ORIGINAL RESEARCH

Randomized, Controlled, Crossover Study of Self-administered Jacobson Relaxation in Chronic, Nonspecific, Low-back Pain

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ABSTRACT

Context • Opioids decrease pain and improve functional capacity and quality of life; however, they are not always effective and are associated with harmful side effects. Few studies have shown that relaxation-based therapies, in comparison with usual care, can decrease pain.

Objective • The objective of the study was to investigate whether a controlled relaxation treatment, Jacobson progressive muscular relaxation (PMR), was effective in relieving chronic low-back pain (CLBP) and reducing pain comorbidities. The research team hypothesized that PMR-controlled relaxation could be more effective in reducing CLBP than music.

Design • The research team designed a randomized, controlled, crossover study.

Setting • The study took place in the pain unit, a clinic, in the Department of Health at Alicante-General Hospital (Alicante, Spain).

Participants • Participants in this study were 58 adults with nononcological CLBP, secondary to lumbar canal stenosis, who had been treated with opioids without any changes in the 3 mo prior to the study.

Intervention • Participants were randomly assigned to 1 of 2 groups, each of which received 2 treatments, but in a different order (ie, either AB or BA where A was the standardized PMR, the intervention, and B was relaxing music, the control. For both groups, the 2 treatment periods were 8 wk in length, with a 1-mo washout period between them.

Outcome Measures • The primary outcome measures included (1) a visual analogue scale—pain and relief intensity; (2) the 12-item short form health survey—quality of life; (3) the hospital anxiety and depression scale—anxiety and depression; and (4) the medical outcomes study sleep scale—sleep disturbances. Secondary outcome measures included a self-efficacy scale and a measure of satisfaction with treatment and compliance.

Results • Pain was mostly mild to moderate. Greater decreases in pain between baseline and postintervention were observed for the PMR vs the control treatment in the mild pain category, with a VAS difference of 1.8 cm and $P = .018$. Significant differences were also found in anxiety, depression, quality of life, and sleep between participants in the 3 pain categories. Self-rated adherence was high.

Conclusions • Findings support the efficacy and acceptability of a self-guided PMR intervention for reducing CLBP with minimal time with a therapist. (*Altern Ther Health Med.* [E-pub ahead of print.])

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The interaction between somatic complaints and psychosocial factors warrants a multidimensional approach for the treatment of patients with chronic low-back pain (CLBP), for which prescriptions for opioids have risen steadily.[1]

Although opioids decrease pain and improve functional capacity and quality of life,[2,3] they are not always effective and are associated with harmful side effects, especially in long-term use like for nononcological pain.[4,5] Thus, nonpharmacological and self-help strategies are important alternatives in decreasing the disabling consequences of chronic pain.[6-9] For such pain, many relaxation techniques have been studied,[10] but most studies have provided little evidence for decreased pain after use; furthermore, the studies have been poorly designed, with few participants.[11-13]

Treatment guidelines emphasize that patients should be encouraged to use therapies they can easily apply themselves, as long as they perceive them to be effective. Possible therapies include Jacobson progressive muscle relaxation (PMR), a controlled relaxation treatment, which teaches patients to relax their muscles through a two-step process. Patients first deliberately contract their muscles and hold the tension; they then release all tension and focus on the sensation of relaxation. The regular practice of PMR might help patients to recognize tension and to voluntarily relax affected muscles.

Through relaxation, the autonomic nervous system (ANS) can be affected positively. The ANS is a system of nerves and ganglia concerned with the distribution and reception of predominantly involuntary impulses to (1) the heart, changing its rate and force of beating; (2) smooth muscles, causing vasoconstriction or dilation of arterioles; and (3) glands, increasing or decreasing their secretions. For example, relaxation can reduce the perception of pain or anxiety.[14] Relaxation therapy involves regular self-practice, which can promote physical or mental relaxation.[15] However, few studies have shown that relaxation-based therapies, in comparison with usual care, have positive effects on physical functioning, pain relief, and mood.[16] Cognitive-behavioral therapies are usually focused on preventing mild pain from becoming disabling pain, decreasing headache-related disability, lessening affective distress, improving quality of life, and reducing overreliance on medication.

