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The efficacy of the addition of the Pilates method over a minimal intervention in the treatment of chronic nonspecific low back pain: a study protocol of a randomized controlled trial[☆]

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Received 28 January 2011; received in revised form 2 May 2011; accepted 21 June 2011

Key indexing terms:

Randomized controlled trial;
Exercise movement techniques;
Low back pain;
Patient education as topic;
Disability evaluation

Abstract

Objective: There is little high-quality evidence on the efficacy of the Pilates-based exercises for the treatment of chronic nonspecific low back pain. Therefore, the objective of this paper is to present a study protocol to investigate the efficacy of adding Pilates-based exercises to a minimum intervention in patients with chronic non-specific low back pain.

Methods: This randomized controlled trial will recruit 86 patients of both sexes, aged between 18 and 60 years, with chronic non-specific low back pain. The participants will be randomly allocated into 2 treatment groups: the Booklet Group, which will receive a booklet with postural orientations, and the Pilates Group, which will receive the same booklet in addition to a Pilates-based exercises program. The general and specific functional capacities of the patient, kinesiophobia, pain intensity, and the global perceived effect will be evaluated by a blinded assessor before randomization and at 6 weeks and 6 months after randomization. In addition, the expectations of the participants and their confidence in the treatment will be evaluated before the randomization and after the first treatment session, respectively.

Conclusions: It is hoped that the results of this study will provide high-quality evidence on the usefulness of Pilates-based exercises in the treatment of chronic non-specific low back pain.

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[☆] Trial registration: ACTRN12610000523000.

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Introduction

Low back pain (LBP) is one of the most common and widely studied musculoskeletal problems in the Western world and is the main cause of disability and work absenteeism in adults younger than 45 years in industrialized societies.¹⁻⁵ It has been estimated that from 11% to 84% of adults will have an LBP episode at least once in their lives and that approximately 40% of these patients will develop *chronic low back pain* (CLBP),⁶⁻⁸ which is defined as persistent pain and disability lasting longer than 3 months.^{1,4,9} These patients use more than 80% of all health care services related to low back problems.⁴ Low back pain has been observed in between 8% and 56% of the population in the United States, which equates to 1 billion dollars per year in medical and other expenses related directly or indirectly to LBP.³

The etiology of LBP is not well defined, but it is known to be multifactorial. Mechanical and postural changes can be classified as nonspecific LBP, which describes much of the pain reported by the population, and may be related to sociodemographic characteristics, physical and psychosocial factors, lifestyle, repetitive movements, pushing and pulling activities, and a static or sitting working posture.^{1,3,10}

Low back pain is also associated with dysfunction of the deep abdominal muscles, such as the transversus abdominis, pelvic floor, diaphragm, and multifidus, and with a reduced coordination and stabilizing activity in the lumbar muscles, especially the extensor muscles.¹⁻³ Low back pain muscle dysfunction is not just a problem of muscle strength and endurance; changes also occur in the neuromuscular mechanisms that affect trunk stability and movement efficiency.⁵ Evidence indicates that patients tend to increase the stiffness of the trunk muscles to gain stability at the expense of spinal function.¹¹

The treatment of LBP generally has a low success rate; therefore, there is a special need for effective and accessible treatments.^{2,4} In general, treatment efficacy is not influenced by the age of the patient or the duration of the symptoms, as these variables are not directly related to disability and pain intensity.⁸ The physiotherapy treatments for LBP that are cited in the literature include exercises, laser treatments, massage, and spinal manipulation; however, the latter 3 techniques elicit small or transient effects. There is no evidence that spinal manipulative therapies are superior to other recommended treatments, such as analgesics, exercises, and physiotherapy, or vice versa. Thus, all of

these therapies are considered to be moderately and equally effective.¹² In fact, it has been suggested that minimal intervention, such as an educational booklet, can also produce a significant improvement in the functional capacity of LBP patients.¹³ Thus, there is still no truly effective treatment of LBP.^{4,9,12}

Recent studies have shown that specific spinal stabilization exercises involving contraction of the multifidus and transversus abdominis muscles with the goal of promoting greater stability of the spine and modulation of neuromuscular control are more effective than minimal intervention and have benefits over other methods of intervention for the reduction of pain and disability.^{1,4,5,14,15}

