ADD NEW PROTOCOL AT THE SAME PATIENTS

INTRODUCTION

The term low back pain is characterized by pain in the lumbar spine region, a condition that affects individuals of both sexes and reduces their ability to perform activities in their daily lives, which results in a substantial economic cost to society [1]. Notably, approximately 70% of the population of Brazil may have an episode of low back pain during their lifetime [2,3].

The etiology regarding the development of low back pain is still unclear due to the innumerable factors that may lead to its onset, some of which may be related to repetitive work, pulling and pushing, falls, poor posture, squatting, heavy lifting, muscle imbalance, and compressive syndromes, among others. Chronic pain is among the main causes of absenteeism at work, medical leave, sick leave, workers' compensation, and low productivity at work [1,4–6].

It is important to emphasize that limited mobility of the lumbar spine due to pain can often be associated with this condition [4]. Another extremely relevant point with regard to spinal nerve injuries, particularly in the lumbar region, is that they are often caused by compressive syndromes such as discal hernias. Such compressions often result in neuropathic pain, which is characterized by spontaneous burning pain, followed by allodynia and hyperalgesia, which can be observed in the nerve pathways of the in the lower limbs [5].

In addition to pharmacological and surgical treatments, there are noninvasive or nonpharmacological treatments such as physiotherapy. Physiotherapy treatments, which have countless approaches, facilitate a decrease in signs and symptoms, such as reduced pain and muscle tension and increased lumbar and hip range of motion, in individuals with chronic low back pain [7]. One of the available treatments is neural mobilization (NM), which is characterized by a set of techniques that aim to impose greater tension on the nervous system through certain postures; slow and rhythmic movements are applied to the peripheral nerves and spinal cord, improving conduction of the nerve impulse [8].

Studies have demonstrated the beneficial effects of NM, including improved joint pain in patients with rheumatoid arthritis [9] and improved cervicobrachial pain [10]. Neural mobilization has demonstrated an excellent prognosis in patients with this type of pain, in addition to presenting other advantages such as low operational cost, easy application and no adverse effects.

Results from the previous studies described above show the beneficial effects of NM treatment. There is a lack of clinical trials regarding the use of NM for different types of pain.

The aim of this study was to compare pain intensity and functional capacity before and after treatment with NM in volunteers with chronic low back pain.

The research questions were as follows:
1. What are the effects of the neural mobilization technique on individuals with chronic low back pain?
2. Is neural mobilization effective?

METHOD

Participants, therapists, center

The participants were recruited for evaluation by establishing the inclusion and exclusion criteria of the study. Individuals of both sexes who met the following criteria were included in the study: chronic low back pain, radiating or not to one of the lower limbs; age 18 years or older; score ≥ 4 on the visual analog scale (VAS).

We excluded individuals with acute low back pain; spondylolisthesis or fibromyalgia; previous spinal surgery; any sequelae that caused limitations in the range of motion of the lower limb or joint deformity; metal plates, screws, neurological disorders who present caution for neural mobilization; cancer; cognitive disturbances or apparent limitations; any type of pain in other regions that is not characteristic of low back pain; advanced diabetes mellitus; under physiotherapeutic treatment for the same reason; decompensated cardiovascular diseases; significant changes in sensitivity; edema in the lower limbs; and pregnant women.

After eligibility was confirmed, all the procedures to be performed during the study were elucidated, and the subjects signed the Free and Informed Consent Terms, according to Resolution 466/12 of the National Health Council - Brazil, confirming their participation in the research.

Sixteen volunteers, 8 women and 8 men, with a mean age of 30,45 ± 10,32 years, participated in this study. After being selected, the volunteers were allocated to Group NM, consisting of individuals with low back pain, and were treated with the technique.

After fulfilling the eligibility criteria, a clinical evaluation and assessments of pain intensity, spinal mobility, peripheral sensitivity and hip goniometry were carried out, and a quality of life questionnaire was administered (details below).

