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RANDOMIZED TRIAL

Effects of Myofascial Release in Nonspecific Chronic Low Back Pain

A Randomized Clinical Trial

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Study Design. Double-blind, randomized parallel sham-controlled trial with concealed allocation and intention-to treat analysis.

Objective. To investigate the effects of an isolate myofascial release (MFR) protocol on pain, disability, and fear-avoidance beliefs in patients with chronic low back pain (CLBP).

Summary of Background Data. MFR is a form of manual medicine widely used by physiotherapists in the management of different musculoskeletal pathologies. Up to this moment, no previous studies have reported the effects of an isolated MFR treatment in patients with CLBP.

Methods. Fifty-four participants, with nonspecific CLBP, were randomized to MFR group (n = 27) receiving four sessions of myofascial treatment, each lasting 40 minutes, and to control group (n = 27) receiving a sham MFR. Variables studied were pain measured by means Short Form McGill Pain Questionnaire (SF-MPQ) and visual analog scale (VAS), disability measured with Roland Morris Questionnaire, and fear-avoidance beliefs measured with Fear-Avoidance Beliefs Questionnaire.

Results. Subjects receiving MFR displayed significant improvements in pain (SF-MPQ) (mean difference −7.8; 95% confidence interval [CI]: −14.5 to −1.1, $P = 0.023$) and sensory SF-MPQ subscale (mean difference −6.1; 95% CI: −10.8 to −1.5, $P = 0.011$) compared to the sham group, but no differences were found in VAS between groups. Disability and the Fear-Avoidance Beliefs Questionnaire score also displayed a significant decrease in the MFR group ($P < 0.05$) as compared to sham MFR.

Conclusion. MFR therapy produced a significant improvement in both pain and disability. Because the minimal clinically important differences in pain and disability are, however, included in the 95% CI, we cannot know whether this improvement is clinically relevant.

Key words: chronic low back pain, fascia, myofascial release, physical therapy modalities.

Level of Evidence: 2

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Low back pain (LBP) is a common condition associated with work absenteeism, disability, and large health care costs[1] with an annual prevalence ranging from 22% to 65%.[2] Such epidemiological data translate into significant negative economic and social effects.[3]

Despite this high prevalence, the etiology and nature of chronic low back pain (CLBP) have not yet been fully understood. It has been suggested that lumbar fasciae might be involved in CLBP.[4–6] Different authors have documented its implication by reporting anatomopathologic[4] and echogenic[5] and mechanical[6] changes in the properties of the lumbar fascia in patients with CLBP compared with healthy subjects.

In addition to the lumbar fascia, other soft tissues have been related to LBP as well. Magnetic resonance imaging studies have shown asymmetries in the muscle cross-sectional area of the quadratus lumborum,[7] psoas,[7,8] or multifidus[9] in subjects with LBP as compared with asymptomatic controls. Based on these results, some studies have suggested that disorders in these muscles may be related to LBP.[10,11]

Manual therapy is one of the possible management options in the treatment of LBP. Myofascial release (MFR) is a form of manual medicine which involves the application of a low-load, long-duration stretch to the myofascial complex, with the intent to restore optimal length of the fascial tissue, decrease pain, and improve functionality.[12]

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There are previous reports of randomized controlled trials dealing with the effects of MFR in the treatment of LBP. All of them have applied a combined intervention of MFR with other therapeutic approaches, such as muscle energy, soft tissue, high-velocity, low-amplitude thrust and cranial sacral techniques,[13] fascial unwinding,[14] conventional occupational therapy,[15] work station modification,[16] or specific back exercises.[17] The present study aims to analyze the effects of an isolated MFR protocol on the pain and disability in patients with CLBP, an issue which has not been addressed in previous studies.

MATERIALS AND METHODS

Design Overview

This was a double-blind, parallel sham-controlled trial with balanced randomization (1:1).

Setting and Participants

The study was conducted at the research laboratory of our center for conducting clinical trials. Individuals aged between 18 and 60 years with a diagnosis of nonspecific CLBP lasting at least 3 months[18] were consecutively recruited from the Orthopaedic Surgery Service of a tertiary referral hospital.