It is important to address complicating factors for cognitive-behavioral therapies that can reduce their effectiveness, including medication overuse, psychiatric comorbidities, and stress and poor coping as well as sleep disturbances.[17] In fact, some studies reported better outcomes related to mild musculoskeletal pain on emotional priming; however, in a hospital setting, reduction of pain is complicated because the pain is mostly a chronic type.[18]

Thus, little consensus exists amongst clinicians[19-22] in their use due to different therapist training profiles, lack of habitual and standardized clinical use, lack of systematic studies of efficacy and safety, and ignorance of the biological basis of clinical response that makes that is still not known which of these components are important and whether all patients would benefit from all them.[23-25]

The main goal of the present study was to investigate whether PMR was effective in relieving CLBP and pain comorbidities.

METHODS

Participants

The research was performed in the Department of Health at Alicante-General Hospital (Alicante, Spain). Participants were recruited during a 1-year period, through specialty pain-care physicians in the hospital's Spinal Column Unit, which referred patients to the hospital's pain unit, a clinic, and 110 patients were assessed for eligibility.

Potential participants were included in the study if they (1) were adults, (2) had nononcological CBLP that was secondary to lumbar canal stenosis, and (3) had used analgesics without any benefit in the 3 months prior to the study.

Potential participants were excluded in the study if they (1) had oncological CBLP, (2) were undergoing surgery, (3) had reading difficulties, (4) had a clinical comorbidity, and (5) suffered from a psychopathology.

The participation rate was 46%. Of the 52 potential participants excluded, 18 had oncological CBLP, 7 were undergoing surgery, 5 had reading difficulties, 4 had a clinical comorbidity, and 3 suffered from a psychopathology.

The study was approved by the Ethics Committee of the Department of Health at Alicante General Hospital (EudraCT No. 2015-001803-30). After the research team explained the aims of the study and the confidentiality of the information to participants, the study obtained informed consent from them. The research was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Procedures

The study was a controlled crossover study in which participants were randomly assigned to 1 of 2 groups, each of which received 2 treatments, but in a different order (ie, either AB or BA where A was the standardized PMR, the intervention, and B was relaxing music, the control). For both groups, the 2 treatment periods were 8 weeks in length, with a 1-month washout period between them to reduce aliased effects.[10,26]

After a participant had sign the informed consent sheet, an investigator gathered relevant information from the patient's medical record. A clinical interview was performed to evaluate physical health and drug use and to obtain a medical history.

The investigator then assigned participants to 1 of the 2 treatment sequences. The assignment was performed using a computer-based block permutation for the generation of a randomization sequence before onset of the study.

Participants completed scales and questionnaires at each of their 8 visits to the clinic, including the visits at baseline and postintervention. The data were used to evaluate the

clinical situation of each patient. All questionnaires were self-administered, supported by clinicians blinded to the treatment condition.

The outcome measures evaluated changes (1) in pain using a visual analogue scale (VAS), (2) in quality of life using the 12-item short form health survey (SF12), (3) in anxiety and depression using the hospital anxiety and depression scale (HADS), and (4) in sleep disturbances using the medical outcomes study sleep (MOS-sleep) questionnaire. Given the self-administered nature of the intervention, the research team was also interested in documenting participants impressions of improvement to determine the relief obtained from treatments, measured using (1) the patient global impression of improvement scale (PGI-I), (2) the clinical global impression of improvement scale (CGI-I), and (3) the chronic pain self-efficacy scale.

After the clinical interview and patient's assignation, the investigator went to each patient's room with the pretest data Then, either the experimental condition (PMR) or the control condition (music) was initiated, as assigned. The investigator gave an explanatory talk for 20 minutes about relaxation.

Participants also completed diaries at home, including pain records and information about compliance. At each visit, the investigator instructed the participant to complete his or her diary weekly. Participants returned the diaries at each visit to the clinic.

Interventions

Progressive Muscular Relaxation. The PMR was based on the work of Bernstein and Borkovec[27,28] and Jacobson and involved a progressive tightening and relaxing of different muscle groups throughout the body, with ongoing suggestions that participants would perceive an increased sense of relaxation and comfort. Four scripts were used for the PMR condition.

The first phase, used in the first 2 sessions during the second and third visits to the clinic, focused on 16 major muscle groups: right and left hands; right and left arms; forehead; face; jaw; neck; chest, shoulders, and upper back; abdomen; right and left thigh; right and left calf—plantar flexion; and right and left shin—dorsiflexion.

