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Supervised exercise with or without laser-guided feedback for people with non-specific chronic low back pain. A randomized controlled clinical trial

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ABSTRACT

Background: Among the most effective therapeutic interventions in non-specific chronic low back pain (NSCLBP), clinical practice guidelines highlight exercise therapy and patient education; However, regarding the combined intervention of exercise and Pain Neuroscience Education (PNE), there is no consensus on the most effective form of exercise.

Objective: To find out what changes occurred after the application of two exercise modalities [Supervised Exercise (SE) and Laser-Guided Exercise (LGE)] and PNE on pain, pain pressure thresholds, disability, catastrophizing, kinesiophobia and lumbar proprioception in subjects with NSCLBP.

Methods: Single-blind randomized clinical controlled trial. 60 subjects with NSCLBP. Both groups performed a total of 16 therapeutic exercise sessions and 8 Pain Neuroscience Education sessions. With the Laser-Guided Exercise Therapy group performing laser-guided exercises.

Results: A significant decrease was observed for pain intensity for both groups between baseline and post-intervention and the 3 month follow-up ($p < 0.001$). There was a significant between-group difference between baseline and post-intervention scores in terms of pain intensity and kinesiophobia in favour of the LGE group.

Conclusion: Supervised exercise with or without laser feedback, when combined with PNE, reduces pain intensity, disability, pain catastrophizing, kinesiophobia and improves proprioception and PPTs in patients with NSCLBP. At a 3-month follow-up, the combination of LGE plus PNE is most effective for reducing pain intensity.

1. Introduction

Non-specific chronic low back pain (NSCLBP) is the most common musculoskeletal condition (Malfliet et al., 2019). It is associated with high levels of disability and economic burden to society, partly because of its peak incidence in the working age population (Gianola et al., 2019). Pain, disability, psychosocial factors (e.g. catastrophizing and kinesiophobia) (Malfliet et al., 2019), lack of self-efficacy (La Touche et al., 2019), impaired postural control (Caña-Pino et al., 2021; Lopes et al., 2017; Salavati et al., 2016) and proprioceptive deficits (Caña-Pino et al., 2021; Puntumetakul et al., 2018) are possible related factors in NSCLBP.

Current evidence-based guidelines for the management of NSCLBP emphasise the need to stay active and the use of patient education and exercise (Foster et al., 2018; Luomajoki et al., 2018; Malfliet et al., 2019; Saragiotta et al., 2016). Exercise programs include muscle strengthening and endurance, specific trunk muscle activation, movement control, trunk mobility, aerobic and general or multimodal exercises. Exercise is known to have a large effect size at improving mobility and increasing strength, in addition to reducing pain intensity and disability in people with NSCLBP (George et al., 2021; Louw et al., 2016; Malfliet et al., 2019).

Previous work has shown that the combination of a supervised exercise (SE) program with pain neuroscience education (PNE) is more

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effective than exercise alone (large effect size for pain intensity) for the management of chronic musculoskeletal pain (Louw et al., 2016; Malfliet et al., 2019). The benefits of combining both interventions have been explained by modifying erroneous beliefs and reducing catastrophizing, kinesiophobia, and fear-avoidance behaviours (Bodes Pardo et al., 2018; Pain Neuroscience Education and Physical; Joypaul et al., 2019; Martinez-Calderon et al., 2020; Rondon-Ramos et al., 2020). A reduction of depressive symptoms, fatigue and pain intensity has also been observed (Louw et al., 2016; O'Connell and Ward, 2018; Wippert et al., 2019). However, regarding the combined intervention of exercise and PNE, there is no consensus on the most effective form of exercise to use in this combined intervention for managing NSCLBP (George et al., 2021; Malfliet et al., 2019).

In recent years, it has been reported that the focus of attention during exercise performance may play an important role in motor skill learning which subsequently, may influence outcomes (Aghakeshizadeh et al., 2021; Bradley and Haladay, 2020; Gallego Izquierdo et al., 2016; Kristiansen et al., 2018; Matheve et al., 2018; Vuillerme and Nafati, 2007). Supervised motor control exercises are characterised by requiring the individual to pay attention to the body movement performed after receiving a patterned and sequenced instruction. i.e. the exercises require the person to focus on their body while moving. This type of exercise is also called applied exercise with an internal focus/locus of movement control (Bourdon et al., 2018).

