Exercise-based and pain education program for adults with chronic low back pain in Brazilian Primary Care: feasibility study

Programa de exercícios físicos e educação em dor para adultos com dor lombar crônica na Atenção Primária brasileira: estudo de viabilidade

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ABSTRACT

BACKGROUND AND OBJECTIVES: Low back pain is the leading cause of disability in Brazil. Most of the evidence on interventions for chronic low back pain (CLBP) comes from high income countries. The objective was to investigate the feasibility of conducting a program based in exercise and pain education in Primary Health Care supported by low-cost mobile technology for adults with CLBP (versus waiting list) and to explore the profile of patients who adhered compared to those who did not adhere.

METHODS: This is a feasibility study with adult residents of Fortaleza, Brazil with CLBP. The Intervention Group consisted of strategies such as physical exercises, pain education, phone calls and support messages to participants. The Control Group was based on a waiting list. Primary outcomes included retention and adherence rates, comprehension of the intervention, credibility, and satisfaction with the intervention. Secondary outcomes included clinical and demographic factors such as pain intensity, disability, recovery prognosis, and physical activity, described according to adherence behavior.

RESULTS: Forty-five individuals were allocated to the Intervention Group and 24 to the Control Group. Overall, 57.8% of participants adhered to the intervention. Retention rates were 53.33% and 58.3% for intervention and control, respectively. The other primary feasibility outcomes were satisfactory. Longer time spent sitting and level of schooling differed the profile of those who adhered to the intervention from those who did not. Higher pain intensity and poorer recovery prognosis, measured at baseline, influenced non-adherence to home exercises.

CONCLUSION: The feasibility of the protocol was adequate for the comprehension of the components, however, adherence to the protocol and the follow-up of the participants were low. The profile of individuals adhering to the intervention includes higher schooling and more time spent sitting at baseline. Characteristics such as higher pain intensity and the influence of psychosocial factors influenced non-adherence to home exercises. Brazilian Registry of Clinical Trials (REBEC RBR-5wqr2j).

Keywords: Low back pain, Primary Health Care, Treatment adherence and compliance.

RESUMO

JUSTIFICATIVA E OBJETIVOS: A dor lombar é a principal causa de incapacidade no Brasil. A maior parte da evidência sobre intervenções para dor lombar crônica (DLC) advém de países desenvolvidos. O objetivo deste estudo foi investigar a viabilidade de conduzir um programa baseado em exercícios e educação em dor na Atenção Primária à Saúde para adultos com DLC (versus lista de espera) e explorar o perfil dos pacientes que aderiram comparado aos que não aderiram à intervenção.

MÉTODOS: Este é um estudo de viabilidade. Foram incluídos adultos com DLC e residentes em Fortaleza, CE, no Brasil. O Grupo Intervenção foi composto por estratégias como exercícios físicos, educação em dor, ligações telefônicas e mensagens de suporte aos participantes. O Grupo Controle consistiu em lista de espera. Os desfechos primários incluíram taxas de retenção e adesão, entendimento da intervenção, credibilidade e satisfação com a intervenção. Os desfechos secundários incluíram fatores clínicos e demográficos, como intensidade de dor, incapacidade, prognóstico de recuperação e atividade física, descritos segundo comportamento de adesão.

RESULTADOS: Quarenta e cinco indivíduos foram alocados para o Grupo Intervenção e 24 para o Grupo Controle. Em geral, 57,8% dos participantes aderiram à intervenção. As taxas de retenção foram 53,33% e 58,3% para intervenção e controle, respectivamente. Os demais desfechos primários de viabilidade foram satisfatórios. Maior tempo sentado e o grau de instrução diferiam o perfil dos aderentes dos não aderentes à intervenção. Maior intensidade de dor e pior prognóstico de recuperação,

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mensurados na avaliação, influenciaram a não adesão aos exercícios domiciliares.
CONCLUSÃO: A viabilidade do protocolo apresentou-se adequada para entendimento dos componentes. Entretanto, a adesão ao protocolo e o seguimento dos participantes foram baixos. O perfil dos indivíduos aderentes à intervenção incluiu maior instrução e mais tempo sentado na sua avaliação inicial. Características como maior intensidade de dor e influência de fatores psicossociais influenciaram a não adesão aos exercícios domiciliares. Registro Brasileiro de Ensaios Clínicos (REBEC RBR-5wqr2j).
Descritores: Atenção Primária à Saúde, Cooperação e adesão ao tratamento, Dor lombar.