The second phase, used in the third and second week combined some of the muscle groups, so that 7 general areas were the focus of relaxation. The third phase used in the fifth and sixth weeks combined muscle groups further into 4 areas, and the fourth and final used during the last 2 weeks phase focused only on general body scanning and relaxation. Compact discs (CDs) of the PMR scripts were provided to participants, with the instruction to listen to the recordings at least once per day or more often if they found the recordings helpful.[29]

Control. An audio CD with relaxing music was used as the control condition. The length of the musical recording was identical to that of the PMR scripts to equalize the use of the audios. Participants were instructed to listen to the recordings at least once per day or more often if they found the recordings helpful.

Outcome Measures

Visual Analog Scale. The primary outcome involved measurement of participant's average pain during the week prior to a clinic visit, using a 10-cm scale, classifying pain as mild ≤4 cm, moderate = 4 to <7 cm, or severe ≥ 7 cm.

Short Form-12. The impact of changes in quality of life on a participant's health status was measured using 12 items on this Likert-style questionnaire, scored from 0 to 100 that are grouped in 8 domains: physical functioning, role physical, mental health, bodily pain, general health, vitality, social functioning and role emotional to evaluate the physical and metal components. [31, 32]

Hospital Anxiety and Depression Scale. The HADS analyzes participants' symptoms of anxiety and depression in the week prior to a clinic visit, with normal = 0 to 7, doubtful = 8 to 10, and clinical problems = 11 to 21 points.[33]

Medical Outcomes Study-Sleep. Evaluation of sleep disturbances requires assessment of multiple dimensions of sleep. Although not a diagnostic tool, the MOS-Sleep scale has been studied in other chronic diseases, providing support for the feasibility, reliability, and validity of this scale. The 12 questions evaluate sleep, with derived subscales for 6 domains: (1) sleep disturbance—4 items, (2) quantity of sleep—1 item scored as the average hours slept per day: 0 to 24 hours, (3) snoring—1 item, (4) awakening due to short of breath or with headache—1 item, (5) sleep adequacy (SLPA)—2 items, and (6) somnolence—3 items.

Patients were also asked to report how often each particular sleep symptom or problem was applicable to them on a 6-point categorical scale, ranging from "all of the time" to "none of the time." The question about time to falling asleep uses a 5-point, categorical-response scale ranging from 0 to 15 minute to more than 60 minutes. It also allows the calculation of global sleep-problem indices (SLP-6 and SLP-9) scored from 0 to 100, which provide a measure for the overall sleep quality. Higher scores indicate more sleep problems, except for the SLPA.[34, 35]

Patient Global Impression of Improvement Scale. The scale measures participants' impressions of improvement regarding the relief obtained from the treatments, scored from 1 to 7.[36]

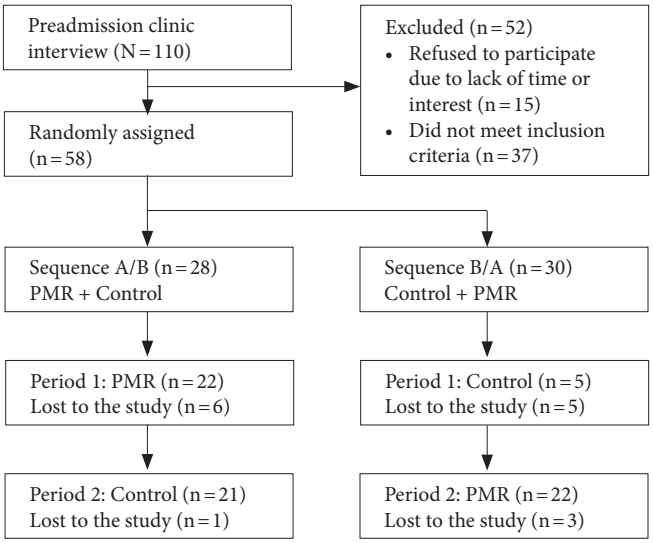
Clinical global impression of improvement scale. It is a 7-point scale that requires the clinician to assess how much the patient's health has improved or worsened relative to a baseline state. [37]

Chronic Pain Self-Efficacy Scale. The scale measures participants' (1) impressions of improvement regarding the relief obtained from the treatments, scored from 0 to 10; (2) satisfaction with treatment to ascertain acceptability, scored from 0 to 4; and (3) compliance as the number of days that the patient completed the 14 days of exercises (ie, if they completed 12 days of treatment within each 14-day phase).[38]

Statistical Analyses

Sample size calculation, using the free software Ene 3.0 from the Autonomous University of Barcelona (Barcelona, Spain), was performed based on the outcome pain intensity and on the

Figure 1. Flow Chart Describing the Progression of Participants During the Study



Reasons for loss to follow-up:

	PMR	Control
Holidays	4	3
Lack of interest	3	2
Change of city	1	0
Worsening pain	1	1
Did not complete postintervention assessments	9	6

[a]Two groups received 2 treatments but in a different order: A/B and B/A, with A being the intervention, Progressive muscle relaxation, and B being the control, a musical intervention.

