Acute and Chronic Effects of Exercise on Health

Physical activity supported by mobile technology program (PAT-Back) for older adults with back pain at primary care: a feasibility study protocol

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Abstract - Aim: Low back pain (LBP) is disabling in older adults. Although physical activity interventions positively affect LBP, older adults are underrepresented in the literature. We aim to investigate the feasibility of conducting a study to evaluate a primary care program of exercise therapy and pain education, supported by mobile technology, for older adults with chronic LBP (compared to best practice advice). **Methods:** In this parallel, two-arm randomized pilot trial, we will recruit adults aged 60 years and older with chronic LBP. The experimental group (Physical Activity supported by low-cost mobile technology for Back pain-PAT-Back) will consist of an 8-week group exercise program based on pain education, exercises, graded activities, and in-home physical activity. Text messages will be sent to promote adherence to home exercises. The control group will receive an evidence-based educational booklet given during one individual consultation. Outcomes will include recruitment rate, adherence and retention rates, level of understanding of the intervention content, perception of the utility of mobile technology, compliance with the accelerometer in a sub-sample of patients, and adverse events. **Discussion:** The results of this study will form the basis for a large randomized controlled trial. This innovative approach to managing LBP in the primary care setting for older adults, if proven to be effective, can bring an important advance in the knowledge of chronic LBP management to this population.

Keywords: low back pain, aged, feasibility studies, physical exercise, mobile health.

Introduction

Low back pain (LBP) is the leading cause of disability worldwide[1,2]. One in four older adults in Brazil suffers from LBP[3], and there is evidence that pain and disability levels worsen with age[4]. Considering the aging of the population primarily in low and middle-income countries, LBP will continue to grow as a significant public health concern[5,6].

Therapeutic approaches that involve physical exercise in primary health care are recommended within clinical practice guidelines[7]. Evidence shows that exercise reduces symptoms of pain and disability in adults with chronic LBP[8,9]. However, most studies do not include older adults, limiting the generalizability of their results to this population[10]. A recent individual participant data analysis from high-quality randomized clinical trials of adults

has demonstrated that older individuals might benefit less from exercise, although age does not interact significantly with the effect of this therapy[11]. Evidence about the effectiveness of exercise-based LBP interventions in this population is limited[12]. Some isolated approaches of education targeting self-efficacy[13] and exercise have[14,-16] shown little effects for older adults, but they are mainly based on small sample studies with heterogeneous methods and a high risk of bias[13-16]. Chronic LBP in older adults occurs within a context of vulnerabilities in body structure and function (e.g. degenerative changes, systemic diseases, depressive symptoms, lack of social support, polypharmacy, history of falls) that are interrelated and contribute to the negative impact of LBP in this population[17-20]. Thus, the therapeutic effects of exercise seen on adults with LBP may not be directly translated to the older adult population.

Clinical practice guidelines often recommend a combination of education and exercises that may include graded activity/exposure that together has the potential to address the biopsychosocial nature of LBP. Some proposed mechanisms of action of these interventions include changes in central pain modulation, positive changes in inflammatory cytokines levels[21,22], improvement in muscle function, and psychosocial factors. These interventions also reinforce self-management while addressing negative beliefs and attitudes towards pain[23]. A multimodal program of care of this nature in older adults with chronic LBP is promising, yet, adherence is challenging[24,25] especially in unfavorable contexts (e.g. areas of poverty and scarce resources). Adherence can be even worse when considering older adults that have difficulties in access, physical limitations, misbeliefs, and competing priorities that can present as barriers to exercise programs. Thus, strategies to tackle adherence such as mobile technology and motivational strategies are recommended[26-28]. In this context, the use of multifaceted exercise programs coupled with the use of low-cost technology that can enhance engagement with self-management strategies may lead to improved chronic LBP outcomes in older adults within a primary health care setting.

Although there are some interventions supported by mobile technology in the literature[29], there are no clinical trials for chronic LBP in older adults in a primary health care setting, especially in socioeconomically disadvantaged scenarios. Thus, the primary aim of the study is to evaluate the feasibility of 1) an eight-week program of physical exercise and pain education, supported by low-cost mobile technology 2) conducting a randomized controlled trial (RCT) to evaluate the intervention on disability and functional capacity in older adults with chronic LBP in a primary care setting. The results of this study will inform the planning and design of a future pragmatic randomized controlled trial.

