Universidade de Brasília

Programa de Pós-Graduação em Educação Física

Economic evaluation of interventions based on physical exercises for the management of people with chronic low back pain

Avaliação econômica de intervenções baseadas em exercícios físicos para o manejo de pessoas com dor lombar crônica

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Members of the examining board for the defense of the PhD thesis by Caroline Ribeiro Tottoli, presented to the Doctoral Program in Physical Education (PPGEF), at the University of Brasília, on August 31, 2023.

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Dedico todos esses anos a Manuela,
o meu grande amor. Ao meu parceiro
de vida, que não me deixou esquecer
o quão valioso é o trabalho que
desempenhei nesse tempo; que me
acolheu e me impulsionou,
na mesma medida.

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LIST OF ACRONYMS AND ABBREVIATIONS

AP	Anteroposterior
ASR	Average Salary Reported
BMI	Body Mass Index
CAPES	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior
CE	Cost-effectiveness Plane
CEA	Cost-effectiveness Analysis
CEAC	Cost-effectiveness Acceptability Curves
CHEERS	Consolidated Health Economic Evaluation Reporting Standards
CLBP	Chronic Low Back Pain
CNLBP	Chronic Non-specific Low Back Pain
EQ-5D-3L	EuroQol Five Dimension Scale
GDP	Gross Domestic Product
HBE	Home-Based Exercises
ICERs	Incremental Cost-effectiveness Ratios
INMB	Incremental net Monetary Benefit
ITT	Intention-to-treat Analysis
LBP	Low Back Pain
LOS	Limits of Stability
MICE	Multiple Chained Equation Imputation
ML	Mediolateral
NE	North-East Quadrant
NRS	Numerical Rating Scale
NW	North-West Quadrant
PE	Pilates Exercises
PSA	Probabilistic Sensitivity Analyses
QALY	Quality-adjusted Live Years
RCT	Randomised Controlled Trial
SD	Standard Deviation
SE	South-East Quadrant
SE	Standard Error
SUR	Seemingly Unrelated Regression

SW	South-West Quadrant
VAS	Visual Analogue Scale
WTP	Willingness to Pay Thresholds

SUMMARY

RESUMO

Objetivo: Investigar a relação custo-efetividade de um programa de exercícios de Pilates em comparação com exercícios domiciliares em indivíduos com dor lombar crônica inespecífica.
Desenho: ensaio clínico aleatorizado com acompanhamento de 6 meses juntamente com uma avaliação econômica.
Participantes: Cento e quarenta e cinco indivíduos (18-50 anos de idade) com dor lombar por ≥ 12 semanas consecutivas foram inscritos e alocados aleatoriamente em uma proporção de 1:1 para grupos de Pilates (n = 72) ou de exercícios domiciliares (n=73).
Intervenções: Método Pilates (exercícios de Pilates solo com acessórios) versus exercícios domiciliares (exercícios posturais, alongamento e fortalecimento muscular e estabilização/mobilização da coluna), duas vezes por semana, durante seis semanas.
Principais medidas de resultados: As avaliações foram realizadas na linha de base, pós-intervenção e acompanhamento de seis meses. Os resultados foram intensidade da dor (0 a 10), incapacidade (0 a 100) e qualidade de vida relacionada à saúde (-0,176 a 1). Os custos incluídos foram custos diretos médicos, custos diretos não-médicos e custos indiretos.
Resultados: No pós-intervenção, o grupo Pilates apresentou intensidade de dor significativamente menor (diferença= -1,14, IC95% -2.05; -0.23), menor incapacidade (diferença= -6,66, IC95% -11,29; - 2,03) e maior qualidade de vida relacionada à saúde (diferença= 0,102, IC95% 0,054; 0,151) em comparação ao grupo de exercícios domiciliares. No acompanhamento, o grupo Pilates apresentou qualidade de vida relacionada à saúde significativamente maior (diferença = 0,055, IC 95% 0,003; 0,106) em comparação ao grupo de exercícios domiciliares, mas não houve diferenças significativas em dor e incapacidade. Um efeito geral significativo do Pilates em comparação com exercícios domiciliares foi encontrado para incapacidade (diferença = -4,4, IC 95% -7,6; -1,1) e qualidade de vida relacionada à saúde (diferença = 0,049, IC 95% 0,022; 0,076).), mas não para dor. Os principais contribuintes para os custos sociais totais foram os custos indiretos em ambos os grupos. Os custos da perda de produtividade no trabalho (presenteísmo) foram maiores no GP, porém, essas diferenças não foram significantes entre os grupos. A intervenção do Pilates dominou a partir de uma perspectiva social, demonstrando ser mais eficaz e menos dispendiosa para dor, incapacidade e QALY.
Conclusões: Nossos resultados demonstraram que o Pilates foi mais efetivo em comparação a exercícios domiciliares em indivíduos com CNLBP, mas é incerto se esses resultados são clinicamente relevantes. Além disso, o Pilates foi custo-efetivo em comparação com exercícios

