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ORIGINAL ARTICLE

Motor control exercises and pain education in individuals with chronic nonspecific low back pain: randomized clinical feasibility trial

Exercícios de controle motor e educação em dor em indivíduos com dor lombar crônica inespecífica: ensaio clínico randomizado de viabilidade

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ABSTRACT

BACKGROUND AND OBJECTIVES: To investigate the feasibility of an intervention program in the context of Primary Health Care in the southern region of Brazil, through exercises and pain education, focusing on the management of chronic low back pain, and thus identify possible modifications that may be necessary before a definitive intervention.

METHODS: Randomized clinical feasibility study. 20 individuals with chronic low back pain were recruited. Participants were allocated into three distinct groups: 1) motor control exercises; 2) pain education approach; 3) the combination of these two interventions. The quantitative outcomes were: recruitment rate, acceptance to participate in the interventions and retention. In addition, the following criteria were assessed qualitatively or by online questionnaire: barriers to interventions, adherence to treatment, satisfaction with treatment, logistics, financial viability and human and material resources.

RESULTS: The total recruitment, acceptance and retention rates were 100%, 50% and 80% intra-group, respectively; acceptance and retention were 57% and 50% in group 1 and 85% and 100% in group 2. The satisfaction and logistics rated as "excellent" by the participants were: the content covered (66.7%), the availability of timetables (55.6%) and the material resources (66.7%). The main barriers encountered were work schedule compatibility, a greater number of sessions and inclement weather.

CONCLUSION: This research concluded that a clinical trial to evaluate the effectiveness of an intervention program using exercises and pain education in the management of chronic low back pain is feasible and justified, although some modifications are necessary.

KEYWORDS: Chronic pain, Low back pain, Feasibility studies, Public health.

RESUMO

JUSTIFICATIVA E OBJETIVOS: Investigar a viabilidade de um programa de intervenção no contexto da Atenção Primária à Saúde na região sul do Brasil, por meio de exercícios e educação em dor, com foco no manejo da dor lombar crônica, e assim identificar possíveis modificações que possam ser necessárias antes de uma intervenção definitiva.

MÉTODOS: Estudo clínico randomizado de viabilidade. Foram recrutados 20 indivíduos com dor lombar crônica. Os participantes foram alocados em três grupos distintos: 1) exercícios de controle motor; 2) abordagem educação em dor; 3) a combinação das duas intervenções. Os desfechos quantitativos foram: taxa de recrutamento, aceitação para participar das intervenções e retenção. Além disso, os seguintes critérios foram avaliados de maneira qualitativa ou pelo questionário online: barreiras nas intervenções, adesão ao tratamento, satisfação com o tratamento, logística, viabilidade financeira e recursos humanos e materiais.

RESULTADOS: As taxas totais de recrutamento, aceitação e retenção obtiveram como resultado, respectivamente: 100%, 50% e 80% intragrupos; aceitação e retenção tiveram como resultado no grupo 1: 57% e 50%; no grupo 2: 85% e 100%. Sobre a satisfação e logística, avaliadas como "ótimo" pelos participantes estão: o conteúdo abordado (66,7%), a disponibilidade de horários (55,6%) e os recursos materiais (66,7%). As principais barreiras encontradas foram compatibilidade de horário com o trabalho, número maior de sessões e intempéries climáticas.

CONCLUSÃO: Esta pesquisa chegou à conclusão de que um ensaio clínico para avaliar a eficácia de um programa de intervenção por meio de exercícios e educação em dor no manejo da dor lombar crônica é viável e justificado, embora sejam necessárias algumas modificações.

DESCRITORES: Dor crônica, Dor lombar, Estudos de viabilidade, Saúde pública.

