Effectiveness and Cost-Effectiveness of Different Weekly Frequencies of Pilates for Chronic Low Back Pain: Randomized Controlled Trial

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Protocol

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G.C. Miyamoto, PT, Master's and Doctoral Program in Physical Therapy, Universidade Cidade de São Paulo, São Paulo, Brazil.

K.F. Moura, PT, Master's and Doctoral Program in Physical Therapy, Universidade Cidade de São Paulo.

Y.R. dos Santos Franco, PT, Master's and Doctoral Program in Physical Therapy, Universidade Cidade de São Paulo.

N.T. Bastos de Oliveira, PT, Master's and Doctoral Program in Physical Therapy, Universidade Cidade de São Paulo.

D.D.V. Amaral, Master's and Doctoral Program in Physical Therapy, Universidade Cidade de São Paulo.

A.N.C. Branco, Master's and Doctoral Program in Physical Therapy, Universidade Cidade de São Paulo.

M.L. da Silva, Master's and Doctoral Program in Physical Therapy, Universidade Cidade de São Paulo.

C. Lin, PT, PhD, Master's and Doctoral Program in Physical Therapy, Universidade Cidade de São Paulo.

C.M.N. Cabral, PT, PhD, Master's and Doctoral Program in Physical Therapy, Universidade Cidade de São Paulo, Rua Cesário Galeno 475, Tatuapé, São Paulo, Brazil, CEP 03071-000. Address all correspondence to Dr Cabral at: cristina.cabral@unicid.edu.br.

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ABSTRACT

Background: The Pilates method has been recommended to patients with low back pain (LBP) but the evidence on effectiveness is inconclusive. In addition, there is still no evidence for the cost-effectiveness of this method or for the ideal number of sessions to achieve the highest effectiveness.

Objective: To investigate the effectiveness and cost-effectiveness of the Pilates method with different weekly frequencies in the treatment of patients with non-specific LBP.

Design: Randomized controlled trial with blinded assessor.

Setting: This study will be conducted at a physical therapy clinic in Sao Paulo, Brazil.

Participants: 296 patients with non-specific LBP between the ages of 18 and 80 will be assessed and randomly allocated to four groups (n=74 patients per group).

Intervention: All groups will receive an educational booklet. The Booklet Group will not receive additional exercises. Pilates Group 1 will follow a Pilates-based program once a week, Pilates Group 2 will follow the same program twice a week, and Pilates Group 3, three times a week. The intervention will last six weeks.

Measurements: A blinded assessor will evaluate pain, quality-adjusted life-years, general and specific disability, kinesiophobia, pain catastrophizing and global perceived effect six weeks, six months and 12 months after randomization.

Limitations: Therapists and patients will not be blinded.

Conclusions: This will be the first study to investigate different weekly frequencies of treatment sessions for non-specific LBP. The results of this study will contribute to a better definition of treatment programs for this population.

BACKGROUND

Chronic low back pain is characterized by pain in the region between the costal margins and the inferior gluteal fold, with or without referred pain in the lower limbs, lasting more than 12 weeks[1]. It is a serious public health problem with enormous social and financial costs. In the United States, approximately 14.5 billion dollars have been spent with direct costs related to this condition[2]. Low back pain is strongly associated with disability, absence from work, and mood changes, such as depression and anxiety[1, 3-5]. According to a systematic review on the prevalence of low back pain, an estimated 18% of adults have point prevalence, 38% have one-year prevalence, and 39% have lifetime prevalence[6]. In addition, around 40% of patients develop chronic low back pain after an acute episode[7].

The European guidelines for the treatment of chronic low back pain recommend medication, behavioral therapy, supervised exercise, educational interventions (short self-care interventions and Back School), multidisciplinary follow-up, and manual therapy[3]. The effect size of these treatments for chronic low back pain is moderate[8, 9]. A systematic review on the cost-effectiveness of the treatments recommended by the guidelines has shown that the cost-effective treatments for chronic low back pain are multidisciplinary intervention, exercise, acupuncture, spinal manipulation, and behavioral cognitive therapy[10]. Exercise therapy is not only considered cost-effective but it is also a good option to treat chronic non-specific low back pain because it is relatively affordable and improves muscle strength, spinal flexibility and stability, motor skills, and overall aerobic conditioning[1]. Systematic reviews on the effectiveness of exercise therapy in the treatment of low back pain show improvements in pain and disability[11, 12].