domiciliares para melhorar a dor, a incapacidade e os anos de vida ajustados pela qualidade de indivíduos com CNLBP nas perspectivas do sistema de saúde público e social.
Número de registro de ensaio clínico: NCT03113292.
Palavras-chave: Dor nas costas; Exercício; Pilates; Incapacidade; Qualidade de vida; Avaliação económica.

ABSTRACT

Objective: To investigate the cost-effectiveness of a Pilates exercise program compared with home-based exercises in individuals with chronic non-specific low back pain.

Design: Randomized controlled trial with a 6-month follow-up alongside an economic evaluation.

Setting: Rehabilitation clinic.

Participants: One hundred and forty-five individuals (18-50 years of age) with low back pain for ≥ 12 consecutive weeks were enrolled and randomly allocated in a 1:1 ratio to either Pilates (n=72) or home-based exercise groups (n=73).

Interventions: Method Pilates (Mat Pilates exercises using accessories) versus home-based exercise (postural exercises, muscle stretching and strengthening, and spine stabilization/mobilization), twice a week, for six weeks.

Main outcome measures: Assessments were performed at baseline, post-intervention, and six months follow-up. Outcomes were pain intensity (0 to 10), disability (0 to100), and health-related quality of life (-0.176 a 1). The included costs were direct medical costs, direct non-medical costs and indirect costs.

Results: At post-intervention, the Pilates group had significantly lower pain intensity (difference= -1.14, 95%CI -2.05; -0.23), less disability (difference= -6.66, 95%CI -11.29; -2.03), and higher health-related quality of life (difference= 0.102, 95%CI 0.054; 0,151) compared to the home-based exercise group. At follow-up, the Pilates group had a significantly higher health-related quality of life (difference= 0.055, 95%CI 0.003; 0.106) compared to the home-based exercise group but there were no significant differences in pain and disability. A significant overall effect of Pilates compared to home-based exercise was found for disability (difference = -4.4, 95%CI -7.6; -1.1), and health-related quality of life (difference = 0.049, 95%CI 0.022; 0.076), but not for pain. The main contributors to total societal costs were indirect costs in both groups. Costs of lost productivity at work (presenteeism) were higher in PG, however, these differences were not significant between groups. Pilates intervention dominated from a societal perspective, demonstrating to be more effective and less costly for pain, disability and QALY.

Conclusions: Our findings demonstrated that Pilates was more effective compared with home-based exercise in individuals with CNLBP, but it is uncertain whether these results are clinically relevant. Additionally, Pilates was cost-effective compared to home-based exercises for improving pain, disability and quality adjusted live years of individuals with CNLBP in the public health system and societal perspectives.

Clinical trial registration number: NCT03113292.

Keywords: Back pain; Exercise; Pilates; Disability; Quality of life; Economic evaluation.