Table 1. Demographic and Clinical Data at Baseline Visit[a]

	Total Population (%) (N = 58)	Sequence A/B (%) (n = 28)	Sequence B/A (%) (n = 30)
Demographics			
Age, y, mean ± SD	51 ± 11	52 ± 11	54 ± 12
Female	74	68	78
BMI, kg/m^2, mean ± SD	26.6 ± 6.5	28.3 ± 5.3	27.3 ± 5.3
Ethnicity: White European	100	100	100
Education			
No completed studies	24	15	31
Primary	33	40	27
Secondary	26	30	23
Superior	17	15	19
Married	72	70	77
Work status			
Not working due to pain (disability)	35	30	38
Working (full- or part-time)	26	40	15
Others (housewife, retired, unemployed, sick leave)	40	30	46
Mean VAS pain—1 cm, mean ± SD	6 ± 2.3	5.5 ± 2.2	6.5 ± 2.4
Precipitation of pain			
Unknown	45	40	50
Following illness	21	24	18
Accident at work	15	20	11
Accident (not work or home)	11	8	14
Following surgery	8	8	7
Drug use			
WHO step I (analgesic, NSAID)	49	54	44
WHO step II (tramadol)	45	50	41
WHO step III (opioids)	38	39	37
WHO step IV (RF, botox)	74	70	78
Intervention techniques (surgery)	42	32	50
Neuromodulators	59	58	59

[a]The study compared 2 treatments: A: intervention = progressive muscle relaxation; B: control = musical intervention. Two groups received both treatments but in a different order: A/B and B/A. No significant differences existed between the groups at baseline.

Abbreviations: SD, standard deviation; BMI, body mass index; VAS, visual analogue scale; WHO, World Health Organization; NSAID, nonsteroidal anti-inflammatory drug; RF, radiofrequency.

results of previous studies of psychological interventions for treatment of chronic pain.[39] To achieve a power of 80% and to be able to detect differences in testing the null hypothesis using a bilateral Student *t* test, the study used a significance level of 5% and assumed a reduction in pain of 50%. To evaluate the changes between the first testing at baseline and the testing postintervention, using a standard deviation (SD) of 8 and assuming 15% losses, the research team found that 58 subjects were needed.

To avoid learned behavior based on memory from the first period of practicing PMR, the research team analyzed period interactions and sequence effects as potential confounding factors with an unequal residual effect.

The Kolmogrov-Smirnov test was used to test normality of the data ($P \geq .05$). Data are expressed as means ± SDs or as percentages for qualitative variables, unless otherwise specified. Preintervention values prior to each condition (PMR or control) were compared using independent student *t* tests or Mann-Whitney *U* tests, according to normality.

To compare data between mild, moderate, and severe pain categories, 1-way analysis of variance (ANOVA) or Kruskal-Wallis tests according to normality were used. Post hoc analyses were performed when significant differences were found. Data were analyzed using the SPSS package, version 22.0 (IBM Corp, Armonk, NY, USA). Significance was set at $P < .05$.

RESULTS

A total of 58 patients were included in the study. Figure 1 illustrates the progression of enrollment of participants. Participants' baseline demographic and clinical characteristics are shown in Table 1. Participants were 74% female and 100% Caucasian, with a mean age of 51 ± 11 years and a mean body mass index of 26.6 ± 6.5 Kg/m^2.

At baseline, participants' pain intensity was mostly moderate—6 ± 2.3 cm—and of an unknown origin—45%.

