

Study Protocol

Official Title: Visceral Manipulation in Patients With Chronic Low Back Pain

NCT03101020

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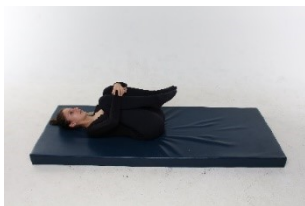
All participants received equal treatment during the assessments and conventional therapy. They were treated one time per week for five weeks. Each session took 50 minutes, starting with 40 minutes of conventional physiotherapy and finishing with 10 minutes of active or placebo visceral manipulation, depending on the participant's group allocation.

Conventional physiotherapy

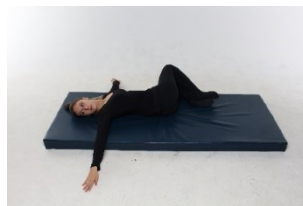
We created a protocol of exercises for individuals with low back pain based on the clinical practice guidelines by Delitto *et al.* (2012). The protocol consisted of general exercises to mobilize, strength, and stabilize the spinal column, pelvis and hip, as it is described at Figure 1. All participants were oriented to keep an active lifestyle focusing on the activities they could perform (Koes *et al.* 2010; Panagopoulos *et al.* 2014).

At the end of the first session, the participants received a list with the description and photos of the exercises they performed during that session and that they would need to do every other day at home; however, there was no control if the participants performed the exercises at home. The criteria to progress the exercises were no pain, no fatigue, and no fear on performing it.

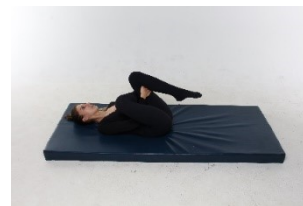
A



B



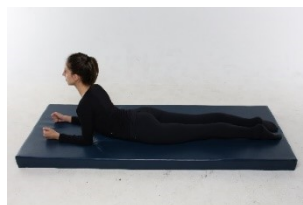
C



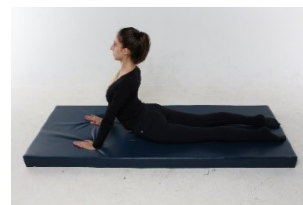
D



E (1)



E (2)



F (1)

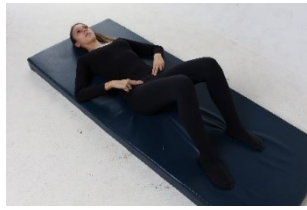


F (2)

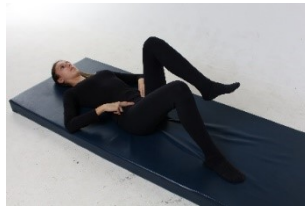


F (3)





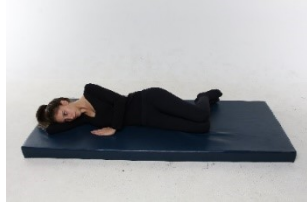
G (1)



G (2)



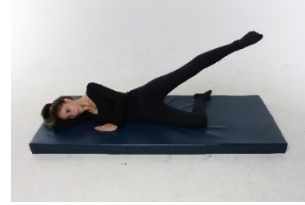
G (3)



H (1)



H (2)



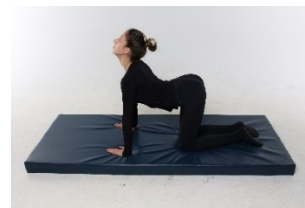
I (1)



I (2)



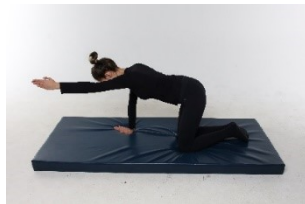
J (1)



J (2)



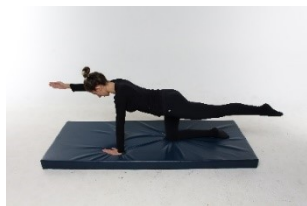
J (3)



K (1)



K (2)



L (1)



L (2)