INTRODUCTION

Low back pain (LBP) is the leading cause of disability in the world. In the last decades, the growth of this condition's global burden has been alarming, mainly due to the increased disability of individuals in low and middle income countries[1]. In Brazil, the data points to an annual prevalence of more than 50% of LBP in adults, and a prevalence of chronic low back pain (CLBP) of up to 14.7%[2]. The impact of LBP in the Brazilian population has resulted in an increase of 79.9% in the total number of years lived with disability in the last 30 years, making this condition responsible for the largest number of years lived with disability and the most frequent reason for absenteeism[3].
In order to reduce disability, international clinical guidelines recommend the management of CLBP in primary care and emphasize the use of multifaceted approaches based on the biopsychosocial model[4]. Therapeutic exercise, education, counseling for self-management, and psychological therapies are recommended for the first line of care for LBP[5]. In Brazil, multifaceted strategies involving education and group exercises have not been the target of investigations in primary care. Currently, most national studies focus on investigating manual techniques[6-8], specific exercise modalities[9-14] and physical agents[15,16], usually delivered individually in specialized outpatient services. This scenario shows the need for exploration regarding how transferable this evidence from the first line of care in the Brazilian primary health care system is, since this approach would have the potential to reduce the impact of LBP on functioning and generate less costs.
As much as multifaceted strategies show good results for patients with LBP around the world[17,18], treatment adherence is a major challenge. According to the World Health Organization (WHO), the rates of non-adherence to long-term treatment for musculoskeletal conditions are high, around 50%[19]. In addition, the international literature also points out that intrinsic and extrinsic factors to the individual with CLBP interfere with adherence to an education and exercise therapy program, such as low level of physical activities, anxiety and depression, increased pain during exercise, and a greater number of barriers[20]. However, little is known about adherence, acceptance, and factors related to adult participation within a program based on the first line of care in low-income communities in the Brazilian context.
Given the scarcity of national evidence on implementation of the first line of care for CLBP, as well as lack of information on adherence and acceptance rates of a multifaceted intervention in the primary care setting in Brazil, a feasibility study is necessary. From this perspective, the primary objective of the present feasibility study was to investigate the feasibility related to adherence, retention, and acceptability of a multifaceted program based on exercise and pain education in Primary Health Care in individuals with CLBP supported by low-cost mobile technology. The aim was also to explore the sociodemographic and clinical profile of patients who adhere to the intervention compared to those who do not. Describing clinical measures of this type of proposal configured the secondary objectives of the study.

METHODS

The present research is a two-arm parallel feasibility study with a 2:1 allocation ratio, reported according to the CONSORT guidelines for feasibility studies of clinical trials[21] and registered in the Brazilian Registry of Clinical Trials (REBEC RBR-5wqr2j).
The present study is linked to the Project Movement of the Federal University of Ceará (UFC) Physical Therapy Department. This project is an extension action that aims at the free treatment and follow-up of people with chronic musculoskeletal pain through physical exercises combined with educational strategies for the adoption of an active lifestyle with the objective of managing pain. Project Movement has a team of students and volunteer physical therapists who perform assistance actions in a group format in the Physical Therapy Department of UFC and in a primary care unit in Fortaleza/Ceará.
Participants were selected between August 2018 and August 2019. Participants were recruited by active search in health centers of Fortaleza, referral by health professionals, telephone contact, and announcement on social networks (Facebook and Instagram). Individuals interested in participating in the study were contacted by the research team and screened for eligibility. Individuals with a primary musculoskeletal complaint of LBP (between the 12th thoracic vertebra to the gluteal fold) for three or more months, with or without irradiation of symptoms to the lower limbs, aged over 18 years, of both genders and residing in the city of Fortaleza were included.
The exclusion criteria were: individuals with severe auditory or cognitive deficits that prevented them from answering the questionnaires, those who complained of LBP with a specific diagnosed origin (fracture, tumor, vertebral stenosis), severe associated systemic or neurological disease, history of spinal surgery, or in concomitant physical therapy treatments for CLBP, or who did not have a cell phone. Those using drugs with analgesic action were not excluded from the project, but the amount and type of drug used were recorded in the pre- and post-intervention periods.

Intervention

This program was described according to the Template for Intervention Description and Replication (TIDieR)[22]. The Intervention Group consisted of a weekly group program (4-6

participants) for six consecutive weeks lasting approximately 120 min each. The group training had three components: education[23-25], therapeutic exercises[26,27], and mobile technology[28]. Details of the intervention are presented in table 1. The educational component was delivered in a standardized manner, by trained staff, through facilitated exposure and discussion of the topics supported by illustrative posters in the rooms of the clinic and the Physical Therapy Department. This was followed by demonstration and group performance of the exercises under the supervision of physical therapists. The progressive prescription of exercises was implemented considering pain intensity, execution quality, and moderate effort perception on the Borg Scale[29]. Prescription for home exercises was supported by a textbook. The mobile technology support component was delivered via text messages and reminder telephone calls for appointments once a week.

Waiting list

The individuals in this group did not receive any intervention protocol within the six-week period, and were kept on the waiting list for assistance in the Project Movement.

Outcome measures

Sociodemographic data were collected for sample characterization purposes, such as age, gender, education, marital status, use of analgesic drugs, practice, of physical exercise and number of comorbidities.

Primary outcomes

The primary outcomes related to feasibility were retention and treatment adherence rates, home exercise adherence, difficulty in comprehending the intervention, credibility, satisfaction, and adverse events, described in table 2. The feasibility outcomes were derived from registries and a form developed by the researchers based on the literature[30]. Some outcomes predicted in the protocol, such as recruitment rate, perception of recovery, acceptance of technology support were not considered due to poor-quality records.