Subjects were excluded if they were pregnant or experienced any spinal tumor or infection, spinal fracture, systemic disease (autoimmune, infectious, vascular, endocrine, metabolic, or neoplastic disease), fibromyalgia, cauda equina syndrome, previous spine surgery, or musculoskeletal injuries of the lower limbs. Other exclusion criteria were any of the contraindications described for myofascial treatment,[19] previous experience with myofascial therapy, or a history of rehabilitation treatment for back pain within the preceding 2 months.

The study was conducted following the ethical requirements established in the Helsinki Declaration of 1964 and its sixth revision of 2008.[20] All participants read an information leaflet and then signed an informed-consent statement before starting the study. The study protocol was approved by the local Ethics Committee. The trial was registered at ClinicalTrials.gov, NCT01241071.

Randomization and Interventions

Fifty-four participants were randomly assigned to MFR (n = 27) or sham groups (n = 27) using a computer-generated random number sequence.[21] A block size of six subjects was applied to determine the assignment into the experimental or sham groups. Investigators were unaware of the block size, and allocation concealment was preserved.

The interventions were applied by a trained physical therapist with more than 10 years of practical experience in manual therapy. The MFR group received a myofascial treatment consisting of four sessions, each lasting 40 minutes (twice a week for 2 weeks). It was not possible to conceal the group assignment from the physical therapist involved in the intervention, because it is an inherent issue in all trials applying manual therapy. The myofascial protocol included a selection of four techniques applied as described previously.[12,22]

Longitudinal sliding of lumbar paravertebral muscles (Figure 1A): a longitudinal sliding along the lumbar paravertebral muscle complex was performed with the physical therapist's olecranon, three times on each side of the spine.

MFR of the thoracolumbar fascia (Figure 1B): a cross-handed hold, with the hands placed on the T12-L1 levels and on the sacrum, was applied along the fascia, without sliding over the skin or forcing the tissue. This technique was applied for 5 minutes.

MFR of quadratus lumborum (Figure 1C): the elbow of the cranial arm was placed above the iliac crest and lateral to the lumbar paravertebral muscles, over the quadratus lumborum region, whereas the caudal hand was placed on the subject's thigh. Low pressure was applied with the elbow obliquely toward the center of the column, whereas the other hand exercised gentle traction along the patient's leg. The duration of this technique was 7 minutes on each side, and it was performed bilaterally.

MFR of the psoas muscle (Figure 1D): with the hands placed laterally 3 cm from the umbilicus, an MFR of the muscle was induced by means of a transversal sliding of the psoas fascia. This sliding was repeated 15 times on both the right and left psoas muscle.

The control group received a sham MFR for 40 minutes per treatment session, two times a week for 2 weeks. The sham MFR was applied by gently placing the hands over the same areas treated in the MFR group, without sliding, just enough to maintain contact for the desired time.[14,17,23]

All the participants maintained their pharmaceutical treatment for LBP during the duration of the study.

Outcomes and Follow-up

The primary outcome of the study was changes in the level of pain. This variable was assessed before the treatment (baseline), immediately after treatment (week 2), and at follow-up (week 12).

Pain perception was assessed by means of the Spanish version of the Short Form McGill Pain Questionnaire (SF-MPQ)[24] and a visual analog scale (VAS). The SF-MPQ consists of a 15-point descriptor of average pain, articulated in 11 points of sensory experience and four of affective experience. The sensory and affective pain rating scores give a value for a total pain experience ranging from 0 (no pain) to 45 (maximum pain). Melzack[25] has shown that the SF-MPQ is a responsive scale, giving both reliable and valid data. The minimal clinically important difference (MCID) has been stated in five points.[26] The VAS for the reporting of subjective pain was completed using a 0 to 100 mm scale with two extremes labeled as "not noticeable at all" (score = 0) and "worst pain imaginable" (score = 100). The VAS has been shown to be a simple and reliable instrument for assessing pain intensity in clinical settings and research.[27] The MCID for this variable has been stated in 20 mm.[28]