HIGHLIGHTS

- Recruitment, retention and acceptance rates were satisfactory
- The findings on feasibility are pioneering in clinical studies and chronic low back pain
- Exercises and education in the management of chronic low back pain are feasible and justified
- The data presented will allow the proposal to be refined in future studies

INTRODUCTION

Low back pain (LBP) is classified as the most serious clinical condition in terms of years lived with disability. In 2020, LBP affected 619 million people worldwide. It is estimated that by 2050 this figure will exceed 800 million[1]. There are some serious causes of LBP (malignancy, vertebral fracture, infection or inflammatory disorders such as axial spondylarthritis) that require identification and specific treatment aimed at the cause, but these causes account for a very small proportion of cases and are classified as LBP of specific origin[2]. However, for more than 85% of LBP cases, the specific nociceptive source cannot be identified and is therefore classified as non-specific LBP[2,3]. In this respect, LBP is characterized by a series of biophysical, psychological and social dimensions that impair function, social participation and personal financial prosperity[2].

Persistent complaints for more than three months are considered chronic[4]. Because it is a very common clinical condition and difficult to treat, chronic non-specific LBP carries a high economic burden5. It is one of the main causes of consultations in primary and specialized care and is considered a public health problem[5]. In Brazil, there are few studies investigating strategies involving education and exercise for the treatment of LBP in primary care[6].

Exercise interventions are widely recommended to reduce pain and disability in individuals with chronic LBP[7]. There is no evidence that one type of exercise or approach is superior to another. Associated with exercise, pain education also promotes positive effects[7] and is a simple, low-cost and easily accessible treatment combination used by primary care professionals[6,8].

Much evidence suggests that individuals with LBP have impaired control and coordination of the trunk muscles, including the deep muscles[9]. Intervention through motor control exercises focuses on activating these muscles and aims to restore control and coordination. The choice of exercise for chronic LBP should consider the patient's preferences, as well as social determinants and socioeconomic status[10]. For this reason, motor control exercises are suitable to be carried out in the context of Primary Health Care (PHC), which prioritizes the use of low-tech resources.

Considering the high prevalence and its impact on public health, new intervention strategies are necessary and extremely relevant, especially in PHC, which is considered the gateway to ensure access to symptom management in public health. However, before conducting a clinical trial with an adequate sample and statistical power, feasibility studies are an essential preliminary step for the development and evaluation of complex interventions[11]. Thus, this study aimed to investigate the feasibility of an intervention program in the context of PHC in the southern region of Brazil, through exercises and education on pain in the management of chronic LBP, and thus identify possible modifications that may be necessary before a definitive intervention.

METHODS

This feasibility study followed the recommendations of the Consolidated Standards of Reporting Trials (CONSORT) 2010 checklist for pilot studies or feasibility trials[12] and was prospectively registered in the Brazilian Registry of Clinical Trials (*Registro Brasileiro de Ensaios Clínicos* - ReBEC), under registration number: U1111-1221-4106. This study was carried out at the School of Physical Education and Physiotherapy of the Federal University of Pelotas (*Escola Superior de Educação Física e Fisioterapia da Universidade Federal de Pelotas* - ESEF/UFPel), in partnership with the Basic Health Unit (*Unidade Básica de Saúde* - UBS) - School of UFPel. The Ethics Committee Involving Human Beings at UFPel approved the study project (opinion number: 5.717.390). All the participants signed a Free and Informed Consent Term (FICT) before taking part in this study.

Patients aged between 18 and 65 with a history of non-specific LBP in the last six months were included in the study. Participants with a previous history of rheumatic disease, tumors, major trauma, fracture or surgery in the lumbar region were excluded.

Participants were recruited by publicizing the study through post ers in community environments, social networks and referrals from professionals at UFPel's UBS School between March and April 2023. The sample size estimate was made to achieve the goals of the primary feasibility endpoints, and not to detect differences in the results of the secondary (clinical) endpoints, in accordance with recommendations for the development of feasibility studies[13]. Furthermore, in feasibility studies, sample calculations may not be appropriate[14]. An appointment was made by prior contact via messaging app. After signing FICT, the participants were assessed using questionnaires and specific tests which allowed sociodemographic and clinical data to be collected to characterize the sample.