Exercise programs for general conditioning, strength and endurance of spinal musculature aid in the reduction of pain intensity and disability.⁵ Furthermore, exercises increase the confidence of patients to use their spine and provide them with experiential evidence to help them overcome the fear of physical activity after a treatment, as they are more effective than general medical care (analgesics and “advice and stay active” approaches) and conventional physiotherapy.^{2,5}

A systematic review of LBP treatments⁴ concluded that the treatments currently used can be divided into 3 groups: ineffective, effective, and those that have not been properly studied to determine their effectiveness. This review suggested that exercise is one of the most effective treatments for LBP in both long and short term because it reduces pain and disability. However, it also included the Pilates method among the techniques that need to be studied as a technique with unknown efficacy. It is important to note here that the first published randomized trials on the effects of Pilates-based exercises appeared only in 2006.

Studies have been performed to compare the effects of Pilates-based exercises to those of a control intervention in healthy participants. The results have shown a significant improvement in flexibility,¹⁶ body composition, and resistance of abdominal and spinal extensor muscles.¹⁷ La Touche et al³ performed a systematic review aimed to analyze scientific articles in which Pilates-based exercises was used as a treatment of nonspecific CLBP. The 2 randomized controlled trials and 1 controlled clinical trial that they retrieved showed an improvement in general function and pain reduction in adults with nonspecific CLBP after participating in a Pilates-based exercises program that was adapted to the condition of each patient.

Another 3 clinical trials have been published subsequent to this systematic review. One of these trials observed that, in patients with LBP, Pilates-based

exercises can improve body weight unloading during the gait cycle and reduce LBP in comparison with those not participating in the intervention¹; and another observed that Pilates-based exercises improve LBP when combined with exercises for posture training, such as hip flexion and eccentric contraction of the psoas.¹⁸ When core strength and back performance were evaluated, the results were also satisfactory.¹⁹ Recently, a systematic review included 3 dissertations and 4 clinical trials and concluded that the Pilates-based exercises are superior to minimal intervention for pain but not for disability at postintervention time point in the treatment of LBP.²⁰ Unfortunately, this review was not able to evaluate the long-term effects of these exercises.

The study protocol presented in this article was designed after a detailed literature review on the application of Pilates-based exercises to the treatment of nonspecific CLBP. The main reason for publishing a study protocol before obtaining research data is to reflect on the study design independently of the results. It is an opportunity for the researcher and reader to consider the methodological quality of the study more critically. Another reason is to prevent risk of publication bias because the researcher will be more inclined to publish the results even if they are unfavorable, which seem more difficult to be published.²¹ The last reason is that, in a design article, there is more space for a detailed description of the content of intervention strategies than in a research article. This can also prevent deviations from the original protocol.

Therefore, the purpose of this study is to describe the protocol for a randomized controlled trial with the addition of Pilates-based exercises to a minimum intervention in patients with non-specific CLBP. The hypothesis of this study is that, immediately after a six-week intervention, the non-specific CLBP patients in the Pilates Group will experience a greater improvement in global perceived effect, general and specific functional capacity and a greater reduction in kinesiophobia and pain intensity when compared to the Booklet Group and that this improvement will persist during the six-month follow-up period.

Methods

Study design

This study will be a randomized controlled trial with a blinded assessor that aims to assess the efficacy of adding Pilates-based exercises to a minimum intervention in patients with nonspecific CLBP. The study has

been approved by the Research Ethics Committee of the Universidade Cidade de Sao Paulo, and all participants will sign a consent form to agree to participate in the study. The study will be conducted at the Physiotherapy Department of the same university. The study flow diagram is presented in Figure 1.

Study population

The study will enroll 86 sedentary patients of both sexes, aged between 18 and 60 years, who have had nonspecific CLBP for more than 3 months (without leg pain) and who are able to move without help. Contraindications for the performance of physical exercises will be evaluated using the Physical Activity Readiness Questionnaire, which has been recommended as a minimum standard of preparticipation evaluation because it can identify participants who need additional evaluation and medical clearance.²²

The exclusion criteria will be the following: regular involvement in Pilates-based exercises; pregnancy; previous surgery of the spine or lower limbs; a history

