INTRODUCTION:

The term low back pain features pain in the lumbar spine region, a condition that affects individuals of both genders in their most active life, which results in a substantial economic cost to society [1], and it should be mentioned that about 70% of the population of Brazil may have an episode of low back pain at some period of his life [2] [3].

It is still not clear the etiology regarding the development of low back pain, 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, imbalances muscle, compressive syndromes, among others [4] [5].

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

Besides pharmacological and surgical treatments, there are non-invasive and non-pharmacological treatments, such as physiotherapy. Physiotherapy treatments, which has countless resources give the individual with chronic low back pain a decrease in signs and symptoms, such as reduced pain and muscle tension, increased the lumbar and hip range of motion, as well as improved postural balance and functionality [6].

One of the available treatments is Neural Mobilization, which is characterized by a set of techniques, which aims to impose greater tension on the nervous system, through certain postures, where slow and rhythmic movements are applied to the peripheral nerves and spinal cord, improving the conduction of the nerve impulse [7]. Neural Mobilization has demonstrated an excellent prognosis in patients with this kind of pain, besides presenting other advantages, such as low operational cost, easy application and no adverse effects [8].

The aim of this study was to evaluate the effect of the application of a protocol of the neural mobilization in individuals with chronic low back pain with or without irradiation for lower limbs, isolated or associated with drug treatment. In addition, to evaluate the effect of the technique on the pain intensity and the functional capacity of the volunteers.

MATERIALS AND METHODS:

This was a prospective randomized, controlled, parallel-group trial. All the study procedures were conducted in accordance with Research Ethics Committee with Human Beings of the Biomedical Sciences Institute of the University of São Paulo – São Paulo,

Brazil (CAAE: 56978016.1.0000.5467). The trial was also registered in Clinical Trials (clinicaltrials.gov - NCT02671409).

The participants were recruited for evaluation by establishing the inclusion and exclusion criteria of the study. Were included in the study individuals of both genders who corresponded to the following criteria: with chronic low back pain, irradiated or not to one of the lower limbs; age from 18 years; score ≥ 4 on the analogue pain scale (VAS).

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

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

Thirty-five individuals volunteers participated in this study, with a mean age of 49.64 years, were 21 women and 14 men. After being selected, the volunteers were allocated to three groups: Neural Mobilization Group (MOB), consisting of individuals with low back pain and treated with the technique, with a total of 18 participants; Neural Mobilization + Medication Group (MOB + MED), constituted by individuals with low back pain, who underwent the mobilization technique associated with medication, a total of 12 participants; and the control group (CONTROL) constituted by healthy individuals without any kind of injury or pain complaint who received the application of the neural mobilization technique, with a total number of 5 participants.

After fulfilling the eligibility criteria, a clinical evaluation and assessments of pain and mobility were carried out, and a quality of life questionnaire was applied (details below).

In order 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 evaluator were encouraged not to discuss the received intervention.

First, all personal data from each subject were obtained. Age, body mass, height, profession, school education. After this first step, the participants were submitted to two evaluations, prior to and at the end of the therapeutic program. Both to assess the pain

intensity and to assess the mobility of the lumbar spine, as well as the application of a quality of life questionnaire. A follow up was done thirty days after the end of the treatment to verify the effect of the protocol after the patients return to the normal daily life activity. A characterization and physical examination card were used for a better analysis of the volunteers. The subjects in all three groups were submitted to the same evaluation protocol.

A visual analogue scale (VAS) was used for the assessment of pain intensity, which consists of a line ranging from 0 to 10, where zero characterizes absence of pain and ten, worst pain. After clarifying how to complete the scale, the volunteer was asked to mark a point on the line that indicated the intensity of pain that he or she was feeling at moment of the evaluation [9].

The Portuguese version of the Roland - Morris Disability Questionnaire (RMDQ) [10] was applied to the subjects of the study. The questionnaire consists in assessing the severity and level of physical disability induced by low back pain through 24 alternatives with dichotomic answers (yes or no). The questionnaire must be self-filled by the volunteers, demonstrating their success or difficulty in performing their daily life tasks associated with their pain, and the final result of the questionnaire is the sum of the yes or the marked responses. As some patients had some difficulty reading or understanding the instructions of the questionnaire, the reading was done together with the researchers.