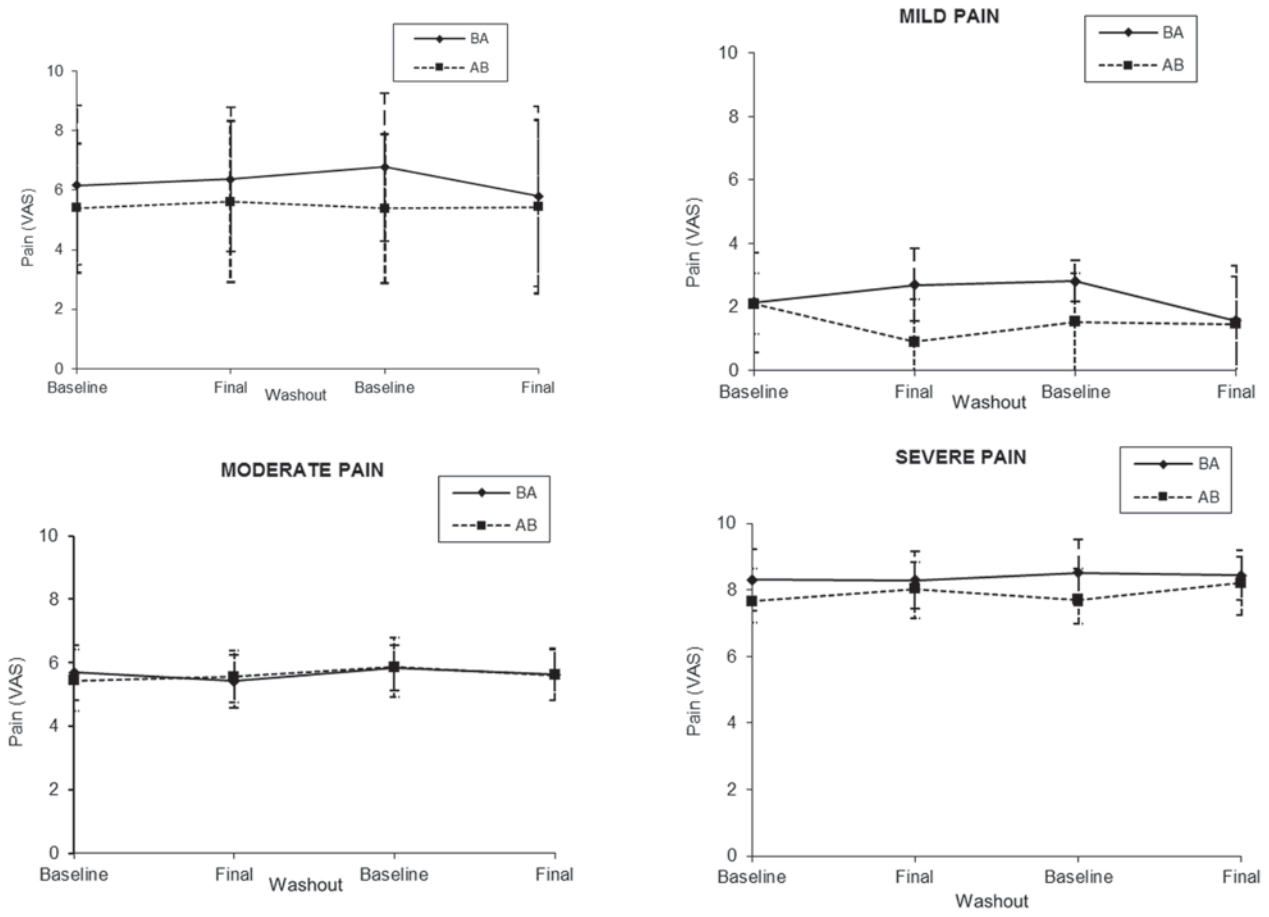
Table 2. Analysis of Pain Intensity Modification (Δ) between Baseline and Postintervention in Function of Initial Pain Category for the Control and Progressive Muscle Relaxation (PMR) Treatments. Of the 58 participants, 22% of suffered from mild pain, 36% from moderate pain, and 42% from severe pain at baseline.

	Control			Intervention		
VAS, cm	**Pre-intervention** Mean +SD	**Δ** Mean +SD	***P* Value**	**Pre-intervention** Mean +SD	**Δ** Mean +SD	***P* Value**
Mild pain (0-3 cm)	2.1 ± 1.4	+0.3 ± 2.6	0.551	2.5 ± 0.9	-1.5 ± 3.0	0.018[a]
Moderate pain (4-6 cm)	5.6 ± 0.8	-0.3 ± 2.1	0.943	5.4 ± 0.8	+0.5 ±1.9	0.08
Severe pain (7-10 cm)	8.0 ± 0.9	+0.4 ± 2	0.627	8.2 ± 1.0	-0.2 ±2.8	0.477

[a]$P < .05$

Abbreviations: VAS, visual analogue scale; SD, standard deviation

Figure 2. Participant Baseline and Postintervention, Pain Intensity Response Curves, Measured Using a Visual Analogue Scale[a]



[a]The VAS scores are shown in cm, with severe = 7 to 10, moderate = 4 to 6, and mild = 0 to 3. The study compared 2 treatments: (a) intervention = progressive muscle relaxation; and (b) control = musical intervention. Two groups received both treatments but in a different order: A/B and B/A. No significant differences existed between the groups at baseline.

