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Myofascial Pain and Treatment

Investigating the effects of myofascial induction therapy techniques on pain, function and quality of life in patients with chronic low back pain

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ABSTRACT

Introduction: Low back pain (LBP) is well documented as a common health problem; it is the leading cause of activity limitation and work absence throughout much of the world, and it causes an enormous economic burden on individuals, families, communities, industry, and governments. The aim of this study was to comparatively investigate the effects of myofascial induction therapy (MIT) against pain neuroscience education (PNE) on pain and function in patients with chronic low back pain (CLBP).

Method: Forty patients with CLBP were included and randomly divided into two groups according to the treatment program (40 min/session, 2 sessions/week during 8-week), as follows: the MIT and the PNE groups. The outcome measures were the fear-avoidance beliefs questionnaire (FABQ), Roland Morris disability questionnaire, McGill pain questionnaire, finger floor test, SF-36 quality-of-life questionnaire, and thoracolumbar fascia ultrasound imaging results. Patients were evaluated before and after treatment.

Results: Within both groups, all outcome scores showed a significant improvement ($p < 0.05$). After 8-week, SF-36 physical function, physical role and mental health scores significantly improved in MIT group compared with PNE group, finger floor test score significantly decreased in MIT group compared with PNE group, and FABQ score significantly decreased in PNE group compared with MIT group ($p < 0.05$).

Conclusions: Although both MIT and PNE were found to be effective on pain and function in patients with CLBP, MIT techniques were substantially better in improving the mobility of trunk flexion and quality of life in these patients.

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1. Introduction

Low back pain (LBP), a widespread health problem seen throughout the world, causes both activity limitation, and loss of the work in the patients and also tremendous global economic burden for families of the patients, communities, industry, and the governments (Hoy et al., 2014). Although acute LBP usually ameliorates within the first 6 weeks (Costa et al., 2012), it can sometimes turn into chronic LBP (CLBP) with a prevalence of 10–15%

(Balagué et al., 2012). As a result of chronic symptoms regarding CLBP, 11–12% of population are disabled (Balagué et al., 2012). The CLBP has more negative effects against acute LBP in the patients since it tends not to improve with time and even tends to get worse (Krismer and Van Tulder, 2007). As the patients develop chronic symptoms in LBP, long-term disability and CLBP-related work-loss occur over time. Furthermore, the patients with CLBP suffer from more painful condition, functional limitations, depression, analgesics usage, doctor visits, higher fear avoidance beliefs, and poorer quality of life (Balagué et al., 2012). For all these reasons, treatment approaches of CLBP are versatile from using of brief education about the problem to surgery. On the other hand, rehabilitation, which consists of massage, chiropractic, occupational, and osteopathic therapies, spinal manipulation and mobilization therapy,

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myofascial induction therapy (MIT), behavioral therapy, pain neuroscience education (PNE), exercise therapy, transcutaneous electrical nerve stimulation (TENS), interferential currents, low-level laser therapy, and/or yoga, is important in terms of both preventing and treating the CLBP (Coulter et al., 2018). The objective of PNE is to provide that patients with CLBP understand the neurobiology and neurophysiology of their pain experience (Puentedura and Flynn, 2016). In this way, pain, pain catastrophization and disability decrease, and then physical performance of patient improves (Puentedura and Flynn, 2016).

The MIT, a manually-applied treatment, consists of many procedures in order to optimize function and balance in the fascial system (de las Penas et al., 2015). As known, body movements include fascial activity. With the aims of local correction, recovery of the global dynamics of the tissue and pain-free body use, remodeling in connective tissue is provided by different mechanical techniques of MIT. After remodeling in quality of the extracellular matrix of the connective tissue, movement restriction is eliminated. Furthermore, there is a biochemical effect on the tissue (mechanotransduction) via MIT applications, which improves elasticity (elastin) and reduces excess collagen and myofibroblasts in the scar area (Comesaña et al., 2017). On the other hand, MIT techniques related to the lumbopelvic region which includes superficial (stroke) techniques and deep procedures are especially based on the treatment of thoracolumbar fascia that is considered as the cause of back pain (de las Penas et al., 2015). Because thoracolumbar fascia extends from cranial base via paraspinal muscles in both thoracic and cervical regions to iliac crest from where continues with the gluteal fascia and fascia lata complex (Willard et al., 2012). The mission of the thoracolumbar fascia is to support the optimal body functioning including lumbopelvic stability, static posture and movement, as well. If there is any dysfunction in proper fascial dynamics, a suboptimal exchange of fluids, decreased in mobility, altered blood circulation, ischemia, deteriorated muscular fibers, increased collagen production and finally development of fibrosis in the myofascial system are observed respectively all of which result in loss of function and physiological movement (de las Penas et al., 2015).