Feasibility criteria

The feasibility criteria adopted in this study were: adherence rate of 60% to 80%[38], retention rate of 80% of the participants[39]. The other feasibility outcomes were considered sufficient if accepted by the majority of participants in the Intervention Group.

Secondary outcomes

The risk of poor prognosis, level of physical activity, kinesiophobia and self-efficacy and trunk mobility, pain intensity and disability were measured at baseline and after treatment by ins-

Table 1. Details of the components of the exercise and pain education program for individuals with low back pain

Week	Educational component	Exercise component	Mobile technology component
1	Subject: Comprehending LBP; Topics: Definition of pain, factors influencing pain, types of pain and transition, neurophysiology of chronic pain, prognosis, first line of care for CLBP, myths about LBP. Delivery of booklet.	Group training: Controlled breathing, lumbopelvic mobility exercise and progressive muscle relaxation; Home exercises: GTE.	Text message: Reminder for relaxation attitudes and pain relief techniques; Telephone call: advice for proposed exercises and support for doubts and difficulties.
2	Subject: Importance of movement. Topics: Definition of movement, repercussions on the body, ways to move, kinesiophobia, effects of inactivity, pain cycle and benefits of physical exercise for pain, walking program.	Group training: Week 1 exercises, preferred direction, bridge and walking; Home exercises: GTE.	Text message: Reminder of the benefits of becoming active and effects of inactivity and encouragement to exercise; Telephone call: Advice for exercises and support for doubts and difficulties.
3	Subject: Gradual exposure to activities; Topics: Impact of CLBP on daily activities, definition, goals and strategies of gradual exposure.	Group training: Week 2 exercises, gradual exposure to the specific activity indicated and squatting; Home exercises: GTE.	Text message: Reminder and encouragement of the importance of physical activity; Telephone call: Advice for exercises and support for doubts and difficulties.
4	Subject: Importance of planning; Topics: What is planning and why, strategies for organizing activities and exercises, balance between activity and rest, respect for limits and appropriate pace, goal setting and action plan.	Group training: Week 3 exercises, lower limb abduction; Home exercises: GTE.	Text message: Reminder and encouragement to set goals and achieve objectives; Telephone call: Advice for exercises and support for doubts and difficulties.
5	Subject: What have we learned so far? Topics: Review of exercise benefits and harms of inactivity, reinforcement of planning and importance of progressing exercises.	Group training: Week 4 exercises and partridge exercises; Home exercises: GTE.	Text message: Encouragement and example of simple habit changes to exercise more; Telephone call: Advice for exercises and support for doubts and difficulties
6	Subject: Testing what was learned; Topics: All topics covered above.	Group training: Progression of the Week 5 exercises; Home exercises: GTE.	Text message: Encouraging exercises and monitoring directed to goal achievement; Telephone call: Advice for exercises and support for doubts and difficulties.

LBP = low back pain; CLBP = chronic low back pain; GTE = group training exercises. Source: the authors.

Table 2. Details of outcomes and measures.

Outcomes	Instruments/measures	Time
Retention	Percentage of reassessed individuals, based on the number of individuals allocated to each group.	T_2
Adherence to treatment	Percentage of individuals attending more than 75% of the face-to-face sessions, considering those allocated to the program.	T_2
Adherence to home exercises	Exercise adherence is defined by the extent to which the patient performs the exercises prescribed by a professional. Perceived home exercise adherence was evaluated with the question: "How much of the prescribed home exercises do you consider you've performed?". Scale of 1-5 points, where 1: "I did not perform the exercises"; 2: "I've performed the exercises the minority of the times"; 3: "I've performed the exercises moderately"; 4: "I've performed the exercises most of the time"; 5: "I've always performed the exercises as prescribed by the physical therapist".	T_2
Difficulty in comprehending the intervention	Difficulty was assessed with the question: "How much difficulty did you have comprehending some information/content during training?". Scale of 1-5 points, where 1: "No difficulty"; 5: "Extreme difficulty"[30].	T_2
Difficulty in comprehending the execution of exercises	Difficulty was assessed using two questions, "How much difficulty did you have comprehending the exercises?" and "How much difficulty did you have performing the exercises at home"? Scale of 1-5 points, where 1: No difficulty; 5: Extreme difficulty[30].	T_2
Credibility	Participants assessed the degree of credibility with the question, "How much credibility does the proposed intervention have?". Scale of 1-5 points, where 1: "No credibility"; 5: "Extreme credibility"[30].	T_2
Satisfaction	Participants rated the degree of satisfaction with the question "How satisfied are you with the physical therapy treatment?". Scale of 1-5 points, where 1: "Very dissatisfied"; 5: "Very satisfied"[30].	T_2
Adverse Events	Recording of the patients' spontaneous report to therapists during the intervention.	T_3
Pain intensity	Numerical Pain Rating Scale NPRS (0-10 points, where zero = no pain; 10 = worse imaginable pain at the time of assessment)[31].	T_1, T_2
Disability	Roland Morris Disability Questionnaire (RMDQ) – 0-24 point scale, where the higher the score, the higher the disability[32].	T_1, T_2
Self-efficacy	Chronic Pain Self-Efficacy Scale (CPSS) - Divided into three subscales: self-efficacy (SE) for pain management, SE for physical function, and SE for coping with symptoms. Each question has answering options ranging in a score from 10 to 100 within a Likert-type scale. The total score of the questionnaire can range from 30 to 300 points, the higher the score the better the individual's SE[33].	T_1
Kinesiophobia	Tampa Scale of Kinesiophobia - Composed of 17 statements with four response options each, whether totally agree, partially agree, totally disagree or partially disagree. Its score ranges from 17 to 68 points[34].	T_1
Level of physical activities	International Physical Activity Questionnaire (IPAQ). It consists of eight questions about days and time spent in the last week doing moderate and vigorous activities and walking. The time spent sitting on a normal weekday and at the weekend is verified. The score for each activity is given in Metabolic Equivalents of Tasks (MET) and individuals are classified as insufficiently active, moderately active, or very active. The result of the time spent sitting is given in minutes. This variable does not affect the individual's physical activity level results.[35]	T_1
Trunk mobility	Fingertip-to-floor Test (FFT). Quantifies the trunk mobility of an individual during an anterior trunk flexion using a tape measure, measuring the distance in cm between the finger and the floor. The higher the result in cm, the lower the mobility[36].	T_1
Prognosis of recovery	START Back Screening Tool (SBST). Assess the risk of poor prognosis of recovery from LBP, composed of 9 questions: questions 1 to 4 are related to pain and disability, and questions 5 to 9 are related to psychosocial factors. The score ranges from 0 to 9 and classifies the individual into high, medium, or low risk for poor recovery prognosis.[37]	T_1

