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# **OPEN** Clinical relevance of combined treatment with exercise in patients with chronic low back pain: a randomized controlled trial

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Low back pain is a widespread public health concern owing to its high prevalence rates according to the Global Burden of Diseases. This study aimed to investigate the effect of exercise alone or in combination with manual therapy and kinesiotherapy on pain sensitivity, disability, kinesiophobia, self-efficacy, and catastrophizing in patients with chronic low back pain (CLBP). A total of 55 participants were enrolled and randomly allocated to one of three groups: (1) exercise alone group (ET; n = 19), (2) exercise + manual therapy group (ETManual therapy; n = 18), and (3) exercise + kinesio tape group (ETkinesiotape; n = 18). The interventions consisted of core stabilization exercises (ET group), prior spinal manipulation with core exercises (ETManual therapy group), and combined application of kinesiotape plus core stabilization exercises (ETkinesiotape group). The primary outcome was disability. The secondary outcomes were pain sensitization, kinesiophobia, catastrophizing, and self-efficacy. Assessments were performed at baseline and at weeks 3, 6, and 12. All therapies applied achieved significant improvements over time after 12 weeks in all parameters analyzed. ETmanualtherapy showed the greatest changes in all variables, with significant differences from the rest of the interventions in Oswestry (ODI) (3 and 6 weeks, respectively). A clinically significant cutoff point was achieved for the ETmanualtherapy group in the ODI parameter (-54.71%, -63.16% and -87.70% at 3, 6, and 12 weeks, respectively). Manual therapy prior to the core exercise technique was the most effective approach to improve health-related functionality compared with exercise alone or exercise combined with kinesiotape in patients with CLBP.

Clinical Trial Registration Number: NCT05544890.

Low back pain is a widespread public health concern<sup>1</sup> owing to its high prevalence. Currently, more than 70% of the population experiences at least one episode of global low back pain<sup>2</sup>, with approximately 577.0 millions people suffering from this pathology worldwide<sup>3</sup>. Up to 85–95% of people do not have a specific patho-anatomical cause attributable to their pain<sup>4</sup>. People with chronic low back pain (CLBP) have severe restrictions on daily life activities, resulting in high levels of pain and disability<sup>5</sup>. The clinical profile of individuals with CLBP is highly intricate, and there is a significant diversity in pain processing mechanisms<sup>3</sup>. Patient-centered approaches have recently been considered key features of patients with persistent pain<sup>6</sup>. CLBP has gained immense importance among healthcare providers<sup>7</sup>. Existing at the present several treatments are currently available for CLBP.

According to the guidelines of the North American Spine Society, physical activity, patient engagement, and positive expectations regarding the nature of treatment are essential for recovery<sup>8</sup>. Exercise treatment not only has a biomechanical impact but also serves as an intervention to foster patient self-management<sup>9</sup>, as it encourages the adoption of strategies to enhance biopsychosocial beliefs<sup>10</sup>. Consequently, high-risk factors can help healthcare professionals identify individuals who may be more susceptible to chronic pain and develop

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comprehensive treatment plans that address both the physical and psychosocial aspects of the condition. Treatments addressing psychosocial factors in high-risk patients are considered more effective than usual care<sup>11</sup>. Catastrophizing, kinesiophobia, and fear of pain are linked to disability via psychological mechanisms<sup>12–14</sup>. Although all components are related to the patient's multidimensional pain experience, anxiety, depression, and severe kinesiophobia were not associated with disability<sup>15</sup>.

Multiple treatment options have been used to improve pain and its associated factors in different CLBP populations, with contradictory and limited effects<sup>16</sup>. Probably inefficient conditioned pain-modulated mechanisms and the presence of psychological factors could be considered contributing factors to the occurrence of CLBP<sup>17</sup>. The optimal treatment strategy for conservative management of CLBP remains controversial<sup>18</sup>. More specifically core stability exercise is more effective in pain reduction and improved physical function in individuals with CLBP in the short term. Moreover, other interventions, such as manual therapy (MT), which has been demonstrated to be useful in patients with CLBP on disability when applied alone<sup>19,20</sup>, seem to be a promising treatment option for patients with CLBP<sup>21,22</sup>. Lastly, kinesiotape (KT) is becoming relatively common in managing the same condition<sup>23</sup>, and it seems that in combination with core exercises, KT is usually used to improve muscle activation due to the placebo effect caused by the expectations generated by KT in the patient<sup>24</sup>.