According to the literature, there are some studies about MIT techniques unrelated with thoracolumbar region. These studies mostly focus on breast cancer survivors with chronic musculoskeletal pain (da Silva et al., 2019) or shoulder/neck pain (Castro-Martín et al., 2017), healthy individuals with scars (Comesaña et al., 2017), subjects with temporomandibular disorders (Rodríguez-Blanco et al., 2015), pain-free healthy individuals (Fernández-Pérez et al., 2008; Heredia-Rizo et al., 2013; Saiz-Llamas et al., 2009). Moreover, these researches also investigated the effects of MIT on pain, range of motion, posture, vital signs and temperature, functional tests including sit and reach test, and Schober's Test, mood and quality of life in these individuals. On the other hand, there is very little study investigating MIT techniques related with thoracolumbar region. Martínez et al. demonstrated that both lumbar spine manipulation and thoracolumbar MIT cause a decrease in electromyographic activity during eccentric contraction of erector spinae and an increase in lumbar flexion in healthy individuals (Martínez et al., 2010). Tozzi et al. also showed that osteopathic fascial manipulation decreases pain perception and improves kidney mobility in patients with non-specific LBP who were evaluated using real-time ultrasound screening (Tozzi et al., 2012).

To date, the effects of MIT techniques related with thoracolumbar region in patients with CLBP have not been investigated. Also, given the economic burden of CLBP, there is a serious need for studies that investigate the effects of different rehabilitation approaches like MIT in patients with CLBP. Therefore, the current

study was planned to comparatively investigate the effects of MIT techniques related with thoracolumbar fascia on pain and function in patients with CLBP.

2. Methods

2.1. Study design

This was a prospective, randomized-controlled and single-blind study. The individuals were randomly allocated using a computer-generated program to either MIT group or PNE (control) group. The outcome measurements were McGill Pain Questionnaire (MPQ), Roland Morris Disability Questionnaire (RMDQ), Fear-Avoidance Beliefs Questionnaire (FABQ), finger floor test, SF-36 quality-of-life questionnaire, and ultrasound test results of thoracolumbar fascia. All measurements were performed in both groups before and after 8-week program.

2.2. Participants

This study was conducted on 40 patients with CLBP who attended the Kocaeli Cihan Hospital Orthopedics and Traumatology department between December 2018 and June 2019. Ethics approval was obtained for this study from the Istanbul Medipol University Non-Interventional Clinical Research Ethics Committee (dated August 15, 2018, number 10840098–604.01.01- E.34131). Written informed consent was obtained from all individuals before participating the study. This study was also registered at [Clinicaltrials.gov](https://clinicaltrials.gov) (NCT03696979).

Inclusion criteria were as follows: age 25–65 years; having low back pain for at least 6 months; did not have physical therapy within the past month before enrolment; and no other disease that may cause low back pain. The exclusion criteria were as follows: having pain resulting from root pressure; serious discopathy; compression fracture; and rheumatologically or inflammatory disease that may cause LBP.

2.3. Interventions

2.3.1. Myofascial induction therapy (MIT)

The MIT techniques related to the lumbopelvic region contain stroke application, deep induction application, cross-hands induction of the lumbar spine, and hip-flexor region induction ('see Fig. 1'). There are also important clinical procedure principles as mentioned below that the physiotherapist paid attention to all these while applying the all related techniques (de las Penas et al., 2015):

- Two mechanical strategies including compression and traction forces affect the myofascial system biomechanically.
- The physiotherapist specified the body region with pain and/or myofascial dysfunction which includes some restriction barriers.
- Each problematic body region needs the specific procedure application.
- After specified the tissue as the first restriction barrier of the body region, the physiotherapist tenses constantly the tissue via applying slow and gradual compression/traction. The constant pressure is applied during approximately 60–90 s.
- After the releasing of the first barrier, the physiotherapist keeps on with the movement in the direction of the facilitation while pausing at each additional restriction barrier.
- The physiotherapist has to improve at least three to six consecutive barriers and the minimum needed time of application in each technique is about 3–5 min.