T_1 = Before randomization, T_2 = 1 week after end of treatment, T_3 = during treatment.

truments translated and validated for the Brazilian population and constitute the secondary outcomes.

Sample Size

The sample size required for this study was 51 participants, 34 in the Intervention Group and 17 in the Control Group (waiting list) for minimum detection of 2 points difference between groups in the NPRS[40] assuming a standard deviation of 2.1 points, considering a 20% loss rate.

Randomization and blinding

Randomization of participants was performed in a 2:1 ratio blocks for intervention and waiting list. The 2:1 ratio was adopted to ensure attendance to more people from the service and to allow secondary analyses regarding adherence to the program. Randomization and allocation were performed by a researcher not involved in the intervention with blocks applied to the participant list using the Excel software.

The study was approved by the Ethics and Research Committee of the Federal University of Ceará (UFC) (3.232.102/2019). All participants signed the Free and Informed Consent Term (FICT) prior to data collection.

Statistical analysis

Descriptions of the participants characteristics and primary and secondary outcomes were given using descriptive measures (mean, standard deviation, and percentage). For descriptive purposes, differences between groups in the immediate post-intervention period were presented.

To characterize the differences between the groups that adhered and did not adhere to the intervention and exercises, the Student's t-test was used for numerical variables (age, pain intensity, disability, kinesiophobia, self-efficacy, physical activity level, SBST, and FFT and, for categorical variables (schooling level, income, physical exercise practice, and use of pain drugs), the Pearson's chi-square test was used. The analyses were processed in the Statistical Package for Social Sciences, 22.0® (SPSS Inc., Chicago, IL, USA), considering an alpha value of 0.05. All analyses were performed by intention to treat.

RESULTS

A total of 443 individuals were recruited during the study period. Of these, 267 were invited to the survey, with 131 potential participants screened for eligibility. Of these, 60 were excluded from the study according to exclusion criteria, availability, and refusal to participate. A total of 71 individuals with CLBP were randomized to the study. After randomization, two individuals were excluded due to a failure to screen for eligibility criteria. Thus, 45 were allocated into the Intervention Group and 24 into the Control Group. Five participants did not attend the intervention. Thus, the study was started with 40 individuals in the Intervention Group and 24 in the Control Group. The final measurements of the study were completed with 24 individuals in the Intervention Group and 14 individuals in the Control Group (Figure 1).

Characteristics of the participants

The majority of participants were female, single, with schooling up to complete secondary education, physically sedentary, and