Multimodal approaches, defined as a combination of different techniques, can improve pain management more comprehensively in patients with  $CLBP^{25}$ . However, information regarding the most effective treatment for individual patients or specific patient subgroups is limited<sup>8,26</sup>. Therefore, the Oswestry Disability Index (ODI) has been used to classify patients with CLBP, reduce the heterogeneity of patients encountered, and monitor changes in disability<sup>27</sup>. To our knowledge, a low number of inquiries have compared the effects of active core exercise combined with passive techniques (MT or KT) with those of exercise alone in patients with CLBP (mild disability). Therefore, this study aimed to investigate the effects of core stability exercise alone or in combination with MT or KT on disability, kinesiophobia, catastrophizing, self-efficacy, and pain sensitivity (PPTs) in CLBP patients with mild disability (ODI < 20%). We hypothesized that exercise combined with MT would provide greater changes and benefits than exercise alone or in combination with KT, in terms of pain sensitivity, disability improvement, and psychosocial well-being.

#### Materials and methods Study design

A simple-blind 12-week randomized controlled trial (RCT) was conducted. Participants were randomly allocated to one of three experimental groups (i.e., ET,  $ET_{manualtherapy}$  or  $ET_{kinesiotape}$ ). The exercise training (ET) group only performed the core exercise program. The manual therapy group received MT before the exercise training intervention ( $ET_{manualtherapy}$ ), and the third group received KT before the exercise training intervention ( $ET_{kinesiotape}$ ). All patients were handled by two physiotherapists with extensive experience (>10 years) in the treatment employed. One of them conducted the interventions for all three groups, whereas the other performed the evaluations, ensuring that the second physiotherapist was blinded to the evaluated group. An independent researcher, using an Excel formula, generated a table of random numbers to blind data collectors and outcome adjudicators to ensure unbiased outcome ascertainment. A block randomization design (block sizes of 4, 6, or 8) was applied to ensure an equal number of participants in each group. As it is impossible to blind participants and treat the physiotherapist with KT application or MT, a single-blind design was chosen. This study was approved by the Research Ethics Committee of the Universidad Católica de Valencia (UCV/2019–2020/138) in accordance with the ethical guidelines of the Helsinki Declaration, 2018<sup>28</sup>. In addition, it has been registered at Clinicaltrial. gov 19/09/22 (NCT05544890). Each participant signed a written informed consent form.

# Participants

70 volunteers participated in this study (38 women and 32 men;  $43.3 \pm 15.1$  years,  $1.70 \pm 0.1$  m,  $69.24 \pm 13.4$  kg). All participants were diagnosed with CLBP at a general orthopaedic clinic and were recruited through advertisements for "a novel mind-body clinical study of CLBP" in flyers. The inclusion criteria were: (i) age between 18 and 65 years, (ii) medical diagnosis of CLBP confirmed by an orthopaedic specialist, and (iii) a maximum value of 20% (mild disability) by ODI. The exclusion criteria were as follows: (i) previous or scheduled surgeries in the lower back and abdominal area, (ii) presence of severe fractures or pathologies, (iii) diagnosis of radiculopathy or neuropathy (with or without spinal canal stenosis), (iv) structural deformity in the spinal column, (v) neurological or psychiatric disorder, and (vi) presence or suspicion of pregnancy.

#### Study procedures

All participants completed a total of twenty-four sessions guided by a physical specialist. All participants were randomized in the first session, and data collection was collected one week before and after the intervention program, at weeks 3 (session 6) and 6 (session 12), before the treatment session.

#### Outcome measures

<u>Disability</u>. Disability (primary outcome) was assessed using the ODI (version 2.0) questionnaire. It was divided into 10 sections (each scored from zero to five, with higher scores indicating higher disability) and was self-administered to assess the limitations of different activities of daily living. The final index was calculated by dividing the total score by the total possible score. The Spanish version used demonstrated high reliability and internal consistency ( $\alpha = 0.86$ )<sup>29</sup>.