Figure 2. Exercise protocol. **A** Erector spinae stretching, in dorsal decubitus pull the knee towards the abdomen – 2 sets of 30 seconds. **B** Knee rolls, roll the knees to one side and the other maintaining both shoulders on the floor – 2 sets of 10 seconds per side. **C** Piriformis stretch, in dorsal decubitus cross one ankle over the opposite knee and pull this leg towards the abdomen – 2 sets of 30 seconds per side. **D** Pelvic tilts, perform pelvic anteversion and retroversion – 10 to 15 repetitions. **E(1)** Back extensions, in ventral decubitus, extend the back supporting the upper body on flexed

elbows – 10 to 15 repetitions. **E(2)** Back extensions progression, the same position but supporting the upper body on the hands with the elbows extended. **F(1)** Activation of abdominal muscles, in dorsal decubitus perform isometric contraction of the profound abdominal muscles during breathing – 3 sets of 10 breathings. **F(2)** Activation of abdominal muscles progression 1, the same exercise but lifting a flexed knee in the air and maintaining it steady during the set – 2 sets of 10 breathings per side. **F(3)** Activation of abdominal muscles progression 2, the same exercise but lifting an extended knee in the air and maintaining it steady during the set – 2 sets of 10 breathings per side. **G(1)** Activation of back and hip muscles, in side lying, perform isometric contraction of unilateral back and hip muscles during breathing – 3 sets of 10 breathings. **G(2)** Activation of back and hip muscles progression 1, the same exercise but lifting a flexed knee and maintaining the ankle together and the leg steady during the set – 2 sets of 10 breathings per side. **G(3)** Activation of back and hip muscles progression 2, the same exercise but lifting an extended knee and maintaining it steady during the set – 2 sets of 10 breathings per side. **H(1)** Bridge exercise – 3 sets of 10 repetitions. **H(2)** Bridge progression, perform a single leg brig exercise – 3 sets of 10 repetitions per side. **I(1,2)** Quadruped Cat and Camel exercise – 10 to 15 repetitions. **J(1)** Single arm or leg raise, in quadruped position raise all limbs (arms and legs) one at a time and maintain the position – 1 set of 30 seconds for each limb. **J(2)** Quadruped opposite arm and leg raise exercise progression – 2 sets of 30 seconds per side. **K(1)** Plank, perform the plank exercise supporting the lower body on the knees – 2 sets of 30 to 60 seconds. **K(2)** Plank progression, perform the plank exercise supporting the lower body on the feet – 2 sets of 30 to 60 seconds. **L(1)** Side plank, perform the side plank exercise supporting the lower body on the knees – 2 sets of 30 to 60 seconds. **L(2)** Side plank progression, perform the side plank exercise supporting the lower body on the feet – 2 sets of 30 to 60 seconds.

Visceral manipulation

During all sessions, the participants had to remain in a hook-lying position and the head over a pillow to decrease the tension on the abdominal wall. A well-trained physiotherapist performed the visceral manipulation over eight spots on the abdomen. Each spot has a specific technique name, which are described in Figure 2, and each technique took 1 minute, except for the last two techniques that were performed 10 times each. For the experimental group (direct visceral manipulation), the therapist performed a deep pressure with the lower palm over those spots. The placebo visceral manipulation involved a light touch over the same spots, without intending to treat the patient, with the same amount of time and repetitions as the experimental group (McSweeney et al. 2012). At the end of the last session, the participants were asked to identify if the technique they received was the experimental or the placebo one.