Abbreviation: VAS, visual analog scale.

No significant differences were observed between patients that received the PMR treatment first versus those that received the control, relaxing music, first.

Primary Outcome Analysis

Adjusted, group differences on pain intensity between baseline and postintervention were obtained from participants' questionnaires and analyzed using the Mann-Whitney *U* test

(Table 2). Similar pain scores were observed in both groups, and no significant differences in the mean decrease in pain intensity were found.

The mean pain VAS scores at baseline for the PMR—6.1 ± 2.4 cm and for the relaxing music—6.0 ± 2.5 cm (data not shown)—did not change significantly by postintervention, with the changes being -0.28 cm and +0.16 cm, respectively, with $P = .22$ (data not shown).

However, when pain was analyzed by VAS intensity categories—with 22% of participants suffering from mild pain, 36% from moderate pain, and 42% from severe pain at baseline (data not shown)—a significant decrease of 1.5 ± 3.0 cm ($P = .018$) was observed in the mild category after PMR treatment. That decrease represented an 80% reduction in pain between baseline and postintervention after 8 weeks of PMR treatment.

No changes in the amount of pain medication taken were observed in any of the groups. No period or sequence effects were found, suggesting no residual effects of one intervention over another; thus, the washout period was long enough to avoid residual effects (Figure 2).

Secondary Outcome Analyses

No significant differences were found in the changes between baseline and postintervention scores in the secondary outcome analyses. However, Table 3 shows significant differences between VAS categories and secondary outcome variables where pain intensity was the most determinant in improving anxiety, depression, quality of life—physical and mental components, and sleep—sleep disturbance, quantity of sleep, shortness of breath, adequacy of sleep and somnolence.

Table 3. Participant Baseline and Postintervention Scores for Clinical Questionnaires

Questionnaires	VAS Category	Control		Intervention		Post hoc Tests[a]
		Baseline Mean ± SD	Postintervention Mean ± SD	Baseline Mean ± SD	Postintervention Mean ± SD	
HADS						
Anxiety	1. Mild	5 ± 3	5 ± 4	7 ± 5	7 ± 4	1 vs 2-3
	2. Moderate	9 ± 3	9 ± 3	8 ± 3	8 ± 4	
	3. Severe	9 ± 3	9 ± 4	10 ± 3	10 ± 4	
Depression	1. Mild	4 ± 4	5 ± 4	5 ± 5	6 ± 3	1 vs 2 vs 3
	2. Moderate	8 ± 4	9 ± 5	7 ± 5	7 ± 4	
	3. Severe	9 ± 4	9 ± 5	10 ± 5	10 ± 4	
SF-12						
Physical functioning	1. Mild	36 ± 12	38 ± 13	38 ± 9	38 ± 13	1 vs 2-3
	2. Moderate	33 ± 11	30 ± 10	32 ± 10	29 ± 8	
	3. Severe	28 ± 7	28 ± 7	30 ± 7	28 ± 10	
Role physical	1. Mild	25 ± 5	25 ± 5	24 ± 4	22 ± 4	1 vs 2-3
	2. Moderate	25 ± 3	23 ± 4	21 ± 1	22 ± 4	
	3. Severe	20 ± 0	20 ± 2	21 ± 2	21 ± 1	
Mental health	1. Mild	39 ± 10	37 ± ± 12	49 ± 10	40 ± 7	NS
	2. Moderate	37 ± 12	42 ± 13	39 ± 11	39 ± 6	
	3. Severe	37 ± 9	39 ± 12	37 ± 12	36 ± 11	
Bodily pain	1. Mild	43 ± 8	40 ± 14	39 ± 9	45 ± 13	1 vs 2 vs 3
	2. Moderate	31 ± 8	33 ± 10	33 ± 10	33 ± 9	
	3. Severe	26 ± 8	28 ± 10	28 ± 9	23 ± 6	
General health	1. Mild	40 ± 13	30 ± 8	35 ± 15	36 ± 8	1 vs 2-3
	2. Moderate	29 ± 8	32 ± 7	28 ± 6	34 ± 12	
	3. Severe	29 ± 6	25 ± 8	29 ± 9	24 ± 7	
Vitality	1. Mild	49 ± 14	49 ± 15	48 ± 13	47 ± 12	1 vs 2-3
	2. Moderate	40 ± 10	38 ± 9	42 ± 9	41 ± 11	
	3. Severe	36 ± 9	38 ± 11	37 ± 11	34 ± 7	
Role-emotional	1. Mild	20 ± 5	19 ± 6	18 ± 6	21 ± 4	1 vs 2 vs 3
	2. Moderate	15 ± 4	18 ± 5	17 ± 5	17 ± 5	
	3. Severe	15 ± 5	15 ± 5	17 ± 6	16 ± 5	
Social functioning	1. Mild	49 ± 9	48 ± 9	46 ± 11	51 ± 9	1 vs 3
	2. Moderate	46 ± 12	42 ± 14	46 ± 13	44 ± 13	
	3. Severe	40 ± 13	38 ± 15	41 ± 13	37 ± 12	
Physical component summary	1. Mild	29 ± 6	36 ± 8	34 ± 7	35 ± 9	1 vs 2 vs 3
	2. Moderate	36 ± 8	31 ± 6	30 ± 5	30 ± 5	
	3. Severe	27 ± 6	26 ± 6	28 ± 6	26 ± 8	
Mental component summary	1. Mild	38 ± 13	34 ± 8	40 ± ± 8	38 ± 6	NS
	2. Moderate	35 ± 11	37 ± 11	38 ± 8	36 ± 11	
	3. Severe	36 ± 7	36 ± 9	34 ± 10	34 ± 11	