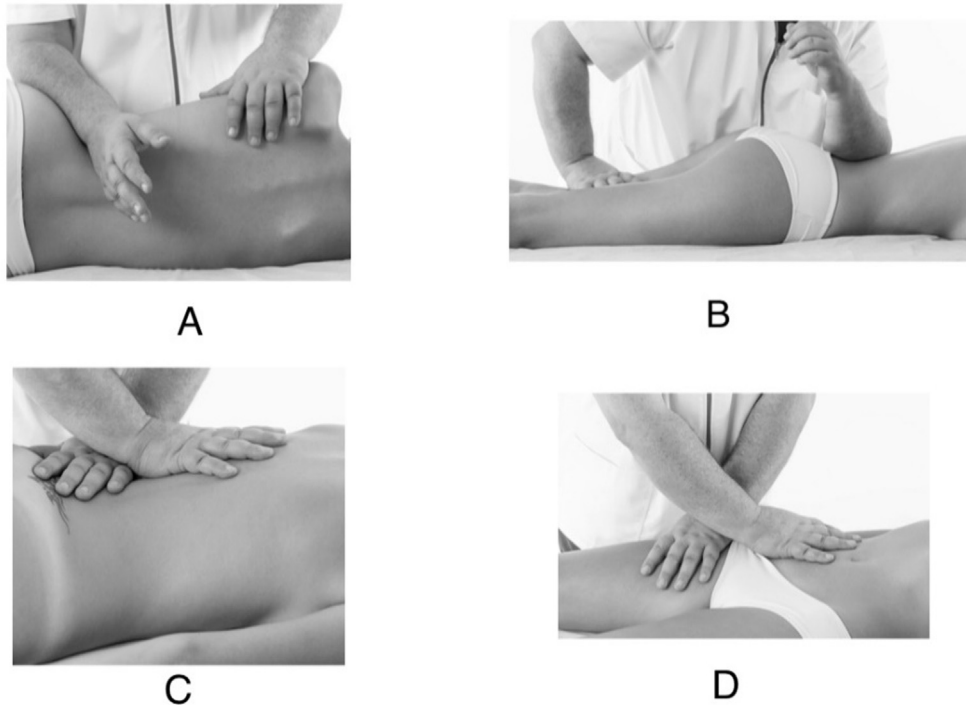


Fig. 1. Myofascial induction techniques. A: Stroke application, B: Deep induction application, C: Cross-hand induction of the lumbar spine. D: Hip flexor region induction (de las Penas et al., 2015).

- While the tension has to be constant, the pressure applied by the physiotherapist may be changed until the first barrier is overcome. Moreover, the pressure should be decreased if an abundant activity and/or pain is perceived.

All of the MIT techniques, which were mentioned in detail as below how applied, were applied to the patients with CLBP for a total of 40 min in a session, twice per week during eight weeks.

2.3.2. Stroke application

The patient was positioned lying down on their side with their cranial hand stabilizing the trunk and the caudal forearm (with the thumb up) placed in the space between the last rib and the iliac crest. The stroke application was then performed by the physiotherapist using their caudal forearm (i.e. with flexion and extension) over the patient's underlying structures. The length of the displacement was about 10 cm ('see Fig. 1-A'). The whole stroke application was repeated in three sets of 15 strokes each set (de las Penas et al., 2015).

2.3.3. Deep induction application

The patient was placed in the prone position with the physiotherapist's elbow placed over the ipsilateral lumbar region between the last rib and the iliac crest, laterally to the paravertebral muscles. Pressure was then applied towards the table by the physiotherapist using their elbow. The other hand of the physiotherapist was placed over the patient's tight tissues in the cranial direction ('see Fig. 1-B'). Through this maneuver, the quadratus lumborum shortens and the access of the technique applied on the problematic body region has been provided. This position was preserved for 3–5 min (de las Penas et al., 2015).

2.3.4. Cross-hand induction of the lumbar spine

The patient was placed in the prone position. The hands of the physiotherapist were both crossed and placed the patient's back.

The physiotherapist applied a small force towards the table in the craniocaudal direction ('see Fig. 1-C') (de las Penas et al., 2015).

2.3.5. Hip flexor region induction

The patient was placed in the supine position. The cranial hand of the physiotherapist was placed on the anterior superior iliac spine and the other hand was placed on the anterior upper third of the thigh. The procedure was performed by pressing with a slight force towards the table in the craniocaudal direction ('see Fig. 1-D'). This position took about 3–5 min (de las Penas et al., 2015).

2.3.6. Pain neuroscience education (PNE)

Mechanism of pain, central processing of pain, how the central nervous system is sensitized in chronic pain, factors that cause chronic pain, and the adverse effects resulting from the fear of pain are explained to the patients on the basis of PNE. Furthermore, the following topics are covered during the education process: Neurophysiology of pain, nociception and nociceptive pathways, neurons, synapses, action potential, spinal inhibition and facilitation, peripheral sensitization, central sensitization, and plasticity of the nervous system. For this purpose, simple pictures, examples, booklets, metaphors, drawings, metaphors and workbook with reading/question-answer assignments are used for education (Louw and Puentedura, 2014). The methods including pictures, examples, drawings and/or metaphors which were created internally were used to explain these training processes to our patients. The PNE was given to the patients twice per week for eight weeks and pain training sessions lasted for 40 min.

2.4. Outcome measurements

The patient introduction form was used to record personal information and demographic characteristics (age, height, weight, body mass index, gender, occupation, and educational status) of

individuals with CLBP. Currently, since there are no specific and objective measurements to evaluate myofascial dysfunction (de las Penas et al., 2015), we used the following the questionnaires, finger floor test and ultrasound.