<u>Kinesiophobia</u>. The Tampa Scale of Kinesiophobia (TSK) was used to measure fear of movement or reinjury. The TSK is a self-administered questionnaire composed of different questions with a 4-point Likert scale ranging

from "strongly disagree" to "strongly agree." The internal consistency of TSK scores ranges from  $\alpha = 0.70-0.83$  in individuals with low back pain<sup>30</sup>. Test–retest reliability ranges from r = 0.64 to 0.80, and concurrent validity is moderate, ranging from r = 0.33 to  $0.59^{31}$ .

<u>Catastrophism</u>. The Pain Catastrophizing Scale (PCS), a self-administered questionnaire (13 items on a Likerttype scale from 0 to 4), was used in this study to assess the level of catastrophizing in the presence of pain. The total score ranges from 0 to 52 points, with higher scores representing higher levels of catastrophizing. The Spanish version of the PCS has an internal consistency of 0.79 and a test–retest reliability of  $0.84^{32}$ .

<u>Self-efficacy</u>. The self-efficacy questionnaire is composed of 19 items with 3 domains that assess self-efficacy for pain management and physical functioning. The Spanish version of the Graded Chronic Pain Scale had a high internal consistency ( $\alpha = 0.87$ )<sup>33</sup>.

<u>Pain sensitivity (PPTs)</u>. The minimal pressure at which the sense of pressure first changes to pain is defined as PPT<sup>34</sup>. PPTs were measured using a manual Wagner Fdk/Fdn series force dial analog Fisher algometer (Wagner Instruments, Greenwich, CT, USA). The instrument consists of a manometer attached to a cylindrical rubber tip (1 cm<sup>2</sup>). The patient must indicate when the pressure begins to be painful. The plunger of the device was positioned perpendicular to the paravertebral muscles, respecting the proximity of 2 cm lateral to the midline between the L2-L3 spinous process. Three PPTs measurements were performed at each site, and the mean value was used for further analysis. The reliability coefficient was high, presenting Cronbach coefficients of 0.9 and  $0.95^{35}$ .

#### Interventions

<u>ET group.</u> A core stabilization exercise program, composed of three sets of specific lumbopelvic exercises, was performed. All subjects carried out the same sessions (twenty-four), two times (approximately 60 min) a week on alternate days. Each session consisted of stabilization exercises (Fig. 1). The first session involved a familiarization session in which the selected exercises were performed and participants were instructed to activate the abdominal muscles. All exercises were performed three times. Dynamic exercises consisted of 10 repetitions, while static exercises were performed for approximately 30 s of isometric contraction. A 30-s rest interval was interspersed between sets, while 2–3 min were provided between exercises<sup>36</sup>. The exercise protocol was conducted by a physiotherapist with 10 years of experience. All procedures were carried out in an individualized manner and overseen by the same professional. All participants in each group received the same protocol prescribed by the same professional. The training regimen, integrating motor control exercises, adhered to the principles outlined by Falla et al.<sup>27</sup>; the participants performed the same training volume Fig. 1.

 $ET_{manualtherapy}$  group. MT techniques were performed by a qualified physical specialist with eight years of experience in MT before the core stabilization exercises in each session. The participant received a single, high-velocity manipulation<sup>37</sup> using a side-lying position, with the target side up, superior leg bent at the hip, knee, and arms folded (Figure S1). The technique was applied bilaterally, one time per side in each session. The patient was stabilized by a physical specialist through the upper arm while rotating the thoracolumbar spine. The force of the thrust was not directed towards a specific lumbar level, but covered the L3-S1 segment. The technique was always applied prior to the exercise session and lasted 5 min per patient. In the 24 sessions carried out in 12 weeks of treatment, we always proceeded in the same way<sup>38,39</sup>.