Table 3. (continued)

MOS-Sleep						
Sleep disturbance	1. Mild	35 ± 26	27 ± 24	43 ± 31	39 ± 29	1 vs 2-3
	2. Moderate	62 ± 29	61 ± 25	49 ± 28	49 ± 31	
	3. Severe	57 ± 23	56 ± 29	57 ± 28	58 ± 22	
Sleep quantity (hours sleep/night)	1. Mild	6 ± 1	7 ± 1	7 ± 1	6 ± 2	1 vs 3
	2. Moderate	6 ± 2	5 ± 2	6 ± 2	6 ± 2	
	3. Severe	5 ± 1	6 ± 2	5 ± 2	5 ± 2	
Snoring	1. Mild	47 ± 40	44 ± 44	24 ± 38	49 ± 46	NS
	2. Moderate	46 ± 34	61 ± 33	51 ± 39	53 ± 36	
	3. Severe	45 ± 39	30 ± 24	52 ± 34	51 ± 30	
Awaken short of breath or with headache	1. Mild	25 ± 28	22 ± 30	18 ± 21	20 ± 23	1 vs 2-3
	2. Moderate	37 ± 29	40 ± 20	38 ± 27	34 ± 25	
	3. Severe	45 ± 27	43 ± 28	32 ± 22	43 ± 27	
Sleep adequacy	1. Mild	55 ± 35	72 ± 31	49 ± 35	67 ± 33	1 vs 2-3
	2. Moderate	30 ± 24	43 ± 31	42 ± 29	45 ± 30	
	3. Severe	34 ± 30	32 ± 26	40 ± 29	38 ± 29	
Somnolence	1. Mild	34 ± 26	27 ± 28	27 ± 22	29 ± 33	1 vs 3
	2. Moderate	45 ± 17	40 ± 22	47 ± 14	33 ± 24	
	3. Severe	51 ± 26	52 ± 30	42 ± 30	52 ± 27	
Global index I SLP-6	1. Mild	34 ± 24	26 ± 23	37 ± ± 27	33 ± 27	1 vs 2-3
	2. Moderate	57 ± 22	51 ± 20	48 ± 22	45 ± 24	
	3. Severe	57 ± 22	56 ± 19	51 ± 20	56 ± 18	
Global index II SLP9	1. Mild	39 ± 23	26 ± 23	48 ± 39	33 ± 27	1 vs 2-3
	2. Moderate	56 ± 23	52 ± 19	50 ± 21	44 ± 23	
	3. Severe	56 ± 21	56 ± 20	53 ± 21	56 ± 17	

Note: Post hoc column refers to comparisons found to be statistically significant ($P < .05$). NS = not statistically significant ($P \geq .05$).