2.4.1. Primer outcome measurements

Pain was measured using the Turkish version of McGill Pain Questionnaire (MPQ) which assesses sensory, affective, evaluative, and miscellaneous aspects of pain and pain intensity in individuals with chronic pain (Melzack, 1975; Olgun et al., 2003). The MPQ contains 4 main subscales evaluating multiple aspects of pain (Pain Rating Index) and a 5-point pain intensity scale (Present Pain Intensity). The questionnaire is interviewer-administered scale that the sets of descriptors were read to the individuals with CLBP who were asked to choose the words that best described the pain. While Pain Rating Index scores range from 0–78, Present Pain Intensity both scores range from 0 to 5 and also indicates overall pain intensity (Melzack, 1975).

The Roland Morris Disability Questionnaire (RMDQ) was used to determine the level of physical competence of the patients. This is a self-reported questionnaire that consists of 24 items that reflect the limitations in different activities of daily living that are attributed to LBP including walking, bending over, sitting, lying down, dressing, sleeping, self-care, and other daily activities. The patient marks each item that applies to his or her current status. Each item receives a score of 1. The total score ranges from 0 (no disability) to 24 (maximum possible disability) (Roland and Morris, 1983).

2.4.2. Secunder outcome measurements

The finger floor test is a method that is used to evaluate the flexibility (mobility) of trunk flexion. Individuals lean forward without bending their knees as far as possible while standing on a platform that is 20 cm high. The platform is regarded as the “0” point. Unless the middle finger of the individual reaches the platform, the vertical distance is recorded positively in centimeters. If the individual goes further, the distance is recorded negatively in centimeters. The test is performed three times. After performed the tests, the best effort is considered as the outcome. The test is also valid and reliable tool for the clinical practice clinical practice and therapeutic trials (Perret et al., 2001).

The Fear-Avoidance Beliefs Questionnaire (FABQ) was developed to evaluate fear-avoidance beliefs about physical activity and work as suitable for routine clinical use in patients with LBP (Waddell et al., 1993). Therefore, the Turkish version of this valid and reliable questionnaire was used in current study (Korkmaz et al., 2009). This is a self-administered questionnaire and consists of 16 questions and 2 subscales including scale 1: fear-avoidance beliefs about work (11 questions) and scale 2: fear-avoidance beliefs about physical activity (5 questions). The questionnaire is scored using a 7-point Likert-type scale from completely disagree (0) to completely agree (6). The score in each section and overall score are used independently. The activity section is scored between 0 and 24, and the work-related section is scored between 0 and 36. Higher scores show a high level of fear avoidance beliefs (Waddell et al., 1993).

Ultrasound was performed on the right and left sides of the dorsum with the patient in the prone position, focusing on the thoracolumbar fascia. Because the fascial planes were more parallel to the skin at intervertebral level 2–3, images were taken 2 cm lateral of the intervertebral disc area between lumbar vertebrae 2 and 3 (Langevin et al., 2009; Stokes et al., 2007). Each ultrasound image was obtained using a Siemens Acuson X 700 and a Linear 10.7 MHz probe. In the ultrasound evaluation, the morphological structure of the thoracolumbar fascia was examined. The Likert scale was used in the study. The Likert scale ratings ranged from 1,

which was “very irregular”, to 10, which was “very regular” (Jamieson, 2004; Norman, 2010). The participants' ratings were divided into four groups, as follows: Group 1 (very irregular) comprised all scans with a median rating of 1–3; Group 2 (slightly irregular) comprised all median scores from 4 to 5; Group 3 (slightly regular) comprised all 6 to 7 median scores; and Group 4 (very regular) comprised all median scores between 8 and 10 (‘see Fig. 2’) (De Coninck et al., 2018; Hallgren, 2012; LaValley and Felson, 2002; Norman, 2010).

To investigate the comparatively effect of MIT and PNE on quality of life in patients with CLBP, 36-Item Short-Form Health Survey (SF-36) was used in current study. The SF-36 is a quality-of-life questionnaire which assesses eight health domains including physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health (Ware Jr and Sherbourne, 1992). This is also a self-administered questionnaire. After the Likert-scale items were added together, each scale was standardized so that it ranged from 0 (the lowest level) to 100 (the highest level) (Ware Jr and Sherbourne, 1992).

2.5. Statistical analysis

The IBM SPSS Statistics V22.0 software program was used to statistically analyze the data that were obtained from the study. One-sample Kolmogorov–Smirnov test was used to determine whether the demographic data showed a normal distribution. In this study, Student-t paired test was used for intragroup analysis. Student's-t independent test was used for intergroup analysis. In this method, the Levene test was used to determine if there was a normal distribution.

3. Results

There were 40 individuals who expressed an interest in participating in the study. All participants completed the study and were entered into the analysis. Demographic characteristics and pain duration were similar between groups (Table 1, $p > 0.05$) in which the individuals were in their early 40s, were evenly distributed by gender (50% male), and experienced pain for approximately 14 months prior to the start of the study.