CHAPTER 1

Author's presentation

A menina do interior de Minas Gerais que sempre teve apreço pelos estudos. Mudou-se com a família para Brasília. Conseguiu uma bolsa de estudos no colégio Mackenzie durante o ensino médio, através do emprego de sua mãe. Ela segurando "as pontas" de um lado, e eu me esforçando para retribuir. Eu sabia que ela estava ali apenas por mim. Aulas pela manhã, a tarde, cursinho a noite e provas aos finais de semana. Essa foi a rotina durante três anos. No final do ensino médio, entrei para a UnB. A fisioterapia não era a primeira opção, mas passou a ser. Decidi que aproveitaria a oportunidade. Projetos de pesquisa, extensão, estágio. Cinco anos depois, apresentei meu TCC e na semana seguinte fiz a prova para ingressar no Mestrado. Eu não queria parar. Durante o Mestrado também experienciei a prática clínica. Percebi que estava no caminho certo: teoria científica e prática clínica caminhando juntas. De mãos dadas. Certa vez, um professor disse que não era a favor do aluno iniciar um mestrado logo após a graduação. De fato, naquela fase, eu era imatura cientificamente falando. No entanto, foi o mestrado que me trouxe até aqui e me permitiu ser uma profissional mais responsável frente ao paciente. Ah! Se a maioria embarcasse nessa e baseasse sua prática em evidências... Fim do mestrado. Mais uma vez, eu queria continuar. Um mês depois, fiz a prova para ingressar no Doutorado. Que jornada! Desenvolvemos um ensaio clínico que, olhando para trás, me faz sentir um orgulho danado! Cento e quarenta e cinco pessoas receberam tratamento para dor lombar crônica. Muitos há cinco, seis anos em lista de espera no sistema de saúde. Foram três etapas de avaliação, coleta, intervenção. Me dividia ainda entre a pesquisa e a prática clínica. Veio a pandemia e logo no início dela eu arrumava as malas para me mudar de país. Na Holanda, estudaria inglês e faria parte do doutorado. Muitos desafios, as coisas não saíram como planejado. Fase difícil. Uma pausa, hora de recalcular a rota. Um ano e meio de Holanda, uma surpresa! Eu me tornaria mãe. Era hora de voltar para o meu país e ficar perto da família. Manuela nasceu no último ano do meu Doutorado. Agora, mais de oitenta por cento do meu tempo era dela. Que loucura! Mas me sentia mais forte, mais capaz. Um ano depois, hora de arrumar as malas novamente. Rumo a Holanda. Haviam algumas coisas pendentes que precisavam ser vividas, desta vez sem os impasses da pandemia. Aqui estou, na Holanda pela segunda vez, escrevendo o último capítulo da minha tese. E enquanto me preparo para o dia da minha defesa, anseio pelo futuro. Até aqui, foi tempo de plantar. Sinto que os frutos começarão a nascer. Tudo no seu tempo. Outra Caroline. Mais resiliente, mais determinada. O Doutorado me transformou: que bom que suportei o processo. Que bom que eu consegui. Que venha a defesa!

CHAPTER 2

Contextualization

Why is low back pain an urgent global public health concern?

Low back pain (LBP) is considered the main cause of disability worldwide [1]. Disability attributed to LBP is higher in the economically active population worldwide [2,3]. In the upcoming decades, a substantial increase in the total burden of disability and, consequently, in the costs related to this problem, is predicted [1,4].

The high prevalence of low back pain in the economically active population causes a great social and economic impact [1]. Moreover, the incidence of LBP is increasing, especially in low- and middle-income countries, which is associate to additional burden to healthcare and social systems [4]. Findings from a cost-of-illness study in Brazil showed that the annually the average absence from work of people with LBP was of around 100, between 2012 and 2016. During this period, a total of 59 million days lost due to LBP were identified and productivity losses represented 79% of societal costs with this condition [5]. This is relevant because in addition to work absenteeism, LBP may lead workers to early retirement [1].

However, although there are recommendations provided by international clinical guidelines for the management of chronic non-specific LBP, the use of low-value interventions (i.e., interventions without evidence-based support) persist [3,6,7]. This involves the use of interventions with minimum or inexistent effect size are being frequently used by health professionals. On the other hand, there is also a lack in the use of treatment approaches that are considered effective [7].

Currently, financial resources are limited and there is a great demand for studies comparing the cost-effectiveness of interventions targeting chronic conditions. Research is essential in the field of chronic non-specific LBP due to the high incidence and prevalence of this condition, in addition to the high costs related to its treatment and those influenced by productivity losses [8]. To the best of our knowledge, there are insufficient data on the costs and effects of therapeutic exercises in the context of chronic non-specific LBP [8].

In order to control the economic and social burden generated by low back pain, reliable studies that determine which treatment strategies are effective are necessary, especially in the context of health economic assessments. This kind of investigation aims to ensure recommendations toward the use of interventions based on scientific evidence and provide guidance to health professionals, in addition to assisting public policy makers and managers regarding the use of more assertive prioritization of financial resources [5,7].