<u>ET<sub>kinesiotape</sub> group</u>. The group that received physical therapy plus KT (Kinesiotape NonDolens<sup>\*</sup> 5 cm × 5 m, Berlin, Germany) had elastic tape applied to the lower back at the beginning of the sessions. The area was cleansed before application to improve adherence. Taping was initiated by placing the patient in a neutral spine position and applying the base of Kinesio Y strips in the sacroiliac joint region, a minimum of 5 cm below the initiation of pain<sup>40</sup>. The tail was subjected to very light to light tension (15–25% of available) or paper-off tension. A 22-cm tape was cut and elongated to a maximum of 5 cm (Fig. 2). After completing the training program, both kinesio-taping strips were retired.

Statistical analysis. Following CONSORT guidelines, peer protocol analysis was performed using the statistical analysis software SPSS 24 (IBM Inc., Chicago, Illinois, USA). Kolmogorov–Smirnov and the Levene tests were checked for normality and homogeneity. To analyze the effects of the experimental programs, a repeated measurement analysis of covariance (ANCOVA) was performed with experimental groups (i.e., ET,  $ET_{manualtherpay}$ , and  $ET_{kinesiotape}$ ) and time (i.e., at baseline, 3, 6, and 12 weeks) on disability, pain, and psychosocial parameters using the Visual Analog Scale measurements (at baseline) as the covariate. Bonferroni corrections were used to examine interaction effects through within- and between-group comparisons; specifically, the effect of group × time interaction was analyzed. The effect size (ES) was estimated by calculating Cohen's d coefficient. ES was classified as trivial (<0.20), small (0.20–0.49), moderate (0.50–0.79), or large (>0.80). The delta percentage ( $\Delta$ %) was calculated using the standard formula: change (%) = [(post-test score – pre-test score)/pretest score] × 100. The 95% confidence level (significance level, p < 0.05) was considered statistically significant. Results are presented as mean difference (MD) and confidence interval (95% (IC95%).

Pro-	10 repetitions of each leg	3 sets 30" rest			
	30" isometric 1 repetition of each side	3 sets 30" rest *Modification: Knees supported			
	Flexion and extension 10 repetitions	3 sets 30" rest			
	10 repetitions	3 sets 30" rest			
De Contraction de la contracti	<b>Pointer</b> 10 repetitions of each leg	3 sets 30" rest			
	<b>Plank</b> 30" isometric 1 repetition	3 sets 30" rest *Modification: Knees supported			
1000 1000 1000 1000 1000 1000 1000 100	Flexion and extension 10 repetitions	3 sets 30" rest			

Figure 1. Lumbo-pelvic core stabilization training program exercise and volume.

# Sample size calculation

The sample size was estimated using de GPower<sup>®</sup> software (Franz Faul, Universität Kiel, Kiel, Germany), version 3.1.9.2. A statistical method to analyze the data will be repeated measures ANOVA. Thus, the calculation was based on the primary outcome of "Pain Perception" and considered an effect size (ES) of Cohen's d coefficient of 0.44, based on the findings from a previous study<sup>41</sup>, a power of 0.90, an alpha error of 0.05, and three groups. A total of 45 participants (fifteen subjects per group) were needed. Moreover, considering the probability of loss



**Figure 2.** Kinesiotape application in the EX+KT group. The tail was applied with a very light to light tension. Taping started in the sacroiliac joint region, a minimum of 5 cm below the initiation area of pain. The KT is removed at the end of the exercise session.

during follow-up (15%), three more participants considering dropout (18 participants \* group) were used with a total of 54 participants. The selected effect size fell within the small category (0.20-0.59), which was justified by previous and subsequent studies<sup>32,33</sup>.

#### **Consent for publication**

Informed consent was taken from the participant for publication of identifying information/images in an online open-access publication.

# Results

# Participation flow and sample characteristics

Eighty participants were assessed for eligibility. Finally, 55 were enrolled to participate in the study. No significant differences between the groups were observed at baseline for any parameter, except for the level of catastrophizing. (Table 1). Seven patients dropped out at follow-up (2 participants at 3 weeks, 4 at 6 weeks, and 1 at 12 weeks), completing the study for a total of 48 participants (see Fig. 3).