Within both the MIT group and PNE group, the MPQ, RMDQ, finger floor test, FABQ, all subscales of SF-36, and ultrasound scores showed a significant improvement after 8-week program (Table 2, $p < 0.05$).

After 8-week, while physical functioning, physical role and mental health subscales scores of SF-36 significantly improved in the MIT group compared with the PNE group, finger floor test score significantly decreased in the MIT group compared with the PNE group (Table 2, $p < 0.05$). However, the FABQ score significantly decreased in the PNE group compared with the MIT group (Table 2, $p < 0.05$). Moreover, ultrasound score was found very close to statistical significance (Table 2, $p = 0.051$). No statistically significant difference was observed in MPQ, RMDQ scores, and bodily pain, general health, vitality, social functioning, and emotional role subscales scores of SF-36 between the two groups (Table 2, $p > 0.05$).

Table 3 showed that whereas 16 (80%) patients in MIT group and 12 (60%) patients in PNE group had irregular thoracolumbar fascia ultrasound results before 8-week program, 6 (30%) patients in MIT group and 6 (30%) patients in PNE group had irregular thoracolumbar fascia ultrasound results after 8-week program (Table 3, $p < 0.05$).

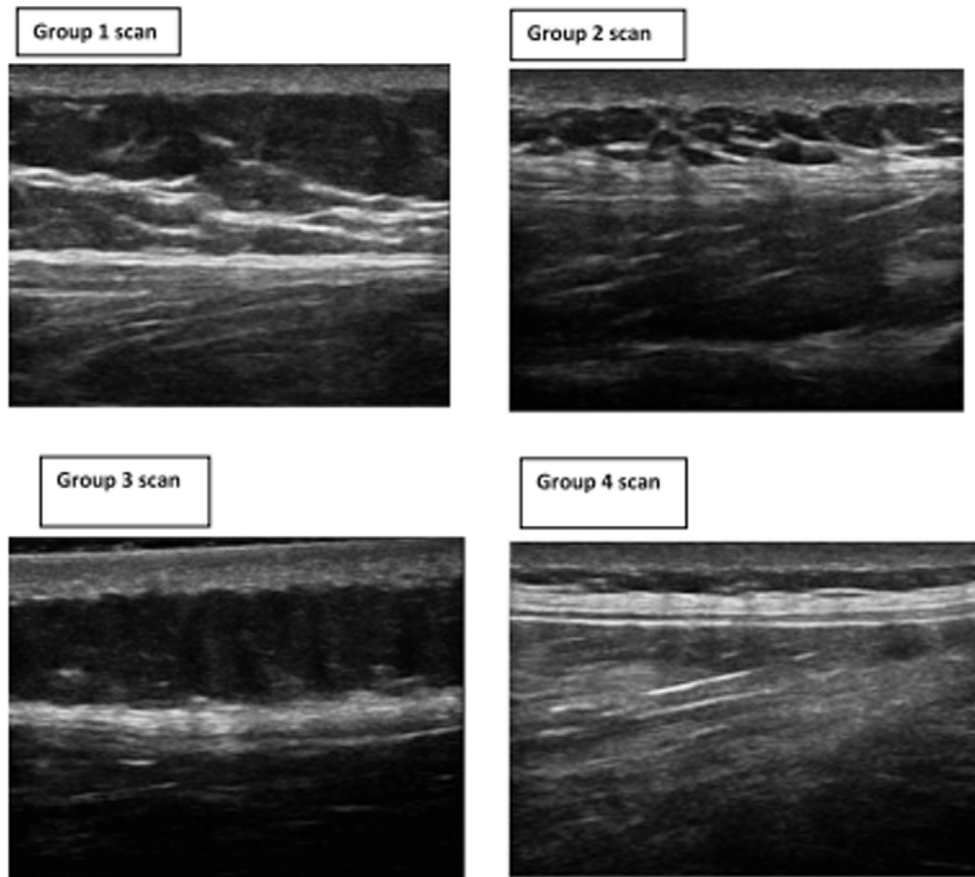


Fig. 2. Morphology of thoracolumbar fascia. Group 1, “very irregular”; Group 2, “slightly irregular”; Group 3, “slightly regular”; and Group 4, “very regular” (De Coninck et al., 2018).

Table 1
Comparison of demographic characteristics and pain duration between the groups.

	MIT group (n = 20) X±SD	PNE group (n = 20) X±SD	p value
Age (year)	41.25 ± 9.12	42.6 ± 7.96	0.612
Gender (n, %)			
Female	10, 50%	10, 50%	1.000
Male	10, 50%	10, 50%	
Weight (kg)	72.8 ± 8.4	76.3 ± 12.45	0.318
Height (cm)	171.7 ± 5.66	170.75 ± 6.56	0.616
BMI (kg/m ²)	24.65 ± 2.24	25.85 ± 3.36	0.189
Pain duration (months)	14.35 ± 3.76	14.15 ± 4.13	0.853

MIT: myofascial induction therapy, PNE: pain neuroscience education, BMI: body mass index, n: frequency, %: percentage, kg: kilogram, cm: centimeter, x: mean, SD: standard deviation, p < 0.05.

