± 1.5

Note: Mean ± standard deviation.

Abbreviations: NDI, Neck Disability Index; PCS, Pain Catastrophizing Scale; PPT-AT, pressure pain threshold of anterior temporalis; PPT-SM, pressure pain threshold of superficial masseter; PPT-SS, pressure pain threshold of sternal portion of sternocleidomastoid; PPT-UP, pressure pain threshold of upper trapezius; PRT, pressure release technique; ROM, range of the opening of the mouth; S-STAI (standardised), Standardised State Anxiety Index; S-ST-DEP (standardised), Standardised State Depression Index; TSK-11, Tampa Scale for Kinesiophobia; VAS, visual analogue scale.

was also an interaction between time and group ($F = 12.12$; $p < .001$). Post hoc tests showed that the participants had significantly lower S-STAI scores at T2 compared to T0 ($p < .001$) and at T1 compared to T0 ($p < .001$). Post hoc test for interaction showed that the participants reported significantly lower S-STAI scores at T2 compared to T0 and at T1 compared to T0 for the PRT group ($p < .001$) (Table 2).

For State-Depression and adjusting for baseline outcomes, the ANOVA model showed significant effects time ($F = 17.20$; $p < .001$). There was also an interaction between time and group ($F = 6.82$; $p < .001$). Post hoc test showed that the participants had significantly lower State-Depression scores at T2 compared to T0 ($p < .001$) and at T1 compared to T0 ($p < .001$). Post hoc test for interaction showed that the participants reported significantly lower State-Depression scores at T2 compared to T0 and at T1 compared to T0 for the PRT group ($p < .001$) (Table 2).

Treatment side effects. Patients did not report any adverse events during or after the intervention or follow-up period. In the current study, any adverse event was defined as sequelae with any

TABLE 3 (A) Effect size and confidence intervals of the treatment groups (Sham and PRT); (B) equivalences of the Cohen's *d* cut-off points and the Ferguson's cut-off points with the correlation coefficient (*r*) and the percentile (%).

	GROUP	DEPENDENT SAMPLES		INDEPENDENT SAMPLES	
		Effect size	Confidence interval 95% (*d* of Cohen)	Effect size	Confidence interval 95% (*d* of Cohen)
VAS T0-T1	SHAM	1.03	(0.53, 1.53)	1.25	(0.75, 1.76)
	PRT	1.86	(1.31, 2.40)		
VAS T0-T2	SHAM	0.75	(0.26, 1.23)	1.36	(0.85, 1.87)
	PRT	1.57	(1.05, 2.10)		
VAS T2-T3	SHAM	0.25	(-0.22, 0.72)	0.56	(0.09, 1.03)
	PRT	0.30	(-0.16, 0.76)		

A)

Minimum necessary	> 0.41
Moderate	> 1.15
Strong	> 2.70

*** Cut-off points according to Ferguson (2009)**

d	Ferguson	*r*	%
0	0	0	50
0.20	0.41	0.10	57.9
0.50	1.15	0.243	69.1
0.80	2.70	0.371	78.8

B)

symptom perceived as distressing and unacceptable to the patient and required treatment.

4 | DISCUSSION

This is the first study investigating the effect of adding the PRT to a standard intervention for the management of chronic myofascial or mixed TMD pain. This randomised clinical trial confirmed that inclusion of PRT into a conservative program can improve self-reported pain in patients with chronic myofascial or mixed TMD pain. The clinical significant improvement depended on the time of follow-up and there were significant interactions between time and group, with both an immediate and short-term effect.

4.1 | Primary outcome

The present study followed the recommendations for non-invasive and reversible therapies for TMD provided by the American Academy for Oro-facial Pain.[8] The results showed that the PRT had a similar effect like manual therapy in general, which also has been shown to be an effective method for the management of pain in TMD both in the immediate and short-term perspective.[21] The

present results matched also with the cervical spine mobilisation that is clinically one of the most effective approaches in reducing pain in TMD according to a recent review by Gil-Martinez et al.[27] In addition, the manual technique used in this study was not invasive, unlike techniques such as dry needling, with moderate evidence according to Girard et al.[28] to reduce short-term pain in acute TMD, but not in chronic TMD like in the present study. Furthermore dry needling may also be associated with pain both during treatment and post-treatment and in this respect the PRT appears to be a less stressful treatment choice.

Although the effects of PRT so far have not been studied in the management of TMD, it has clearly been shown to have clinical relevance in other musculoskeletal pathologies, such as non-specific cervicalgia and shoulder impingement.[29,30] These studies demonstrated good results in terms of pain reduction compared to both sham intervention and ultrasound, although it was similar to the effect of ischemic compression. It can be speculated that the key to the success in the present study was to apply PRT in two anatomical regions, the cervical and trigeminal region, since both masticatory and cervical muscles can refer pain to the oro-facial and temporomandibular areas.[11]

Secondary outcomes. In relation to secondary outcome measures it was observed that for all PPTs the effects only depended on time. So, the PRT treatment had no specific effect on mechanical pain sensitivity. This could possibly be due to the effect of the occlusal splint and self-care as pointed out by Okeson et al.[14] who suggested that the occlusal splint and self-care treatment are capable to reduce muscle pain. Another interpretation is that sham PRT and PRT had similar non-specific effects on PPTs.