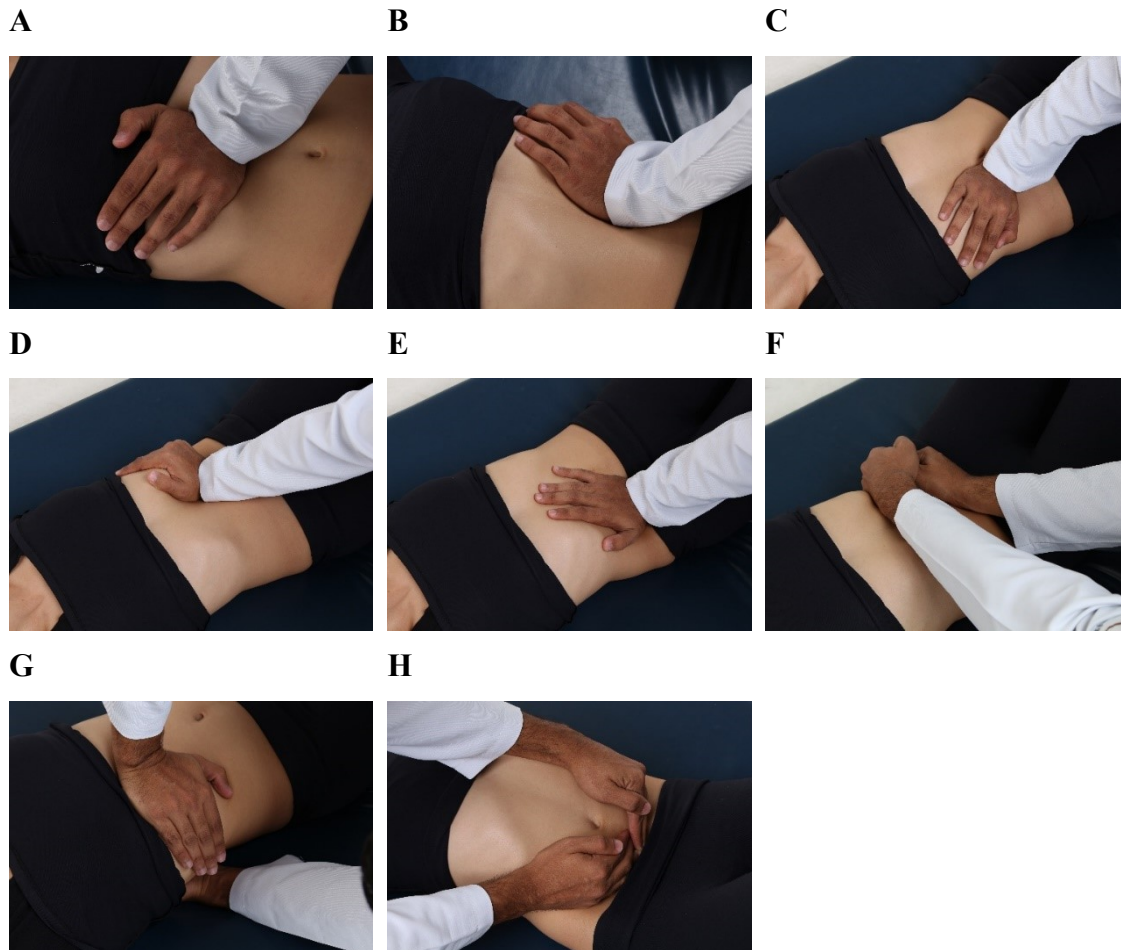


Figure 3. Visceral manipulation protocol. Orientation of the pictures, cranial to the left and caudal to the right. **A** Cardia manipulation – 1 minute. **B** Pylorus manipulation – 1 minute. **C** Oddi sphincter manipulation – 1 minute. **D** Duodeno-jejunal valve manipulation – 1 minute. **E** Ileocecal valve manipulation - 1 minute. **F** Sigmoid colon manipulation – 1 minute. **G** Liver global manipulation – 10 repetitions. **H** Global hemodynamic manipulation – 10 repetitions with pressure during expiration and another 10 for inspiration.

Outcomes

All participants were assessed three times, pre-treatment, post-treatment and follow-up. Pre-treatment assessment was one week before the first session of treatment, post-treatment was right after the last session of treatment and the follow-up was one week after the last session of treatment. A team member, which was not involved with the interventions, was responsible for collecting all the baseline measures and outcomes.

Primary outcome

Pain intensity was evaluated through a Visual Analog Pain Scale of 11 points, where the participant choose a number from 0 to 10, 0 equals to “no pain at all” and 10 to “unbearable pain” (Childs *et al.*, 2005).

Secondary outcomes

Lumbar spine mobility was assessed through the original Schober Test. Roland-Morris Disability Questionnaire was used for General functionality and Patient Specific Functional Scale was used for Specific functionality (Tousignant *et al.* 2005; Nusbaum *et al.* 2001; Kowalchuk-Horn *et al.*, 2011; Oliveira *et al.*, 2008; Stratford *et al.*, 1995).