4. Discussion

This is the first study investigating the efficacy of MIT techniques related with thoracolumbar region versus PNE on pain, physical competence level, mobility of trunk, fear-avoidance beliefs about physical activity and work, ultrasound images of thoracolumbar fascia serving as a valuable objective measurement tool for this study and quality of life in patients with CLBP in the literature to our knowledge. It revealed that while 8-week MIT applications provided increased mobility of trunk, better quality of life and more regular images in ultrasound evaluation of thoracolumbar fascia in the patients with CLBP, 8-week PNE provided greater reduction in fear avoidance beliefs about physical activity and work related with CLBP in the patients. On the other hand, the

superiority of these two applications to each other on pain, physical competence level and some subscales scores of SF-36 could not be demonstrated in current study. Given the intragroup analysis, each training was found effective on pain, physical competence level, mobility of trunk, fear-avoidance beliefs about physical activity and work, ultrasound images of thoracolumbar fascia serving as a valuable objective measurement tool for this study and quality of life separately.

Based on the results of current study, while both 8-week MIT and PNE had a healing effect on pain intensity in patients with CLBM separately, there was no superiority of MIT techniques on pain. In the literature, there are contradictory results regarding the effects of MIT techniques on pain perception (Castro-Martín et al., 2017; da Silva et al., 2019; Rodríguez-Blanco et al., 2015; Saíz-Llamas et al., 2009); however, all of them present valuable knowledge about MIT applications outside the thoracolumbar region. In accordance with our results, a newly published meta-analysis about female survivors with breast cancer showed that manual therapy including MIT, myofascial release, classic massage, ischemic compression of trigger points, and myofascial therapy has positive effects on the chronic musculoskeletal pain in the upper limbs and thorax (da Silva et al., 2019). Similarly, Castro-Martín et al. also showed that an important reduction in pain intensity which evaluated using visual analog scale occurs via a single 30 min' session compared to a control group applied placebo electrotherapy (pulsed shortwave therapy) in 21 breast cancer survivors (Castro-Martín et al., 2017). Unlike these results and ours, Rodríguez-Blanco et al. and Heredia-Rizo et al. showed that there is no comparatively immediate effect on orofacial sensitivity to

Table 2
Effects of MIT on the outcomes in patients with CLBP.

	MIT group (n = 20)				PNE group (n = 20)				Differences between groups	
	Before X±SD	After X±SD	Change X±SD	p value	Before X±SD	After X±SD	Change X±SD	p value	p value	
MPQ (0–78)	50.55 ± 6.03	25.2 ± 5.32	25.35 ± 8.64	< 0.001	53.45 ± 7.36	31.9 ± 3.98	21.55 ± 6.93	< 0.001	0.133	
RMDQ (0–24)	14.9 ± 2.38	8.05 ± 1.43	6.85 ± 2.81	< 0.001	16.65 ± 2.08	11.1 ± 2.42	5.55 ± 3.88	< 0.001	0.233	
Finger floor test (cm)	5.5 ± 2.35	2.45 ± 0.88	3.05 ± 1.84	< 0.001	4.75 ± 2.75	3.95 ± 2.08	0.8 ± 0.83	< 0.001	< 0.001	
FABQ (0–60)	50.7 ± 5.68	25.5 ± 4.21	25.2 ± 6.39	< 0.001	51 ± 6.2	25 ± 3.65	26 ± 6.98	< 0.001	< 0.001	
Ultrasound (1–10)	4.2 ± 1.7	6.1 ± 1.41	-1.9 ± 2.14	0.001	4.95 ± 1.43	5.75 ± 1.11	-0.8 ± 1.15	0.006	0.051	
SF-36 Physical functioning (0–100)	50.45 ± 3.97	76.6 ± 6.55	-26.15 ± 8.17	< 0.001	48.6 ± 4.42	62.2 ± 6.27	-13.6 ± 7.17	< 0.001	< 0.001	
SF-36 Physical role (0–100)	46.9 ± 6.42	65.65 ± 10.14	-18.75 ± 8.85	< 0.001	43.9 ± 5.26	55.27 ± 5.32	-11.37 ± 4.8	< 0.001	0.003	
SF-36 Bodily pain (0–100)	46.92 ± 5.56	64.12 ± 6.42	-17.2 ± 7.38	< 0.001	42.75 ± 7.36	57.77 ± 3.62	-15.02 ± 7.31	< 0.001	0.355	
SF-36 General health (0–100)	41.7 ± 6.55	56.3 ± 8.14	-14.6 ± 7.35	< 0.001	42.05 ± 5.33	54.15 ± 5.16	-12.1 ± 5.21	< 0.001	0.239	
SF-36 Vitality (0–100)	34.65 ± 6.16	47.55 ± 5.58	-12.9 ± 7.89	< 0.001	42.1 ± 5.36	51.62 ± 5.13	-9.52 ± 4.31	< 0.001	0.131	
SF-36 Social functioning (0–100)	46.22 ± 4.46	63 ± 6.81	-16.77 ± 6.08	< 0.001	47.5 ± 5.46	62.9 ± 5.23	-15.4 ± 5.42	< 0.001	0.225	
SF-36 Emotional role (0–100)	46.38 ± 3.87	64.05 ± 5.41	-17.66 ± 5.62	< 0.001	47.42 ± 5	62.51 ± 5.29	-15.09 ± 6.63	< 0.001	0.253	
SF-36 Mental health (0–100)	48.65 ± 3.92	79.7 ± 7.2	-31.05 ± 7.56	< 0.001	51.9 ± 4.12	66.2 ± 5.47	-14.3 ± 6.34	< 0.001	< 0.001	