Regarding the ROM, the PRT group improved more than 4 mm compared to placebo which is suggested to represent a clinically relevant effect following manual therapy.[31]

The NDI scores did not indicate significant cervical disability in the myofascial TMD patients; however, the PRT group improved more than five NDI points which is suggested to represent the minimum relevant clinical amount of improvement according to Vernon et al.[22] These findings are consistent with other studies[20,32] who found that manual PRT applied to the upper trapezius increases active cervical movement more than compared to sham.

It is an interesting observation that both the ROM and NDI suggested similar effects of PRT in accordance with the notion of a reciprocal cervical-cranial-mandibular functionality.[33] Silveira et al.[34] also suggested that changes in mandibular dysfunction could be explained by changes in cervical disability and vice versa in patients with TMD although there is no evidence for a causal relationship. Nevertheless the PRT seems to restore both the mandibular and cervical movements perhaps as reflected in the lower self-reported VAS pain scores.

Finally, regarding the psychosocial measures, the included myofascial TMD pain patients appeared to only have mild and non-pathological baseline levels of distress, yet all measures improved significantly after the application of the PRT. So far there are no specific studies that link PRT to psychosocial factors; however, the OPPERA study,[35] has clearly demonstrated the association between TMD pain and depression, although there is still ambiguity about its directionality. Furthermore, kinesiophobia has been recognised as an important component of chronic pain, and correlates directly with pain catastrophizing, depression and anxiety.[27] Other authors, for example, Hassett et al.[36] and Gil-Martinez et al.[24] suggest that psychosocial disorders, especially depression and anxiety, play an important role in exacerbating pain perception. Moreover, it is also proposed that neck disability and kinesiophobia are covariables of oro-facial pain and mandibular disability for chronic TMD.[27]

The present results could indicate that the observed improvement in self-reported pain and physical function could be linked to improvement of the kinesiophobia, the catastrophizing scores and the rest of the psychosocial variables although these changes could occur independently. This scenario has important future clinical implications for the evaluation and treatment of chronic TMD pain. The variables studied, especially those related to psychosocial function could act as predisposing, perpetuating factors or as a consequence of the disorder.

The present study had some limitations. The lack of double-blinding could be considered a bias but it was deemed to interfere too much with the feasibility and practical organisation of the study and manual therapy is notoriously difficult to perform blinded. It may also be a limitation that no long-term follow-up was done and it is not known if the observed treatment effect after 3 months would be lasting. Further studies may look into the long-terms effects of PRT. It would also have been an advantage to include a statement or rating of the expectations and anticipation of treatment effects in the two groups because of the strong impact on placebo responses.[37] However, the attempt to include a sham PRT is a significant advantage in the interpretation of the present results. It should also be mentioned that the present study was registered after initiation of the project due to a logistic error but strictly adhered to the original protocol. Finally, other types of oro-facial myofascial pain conditions, for example, defined by the temporal frequency (infrequent, frequent and highly frequent) and with or without referred pain could be interesting to study in further evaluation of the efficacy of PRT.

5 | CONCLUSIONS

The results of this study suggest that the PRT, applied to the latent and active trigger points of the masticatory and cervical muscles, is an effective therapy for the treatment of chronic pain in myofascial TMDs. The decrease in self-reported oro-facial pain was significantly greater than the increase in pain threshold due to the pressure stimulation of the treated muscles. This reported pain improvement showed moderate effect sizes with clinical relevance both in the immediate and short-term perspective.

The combined treatment of the cervical and masticatory muscles significantly improved the opening of the mouth and cervical functionality as well as a clear improvement in the parameters of kinesiophobia, which could in turn improve motor behaviour. In addition,

PRT significantly improved the psychosocial factors of catastrophizing, anxiety and depression.

AUTHOR CONTRIBUTIONS

Conceptualisation, Methodology, Software, Validation, Investigation, Data curation, Writing–original draft, Visualisation and Project administration: Gema Serrano-Hernanz. Forma analysis: Gema Serrano-Hernanz, Teresa Angulo-Carrere, Ana M. Álvarez-Méndez. Resources: Gema Serrano-Hernanz, Ignacio Ardizone-García. Writing–review and editing: Gema Serrano-Hernanz, Teresa Angulo-Carrere, Peter Svensson, Ana M. Álvarez-Méndez. Supervision: Ana M. Álvarez-Méndez.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding authors upon reasonable request.

ORCID

Gema Serrano-Hernanz https://orcid.org/0000-0002-2446-9490
Teresa Angulo-Carrere https://orcid.org/0000-0001-5176-6418
Ignacio Ardizone-García https://orcid.org/0000-0003-3943-0502
Peter Svensson https://orcid.org/0000-0001-5809-8037
Ana M. Álvarez-Méndez https://orcid.org/0000-0002-1178-9073

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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