# Program feasibility and safety: attendance. Compliance and adverse events

Eighty participants were assessed for eligibility. Ultimately, 55 participants were enrolled in the study. No significant differences between the groups were observed at baseline for any parameter, except for the level of catastrophizing. (Table 1). Seven patients dropped out at follow-up (2 participants at 3 weeks, 4 at 6 weeks, and 1 at 12 weeks), completing the study for a total of 48 participants.

# Results on disability, pain sensitivity, kinesiophobia, catastrophizing and self-efficacy

Regarding ODI, RM ANCOVA showed statistically significant differences in the effect of Group\*Time interaction ( $F_{[4.09, 87, 99]} = 9.54$ , p = < 0.001,  $\eta^2 p = 0.048$ ). Bonferroni's post hoc analysis showed statistically significant differences at 3 weeks (ET<sub>manualtherapy</sub> vs. ET [MD<sub>3weeks</sub> = -0.057, CI<sub>95%</sub> = -0.096, -0.018, p = < 0.001])

Variable	All participants (n=48)	ET (n=17)	ET <sub>Manual Therapy</sub> (n=16)	$\frac{\text{ET}_{\text{Kinesiotape}}}{(n=15)}$	
Sex					
Male	21 (43.75%)	8 (47.06%)	7 (43.75%)	6 (40%)	
Female	27 (56.25%)	9 (52.94%)	9 (56.25%)	9 (60%)	
Age	43.37±15.10	$41.75 \pm 15.28$	$45.18 \pm 14.11$	$49.18 \pm 15.89$	
Height	$1.70 \pm 0.10$	$1.69 \pm 0.10$	$1.70 \pm 0.11$	$1.69\pm0.10$	
Weight	69.24±13.38	69.34±12.02	73.87±15.44	$64.50 \pm 11.46$	
Body mass index, kg/m <sup>2</sup>	23.76±2.90	23.95±3.11	$25.02 \pm 2.76$	$22.20\pm2.27$	
PPTs	8.17±1.14	$7.73 \pm 1.50$	$8.57 \pm 0.71$	$8.20\pm0.99$	
ODI	$0.13 \pm 0.04$	$0.14 \pm 0.04$	$0.13 \pm 0.04$	$0.13\pm0.04$	
TSK-11	26.68±6.78	$23.43 \pm 5.56$	27.50±8	$29.12 \pm 5.58$	
PCS	21.81±9.95	$17.63 \pm 7.34$	$19.63 \pm 4.05$	$28.19 \pm 13.14^*$	
Self-efficacy	22.67±11.69	$25.81 \pm 13.21$	$19.50 \pm 12.02$	$22.69 \pm 9.37$	

 Table 1. Sample characteristics at baseline. Values are mean ± SD unless otherwise indicated. *PPTs* pain sensitivity, *ODI* oswestry disability index, *TSK* Tampa Scale for Kinesiophobia, *PCS* Pain Catastrophizing Scale.

 \*Significant differences between groups.



Figure 3. Flow chart study procedure.

and  $ET_{manualtherapy}$  vs.  $ET_{kinesiotape}$  [MD<sub>3weeks</sub> = -0.047, CI<sub>95%</sub> = -0.086, -0.008, *p* = 0.005]), at 6 weeks  $ET_{manualtherapy}$  vs.  $ET_{kinesiotape}$  (MD<sub>6weeks</sub> = -0.039, CI<sub>95%</sub> = -0.078, -2.715, *p* = 0.046) and at 12 weeks  $ET_{manualtherapy}$  vs.  $ET_{kinesiotape}$  (MD<sub>12weeks</sub> = -0.040, CI<sub>95%</sub> = -0.079, -7.57, *p* = 0.040)), see Fig. 4.

# Results on kinesiophobia, catastrophizing and self-efficacy

Regarding TSK, RM ANCOVA found statistically significant differences in the effect of Group\*Time interaction ( $F_{[1.73, 76.22]} = 3.72$ , p = 0.034,  $\eta^2 p = 0.027$ ). Bonferroni's post hoc analysis showed no statistically significant differences for any of the comparisons, see Fig. 5.

As to PCS, RM ANCOVA showed statistically significant differences in the effect of Group\*Time interaction  $(F_{[3.45, 75.94]} = 5.61, p = <0.001, \eta^2 p = 0.034)$ . Bonferroni's post hoc analysis showed no statistically significant differences for any of the comparisons, see Fig. 6.