On the other hand, some exercises are characterised by the effect produced after the requested movement is performed, i.e. cues are provided which are related to the environment or the outcome of a movement (i.e. exercise with an external focus/locus). With the development of rehabilitation technologies, new opportunities for providing external information have emerged, usually in the form of simple instruments such as luminous lasers (Bradley and Haladay, 2020; Gallego Izquierdo et al., 2016) or inertial motion sensors (Matheve et al., 2018). In addition, exercises with an external locus such as exercises guided by a laser, reduces the awareness required for supervised exercise without an external locus, and may lead to a greater retention of learned movement patterns compared to a traditional supervised exercise, an outcome which will be of benefit to the patient in the long term (Aghakeshizadeh et al., 2021). In addition, it favours goal-action coupling, diverting concentration from oneself to the goal of the task. Therapeutic exercise using an external approach facilitates the establishment of effective neural connections that optimise exercise performance. The Laser-Guided Exercise (LGE) is a procedure applied by a laser pointer placed on the head/trunk/abdomen of the subject. Previous studies have demonstrated the benefit of laser-guided exercise in other populations including neck pain (Bradley and Haladay, 2020; Gallego Izquierdo et al., 2016), patellofemoral pain (Aghakeshizadeh et al., 2021), and in healthy subjects (Kristiansen et al., 2018; Vuillerme and Nafati, 2007), for reducing pain intensity, disability, improving mobility, and enhancing proprioception (Bradley and Haladay, 2020; Gallego Izquierdo et al., 2016), however, there are no studies that have evaluated the benefit of LGE for patients with NSCLBP over the same exercises without an external focus. Furthermore, to the best of the authors' knowledge, there are also no studies that simultaneously use laser as an externally focused device and exercise in subjects with NSCLBP.

Thus, the aims of this study were: i) to analyse the effects of combining PNE and supervised exercise with and without laser guidance for people with NSCLBP and ii) to assess the impact of both interventions three months after the end of the intervention on pain, pain pressure thresholds, disability, catastrophizing, kinesiophobia and lumbar proprioception.

2. Methods

This study was a single-blind randomized controlled trial. The trial was performed following the recommendations of the CONSORT

statement (Moher et al., 2010) and the Declaration of Helsinki. The study was approved by the Ethical Research Committee of the University of Extremadura, Spain (project code 77 // 2018, approval date: 6/07/2018) and was registered at clinicaltrials.gov with registration number NCT03635242.

2.1. Sample size calculation

A convenience sample of 30 participants per group was considered in this study. This sample size was considered to be sufficient to detect an effect size of $\delta = 0.50$ given a 2-sided level 5 % paired sampled *t*-test and a statistical power of 80 %. The sample size was calculated using Jamovi 1.6 computer software, the [Jamovi project](https://www.jamovi.org) (2020).

2.2. Settings and participants

Participants were recruited from a private physiotherapy clinic in Badajoz, Spain. The eligible potential sample was comprised of 70 patients with NSCLBP (Fig. 1). Patients aged between 18 and 45 years (Lee et al., 2014; Lopes et al., 2017) suffering from "pain between the costal margins and the inferior gluteal folds with or without referred pain to the leg" were included (Alsufiany et al., 2020; Maher et al., 2017; Scholz et al., 2019). The diagnosis of NSCLBP was made by a general physician at the same clinic. Participants had to be experiencing NSCLBP for ≥ 3 months (Alsufiany et al., 2020; Maher et al., 2017) and score at least 3/10 on the Numerical Pain Rating Scale (NPRS) to be included.

Participants were excluded if they presented with any of the following (Alsufiany et al., 2020): (1) neurological symptoms (Scholz et al., 2019); (2) fibromyalgia, complex regional pain syndrome, chronic fatigue syndrome; (3) pregnancy, including 6 months postpartum; (4) consumption of analgesic medication in the 24 h before enrolment in the study; (5) signs of neuropathic pain (such as e.g. a painful radiculopathy) (Scholz et al., 2019); (6) a history of back and/or lower limb surgery; (7) metal spine implants; (8) trauma to the back or lower extremities in the last 3 months; (9) neurological or vestibular disorders; (10) a diagnosed psychiatric disorder or severe cognitive impairment that prevented the PNE program from being completed (Galan-Martín et al., 2020); (11) physical conditions (e.g. balance disorders) that prevented the completion of the exercise program (Galan-Martín et al., 2020); (12) patients with associated pathologies that made it impossible to perform the PNE program (i.e. myopathies and neurological disorders), and (13) current treatment with alternative therapies (e.g. acupuncture) (da Silva et al., 2016; Pain Neuroscience Education and Physical). Two experienced independent physiotherapists who assessed the suitability of each participant based on the eligibility criteria examined participants at baseline. These researchers were not involved in the interventions.

2.3. Randomization

Each participant was assigned a numeric code. The randomization process was performed by an statistician by simulating a continuous uniform distribution with IBM SPSS 22. Then, patients were sorted according to their values so that the first 30 were assigned to a Supervised Exercise (SE) group and the remainder to the LGE group.

2.4. Procedures

Several descriptive measurements were collected for sample characterization including age, time since the onset of low back pain, pain intensity, body mass index (BMI), pain pressure thresholds, disability, catastrophizing, kinesiophobia and lumbar proprioception.

