

CLINICAL PAPER

Impact of pelvic floor muscle training on pain and functional disability in patients with non-specific low back pain: a pilot three-armed randomized controlled trial

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Abstract

Background. It has been suggested that pelvic floor dysfunction may contribute to the development of chronic non-specific low back pain (LBP). However, there is limited evidence of the impact of pelvic floor muscle training (PFMT) on clinical outcomes such as pain or disability in the conservative management of LBP.

Objective. The aim of this study was to investigate the effectiveness of PFMT in contrast to conventional treatment by comparing the disability and pain scores of patients with non-specific LBP.

Methods. Thirty-seven participants with chronic non-specific LBP were recruited. They were randomly assigned to: a control group ($n=11$) who received routine physiotherapy treatment and regular exercises; or one of two intervention groups who received either routine physiotherapy treatment and PFMT alone ($n=12$), or routine physiotherapy treatment and PFMT focusing on transversus abdominis muscle coactivation ($n=14$). The clinical characteristics of the participants were measured using the Oswestry Disability Index and the Numerical Pain Rating Scale.

Results. Pain intensity and functional disability were significantly decreased in the control group ($P<0.05$) and the two intervention groups ($P<0.05$). There was no significant difference between the groups after treatment.

Conclusion. Pelvic floor muscle training focusing on transversus abdominis muscle coactivation could be included in the conservative management of patients with non-specific LBP after reviewing their pelvic health history and performing a clinical assessment of their pelvic floor.

Keywords: disability, low back pain, pain, pelvic floor muscle training, rehabilitation.

Introduction

Low back pain (LBP) is a common condition worldwide: 60–80% of people are affected by it at some time in their lives (Balagué *et al.* 2012).

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It is defined as pain located between the twelfth rib and the inferior gluteal fold, which may or may not radiate into the lower limbs (Henrotin *et al.* 2006). This condition is not gender dependent, and all age groups can be affected (Jordan *et al.* 2010). In most cases, LBP is categorized as “non-specific” because the symptoms are not attributable to a specific pathology (e.g. infection, tumour, osteoporosis, fracture, structural deformity, inflammatory disorder, radicular syndrome or cauda equina syndrome) (Balagué *et al.* 2012).

The natural evolution of the pathology tends towards a spontaneous resolution of symptoms after 6–12 weeks (van den Hoogen *et al.* 1998). After more than 3 months of painful symptoms, LBP is considered chronic and has a significant impact on a patient’s quality of life. The risk of recurrence ranges from 50% over the first 12 months to 70% over subsequent years in active populations (Hestbaek *et al.* 2003). In fact, chronic non-specific LBP is associated with the greatest social and economic cost in comparison to other diseases (Dagenais *et al.* 2008).

The latest international recommendations for the treatment of chronic non-specific LBP favour a multidisciplinary approach (Corp *et al.* 2021). Non-pharmacological conservative treatments often involve cognitive behavioural therapy, physical agents, therapeutic education and supervised exercise. However, there has been no consensus on an optimal exercise protocol to date (Corp *et al.* 2021). Currently, lumbar stabilization and abdominal strengthening exercises are commonly used (Saragiotto *et al.* 2016); the objective is to maintain active trunk stability by improving neuromuscular control, endurance and the strength of the abdominal cavity muscles (Richardson & Jull 1995). These objectives are consistent with the concept of core stability, in which the abdominal cavity is considered to be an anatomical unit in which intra-abdominal pressure (IAP) is distributed in all directions (Richardson *et al.* 2004). The management of this pressure is achieved through the synergistic action of the pelvic floor muscles (PFMs), the spine, the abdominal muscles and the diaphragm. This coordinated synergistic response is necessary for proper continence, respiration and spinal stability (Hodges *et al.* 2007).

In healthy subjects, the transversus abdominis (TrA) and PFMs share a common synergistic and anticipatory response that contributes to increased IAP, which generates spinal stiffness (Hodges *et al.* 2007). Specifically, contraction of the TrA

and PFMs increases thoracolumbar fascia tension and stabilizes the sacroiliac joint, respectively (Pel *et al.* 2008). Therefore, any biomechanical alteration of the structures that control IAP can lead to dysfunctions such as incontinence or lumbopelvic pain (Grewar & McLean 2008). This finding is supported by Welk & Baverstock’s (2020) scoping review, which highlighted the positive correlation between urinary incontinence (UI) and non-specific LBP. Smith *et al.* (2007) and Arab *et al.* (2010) also highlighted similarities in pathophysiological mechanisms, and both study populations exhibited impaired trunk and PFM activation. However, all these pathological hypotheses are based on weak observational studies.