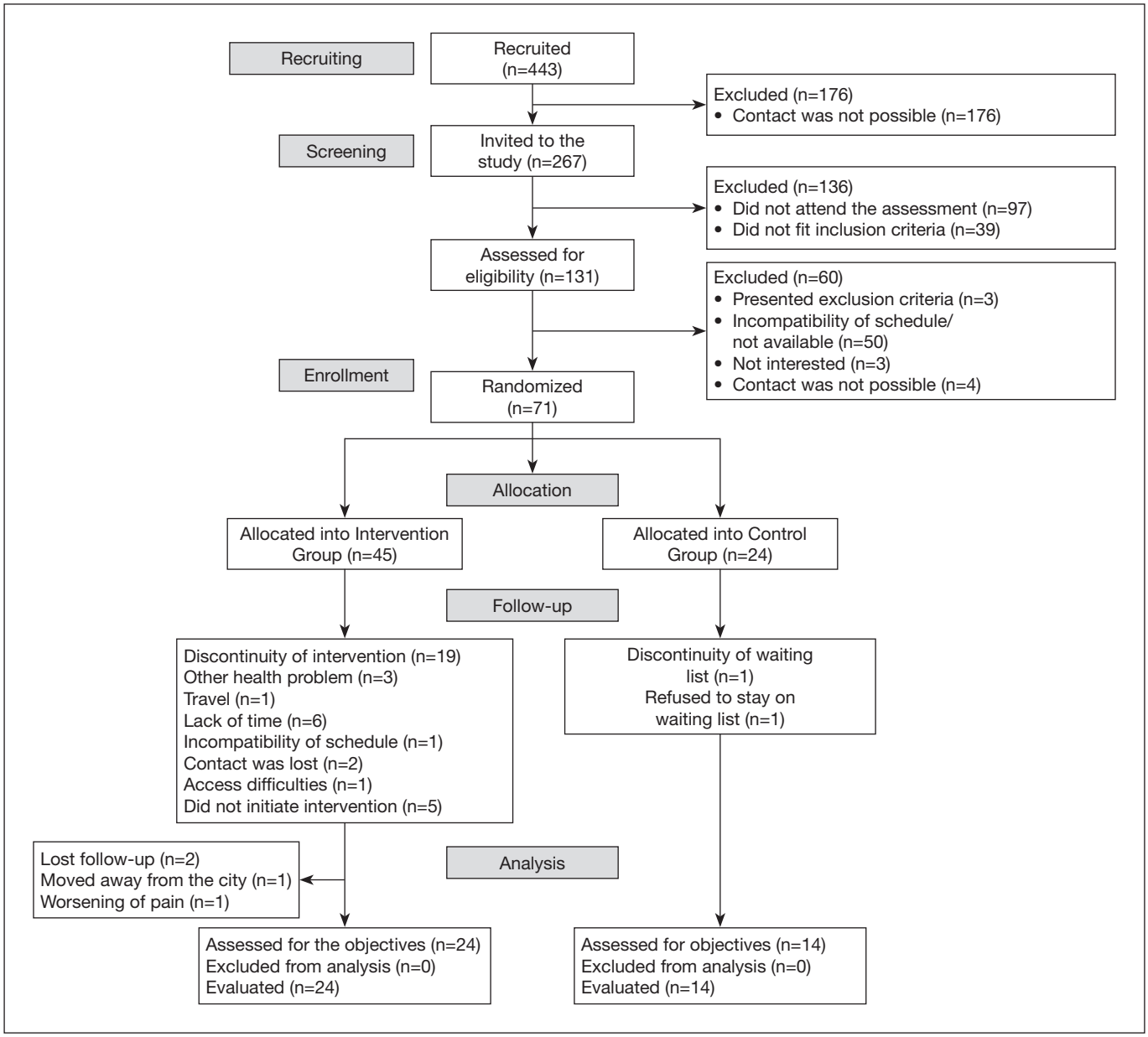

Figure 1. Research flowchart

with family income less than two minimum wages. Details of participants characteristics before randomization and intervention are presented in table 3.

Primary outcomes

Retention of study participants

The initial screening included 131 potential participants for eligibility. Of these, 71 individuals participated in the study. Participant retention in the intervention and control groups was 53.33% (24/45) and 58.3% (14/24), respectively. The study retention rate was considered low for both groups.

Treatment adherence

Adherence to the training protocol was 57.8% (26/45), considering allocated and completed protocol. Of the 40 individuals who started the intervention, 26 finished the treatment and 24 completed the outcome measures. According to participants who did not adhere to the care program, the main reason for dropping out was incompatibility of schedule. Two participants could not be followed up, even after repeated attempts at scheduling.

Adherence to therapeutic exercises

Of the 26 patients who adhered to the intervention, 24 were reassessed. Of these, 20.8% (5/24) performed the exercises a minority of the time and 79.2% (19/24) performed the exercises most of the time or always, according to self-perception.

Level of treatment comprehension

A rate of 87.5% of the participants who received the intervention reported no or little difficulty comprehending any information or content at the time of the training. The same percentage also reported no or little difficulty comprehending the exercises. Regarding the difficulty of performing the proposed exercises at home, 75% of the participants mentioned none or little difficulty, and 25% mentioned moderate difficulty.

Intervention credibility and satisfaction

Most participants who were monitored (95.8%) considered the intervention to have extreme or great credibility. When evaluating satisfaction, 100% reported high satisfaction with the intervention.

Adverse Events

Expected adverse events were reported, such as the occurrence of fatigue or muscle and/or joint pain after doing the exercises. These transient events were managed by reducing the load and/or range of motion and adapting the exercise position. During the intervention, all participants in the Intervention Group reported the occurrence of pain or fatigue in peripheral joints or the lumbar spine. Episodes of limiting pain increase were observed only in four cases, mainly during face-to-face walking, and the symptom was transient.