Considering the need to prioritize research in Brazil focusing on low back pain, the substantial increase in health expenses and the gap between clinical practice and scientific evidence, we developed four studies that make part of this thesis:

1) Effectiveness and cost-effectiveness of Pilates versus home-based exercises in individuals with chronic non-specific low back pain: randomised controlled trial protocol (Chapter 4);
2) Effectiveness of Pilates compared with home-based exercises in individuals with chronic non-specific low back pain: randomised controlled trial (Chapter 5);
3) Cost-effectiveness of Pilates versus home-based exercises in individuals with chronic non-specific low back pain: economic evaluation alongside a randomised controlled trial (Chapter 6);
4) Is kinesiophobia associated with disturbances in dynamic balance in individuals with chronic non-specific low back pain? (Chapter 8).

CHAPTER 3

Organization of the thesis

This thesis begins with the protocol of the main studies, published in the European Journal of Physiotherapy at the beginning of the doctorate (Chapter 4). In Chapter 5, we present the study that investigated the effectiveness of a Pilates exercise program compared with home-based exercises in individuals with chronic non-specific low back pain. This study was submitted to the Archives of Physical Medicine and Rehabilitation. Then, the study that verified the cost-effectiveness of a Pilates exercise program compared with home-based exercises in individuals with chronic non-specific low back pain, is presented in Chapter 6 and is in process of correction for submission. These three studies described make up the main body of the thesis.

In the final considerations (Chapter 7), we explore the main conclusions of the developed studies, point out clinical and management implications, as well as describe suggestions for future studies. Additionally, in Chapter 8 we present the paper that investigated the association between deficits in dynamic balance, age and body mass index (BMI), and kinesiophobia. The manuscript is a production that was also developed throughout the doctorate.

Finally, we address the main societal contributions in Chapter 9. Abstracts published in conference proceedings, interviews and other productions that somehow contributed to the academic community and also to society.

CHAPTER 4

Paper 1: Effectiveness and cost-effectiveness of Pilates versus home-based exercises in individuals with chronic non-specific low back pain: randomised controlled trial protocol

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ORIGINAL ARTICLE

Effectiveness and cost-effectiveness of Pilates versus home-based exercises in individuals with chronic non-specific low back pain: randomised controlled trial protocol

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Effectiveness and cost-effectiveness of Pilates versus home-based exercises in individuals with chronic non-specific low back pain: randomised controlled trial protocol

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Abstract

Background: The use of exercise in primary healthcare is recommended for the management of chronic non-specific low back pain (CNLBP). Home-based exercises are effective and widely adopted in this setting. Pilates may be useful as primary care strategy; however, evidence is controversial.

Study design: Randomised controlled trial with economic evaluation, conducted in a clinical setting.

Objective: To compare the effectiveness and cost-effectiveness of Pilates versus home-based exercises in individuals with CNLBP.

Methods: One hundred and forty-four participants (aged 18–50 years and with CNLBP >12 consecutive weeks previous to the study) will be recruited, enrolled and randomly allocated to one of two groups: (1) Pilates (n ¼ 72) or (2) home-based exercises (n ¼ 72). The Pilates group will receive matbased exercises and the Home-Based Exercise group will receive a prescription of strength, stretching and postural exercises. The intervention will last six weeks (twice-weekly sessions). Assessments will be performed at baseline, at the end of the intervention (6 weeks) and after six months follow-up. Primary outcomes: pain intensity and disability; secondary outcomes: static balance, quality of life and perception of recovery.

Conclusions: This RCT may yield results applicable to the decision-making of health system managers.

Keywords: Physical therapy; costs and cost analysis; treatment outcome; low back pain; quality of life

4.1 Introduction

Low back pain (LBP) is characterised by pain, muscle tension or stiffness located below the 12th rib and above the gluteal folds [1]. Chronic non-specific LBP (CNLBP) is distinguished by persistent pain for more than 12 weeks, without a clear cause [1,2]. This condition is considered one of the most common causes of disability and absenteeism worldwide [2,3]. It is estimated that 80% of adults have at least one episode of LBP during their lifetime and approximately 40% will develop CNLBP after an acute episode. CNLBP is associated with social and economic problems, for instance, US$8 billion were spent on indirect costs in the United States in 2004 [4], and Hong et al. [5] reported treatment expenditures of £2.8 billion. In Brazil in 2016, approximately US$71 million were spent on direct costs by the public healthcare system, with spinal disorders [6].