Several recent studies have evaluated the effect of PFM exercises (PFMEs) in the treatment of chronic non-specific LBP (Mohseni-Bandpei *et al.* 2011; Bi *et al.* 2013; Rathi 2013; Ghaderi *et al.* 2016; Akhtar *et al.* 2017). A systematic review by Messerli *et al.* (2022) concluded that the addition of PFM strengthening could be beneficial in the treatment of non-specific LBP based on outcomes such as disability or pain scores. However, in view of the moderate quality of the studies included, the heterogeneity of the populations involved and the small differences in intergroup results in terms of pain, it is difficult to confirm the real effectiveness of PFM training (PFMT) for these patients. Furthermore, the mode of contraction of the PFMs differed between the different studies: some added isolated training of the PFMs, while others combine TrA and PFM contractions to facilitate physiological synergy.

The aim of the present study was to clarify whether this difference in protocols has a real clinical impact. The effect of two modalities of PFMT (i.e. in isolation and in synergistic contraction with the TrA) on disability and pain scores compared to conventional treatment alone was investigated in patients with non-specific LBP. The primary and secondary null hypotheses were that there was no difference between: (1) isolated and synergic contraction of the PFMs; and (2) PFMT adding two treatment modalities and routine treatment.

Participants and methods

The present pilot superiority multicentre randomized controlled trial (RCT) involving three parallel groups was conducted between 2020 and 2021. The results are reported following the

multi-arm parallel-group RCTs extension guideline of the Consolidated Standards of Reporting Trials 2010 Statement (Juszczak *et al.* 2019).

Study design and sampling

Following ethical approval from the Medical Ethics Board of the Centre Hospitalier Universitaire (CHU) Brugmann, Brussels, Belgium (reference: B200-2020-104), participants were recruited between September 2020 and January 2021 through social media, and advertisements were distributed in physiotherapy centres and at CHU Brugmann. Patients were included if they were aged between 20 and 50 years old, and suffered from LBP, as defined by Henrotin *et al.* (2006). The exclusion criteria were: pregnancy and the postnatal period, UI, a history of pelvic or spinal surgery, spinal pathology, or infection. All participants were asked to sign a consent form after they received written information about the aims and design of the study. Those who met the inclusion and exclusion criteria were randomly assigned to one of three groups through a simple scheme: a randomization code was generated, placed in a sealed envelope and copied to the three independently trained physical therapy students who performed all the assessments (A.G., C.T. and P.G.) (Suresh 2011).

Outcome measures

All participants completed a questionnaire about their demographic data and medical history. Functional disability was evaluated with the Oswestry Disability Index (ODI). Pain intensity was rated on the Numerical Pain Rating Scale (NPRS), a visual analogue scale from (0) no pain to (10) maximum pain. The outcome measures were assessed at baseline and after treatment. The ODI and NPRS are valid and reliable scales (Childs *et al.* 2005; Dawson *et al.* 2010).

Treatment

Patients with chronic non-specific LBP were recruited and randomly assigned to either a control group (G0), or one of two intervention groups (G1 and G2). All participants followed a 6-week treatment plan of routine treatment with (G1 and G2) or without (G0) additional PFMEs.

Routine treatment comprised transcutaneous electrical nerve stimulation, hot packs, manual therapy and regular exercises. Routine treatment was performed for 30 min twice a week

for 6 weeks with a trained physiotherapist student (A.G., C.T. and P.G.). A choice of transcutaneous electrical nerve stimulation, hot pack or manual therapy administered to the low back area for 10 min was offered to all those taking part. Based on the results of Messerli *et al.*'s (2022) systematic review, participants performed regular exercises for 20 min, with three sets of 10 repetitions for each exercise. These included strengthening and endurance exercises for the abdominal and paravertebral muscles (Fig. 1).

Participants in the G1 experimental group were given routine treatment and additional PFMEs. The PFME programme was based on:

- 2–3 s of maximal voluntary PFM contraction followed by a 10-s rest for five repetitions; and
- 6 s of submaximal voluntary PFM contraction followed by a 6-s rest for three sets of 10 repetitions.