Methods

Design

We will conduct a pilot parallel RCT comparing the effectiveness of an intervention involving physical activity and pain education, supported by low-cost mobile technology to best practice advice at eight weeks of follow-up (Figure 1). This trial has been designed and reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement for pilot and feasibility trials and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement[30,31]. This protocol was registered at the Clinical Trials Registry (REBEC RBR-653xcn) and was approved by the Human Research Ethics Committee from the Federal University of Ceará (3.836.257/2020).

Participants

We will recruit community-dwelling older adults with non-specific LBP who are users of primary health centers from a low-income area in Fortaleza, Brazil.

Recruitment method

Patients will be identified through advertisement or referral. The project will be advertised at local primary

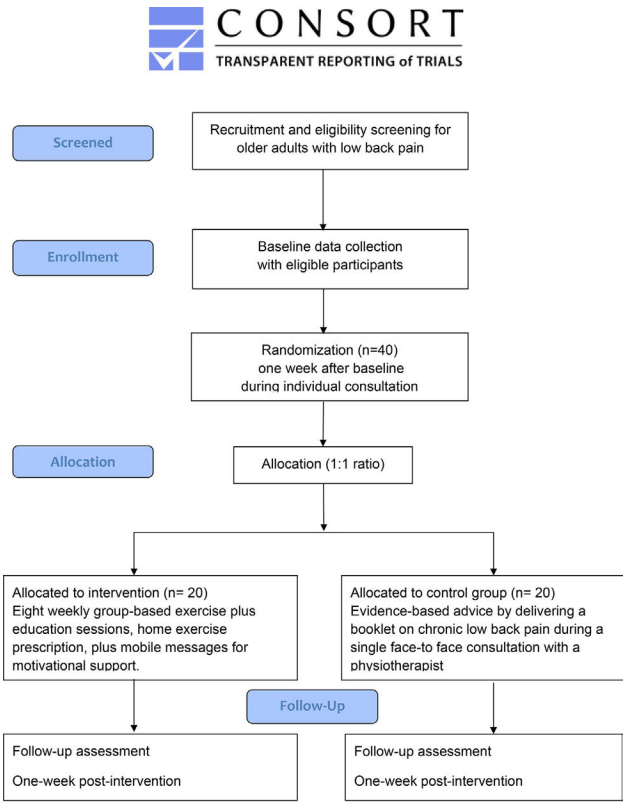

Figure 1 - Study flowchart according to CONSORT recommendations.

health care units, that is, public units registered at the Brazilian Unified Health System, media, and local senior centers. Potential participants will be referred to the study by health care professionals (e.g., family physicians, public health care nurses, physiotherapists) or will be able to contact the research team directly. The enrollment period will extend over 12 months. On the completion of the eligibility assessment, the researcher will ask those who are eligible to provide written informed consent prior to enrolling in the trial.

Inclusion criteria

- Community-dwelling older adults aged 60 years and older;
- chronic non-specific LBP (i.e. LBP pain unrelated to specific causes, with a duration of at least 12 weeks, with or without associated leg pain);
- residents in Fortaleza;
- mobile phone users;
- at least medium (minimum score of three points) in the Start Back Screening Tool (SBST), which suggests referral for rehabilitation[32].

Exclusion criteria

- specific LBP (e.g. history of malignancy, a recent history of trauma to the spine or a fracture, vertebral stenosis);
- acute or decompensated systemic or neurological disease, rheumatic diseases, thoracic/abdominal surgeries, or those who underwent physical therapy treatments in the previous 12 months, with a history of spine surgery;
- serious visual deficits or severe cognitive deficits detected by the Mini-Mental State Examination that won't be able to fill in questionnaires will be excluded from the trial[33];
- contraindications or limitations that prevent walking for a minimum of ten continuous minutes will be excluded from the study.

Those using analgesic medication will not be excluded from the study, but dosage, frequency, and type of medication used will be recorded during the pre- and post-intervention periods. Additionally, comorbidities associated with the aging process (e.g. knee osteoarthritis) will not be a reason for exclusion, but they will be recorded.