[a]The questionnaires included the HADS the SF-12, and the sleep (MOS-sleep) questionnaire, and evaluation included post hoc tests performed in the treatment groups at baseline and postintervention. The VAS categories were mild = to 3 cm (1), moderate = 4 to 6 cm (2), and severe = 7 to 10 cm (3).

Abbreviations: VAS, visual analog scale; SD, standard deviation; HADS, hospital anxiety and depression scale; SF-12, short form 12; MOS, medical outcomes study.

Patients receiving PMR in both groups reported moderate-to-high ratings of treatment satisfaction and global satisfaction. Most participants were satisfied with the treatment and rated it as acceptable, completing all 4 phases of 14 days. With regard to overall completion of phases, 15% of participants completed fewer than 10 days, where 32% completed between 10 and 13 days, and 53% completed 13 to 14 days. The mean number of days of treatment that patients completed was 12 days for both the control and the PMR. In terms of feasibility, no patient reported any adverse effects as a result of the study's procedures.

DISCUSSION

The present study suggests that PMR is effective for patients presenting with pain of mild intensity, because the treatment reduced the pain scores measured at baseline by 80% after 8 weeks of treatment. This decrease was significantly different from the control condition, where pain was increased in 14% of participants. The key findings of the current study are (1) PMR was effective in reducing pain in patients with mild pain, (2) pain intensity significantly affected comorbidities—anxiety, depression, sleep, and quality of life; and (3) patients had good compliance and satisfaction with the PMR therapy. The current study extends previous work by demonstrating the efficacy of a self-administered intervention for chronic pain, with minimal therapist time.[40]

The goal of PMR for pain management is to help patients learn and develop more effective strategies for coping with anxiety and, ultimately, to change the manner in which they behave with regard to feared activities.[9] The benefits of such use of cognitive strategies has been observed in sufferers with long-term chronic pain and has been rated as particularly effective.[41,42] Palermo et al[43] showed that a group of patients with headaches, who were receiving psychotherapy and behavioral therapy through an internet application, significantly reduced their limitations of activities and their pain intensity when comparing the results of changes in VAS scores between baseline and postintervention (-1,6 cm) and at 3 months postintervention (-2,3 cm).[44,45]

Based primarily on open-label studies, Seshia et al[46] showed the benefits of relaxation for comorbidities of chronic daily headache, such as anxiety and depressive disorders, other pain syndromes, and sleep disorders. Regarding sleep, Bae et al[47] found evidence of a significantly decreased degree of sleep loss in patients with atopic dermatitis who were

randomly assigned to a PMR group (n = 15), with $P < .001$, but not among controls (n = 10). Also, anxiety state scores showed significant improvement after treatment in the PMR group only ($P = .005$).

The present study documents that chronic moderate and severe pain are particularly strong predictors of the chronicity of depression, the course of anxiety, lower quality of life, and sleep problems, using standardized and previously validated tools. The association between pain and course of depression and anxiety could be due to the disabling impact of pain, which can induce patients to limit daily activity and to restrict physical and social role functioning.[48] In addition, sleep problems can contribute significantly to the diminished quality of life of patients, particularly regarding their physical health. Additional studies are needed to further delineate the specific sleep problems in patients with pain.

However, the current findings should be interpreted in light of some limitations. The sample size was small; young adults were not included; and the data were obtained from a single clinic, limiting the generalization of the findings. Difficulty with recruitment, including the high percentage of losses of participants, meant that the current study was underpowered, and the actual mean difference was therefore smaller than if it had been powered correctly.

In addition, the current study was a crossover study and was subject to recall bias, because the control group used relaxing music, which is considered to be a simple way to improve a person's mood and decrease anxiety and pain associated with some medical procedures.[25] Of greatest concern for the interpretation of the current study's findings is the basic principle that PMR is a skill that is learned through practice and 14 days of treatment may not be enough for patients experiencing chronic pain.

CONCLUSIONS

The results of the current study suggest that PMR is a beneficial treatment for mild CLBP, whereas moderate and severe pain intensity are related to a worse course of depression and anxiety, lower quality of life, and sleep problems. To compare relaxation-based interventions better and to generalize across different interventions and populations, future research should aim for more specific descriptions of the procedures and elements of the intervention being investigated.

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AUTHOR DISCLOSURE STATEMENT

The authors declare that they have no conflicts of interest related to the study.

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