Individuals with CNLBP may have a compromised spinal stability due to a reduced neural drive to stabilising muscles [7], and coordination impairments [8], which leads to deficits in postural control [7]. Thus, exercise therapies are deemed to be beneficial for CNLBP and probably are the conventional treatment most widely used in the world [9]. Exercises with a focus on muscle strengthening [10] and vertebral stabilisation, including Pilates [11–15], have been prominent in recent years and are commonly used for the management of CNLBP in Brazil. Exercises delivered at home are commonly adopted in primary health care settings [16] and are recommended to manage chronic conditions [17]. Supervised home-based exercises improved flexibility, pain and functionality in individuals with CNLBP and were considered as effective as standard physiotherapy interventions delivered in other settings (e.g. stretching and strengthening exercises) [18,19], and showed long-term effects for up to one year [20].

Studies have shown positive results of Pilates in the improvement of pain and physical condition in individuals with CNLBP [11,12,21–23]. Furthermore, the addition of Pilates to a minimal intervention (educational booklet) provided short-term pain relief and reduction in the severity of disability, but without long-term effects [12]. However, systematic reviews indicated that the evidence for Pilates still needs to be consolidated [15,24,25]. Despite the positive effects, recurrent high risk of bias [15,25], lack of intention-to-treat analysis [25] and lack of standardisation of Pilates protocols introduce uncertainty [22], which warrants further studies.

Currently, given the limited financial resources, there is a great demand for studies comparing the cost-effectiveness of interventions. Research is essential in the field of CNLBP because of the high incidence and prevalence, and subsequent high costs related to healthcare and absenteeism [26]. To the best of our knowledge, there is insufficient data on costs and effects of exercise for CNLBP [26], and no study has compared Pilates to home-based exercises. To date, only one RCT has been published comparing different weekly frequencies of Pilates and also assessed costs and cost-effectiveness in individuals with CNLBP [27].

The use of exercise interventions in the primary care setting is a policy of the Brazilian Ministry of Health, and studies have reported using Pilates as an intervention strategy [28,29]. However, Pilates is not formally included as a primary healthcare intervention in Brazil; although, it could be useful for the management of chronic conditions such as CNLBP. We raise the question of whether Pilates is good value for money at this healthcare level, hence the need to investigate if Pilates has better outcomes compared to home-based exercises. Therefore, the aim of the present study is to compare the effectiveness and cost-effectiveness of a Pilates programme versus home-based exercises in individuals with CNLBP. It is hypothesised that Pilates will be more effective and cost-effective compared to home-based exercises, on the outcomes of interest.

4.2 Methods

4.2.1. Study design

This is a randomised controlled trial (RCT) with two parallel groups and an economic evaluation alongside. The study will be conducted in a clinical setting, and the assessments will be performed in a Physiotherapy Evaluation and Intervention Laboratory in the city of Brasilia, Brazil. The RCT will be reported according to the CONSORT statement, and the cost-effectiveness analysis will be conducted and reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS).

4.2.2. Eligibility criteria

The initial evaluation will include patient history and a physical evaluation. Participants will be included according to the following criteria: (1) male or female gender (18–50 years of age); (2) CNLBP for more than 12 consecutive weeks previous to the study; (3) not having attended Pilates or physiotherapy sessions for treatment of LBP, for at least six months prior to enrolment. The exclusion criteria: (1) history of trauma or fractures of the spine; (2) diagnosis of spine osteoarthritis, disc herniation or spondylolisthesis; (3) self-reported referred pain (visceral, abdominoplasty, appendicitis, abdominal and pelvic surgeries); (4) previous spinal surgery; (5) presence of root symptoms (e.g. sciatica and cauda equina syndrome), classified by the Quebec Task Force [30] as levels 3 and 4; (6) pregnancy.

Participants will be recruited through posters placed in strategic points on the university campus and at health facilities, communication in local media, and posts on social networks. We will also recruit patients from a waiting list of a local physiotherapy clinic.

Participants will be invited to participate by signing an informed consent form. This study was approved by the Institutional Review Board (n. 2.163.607; 8 July 2017) and registered at ClinicalTrials.gov (NCT03113292). The data will be stored in a secure database, and only the blind assessor (physiotherapist) will have access to this information to ensure confidentiality.