Procedures

At baseline, a blinded assessor will interview participants on demographic and anthropometric information, study outcomes, as well as about the state of health in general, the presence of comorbidities associated with treatments, and the number of falls in the previous six weeks. After providing consent, participants will be randomized either to intervention or control groups. Participants will receive an individual consultation (up to one hour) to establish the initial exercise dosage for the program, for those allocated to the intervention group, or to receive an educational booklet during an individual consultation. All participants will be invited to attend a face-to-face follow-up visit with a blinded assessor at eight weeks post-randomization. If participants are unable to attend the follow-up visit, we will either mail a follow-up package or complete the questionnaires over the phone with our primary outcome measures. To assure assessor blinding we will ask the blinded assessor to guess each patient allocation. Data analysis will also be conducted by a blinded statistician.

Group allocation

Eligible participants will be randomly allocated (1:1) to either a multifaceted program or a standard care group that will receive an educational booklet. Randomization will occur after confirmation of eligibility and baseline assessment, prior to the first consultation with a physiotherapist. Allocation will be blinded and performed using a computer-generated random allocation schedule (using permuted blocks) operated by a remote researcher not involved in the study. Neither physical therapists nor participants will be blinded to allocation due to the nature of the proposed intervention.

Intervention group: the PAT-Back program

The Physical Activity supported by low-cost mobile technology for Back pain (PAT-Back) program is described according to the Template for Intervention Description and Replication (Tidier) guidance[34]. Participants will be invited to join one weekly 90-min group session for 8 weeks. The PAT-Back program will consist of patient education and supervised and home exercises and will be based on the biopsychosocial model of pain. All sessions will be conducted using cognitive-behavioral principles.

Prior to initiating PAT-Back, each participant will undergo an individual session for both baseline assessment and identification of exercise targets. The format of all sessions will include 20 min of physiotherapist-delivered education plus 60 min of supervised exercise therapy (see Table 1). Participants will also be asked to perform home exercises three to five times per week for the duration of the intervention. The education component will target pain self-management and will be focused on the role of exercise in the management of chronic LBP such as pain neurophysiology, behavior changes, and strategies for coping with pain. Group exercises will involve the modalities of relaxation, mobility, strengthening of large muscle groups in a closed kinetic chain, and progression towards functional positions and tasks, plus a home walking program. Details of the intervention are described in Table 2.

Supervised and home exercises will be individualized. Exercises will be delivered using principles of graded activity. Physiotherapists will use the modified 0-10

Table 1 - Details of the program components.

Week	Educational component	Exercise component	Mobile technology component
1	Theme: Understanding low back pain. Objective: To clarify the patient about his condition;Topics: Definition of pain, factors that influence pain, types of pain and transition, neurophysiology of chronic pain, pain ≠ injury, prognosis in the older adults, myths about low back pain. Exercise booklet delivery	Group training: diaphragmatic breathing, lumbar-pelvic mobility exercise, global stretching, and progressive muscle relaxation; Home exercises: group-trained exercises	Messages: reminder for attitudes of relaxation and pain relief techniques
2	Theme: The importance of moving. Objective: Highlight exercise as a remedy for low back pain and encourage engagement in physical activity. Topics: Definition of movement, body repercussions, ways of moving, the cycle of pain - fear avoidance, effects of inactivity, benefits of physical exercise for pain, walking program, 1st line of care for LBP	Group training: exercises from week 1, bridge and walking circuit; Home exercises: group-trained exercises	Messages: Reminder of benefits of becoming active and effects of inactivity, and incentive to exercise
3	Theme: Gradual exposure to the activity. Objective: To present gradual exposure as a resource to overcome fear, dysfunctional beliefs of movement, or dysfunctional behaviors. Topics: Belief in fear and behavioral avoidance, pain effects, the impact of LBP in daily activities, definition, aims, and strategies of gradual exposure	Group training: exercises for week 2, gradual exposure to the specific activity indicated and exercise of sitting and standing; Home exercises: group-trained exercises	Messages: Reminder for personalized gradual exposure strategies
4	Theme: Management of biopsychosocial factors in low back pain and aging. Objective: To promote an understanding of the contribution of relevant biopsychosocial factors that impact LBP and how to control them. Topics: Common comorbidities and the importance of their management in the care of LBP; sleep quality and measures for restful sleep, measures for reducing stress and distraction, and leisure	Group training: exercises for week 3, abduction of lower limbs, truck extension; Home exercises: group-trained exercises	Messages: a reminder to control biopsychosocial factors.
5	Theme: The importance of planning. Objective: Organize the exercise routine at home, guide rhythm, micro pause, and division of tasks. Topics: What is and why to plan, strategies for organizing activities and exercises, the balance between activity and rest, respect for the appropriate limit and pace, the definition of goals, and action plan based on the SMART system	Group training: week 4 exercises and, partial curl exercise; Home exercises: group-trained exercises	Messages: Reminder and incentive to set goals and achieve objectives.
6	Theme: How to do self-management in pain? Objective: To reinforce LBP self-management skills and strategies for implementation; Topics: Problems of implementation and solutions in acute exacerbation of pain through the principles of resolution problems, decision-making, use of resources, goal setting and action planning, and self-adaptation, therapist-patient partnership	Group training: progression of week 5 exercises and step up and down exercises; Home exercises: group-trained exercises	Messages: Reminder for self-management implementation strategies
7	Theme: What have we learned so far? Objective: To establish an important intervention. Topics for the confrontation and continuous management of DLC; Topics: Exercise benefits and impairment of inactivity, reinforcement of planning, and importance of progressing exercises	Group training: progression of week 6 exercises and plantar flexion exercises. Home exercises: group-trained exercises	Messages: Encouraging exercises and monitoring them to achieve objectives
8	Theme: You are in control, but you are not alone! Objective: Obtain feedback on changes, help resolve doubts and problems, provide positive reinforcement of advances, and assist in facing barriers	Group training: progression of exercises for week 7; Home exercises: group-trained exercises	Messages: Encouraging exercises and monitoring them