MIT: myofascial induction therapy, PNE: pain neuroscience education, MPQ: McGill pain questionnaire, RMDQ: Roland Morris Disability Questionnaire, cm: centimeter, FABQ: Fear-avoidance beliefs questionnaire, SF-36: Short-Form Health Survey, x: mean, SD: standard deviation, p: statistical significance value. p < 0.05.

Table 3
The rates of the groups according to thoracolumbar fascia ultrasound results.

	MIT group (n = 20)				PNE group (n = 20)			
	Before		After		Before		After	
	n	%	n	%	n	%	n	%
Group 1 (very irregular, 1–3 scores)	5	25	1	5	2	10	0	0
Group 2 (slightly irregular, 4–5 scores)	11	55	5	25	10	50	6	30
Group 3 (slightly regular, 6–7 scores)	4	20	13	65	7	35	13	65
Group 4 (very regular, 8–10 scores)	0	0	1	5	1	5	1	5

MIT: myofascial induction therapy, PNE: pain neuroscience education, n: frequency, %: percentage.

mechanical pressure pain of the masseter muscles evaluated using a pressure algometry after adding a MIT technique to a multimodal protocol in either 60 subjects with temporomandibular disorders (Rodríguez-Blanco et al., 2015) or 48 pain-free healthy individuals (Heredia-Rizo et al., 2013). Saíz-Llamas et al. demonstrated similarly that bilateral pressure pain thresholds do not change following a real one-session cervical MIT technique when compared with a control group received a sham-manual procedure in 35 asymptomatic subjects (Saíz-Llamas et al., 2009). These differences between results of studies and ours may arise from both the shortness of the MIT application and inclusion of healthy population. Further studies should be conducted with different durations and combinations of the MIT application and participation of larger patient numbers following the guidance of our results.

It has been known that CLBP reduces both endurance and flexibility of the body and therefore limits the range of motion at the waist and activities during daily living activities in the patients (Hwangbo et al., 2015). In our study, as the mobility of trunk increased in patients with CLBP after 8-week MIT applications compared with control group, fear avoidance beliefs about physical activity and work decreased in the patients after 8-week PNE compared with MIT. There was no intragroup difference regarding physical competence level of our patients. According to intragroup analysis of our groups, each training had considerable effects on physical competence level, mobility of trunk, and fear-avoidance

beliefs about physical activity and work separately. In the literature, there is no study investigating the effects of MIT on either physical competence level or fear avoidance beliefs about physical activity and work in patients with CLBP. On the other hand, the effectiveness of MIT on the mobility of trunk was wondered by some researchers. A pilot study without a control group belonging to Chamorro Comesaña et al found that 8-week MIT application provides functional improvement evaluated using Schober's test (score increased from 14.5 cm during the first session to 15.3 cm during the final one) in healthy individuals with scars in consistent with our results (Comesaña et al., 2017). Castro-Martín et al also consistently demonstrated in randomized, single-blind, placebo-controlled crossover study that a single 30-min MIT session and 4-week MIT improves neck-shoulder range of motions in breast cancer survivors (Castro-Martín et al., 2017). Moreover, Saíz-Llamas et al demonstrated that cervical range of motions belonging to 35 asymptomatic subjects increase following a real one-session cervical MIT technique when compared with a control group received a sham-manual procedure (Saíz-Llamas et al., 2009). In contrast to our results, Rodríguez-Blanco et al revealed that there is no improvement in intergroup comparison of immediate MIT versus a control group on maximal vertical mouth opening, lumbar and suboccipital mobility after adding a MIT technique to a multimodal protocol in 60 subjects with temporomandibular disorders. However, there is a considerable improvement in intergroup analysis of both groups in terms of increases in suboccipital flexion and sit-and-reach test (Rodríguez-Blanco et al., 2015). Heredia-Rizo et al similarly found that there is no improvement in neither intragroup nor the intergroup comparisons regarding effects of immediate MIT on maximal vertical mouth opening after adding a MIT technique to a multimodal protocol in 48 pain-free healthy individuals (Heredia-Rizo et al., 2013). One session MIT application may not be enough to improve mobility in patients or healthy subjects. Therefore, further studies should be planned with enough training duration along with different measurement tools.

