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Supervised and unsupervised physical exercises program in the treatment of chronic back pain: randomized clinical test

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ABSTRACT

Purpose: Evaluate the efficacy of an exercise protocol for the rehabilitation of chronic low back pain under supervision and unsupervised in pain reduction. *Methods:* Randomized clinical trial. The subjects performed Exercise Protocol for Chronic Pain of Spine during 12 weeks. There were two groups: Group A Supervised care and Group B performed the same protocol in an unsupervised manner. *Results:* There were reductions in the pain scale after 12 weeks of intervention in both the groups. In the comparison intergroups, there was no statistically significant difference. Regarding the instruments of quality of life all domains report superiority in Group A compared to Group B. Flexibility is superior in Group A. Group B presented better ability to walk . In the back limitations due to low back pain, both groups had less limitation in the back after 12 weeks of intervention. Functional capacity of the spine in both groups improved. Regarding the depression and anxiety scores Group A had lower rates. *Conclusion:* Both rehabilitation protocols are effective, showing no significant differences between the groups.

Keywords **-** Back school, lumbar pain, quality of life, physical exercise, unsupervised exercises.

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I. INTRODUCTION

Low back pain is a worldwide public health problem, affecting 50% to 85% of the population that is afflicted by an acute episode at some point in their life. Chronic low back pain is defined by the persistent incapacitating pain in the lumbar spine, with or without radiation to the lower limbs, for more than 12 weeks [1, 2, 3]

A study by Ferreira et al [4], aimed to determine the prevalence of back pain in a population-based sample of adults, verified possible associations with demographic, socioeconomic, behavioral and health variables. Where the authors conclude that the prevalence of back pain is high. Where low back pain was more frequent, it could generate greater demand and high costs to the national health system (NHS). Such a problem requires identification of its causes and the establishment of prevention and rehabilitation strategies. The National Health Interview Study [5] 2002 found that 26.4% of the 30,000 participants had experienced at least one full day of back pain in the past three months.

Chronic low back pain (CLBP) is defined as pain or discomfort below the costal margin and above the lower gluteus, with or without irradiation of leg pain, defined as persistent pain for at least 12 weeks, being the non-specific or mechanic low back pain the anatomical-clinical form of presentation and the most prevalent of the causes of mechanical and degenerative nature. Several structures in the posterior part, including the joints, the intervertebral discs and the connective tissues, can contribute to the aggravation of the symptoms [6]. The recommendations are given in relation to "unspecific" chronic low back pain, that is low back pain that is not attributable to a specific cause, for example, infection, tumor, osteoporosis, fracture, structural deformity, inflammatory disorder (e.g. ankylosing spondylitis, radicular syndrome, or cauda equina syndrome) [7, 8].

When the pain is continuous over a long period, it can lead to serious consequences in several

daily aspects of an individual's life, including generating disability, thus affecting one's quality of life [9]

Among the most promising intervention strategies for CLBP is physical exercise, which is often associated with a long series of health benefits. An active lifestyle, to some extent, protects against CLBP in childhood, during working years and in the elderly. Physical exercise is a well-established treatment for CLBP patients and it is among the approved clinical rehabilitation guidelines and is recommended as self-management strategy [1]. Many studies have shown that exercise can improve torso strength, flexibility, endurance, aerobic conditioning and stabilization [10].

Physical exercise may also reduce the recurrence of low back pain and its duration. Strengthening exercises are effective in relieving the symptoms of chronic low back pain. Home exercise as well as intensive group training programs have been referred to in the decreasing of pain, playing an important role not only from the physiologically point of view, but may also have positive psychosocial consequences [11, 12]