BORG rating of perceived exertion (RPE) for the progression after each exercise, and the target area will be exercises performed at moderate intensity[35,36]. Home exercises will be progressed over 8 weeks according to participants' progression. In addition, during session four participants will develop with the therapist an action plan, which will include the organization of daily tasks, activity pacing, and the home exercise program (Table 2). Exercise sessions will start with a 10-min warm-up walking program aiming at an intensity of 5-6/10 BORG RPE. In sequence, participants complete pelvic mobility exercises, stretching and strengthening large muscle groups of the lower limb and pelvis. We will include progressive training of activities in which they said they were limited due to their LBP (using the Patient-Specific Functional Scale (PSFS). Finally, the session will end with breathing diaphragmatic exercises and progressive muscle relaxation exercises for relaxation. We will measure participants' vital signs (blood pressure and heart rate) at the beginning and the end of each session.

Exercise progression will be set at varying positioning, frequency, and intensity, and will be registered using a

Table 2 - Description of the physical exercise component.

Exercise	Initial approach	Progression
Diaphragmatic breathing	Starting position: supine position with bent knees. Description: inhalation / exhalation with abdominal movement. (5 min)	After performing the pattern properly, the participant evolves to a sitting, standing, and double task. Home frequency recommendation: 7x/ week, 1x/day
Pelvic Tilt	Starting position: sitting in a comfortable position Avel. Description: Execution of retroversion before pelvis version within non-painful range (2 min).	The participant can evolve to standing and four supports, with the addition of repetitions. Home frequency recommendation : 3x / week, 1x / day
Progressive muscle relaxation	Starting position: supine position Description: With his eyes closed, the participant is guided to think about pleasant situations and to breathe calmly. Contract, maintain muscle contraction for a few moments and relax areas of the face, arms, hands, legs, and feet (10 min).	No progression Home frequency recommendation: 7x / week, 1x / day
Overall stretch	Position: Standing or sitting Description: stretching of the posterior and anterior trunk chair, and upper and lower limbs (30 s each muscle group). (5 min)	The participant is oriented to reach greater amplitudes Home frequency recommendation: 7x / week, 1x / day
Bridge	Initial position: Participant in the supine position, knee and arm flexion in pronation extended to the side of the body. Description: And hip lift and return to the initial position, associated with diaphragmatic breathing (repetitions in 1 min).	The participant will evolve, in order, with several repetitions, lift, load, and unipodal support according to perceived effort on the BORG scale. Target recommendation: 2x10 repetitions Home frequency recommendation: 3x / week, 1x / day
Sit and stand	Starting position: Participant sitting in a firm chair. Description: Get up and sit again without using your arms (repetitions in 1 min).	The participant will evolve, in order, with several repetitions, series, and speed according to the perception of effort on the BORG scale. Target recommendation: 3x10 repetitions with speed increase. Home frequency recommendation: 3x/week, 1x/day
Gradual exposure	Activity-dependent, guided by the principles of reinforcement, and rhythm. Safely repeats in 1 min.	The participant will evolve to a more challenging position and/or range. Target: Complete the task safely. Home target recommendation: 3x/week, 1x/day
Abduction of lower limbs	Starting position: Standing participant, positioned in front of a firm support surface. Description: Request that you lift one leg to the side and return to the center, slowly. The same is done on the contralateral leg after the initial leg series (repetitions per member in 1 min).	The participant will evolve, in order, with several repetitions, series, change to lateral decubitus, and speed according to the perception of effort on the BORG scale. Target recommendation: 3x10 repetitions with speed increase. Home frequency recommendation: 3x / week, 1x/day