The selected participants will be entered sequentially. After informed consent and baseline measurements, they will be randomly allocated to one of two groups: (1) Pilates or (2) home-based exercises. Randomisation will be based on a table with random numbers generated using the website http://www.random.org. For this process, opaque and sealed envelopes containing cards with the names of the interventions will be used to ensure concealed allocation. A research assistant who will not be aware of any patient characteristics will perform the allocation procedure.

4.2.3. Outcome measures

The outcome assessments will be performed at three different moments: (1) baseline (pre-intervention); (2) at the end of the intervention period (six weeks); and (3) after six months of follow up. The primary outcomes will be pain intensity and disability. The secondary outcomes will be quality of life, balance, and perception of recovery. The study timeline is depicted in Table 1. All outcomes are considered core outcomes for non-specific LBP research [31].

Pain intensity will be measured using the visual analogue scale (VAS) [32]. This scale is characterised by a 10-cm line marked at ‘zero (0)’ and ‘ten (10)’, where zero represents no pain and ten represents the worst possible pain. Participants will be instructed to place a mark on the line to represent the intensity of their pain (measured in centimetres), considering the average pain of the last seven days.

Disability will be measured by the Brazilian version of the Quebec Back Pain Disability Scale Questionnaire [33]. The score ranges from 0 to 100 (with 0 representing no disability and 100 representing the highest level of disability).

Perceived recovery will be measured using the Global Perceived Effect Scale (11-point scale), ranging from –5 (‘much worse’), 0 (‘no change’), to 5 (‘completely recovered’) [34].

For the measurement of health states (utility), the EQ-5D-3L will be used. This is the only version that has been translated and validated for the Brazilian population [35]. The questionnaire evaluates five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). The answers for each dimension allow for three possibilities based on severity levels (I have no problems/I have some problems/I am unable).

The Balance System platform (Biodex Medical Systems, Shirley, NY) will be used to assess static balance. The platform consists of a circular base with a surface inclination mobility up to 20 in a range of 360 movements. The platform is able to move in the anteroposterior (AP) and mediolateral (ML) axes. The following indices will be calculated: (1) postural stability index: emphasises the ability to maintain the centre of balance. The score on this test assesses deviations from the centre, thus a lower score represents a better test result. The participants will perform the test in a stable condition with eyes open and closed, in bipedal support; (2) limits of stability (LOS) index: challenges the individual to move and control their centre of gravity within their support base, in bipedal position and in a stable condition. The individual must shift the weight to move the cursor from the centre target to a blinking target, and back as quickly and with as little deviation as possible [36]. If pain is elicited, the testing session will be terminated immediately and the participant will be evaluated after a rest interval or, if appropriate, at another moment.

Adverse events

We will consider treatment-related adverse events, defined as ‘Any adverse experience during treatment resulting in death, life-threatening adverse experience, hospitalization or prolongation of existing hospitalization, or persistent or significant disability or incapacity’ [37]. Adverse events will be monitored in both groups to ensure safety. Individuals will be instructed to inform the occurrence of adverse events during and after the Pilates session (if any, the therapist will record the adverse event on the patient’s chart). Participants of the home-based group will inform the researchers via text message or the exercise sheet.

4.2.4. Blinding

Blinding of the therapist and participants will not be possible due to the nature of the intervention. However, outcome measures will be performed by a blind assessor who will not be aware of group allocation. The assessor performing the statistical analysis will be blind to group allocation (i.e. dataset with the groups/individuals numerically coded).

Table 1. Time line of the study.

	Enrolment	Before randomization	Allocation	Intervention	Post Intervention	Follow-up
TIMEPOINT			**0**	***Six weeks, 2x/week***	***6th week***	***6 months***
ENROLMENT:						
Eligibility criteria	X					
Informed consent	X					
Allocation			X			
INTERVENTIONS:						
Pilates				↔		
Home-Based Exercise				↔		
ASSESSMENTS:						
Demographic data	X					
Primary outcomes: Pain Disability		X			X	X
Secondary outcomes: Balance Quality of Life		X			X	X
Secondary outcome: Perception of Recovery					X	X
Economic data		X			X	X