It was applied the Oswestry Disability Index (ODI) version 2.0, validated in 2007 by Vigatto et al [11]. The scale consists on a list of ten questions with six possible answers, each answer has a score ranging from 0 to 5, in the order in which they are listed, that is, the first value is 0 and the last value is 5. The first question assesses the intensity of the pain and the others assess the effect caused by the pain on the performance of activities of daily living, like personal cares, dress up, sleep and so forth [12].

To analyze the total score obtained in this questionnaire, there is a mathematical formula that can be used. After adding all the results marked by the individuals in the questionnaire were used a mathematical formula to calculate the total score obtained in percentage for each volunteer. The total score is divided by the number of answered questions divided by 5. The result of this division is multiplied by 100 and the final values are given in percentages, thus ([score \div (number of answered questions X 5)] X 100)[12].

In order to evaluate the mobility of the lumbar spine, the 3rd finger to the ground distance test was used. This test consists of an active test, where the individual is placed in an orthostatic position, with the feet separated in the hip line, keeping knee extended and heel leaning on the ground, then the participant is asked to perform a trunk flexion with the arms extended and 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 given in centimeters (cm) is considered as the mobility of the volunteer lumbar spine [13] [14].

The Neural Mobilization technique was performed by the same physiotherapist, from the first to the last session, on interleaved days. The protocol of the technique consists in applying a total number of 10 interventions in each patient, with a total duration of 10 minutes, divided into four series of 2 minutes with a 30-second interval between each series according to the protocol proposed in 2012 by Santos et al [15].

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 applies the technique only to the lower limb in which the individual presents some impairment due to low back pain, observed in the previous physical examination, or in case of absence of irradiation for any of the limbs, the technique was applied only to the right lower limb according to Santos et al 2012 [15].

In the period from July 2016 until September 2017, we screened 60 subjects for eligibility but only 35 individuals had finished all the study protocol according to the includes and exclude criteria. Next, in figure 2 we have a flowchart about the study design, that explain all the procedures realized with the volunteers in all groups.

The statistical analysis was the ANOVA test with repeated measures for the time factor were 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 level of significance for the statistical analysis was 5% ($p \le 0.05$), using the standard error as mean \pm SEM [16].

RESULTS:

A total of 35 patients concluded the study and were analyzed. Characteristics of participants included in each group were presented in <u>Table 1</u> and were homogenous for age at baseline. After the application of the Neural Mobilization technique, the patients were reassessed and the data obtained in both, the initial and final evaluation were submitted to statistical analysis.

Visual Analogue Scale:

Our results demonstrated an improvement in pain in patients treated with neural mobilization. There was a mean reduction in the VAS scale from average 8.47 to 4.05, which was statistically significant in group MOB (Figure 3).

The decrease of pain sensitivity started at the 4th session for patients treated with neural mobilization only (MOB) and from the 5th treatment session for the patients using medicament plus therapeutic treatment group (MOB + MED). The improvements remained until the end of the treatment (Figure 3).

EVA was 1.5 for MOB group and 2.6 for MOB+MED thirty days after the end of the sessions. Control group (CONTROL), composed of individuals without any kind of pain or injury and who were treated with the neural mobilization technique, it was noted pain intensity on the VAS scale remained at zero until the follow up evaluation (Figure 3).

It should be mentioned that it was not possible to observe a statistically significant difference between the MOB and MOB + MED groups, which suggests that the Neural Mobilization technique alone can improve the pain of these individuals, and it could be considered an adjuvant therapy to the drug treatment of patients (Figure 3).

Roland-Morris Disability Questionnaire (RMDQ):

By adding the yes answers and reaching a value equal to or lower than 10 points, it shows that the person with low back pain presents without some kind of disability, that is, despite the pain, there is no impeding the accomplishment of their daily life tasks. However, if the total varies between 11 and 14 yes / indicated alternatives, it indicates a mild or moderate inability of this individual to perform their daily activities. When the positive responses are equal to or greater than 15, it indicates that this individual has a severe disability [12].