Step up and down	Starting position: Participant standing, with a close support surface. Description: ask to go up a step and go down, alternating legs (repetitions in 1 min).	The participant will evolve, in order, with several repetitions, series, and speed according to the perception of effort on the BORG scale. Target recommendation: 3x10 repetitions with increased speed. Home frequency recommendation: 3x/week, 1x/day
Partial Curl	Initial position: Patient supine, knees bent, feet flat on the surface Description: trunk partial flexion raising the scapular waist to its limit.	The participant will evolve, in order, with several repetitions, amplitude, series, and load according to the perception of effort on the BORG scale. Target recommendation: 3x10 repetitions with increased load and speed. Home frequency recommendation: 3x/ week, 1x/ day
Tiptoe (plantar flexion)	Initial position: The participant is standing, positioned in front of a support surface. Description: ask him to lift his heel and stand on his toes, then request the return, slowly (repetitions in 1 min)	The participant will evolve, in order, with several repetitions, support, and series according to the perception of effort on the BORG scale. Target recommendation: 3x10 repetitions. Home frequency recommendation: 3x / week, 1x / day
Trunk extension	Initial position: Participant in the prone position, with the support of the elbows, extends the trunk, up to its limit. Description: Raise the trunk and return.	The participant will evolve, in order, with several repetitions, support, and series according to the perception of effort. Home frequency recommendation: 3x/week, 1x/day
Walking circuit	Make sure that the participant has adequate footwear, HR, and PA in normal parameters. Pay attention to the effort and complaints to stop at any time. Description: The participant will walk on a circuit that will involve free walking, with speed obstacles to perceive moderate effort for 10 min. Training at home: Free walk for a minimum of 10 min.	The participant will be instructed to increase the walking pace to perform a greater number of walking cycles when the perceived exertion is less than moderate. Home target recommendation: 90 min/week. Progressing time and walking pace for moderate perceived effort.

printed spreadsheet for monitoring purposes. We will give performance feedback to encourage gradual improvement and positive reinforcement. The exercises will be proposed gradually so that they are incorporated into a home program throughout the following week. An exercise booklet will be delivered for home training of the program. The team will monitor progress or the need to interrupt or modify the exercise in the case of pain worsening

persists after a session (for at least 48h), or in the presence of an acute systemic change. The last treatment session will be focused on the transition to independence and the progression of exercises at home, work (if applicable), and leisure time.

Home exercise training and exercise progression will be tracked using printed diaries for monitoring purposes. Additionally, participants will receive text messages via mobile phone messages (via Whatsapp® or SMS, depending on the participant's preference) three times a week, at their preferred day period (morning or afternoon) with texts directed to support and encourage the engagement on home exercises in between-sessions. The messages were developed through a process involving evidence review, development, and draft by researchers and pre-tested to solicit elderly's feedback. The text messages will be semi-personalized including their preferred contact name and preferred shift. See the proposed theoretical feasibility model (Figure 2).

Control group

The control group will have access to an evidence-based educational booklet in either printed format provided during a one-to-one consultation with a physiotherapist (up to one hour). The booklet includes the best information on chronic LBP natural history and general self-management strategies for this condition, and it will be made available to all participants during the initial consultation. The booklet was previously designed by researchers from the present research team through the consultation of experts and patients with chronic LBP.