4.2.5. Description of the interventions

Pilates

The physiotherapist providing the Pilates intervention is a certified and experienced Pilates instructor, with expertise also in the prescription of conventional exercises. The sessions will be 50-minutes long, with a maximum of three to four participants per session and will include 7–10 exercises. For each exercise, two sets of 8–12 repetitions will be performed, according to the capabilities of each participant. If required, exercises will be adapted and modified individually for the three levels of difficulty used in Pilates: basic, intermediate and advanced. Progress will be based on the absence of postural compensations when performing the minimum number of repetitions. The programme will consist of mat-based Pilates exercises with the use of accessories (Table 2). In the first two sessions, individuals will receive instructions on the method and will undergo a process of familiarization. After the familiarization period, the six-week intervention will commence. The exercises will be based on the Pilates principles: (1) breathing – coordination of the body during the inspiratory and expiratory phase and deep muscle activation; (2) axial elongation and core control; (3) segmental mobilisation and spinal stabilisation; (4) organisation of the head, neck and shoulders; (5) weight bearing and alignment of the extremities; (6) movement integration – motor learning with refinement and coordination.

Home-based exercise

This group will be supervised by another physiotherapist. Initially, participants will undergo a face-to-face familiarization phase (two sessions). After the familiarization, the six--week intervention will commence. The exercises will be prescribed twice a week, using a booklet containing the description of the sets and repetitions, as well as guidelines and precautions. Additionally, the expected duration to perform all exercises will be around 50 minutes per session (similar to the Pilates group). The protocol will include postural exercises, muscle stretching and strengthening, and spinal stabilization/mobilization, based on previous studies [18,38–40] (Table 2). The progression to the next level (stage II) will be performed by altering the body position during the exercises, with the intention to provide variations in the arm levers and range of motion. In addition, the progression will occur on the absence of postural compensations when performing the minimum number of repetitions (at the halfway point of the intervention, a face-to-face session will be held to change the exercises and carry out the progression). The difficulty level will be determined individually. During the intervention, all participants will be instructed to complete a printed exercise sheet to monitor the performance of the exercises (twice a week), adherence, and to report possible adverse effects. Participants will be contacted weekly via e-mail and/or text messaging (WhatsAppVR) for supervision and checking of prescribed exercises, as well as monitoring of possible adverse effects. During the weekly message, the physiotherapist will ask for the adherence and if the participants performed the exercises as scheduled (twice a week), and will also send messages with gentle reminders about the importance of performing the exercises, as instructed, and to fill in the diary.

Table 2. Description of the progression (stages) and groups' protocols.

		Pilates	
	Stage I	**Stage II**	**Stage III**
Aim	Stabilization Pain Management	Segmental Mobilization	Dynamic Stabilization Proprioceptive phase
Example of Exercises	*Bent Knee Opening* *Arm Arcs* *Sidelying*	*Pelvic Clock* *Bridging* *Prone Press Up*	*Dart* *Sidekick* *Leg Pull Front*
	2 weeks 2x/week 2 sets x 8 repetitions (1 min rest interval between sets)	2 weeks 2x/week 2 sets x 10 repetitions (1 min rest interval between sets)	2 weeks 2x/week 2 sets x 12 repetitions (1 min rest interval between sets)

	Home-Based Exercise	
	Stage I	**Stage II**
Aim	Warming-up Stretching Muscle Strength	Warming-up Stretching Muscle Strength
Example of Exercises	Strengthening abdominal and posterior trunk muscles Joint flexibility (spine and lower limbs)	Strengthening abdominal and posterior trunk muscles Joint flexibility (spine, upper limbs and lower limbs)
	3 weeks 2x/week 3 sets x 10 repetitions (1 min rest interval between sets)	3 weeks 2x/week 3 sets x 15 repetitions (1 min rest interval between sets)

Participants of both groups will be allowed to take their usual medication, and this information will be monitored during post-intervention re-evaluations.

4.2.6. Statistical analysis

The sample size calculation considered a statistical power of 80% and confidence interval of 95% to detect differences in pain intensity and disability between the Pilates and Home-Based Exercise groups, equivalent to differences in means from previous studies. The pain intensity mean and SD of the Pilates group were based on a previous study [27] (3.30 ± 2.30), and for the Home-Based Exercise group on a pilot study (2.15 ± 1.99). The disability mean and SD were based on a pilot study (8.4 ± 5.6 for the Pilates group and 13.6 ± 13.6 for the Home-Based Exercise group). The calculation demonstrated a sample size of 126 participants. Assuming a dropout of 15%, we determined that 144 participants will be needed (72 per group).