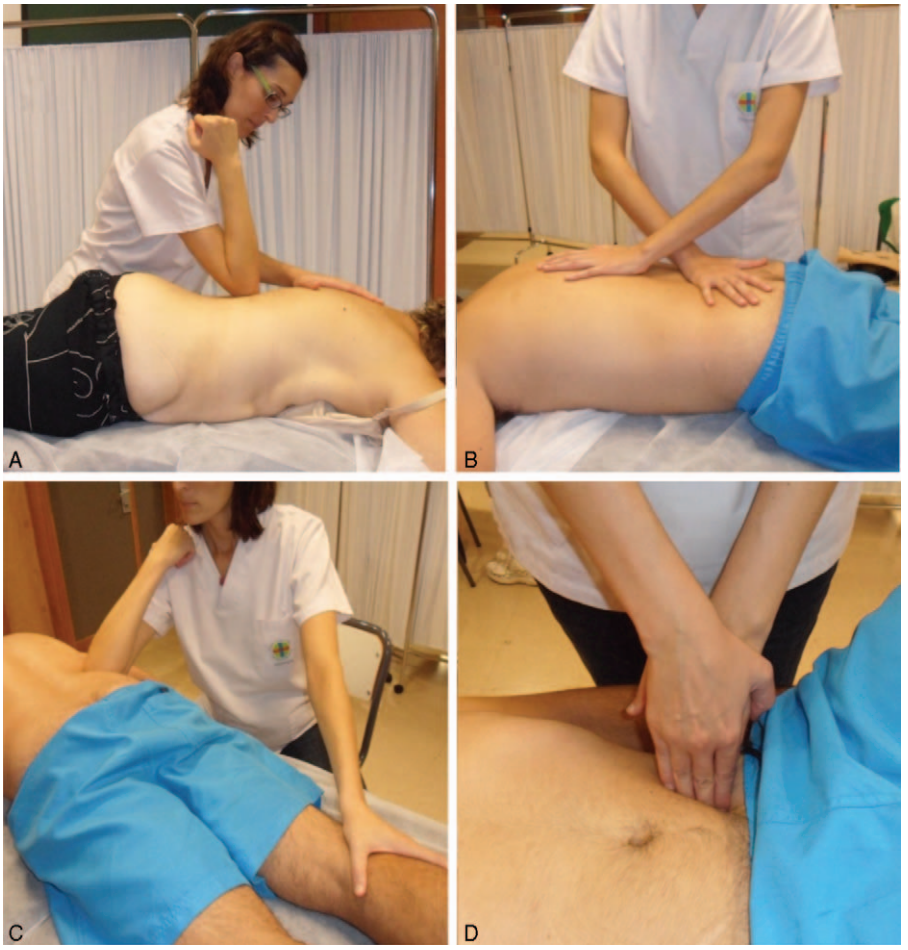

Figure 1. Myofascial release protocol for the intervention group. **A**, Longitudinal sliding of lumbar paravertebral muscles. **B**, Myofascial release of the thoracolumbar fascia. **C**, Myofascial release of quadratus lumborum. **D**, Myofascial release of psoas muscle.

The secondary outcomes of the study were disability and fear-avoidance beliefs.

The degree of disability resulting from back pain was measured by means of the Spanish version of the Roland-Morris Questionnaire (RMQ),[29] with a score ranging from 0 (no disability) to 24 (maximum disability). The MCID for this variable has been stated in three points.[30]

The Spanish version of the Fear-Avoidance Beliefs Questionnaire (FABQ)[31] is a self-report questionnaire which consists of 16 independent sentences that can be rated by the participant on a seven-point Likert scale that ranges from 0 (''completely disagree'') to 6 (''completely agree''). The questionnaire contains two subscales: FABQ-Work (ranging from 0 to 42) and FABQ-Physical Activity (ranging from 0 to 24), which assess the patient's attitudes and beliefs about how occupational or physical activities may influence his or her LBP. An MCID value of six points have been stated, specifically, for the Physical Activity subscale.[32] The FABQ has been shown to have good reliability and validity.[33]

Disability and fear-avoidance beliefs were registered at the same specified times as the primary outcomes.