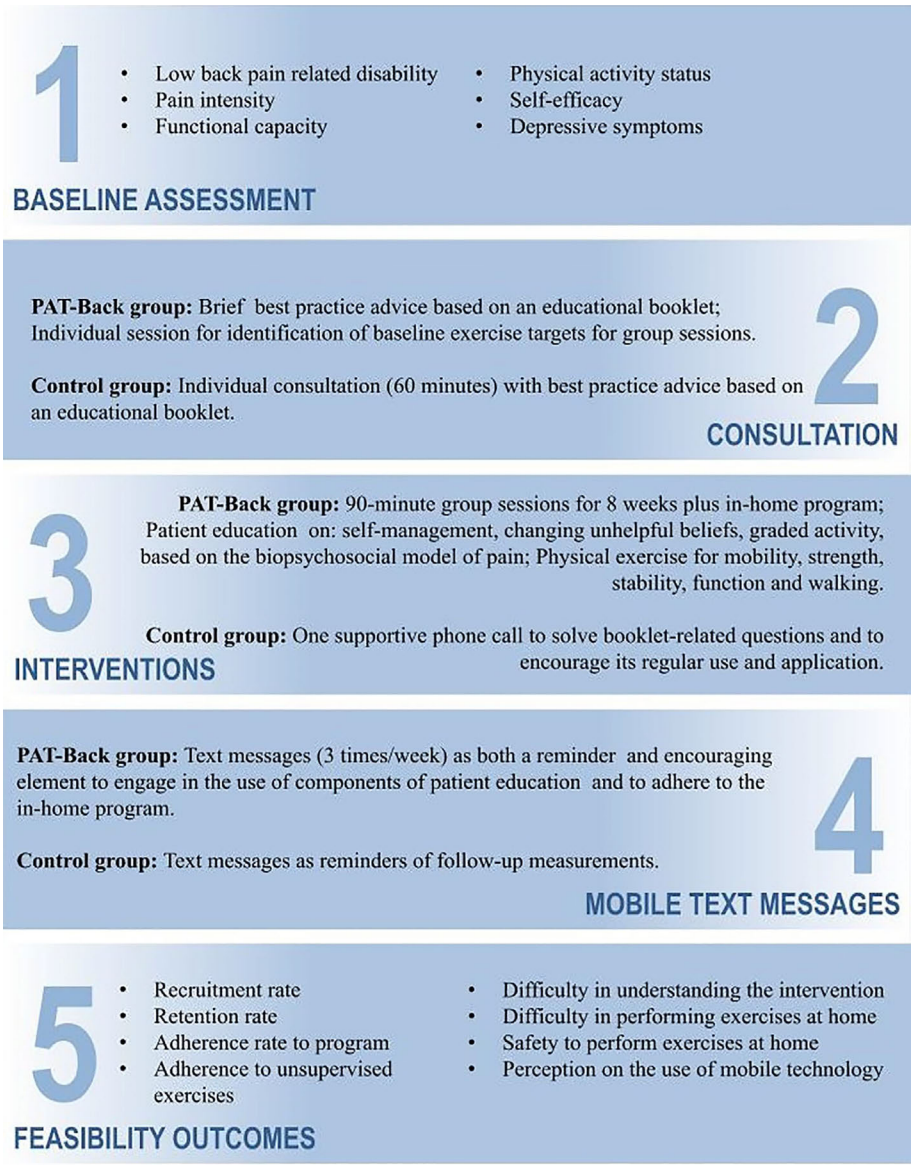

Figure 2 - The proposed theoretical feasibility model of the PAT-Back feasibility study.

Participants from the control group will also receive a phone call four weeks after the initial consultation to solve booklet-related questions and reinforce their related topics. Both in the seventh and eighth weeks, weekly text messages will be sent as reminders to attend follow-up sessions.

Outcomes

Primary outcomes

Feasibility

Feasibility outcomes will include recruitment, adherence and retention rates, level of understanding of the education and intervention content, perception of the utility of mobile technology, and adverse events. We will also measure compliance using a wearable accelerometer in a sub-sample of patients. Table 3 describes the details of both feasibility outcomes and criteria for the next steps for the full RCT.

Secondary outcomes

The self-reported outcomes will be collected to allow for an investigation of the burden of data collection as well as to observe trends in outcomes. LBP-related disability, pain intensity, and functional capacity were measured at baseline and immediate follow-up (8 weeks). Data collection will be conducted through

Table 3 - Details of outcomes and feasibility measures.