In the literature, there is only one study investigating the effects of MIT on ultrasound images (Comesaña et al., 2017). The results of that study without a control group demonstrated that the thickness of the women' scar tissue evaluated using ultrasound images decreased from the first session to last session of 8-week MIT in

healthy individuals with scars (Comesaña et al., 2017). This improvement is consistent with our positive results regarding more regular images in ultrasound evaluation of thoracolumbar fascia in the patients with CLBP after 8-week MIT application against PNE. Given the lack of studies which investigate the effects of MIT with objective measurement tools in the patients with CLBP, our study in which the ultrasound was used to evaluate the morphological structure of the thoracolumbar fascia is gaining importance. However, statistical difference between our groups remained at the border. Therefore, there is an urgent requirement for many studies with larger population.

Another important finding of our study was that quality of life in patients with CLBP improved both within and between groups after 8-week MIT and PNE trainings. In consistent with our finding, Chamorro Comesaña et al. found that 8-week MIT application improves quality of life evaluated using SF-36 (especially in subscales of pain and vitality) in healthy individuals with scars (Comesaña et al., 2017). It may derive from improvement of other parameters regarding function and pain. On the other hand, there is also a contradictory result on quality of life in the literature. The meta-analysis about breast cancer survivors showed that manual therapy including MIT has no important effect on quality of life (da Silva et al., 2019). This different finding may arise from different patient population because cancer has more pathologic and complex process according to LBP. Further studies are therefore needed.

4.1. Limitations

Although this is the first study showed the effects of 8-week MIT therapy versus PNE on pain, function and quality of life in patients with CLBP, there are some limitations. As known, exercise therapy is vital for rehabilitation of this patient group. Therefore, we considered adding a standard exercise protocol to both groups before starting the study. However, considering the confounding effect on the MIT of dose change depending on the learning effect and self-application feature of exercise during off-session hours, we found more appropriate to give exercise therapy to the participants at the end of 8 weeks. In fact, MIT was also applied to patients in the PNE group who still had pain after 8-week training duration. Another limitation of current study is regarding reluctant of patients in the PNE group. Since there was no manual application in PNE group, we could not consider that the patients in PNE group may not be willing to continue the treatment for 8 weeks. Further researchers should take into account this situation.

4.2. Conclusion

It is important to prevent long-term disability and work-loss related with CLBP. Therefore, non-invasive, time-effective and different rehabilitation strategies such as MIT are still needed according to the current literature. From this point of the view, current study about the patients with CLBP who may suffer from painful condition, functional limitations, mood disturbances, high fear avoidance beliefs, and poor quality of life has many valuable insights. Firstly, 8-week MIT against a control group has enough duration and healing effect to improve mobility of trunk, quality of life and regular images in ultrasound in the patients with CLBP. Secondly, our study also demonstrated that 8-week PNE without any manual intervention like MIT can reduce fear avoidance beliefs about physical activity and work in CLBP patients. Finally, although there is not any superiority of these MIT and PNE to each other on pain, physical competence level and some subscales scores of SF-36, each training was found effective on pain, physical competence level, mobility of trunk, fear-avoidance beliefs about physical activity and work, ultrasound images of thoracolumbar fascia and

quality of life separately. Hence, our study, the first study in the literature in terms of demonstrating the effectiveness of MIT with both objective measurement tool and current commonly used measurement methods, will be a guide for further studies. Our encouraging study also shows the magnitude of the need. Therefore, further studies should be conducted with larger sample sizes, combined with different rehabilitation and/or treatment modalities regarding CLBP in patients with CLBP.

Trial registry number

This trial was registered at [Clinicaltrials.gov](https://clinicaltrials.gov) (NCT03696979).

Ethical statement

Ethics approval was obtained for this study from the Medipol University Non-Interventional Clinical Research Ethics Committee (dated August 15, 2018, number 10840098–604.01.01- E.34131).

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CRediT authorship contribution statement

Mehmet Ünal: Conceptualization, Methodology, Software, Writing - review & editing, Writing - original draft, Resources, Formal analysis. **Ender Evcik:** Visualization, Investigation. **Muammer Kocatürk:** Data curation, Writing - original draft, Resources. **Z. Candan Algun:** Supervision, Formal analysis.

Declaration of competing interest

The authors report no conflict of interest.

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