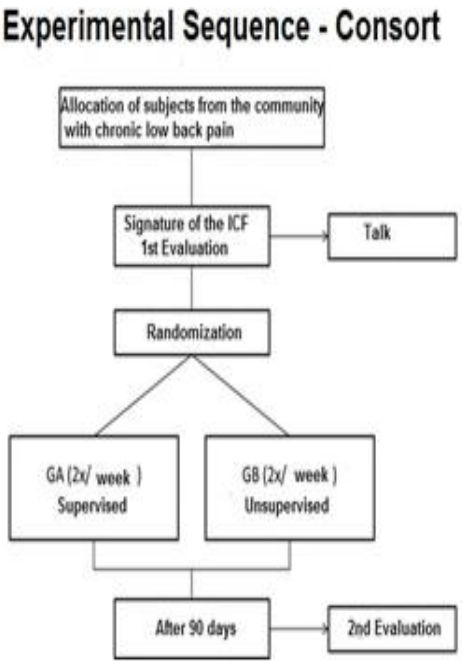
Different methods are used for prevention and treatment of CLBP. In this sense, the Back School emerged in 1969. This program has as its main characteristics to teach individuals to care for their spine through explanations and notions of anatomy and biomechanics, where practical exercises are introduced for the purpose of muscle strengthening and stretching [13]. The success of the low back rehabilitation programs depends on the adherence of patients. Commuting problems, lack of time and financial resources are determining factors for non-compliance with supervised rehabilitation programs. Unsupervised training [14] comes as an attractive, low-cost alternative that is characterized by a method whereby the individual is able to manage his time and exercises while being supervised from a distance (telephone calls, mobile apps, whatssapp and one-on-one meetings).

Thus, our objective was to evaluate the efficacy of an exercise protocol for rehabilitation of chronic low back pain under supervision compared to the same protocol without supervision in relation to pain, and as secondary objective to evaluate the quality of life, functional capacity and flexibility.

II. METHODS

Randomized Clinical Trial (NCT 02703402). Participants were selected through four public appeals in the local media. Data collection was performed at the Hospital das Clinicas de Porto Alegre (HCPA), from March 2016 to August 2017.
Men and women in the age group of 30 to 55, whose pain had no irradiation of the lower limbs and presented evolution of more than 12 weeks were selected. In addition, the Visual Analogue Scale (VAS) was used to classify the level of pain that was above three (moderate).

Participants who presented osteoarticular problems of lower limbs, post-surgery and with anesthetic block were excluded. Individuals with comorbidities that prevented them from participating as well as those who had rheumatic diseases, recent fractures, tumors, pregnant women, smokers and physical activities practitioners in general. Experimental sequence can be visualized in fig 1.
Figure 1



III. INTERVENTIONS

Participants who were interested and met the inclusion criteria went through an initial interview, where they were informed about the study. After the criteria were met, the informed consent form (ICF) was presented and read. Doubts were widely discussed and the necessary explanations were offered. After signing the forms, the questionnaires were applied; a 6-minute walk test and the sit-and-reach test were performed in one of the institution's corridors and in the physiatry and rehabilitation sector, respectively. After all the tests, they attended a lecture with orientations about posture and back pain, the importance of exercise and explanations about the study. After that, they were randomly allocated to one of the two study groups (Group A and Group B). The groups performed the exercises twice a week for 12 weeks. The randomization was generated by a random table of numbers by the program *SPSS 18.0*, with uniform distribution and division into two groups. The codes generated were

distributed in brown envelops sealed, numbered in sequence. The responsible did not participated in the other stages of the study, and the outcome evaluators were blinded for the groups.

The exercises were composed of muscle strengthening, mobility and stretching presented at fig 2. The manual with the exercises was created by HCPA Physiatry and Rehabilitation department with the purpose of rehabilitating patients with chronic back pain. The members of Group A participated in meetings supervised by Physical Education Professionals, who used the manual as a reference during the follow-up. The meetings were held in the hospital's Physiatry and Rehabilitation department, in a group or individually. The participants of Group B received the printed manual containing the same exercises of Group A, for unsupervised performance. Before starting, the participants were individually guided by one of the Physical Education Professionals. During the program, they were accompanied by weekly calls and a monthly meeting in order to clarify doubts about the execution of the exercises. Participants from both groups were added to whatsApp groups to receive reminders and facilitate the communication among the professionals who accompanied the groups

Figure 2. Description of joint mobility, muscle strengthening and stretching exercises (Total 20-30 min)