An investigator from the Orthopaedic Surgery Service was responsible for the enrollment of the participants, whereas an external investigator was responsible for the individual patients' assignments to the intervention groups. Both the participants and the investigator assessing the outcomes were blind to the group assignments, so allocation concealment and masking were preserved throughout the study.

Statistical Analysis

The statistical analysis was performed based on intention to treat using SPSS Statistics version 19.0 (SPSS Inc., Chicago, IL).

Two-way mixed analysis of variance (ANOVA) tests were used to compare the study effects on the outcome measures between the groups, with time serving as the within-group factor, and the intervention type as the between-group factor.

The desired sample size was calculated by an external researcher and determined a priori—based on a preliminary study—to allow at least 80% power to detect a between-group effect of two points on VAS. This difference was chosen to be consistent with the MCID established for this variable.[30] The resulting sample size was 54 participants and arbitrarily assuming 10% drops at follow-up; the sample was established in 60 patients. The significance level of this study was $P < 0.05$.

RESULTS

Fifty-six subjects accepted to participate in the study, and from them two were excluded for receiving other rehabilitation treatments at that time. Therefore, 54 participants were ultimately randomly allocated to the MFR group (mean age 46.6 [10.3] yr) and the sham group (mean age 46.4 [11.4] yr). The baseline descriptive characteristics of all patients are summarized in Table 1.

The rate of dropout was 11% in the follow-up time. The flow diagram of the study is reported in Figure 2.

Data for all outcomes for the experimental and control groups are presented in Table 2.

Pain

A significant group × time interaction was shown for total SF-MPQ and sensory SF-MPQ scores ($P = 0.04$). As reported in Table 2, significant differences between groups were found at week 12 in total SF-MPQ (mean difference MFR-Sham: −7.8; 95% confidence interval [CI]: −14.5 to −1.1) and sensory SF-MPQ (mean difference MFR-Sham: −6.1; 95% CI: −10.8 to −1.5).

The pain assessment using the VAS showed a significant main effect of time ($P < 0.01$). A statistically significant decrease in the pain-rating score was found in both groups at week 2 and at week 12.

Disability

The ANOVA showed a significant group × time interaction effect for RMQ score ($P = 0.03$). The *post-hoc* analyses revealed significant differences between groups at 12 week follow-up (mean difference MFR-Sham: −3.7; 95% CI: −7.6 to −0.2).

Fear-Avoidance Beliefs Questionnaire

The ANOVA test only showed a significant group × time interaction for total FABQ score ($P = 0.05$). Significant differences between groups were observed immediately after treatment (mean difference MFR-Sham: −14.3; 95% CI: −27.8 to −0.8) and at follow-up (mean difference MFR-Sham: −13.5; 95% CI: −27.6–0.5).

None of the patients in both groups reported any adverse event or intolerance to the intervention applied.

DISCUSSION

To the best of our knowledge, this is the first study that analyzes the effects of an isolated MFR protocol in LBP subjects. With regard to the main aim of the study, our results showed a statistically significant decrease in the degree of pain in MFR group, measured by means of the SF-MPQ, compared to the sham group at 12-week follow-up. This effect was, however, not observed in pain assessment using the VAS.

Our study did not show significant differences between groups in SF-MPQ scores immediately after treatment. Contrary to these results, Tozzi *et al*[14] reported a decrease in pain only in the LBP participants included in their intervention group. The methodological differences between the two studies (MFR combined with fascial unwinding in Tozzi's study), the muscles chosen (psoas and pelvic floor muscles in Tozzi's study), and the duration of the protocol (only one session in Tozzi's study), could explain the discrepancies. We suggest that the improvement reported by the intervention and the sham group immediately after treatment might be related with one or several of the following mechanisms: input to central nervous system by the laying-on of hands based on the gate control theory,[34] placebo effect,[35] the expectation of a therapeutic effect,[13] or a regression to the mean.