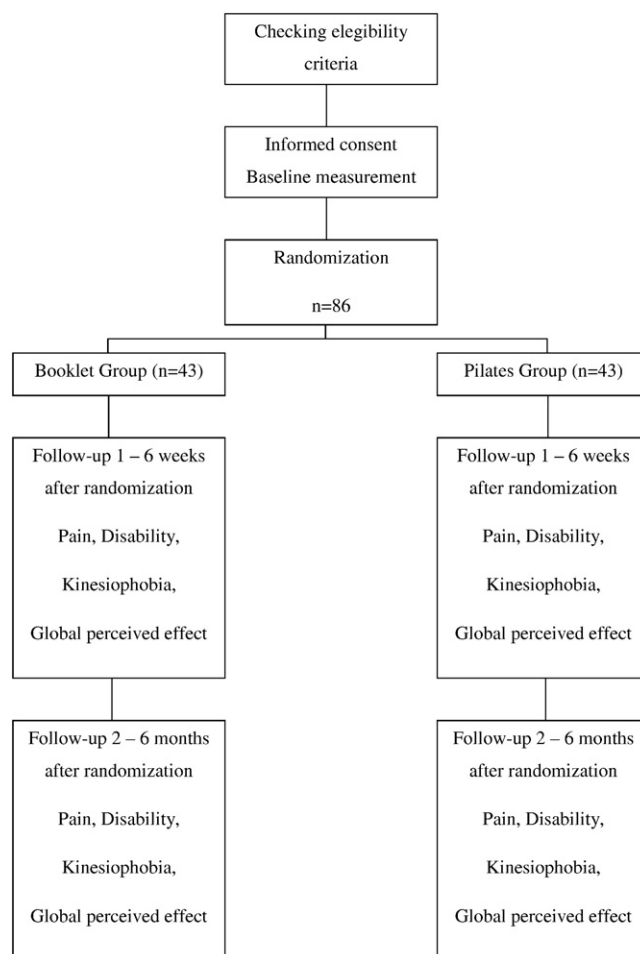


Fig 1. Study flow diagram of the randomized controlled trial.

of spinal fracture; serious inflammatory, rheumatic, or neurological conditions; uncontrolled systemic metabolic disease; disk herniation; tumor; infection; severe osteoporosis; structural deformities; nerve root compromise or cauda equina syndrome; inability to understand written and spoken Portuguese; and receiving physiotherapy for CLBP over the last 6 months.^{2,5}

The participants will be randomly allocated into 2 groups by a simple randomization method: the Booklet Group, which will receive a booklet describing postural orientations, and the Pilates Group, which will receive the same booklet and will also participate in a Pilates-based exercises treatment program. The randomization schedule will be generated by a computer by an independent researcher. For each participant, the researcher will take a sealed opaque envelope from a box following a numerical sequence; the envelope will contain a letter indicating whether the patient will be allocated to the Booklet or the Pilates Group.

Sample size calculation

The study is designed to detect a clinically significant difference of 1 point on the 11-point pain intensity numerical rating scale (estimated standard deviation = 1.4), 1 point on the 11-point patient-specific functional scale (estimated standard deviation = 1.4), 1 point on the 11-point global perceived effect scale (estimated standard deviation = 1.3), and 4 points on the 24-item Roland Morris Disability Questionnaire (estimated standard deviation = 4.9). The specifications include a α of .05, a statistical power of 80%, and loss to follow-up of 15%.

Interventions

All participants will receive a booklet containing information about LBP and the anatomy of the spine and pelvis as well as a discussion of the posture and movement issues involved in the activities of daily life.²³

The Booklet Group will not receive additional exercises and will agree not to receive treatment elsewhere for the first 6 weeks of participation in the study. However, this group will have direct access to the physiotherapist in charge of the intervention, who will clarify any questions about the information of the booklet. In their first session, the participants from this group will receive an orientation to the postures adopted in daily routine activities that are explained in the booklet. Furthermore, they will receive phone

calls from the physiotherapist twice a week to inquire about their compliance with the booklet.