Table 3. Initial characteristics of the study participants. Fortaleza (CE), Brazil, (2018-2019).

Variables	Intervention Group (n=45)	Control Group (n=24)
Gender (n, %)		
Female	30 (66.67)	17 (70.83)
Male	15 (33. 33)	7 (29.17)
Mean age (±SD), in years	43.49 (±14.91)	47.66 (±17.72)
Marital status (n, %)		
Single	24 (53.33)	9 (37.50)
Married	15 (33.33)	10 (41.67)
Schooling (n, %)		
Complete elementary school	12 (26.67)	7 (29.17)
Complete Secondary education	17 (37.78)	6 (25.00)
College degree	13 (28.89)	10 (41.66)
Postgraduate degree	3 (6.66)	1 (4.17)
Family income (n, %)		
Up to 1 minimum-wage	17 (37.78)	7 (29.17)
From 1 to 2 minimum-wages	19 (42.22)	13 (54.17)
More than 2 minimum-wages	9 (20.00)	3 (12.50)
Comorbidities (n, %)		
None	10 (22.2)	6 (25.00)
Up to two	23 (51.11)	11 (45.83)
More than two	12 (26.67)	6 (25.00)
Use of analgesic drugs (n, %)		
Yes	21 (46.67)	14 (58.33)
No	24 (53.33)	10 (41.67)
Physical exercise practice (n, %)		
Yes	17 (37.78)	10 (41.6)
No	28 (62.22)	14 (58.33)
Pain intensity (±SD), 0-10 points	4.51 (±2.87)	4.91 (±2.98)
LBP disability (±SD), 0-24 points	14.20 (±5.38)	14 (±5.64)
Level of physic activity (LPA; n, %)		
Low	15 (33.3)	7(29.2)
Moderate	22 (48.8)	10(41.6)
High	7 (15.5)	7 (29.2)
Total IPAQ-MET	1826.13 (±2078.41)	2149.37 (±2403.67)
IPAQ sitting week/min	299.27 (±172.16)	339.79 (±171.57)
IPAQ sitting weekend/min	323.36 (±175.52)	302.5 (±178.88)
Kinesiophobia (±SD) (17-68)	45.82 (±7.76)	41.08 (±5.89)
Self-efficacy		
Total self-efficacy (±SD) (30-300)	185.52 (±47.99)	192.24 (±40.29)
Self-efficacy for pain management (±SD) (10-100)	61.24 (±19.45)	66.25 (±17.17)
Self-efficacy for physical function (±SD) (10-100)	64.69 (±22.49)	66.23 (±16.71)
Self-efficacy when dealing with other symptoms (±SD) (10-100)	58.32 (±16.10)	59.76 (±16.24)
Recovery prognosis (SBST)		
Total SBST (±SD) (0-9)	5.33 (±2.17)	5.04 (±2.19)
Total psychosocial SBST (±SD) (0-5)	2.75 (±1.50)	2.75 (±1.45)
Trunk movement, in cm (±SD)	21.28 (15.38)	23.77 (±12.56)

[A] Categorical variables are expressed as numbers and percentages. Continuous variables are expressed as mean and standard deviation (SD). MET = metabolic equivalent of task; Min = minutes; SBST = Start Back Screening Tool; IPAQ = International physical activity questionnaire

Secondary outcomes

Comparison of participants' profile regarding adherence

Participants allocated for intervention showed some distinct characteristics at the baseline when adherence or non-adherence after six weeks was analyzed. Time spent sitting per week showed a difference between the adhering and non-adhering groups (p=0.03, CI= -239.565 to -12.606), being significantly higher in the Intervention Group. In addition, among the categorical variables, differences were found between the groups for schooling level (p= 0.02); the adhering group had a higher level of schooling than the non-adhering group (Table 4).

Comparing the profile of participants who adhered and did not adhere to exercise, pain intensity and recovery prognosis (total SBST and psychosocial SBST) showed statistically significant difference between groups (p= 0.032; CI= 0.264 – 5.315), (p=0.024; CI= 0.349 – 4.577), (p=0.022; CI= 0.254 – 3.009), respectively. The group that did not adhere to exercise had a higher pain intensity and a less favorable recovery prognosis than the group that adhered.

Observed clinical differences between intervention and waiting list

Due to sample loss, comparison analyses were not performed. Data presented after the intervention refer to participants who remained in the study in the follow-up period. Mean differences between groups for the pain intensity and disability outcomes serve only to demonstrate trends and should be interpreted with caution (Table 5).

Table 5. Secondary outcomes after six weeks.

Outcomes	Intervention Group (n=24)	Control Group (n=14)
Pain intensity (0-10) (±SD)	1.39 (±1.61)	4.28 (±3.07)
Disability (0-24) (±SD)	3.96 (±5.51)	12.50 (±4.94)

SD = standard deviation

DISCUSSION

The exercise and pain education program for patients with CLBP showed feasibility in six of the eight investigated criteria, namely: adherence to home exercises, difficulty comprehending the intervention, credibility, satisfaction, and adverse events. These findings suggest feasibility of implementing pain education and exercise in this population, supported by low-cost mobile technology in Brazilian primary care settings. However, prior modifications need to be implemented in order to improve rates of adherence and retention.