Interestingly, our results showed significant differences between groups in the SF-MPQ, at follow-up, suggesting that the effectiveness of the MFR treatment was beyond the possible short-term placebo effect. Although the mean

TABLE 1. Anthropometric and Clinical Features of the Participants

Parameter	MFR (n = 27)	Sham (n = 27)
Age (yr)	46.6 (10.3)	46.4 (11.4)
Sex (male/female)	11/16	10/17
Body mass index (kg/m^2)	25.8 (4.8)	25.8 (3.7)
Disease duration (yr)	7.9 (5.3)	7.1 (6.9)
SF-MPQ (0–45)	22.3 (8.3)	23 (9.3)
SF-MPQ-sens (0–33)	15.7 (6.3)	16.5 (6.6)
SF-MPQ-afect (0–12)	6.6 (2.8)	6.3 (3.3)
Visual analog scale (0–100)	60.5 (23.9)	63.3 (24)
RMQ (0–24)	11.1 (5.5)	11.1 (4.9)
FABQ (0–96)	59.7 (20.1)	63.6 (18.3)
FABQ-PA (0–24)	18.3 (4.6)	18.4 (4.9)
FABQ-W (0–42)	27.2 (10.2)	30.8 (9.8)

Data are mean (SD).

FABQ indicates Fear Avoidance Beliefs Questionnaire; FABQ-PA, Fear Avoidance Beliefs Questionnaire Physical Activity Scale; FABQ-W, Fear-Avoidance Beliefs Questionnaire Work Scale; MFR, myofascial release; RMQ, Roland-Morris Questionnaire; SF-MPQ; Short Form McGill Pain Questionnaire; SF-MPQ- afect, Short Form McGill Pain Questionnaire affective scale; SF-MPQ-sens, Short Form McGill Pain Questionnaire sensitive scale.