**Figure 4.** The figure shows the changes produced on ODI questionnaire in each subject and group (ET: exercise;  $ET_{manualtherapy}$ : exercise prior manual therapy;  $ET_{kinesiotape}$ : exercise combined with kinesiotaping).

Concerning SE, RM ANCOVA showed statistically significant differences in the main effect of Group\*Time interaction ( $F_{[3.61, 79.45]} = 2.08$ , p = 0.097,  $\eta^2 p = 0.008$ ). Bonferroni's post hoc analysis showed no statistically significant differences for any of the comparisons, see Fig. 7.



**Figure 5.** The figure shows the changes produced on TSK questionnaire in each subject and group (ET: exercise;  $ET_{manualtherapy}$ : exercise prior manual therapy;  $ET_{kinesiotape}$ : exercise combined with kinesiotaping).

#### **Results on pain sensitivity**

In terms of pain sensitivity, RM ANCOVA showed statistically significant differences in the effect of Group\*Time interaction ( $F_{[3.55, 78.18]} = 1.79$ , p = 0.146,  $\eta^2 p = 0.014$ ). Bonferroni's post hoc analysis showed no statistically significant differences for any of the comparisons.

#### The *delta* percentage ( $\Delta$ %)

The absolute and delta change between the time study periods of each outcome is shown in the table in supplementary material (Table S1).

#### Adverse events

No adverse events or unintended effects were reported.



**Figure 6.** The figure shows the changes produced on PCS questionnaire in each subject and group (ET: exercise;  $ET_{manualtherapy}$ : exercise prior manual therapy;  $ET_{kinesiotapc}$ : exercise combined with kinesiotaping).



**Figure 7.** The figure shows the changes produced on Self-Efficacy questionnaire in each subject and group (ET: exercise;  $ET_{manualtherapy}$ : exercise prior manual therapy;  $ET_{kinesiotape}$ : exercise combined with kinesiotaping).

#### Discussion

The main findings were that all the therapeutic approaches analyzed improved all the variables after 12 weeks, without significant differences between groups in most of the parameters. It should be highlighted that the  $ET_{manualtherapy}$  group showed significant changes at 3 weeks in the ODI score compared with the ET group. At weeks 6 and 12, no differences in functionality were observed between the ET group and  $ET_{manualtherapy}$ . During this period, the  $ET_{Kinesiotaping}$  group showed the poorest results. Furthermore, no significant differences were observed in the TSK, PCS, SF, and PPTs scores at 3, 6, and 12 weeks. Despite non-statistically significant differences among the three therapeutic modalities in the rest of the variables, moderate-to-large effect sizes were observed at 3, 6, and 12 weeks in most of the parameters analyzed in the different groups. Researchers must ensure clear and transparent measurements, and report adherence and dropout data. The present study showed a dropout rate of approximately 15%. Considering the study design, the principle of randomization could be detrimental to pain management in patients with chronic pain<sup>42</sup>. We considered the abandonment rate satisfactory. Furthermore, it is crucial to emphasize the stringent eligibility criteria employed in this study.

Core exercise and MT have been shown to be effective treatment (in an isolated application) modalities in reducing disability, with no significant differences between them<sup>43</sup>. Core stabilization exercises have been shown to be as effective as MT in decreasing disability and improving quality of life<sup>44</sup>. Recent research indicates that MT combined with specific adjuvant exercise was beneficial in treating CLBP with respect to changes in pain<sup>45</sup>. Regarding our findings, adding MT prior to core stabilization exercises improved the reduction of disability after three weeks of treatment compared to either exercise alone or exercises with KT. This is in accordance with clinical guidelines that establish a combination of MT and EX<sup>46</sup>. The findings of the present study showed improvement during the first three weeks of treatment. Thus, in terms of ODI improvement, the ET<sub>manualtherapy</sub> group demonstrated a 54.7% increase, whereas the ET and ET<sub>kinesiotape</sub> groups experienced an increases of 27.1% and 19.9%, respectively. Regarding ODI scores in patients with CLBP, the minimal clinically important change for disability should be at least 25%<sup>47</sup>. In the present study, both the ET and ET<sub>manualtherapy</sub> groups showed an improvement greater than 25% (27.1% and 54.7% respectively), and therefore can be considered useful treatment modalities.