In the MOB group, 17 individuals were evaluated. In the initial measurement, we observed that 15 individuals presented in the normal parameter, not showing any kind of incapacity in performing daily life activities. Two individuals from the same group, presented, in the initial measurement, a severe incapacity to perform the activities of daily living. At the end of the treatment, this questionnaire was reapplied, and 16 of the subjects presented normal parameters, and one of the individuals with severe disability returned to normal levels; the other individual who also presented a severe level of disability, partially reversed their condition, going to mild/moderate disability when performing activities of daily living (Table 2).

In the MOB + MED group, eleven individuals were evaluated. In the initial measurement, we observed that 6 individuals presented in the normal parameter; 3 subjects had mild / moderate disability and 2 individuals from the same group, presented, in the initial measurement, a severe incapacity to perform the activities of daily living. After the end of the treatment, the questionnaire was reapplied, and 9 of the individuals presented in the normal parameter. Three of the individuals with some degree of disability, returned to normal levels

and only 2 individuals who had a severe level of disability did not improve their disability when performing activities of daily living (Table 2).

In the control group (CONTROL), composed of 5 healthy individuals, with no complaints of low back pain and without injury, initially they had normal parameters, and did not present any type of disability when performing daily life activities, after the application of the proposed protocol (Table 2).

The Oswestry Disability Index (ODI):

In the initial measure (I) of the ODI were assessed after the application of the mathematical formula to evaluate the level of incapacity of the individuals. The first application of ODI can be classified into five levels of disability. The first stage classified in 0-20%, characterizes a minimal disability. The second stage in the range of 21-40%, characterizes a moderate disability. Followed for the range of 41-60%, that characterizes an intense disability. The range of 61-80% characterizes an immobilization. And finally, the range of 80-100%, that means invalidity.

The Final measure (F) of the ODI assessed was the effect of the treatment in the evolution of the clinical condition after the appliance of the mathematical formula. The first stage classifies the evolution in excellent in the range of 0-20%. The range of 21-40% classifies the evolution in great. The range of 41-60%, classifies the evolution in maintenance. The range of 61-100%, classifies the evolution after the treatment as worse.

Comparing the initial and the final measure of the ODI, it can be observed an improvement of the clinical condition of the subjects assessed in both groups, MOB, and MOB+MED. Only the CONTROL group maintained the same results in both measures (Table 3).

Lumbar mobility:

The mobility of lumbar spine was evaluated and subjects with low back pain and treated with Neural Mobilization (MOB), had at the initial evaluation (I) an average of 20.66 cm from the ground and of 15.4 cm at the final evaluation, an improvement of 25% (* p <0.0001). Patients with LBP treated with medication and neural mobilization treatment (MOB + MED), presented and initial distance (I) of 25.5 cm (average) from the ground and of 18 cm (F) at the end of treatment. There was an improvement of 28 % of the recovery, a statistically significant improvement (#p<0.05) compared with the same group before treatment. In Control group, no difference was observed (Figure 4).

DISCUSSION:

Low back pain represents one of the biggest health problems all over the world, which causes an effective social and economic impacts on the society, linked to the high level of disability and work absence [17] [18] [19] [20].

Some studies show that the costs associated with chronic low back pain exceed a few billion dollars [20], which shows us how important is the search for effective and low-cost treatments aimed at minimizing the global financial impacts caused by chronic low back pain.

The European guidelines for chronic low back pain recommend several types of conservative treatment for this condition, among them, manual therapies such as manipulations and mobilizations [21].

Some systematic reviews state that use manipulation and mobilization to treat chronic low back pain may have positive effects, but they emphasize that their effect may vary according to the time of application, patient and physiotherapist handling, type of technique, the range of application, and the outcomes analyzed [22] [23].