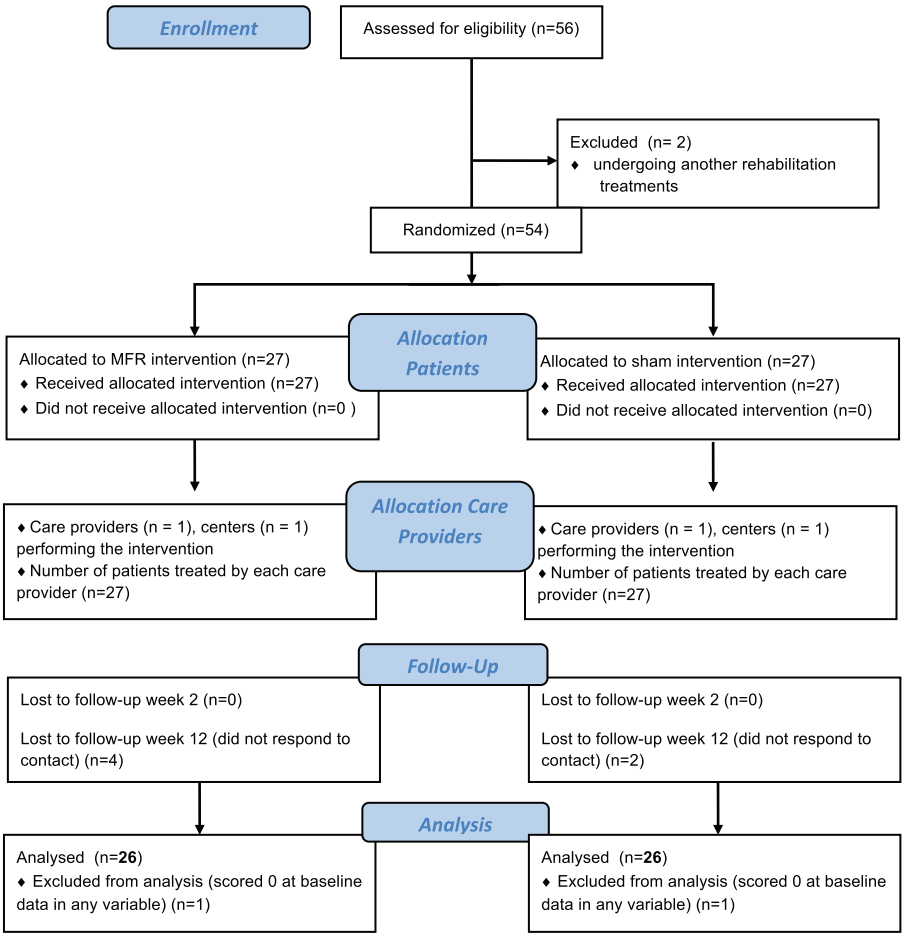

Figure 2. Flow diagram of the study. MFR indicates myofascial release.

difference between groups reaches the MCID[26] these results must be carefully interpreted because the MCID is included between the boundaries of the CI, therefore we cannot know whether this improvement is clinically relevant. These results are consistent with Ajimsha *et al*,[17] who studied the effects of an MFR and therapeutic-exercise combined treatment in LBP and also found statistically significant differences between groups at 8 and 12 weeks follow-up. Our study, however, offers new evidence about the MFR approach, as Ajimsha *et al* did not analyze the effects of the isolated technique.

As a secondary outcome, RMQ score displayed a statistically significant decrease at week 12 in the MFR *versus* sham group. Nevertheless, the extent of the CI does not allow to ensure that the differences observed between groups in disability are clinically important.[30] A study by Licciardone[13] on LBP subjects did not find differences in disability between the osteopathic manipulative treatment and the sham manipulation. The author explained these results with the relatively low baseline RMQ scores. The participants in the present study reported a level of disability greater by four points than that in Licciardone's study.

Previous randomized controlled trials conducted on subjects with CLBP have reported a statistically significant improvement in disability using other manual therapies such as spinal manipulation[36] or a combination of different manual therapy treatments including muscle energy[37] or stretching techniques.[38] Our study also has shown an improvement in disability but, unlike the previous studies, our intervention consisted on an isolate MFR treatment. Moreover, MFR is a *soft manual therapy* technique of gentle manual forces, which is generally well- accepted by the subjects.

Regarding the FABQ our results showed statistically significant differences between groups at both measurement times. In fact, a 14- and 13-point reduction in the score was found between groups immediately after treatment and at week 12 follow-up, respectively, nevertheless this result did not reach the clinical relevance.[39] Our study design cannot provide an insight into the exact mechanism for this considerable change but, considering a global view of the results, it would be possible that the reduction on FABQ score was related to the improvement in pain and disability in the MFR group. The increasing acceptance of the idea that psychosocial factors play a crucial role in LBP, has led to the development of a psychosocial model based on fear-avoidance behavior, in an attempt to explain the complexity of LBP.[33,40,41]

TABLE 2. Differences Between Groups of the Outcome Measures and Minimal Clinically Important Difference %