Outcomes	Instruments / measures	Analyze	Feasibility criteria
Recruitment rate	Electronic registration of participants recruited in 12 months	Number of participants recruited	Proceed ≥ 100 Proceed with change 99-61 Proceed with significant changes ≤ 60
	Electronic registration of eligible participants who agreed to participate in 12 months	Percentage of eligible people who consented to participate and were randomized	Proceed ≥ 50% Proceed with change 49-26% Proceed with significant changes ≤ 25%
Retention rate	Registrations allocated participants who completed follow-up action immediately	Percentage of participants who completed follow-up measures after randomization	Proceed ≥ 85% Proceed with change 84-61% Proceed with significant changes ≤ 60%
Adherence rate to program	Electronic weekly attendance record	Percentage of individuals who completed 75% of attendance in 8 weeks	Proceed x ≥ 75% Proceed with change 74-51% Proceed with significant changes ≤ 50%
Adherence to unsupervised exercises	Brazilian Portuguese version of the Exercise Adherence Rating Scale (EARS-Br)[37]	Percentage of participants who score 17 points or more	Proceed ≥ 70% Proceed with change 69-51% Proceed with significant changes ≤ 50%
	Written journal of frequency of execution of the prescribed exercises completed by the participant himself	Percentage of participants who performed 75% of training in group	-
Difficulty understanding the intervention	Feasibility forms through the question: How much difficulty did you have understanding any content/instruction at the time of training?	Percentage of participants with a mean response s on a Likert scale (0-10) equal to or greater than 5	Proceed ≤ 50% Proceed with change 51-74% Proceed with many changes ≥ 75%
Difficulty performing exercises at home	Feasibility forms through the question: How much difficulty did you have performing the exercises at home?	Percentage of participants with a mean response on a Likert scale (0-10) equal to or greater than 5	Proceed ≤ 50% Proceed with change 51-74% Proceed with significant changes ≥ 75%
Safety to perform exercises at home	Feasibility forms through the question: How safe did you feel to perform the exercises at home?	Percentage of participants with an average of responses on a Likert scale (0-10) equal to or greater than 5	Proceed x ≥ 75% Proceed with change 74-51% Proceed with significant changes ≤ 50%
Perception of the use of mobile technology	Feasibility forms through the question: How much do you believe that text messages will motivate you to perform the exercises?	Percentage of participants with an average of responses on a Likert scale (0-10) equal to or greater than 5	Proceed ≥ 75% Proceed with change 74-51% Proceed with significant changes x ≤ 50%
Compliance with the accelerometer protocol	Use of the accelerometer on the right side of participants' waist (Actigraph, model wGT3X-BT) for at least 10 h a day for at least four days (removing the first and last days and disregarding days with less than 600 min, and periods of less than 90 min of no activity record)[38]	Percentage of participants using it according to the minimum established period.	-
Adverse events	Electronic registration of event reporting by patients	-	-

face-to-face interviews as online data collection may not be feasible given the low social-economical and education status of the target population group in this study.

Disability

The Roland Morris Disability Questionnaire will be used to assess LBP-related disability. It is composed of 24 questions that verify disability as a result of low back pain, relating it to activities of daily living, pain, and function (0-24). The higher the score, the greater the individual's disability. Roland Morris's questionnaire was properly translated and adapted to Brazilian Portuguese[39].

Pain intensity

We will measure pain intensity using the Numerical Rating scale (0-10 points), with 0 being no pain and 10 unbearable or the worst pain you have ever felt in the last week, the pain region being identified by a schematic body drawing. This scale has been used internationally, having adequate psychometric properties[40].

Functional capacity

The Short Physical Performance Battery measure (SPPB) uses three tasks to evaluate static balance in the standing position, speed of normal and habitual gait, and the estimated muscular strength of the limbs lower by lifting and sitting on the chair for five consecutive times, without the aid of upper limbs. The results of the SPPB allow the indication of four categories for the participants, depending on their performance: 0 to 3 points indicate disability or very poor performance; 4 to 6 points, low performance; 7 to 9 points moderate performance; whereas 10 to 12 points indicate good performance, and the test has been proved to predict disability[41].

The Patient-Specific Functional Scale, in which the individual reports three daily activities relevant to them and that they have difficulty in performing due to LBP. This scale is rated from 0 to 10 points where the greater the activity limitation the higher the scores[42,43].

Physical activity level

The level of physical activity of the participants will be reported using the short version of the International Physical Activity - IPAQ, which estimates the time spent, per week, on vigorous, light, and moderate activities. The questionnaire has a format that allows the participant to self-report their activities during the week preceding the data collection. It allows categorizing patients into categories of the low, moderate, or high levels of physical activity, according to combinations of activities and corresponding calculation of METminutes/week[44].