All the interventions were performed by a single physiotherapist with 7 years of experience in treating people with NSCLBP via exercise and PNE (A.C.P.). This physiotherapist was blinded to all outcome measurements. The interventions were implemented in accordance with

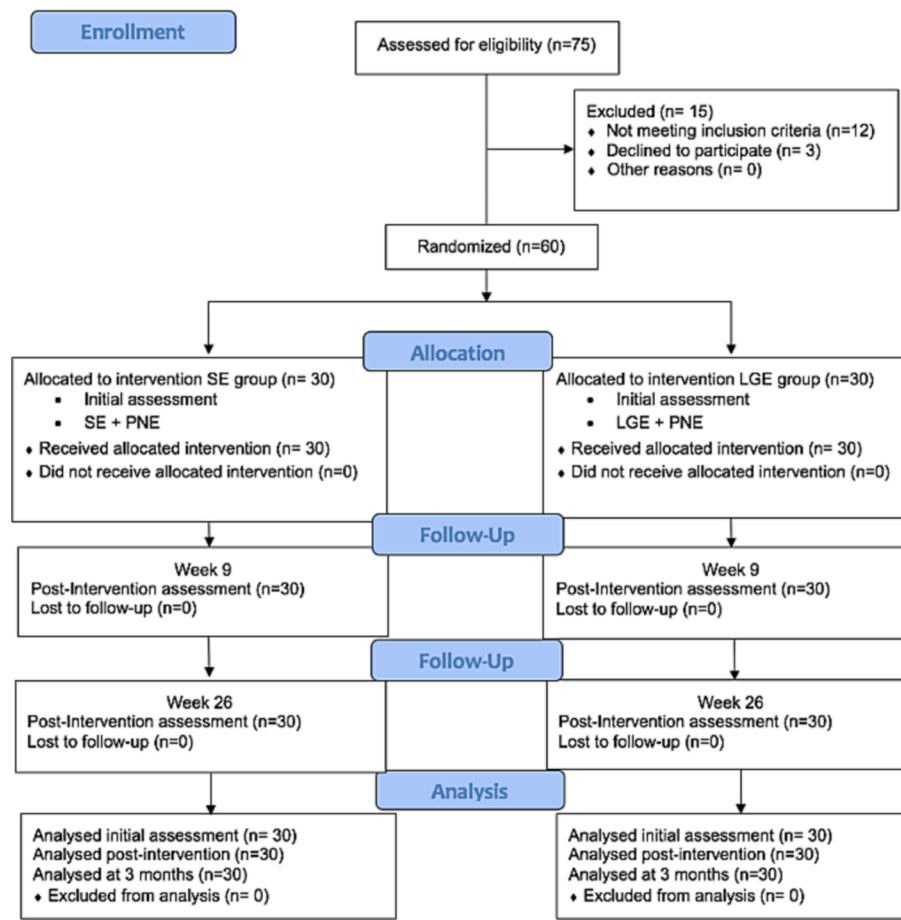


Fig. 1. Flowchart of the study.

the recommendations of the CERT ([Consensus on Exercise Reporting Template \(CERT\): Modified Delphi Study | Physical Therapy | Oxford Academic, 2021](#)) and TIDIER ([Hoffmann et al., 2014](#)) statements. The exercises for the SE and LGE groups were performed in the order shown in [Supplementary material](#).

2.4.1. Interventions

The interventions were carried out at the Faculty of Medicine and Health Sciences (Badajoz). Patients were randomly assigned to the SE and LGE groups. Patients assigned to SE group carried out a supervised exercise program plus PNE program. On the other hand, participants assigned to LGE group performed the same exercise program plus PNE. However, in this group were laser-guided using an external focus to perform the exercises. A total of sixteen 1-hour supervised sessions (2 sessions/week over 8 weeks) were performed. All the sessions were conducted in groups of five patients.

The exercise program consisting of lumbar movement control exercises. The physiotherapist responsible for the intervention corrected each participant individually as required when performing the movement control exercises to ensure the correct technique. All exercises were executed following verbal commands. The exercises were progressed from the supine position through to standing, 4-point kneeling and sitting according to exercise tolerance. The patients were advised that the initial exposure to the exercises may lead to pain but that the onset of pain was not a reason to stop the activity ([Galán-Martín et al., 2019](#)). ([Supplementary material \(SE group\)](#)).

Participants in the LGE group were placed the laser apparatus at a midpoint between the two anterosuperior iliac spines and held in place with a strap around the pelvis and was positioned so that neutral pelvis alignment would point the laser at the bulls-eye on the target. This was

the patient's target goal position. The target was placed on the wall at a distance of 1.5 m from the participant. Movement and guidance by the laser depended on the type of exercise. There were exercises where the participant had to keep the laser light fixed on the red center point of the target and other exercises where the participant guided the laser light along the black vertical line. Specified in [Supplementary material \(LGE group\)](#).

The PNE program consisted of eight educational sessions, each lasting 1 h, which were provided in groups of five patients, with a frequency of 1 session/week over the 8 week period on different days to the exercise program. ([Bodes Pardo et al., 2018](#); [Cuenda-Gago and Espejo-Antunez, 2017](#)). The PNE program was delivered at the same location as the exercise therapy program by the same physiotherapist. The content of the PNE program included concepts of the neurophysiology of pain. The sessions consisted of a verbal explanation with a visual presentation about aspects related to pain (acute vs. chronic pain, central sensitization...) ([Hoffmann et al., 2014](#)). Using the following mode of administration: (1) Anatomical explanation of the main stabilising muscles of the lumbar spine (weeks 1 and 2); (2) Audiovisual material through oral explanations (weeks 3 and 4); (3) Written educational material (weeks 5 and 6); (4) Playful sessions (weeks 7 and 8).