Outcome	Group						Difference Between Groups		Patients Achieving MCID (%)			
	Baseline		Week 2		Week 12		Week 2	Week 12	Week 2		Week 12	
	MFR	Sham	MFR	Sham	MFR	Sham	MFR Minus Sham	MFR Minus Sham	MFR	Sham	MFR	Sham
SF-MPQ (0–45)	22.9 (19.5–26.2)	23.3 (20.0–26.7)	13.08 (9.5–18.2)	18 (13.6–22.3)	15.28 (11.1–20.6)	23.7 (18.9–28.4)	−4.1 (−10.2–2.1)	−7.8 (−14.5 to −1.1)*	65.4	53.8	59.1	29.1
SF-MPQ-sens. (0–33)	16.1 (13.7–18.6)	16.9 (14.4–19.4)	9.7 (6.6–12.8)	13.1 (9.9–16.1)	11.1 (7.8–14.4)	17.3 (14.0–20.5)	−3.3 (−7.7–1.1)	−6.1 (−10.8 to −1.5)*	–	–	–	–
SF-MPQ-afect. (0–12)	6.7 (5.5–7.9)	6.5 (5.2–7.7)	4.5 (3.1–5.9)	5.0 (3.5–6.4)	4.7 (3.1–6.4)	6.4 (4.8–8.1)	−0.5 (−2.5–1.5)	−1.7 (−4.1–0.6)	–	–	–	–
Visual analog scale (0–100)	63.0 (54.2–71.6)	64.6 (56.0–73.4)	27.1 (17.1–37.2)	33.8 (23.7–43.8)	43.0 (31.1–54.9)	52.0 (40.1–63.9)	−6.6 (−20.9–7.6)	−9.0 (−25.8–7.9)	73.1	61.5	50	37.5
RMQ (0–24)	11.2 (9.2–13.2)	11.6 (9.6–13.6)	7.5 (5.0–10.1)	10.1 (7.6–12.6)	8.1 (5.4–10.9)	11.8 (9.1–14.5)	−2.6 (−6.2 to −1.0)	−3.7 (−7.6 to −0.2)*	57.7	34.6	81.8	25
FABQ (0–96)	60.3 (52.9–67.8)	64.9 (57.4–72.3)	48.6 (39.1–58.1)	62.59 (53.3–72.4)	48.1 (38.1–58.1)	61.6 (51.7–71.6)	−14.3 (−27.8 to −0.8)*	−13.5 (−27.6–0.5)*	–	–	–	–
FABQ-PA (0–24)	18.4 (16.6–20.3)	18.7 (16.9–20.6)	16.3 (13.8–18.7)	18.9 (16.4–21.3)	15.3 (13.0–17.6)	18.5 (16.2–20.8)	−2.6 (−6.1–0.8)	−3.2 (−6.4–0.1)	19.2	11.5	22.7	20.8
FABQ-W (0–42)	27.5 (23.5–31.4)	31.4 (27.5–35.3)	22.8 (18.0–27.7)	28.6 (23.8–33.5)	22.1 (17.2–27.1)	28.9 (23.9–33.8)	−5.8 (−12.6–1.1)	−6.7 (−13.7 to −0.3)	–	–	–	–

Data are mean (CI 95%).

FABQ indicates Fear Avoidance Beliefs Questionnaire; FABQ-PA, Fear-Avoidance Beliefs Questionnaire Physical Activity Scale; FABQ-W, Fear-Avoidance Beliefs Questionnaire Work Scale; MCID, minimal clinically important difference; RMQ, Roland-Morris Questionnaire; SF-MPQ; Short Form McGill Pain Questionnaire; SF-MPQ- afect, Short Form McGill Pain Questionnaire affective scale; SF-MPQ-sens, Short Form McGill Pain Questionnaire sensitive scale.

*$P \leq 0.05$.

Limitations

One of the limitations of our study was that no measurement of treatment credibility was performed so we cannot ensure the success of participants blinding. Secondly, it is difficult to standardize some specific parameters, such as pressure exerted, when manual therapy techniques are used and, generally, this is assumed as a limitation for the study of myofascial therapies.[42]

Finally, we have to state that the final sample size was small. Maybe, this situation could explain that no clinically relevant changes have been reported.

In conclusion, the present study has shown that MFR Therapy produced a significant improvement in both pain and disability. Because the MCIDs in pain and disability are included in the 95% CI, we cannot know whether this improvement is clinically relevant. Subsequent larger sample size trials are necessary to support the clinical relevance of MFR as an isolated technique, or its usefulness as a complement of other forms of physiotherapy treatment.

➢ Key Points

- ❑ This is the first randomized controlled trial aimed to analyze the effects of an isolate MFR intervention in subjects with CLBP.
- ❑ MFR therapy improved pain and disability in subjects with CLBP, but these effects may be too small to be clinically worthwhile.
- ❑ MFR therapy also was shown to reduce the score in the FABQ of subjects with CLBP.

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