Intervention procedures

The individuals were allocated through block randomization by a researcher unaware of the interventions, using a virtual random allocation sequence mechanism, dividing them into three distinct groups: 1) motor control exercises; 2) pain education approach; 3) a combination of these two interventions. The same researcher was responsible for maintaining the confidentiality of the allocation and for revealing it to the researchers responsible only at the time of the intervention. The researchers responsible for the interventions remained blind to the clinical outcome assessments.

In order to carry out the interventions, training was given by the teacher in charge to twelve undergraduate students, in four meetings lasting 2 hours each, in which the students received instructions on how to apply the questionnaires and evaluation tests and the stages of the intervention. The training covered aspects of pain education (identifying beliefs, addressing concepts of pain physiology and communication skills to assess understanding and discuss recovery).

The exercise protocol was presented with a theoretical basis followed by the students' practice in order to understand the progression through the different stages of the intervention, so as to maintain a standard in the sessions. The interventions were carried out in isolation (only exercises or only pain education, for example), so that the researchers applying them were unaware of the participants' allocation to the groups in this study (whether

the participant would only receive the intervention for which they were responsible or whether they would also be part of group 3, for example). The assessments and interventions were always carried out under the supervision of three teachers from the institution.

Intervention

The intervention protocol lasted five weeks, with simultaneous approaches and individual assessment of participants who had previously been blinded to the intervention. The interventions were carried out in person in the practical classrooms of the physiotherapy course and in the ESEF/UFPel sports hall.

Group 1 (exercise intervention) received the group intervention twice a week[15]. Group 2 (pain education) received the intervention individually, once a week[15]. The sessions lasted an average of 40 minutes each in both groups, according to the usual clinical practice[9] and the understanding of each participant. The proposal for group 3 was to combine the interventions of groups 1 and 2, with exercise twice a week and pain education once a week. The participants were assessed individually and the progression of the interventions depended on individual progress.

Motor control exercises

The exercise program was divided into three training stages, with a progressive increase in the level of difficulty. The first stage involved learning the isometric contraction of the transverse abdominis and multifidus muscles in the prone, supine and four-legged positions. To ensure correct activation of the transverse abdominis, the participants were told that the lower part of the anterior abdominal wall below the level of the umbilical scar must be pushed towards the spine for this muscle to act. Progressively, the participants were instructed to increase the hold time and the repetition of contraction to up to 10 repetitions of contraction x 10 seconds of hold. When the patients were able to perform this exercise and control their pelvic and lumbar movements, they moved on to the next stage.

In the second stage, the level of complexity was increased to functional exercises with coordination of the trunk and upper limbs, while maintaining trunk stability[16]. The patients were taught to perform abdominal co-contraction in different postures and functional activities: supine position with alternating elevation of the lower limbs (LL), "bridge" exercises, 4-support position with alternating elevation of the upper limbs (UL) and LL, squats with the lumbar spine resting on the wall, and elevation of the UL in a sitting and standing position.

After learning all the exercises in stages 1 and 2, there was a progression of exercises using tasks with trunk coordination and weight bearing on the upper limbs, while maintaining trunk stability: lifting a gym ball or dumbbells in the supine, sitting and standing positions; holding weights in the hands while performing the activities of sitting, standing, walking and climbing steps.

Education on pain

The educational program was carried out based on the protocol described by a reference study[8]. The protocol consisted of three major steps: (I) clarify any inappropriate beliefs about the nature of LBP; (II) present key concepts of the neurophysiology of pain; (III) assess understanding and discuss recovery.

(I) Clarifying any inappropriate beliefs about the nature of LBP: in this part the researcher identified any inappropriate beliefs, those that could be associated with poor recovery from LBP, such as unsatisfactory recovery expectations, intentions to avoid activities due to fear of injury and beliefs about reliance on passive treatment approaches. These topics were addressed through discussions about possible beliefs, such as: "those with LBP need to rest when making a movement", "those with LBP should avoid impact activities", "flexing (bending) the lumbar spine frequently will increase LBP", etc. These beliefs were identified by the participant as understandable, but mistaken and unproductive. Less threatening, evidence-based information was provided about the nature of the intervertebral disc, its inability to "glide" and its relationship to LBP.

(II) Introduction of the main aspects of pain biology: this part was designed to complement part I. Pain was presented as being a protective output of the brain that is influenced by many factors, rather than being a robust signal of tissue damage. The concept of nociplastic pain was introduced, which originates from altered nociception phenomena. Although there is no clear evidence of actual tissue damage or threat of damage causing activation of peripheral nociceptors, or evidence of disease or damage to the somatosensory system causing pain, there is the presence of pain.

(III) The final component of the intervention: assessing understanding and discussing recovery reinforced the concepts outlined in part I and II. It was reinforced that understanding the cause of symptoms and their variable relationship to tissue damage is the most important starting point for a good recovery. Exercise was recommended for most people with LBP. Participants were encouraged to keep active with gradual activities. For example, start with a 10-minute walk and progress according to your ability until you reach 30 minutes. During the sessions, a self-explanatory video was provided with mobility and stretching exercises that were easy to understand and perform, with the aim of helping with strategies for maintaining physical activity in the home environment.

Outcome measures

The primary outcomes measured in this study were outcomes related to the feasibility of a larger clinical trial with adequate statistical power, such as: a) recruitment rate; b) acceptance rate for participation in the interventions; c) retention rate; d) barriers to the interventions; e) adherence to treatment; f) satisfaction with treatment; g) logistics and financial feasibility; and h) human and material resources.

a) the recruitment rate was defined as the percentage of participants enrolled and assessed pre-intervention; b) the

acceptance rate to participate in the interventions was assessed by the percentage of individuals who agreed to start the proposed interventions; c) the retention rate was assessed by the percentage of patients who started and completed the intervention program; d) the barriers to starting the interventions were questioned through open questions to the potential participants recruited, as well as those reported during the interventions; e) adherence to the interventions was based on the researchers' perception of the participants' compliance and engagement when carrying out the activities proposed during the intervention protocol. Detailed notes were recorded during each session, focusing on participation, correction of movements, interaction with the researchers and receptiveness to instructions; f) satisfaction with the treatment took into account the variables content covered and the number of appointments; g) the evaluation of the logistics of the intervention took into account travel and availability of schedules; h) material resources were evaluated according to the availability of rooms, chairs, stretchers and evaluation instruments; i) the viability of human resources was evaluated based on criteria such as training and qualification of the team of researchers.

Satisfaction with the treatment, the evaluation of logistics and the viability of material resources were assessed using an online questionnaire made available to participants who took part in the intervention protocol. For the quantitative analyses, results above 70% were considered satisfactory and feasible for future study. Percentages between 40% and 70% were considered sufficient, requiring few logistical repairs, while percentages below 40% were considered unsatisfactory. The definitions, criteria and cut-off points were drawn up by the study team during the development of this project, adapted and based on previous similar studies[6,17,18].

In addition, the secondary outcomes measured were clinical outcomes, assessed at the pre-intervention stage. The questionnaire on sociodemographic and clinical data was used to characterize the sample: age, gender, occupation, income, educational level and level of physical activity.

Pain intensity was measured using the Numeric Pain Rating Scale (NPRS), in which the subject chooses a whole number (0 - 10) that best describes the intensity of their pain[19]. Disability was measured using the Roland Morris Disability Questionnaire (RMDQ), which consists of 24 questions with "yes" or "no" answers[20].

Kinesiophobia was measured using the Tampa Scale for Kinesiophobia (TSK), which is a self-administered questionnaire made up of questions that address pain and the intensity of symptoms[21]. Depression and anxiety levels were measured using the Beck Depression Inventory (BDI) and the Beck Anxiety Inventory (BAI), used to assess the perception of depressive symptoms. The items analyzed referred to symptoms and thoughts such as: sadness, feelings of guilt, loss of libido, sleep disturbances, loss of appetite, among others[22,23].

Sleep quality and behavior were measured using the Pittsburg Sleep Quality Index (PSQI)[24]. The quantitative assessment of fears and beliefs was measured using the Fear Avoidance Belief Questionnaire (FABQ), to quantify fears related to physical and work activities[25].

All the questionnaires used were validated and translated into Portuguese. The Lasègue test and the evaluation of active movements (flexion, extension, rotation and lateral inclination) were also carried out to verify the reproduction or relief of symptoms[26]. The pressure pain threshold was measured using a portable digital algometer (Wagner FDX-10, Wagner Instruments, Greenwich), with a flat, circular rubber tip with a surface area of 1.0 cm^2, and the average of three measurements on each side of the lumbar spine at L4 and L5 was calculated.

All the evaluation measures were carried out by the same researchers, previously trained in the respective instruments and blinded to the interventions.

Statistical analysis

Descriptive analysis was used to analyze and describe the results. The data for each outcome was presented in relative or absolute form, using percentage calculations.

RESULTS

Between the months of March and April 2023, 20 participants were recruited for eligibility, being included and evaluated at the pre-intervention moment following the specific questionnaires and tests, obtaining a recruitment rate of 100%. After randomization, the 20 recruited participants were allocated into three different groups; they were given the interventions and then the post-intervention assessment. Figure 1 illustrates the flowchart of this study.

The sample consisted of 13 women and 7 men, aged between 21 and 60. Of these, 20% were under the age of 25. The most common symptoms reported by the participants were: tiredness, fatigue, localized/generalized pain, non-restorative sleep, tingling and joint stiffness. Of the specific movements, extension of the lumbar spine generated the most discomfort when performing the movement. Five participants had already started some form of physiotherapy treatment. More than half of the participants (57%) spent more than six hours sitting during the week. The characteristics of the sample are described in Table 1.

Regarding the clinical characteristics of the participants: in terms of pain intensity, 75% of the sample reported feeling pain equal to or greater than 5; 20% tested positive for disability; 75% had moderate to severe kinesiophobia; 70% of the patients had sleep disorders. As for psychological symptoms, 50% had moderate to severe depression and 45% moderate to severe anxiety. Regarding fears and beliefs related to physical activity and work, 70% and 60% had strong fears and beliefs, respectively. The clinical characteristics of the participants are described in Table 2.

Following the primary measures:

a) Recruitment rate: 20 participants were enrolled, contacted and assessed pre-intervention, achieving a 100% rate.
b) Acceptance rate: of the 20 participants included, 10 started the interventions, obtaining an acceptance rate of 50%. Intra-group observations indicated that group 1 (motor control exercises), group 2 (pain education) and group 3 (combination of interventions) had acceptance rates of 57%, 85% and 0%.
c) Retention rate: of the 10 participants who started the interventions, two did not complete the five-week protocol,

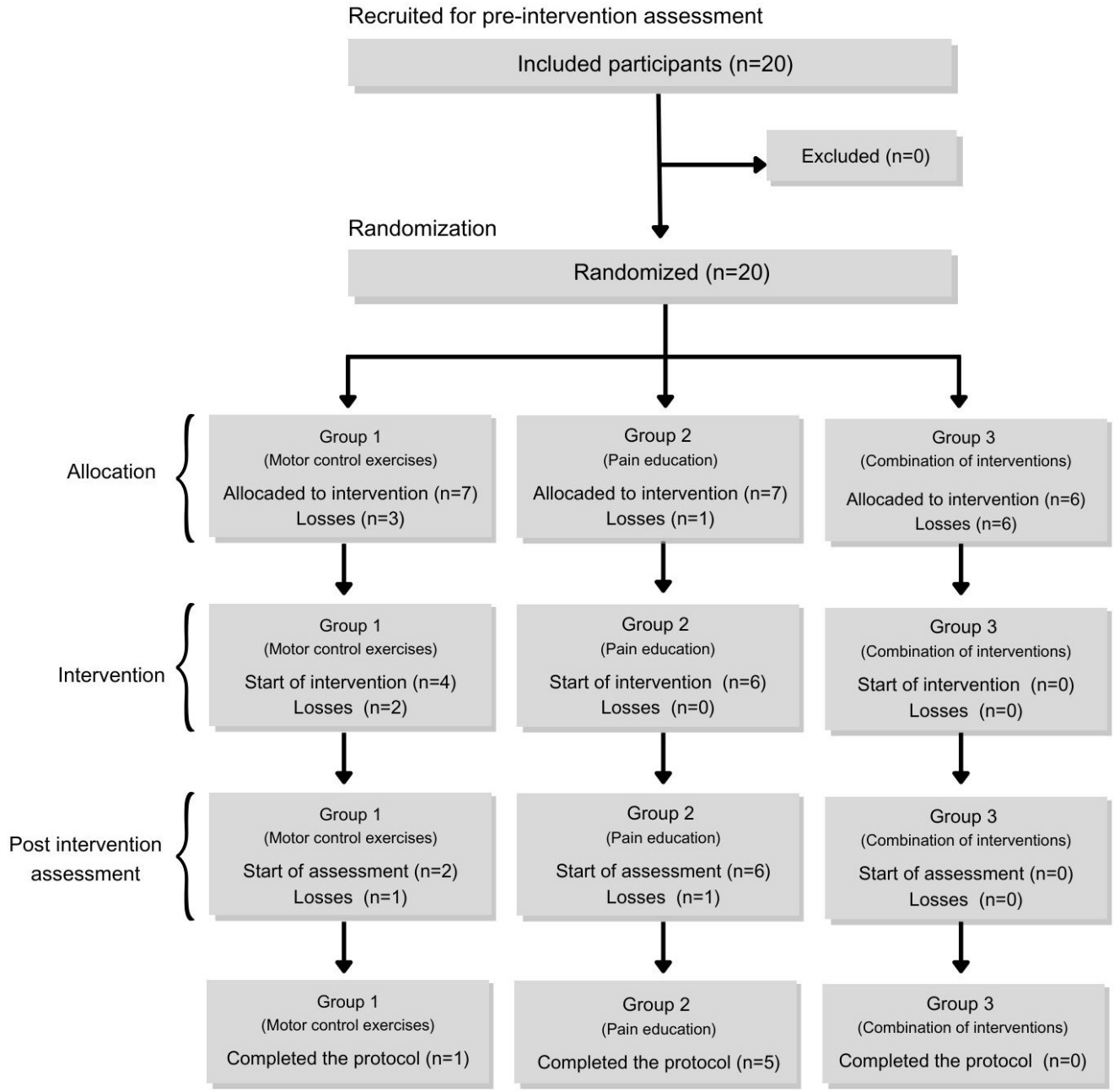

Figure 1. Flowchart of the feasibility randomized clinical trial phases - recruitment, pre-intervention assessment, allocation, intervention and post-intervention assessment.

resulting in a rate of 80%, these being participants in the group that received the exercise intervention. Thus, the retention rates in the groups evaluated were: group 1 (exercises) 50% and group 2 (pain education) 100%.

d) Barriers: the reasons given for not accepting the start of the intervention, as reported by the participants, were work schedule compatibility, reported improvement in clinical condition and the higher number of sessions per week observed in the group with the simultaneous approaches, as well as participants who did not return after the researchers contacted them. The barriers to participation during the intervention were the inclement weather (heavy rain and strong winds), which made it difficult to get to the venue and led to occasional absences.

e) Adherence to treatment: the perception of adherence was high, corresponding to the participants' expectations of commitment to the treatment proposed by the researchers; some exceptions were noted in specific exercises, such as squats. No adverse effects were observed during the data collection period. All individuals were treated according to the intervention assigned.

f) Satisfaction with the treatment: 66.7% of participants rated the content as excellent, 22.2% as good and 11.1% as poor. With regard to the number of visits, 55.6% rated it as excellent, 33.3% as good and 11.1% as fair.

Table 1. Sample characteristics.

Variables	n = 20	%
Gender		
Male	7	35%
Female	13	65%
Age range		
18 to 30 years old	7	35%
31 to 45 years old	5	25%
46 to 59 years old	7	35%
60 years or older	1	5%
Education		
Incomplete elementary education	2	10%
Complete high school	4	20%
Incomplete higher education	7	35%
Complete higher education	6	30%
Complete postgraduate degree	1	5%
Occupation		
Students	5	25%
Teachers	4	20%
Health professionals	2	10%
Religious service providers	2	10%
Other	7	35%
Family income		
Between 1 and 2 minimum wages	6	30%
Between 2 and 3 minimum wages	4	20%
Between 4 and 6 minimum wages	4	20%
Between 7 and 9 minimum wages	3	15%
More than 10 minimum wages	3	15%

g) Logistics: the participants were asked about their commute and the availability of appointment times. Regarding transportation, 44.4% of the sample rated it as excellent, 33.3% as good and 22.2% as fair. With regard to the availability of opening hours, 55.6% rated it as excellent, 33.3% as good and 11.1% as fair.

h) With regard to material resources, the results found through the questionnaire were that 66.7% of the participants rated the infrastructure as excellent and 33.3% as good.

i) Feasibility of human resources: the proposed objectives were met. The team showed adequate qualifications, availability of researchers at all times defined in the program, as well as adequate knowledge to develop the proposed intervention. The results of the primary outcomes are described in Table 3.

Table 2. Clinical characteristics of the sample based on the number of participants with moderate to severe alterations, mean and standard deviation in the questionnaires and tests applied.

	n (%)	Mean	Standard deviation
Pain intensity (NPRS)	15 (75%)	5.27	±2.42
Disabling (RMDQ)	4 (20%)	10.25	±4.29
Kinesiophobia (TSK)	15 (75%)	40.9	±8.55
Depression (BDI)	10 (50%)	11.95	±8.15
Anxiety (BAI)	9 (45%)	11.45	±9.23
Sleep quality (PSQI)	14 (70%)	8.7	±4.31
Fear belief (FABQ - PA)	14 (70%)	18.5	±6.78
Fear belief (FABQ - WA)	12 (60%)	22.8	±17.35
Left algometry	NA	5.74	±4.60
Right algometry	NA	5.75	±4.03

NPRS = Numeric Pain Rating Scale; RMDQ = Roland Morris Disability Questionnaire; TSK = Tampa Scale for Kinesiophobia; BDI = Beck Depression Inventory; BAI = Beck Anxiety Inventory; PSQI = Pittsburgh Sleep Quality Index; FABQ = Fear Avoidance Belief Questionnaire; PA = physical activity; WA = work activities; NA = not applicable.

DISCUSSION

The aim of this study was to assess the feasibility of an intervention protocol for individuals with chronic non-specific LBP and to identify possible modifications for future studies. The results showed that the overall recruitment and retention rates were equal to or higher than 80%, proving to be satisfactory. The overall acceptance rate was 50%, which was considered sufficient. The intra-group analysis found that the acceptance and retention rates in group 2 (pain education) were 100% and 85% respectively, considered satisfactory.

On the other hand, acceptance and retention rates of 57% and 50% respectively were found in group 1 (exercises), being characterized as sufficient. The percentage drop from recruitment can be closely related to the described barriers of lack of compatibility with schedules and the greater number of sessions per week, adversities also observed and evidenced in group 3 (simultaneous approaches), whose acceptance rate was 0%. Similarly, in a previous feasibility study on chronic pain management, analysis of acceptability indicators showed an acceptance rate of 52% and a retention rate of 60%. The main reasons reported for failure to complete the program were personal commitments, incompatibility with work schedules, intense pain and financial difficulties in covering ticket costs[27].

The present study, in addition to presenting a very similar acceptance rate, also showed losses throughout the intervention, and although with a retention rate 20% higher than that of the study already mentioned[27], the main reasons for those not retained, in addition to incompatibility of schedules, were the improvement in clinical condition and difficulty in participating in the group of interventions that required a greater number of sessions per week. The participants' perception of adherence to the proposed treatment during the sessions and satisfaction with the treatment,

Table 3. Quantitative results of primary outcomes.

	n		%	
Recruitment rate	20		100	
Acceptance rate	10		50	
G1	4		57	
G2	6		85	
G3	0		0	
Retention rate	8		80	
G1	2		50	
G2	6		100	
Satisfaction and logistics	**Excellent**	**Good**	**Regular**	**Unsatisfactory**
Content covered	66.7%	22.2%	0%	11.1%
Number of appointments	55.6%	33.3%	11.1%	0%
Travel	44.4%	33.3%	22.2%	0%
Availability of schedules	55.6%	33.3%	11.1%	0%
Material resources	66.7%	33.3%	0%	0%

G1 = Group 1; G2 = Group 2; G3 = Group 3.

reported through the online questionnaire, were compatible with expectations. This is in line with what is found in the literature, in which symptomatological and self-management changes over time depend greatly on each patient[28]. Therefore, barriers to initiating and maintaining participants in interventions must be considered when implementing a future clinical trial.

This feasibility study also provided other important additional information for implementing a future clinical trial. From the characterization of the sample, it was possible to observe a high number of individuals under the age of 30 with chronic LBP, predominantly women with an income of less than two minimum wages, students and teachers. Numerous individuals with deficits in sleep quality and indicators of kinesiophobia were also observed. Lifestyle is an important factor in individuals with chronic LBP. Poor sleep quality can aggravate the development of disabling LBP and, consequently, harm psychological well-being/emotional suffering[29].

Strengths and limitations

This study was prospectively registered, followed CONSORT recommendations for pilot studies or feasibility trials, had adequate randomization methods, allocation concealment and blinding of assessors. The protocol used to carry out the interventions, both through exercises and the pain education approach, was carried out in a standardized way and in accordance with recommendations from current clinical practice guidelines[26], proving to be adequate, viable and meeting the expectations of the participants.

Carrying out a feasibility study is an important step before carrying out a complete clinical trial[13], especially in a context where there are few high-quality clinical trials, which lacks recommendations from previous experiences for such a study, as is the case with complex interventions for the treatment of patients with LBP in primary care. As this is a pioneering study in the southern region of Brazil, the findings presented on the feasibility of clinical studies involving individuals with chronic LBP are extremely important for definitive studies. Therefore, chronic health conditions and their repercussions on the functional capacity of individuals with high prevalence and multicausality reinforce the importance of the insertion and work of physiotherapists in primary health care policies[30].

This study also has some limitations. The long time between the pre-intervention moment and the start of interventions may have caused losses, due to the academic vacation period. Displacement associated with climate instability were factors that made it difficult to implement the intervention schedule, as the research was carried out in the winter months, with a greater probability of heavy rainfall. Finally, it was not possible to blind the researchers responsible for the intervention or the patients, due to the very nature of the interventions.

Recommendations

Although this study showed feasibility in implementing an intervention program for individuals with chronic LBP, improvements can be made in future studies. Assessing the availability of time with greater scope would be important, since most individuals with clinical conditions fall into the economically active population, with compatibility with working hours being a current barrier. One possibility for greater group acceptance of combined interventions in future studies would be to perform a combination of exercise interventions plus pain education on the same day the participant attends.

The place where the interventions will be carried out is a point that must be considered in advance, since difficult-to-access places can become a barrier, making it difficult to travel in areas of greater vulnerability. To reduce patient losses throughout the intervention, it is suggested to offer this type of program in a location close to participants' homes. Thus, a larger-scale implementation must consider a greater variety of locations and times appropriate for the program[28].

Also noteworthy is the appreciation of group programs carried out in primary care and, mainly, in units that have the Family Health Strategy, as they promote health education and the active participation of the participant, transforming their behavior in search of better results in health[27]. This study presented data that will allow the refinement of the intervention proposal for the management of chronic LBP in primary care for future studies with adequate design and sample size.

CONCLUSION

This study concluded that a clinical trial to evaluate the effectiveness of an intervention program using exercise and pain education in the management of chronic LBP in primary care is feasible and justified, although some minor modifications are necessary.

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