The Pilates Group will receive a treatment protocol that consists of specific training with individual Pilates-based exercises performed on the ground. Each session will last for 1 hour, and participants in the Pilates group will complete 2 sessions per week over 6 weeks. Before the start of the exercise program, all participants in the Pilates Group will receive a basic introduction to the Pilates-based exercises and will be trained to activate the *powerhouse*, which involves isometric contraction of the transversus abdominis, pelvic floor, and multifidus muscles while exhaling during diaphragmatic breathing.²⁴

The start of the training program will consist of floor exercises using a 55-cm ball on a rubber mat, including the following: spine stretches, saw, mermaid, one-leg stretch, double-leg stretch, crisscross, swan dive, swimming, spine twist, one-leg kick, double-leg kick, shoulder bridge, one-leg circle, side kick, and 3 to 5 minutes of relaxation at the end using a rubber roller. All exercises will be progressed so that they can be performed at 3 difficulty levels: basic, intermediate, and advanced. The level of difficulty of each exercise will be determined individually for each participant, and the exercises will progress in difficulty in response to reductions in the postural compensations presented by the participant.^{2,18,25}

After the 6-month follow-up period, treatment using Pilates-based exercises will also be offered to participants in the Booklet Group.

Assessments

A previously trained, blinded assessor who has experience in this topic will confirm the inclusion and exclusion criteria and will obtain demographic and anthropometric data from the participants using a questionnaire specifically developed for this study. This questionnaire will also include questions about the use of medications by the participant and will be used in all evaluations throughout the study. After the assessment of eligibility is completed, the participants will sign a consent form to participate in the study. Before randomization, the same researcher will evaluate the general and specific functional capacities of the participant and his or her level of kinesiophobia and pain intensity.

All of the scales and questionnaires that will be used have been translated and adapted to Brazilian Portuguese, and their clinimetric properties have been evaluated. The Pain Numerical Rating Scale is a

method that evaluates pain intensity using an 11-point numerical scale (0-10), where 0 corresponds to “no pain” and 10 to “worse pain possible.” The participants will be asked to rate their pain using this scale.²⁶ The Global Perceived Effect Scale evaluates the global impression of recovery, comparing the initial symptoms of LBP with the symptoms in the final days of treatment. It is an 11-point numeric scale (-5 to 5), with -5 corresponding to “vastly worse,” 0 to “no change,” and 5 to “completely recovered”; a higher score indicates a greater degree of recovery.²⁶ On the Patient-Specific Functional Scale, the participants identify 3 important activities that they find difficult or that they feel they cannot perform because of CLBP. In addition, the participants rate on an 11-point scale (0-10) how they are able to perform the identified activities they feel, where 0 is “unable to perform activity” and 10 is “able to perform activity at preinjury level.” The composite score thus varies from 0 to 10 (which is the average of the 3 activities chosen by the patient); a higher score indicates a greater functional capacity.²⁶ The Roland Morris Disability Questionnaire evaluates general functional capacity using the physical limitations resulting from pain reported in the low back. The questionnaire is composed of 24 yes-or-no questions related to routine daily activities, where each positive answer corresponds to 1 point. The final score is determined as the sum of obtained values. Values close to 0 represent the best results (ie, lower disability), and values close to 24 indicate worse results (ie, greater disability). Values more than 14 points are considered to indicate severe spinal impairment.²⁶⁻²⁸ The Tampa Scale for Kinesiophobia consists of a self-administered questionnaire composed of 17 questions that address pain and intensity of symptoms. The scores for each item range from 1 to 4 points; the response “strongly disagree” is equivalent to 1 point, “partially disagree” is equivalent to 2 points, “partially agree” to 3 points, and “strongly agree” to 4 points. Four items (questions 4, 8, 12, and 16) are reverse-coded when determining the final score. The final score can vary between 17 and 68 points; a higher score indicates greater kinesiophobia.^{29,30} All of the scales and questionnaires described above will be administered once before the randomization of the groups and again immediately after the 6-week intervention and after a 6-month follow-up period.

The Expectation of Improvement Scale will be used only before randomization to evaluate the expectations of the participant before he or she has been placed into a treatment group. This scale is a method for evaluating the improvement that a patient expects to result from treatment, which is measured by an 11-point numerical

scale (0-10) where 0 is “no improvement” and 10 is “the best improvement possible.” The Treatment Credibility Scale³¹ will be used only after the first treatment session for both groups. It is composed of 4 questions that evaluate a patient’s level of confidence in the treatment and level of confidence that his or her symptoms will improve. The credibility score varies from 0 to 6, where 0 represents “not at all confident” and 6 is “absolutely confident.”