The time of each contraction was increased over the 6-week treatment period, and the postures for the exercises were changed (i.e. lying down, then the side-lying, four-legged and sitting positions) following evidence published in the literature (Mohseni-Bandpei *et al.* 2011; Bi *et al.* 2013; Bhatnagar & Sahu 2017).

The G2 experimental group programme was almost identical to the control group. However, the regular exercises for the deep abdominal and lumbar muscles (TrA and multifidus) focused on PFMs at submaximal voluntary contraction, as described by Ghaderi *et al.* (2016). Controlled and validated by one of the physical therapy students (A.G., C.T. and P.G.), participants learned how to co-activate the TrA and PFMs during the first session.

Additionally, the patients were asked to do these exercises once a week at home. In all three groups, the exercises (i.e. routine treatment alone, stabilization exercises and PFMEs) were taught by a physical therapy student (A.G., C.T. and P.G.), and a booklet including exercise instructions was provided to the participants for the home-based sessions.

Statistical analysis

The medians and percentiles of the outcome measures were calculated for all the participants. Statistical analysis was performed using the Statistical Package for Social Sciences 17.0 (SPSS Inc., Chicago, IL, USA) for Microsoft Windows (Microsoft Corporation, Redmond, WA, USA). The data for each group were tested

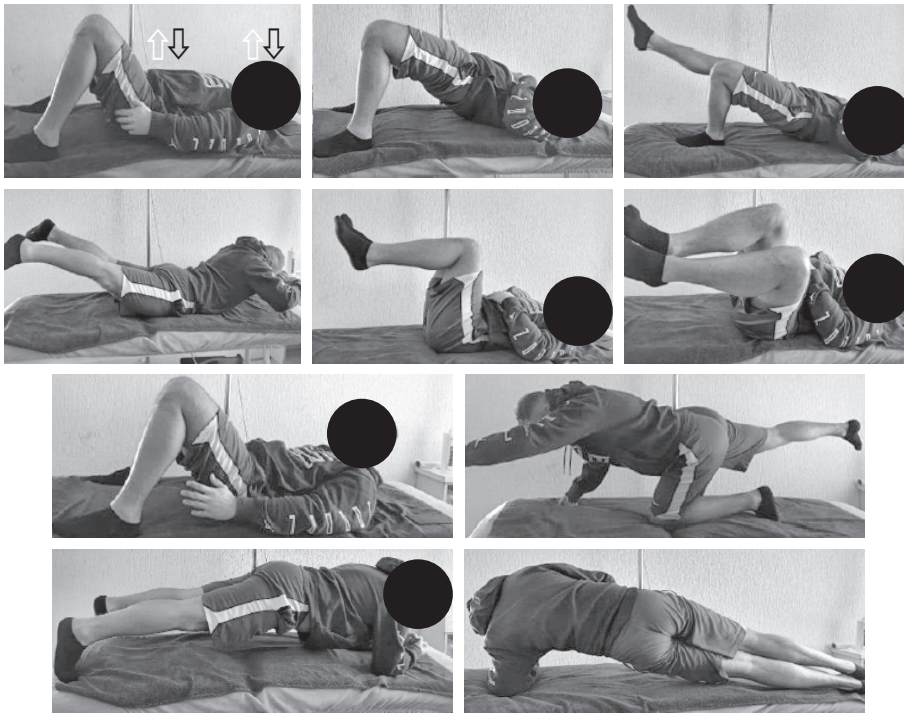


Figure 1. Regular exercises performed during routine treatment. For the G2 intervention group, participants were asked to perform coactivation of their abdominal and pelvic floor muscles while they maintained these positions.

for normal distribution using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Differences between groups at baseline were analysed using the Kruskal–Wallis test. Differences within and between the three groups after treatment were assessed using the Wilcoxon signed-rank and Kruskal–Wallis tests, respectively. Significance was accepted for values of $P < 0.05$ in all analyses.

Results

In total, 37 participants were randomized (G0, $n = 11$; G1, $n = 12$; G2, $n = 14$). A flowchart indicating the recruitment and treatment allocations of the patients is shown in Fig. 2.

At the end of the 6-week treatment period, a complete set of data was available for all the patients in the G0 control group, and 11/12 and 11/14 in the G1 and G2 experimental groups, respectively. Baseline demographic and clinical characteristics are shown in Table 1.

There were no statistically significant differences between the groups for clinical characteristics at the baseline. The outcome measures did not show a normal distribution in each group. Significant improvements in pain intensity and functional disability were found in each group following treatment ($P < 0.05$ in all instances). Table 2 provides detailed information about within-group changes following treatment.