Table 4. Description of the profile of participants who adhered and did not adhere to the intervention and prescribed exercise. Fortaleza (CE), Brazil, (2018-2019).

Variables	GAi (n=26)	GNAi (n=19)	GAe (n=19)	GNAe (n=5)
Age	43.88 (±15.1)	43.32 (±15.11)	44.32 (±16.197)	39.60 (±13.428)
Female gender (n, %)	16(61.5%)	14(73.7%)	11(57.9%)	3(60%)
Physical exercises practice – (NO) (n, %)	16(61.5%)	11(57.9%)	11(57.9%)	3(60%)
Low schooling (elementary school) (n, %)	3(12%)*	8(42.1%)	19(100%)	5(100%)
Family income > 1 minimum wage (n, %)	17(65.3%)	11(57.9%)	3(15.7%)	2(40%)
Drug use (YES) (n, %)	12(46.1%)	11(57.9%)	6(31.5%)	4(80%)
Pain (0-10) (±SD)	3.88 (±2.56)	5.26 (±2.97)	3.21 (±2.573)*	6.00 (±1.581)
Disability (0-24) (±SD)	14.35 (±5.60)	14.00 (±5.20)	13.63 (±5.44)	15.40 (±6.22)
Kinesiophobia (17-68) (±SD)	46.23 (±7.66)	45.26 (±8.06)	45.37 (±8.11)	46.40 (±5.41)
Self-efficacy				
Total self-efficacy (30-300) (±SD)	185.44 (±48.96)	185.63 (±45.22)	191.90 (±52.944)	158.98 (±35.312)
Self-efficacy for pain control (10-100) (±SD)	60.46 (±20.25)	62.31 (±18.80)	61.053 (±22.064)	57.600 (±16.211)
Self-efficacy for functionality (10-100) (±SD)	66.36 (±21.34)	62.41 (±23.79)	69.532 (±21.251)	53.334 (±23.359)
Self-efficacy when dealing with other symptoms (10-100) (±SD)	58.65 (±17.62)	57.87 (±13.71)	61.315 (±18.173)	48.250 (±16.830)
Level of physical activities (IPAQ)				
Total IPAQ/MET(±SD)	1457.44 (±1642.64)	2330.67 (±2471.21)	1514.44 (±1844.74)	1283.80 (±1189.71)
IPAQ sitting week/min (±SD)	374.58* (±202.16)	248.49 (±162.07)	393.11 (±222.66)	366.00 (±116.96)
IPAQ sitting weekend/min (±SD)	380.35 (±211.81)	297.65 (±162.59)	397.32 (±225.48)	336.00 (±156.46)
Recovery prognosis (SBST)				
Total SBST (0-9) (±SD)	5.46 (±2.19)	5.16 (±2.19)	4.74 (±2.15)*	7.20 (±1.30)
Psychosocial SBST (0-5) (±SD)	2.85 (±1.48)	2.63 (±1.57)	2.37 (±1.38)*	4.00 (±1.00)
Trunk mobility in cm (±SD)	24.06 (17.03)	19.21 (14.36)	21.71 (±15.89)	33.40 (±23.23)

GAi = Group adherent to intervention; GNAi = Group not adherent to intervention; GAe = Group adherent to exercise; GNAe = Group not adherent to exercise; n: number of participants; IPAQ = International Physical Activity Questionnaire; MET = Metabolic Task Equivalent; Min = minutes; SBST = Start Back Screening Tool.

Feasibility

An adherence rate of 57.8% of participants was recorded in this program, a value below the expected threshold, even with the use of a motivational strategy to reinforce attendance. Other physical therapy interventions based on active treatments for CLBP have adherence rates ranging from 60% to 80%[38,41] and reinforce the challenge of adherence in programs for the management of CLBP. On the other hand, the adherence rate for exercise was found to be adequate. A systematic review pointed out that the use of motivational strategies aimed at behavior change may favor the adherence to home exercises in individuals with CLBP[42].

A retention rate below the recommended values was recorded. Although the criterion was more flexible (80%), the general recommendation is that clinical trials have a retention rate of 85% of participants. Since this is evaluated in clinical trial methodological quality scales, such as the Physiotherapy Evidence Database Scale (PEDro Scale)[39], it's necessary to understand which aspects of the research context or protocol interfered with this rate. The literature already points out this difficulty, however, little is known about strategies to improve this participation rate, especially in countries like Brazil, in which no monetary incentive is allowed for participation in researches[43].

Despite the problems of adherence and retention, satisfactory viability of the comprehension of the intervention components, credibility, and satisfaction were recorded. In the criterion of intervention comprehension, the educational content comprehension was assessed as positive. A study based on neuroeducation found that most participants (75%) found that the educational component was easy[44]. It is worth noting that the language used in the program was adapted and clarified for the schooling level of the population.