Position	Exercise	Repetition*
Sitting on a bench, feet resting on the ground and back straight.	Bring the ear toward the shoulder, go back and correct, repeat to the other side	20x
	2.Turn head by looking over shoulder, stop in the middle to correct, repeat to the other side.	20x
	3. Bring the chin towards the chest, go back and correct.	20x
	4. Lift shoulders and relax.	20x
	5. Rotate both shoulders backward.	20x
	6. Rotate both shoulders foward.	20x
	7. Tilt the trunk sideways, go back and correct, repeat to the other side.	20x
	8.Loosen the trunk to the front by flexing the spine, return to the initial position starting the movement by the waist and finishing by the head.	20x
	9. Take both outstretched arms towards back and relax.	20x
	10. Raise one arm forward and the other backward by turning the head to the back arm.	20x
Lying on the stomach, arms at the side of the body, knees bent and feet resting on the ground.	11. Contract the abdomen and buttocks by forcing the low back against the ground.	20x
	12. Contract the abdomen and buttocks by lifting the hips off the floor, lower them slowly, first the back and then the buttocks.	20x
	13. Pull both knees over the abdomen, keeping the shoulders relaxed, return without releasing the legs.	20x
	14. Put your hands on the nape of the neck: inhale, raise your torso exhaling slowly, return inhaling.	20x
Sitting on the floor.	15. With one leg flexed and the other stretched, back straight. Move both hands toward the foot of the leg that is extended. Keep position for 20 seconds and relax. Repeat with the other leg.	1x
Hands and knees position.	16. Extended elbows, raise low back and relax, mobilizing the hip.	20x
	17. Sit on the heels and stretch the torso to the front, extending the arms. Hold for 20 seconds and release.	1x

Figure 2

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IV. DATA COLLECTION INSTRUMENTS

1 Identification Questionnaire. Socio-demographic characteristics.

2 Roland-Morris Questionnaire. Evaluates limitations in the back due to low back pain. Composed of 24 questions selected to cover a range of aspects related to activities of daily living, to pain and function. This questionnaire has a score of 14, that is, individuals evaluated with a score greater than 14 have disability [15].

3 Visual Analog Scale for Pain. Scale consisting of a ruler divided into eleven equal parts, numbered successively from 0 to 10 [16].

4 Medical Outcomes Study 36 - Item Short-Form Survey (SF-36). To evaluate the quality of life. Questionnaire with 36 items that measure eight domains (variables): functional capacity, physical aspects, pain, general health state, vitality, social aspects, emotional aspects [17].

5 Oswestry Index - Functional Spine Capacity: Initial Oswestry Disability Index (ODI) (version 1.0) includes 10 sections of questions that assess daily activities [18].

6 Six Minute Walk Test (functional capacity). The six minute walk test measures the distance (meters) that the individual can walk for 6 minutes, on a smooth and flat surface [19].

7 Wells Bank. The individual is seated. With the legs extended the person is oriented to move the marker on a millimeter surface (sit and reach test) [20].

8 Depression: Promis - Depression - Short Form 8-A Anxiety: Promis - Emotional Distress - Anxiety -Short Form 8-A. Self-administered questionnaire of 16 questions related to feelings of distress, anxiety and depression. These questionnaires were validated for the Portuguese language by De Castro et al. (2014) and their scores vary from 1 to 5 in each question, where 1 represents the lowest score and 5 is the maximum score for the question, referring to the events of seven days prior to the application of the questionnaire. Their final score is reached after counting the gross value resulting from the questionnaire responses being transformed into a T-score value, and from that value individuals are classified as normal (up to 55), with mild depression / anxiety (55 to 60), moderate depression / anxiety (60 to 70) and severe depression / anxiety (over 70) [21, 22].

9 Drug Use Control Worksheet. For the evaluation of drug use.

10 Home Exercising Control Worksheet.

[1] Statistical planning

The data collected were analyzed using the statistical software SPSS version 18.0 IBM Company.

The categorical variables were presented by absolute frequencies and percentages. Continuous variables with normal distribution were presented by average and standard deviation and those without a normal distribution as median and interquartile range (IQR). In order to compare quantitative variables within the same group, before and after the intervention, the model of generalized estimating equations (GEE) with multiple comparisons adjusted by BONFERRONI was used to the pre and post variations between control and intervention were compared through analysis of covariance (ANCOVA) always controlling by basal values of each variable. Normality was assessed by the SHAPIRO-WILK test, being considered $p < 0.05$ for statistical significance in the tests.

[2] SAMPLE SIZE

From the study by Zanini et al. [23], where a standard deviation of 1.82 was found in the exercise group and 1.73 in the control group, considering a power of 80%, a significance level of 5% to be able to detect a difference of "2" points in the intra-group visual pain scale, 14 participants in each group (total n = 28) were required.

The sample size data were calculated using the statistical program WINPEPI V11.43.

V. RESULTS

Participants allocation can be visualized in fig 3.

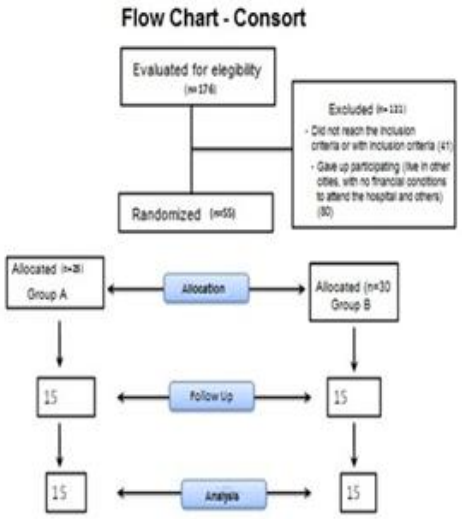

Figure 3

Table 1 describes participants clinical characteristics with chronic low back pain. The clinical trial was performed between March 2016 and August 2017. Thirty patients were included, 15 in Group A (Supervised) and 15 in group B (Unsupervised). Males accounted for 66.7% of group A and 60% of Group B. Regarding education, 73.3% of participants in both groups had above 11 years of schooling. As regards to the continuous use of drugs for pain 26.7% in Group A compared to

13.3% in Group B. Group B had higher BMI than Group A according to table 1.

In table 2 the results regarding to Pain (VAS) pre and post intervention can be visualized.

Regarding quality of life, we observed that all domains in both groups showed improvement when compared to pre and post intervention evaluations. However, when analyzed if there was difference between the improvement of Group A compared to improvement of Group B, no domain had a statistically relevant difference. Two other important variables related to the limitations of low back problems are levels of flexibility, presenting numerically superiority in group A, but with no statistical relevance. The physical ability to walk presented better performance in group B, according to table 3, but the statistical analysis did not confirm this difference as significant.

Table 4 presents Instruments that assess the limitations of the back due to low back pain, where both groups had less limitation in the back after 12 weeks of intervention. The functional capacity of the spine in both groups improved post-intervention. As for depression and anxiety scores, group A reported lower indices when compared to group B, but it is not statistically relevant.

Table 1 – Sample characteristics

Characteristics	Group A - Supervised - (n=15)	Group B – Unsupervised - (n=15)
Gender- No. (%)		
Male	10 (66.7%)	9 (60%)
Female	5 (33.3%)	6 (40%)
Education (years of schooling) – No. (%)		
0 a 8	1 (6.7%)	1 (6.7%)
9 a 11	3 (20%)	3 (20%)
> 11	11 (73.3%)	11 (73.3%)
Continuous use of pain medications No. (%)	4 (26.7%)	2 (13.3%)
BMI (average ± SD)	25.2 ± 8.6	28.7 ± 6.3

Table 1

Table 2 – Results related to pain (VAS)

Group	Pre (average ± SD)	Post (average ± SD)	P Value
A (Supervised)	6.8 ± 1.42	1.67 ± 1.95	<0.0001
B (Unsupervised)	7.4 ± 1.5	2.8 ± 2.6	<0.0001
		Difference	
Comparison between Groups (A-B)*		-1.311	0.140

Table 2

Table 3

Table 3 - Results related to Quality of Life, Flexibility and Functional Capacity

Findings	Group A - Supervised			Group B - Unsupervised			Comparison between groups A-
	Pre (average ± DP)	Post (average ± DP)	Difference (95% CI) §	Pre (average ± DP)	Post (average ± DP)	Difference (95% CI) §	Difference (95% CI) §
SF - 36							
Functional Capacity	61.5 ± 21.15	84 ± 15	25.1 (14.7 a 35.5)	52 ± 18	76 ± 20.8	21.2 (11.5 a 30.8)	3.94 (-10.4 a 18.3)
Physical Aspects	48.3 ± 38.3	88.3 ± 26.5	46.8 (27.7 a 65.9)	31.6 ± 38.3	73.3 ± 42.7	34.8 (15.7 a 53.8)	12.0 (-15.2 a 39.3)
Pain	37.4 ± 13.9	71.5 ± 19.2	35.4 (24.5 a 46.3)	32.8 ± 13.7	61.2 ± 19.4	26.1 (15.6 a 36.6)	9.2 (-6.0 a 24.6)
General Health State	61.5 ± 24.11	73.6 ± 21.6	8.4 (0.5 a 16.3)	68.6 ± 16.02	84.9 ± 9	18.5 (9.9 a 27.2)	-10.1 (-21.9 a 1.5)
Vitality	47.3 ± 22.4	74 ± 17.9	28.8 (20.3 a 37.3)	41.3 ± 19.4	67.8 ± 15.8	24.8 (16.0 a 33.5)	4.0 (-8.2 a 16.3)
Social Aspects	63.3 ± 24.7	83.3 ± 18	19.3 (9.1 a 29.4)	65.1 ± 26	79.1 ± 21.4	13.2 (2.7 a 23.7)	6.1 (-8.4 a 20.7)
Economic Aspects	50 ± 36.3	82.2 ± 27.7	33.6 (16.5 a 50.7)	42.2 ± 42.6	77.7 ± 37	33.0 (16.5 a 49.5)	0.61 (-23.2 a 24.4)
Mental Health	64.5 ± 24.6	83.4 ± 15.8	17.4 (9.5 a 25.3)	67.2 ± 21.8	79 ± 16.1	11.8 (3.3 a 20.3)	5.6 (-5.9 a 17.2)
Six Minute Walk Test	573.2 ± 53.2	598.5 ± 83.7	79.4 (36.6 a 122.1)	482.13 ± 92.0	583.6 ± 77.6	83.3 (40.6 a 126.1)	-3.9 (-66.3 a 58.5)
Wells Bank	15.9 ± 9.5	21.7 ± 8.9	5.7 (2.8 a 8.7)	16 ± 8.6	21.4 ± 8.3	5.2 (2.2 a 8.2)	0.546 (-3.6 a 4.7)

§ Adjusted for multiple comparisons: Bonferroni

Table 4

Table 4 - Results of Limitations and Functional Capacity of the Spine, Depression and Anxiety

Findings	Group A - Supervised			Group B - Unsupervised			Comparison between groups A-B§
	Pre (average ± DP)	Post (average ± DP)	Difference (95% CI) §	Pre (average ± DP)	Post (average ± DP)	Difference (95% CI) §	Difference (95% CI) §
Roland Morris	8.9 ± 5.8	1.6 ± 2.9	-7.9 (-9.9 a -5.9)	10.8 ± 5.5	4.0 ± 4.8	-6.1 (-8.1 a -4.1)	-1.7 (-4.5 a 1.0)
Owestry	45 ± 9.9	30.1 ± 9.4	-15.6 (-21.9 a -9.3)	48.5 ± 13.3	35.0 ± 16.3	-12.7 (-19.0 a -6.4)	-2.9 (-11.8 a 6.0)
Promis Anxiety	61.0 ± 5.4	52.8 ± 8.5	-8.0 (-12.2 a -3.8)	60.2 ± 4.7	54.4 ± 7.5	-5.9 (-9.9 a -1.8)	-2.1 (-7.9 a 3.6)
Promis Depression	56.5 ± 7.0	47.6 ± 7.7	-8.1 (-11.8 a -4.5)	52.0 ± 5.5	48.2 ± 7.7	-5.0 (-8.7 a -1.2)	-3.1 (-8.5 a 2.2)
§ Adjusted for multiple comparisons: Bonferroni							

VI. DISCUSSION

More than a third of the Brazilian population believes that chronic pain compromises habitual activities and more than three quarters considers chronic pain limiting for recreational activities, social and family relationships. The Back (Spine) school emerges in the seventies as an important alternative of rehabilitation under supervision, consisting of postural and educational exercises for the prevention and treatment of individuals with back pain, aiming to understand the relationship between posture habits and pain. Cassarotto Cols [24], evaluated the efficacy of the Spine School in N =15 patients, with frequency of 5 times a week, for eight months, finding no pain in 93% of the participants. More recently, Borges et al. [25], evaluated the effectiveness of the Spine school in N = 29 subjects pre and post intervention of 8 sessions, verifying 56,7% improvement in low back pain and 60% in physical function. Factors that are determinant for adherence to the rehabilitation process such as cost and time for commuting, work absence, distance from the rehabilitation center, inability of NHS services to meet patient demand, all contribute to the no continuation of the supervised programs. Remote supervised training appears as an important alternative for the adherence to the back rehabilitation programs.

Anar et al. [26] analyzed the relationship between adherence of remote supervised programs in terms of levels of pain, flexibility, finding as main results an adherence of 55% and a 2.7 points reduction on the pain scale.

Our findings compare with these results with some superiority in the reduction of low back pain (5 points in the VAS Pain scale after 12 weeks), in shorter periods of intervention than in the abovementioned studies, 8 months [1]. When we compared Supervised Group A versus Unsupervised Group B, we did not find significant differences between them, which seems to us that in this sample of patients that traditional training with supervision can be safely proposed and with important pain reduction with remote supervision. This factor seems very important in the current scenario of the National Health System, as it would help a larger number of patients to be evaluated, trained and generating lower costs.

When we observed our results regarding quality of life and low back limiting pain, evaluated by the SF36 and Roland Morris questionnaires, both groups presented important changes in the improvement on the quality of life and lower rates of pain limitation in relation to the low back after the intervention period. These findings are confirmed by Norris cols [27] in a six-week study in individuals with chronic low back pain, where there was a significant reduction of pain and in the disability generated by it, as well as improvement in the scores of quality of life in the group of subjects studied and 89% of patients considered pain intensity and functional disability acceptable.

Aerobic capacity was assessed in our study by the six-minute walk test. A submaximal test with good reproducibility and a cut-off point established by important studies such as Solvd [28], which had a distance of 300m as an important marker of higher mortality and re-hospitalization of cardiac patients. Our results demonstrate that our population of patients with low back pain had an acceptable walkability of 589.5 ± 83.7 m in Group A versus 583.6 ± 77m. These findings appear to be very positive in reducing the risk of cardiovascular diseases such as promoting greater oxygen intake and distribution in bone tissues and structures. Some studies reinforce this type of evaluation as important as that of Tritilanunt et al. [29], where an aerobic exercise program promoted greater pain relief after three months of intervention in patients with low back pain.

Another important result in our study was the improvement in the levels of flexibility after 12 weeks of intervention, where we did not find differences between the groups, with a significant

average increase of 5 cm in the sit and reach test in both groups. These results are similar to studies that demonstrate that in a few weeks of Stretching exercises, benefits were achieved in both mobility and pain reduction, such as that of Nogueira et al. [30], whom in only 7 sessions of Spine School had already shown 18% improvement in the flexibility levels of the torso posterior region and lower limbs. We believe that this study have important external validity, because its results suggest a form of treatment with distant supervision could contribute with the maintenance of activity levels, factor that helps in the course of treatment of low back pain, as well reduces the dependency rates of the National Health Service. Other positive factor is that our study stimulates the individual self-management in regards to the treatment and importance of the regular practice of physical exercise.

VII. CONCLUSION

We have concluded that the protocol with supervision, when compared to the one performed without supervision, showed that both are an important tool for the treatment of Chronic Low Back Pain in relation to pain, physical capacity, quality of life and flexibility, not finding a significant difference between the groups.

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Conflict of Interest Statement
No conflict of interest has been declared by the author(s).

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