As shown in Table 3, no significant differences were found between the three groups in terms of pain intensity and functional disability ($P < 0.05$).

Discussion

The present study is the first to assess whether, compared to routine treatment, adding PFMT alone or with TrA muscle coactivation exercises is more effective at reducing self-reported pain and disability in people with chronic non-specific LBP.

The results show that routine treatment alone, and with PFMT or TrA coactivation exercises focusing on the pelvic floor improved functional disability and pain intensity among the population with LBP. This is consistent with the literature, as shown by Ghaderi *et al.* (2016) and Bi *et al.* (2013). However, even though the present authors observed a favourable effect by adding PFMT (alone or with TrA coactivation) to another exercise intervention, this was smaller than the minimum clinically important difference for the ODI for G1 (PFMT alone) and G2 (PFMT with TrA coactivation), which is estimated to be 12.8, and also for the NPRS for G2, which is estimated to be 2.2 (Childs *et al.* 2005; Copay *et al.* 2008). This information was also highlighted in a meta-analysis by Bernard *et al.* (2021), which showed that, despite a small favourable effect as a result of adding PFMT to another exercise intervention

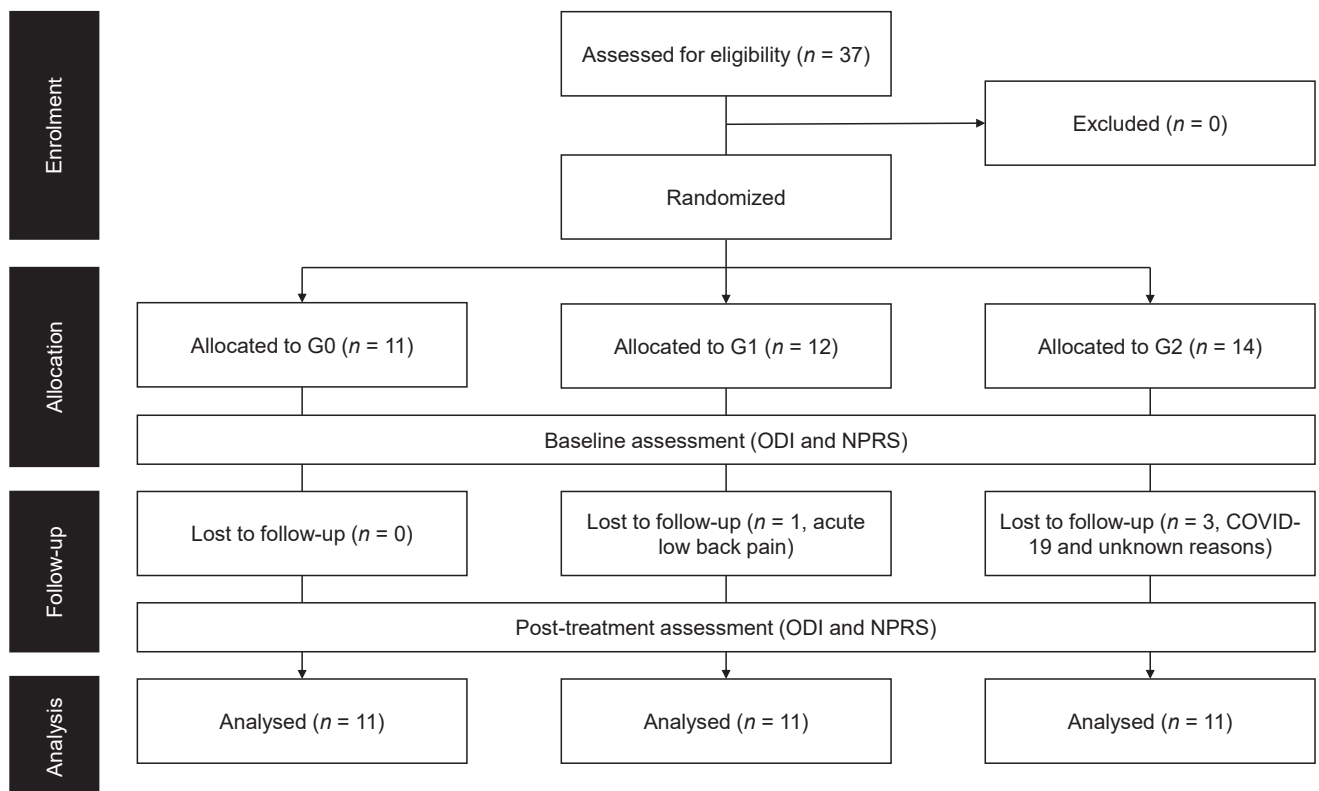


Figure 2. Flowchart detailing the enrolment, allocation and follow-up of participants with chronic non-specific low back pain and disability who were included in a study comparing the effects of 6 weeks of: (G0, control group) routine treatment alone; (G1, intervention group 1) a combination of routine treatment and pelvic floor muscle training; or (G2, intervention group 2) a combination of routine treatment and pelvic floor muscle training focused on deep abdominal and lumbar muscle contraction: (ODI) Oswestry Disability Index; and (NPRS) Numerical Pain Rating Scale.

Table 1. Demographics and clinical characteristics (median and twenty-fifth to seventy-fifth percentile) of the participants with low back pain in the control (G0) and intervention groups (G1 and G2) at baseline: (N/A) not applicable

Variable	Group							P-value
	G0 (n = 11)		G1 (n = 12)		G2 (n = 14)			
	Median	Percentile	Median	Percentile	Median	Percentile		
Age (years)	39	30–50	22.5	21–26	30.5	21.5–35.0	0.025	
Sex [male:female (n)]	5:6	N/A	1:11	N/A	1:13	N/A	N/A	
Height (cm)	173	161–190	168	159–172	168	163.25–174.75	0.512	
Weight (kg)	83	65–90	58	50.75–62.25	70	61.75–81.75	0.005	
Body mass index	24.77	22.72–28.09	20.61	19.72–21.61	24.31	21.12–28.47	0.016	