The literature shows that patients with chronic non-specific low back pain usually present with lumbar hypermobility, mobility deficits (in the thoracic, lumbopelvic, and hip regions), and reduction in trunk and pelvic muscle strength and resistance. These patients can

benefit from neuromuscular reeducation and strengthening exercises for the trunk and pelvic muscles because these exercises can improve muscle dynamics and maintain lumbosacral stability[13]. Muscle disorders in low back pain result from changes in the neuromuscular mechanisms that affect trunk stability and movement efficiency. In addition, due to the detriment of spinal function, the patients tend to increase trunk muscle stiffness to gain stability[14-17]. However, a systematic review on spinal stability exercises[18] have shown that these methods are effective in reducing pain and improving disability because they modulate neuromuscular control and promote greater spinal stability.

The Pilates method was developed by Joseph Hubertus Pilates and involves six basic principles: breathing, centering, concentration, control, precision, and fluidity[19]. Centering consists of isometric muscle contractions known as 'powerhouse' combined with the exercises[19, 20]. The following muscles are involved in powerhouse: anterior abdominal muscles (transversus abdominis, external and internal oblique, and rectus abdominis), posterior abdominal muscles (multifidus), hip extensors (gluteus maximus, hamstrings, and posterior part of hip adductor), hip flexors (iliopsoas, rectus femoris, sartorius, tensor fasciae latae, and anterior part of hip adductor), and the pelvic floor muscles[19]. The powerhouse is responsible for stabilizing the spine and pelvis in the static posture and assisting in the body's dynamic stability during the exercises[19].

The Pilates method includes various strengthening and stretching exercises divided into two types: mat Pilates (performed on the ground with or without accessories) and equipment-based Pilates (performed on machines with or without springs)[19]. The resistance of the springs can be used to make the exercises easier or more difficult, according to the aim of the exercise[20]. However, there is no difference between mat Pilates and equipment-based Pilates with regard to improvement of symptoms in patients with chronic non-specific low back pain[21]. There are two categories of Pilates: the traditional and the contemporary. The

traditional approach is more suitable for individuals without injury, focusing on the spine and involving more vigorous exercises with a high level of difficulty[22]. The modified or contemporary method can be prescribed to the general population, including patients in rehabilitation. It is aimed at spinal alignment and neutral posture and involves exercises adapted to the individual's physical condition with a gradual increase in the level of difficulty and complexity according to personal skills and characteristics[22, 23].

At present, there are five published systematic reviews[23-28] on the effectiveness of Pilates in the treatment of chronic low back pain. A systematic review[29] of these reviews was also published showing conflicting results and suggesting that the evidence on the effectiveness of Pilates in the treatment of chronic non-specific low back pain is inconclusive, given that the results presented by the reviews are very heterogeneous. All of the systematic reviews published to date[23-29] on the effectiveness of Pilates in chronic low back pain report that the majority of the assessed studies have low methodological quality and that more high quality studies are needed with larger samples. These reviews[23-29] also suggest that the lack of a defined time period and weekly frequency of Pilates for patients with low back pain is a limiting factor for the use of the method. Each study assessed in the meta-analyses used different weekly frequencies and total number of sessions in the exercise program, which varied between one and three sessions per week (with or without supervision) over periods of four to 12 weeks[21, 30-43]. This variation may have interfered with the results of the systematic reviews, and it shows the lack of consensus with regard to the ideal number of sessions, weekly frequency, and intervals between sessions.

A recent study[44] employed the Delphi technique to assess 30 physical therapists with experience in treating patients with chronic low back pain using Pilates and showed that the physical therapists recommend supervised sessions of 30 to 60 minutes each, twice weekly, for three to six months. Nevertheless, the authors of this study could not guarantee the

precision of the results and suggested that future studies should be conducted to validate their findings. In contrast, the European guidelines[3] for the treatment of chronic low back pain show that four sessions of exercise-based treatment have the same benefits as eight sessions. Thus, identifying the ideal weekly frequency for these patients could promote greater clinical effects and increase their size. Some studies that used exercise to treat chronic non-specific low back pain have shown improvements in pain and disability after six weeks of treatment[18, 28]. Although the effects are still moderate, they can be considered clinically significant[45]. Thus, it can be concluded that the effects of treatment for non-specific chronic low back pain are not influenced by the number of weeks of intervention, but by the number of sessions.

Low back pain generates high treatment costs all over the world[2], therefore more effective affordable treatments are needed. However, the guidelines provide little information on the cost-effectiveness of the recommended treatments[10, 46] due to the small number of studies available on this topic. The primary objective of this study is to investigate the effectiveness of the addition of modified Pilates to a minimal intervention for patients with chronic non-specific low back pain. The secondary objective is to investigate the effectiveness of different weekly frequencies and the cost-effectiveness of modified Pilates for patients with chronic non-specific low back pain.

METHODS

Study Design

Randomized controlled trial with blinded assessor.

Study Setting

The study will be conducted at a physical therapy clinic in Sao Paulo, SP, Brazil.

Sample size

The sample of 74 participants per group was determined by a sample calculation designed to detect a clinically significant difference of 1 point in pain intensity on the Pain Numerical Rating scale (estimate for standard deviation=1.84 points) after intervention and four points on the Roland Morris Disability Questionnaire (estimate for standard deviation=4.9 points) after intervention. The calculation was done considering the primary objective of this study. The following specifications were considered: α=0.05, statistical power of 80%, and follow-up loss of 15%.

Eligibility Criteria

The study will include 296 patients from the community of both genders with chronic non-specific low back pain for at least three months and age between 18 and 80 years. Advertisements will be placed in a regional newspaper and on the university website. The exclusion criteria will be any contraindication to exercise (assessed by the Physical Activity Readiness Questionnaire)[47], Pilates treatment for low back pain in the last three months, pregnancy, serious spinal pathologies, and previous or scheduled spinal decompression surgery[1].

Assessment

Initially, the participants will sign an Informed Consent Form to take part in the study. A previously trained blinded assessor will conduct the assessment to confirm the eligibility criteria and collect demographic and anthropometric data from the participants, as well as information on type of medication, previous physical therapy treatment or other treatment (if any) for low back pain. After assessing participant eligibility, the assessor will evaluate the outcomes. This initial evaluation will be done before the patients are randomized to the

treatment groups. Due to the nature of the interventions, it will not be possible to blind the patients and therapists involved in the study. The assessor will be aware of the allocation only after data analysis.

All of the scales and questionnaires to be used have already been translated and adapted to Brazilian-Portuguese and have adequate measurement properties[48-53]. The primary outcomes will be pain intensity and disability assessed six weeks after randomization. The secondary outcomes will be quality-adjusted life-years, specific functional disability, global impression of recovery, pain catastrophizing and kinesiophobia six weeks, six months, and 12 months after randomization. Other secondary outcomes will be pain intensity and disability six and 12 months after randomization.

The Pain Numerical Rating Scale assesses pain intensity on an 11-point numerical scale (0 to 10), with 0 being “no pain” and 10 being “pain as bad as could be”. The patient will be asked to rate their average pain in the last seven days.[48] The Roland Morris Disability Questionnaire evaluates general functional disability caused by the physical limitations resulting from referred pain to low back in the last 24 hours. It consists of 24 yes/no questions related to normal daily activities, with affirmative answers worth one point. The score is the sum of the points and the lower the score is, the better the results. Scores close to 24 indicate greater limitation. Scores above 14 points represent severe spinal compromise.[48, 49, 54]

The Global Perceived Effect Scale evaluates global impression of recovery comparing the onset of symptoms to the last few days. It is an 11-point numerical scale (-5 to 5) that varies from “vastly worse” to “completely recovered”. A higher score means better recovery from the condition.[48] In the Patient-Specific Functional Scale, the participants identify three important activities which they are having difficulty doing or which they are unable to perform due to chronic low back pain at the time of the assessment. The participants will mark on an 11-point scale (0 to 10) how capable they feel of performing these activities, with

0 meaning “unable to perform the activity” and 10 meaning “able to perform the activity at preinjury level”. The score ranges from zero to 10, and the average of the scores of the three activities is calculated; the higher the score is, the greater the functional ability.[48]

The Pain Catastrophizing Scale has 13 items regarding thoughts and feelings when patients experience pain. This instrument has three subscales: rumination, magnification and helplessness. The scores vary from 0 (not at all) to 4 (always) points and the maximum score is 52 points, and the higher the score indicates higher pain catastrophising [55, 56]. The Tampa Scale for Kinesiophobia consists of 17 questions related to pain and intensity of symptoms. The scores vary from 0 to 4 points, with 1 point for the answer “strongly disagree”, 2 points for “partially disagree”, 3 for “partially agree”, and 4 for “strongly agree”. To calculate the final total score, it is necessary to invert the scores of questions 4, 8, 12, and 16. The total score ranges from 17 to 68 points, and the higher the score is, the more severe the kinesiophobia.[50, 51] The Short Form 6 Dimensions questionnaire (SF-6D) measures the health-related quality of life[57, 58], taking the following items into consideration: physical functioning, role limitation, social functioning, pain, mental health, and vitality[57]. The SF-6D score varies on a scale of 0 to 1, with 0 representing the worse health condition and 1 representing the best health condition[52, 53, 57, 58]. These scales and questionnaires will be applied at baseline and at the six-week, six-month, and 12-month follow-ups in all groups. The six-week, six-month, and 12-month follow-ups will be done over the phone to minimize the loss of participants. Recruitment began in September 2014 and has the target date of December 2016 for completion. Table 1 shows the timeline of the study.

Randomization and interventions

The process of randomization will be performed on Microsoft Excel for Windows by a researcher who was not involved in participant recruitment. Allocation will be concealed in

sequentially numbered, sealed opaque envelopes. After assessment, the eligible participants will be referred to the physical therapist responsible for the treatments, who will conduct the randomized allocation to one of four treatment groups: Booklet Group, Pilates Group 1, Pilates Group 2, and Pilates Group 3.

All groups will receive an educational booklet containing information on the anatomy of the spine and pelvis, low back pain, and recommendations related to posture and movements of activities of daily living[4]. The Booklet Group will not receive additional exercises and will be advised not to receive treatment elsewhere during the first six weeks of participation in the study. After the 12-month follow-up, the intervention based on the Pilates method will be offered to this group.

Pilates Groups 1, 2, and 3 will receive an exercise program based on mat Pilates (performed on the ground with or without accessories) and equipment-based Pilates (performed on the Cadillac, Reformer, Barrel and Chair machines) for six weeks, and the sessions will last one hour. In Pilates Group 1, the weekly frequency of treatment will be once a week (six treatment sessions). In Pilates Group 2, the weekly frequency will be twice a week (12 treatment sessions). In Pilates Group 3, the weekly frequency will be three times a week (18 sessions).

In the first session, all participants of the Pilates groups will receive instructions on the Pilates method and training for the activation of the powerhouse, which consists mainly of isometric contraction of the deep abdominal muscles (transversus abdominis, gluteus maximus, and pelvic floor) while exhaling[19, 20, 59]. The powerhouse is activated during exercise throughout the session. The main muscles that will be trained are: biceps brachii, deltoids, pectorals, serratus anterior, rhomboids, latissimus dorsi, transversus abdominals, external oblique, internal oblique, rectus abdominis, multifidus, gluteus maximus, gluteus medius, hamstrings, hip adductors, iliopsoas, rectus femoris, sartorius, tensor fasciae latae,

and pelvic floor muscles. Exercises with concentric and eccentric contraction will be done in all planes of movement[19, 20]. A single series of each exercise will be performed and the number of repetitions will vary from eight to 12 (corresponding to approximately 60 to 70% of one repetition maximum assessed by the Borg scale) with a two-minute interval between exercises[60, 61].

The exercises will be done at three levels of difficulty: basic, intermediate, and advanced. Some basic exercises can still be adapted to the conditions of each patient by reducing or increasing resistance. In some exercises, it is possible to lower the resistance of the spring to make the movement easier. For example, a roll up exercise using the tower bar on the Cadillac, which involves trunk flexion movement articulating the spine in supine position, can be done with the spring in the low position to make the movement more difficult or with the spring in the high position to make the movement easier. The level of difficulty of the exercises will be defined individually and the evolution of the exercises will depend on individual postural compensations and comfort, with increases of one to two repetitions in relation to the desired number (2 to 10% load increase)[60, 61] or with modifications to the exercise according to the level of difficulty[33, 62, 63]. The strategy to prevent bias is the individual monitoring of the participant by a trained physical therapist and the control of the level of exercise difficulty presented by the participant; thus, exercises can be adapted if the participant's symptoms get worse. Participants that may need additional interventions will be referred to the outpatient Physical Therapy Clinic from the Universidade Cidade de São Paulo. During the study, the participants will be allowed to use their usual medication and this information will be monitored during the reassessments at six week, six-month and 12-month. The participants will be able to make up any missed sessions as long as the total intervention period, including make-up sessions, does not exceed eight weeks. Adverse events will be monitored by the intensity of pain during exercises execution.

Economic assessment

The economic assessment of the intervention will consist in cost-effectiveness and cost-utility analyses in terms of incremental cost per quality-adjusted life-years (QALY) if Pilates shows to be more effective than minimal intervention. The costs will be measured by the estimate of direct costs to the public health system, costs to the private health system, and out-of-pocket expenses at six weeks, six months, and 12 months. These data will be collected using a questionnaire at follow-up every six weeks and will be analyzed in the six and 12-month follow-ups. Based on this estimate, the costs will be measured based on the participants' use of the resources. In this study, intervention costs and out-of-pocket expenses incurred by the participants will be identified, measured, and validated. Table 1 shows the types of resources that will be captured, sources of data, and proposed assessment methods. The costs of absenteeism from work will be estimated by the number of days away from work multiplied by the average wage rate. For the cost-effectiveness analyses, we will use the Pain Numerical Rating Scale and the Roland Morris Disability Questionnaire as measures of effectiveness. For the cost-utility analyses, we will use the SF-6D as a measure of utility. The sensitivity analysis will test uncertainty in key parameters, such as the selection of cost weights and statistical variation in quality of life scores.

Statistical analysis

A committee for data monitoring will consist of one author from the study that is not involved with data collection and have no conflict of interest. Auditing of the randomization process of the participants in the intervention groups will be held monthly. Statistical analysis will be performed by a researcher who will receive the data encoded. All data will be entered twice into the database. The statistician will receive the coded data and will be blind to the

participant's allocation to intervention groups. The mean effects of the interventions and the group differences for all outcomes will be calculated using linear mixed models that incorporate terms for the treatment groups, time (follow-ups), and interaction terms "treatment groups" versus "time". The term "time" will be coded as a categorical variable (i.e. four variables will be created for the categories baseline, six-week follow-up, six-month follow-up, and 12 month follow-up). The coefficients of treatment versus time interactions will be equivalent to the estimates for the group differences. No interim analysis will be performed. The analyses will follow the intention-to-treat principle. If a participant drops out of treatment, no additional outcome will be collected and the missing data will not be replaced. The software SPSS for Windows will be used for all statistical analyses and the level of significance will be set at 5%.

Ethics

All participants that agree to participate of the study will sign two informed consent forms. This study has already been approved by the Research Ethics Committee of Universidade Cidade de São Paulo (CAAE: 29303014.7.0000.0064) and prospectively registered in Clinical Trials Registry (NCT02241538). The collected data will be stored in locked cabinets and only the blinded evaluator will have access to this information. Later, the data will be entered and saved on computers with password protection to ensure confidentiality. Any modification in eligibility criteria, outcomes and analysis will be reported before enrolment of the first participant. The Sao Paulo Research Foundation (FAPESP) provided a scholarship to the principal investigator of this study (2013/26321-8). The funder had no part in designing the study and in its implementation analysis, data interpretation and presentation of the results.

DISCUSSION

The present randomized controlled trial with blinded assessor will be the first to investigate the effectiveness and cost-effectiveness of different weekly frequencies of Pilates or any other type of exercise for the treatment of chronic non-specific low back pain. One study, which analyzed the opinion of physical therapists who use Pilates to treat chronic low back pain, suggested that the treatment should be provided in twice-weekly sessions of 30 to 60 minutes each[44]. The American College of Sports Medicine recommends a frequency of two to three times a week for resistance training[64]. However, there is still no consensus on the ideal weekly frequency for clinical improvement of stabilization and motor control in patients with chronic low back pain. Therefore, we suggest that the weekly frequency of a treatment can influence results, although there are no studies that have conducted this investigation. We also suggest that the higher the weekly frequency is, the better the results, given that two studies[33, 39] did not find significant differences for disability after a program of once-weekly supervised sessions of Pilates to treat chronic non-specific low back pain. In addition, the medium and long-term effects of Pilates in the treatment of patients with chronic non-specific low back pain are still undefined. Only two published studies[35, 43] have performed a medium-term analysis, therefore this will be the first study to assess the medium and long-term effects of different weekly frequencies of Pilates in these patients and the first study to investigate the long-term benefits of this intervention.

A systematic review with meta-regression showed that exercise in general has little effect on pain reduction and improvement in disability in patients with chronic low back pain. It also showed that the number of sessions may be associated with the effect size of the treatment[65]. Nevertheless, no studies have proposed an investigation of the weekly frequency of an exercise program for patients with chronic non-specific low back pain. Consequently, the results of the present study will contribute to clinical practice by identifying the ideal

frequency of a Pilates-based exercise program for these patients. They will also help to determine whether this intervention is cost-effective, given that Pilates is considered a high-cost method. Our research group aims to publish the results of this study in an internationally recognized journal and release of the spreadsheet with the data encoded is expected to occur during the first semester of 2017.

This study has been registered and has a relevant sample size to minimize bias. The patients will be randomized using the process of concealed allocation with blinded assessment and intention-to-treat analysis. The treatment will be provided by four physical therapists with four years of experience in Pilates and trained for the study interventions. It will not be possible to blind the therapists and patients to intervention; however, systematic reviews[28, 29] have shown that Pilates exercises are beneficial to patients with chronic non-specific low back pain compared to minimal intervention. It should be noted that these results are not conclusive because of the lack of high quality studies with considerable samples related to this intervention.

The results of this study will guide future research aimed at identifying the ideal exercise program to treat patients with chronic non-specific low back pain, taking into account weekly frequency, interval between sessions, exercise intensity, and number of repetitions. The results will also provide a foundation for the definition of a cost-effective exercise program based on weekly frequency or on different types of exercise to treat these patients. Currently, cost-effectiveness analysis is considered one of the priorities of research on patients with low back pain.

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Dr Cabral and Ms Miyamoto developed the study. Dr Cabral and Ms Miyamoto initiated the study design. Ms Oliveira, Mr Franco, Mr Amaral, Ms Branco, Ms Moura, and Ms da Silva helped with the implementation and data collection. Ms Oliveira and Ms Moura are the technical fellows, and Mr Amaral, Ms Branco, and Ms da Silva are the undergraduate researchers. Dr Cabral provided statistical support in the clinical trial design and will perform the primary statistical analysis. Dr Cabral and Ms Miyamoto contributed to the improvement of the study protocol, and all authors approved the final manuscript.

This study was approved by the Human Research Ethics Approval Committee of Comitê de Ética em Pesquisa da Universidade Cidade de São Paulo (approval number: CAAE 29303014.7.0000.0064).

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Table 1. Timeline for the schedule of enrolment, interventions, and assessments

Outcomes	**Enrolment**	**Before randomization**	**Intervention period (6 weeks)**	**6-week follow-up after randomization**	**6-month follow-up after randomization**	**12-month follow-up after randomization**
Eligibility criteria	X					
Demographic data	X					
Informed consent	X					
Primary outcomes						
Pain intensity		X		X		
General disability		X		X		
Secondary outcomes						
Pain intensity					X	X
General disability					X	X
Specific disability		X		X	X	X
Global perceived effect		X		X	X	X
Pain catastrophizing		X		X	X	X
Kinesiophobia		X		X	X	X
Interventions						
Booklet			X			
Booklet + Pilates 1			X			
Booklet + Pilates 2			X			

Booklet + Pilates 3	X

*Pilates 1: Pilates once a week; Pilates 2: Pilates twice a week; Pilates 3: Pilates three times a week.

Table 2. Assessment of utilized resource.

Type of resource	**Assessment instrument**	**Assessment method**	**Sources**
Physical therapy sessions	Physical therapist report	Wage rates	Physical Therapy Council table of fees
Medication, visits to general practitioners in public and private health clinics and/or health professionals, hospital stay, visits to emergency departments	Questionnaires every six weeks for analysis in the follow-ups at six weeks, six months, and 12 months	Published prices (costs for public and private health system) and/or real out-of-pocket expenses incurred by the participants	Pharmaceutical websites, table of medical fees for health services
Visits to community or alternative services or complementary health professionals	Questionnaires every six weeks for analysis in the follow-ups at six weeks, six months, and 12 months	Real out-of-pocket expenses incurred by the participants	Table of fees for health services

Effectiveness and Cost-Effectiveness of Different Weekly Frequencies of Pilates for Chronic Low Back Pain: Randomized Controlled Trial

Gisela Cristiane Miyamoto, Katherinne Ferro Moura, Yuri Rafael dos Santos Franco, Naiane Teixeira Bastos de Oliveira, Diego Diulgeroglo Vicco Amaral, Amanda Nery Castelo Branco, Maria Liliane da Silva, Christine Lin and Cristina Maria Nunes Cabral

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