Self-efficacy to cope with low back pain

The Self-Efficacy Scale for Chronic Pain (Likert scale, 30-300) measures the perception of self-efficacy and the ability to deal with pain and its repercussions. The higher the score, the greater the perceived self-efficiency. The scale was adapted to Brazilian Portuguese[45].

Depressive symptoms

Depressive symptoms will be assessed using the Depression Scale of the Center for Epidemiological Studies (CES-D) (0-60 points)[46]. This consists of 20 questions associated with the senses perceived and experienced in the last week experienced by the participant, and the responses are associated with the frequency at which the participant perceives the feelings described. The higher the score, the higher the presence of these symptoms. Batistone et al. identified that the cutoff point of the instrument with a value above 11 points was associated with the presence of symptoms of depression. In addition, all participants will be asked about the presence of clinically diagnosed depression, for descriptive purposes[47].

Additional measures

We will collect anthropometric (e.g. body mass index), demographic (e.g. years of schooling and gender), and clinical data (e.g. comorbidities and the use of medication for pain). We will also collect information on concurrent care seeking during the program at follow-up.

Implementation and monitoring plan

The research team will be composed of physiotherapists experienced in the field of aging and pain and physiotherapists in training, who will undergo two 4-h training sessions covering all protocol-related procedures under the supervision of coauthors of this protocol. Coauthors FJM and AN will regularly observe researchers implementing supervision to ensure the quality of the protocol.

Data management

This study will use Research Electronic Data (REDCap) for data capture, management, and storage. Each participant will receive a trial identification number, and any identifiers will be masked for the confidentiality of identity. Using REDCap will also allow us to monitor data collection in terms of completeness and accuracy of data, and also for the ongoing quality of data procedures.

Sample size calculation

A sample size calculation was not performed given the feasibility nature of this study. We estimated that a total of 40 participants (20 per group) would be adequate for this study[48].

Statistical analysis

The description of the characteristics of the participants and feasibility outcomes will be reported using frequency, mean and standard deviations or median and interquartile ranges when appropriate. The feasibility rates will be described in absolute numbers and percentages (details in Table 3). We will present mean and 95% confidence intervals of clinical outcomes to observe trends. The analyses will be processed in the program Statistical Package for Social Sciences, 22.0 (SPSS Inc., Chicago, IL), considering an alpha value of 0.05.

Discussion

The results of this study will add to the limited available evidence for the management of non-specific chronic LBP in older adults. Findings will support the potential modification of the program as well as improvement of the methods of the RCT. The results of this study will form the foundation for the conduct of a large RCT to evaluate the effectiveness of the intervention. The results of this study will be the first necessary step to investigating the effectiveness of this intervention for the management of LBP in older adults within a primary care setting.

Potential limitations of this study include the differences in intervention frequency between the two treatment groups, meaning that individuals in the control group will have poorer therapeutic alliance leading to potentially lower non-specific intervention effects as well as potentially higher dropout rates. We intend to minimize the risk by addressing personal motivations and the relevance of contributing to the study prior to randomization, and by conducting a telephone call at 4 weeks to clarify the information about the booklet for the control group only. Moreover, PAT-Back includes mobile text messages. Whereas online mobile messages are very popular among Brazilians and their use is increasing in all age groups, including the older population, we acknowledge that their use might be less accessible for some of them. To minimize this limitation, the inclusion criteria state that only those that are mobile phone users can be included in this study.

Our assessment protocols for primary outcomes accommodate both in-person and telephone assessments and flexible assessment times if needed, and we will monitor absences and repeated attempts to reschedule during the intervention period to adapt procedures (e.g. offer opportunities for flexible reschedule) to facilitate continued participation for those at risk of dropout. Other strengths of this study include the feasible infrastructure required for implementing the intervention protocol (weekly supervised therapy, home exercises, plus mobile text messages for adherence) and the selected secondary outcome measures that are relevant for the older population. Thus, this innovative intervention was conceived to be easily implemented in Primary Health Care units for the ageing population if its effectiveness turns out to be favorable during the future course of investigations. As literature is scarce and brings inconsistent findings for the management of chronic low back pain in older adults, the results of this study have the potential to contribute to the discussion of specifically targeting this population in low back pain investigations including the use of adjunctive low-cost support strategies (i.e. mobile messages and booklet) aiming to reduce the burden and increase autonomy in them.

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