Oswestry Disability Index (%)	28	14–46	18	14–24	22	14–32	0.481	
Numerical Pain Rating Scale	4	4–6	5	4–6	4	3–6	0.716	

Table 2. Within-group changes in the clinical characteristics [median (twenty-fifth to seventy-fifth percentile)] of the participants with low back pain in the control (G0) and intervention groups (G1 and G2) before and after 6 weeks of treatment. Bold P-values indicate statistically significant within-group changes

Variable	Group								
	G0 (n = 11)			G1 (n = 12)			G2 (n = 14)		
	Before	After	P-value	Before	After	P-value	Before	After	P-value
Oswestry Disability Index (%)	28 (14–46)	12 (8.88–26.00)	0.003	18 (14–24)	10 (6–16)	0.005	22 (14–32)	16 (10–18)	0.009
Numerical Pain Rating Scale	4 (4–6)	2.5 (2.0–3.0)	0.004	5 (4–6)	3 (1–4)	0.004	4 (3–6)	3 (2–4)	0.007

Table 3. Between-group changes in the clinical characteristics (median and twenty-fifth to seventy-fifth percentile) of the participants with low back pain in the control (G0) and intervention groups (G1 and G2) after 6 weeks of treatment

Variable	Group						P-value
	G0 (n = 11)		G1 (n = 12)		G2 (n = 14)		
	Median	Percentile	Median	Percentile	Median	Percentile	
Oswestry Disability Index (%)	12	9.44–26.00	10	7–15	16	11–18	0.358
Numerical Pain Rating Scale	2.5	2.0–3.0	3.0	1.5–3.5	3.0	2.0–3.5	0.819

to decrease self-reported pain severity, this was smaller than the minimum clinically important difference in the six RCTs included.

The results of the present study demonstrate that adding PFMT (alone or with TrA coactivation) to routine physiotherapy treatment was not superior to the routine physiotherapy programme alone in patients with chronic LBP for self-reported pain severity and disability. These results are not consistent with the findings of some studies (Bi *et al.* 2013; Ghaderi *et al.* 2016; Bhatnagar & Sahu 2017), but this difference can be explained by the duration of the intervention. Indeed, Bernard *et al.*'s (2021) subgroup analyses of these durations showed a non-significant effect of additional PFMT on self-reported pain severity when the intervention lasted 8 weeks or less, while a significant effect was found when it lasted for longer than this.

Finally, the present study found no significant difference between PFMT alone and PFMT with TrA coactivation. Even if there is no comparable study, these results are not consistent with: core stability theory; or emerging evidence of the role of the pelvic floor in spinal control through coactivation of the TrA with the PFMs, and the increased tension of the iliolumbar and interosseous ligaments during a PFM contraction (Pel *et al.* 2008; Lee *et al.* 2016).