Neural mobilization is a type of mobilization, and a noninvasive physiotherapeutic technique that aims to reestablish the conductivity of the nerve impulse, reducing the intensity of pain caused by peripheral neuropathy and, in some studies with laboratory animals with neuropathic pain, has been able to regenerate the sciatic nerve after the application of the technique [24] [15].

Serrano et al, 2002, says that pain is impossible to measure directly and objectively, but that it would be possible to perform a quantitative estimation of pain intensity, with VAS (Visual Analog Scale). This is one of the best scales used to make the description of the pain more objective and accurate and was chosen for this work [9].

Based on our results, we can suggest that the Neural Mobilization technique when applied in individuals with chronic low back pain, either alone or through association with drug therapy, were able to decrease pain sensitivity.

We observed a significant improvement in the nociceptive response of patients treated with the Neural Mobilization technique. All individuals obtained a significant improvement in the pain after the treatment, evaluated through the Visual Analogue Scale (VAS). Our results corroborate with the Boeing et al., 2004 where those authors showed an improvement in pain in all individuals with sciatica treated using another protocol of this technique [25].

Our results also corroborate the results obtained by Sweeney and Harms in 1996, where the authors observed a reversal of allodynia and hyperalgesia, and an improvement of the range of motion of the affected limb after neural mobilization technique [26].

When we analyzed the functional capacity of all patients, we also observed an improved in their mobility. We could observe a statistically significant improvement in the mobility of the lumbar spine of the individuals in the patients with low back pain with or without an addition of medicament, evaluated through the third finger distance test. We observed an average of 25% for patients without drug acquisition and a 28% for the patients that take pills with the mobilization treatments. A statistically significant improvement. It should be mentioned, the in Boeing study, she also observed an improvement in patients mobility but using another clinical test to assess lumbar mobility (Shöber's test) [25].

Recent studies, Barbosa *et al* (2015) observed a statistically significant improvement in lumbar mobility of individuals with sciatica who underwent treatment with Neural Mobilization of the sciatic nerve, using another clinical test to assess the mobility of our study [27].

Regarding the Roland-Morris Disability Questionnaire (RMDQ) and Oswestry Disability Index (ODI), we also used to analyze the level of physical disability induced by low back pain in each study volunteer. In our work, we can suggest that the protocol proposed was able to improve the disability of individuals treated only with the neural mobilization technique from mild to normal in almost all patients in RMDQ. It should be mentioned that the individuals treated with the combination of medicaments had a higher level of disability than the patients that received only MOB treatment in RMDQ.

In RMDQ, the results obtained so far in this questionnaire suggest that the protocol proposed in this study was able to aid in the improvement of the mild and moderate disability of individuals treated only with the neural mobilization technique and also associated with drug treatment. It should be mentioned that the individuals treated with the combination of treatments (MOB + MED group) had a higher level of disability than the MOB group.

We could also observe an improvement in the individuals' disability through ODI, comparing before and after the technique, where the subjects treated with MOB only had a lower level of disability compared to the MOB + MED group, both of which obtained a reduction of the level of disability after the application of the proposed protocol.

Based on both questionnaire applied in this study, we could demonstrate their success in improving the quality of life from all patients analyzed in this program.

This technique proves to be a possible adjunct therapy to the drug treatment, since it has no side effects, and may help in reducing the dose and administration period of the medication. In addition to improving their functional capacity and quality of life, thus demonstrating their importance for clinical practice.

CONCLUSION:

In summary, we can affirm that the technique chosen for the treatment of individuals with chronic low back pain, with or without irradiation to one of the lower limbs, was effective in reducing the pain intensity of these patients when comparing the initial with the final evaluation, as well as between treatment sessions.

In addition, the protocol postponed by our study, with 10 interventions of the neural mobilization technique performed in 4 sets of 2 minutes each, was able to interfere both in the pain intensity of these individuals and in the mobility of the lumbar spine, which in general, accelerates the process of improvement of the functional capacity of these individuals and return to normal daily life activities.

It should be mentioned that the Neural Mobilization technique can also be associated with other conventional non-invasive treatments, such as drug treatment, thus becoming a supporting tool in the treatment, since it does not present deleterious effects after its application.