Statistical analysis

Data will be double-entered. The statistical analysis will be performed on an intent-to-treat basis. The effects of the intervention on pain intensity, global perceived effect of improvement, general and specific functional capacity, and kinesiophobia will be calculated using linear mixed models (random intercepts and fixed coefficients), which will incorporate terms for treatment, time, and treatment by time interactions. The level of significance will be set at $\alpha = .05$. The data will be analyzed using the SPSS Statistics 19 software (IBM Corporation, New York, NY).

Results

The enrollment of participants into this study started in August 2010, and it is expected to be completed in December 2011. The first results of this study should be available in July 2012. At the moment of submission of this article, 56 patients have already been randomized and 26 patients have completed the 6-week follow up; the remaining patients are still receiving the interventions. To date, there are no dropouts from any of the interventions.

Discussion

The Pilates method was developed by Joseph Hubertus Pilates and consists of comprehensive body conditioning for the development of the body and mind that promotes better body awareness and improves posture.^{5,24} It is based on the philosophy and principles of Asian cultures, drawing on activities like meditation, yoga, and martial arts to control muscles by performing movements while maintaining as much awareness as possible.^{32,33} The exercises mainly involve isometric contractions of the *powerhouse*, which is the muscular center responsible for the static and dynamic stabilization of the body. These exercises are considered to be similar to spinal stabilization exercises. During isotonic

exercises, the *powerhouse* strength center is activated during exhalation, when there is demand for contraction of the multifidus, transversus abdominis, pelvic floor, and diaphragm muscles, with the goal of reducing joint compression and altering the pelvic tilt.^{1,2,33}

The method includes several stretching and strengthening exercises, which can be divided into 2 categories: mat Pilates (exercises performed on the ground) and exercises with the Pilates apparatus. The first exercises developed by Pilates were performed on the ground; he then created a series of apparatuses on which to perform exercises against resistance provided by springs and pulleys.^{34,32} The latter method can be incorporated into a treatment plan to improve strength, range of motion, coordination, balance, muscle symmetry, flexibility, proprioception, body definition, and general health.^{2,34} The exercises are adapted to the condition of the participant, and difficulty is gradually increased while respecting individual abilities and characteristics. The springs and pulleys of each apparatus can be used to make the exercises easier or more difficult. Furthermore, modified Pilates method movements can be used by the general population; and the complexity of the exercises can be increased gradually as more dynamic movements are progressively added.^{2,33}

In recent years, Pilates-based exercises have begun to be used by physiotherapists to support the rehabilitation programs for musculoskeletal conditions, sports injuries, and neurological disorders, focusing especially on the spine and its stabilization. The increasing use of Pilates-based exercises makes it imperative to understand, among other characteristics, its applications, its contraindications, and how to use it appropriately. With this knowledge, practitioners can prescribe an appropriate technique for each patient. However, there is still little scientific evidence regarding the benefits of Pilates-based exercises, especially for a sedentary population.^{3,33,34}

It is known, based on evidence from patients with CLBP, that exercises can help patients to overcome their fear of physical activity after treatment; previous work has concluded that the Pilates-based exercises have a beneficial effect. However, no studies using Pilates-based exercises have measured kinesiophobia in these patients.² Furthermore, there are only 6 studies on the use of Pilates-based exercises in the treatment of nonspecific CLBP. These studies recruited small sample sizes ranging from 28 to 53 participants and generally used scales and questionnaires that evaluated pain intensity and disability but did not address the specific functional capacity of the patient and global perceived effect.^{1,2,5,9,18,19} This type of evaluation is

representative of the improvement in nonspecific CLBP^{35,36} and is proposed for this study.

Limitations

A possible limitation of our study is that the trial therapist and the patients are not blinded to the treatment allocation. We are unaware of a method to blind therapist and patients in trials of exercise. However, we cannot exclude the possibility that the lack of therapist and patient blinding will introduce some degree of bias into our results.

Conclusions

This randomized controlled trial proposes to evaluate the efficacy of adding the Pilates-based exercises to a minimal intervention, with the hypothesis that the participants from the Pilates Group will show more evident improvement of symptoms compared with the participants from the Booklet Group.

Funding sources and potential conflicts of interest

TG holds a research fellowship funded by the Programa Institucional de Iniciação Científica, Universidade Cidade de São Paulo. No conflicts of interest were reported for this study.

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