This pilot RCT has several strengths. It was a multicentre, multi-armed RCT that followed a registered protocol. The outcomes included in the results are validated measures to assess self-reported pain severity and physical function that are commonly used in research and clinical practice.

However, there are also some limitations; for example, the sample size. Indeed, based on sample estimation with a power of $1 - \beta = 80\%$, a significance level of $\alpha < 0.05$ and Bi *et al.*'s (2013) results for ODI data, 69 participants were needed for each group, and therefore, the sample size was too small to allow any firm conclusions to be drawn. The intervention duration was too short to produce significant results, as demonstrated by Bernard *et al.*'s (2021) subgroup analyses, and it

will be interesting to use a long-term follow-up to evaluate each group's improvements after almost 2 months. The three groups differed significantly with regard to their demographics at baseline. The participants and physical therapy students (A.G., C.T. and P.G.) were not blinded during the treatments and assessments. Even if an RCT has a strong design, it would be more interesting to use a double-blinded approach to limit performance and detection bias. Finally, a lack of objective assessment of pelvic floor function and the participants' capacity to contract their PFMs is another limitation. Indeed, Bump *et al.* (1991) reported that, after simple verbal or written instructions, only 49% of patients performed an ideal PFM contraction, and 25% performed a contraction that could potentially cause incontinence (Bump *et al.* 1991). Moreover, even if the optimal parameters for a PFMT regimen in people with non-specific LBP are still unknown, research has highlighted the importance of the different variables needed for a programme of PFMT. For example, during a baseline PFM assessment, the PERFECT scheme (Laycock & Jerwood 2001) assesses endurance, fast contraction or explosivity, and patients' specific difficulties. However, physiotherapists without PFM rehabilitation skills cannot perform an internal assessment of the pelvic floor. Nevertheless, asking clinical questions about the symptoms of PFM disorders or using a self-reported symptom questionnaires can be useful for redirecting patients to a pelvic floor physiotherapist.

Clinical relevance

Chronic LBP is one of the most commonly seen conditions in physiotherapy. However, its pathophysiology is multifactorial and its management is complex. To date, the latest Cochrane recommendations on the subject (Hayden *et al.* 2021) tend to show that strengthening exercises are effective in the treatment of chronic non-specific LBP, and core strengthening appears to be the most favoured approach (Hayden *et al.* 2021). Clinical evidence shows a synergistic relationship between the deep trunk muscles and those

of the pelvic floor in the management of IAP. Therefore, it is pertinent to ask whether adding PFMT to the strengthening programme of LBP patients is clinically useful.

Although the present study found no difference between the different modalities of PFMT contraction and standard treatment, the results are not consistent with the literature on the subject (Bi *et al.* 2013; Ghaderi *et al.* 2016; Bhatnagar & Sahu 2017). This can be explained by the limitations of the present research as well as the population studied. Indeed, the study by Ghaderi *et al.* (2016) showed a significant improvement in pain, disability and UI in incontinent women with chronic LBP. Similarly, a meta-analysis by Vesentini *et al.* (2020) demonstrated that PFM strengthening in postpartum women with LBP significantly improves pain and disability in the short term (Vesentini *et al.* 2020). Although not included in the National Institute for Health and Care Excellence guidelines for the treatment of non-specific LBP (NICE 2016), PFMT combined with other physical exercises may be considered to be clinically relevant for patients with chronic LBP and pelvic health risk factors (e.g. gender, parity, the postpartum period and pelvic floor dysfunction) after assessment of the PFM, and according to their needs, preferences and capacities.

The present study did not show any difference between the two experimental modalities, i.e. PFMT alone or coactivation with the TrA muscle. Although it is not possible to establish a recommendation based on these results, the methodological limitations mean that it may be more appropriate to propose exercises that enhance the physiological synergy of the muscles according to the preferences and capacities of the individual patient.

Conclusion

Considering the potentially positive effects on pain and disability, and the unlikelihood of undesirable side effects, PFMT associated with the deep muscles of the abdominal cavity could be included to the conservative treatment of patients with non-specific LBP depending on their pelvic health needs. A careful consideration of each individual's PFMs may be required before initiating relevant strengthening exercises and associated stability training protocols. Furthermore, larger-scale studies with long-term follow-up, blinded examiners and PFM baseline assessment are required before the present findings can be applied to the general population.

Trial registration

None.

Conflict of interest

The authors report no conflict of interest.

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