2.5. Outcome measures

The study participants were evaluated before the intervention (week 0), after the intervention (after a week last session-Week 9), and at 3 months after finishing the intervention (week 20).

2.5.1. Primary outcome

The primary outcome was perceived pain intensity, measured using a

NPRS. NPRS is a subjective measure in which individuals rate their pain on an 11-point numerical scale; the scale ranges from 0 (“no pain at all”) to 10 (“worst imaginable pain”) (Dworkin et al., 2005). NPRS exhibited a standard error of measurement (SEM) of 1.02 points, corresponding to a minimum variation in the 95 % confidence level (MDC₉₅) of 2 points (Childs et al., 2005).

2.5.2. Secondary outcomes

2.5.2.1. Pressure pain threshold (PPT). The selected points for PPT measurement were 5 cm lateral to the spinous process of L3 bilaterally (PPT-L3 right and left) and a remote distal point from the lumbar region (2 cm from the lateral epicondyle bilaterally) (PTT-lateral epicondyle right and left). A mechanical pressure algometer (model FPX 25, Wagner Instruments, Greenwich, CT, USA), with a surface area of 1 cm² was used for the PPT measurements (Chesterton et al., 2007; Imamura et al., 2016).

2.5.2.2. Disability. Disability related to low back pain was assessed using the Roland–Morris Disability Questionnaire (RMDQ) (Kovacs et al., 2002) and the Oswestry Low Back Pain Disability (ODI) questionnaire (Alcántara-Bumbiedro et al., 2006). The RMDQ includes 24 questions related to physical function that may be altered by low back pain. Its score range from 0 to 24 with higher scores indicating higher levels of disability (La Touche et al., 2019; La Touche et al., 2019; Roland and Fairbank, 2000).

The ODI is comprised of 10 sections related to the effect of low back pain on typical daily life activities. Scores of each section range between 0 and 5. Higher ODI scores indicate greater disability (Alcántara-Bumbiedro et al., 2006).

2.5.2.3. Pain catastrophizing. Pain catastrophizing was assessed with The Pain Catastrophizing Scale (PCS) (García Campayo et al., 2008; George et al., 2010). The PCS it is a self-administered Likert scale comprising 13 items, where patients refer to their past painful experiences and indicate the degree to which they have experienced each of the 13 thoughts or feelings. Each item is scored from 0 (never) to 4 (always) (total score = 0–52). Higher scores indicate higher levels of pain catastrophizing (Malffiet et al., 2019).

2.5.2.4. Kinesiophobia. The TSK-11 has been validated for use in patients with chronic low back pain (Vlaeyen et al., 1995). The TSK-11 is comprised of 11 items designed to assess the patient’s fear of moving and re-injury. Each item is scored with a 4-point Likert scale (1 = “strongly disagree”, 4 = “strongly agree”). Its total score thus ranges from 11 to 44 points. Higher scores correspond with a greater fear of pain, movement and injury (Gómez-Pérez et al., 2011; Roelofs et al., 2007).

2.5.2.5. Lumbar repositioning error (LRE). Participants were required to actively flex their lumbar spine from 0 to 30° (measure 1), while being led by the evaluator. They had 10 s to memorise this final position and actively returned to the initial position. Then participants were asked to actively reproduce the 30° lumbar flexion position (measure 2). The LRE was calculated by using an inclinometer (Iphone® smartphone app, Apple Inc, Cupertino, CA, USA) (Caña-Pino et al., 2021).

2.6. Statistical analysis

Statistical analyses were performed using SPSS version 25.0. (SPSS Inc., Chicago, IL, USA) and the Jamovi project (2020). The significance level was set at P < 0.05. A descriptive analysis was performed for each of the variables (age, height, weight, body mass index, average duration of pain, pain, PPT, disability, catastrophizing, kinesiophobia and LRE). Normative distribution of the data was evaluated using the Shapiro-Wilk

test. Descriptive data included means and standard deviations (SDs). The variables of both intervention groups at baseline were compared by independent samples t-test. To compare both within-group and between-group difference, we applied a Repeated measures model with interaction and were considered Post Hoc results provided according to HSD’s Tukey. The effect size for within-group mean differences was calculated using Cohen’s d coefficient, with d = 0.2 being considered a “small” effect size, 0.5 a “medium” effect size and 0.8 a “large” effect size.

3. Results

The flow of participants through the study is depicted in Fig. 1. All 60 patients completed the study and their data were used in the final analyses. No statistically significant between- group differences were observed at baseline (all P > 0.05) (Table 1). Table 1 shows the mean values and SDs of the main characteristics for each group (SE and LGE).