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Legends according the text:

Figure 1: Representation of the application of the Neural Mobilization technique (1 - with) the patient sit on a common chair, we stand the leg that should be treat, until the lower limb comes completely extended; 2 - after we realize an adduction followed by an internal rotation, with an exacerbation of the extension until the patient refers some discomfort (that will not have be pain); 3 and 4 - them, we start alternately movements of dorsiflexion and plantar flexion about five time each; 5 and 6 - at the end, we realize elevation and depression of the lower limb alternately about five times. The steps 3-4 and 5-6 must be alternately until the end of each series of two minutes each one).

Figure 2: Participant flowchart in the study.

Figure 3: Intensity of pain before (I = Initial Measure), during (s = sessions) and after (F = final measure and FP = Follow-up) treatment with Neural Mobilization (MOB n = 18), associated medication (MOB + MED n = 12) and the control group (CONTROL n=5). The symbols represent the statistical significant difference between times analyzed (* p<0.0008 between 4th session and initial measure (I) in MOB group; ** p<0.0001 between final measure (F) and initial (I) in MOB group; # p<0.0003 between 5th session and initial measure (I) in MOB + MED group; ## p<0.0001 between final measure (F) and initial (I) in MOB + MED group).

Figure 4: Lumbar spine mobility before (I = Initial Measure) and after (F = Final Measure) treatment. The symbols represent the statistical significant difference between times analyzed (* p<0.0001 between final measure (F) and initial (I) in MOB group; # p<0.05 between final measure (F) and initial (I) in MOB + MED group).

Table 1: Characterization of the participants of the study in each group.

Table 2: Analysis of results obtained in the initial (I) and final (F) measurements on the Roland-Morris Disability Questionnaire in MOB, MOB + MED and CONTROL groups, before and after the proposed treatment.

Table 3: Analysis of results obtained in the initial (I) and final (F) measurements on the Oswestry Disability Index in MOB, MOB + MED and CONTROL groups, before and after the proposed treatment.

Table 1:

GROUPS:		Control group	MOB group	MOB + MED group
Main age (yr)		28,4±11,5	43,4±13,9	43,3±15,0
<u>Gender</u>	M	2	7	5
	F	3	11	7
Education	Elementary	0	0	2
	High school	4	12	9
	University	1	6	1
	Not Finished	0	0	0
Ocupation Status	Full-time Worker	1	10	1
	Part-time Worker	1	7	3
	Unemployed	0	0	3
	Retired	0	1	1
	Disabled	0	0	3
	Student only	3	0	1

Table 2:

Roland-Morris Disability Questionnaire (RMDQ)						
Group-time	0 a10 - Normal	11 a 14 – Mild/Moderate desability	15 a 24 – Seevre disability			
MOB - I	15	0				
MOB -F	16	1	0			
MOB+MED - I	6	3	2			
MOB+MED - F	9	0	2			
Control – I	5	0	0			
Control – F	5	0	0			

Table 3:

Oswestry Disability Index (ODI)							
Group - Time	<u>0-20%</u>	<u>21-40%</u>	41-60%	<u>61-80%</u>	80-100%		
<u>MOB - I</u>	7	7	1	1	0		
MOB -F	14	1	1	0	0		
MOB+MED - I	0	8	3	0	0		
MOB+MED - F	7	2	2	0	0		
<u>Control – I</u>	5	0	0	0	0		
<u>Control – F</u>	5	0	0	0	0		

Figure 1:



Figure 2:

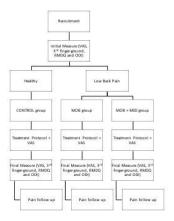


Figure 3:

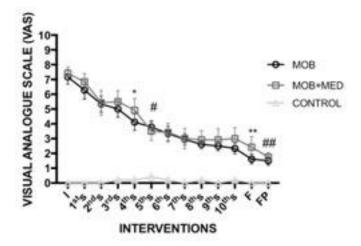


Figure 4:

