

ORIGINAL ARTICLE

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EFFECT OF ORIENTATION THROUGH A BOOKLET OF STRETCHING AND STRENGTHENING EXERCISE IN PATIENTS WITH LOW BACK PAIN: BOOKLET OF EXERCISE FOR LOW BACK PAIN

¹Daniele Tatiane Lizier, BSc²Marcelo Vaz Perez, MD, PhD,^{*3}Rioko Kimiko Sakata

ABSTRACT

Background: Although exercising is common among the multidisciplinary approach, but its analgesic effect is still controversial. The purpose of this study was to evaluate the analgesic effect of an exercise program through a booklet for people with chronic non-specific lower back pain, under the direction of a physiotherapist or as an entirely self-directed program.

Methods: A prospective and randomized study was done in 44 patients, with pain intensity greater than 3 by VAS. Patients in G1 received a booklet with the exercise program and once a week they had a physiotherapist's guidance while performing them at the pain care center, while patients in G2 received just the booklet and once a week they went to the pain care center to answer some questionnaires. All patients were expected to perform the exercises once a day at home. There were evaluated pain intensity and quality of life before the treatment, after 6 and then 12 weeks. Acetaminophen could be used as necessary.

Results: Pain intensity was lower in G1 than in G2, and there was a significant reduction in pain intensity in G1 but not in G2. G1 patients needed less acetaminophen than the patients in G2. Quality of life was higher in G1 than in G2.

Conclusions: the patients showed a better outcome (pain intensity, quality of life, and less acetaminophen intake) when the stretching and strengthening exercise program was performed under the direction of a physiotherapist, compared to the patients who had an entirely self-directed exercise program for chronic non-specific lower back pain.

Keywords: low back pain, non-specific, physiotherapy, exercises, orientation, booklet

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CORRESPONDING AUTHOR

^{*3}Rioko Kimiko Sakata

Rioko Kimiko Sakata- Rua Três de Maio 61,
Vila Clementino, São Paulo,
SP; CEP 04044-020

¹Physiotherapist, Federal University of São Paulo- Rua Botucatu 593, São Paulo.

²Pain Clinician, Federal University of São Paulo- Rua Botucatu 593, São Paulo.

INTRODUCTION

Lower back pain is one of the most common causes of disability and has a lifetime prevalence of 60-85%^{1,2,3}, with a point of prevalence in about 15% of the adults.^{1,4,5} The majority of lower back pain complaints (90%) have no identified specific cause.^{1,3,5} Although no anatomical changes occur, non-specific lower back pain can limit everyday activities, leisure pursuits and also result in disability, which can increase the cost to the society.^{1,2,5}

Due to the variety of the involved factors, there is no therapeutic technique that is effective for all patients. Although the chronic lower back pain is increasingly recognized as a complex syndrome with multifactorial etiology, the pathogenic mechanisms leading to the development of a chronic pain in this condition remain poorly understood. Lack or excess of physical exercises can lead to a damage of the musculoskeletal components.⁶ Many treatments are employed, but the results of the effectiveness of interventions can vary.

There are many documented exercises that treat lower back pain⁷⁻¹¹ and the patients are often instructed to do the exercises. Although exercising is common among the multidisciplinary approach, but its analgesic effect is still controversial. In a review of the exercises for non-specific lower back pain, the authors showed that the pain reduction is small but significant.¹² In patients with non-specific lower back pain, exercising at home produced a greater effect than the use of anti-inflammatory drugs.¹³ A different article showed that exercising seemed to be effective in reducing the pain and improved the function in those with chronic lower back pain, but it was a small effect.¹⁴ Exercising can cause the opposite effects of nitric oxide, prostaglandin inhibition and increase the production of endogenous opioids.^{15,16,17} However, other studies found no additional effect with a combination of the exercise program for patients with non-specific lower back pain.¹⁸⁻²¹ In another review, there was a lack of evidence on the efficacy of the exercises.²² More studies are needed in order to evaluate the effects of exercise in patients with chronic non-specific lower back pain.

The purpose of this study was to compare the analgesic effect of stretching and strengthening exercises from a booklet, which could be performed both under the supervision of a physiotherapist in a pain care center or at home without any supervision. The exercises should be performed once a day for chronic non-specific lower back pain.

METHODS

After approval from the Ethics Committee (1871/07) and the written consent from the participants, this prospective randomized trial was conducted to investigate the efficacy of the guidance through a booklet of exercises in patients with low back pain. The trial was registered at ClinicalTrials.gov with number NCT00986505.

There were included 44 adult patients with non-specific chronic low back pain, (more than 3 months) with a pain intensity greater than 3 by VAS (visual analogue scale). The exclusion criteria: renal, gastrointestinal, rheumatologic diseases, current treatment with other types of physical therapy, cognitive impairments, and pregnancy. Radiological examination (X-ray) was performed to exclude patients with structural spinal lesions.

A researcher who wasn't involved in any other study procedures randomly allocated the patients into the physiotherapist group (G1) or the control group (G2), through the Randomizer® computer program. The participants were allocated by opaque consecutively numbered sealed envelopes. The researcher just opened the envelope on the day when the study started. There was used an information booklet describing the physiotherapy modalities.²³⁻²⁵ All participants received a booklet with different types of a standardized simple exercise program, that described exercises designed to stretch and strengthen back and abdominal muscles, to be performed at home. The booklet included a sit-up exercise for trunk flexor muscles and an extension exercise for trunk extensor muscles, stretch abdominal and back muscles, iliopsoas, gluteal muscles, and hamstrings. The exercises focused mainly on increasing overall physical activity and spinal mobility. Once a week, during 12 weeks, the exercises were administered by a physiotherapist at the pain center for G1 patients, individually. Patients in G2 didn't have any assistance from the physiotherapist and needed to follow the booklet instructions at home, once a day. They also had to answer the questionnaires once a week, at the pain care center. All G1 and G2 participants should perform the exercises for 15 minutes every day at home. Appropriate body mechanics were instructed using the booklet with pictures.

Pain intensity and quality of life were the first measured outcomes in this study. Pain intensity was evaluated by using a 10cm visual analog scale (VAS). The quality of life was evaluated by SF-36 questionnaire. The answers were recorded before the treatment start, 6 weeks and then 12 weeks after the beginning of it (T0, T6 and T12, respectively). The interventions were

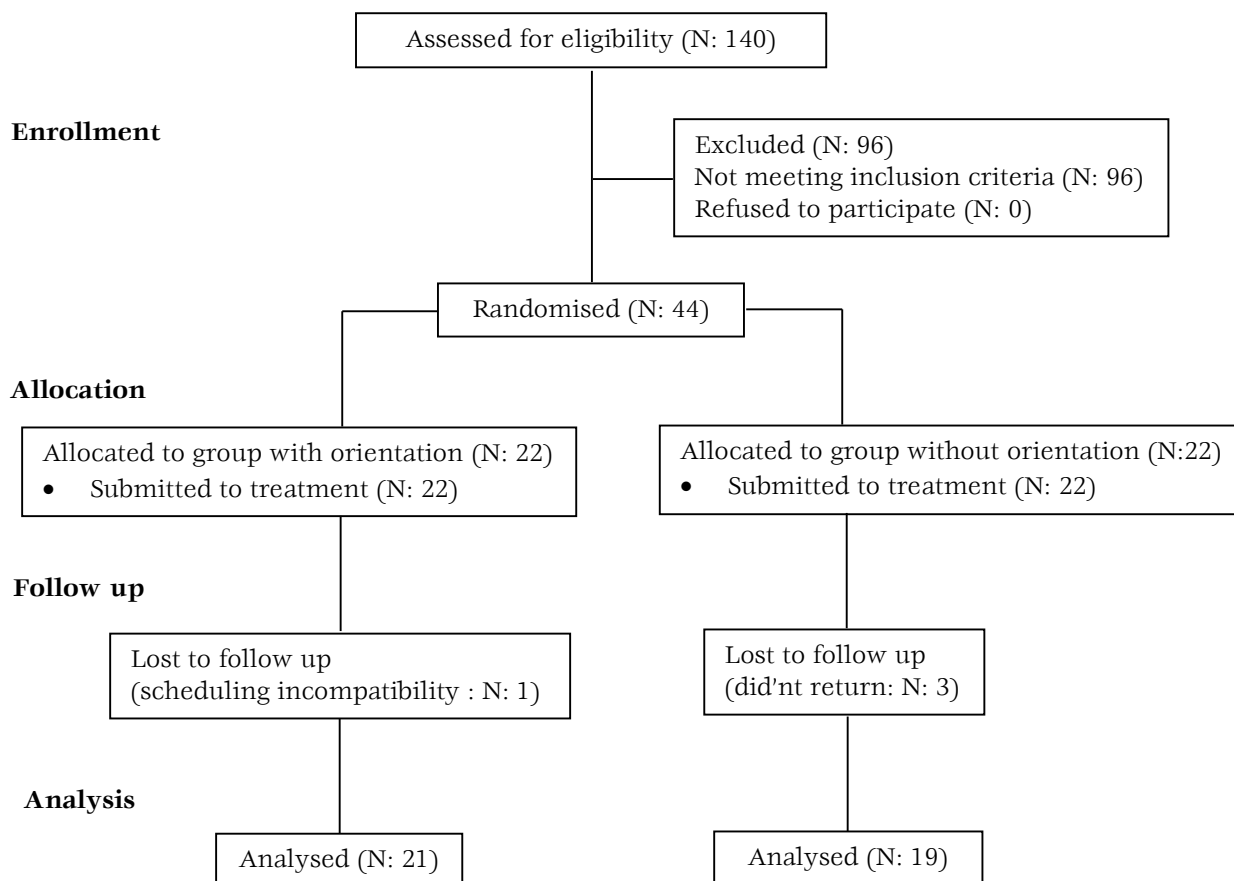
administered by one researcher while the assessment of the outcome was made by another one. Side effects were recorded as well. Acetaminophen 500mg per dose as supplement analgesic (up to 4 g/day) could be used if necessary and recorded on a form by the patient.

For sample calculation and for the analysis of the results was used the SPSS 15.0 for windows[®]. Based on the preliminary examination²⁶, we estimated

the standard deviation (SD) group by VAS score to 2.0. A difference of at least 3 out of 10 on VAS scale score was considered significant. For a power of 0.95 and alpha level of 0.05 a sample size of 16 patients in each group was calculated as appropriate. Students t-test was used to compare patient age, while chi-squared tests were used to compare gender and analgesic supplementation. A Mann-Whitney test was used to compare pain intensity and quality of life.

RESULTS

Figure 1: Consort Flow Diagram



Forty four patients were included in this study, but 4 dropped out during the treatment period: 1 patient from G1 and 3 from G2 (found in Consort Flow Diagram; Figure 1). The recruitment was done between october 2007 and march 2011. There was no difference in demographic data of the patients between the groups (Table 1).

Table 1: Demographic data

		G1 (N = 21)	G2 (N = 19)	P
Gender	M	6 (28.6%)	7 (36.8%)	0.577 ¹
	W	15 (71.4%)	12 (63.2%)	
Age	Years	54.4 ± 12.6	52.5 ± 17	0.688 ²
Weight	Kg	74.6 ± 16.3	80.5 ± 18.6	0.360 ²
Height	Cm	1.7 ± 0.1	1.6 ± 0.1	0.113 ²

G1: with orientation G2: without orientation; alpha level 0.05; ¹: chi-square test; ²: Student T test.

Table 2: Pain intensity by VAS (cm; mean ± SD)

Times	G1 (N = 21)	G2 (N = 19)	P
T0	5.6 ± 2.0	6.0 ± 2.3	0.992
T6	2.6 ± 2.0	4.8 ± 2.5	0.034
T12	1.5 ± 1.6	5.1 ± 2.6	0.001
P	< 0,001	0,179	

G1: with orientation G2: without orientation; T0: before treatment, T6: after 6 weeks; T12: after 12 weeks; Mann-Whitney test.

Table 3: Quality of life (SF-36) (mean ± SD)

Domains	Times	G1	G2	P
Functional capacity	T0	54.2 ± 16.7	55.7 ± 25.8	0.6161
	T6	68.0 ± 18.6	55.2 ± 22.6	0.0653
	T12	74.2 ± 19.6	52.6 ± 23.2	0.0022*
Physical aspects	T0	30.0 ± 33.1	44.7 ± 40.4	0.2884
	T6	68.0 ± 32.4	47.3 ± 42.4	0.1420
	T12	80.0 ± 26.4	48.9 ± 37.9	0.0106*

Pain	T0	45.8 ± 22.4	41.0 ± 15.9	0.5418
	T6	60.9 ± 18.3	43.4 ± 15.6	0.0085*
	T12	75.7 ± 15.8	45.0 ± 15.0	<0.000*
General state of health	T0	62.2 ± 16.4	63.9 ± 19.8	0.8284
	T6	72.7 ± 19.0	66.9 ± 18.2	0.3226
	T12	8.7 ± 17.9	66.7 ± 18.0	0.0395*
Vitality	T0	51.0 ± 14.5	48.7 ± 15.9	0.5506
	T6	64.7 ± 14.0	51.0 ± 15.0	0.0147*
	T12	67.3 ± 17.0	50.1 ± 15.2	0.0016*
Social aspects	T0	82.1 ± 20.0	58.7 ± 18.9	0.2296
	T6	56.8 ± 23.6	62.4 ± 18.4	0.0630
	T12	62.4 ± 18.4	58.7 ± 18.9	0.0025*
Emocional aspects	T0	66.4 ± 36.0	68.3 ± 26.0	0.9565
	T6	75.3 ± 33.6	73.6 ± 26.2	0.6918
	T12	80.9 ± 32.2	71.9 ± 27.8	0.2676
Mental health	T0	52.7 ± 8.3	54.5 ± 14.0	0.7244
	T6	56.9 ± 12.1	57.5 ± 14.1	0.8283
	T12	61.6 ± 11.2	55.5 ± 13.4	0.1039

G1: with orientation G2: without orientation; T0: before treatment, T6: after 6 weeks; T12: after 12 weeks; alpha level 0.05; *: statistically significant difference; Mann Whitney test

Pain intensity was lower in G1 than in G2 at T6 and T12, and there was a significant reduction in pain intensity in G1 but not in G2 (table 2). G1 patients needed less acetaminophen (38.1%), statistically significant, than the patients in G2 (79.0); ($P = 0.009$, Chi-squared test). Quality of life was higher and statistically significant in G1 in terms of functional capacity (T12), physical aspects (T12), pain score (T6 and T12), general state of health (T12), vitality (T6 and T12), and social aspects (T12) (Table 3). No side effects associated with acetaminophen, such as epigastric discomfort, were observed, nor with the exercise program (pain).

DISCUSSION

In this study, when the exercise programs were performed under the supervision of a physiotherapist, the pain intensity was lower, less acetaminophen intake was needed, and there was a better quality of life, compared to the patients who had an entirely self-directed exercise program, for chronic non-specific lower back pain.

The patients with anatomical alterations were excluded because there are many types and severity of lesions that cause different intensity of pain. Patients with diseases that alter the drug metabolism or excretion which can modify the results were excluded as well.

Non-specific low back pain was chosen for this study because it is a salient health problem due to its high prevalence and strong association with disability. Diagnostic triage is used to distinguish those patients with non-spinal or serious spinal disorders from those with pain of musculoskeletal origin, through history and examination, with

particular emphasis on the so-called red flags. The red flags consistently reported in the published work include weight loss, previous history of cancer, night pain, age over 50 years old, violent trauma, fever, saddle anaesthesia, difficulty with micturition, intravenous drug misuse, progressive neurological disturbances and use of systemic steroids.^{3, 5} Only patients with non-specific lower back pain were selected because the manifestation of different types of back pain would make the interpretation of the results more difficult. The number of selected patients was higher than the number of the indicated ones by the power calculation to ensure sufficient power.

Patients with non-specific chronic lower back pain are typically prescribed a regimen of regular physical exercises to improve pain and function, increase workability and prevent pain recurrence.

In some treatment studies of chronic lower back pain, exercise programs are strongly recommended to improve chronic non-specific lower back pain, preserve workability, and prevent pain recurrence.^{1,14,27} In a review of treatments for chronic lower back pain, exercise was a consistent recommendation.²⁷ Some authors have found that exercises are effective for patients with non-specific lower back pain, but they could not conclude what type of exercise is the most effective or comparatively more effective.^{3, 26, 28, 29}

Strengthening exercises are considered effective for muscle activation, endurance and strength. In a separate study, both general exercises and trunk stabilization exercises promoted a positive effect. However, the combination of the two types of exercise maintained the benefits for greater periods of time.³⁰ This study used a combination of exercises within the limits of the patient's pain threshold and range of motion.

The results indicate that the combination of exercises is the best choice for a successful rehabilitation and for preventing recurrences. In one review article, the results showed that combining aerobic exercise with stretching and strengthening was more effective than only stretching or strengthening.³¹

The duration of the exercise, as directed by the booklet under the supervision of a physical therapist, was 15 minutes, following the model of previous studies⁹. However, studies vary in exercise duration and other studies have tested exercise periods ranging from 45 to 60 minutes per session.^{30, 32}

Although the exercise duration was short, the 15 minutes spent on exercising were enough to reduce the pain intensity. In this study, the

exercises were performed every day, based on other similar studies.^{14, 23} Encouraging patients to visit a pain clinic in response to their symptoms may promote a more rapid effect, but it can complicate the treatment, resulting in work absenteeism beyond the time required to visit the clinic.

The follow-up period of the study was 12 weeks, like other similar studies, which ranged from 4 to 12 weeks.^{23, 32} The tools used for the outcome measurement are easy and valid for studies.

In order to obtain a satisfactory result, patients must adhere to the treatment, but it doesn't happen always.³³ The lack of treatment adherence is a limiting factor when exercising at home.³⁴ When the patient performs the exercises, good results are usually obtained.^{23,34} The compliance depends on the patient's enjoyment of the type of exercise, the number of prescribed exercises, and professional supervision. The adherence to the prescribed exercises is usually low, what requires the supervision of a therapist. The patients have more benefits when they are supervised by a qualified professional.³¹ Another important factor in maintaining the patient adherence is the adaptation of the exercise program to the patients' physical conditions in order to avoid the exacerbation of pain and the treatment abandonment.³⁵

The exercises were based on studies that oriented stretch and strengthen as the primary set for lower back pain.^{13, 14, 20, 24}

Both groups received the same booklet but there were less dropouts in the group monitored by the physiotherapist, probably because the patients had an additional incentive to keep the treatment. This result shows that the guidance provided through the booklet had less influence on the patient's decision to keep the treatment than the additional incentive.

Performing exercises under the guidance of a physiotherapist also improves the quality of life.¹⁰ In this study, a greater improvement was achieved in the group that had the professional guidance during the exercise. This result may reflect the patient's difficulty to understand how to perform the exercises correctly, but it also may be the result of low adherence in reading the booklet in the first place. Among the patients treated for chronic non-specific lower back pain, up to 60% reported little or no adherence to the home exercise programs. The adherence rates are typically low for treatments that require long-term self-management.^{34, 35} Patient compliance is necessary for these home exercise programs to be successful.

Physiotherapist and patient are involved in different interactive dimensions, and perform duties associated with the roles that are granted to them in the therapeutic process, and it includes quality of life. The treatment was designed to keep the specifics of training in physical therapy without omitting a humanizing perspective.

In this study, such as in other reaserch, we observed a higher prevalence of lower back pain among females. Possible explanations for this include anatomical and functional differences between men and women.²

Numerous attempts have been made to isolate factors that influence compliance. In order to improve the chances of adherence with an long term exercise program, some issues need to be addressed, such as following a simple regime, setting attainable goals, the patient's understanding of the importance and benefits of the exercise; and regularly follow up with a healthcare provider, such as a physiotherapist to provide the encouragement and to make adjustments to the regimen.³⁶ A review revealed over 200 factors that may be related to the patient compliance. These factors include sociodemographic variables, accessibility of setting, patient attitude, and type of regimen.²⁵

In conclusion, the booklet stretching and strengthening exercises performed with a physiotherapeutic supervision once a week and also performed once a day at home showed a better effect compared to those performed by the patientes alone at home in: pain intensity, quality of life, and supplementation of paracetamol in patients with chronic non-specific lower back pain.

CONCLUSIONS

The patients showed a better outcome (pain intensity, quality of life, and less acetaminophen intake) when the stretching and strengthening exercise program was performed under the direction of a physiotherapist, compared to the patients who had an entirely self-directed exercise program for chronic non-specific lower back pain.

Limitations

There is no way to ensure the compliance of the patients at home. It's not possible to know whether the patient can do the exercises. Some methods of measuring compliance for drug studies are pill counts and blood traces, but it is very difficult to evaluate it if the patient is exercising at home. In studies with exercises at home, the assessment of the effect rely on the patient's self-report. It may include the use of a questionnaire, a patient diary (eg, log sheet), or an interview.

The major limitations were the difficulty of being a double blind study, limited follow-up, and adherence in performing the exercises at home. With exercises it's impossible to conduct a double-blind study like that one using identical drug and placebo.

We didn't measure the satisfaction of the patients who were doing the exercises on their own or guided by a physiotherapist and dropout in the longitudinal randomised controlled trial is common and potential source of bias in terms of evidence based medicine.

Recommendations for future research

A future research is recommended to investigate methods of improving compliance with home exercise programs and assessing the impact of these interventions. As compliance is the key point of the exercise program at home, its measurement is necessary.

Although the self report methods may tend to overestimate compliance, they are still the most cost effective, feasible, and frequently used available methods for assessing compliance with an exercise regimen.

Good communication and backup are necessary to improve compliance and also produce a better outcome. When the booklet is a handout, there should be proper information about the importance of lower back pain exercises. Patients should have an easy way to get help in case they have any difficulty to understand the booklet.

Factors that influence the results of the treatment should be evaluated as well.

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