Adherence profile

In the present study, the level of schooling of individuals with CLBP was related to adherence to the proposed intervention, which indicates that the higher the level of literacy, the higher the likelihood of adherence. A meta-analysis showed that there is a positive association between adherence and schooling, in which people with higher schooling levels have higher treatment adherence, a relationship observed specially in chronic conditions[45]. Another aspect observed was the difference between the groups, such as the time spent sitting, in which the less active routine pre-intervention predominated in the adherent group. Unlike what was observed in this study, the literature has shown that physically active individuals at baseline are more likely to adhere to interventions with physical exercise[20]. This finding suggests that less active individuals identified more with the proposed biopsychosocial group intervention, in which one of the main goals is to stimulate changes in lifestyle habits and encourage regular physical exercise.

The group of participants who self-reported minimal adherence to home exercises had higher pain intensity and higher risk of poor recovery prognosis than the group that adhered. Although greater pain intensity was found in the group reporting minimal adherence, it is not well established in the literature whether baseline pain intensity really influences the adherence of individuals to exercise interventions, with conflicting results in the evidence[20,46].

It is known that psychosocial factors such as pain catastrophizing, depressive symptoms, and false beliefs about the condition may influence poor prognosis and exercise adherence[46]. Not all patients who adhered to the intervention were adherent to home exercise. Based on the present results and with what is available in the literature, the belief is that insecurity related to lack of supervision during home exercise, as well as failure to align the exercises in the daily life routine, influenced non-adherence to home exercise[42,47].

Potential Clinical Impact

The short-term results of this study on the outcomes of pain and disability for the group involved in the multifaceted program suggest potential for relevant changes in these outcomes. Although the literature shows that programs of this nature are beneficial to those with this health condition[18], there is limitation of the data when investigated in settings such as the present analysis. The literature points out that unfavorable socioeconomic contexts are associated with worse outcomes in CLBP[48]. Thus, the preliminary results add strength to the feasibility results. However, it is important to remember that the results of this study do not allow clinical differences to be detected.

Limitations and strengths of the study

Some limitations of this feasibility study should be listed. The main limitation was related to sample loss. A possible contributing factor was the fact that, in this study, users were not allocated immediately after evaluation. As for the Control Group participants, they may have missed the follow-up because they did not receive intervention during the proposed program period. Regarding the pain and disability outcomes, these findings should be interpreted with limitations considering the sample size. Furthermore, due to insufficient data quality, some outcomes predicted in the protocol, such as recruitment rate, perception of recovery, and acceptance of technology support were not reported, leading to a deviation from the protocol.

The present study was the first to investigate the feasibility of a multifaceted, mobile technology-supported intervention in a limited socioeconomic setting for CLBP. The protocol considered the latest primary care line recommendations for CLBP[5]. The program showed potential applicability in primary care as it is a strategy that does not require the primary health care facility to invest in hard or high cost technology. The literature points out that group format programs are favorable in community settings, since they have similar efficacy to individual programs and potentially lower health care costs[49]. The approaches described in this study are also in accordance with the practices recommended in the *35º Caderno de Atenção Básica* (35th Basic Care Booklet), entitled Strategies for the care of chronic disease patients, however, the document does not bring specifications for chronic pain[50].

This study anticipates some possibilities and challenges to implement strategies described in the international literature or tested only in the outpatient setting in Brazilian Primary Care. The present study also made it possible to identify the profile of those with a greater tendency to adhere and not adhere to the intervention, which can favor the indication of this and other possible protocol formats. In addition, a trend toward positive clinical

outcomes was observed for the Intervention Group, showing the potential for implementation.

Recommendations

The present results point to improvements to be made to the study protocol before its expanded implementation. To increase the protocol adherence rates, participants should be offered chances to make up for their absences, more appointment times, and more access points in the network. So that the protocol has a higher number of engaged participants, it is necessary for the group to become even closer to the flow of services offered in the primary health care network so that the protocol has a higher number of engaged participants, as well as flexibility in the way data is collected during follow-up.

As some of the participants dropped out of the protocol due to availability or absences exceeding 30% of the protocol, similar groups should monitor participants not only in person, but also through the phone via telephone calls or a text message app, so that the main study outcomes are monitored. The teams involved should continue to receive monitoring throughout the protocol weeks to ensure that there are no factors associated with the nature of the intervention and with dropout. Future studies should focus on large-scale implementation of interventions with proven efficacy in the healthcare system and on assisting people with CLBP to engage in these proposed interventions.

CONCLUSION

The feasibility of the protocol was adequate for the comprehension of the components, however, adherence to the protocol and follow-up of participants were low. The profile of individuals adhering to the intervention includes higher schooling levels and more time spent sitting during their day to day. Characteristics such as higher pain intensity and the influence of psychosocial factors influenced the non-adherence to home exercises. Preliminary results indicate benefits of the program for individuals with CLBP and suggest the expansion of the implementation as long as there are previous modifications for the improvement of actions of this nature in contexts similar to the present study.

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