A significant time * group interaction was observed for pain intensity for both groups between baseline and post-intervention and between baseline and the 3 month follow-up (P < 0.001) and higher effect sizes for LGE group (Table 2) (Fig. 2A). On the other hand, when we compared pain intensity between groups, we observed statistically significant differences post-treatment (P < 0.001) and 3-month follow-up (P < 0.001) with high effect sizes. The time * group interaction was significant for the pain intensity variable (P = 0.01).

For the secondary outcomes, there were significant improvements between baseline and post-intervention and between baseline and the 3 month follow-up for all outcome measures in both intervention groups (all P = 0.001). However, a statistically significant difference within-groups was observed for PPT-L3 right and PPT-L3 left (SE, P < 0.05; LGE, P < 0.001) between post-treatment and the 3 month follow-up (Table 2). No significance within-group difference was found for pain intensity, PPT-lateral epicondyle right and left, disability, pain

Table 1
Baseline characteristics.

	SE (n = 30) Mean ± SD	LGE (n = 30) Mean ± SD	p Value
Mean age (years)	35.30 ± 7.10	32.00 ± 6.78	0.052
Height (cm)	171.30 ± 0.08	170.23 ± 0.10	0.544
Weight (kg)	71.77 ± 10.11	69.50 ± 11.42	0.668
Body mass index (kg/m ²)	24.44 ± 3.30	23.92 ± 3.10	0.626
Average duration of pain (months)	37.83 ± 39.82	35.73 ± 30.75	0.361
Pain (NPRS) (0–10)	7.38 ± 1.18	6.97 ± 1.05	0.095
PPT L3 right (Kg/cm2)	1.99 ± 1.06	2.12 ± 1.07	0.625
PPT L3 left (Kg/cm2)	2.15 ± 1.08	2.27 ± 1.18	0.766
PPT lateral epicondyle right (Kg/cm2)	1.77 ± 0.79	1.79 ± 0.72	0.865
PPT lateral epicondyle left (Kg/cm2)	1.69 ± 0.73	1.75 ± 0.65	0.717
Disability (RMDQ) (0–24)	9.80 ± 4.72	9.08 ± 5.77	0.289
Disability (ODI) (0–50)	13.60 ± 6.13	12.10 ± 7.71	0.254
Catastrophism (PCS) (0–52)	20.20 ± 7.83	19.60 ± 8.99	0.778
Kinesiophobia (TSK-11) (11–44)	27.43 ± 6.94	28.03 ± 5.77	0.579
Lumbar Joint Repositioning Error (JPS standing) (°)	5.20 ± 2.81	5.77 ± 3.00	0.549
Lumbar Joint Repositioning Error (JPS sitting) (°)	3.87 ± 2.67	4.44 ± 2.06	0.175

cm: centimeters; Kg: kilograms; m: meters; SD: Standard Deviation; SE: Supervised Exercise; LGE: Laser-Guided Exercise; NPRS: Numerical Pain Rating Scale; PPT: Pressure Pain Threshold; RMDQ: Roland Morris Disability Questionnaire; ODI: Oswestry Disability Index; PCS: Pain Catastrophizing Scale; TSK-11: Kinesiophobia Tampa Scale; JPS: Joint Position Sense.

* P < 0,05: Statistical significance.

Table 2
Outcome Measures within and between groups.

		GroupSE(n = 30) LGE (n = 30)	Differences between-groups					Differences within-groups						
			Baseline Mean \pm SD	EffectSize (d) P value	Post-treatment Mean \pm SD	EffectSize (d) P value	3 mo follow-up Mean \pm SD	EffectSize (d) P value	(Baseline-Post-treatment) 95 % CI	EffectSize (d)	(Baseline-3 mo follow-up) 95 % CI	EffectSize (d)	(Post-3 mo follow-up) 95 % CI	EffectSize (d)
Pain Intensity	NPRS	SE	7.38 \pm 1.18	0.37 P = 0.56	3.06 \pm 2.08	0.72 P < 0.001**	3.27 \pm 2.05	0.86 P < 0.001**	4.32 (3.50, 5.14)**	1.96	4.12 (3.26, 4.97)**	1.79	-0.20 (-0.83, 0.43)	-0.12
		LGE	6.97 \pm 1.05		1.19 \pm 1.00		1.77 \pm 1.26		5.27 (4.59, 5.94)**	2.90	5.11 (4.49, 5.74)**	3.33	-0.58 (-1.19, 0.04)	-0.38
Algotmetry (PPT) (Kg/cm2)	L3 right	SE	1.99 \pm 1.07	-0.12 P = 0.10	3.86 \pm 1.78	0.04 P = 1.00	3.59 \pm 2.03	0.22 P = 0.96	-1.87 (-2.36, -1.38)**	1.42	-1.61 (-2.20, -1.01)**	-1.01	0.26 (-0.03, 0.55)*	0.33
		LGE	2.12 \pm 1.06		3.79 \pm 1.93		3.14 \pm 2.10		-1.67 (-2.14, -1.20)**	1.33	-1.01 (-1.59, -0.42)**	-0.70	0.68 (0.34, 1.03)**	0.79
	L3 left	SE	2.14 \pm 1.08	-0.11 P = 0.10	3.81 \pm 1.89	-0.04 P = 1.00	3.66 \pm 2.04	0.29 P = 0.1	-1.67 (-2.25, -1.08)**	1.06	-1.51 (-2.13, -0.89)**	-0.91	0.16 (-0.05, 0.37)*	0.28
		LGE	2.27 \pm 1.18		3.90 \pm 1.91		3.06 \pm 2.01		-1.63 (-2.19, -1.06)**	1.07	-0.75 (-1.22, -0.28)**	-0.64	0.83 (0.25, 1.40)**	0.58
	Lateral epicondyle right	SE	1.77 \pm 0.76	-0.03 P = 1.00	2.95 \pm 1.20	0.03 P = 1.00	2.74 \pm 1.33	-0.08 P = 1.00	-1.19 (-1.55, -0.82)**	1.20	-0.97 (-1.35, -0.59)**	-0.96	0.22 (-0.01, 0.44)	0.36
		LGE	1.79 \pm 0.72		2.91 \pm 1.61		2.85 \pm 1.43		-1.12 (-1.54, -0.69)**	0.98	-1.06 (-1.46, -0.66)**	-1.08	0.07 (-0.16, 0.30)	0.12
	Lateral epicondyle left	SE	1.69 \pm 0.73	-0.08 P = 1.00	3.10 \pm 1.42	0.32 P = 0.80	2.95 \pm 1.45	0.20 P = 0.1	-1.41 (-1.89, -0.92)**	1.08	-1.26 (-1.75, -0.76)**	-0.94	0.15 (-0.01, 0.31)	0.34
		LGE	1.75 \pm 0.65		2.67 \pm 1.22		2.67 \pm 1.33		-0.91 (-1.30, -0.53)**	0.88	-0.92 (-1.42, -0.43)**	-0.75	-0.02 (-0.17, 0.13)	-0.05
Disability	RMDQ	SE	9.80 \pm 4.72	0.14 P = 0.1	2.80 \pm 2.34	-0.29 P = 0.90	3.43 \pm 2.24	-0.24 P = 0.1	7.00 (5.56, 8.44)**	1.81	6.37 (4.86, 7.86)**	1.58	-0.63 (-1.36, 0.01)	-0.32
		LGE	9.08 \pm 5.77		3.83 \pm 4.48		4.19 \pm 3.91		5.25 (3.06, 7.45)**	0.89	4.67 (3.03, 6.32)**	1.14	-0.35 (-2.28, 1.59)	-0.07
	ODI	SE	13.60 \pm 6.13	0.22 P = 0.95	5.30 \pm 4.05	0.18 P = 0.97	5.87 \pm 4.70	0.21 P = 0.98	8.30 (6.43, 10.17)**	1.65	7.73 (6.02, 9.44)**	1.69	-0.57 (-1.47, 0.34)	-0.23
		LGE	12.07 \pm 7.71		4.50 \pm 4.70		4.92 \pm 4.41		7.57 (4.99, 10.14)**	1.10	7.00 (4.39, 9.61)**	1.08	-0.54 (-2.52, 1.44)	-0.11
Catastrophism	PCS	SE	20.17 \pm 7.84	0.07 P = 0.10	7.50 \pm 5.67	-0.04 P = 1.00	10.27 \pm 7.71	0.24 P = 0.95	12.67 (10.14, 15.20)**	1.87	9.90 (6.65, 13.15)**	1.14	-2.77 (-5.04, -0.50)	-0.45
		LGE	19.57 \pm 8.99		7.73 \pm 6.70		8.27 \pm 8.90		11.83 (8.15, 15.52)**	1.20	10.73 (6.91, 14.55)**	1.14	-0.81 (-3.41, 1.80)	-0.13

(continued on next page)

Table 2 (continued)

		GroupSE(n = 30) LGE (n = 30)	Differences between-groups						Differences within-groups					
			Baseline Mean ± SD	EffectSize (d) P value	Post-treatment Mean ± SD	EffectSize (d) P value	3 mo follow-up Mean ± SD	EffectSize (d) P value	(Baseline-Post-treatment) 95 % CI	EffectSize (d)	(Baseline-3 mo follow-up) 95 % CI	EffectSize (d)	(Post-3 mo follow-up) 95 % CI	EffectSize (d)
Kinesiophobia	TSK-11	SE	27.43 ± 6.94	-0.09 P = 0.97	18.60 ± 3.93	0.81 P < 0.05*	18.33 ± 5.52	0.26 P = 0.32	8.83 (6.57, 11.10)**	1.46	9.10 (6.38, 11.82)**	1.25	0.27 (-1.29, 1.83)	0.06
		LGE	28.03 ± 5.77		14.93 ± 5.03		16.96 ± 5.13		13.10 (10.33, 15.87) **	1.77	11.77 (8.59, 14.94) **	1.50	-1.96 (-4.19, 0.27)	-0.36
Joint Position Sense (lumbar flexion) (°)	Standing	SE	5.20 ± 2.81	-0.20 P = 0.94	1.93 ± 1.54	-0.29 P = 0.80	2.25 ± 1.32	-0.13 P = 0.74	3.27 (2.15, 4.39)**	1.09	2.96 (2.02, 3.89)**	1.18	-0.31 (-1.03, 0.40)	-0.16
		LGE	5.77 ± 3.00		4.47 ± 1.67		2.46 ± 2.00		1.30 (-3.33, 5.94)**	0.11	3.45 (2.35, 4.55)**	1.27	2.47 (-2.90, 7.85)	0.19
	Sitting	SE	3.87 ± 2.67	-0.24 P = 0.96	1.52 ± 1.00	-0.13 P = 0.99	1.91 ± 1.92	-0.25 P = 0.82	2.34 (1.33, 3.35)**	0.87	1.96 (0.67, 3.24)**	0.57	-0.39 (-1.13, 0.35)	-0.20
		LGE	4.44 ± 2.06		1.73 ± 2.05		2.39 ± 1.84		2.71 (1.95, 3.47)**	1.34	2.02 (1.27, 2.77)**	1.09	-0.58 (-1.70, 0.54)	-0.21

* and ** indicates significant within-between groups differences between Baseline post treatment and between 3 months follow-up post-treatment and baseline (P < 0.05 and P < 0.001, respectively) according to HSD's Tukey comparison from a Repeated measures model with interaction; SD: Standard Deviation; CI: confidence interval; SE:Supervised Exercise; LGE: Laser-Guided Exercise; NPRS: Numerical Pain Rating Scale; PPT: Pressure Pain Threshold; RMDQ: Roland Morris Disability Questionnaire; ODI: Oswestry Disability Index; PCS: Pain Catastrophizing Scale; TSK-11: Kinesiophobia Tampa Scale.

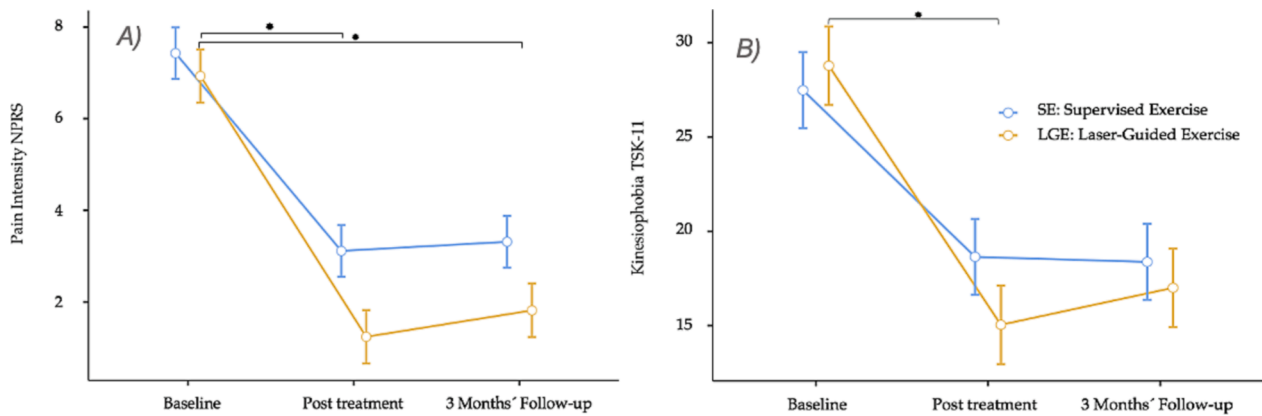


Fig. 2. A) Between-group comparisons in low back pain intensity (NPRS). B) Between-group comparisons in kinesiophobia (TSK-11).

catastrophizing, kinesiophobia or LRE post-intervention or at the 3 month follow up ($P > 0.05$) (Table 2).

There was a significant between-group difference post-intervention scores in terms of kinesiophobia (TSK-11) ($P = 0.04$) and a high effect size ($d = 0.81$) (Table 2, Fig. 2B). The time * group interaction was significant for the kinesiophobia (TSK-11) variable ($P = 0.02$). No significant between-group differences and time * group interaction were observed for local and remote PPTs, disability, pain catastrophizing or LRE (all $P > 0.05$).

4. Discussion

The aims of this study were to compare the effects of supervised exercise with or without laser guided feedback combined with PNE on pain intensity, PPTs, disability, pain catastrophizing, kinesiophobia and lumbar proprioception in people with NSCLBP. Our results showed improvements for all outcomes in both groups immediately after the intervention in the within-group analysis. The group that performed their laser-guided exercises showed greater improvements in pain intensity (after intervention and at 3-month follow-up) and kinesiophobia (after intervention) in comparison to the group that exercised without the laser feedback.