To preserve the accuracy of the intervention effectiveness, participants who missed more than two sessions were excluded from the study. All subjects were assessed by a blinded evaluator. Both participants and evaluators were encouraged not to discuss the intervention.

Intervention

The Neural Mobilization technique was performed by the same physiotherapist from the first to the last session on alternate days. Treatment with the technique consists of applying a total of 10 interventions in each patient, with a total duration of 10 minutes, divided into four series of 2 minutes each, with a 30 second interval between each series, according to the protocol proposed in 2012 by Santos et al. [11].

The technique was applied with the participant seated in a suitable chair, with a flexed hip (90) and extended knees (Figure 1). Next, the physiotherapist applied the technique only to the lower limb in which the individual presented with some impairment due to low back pain, observed in the previous physical examination; in case of absence of pain radiation to any of the limbs, the technique was applied only to the right lower limb according to Santos et al. 2012 [11].

During the period from July 2016 until September 2017, we screened 60 subjects for eligibility; of those, only 16 individuals completed the entire study protocol according

to the inclusion and exclusion criteria. Table 1 shows a flowchart of the study design that explains all the procedures implemented with the volunteers in all groups.

Calculation of the sample

The sample size was calculated based on the visual analog scale for pain, which was considered the primary end point. To this end, the variance reported in the study by Murphy et al., 2006, whose objective was to evaluate neural mobilization as a technique for treatment. Considering the mean and standard deviation of the pre-intervention and post-intervention of this study, with an alpha value (α) of 0.05 and 90%, it was determined that 20 subjects were required for the experimental group [12].

Outcome measures

First, all personal data from each subject were obtained, including age, occupation and education. After this first step, the participants submitted to two evaluations, one prior to and one at the end of the therapeutic program. Both evaluations were to assess pain intensity and mobility of the lumbar spine and to measure cytokines.

Visual Analog Scale (VAS):

A visual analog scale was used for the assessment of pain intensity; it consists of a line ranging from 0 to 10, where zero represents the absence of pain and ten represents the worst pain. After instruction in how to complete the scale, the volunteer was asked to mark a point on the line that indicated the intensity of the pain that he or she was feeling at the moment of evaluation [13].

Mobility of the lumbar spine:

Two tests were used to evaluate the mobility of the lumbar spine: the 3rd finger to the ground and goniometry.
The test of the 3rd finger to the ground distance consists of an active test in which the individual is placed in an orthostatic position, with the feet separated in line with the hips, keeping the knee extended and heel touching the ground. Then, the participant is asked to perform trunk flexion with the arms extended and to try to bring his hand

closer to the ground. Then, using a tape measure, the distance between the tip of the 3rd finger and the ground is measured, and the value in centimeters is considered the mobility of the volunteer's lumbar spine [1,14].

Goniometry refers to the measurement of individuals' joint angles; it was applied before the first session and after the last session of neural mobilization. To minimize measurement error, the physiotherapist in charge underwent training. Goniometric measurements of the hip joint of the participants in this study were used for both thigh flexion; the amplitude varies between 0 - 131° ± 6.4°, and the articular range varies from 0 to 13° ± 5.4°; measurements may vary from individual to individual more or less within these established values [15].

Evaluation of Cytokines:

Blood was collected from each group to evaluate the possible impact of the technique on pro- and anti-inflammatory cytokines. Two collections were performed: the initial measurement (I) and the final measurement after the last session (F) of treatment. To evaluate the cytokine concentration, the blood serum of the individuals was used for these analyses.

For specific IL-1β, IL-4, IL-6, and FTN-α cytokines, specific reagents contained in the Milliplex®TM Map kit (Millipore Corporation, Darmstadt-Germany) were assessed by Multiplex (Enzime-Linked ImmunoSorbent Assay) according to the protocol specified by the manufacturer.

Data analysis

The statistical analysis consisted of ANOVA with repeated measures for the time factor, which was performed to test between-group differences (followed by the Tukey-Kramer post hoc test), and a paired *t*-test was performed to test within-group differences. The results were considered statistically significant if $p \leq 0.05$, using the standard error of the mean ± SEM [18].