Exercise prescriptions using contemporary pain science and biopsychosocial approaches should be emphasized in practice<sup>48</sup>. Therefore, all groups performed exercise as a common exercise, and it is likely that the observed improvement in all evaluated parameters was a result of this shared intervention. Kinesiophobia, selfefficacy, and catastrophizing in patients with CLBP have been suggested to influence functional disability. TSK and PCS are widely used tools to measure fear of movement and pain-related catastrophic thinking in people with chronic spinal disorders<sup>49</sup>. Our results showed that the levels were reduced in all three intervention groups. Furthermore, no differences were observed between the groups with respect to pain sensitivity. Differences were found between ODI score groups with respect to pain sensitivity, TSK, PCS, and SF because baseline psychological factors nor PPTs were significantly associated with disability after 3 months<sup>50</sup>. MT may address psychosocial or other factors that may contribute to disability, enhancing an individualized biopsychosocial approach in the management of patients with CLBP<sup>18</sup>.

The results suggest that the addition of MT to EX had an additional short-term effect on disability. In accordance with our results, reductions in pain catastrophizing and kinesiophobia partially mediated the pathway to improve physical function when using exercise for CLBP<sup>51</sup>. The variables PCS, TSK, and SF could have been included as covariables in the statistical analysis. In the present research, they were not included because the findings demonstrated inconsistent use of covariates in statistical models in chronic pain clinical trials<sup>52</sup>. Moreover, the baseline differences in the PCS scores between the groups could be considered a limitation. In the experimental design of this research, the effect of treatments was not assessed. Instead, it was evaluated which of the three interventions was superior in each of the variables. In relation to the eligibility criteria, the reason why patients with previous or scheduled surgeries in the hip o lower limb area was because several authors demonstrated that these interventions had no impact on the abdominal muscles<sup>53</sup>. The changes in abdominal structure induced by trunk surgery may influenced the alteration of transversus muscular activity<sup>54</sup>. It should be noted that the internus oblique/transversus abdominis muscle activity in patients without trunk surgery are higher<sup>55</sup>. In contrast, the specificity criteria based on the ODI (only stage two patients where included) of the subjects with CLBP analyzed must also be considered as a strength. The value for mild disability was based on previous studies. More specific and homogeneous patient subgroups have been established based on the ODI questionnaire<sup>56</sup>. Future studies should evaluate whether the benefits of core exercise associated with MT are valid in patients with higher ODI disability levels.

#### Conclusion

Based on the significant differences observed in ODI scores in the short, medium, and long term (3, 6, and 12 weeks, respectively), the  $ET_{manual therapy}$  approach may be a favorable option for improving disability in patients with CLBP (ODI < 20%) compared to other modalities. Although core stability exercise alone is an effective technique for reducing disability, the addition of the passive MT technique produces a large effect size at the early stage of treatment (3 weeks) on disability and kinesiophobia, catastrophizing, and self-efficacy decrease after 12 weeks across both isolated and combined exercise along with PPTs.

#### Data availability

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Received: 4 July 2023; Accepted: 22 July 2024 Published online: 24 July 2024

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# Acknowledgements

We would like to thank all participants of the present study.

# Author contributions

For research articles with several authors, a short paragraph specifying their individual contributions must be provided. The following statements should be used "P.B.G and J.V.M, conceptualization; P.B.G, methodology; P.G.B software; L.B.V, C.B. and F.R.B, validation; J.V.M and I.J.B, formal analysis; P.G.B, data curation; P.B.G, writing—original draft preparation; J.V. and P.G.B, writing and editing— and C.B and LBV review the final manuscript . All authors have read and agreed to the published version of the manuscript."

# Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-forprofit sectors.

#### **Competing interests**

The authors declare no competing interests.

# Additional information

**Supplementary Information** The online version contains supplementary material available at https://doi.org/10.1038/s41598-024-68192-2.

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