Importantly, the mean difference in pain intensity for both groups at the two post-intervention measurements times exceeded the minimum detectable change (MDC) for the NPRS (≥ 2 points) (Farrar et al., 2001). Both groups obtained statistically significant results for the pain intensity variable, with therapeutic exercise plus PNE being an effective method for NSCLBP. These results are consistent with those of other studies which have used coordination/stabilisation exercise, aerobic exercise, strength/resistance exercise, motor control exercises, with the same number of sessions (Ahmed et al., 2013; Bodes Pardo et al., 2018; Galán-Martín et al., 2019; Lopes et al., 2017; Moseley, 2003; Patti et al., 2016; Ryan et al., 2010; Salavati et al., 2016; Suh et al., 2019). A time * group interaction was observed for the primary variable pain intensity, where significant differences were obtained between groups after the intervention and 3 months of follow-up with better results for the LGE group. These results are similar to those reported by other studies (Bradley and Haladay, 2020; Gallego Izquierdo et al., 2016) in cervical pain. Regarding the medium-term effects for the NPRS, the current results (mean differences) are slightly better than those reported by other studies in people with NSCLBP (Bodes Pardo et al., 2018; Miyamoto et al., 2013). Our sample was composed of participants with a lower average age than in other studies (Bodes Pardo et al., 2018; Miyamoto et al., 2013), and this may have influenced the ability to learn the proposed exercises. Previous studies have shown that the application of LGE in other regions (e.g. cervical spine) in populations with a mean age similar to our participants, resulted in a lower reduction of pain intensity (~45 % decrease) in comparison to our study (~75 % decrease)

(Bradley and Haladay, 2020; Gallego Izquierdo et al., 2016).

Regarding the secondary outcome measures, significant changes were found for local (L3) and remote (lateral epicondyle) PPTs in both intervention groups post-intervention. These changes exceeded the MDC established for PPTs (i.e. 1.2 Kg/cm²) at all measurement timepoints (Bodes Pardo et al., 2018). Our results are in accordance with previous studies, where an improvement in PPTs both locally and at a remote site was found after treatment (Bodes Pardo et al., 2018; Pain Neuroscience Education and Physical). PPT measurements taken remotely have been suggested as a useful marker to assess altered central pain mechanisms (Arroyo-Fernandez et al., 2020; Doménech-García et al., 2016).

In terms of disability, the effect sizes found in both groups are consistent with the results of a meta-analysis where benefits of exercise in terms of reducing disability, as measured by the ODI, was found to be high in people with NSCLBP (effect size > 0.8) (Owen et al., 2020). A significant post-treatment change was also observed for the RMQD ($P < 0.001$) in both groups (SE: 7 points and LGE: 5.25), with effects maintained at the 3 month follow-up and similar to that obtained with other exercise-based interventions (e.g. motor control exercises for the lumbar spine, stretching and aerobic exercise, effect size > 0.8) (Bodes Pardo et al., 2018; Miyamoto et al., 2013). Our results differ from those shown by Ryan et al. (Ryan et al., 2010) who found that the use of PNE alone had a greater effect on RMDQ, pain and self-efficacy than PNE plus exercise.

Significant improvements in pain catastrophizing and kinesiophobia were found in both groups post-intervention with large effect sizes (< 0.80). Similar to our study, Galán-Martín et al. (Pain Neuroscience Education and Physical) reported a significant post-intervention reduction in pain catastrophizing after implementing a combined approach consisting of exercise plus PNE. We observed significant improvements in kinesiophobia in favour of the LGE group with a moderate effect size ($d = 0.63$). This is consistent with the idea that focusing on the movements themselves (i.e. the internal focus) which was a characteristic of the SE group would not be an optimal approach in case of fear of movement (Chiviacowsky et al., 2010). Kinesiophobia can also lead to avoidance of potentially painful movements (La Touche et al., 2019; La Touche et al., 2019). One of the possible solutions for the high levels of kinesiophobia that people with NSCLBP often present, according to the results of this study, may be the use of an external focus, where the patient's attention is focused on the results of his or her movements and not on the body movements performed (i.e. internal focus).

Finally, in this study we found significant post-intervention improvements for both groups in lumbar proprioception as measured by LRE in standing and sitting. Low back pain can negatively influence proprioceptive acuity. As a consequence, these patients may be more dependent on an external locus (Matheve et al., 2018).

4.1. Study limitations

The present study has some important limitations that need to be acknowledged. The sample of the study comprised young adults with relatively mild NSCLBP without previous orthopaedic or rheumatic disease so our results cannot be extrapolated to adults presenting with specific causes of low back pain. On the other hand, no sociodemographic factors with potential effect on the results (eg, occupation or educational background). The effects of PNE on the outcome variables are unknown, since it has been performed in combination with therapeutic exercise. Finally, the effect of both interventions was only assessed at 3-month follow-up; therefore, future studies should investigate longer-term effects.

5. Conclusion

Supervised exercise with or without laser feedback, when combined with PNE, reduces pain intensity, disability, pain catastrophizing, kinesiophobia and improves proprioception and PPTs in patients with NSCLBP. At a 3-month follow-up, the combination of LGE plus PNE is most effective for reducing pain intensity.

Ethical approval

The research protocol was reviewed and approved by the Institutional Review Board (Research Ethics Committee of the University of Extremadura, Spain No Register: 77 // 2018). Approval date: 6/07/2018.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jelekin.2023.102776>.

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