The data normality assumptions will be evaluated using the Shapiro–Wilk test. If the assumptions are confirmed, the effectiveness will be analysed using a linear mixed model, including a between-groups difference at each time-point (baseline, post-intervention and follow-up) and an overall effect difference. For the comparisons, mean differences and 95% confidence interval (95%CI) will be calculated. If the normality assumptions are not met, non-parametric variants will be used. All analyses will be performed based on intention-to-treat principle. Dropouts will be included in the analysis by multiple imputation method. The significance will be set at 5% ($p<.05$), with 95%CI.

4.2.7. Economic evaluation

Concurrently with the RCT, a cost-effectiveness study will be conducted comparing the Pilates group and the Home-Based Exercise group regarding costs and outcomes from the perspectives of public healthcare and society. In the first perspective, only the costs incurred by the public healthcare system will be included in the analysis, i.e. direct costs related to consultations, medications, tests, hospitalisations and professional fees. In the second perspective, private health care expenses, costs incurred by patients related to transportation and support by caregivers (when applicable), as well as indirect costs related to missed workdays and loss of productivity at work will be included.

To obtain the economic data, a questionnaire will be administered to the participants at pre-intervention, post-intervention and follow up. The questionnaire will be completed by the participants, who will indicate the quantity and frequency of the items used (Table 3). The cost of the items will be obtained from nationally available databases: (i) for medication costs, the Health Price Database, publicly available from the Ministry of Health (http://bps.saude.gov.br/); (ii) for medical consultations, tests and hospitalisations, the mean cost paid by the Ministry of Health to public health services, available on the TABNET/DATASUS website (http://datasus.saude.gov.br); (iii) for the indirect costs related to absence from work and loss of productivity, the average income per gender and five-year age category. All costs will be expressed in national currency (R$); subsequently, they will be converted to US dollars (US$) and Euros (€).

The target population of the study will be the same as described in the RCT. The time line will be less than one year (six weeks of intervention plus six months of follow-up), which exempts the cost and health outcomes from discount rates.

The incremental cost-effectiveness ratios for the primary outcomes (pain and disability) and cost–utility ratios will be calculated from the public healthcare and societal perspectives. The cost–utility ratio will express the incremental costs per quality-adjusted life year (QALY). QALYs will be derived from the EQ-5D-3L. In addition to the incremental cost–utility ratio calculation, we will calculate the absolute and incremental net monetary benefit (NMB and INMB), which are other parameters used to express the results of a cost-effectiveness study. Sensitivity analyses will be conducted to measure the impact of uncertainty on the results. The study will follow the recommendations of national [41] and international [42] guidelines on good practices in economic evaluation.

4.3. Discussion

The evidence for Pilates in the management of CNLBP is still controversial. Previous systematic reviews pointed out that, for pain intensity and functionality, Pilates was not superior to other exercise therapies [15,43]. In addition, studies with larger samples and standardised protocols are needed [22]. In view of common biases in Pilates research, we set out to adopt measures of methodological control. A sample size calculation was carried out in order to achieve adequate statistical power. We will perform an intention-to-treat analysis, given the intervention benefits in daily clinical practice, preservation of sample size, and initial group allocation [44]. Another feature will be the economic evaluation alongside the RCT, which allows the benefits of an experimental design that maximizes internal validity and collects economic data alongside a trial rather than funding a stand-alone economic study.

Table 3. Description of the cost items that will be included in the economic evaluation (LBP: Low back pain).

	Definition	Calculation
Direct costs:		
Consultations (last 6 weeks)	Number of consultations due to LBP, by a health professional	Number of consultations multiplied by the value reimbursed by the Ministry of Health, by health professional
Caregiving or companion during consultations (last 6 weeks)	Number of hours spent during the consultation (including transport) due to LBP. The number of hours will be accounted for patients and caregiver/companion (when applicable)	Total number of hours multiplied by the Brazil's overall average salary per hour, stratified by patient and caregiver/companion
Transport (last 6 weeks)	Number of displacements for consultation, exams, and get drug due to LBP	Total number of displacements by type of transport used
Emergency hospitalization (last 6 weeks)	Number of times the patient was hospitalized in an emergency facility due to LBP	Total number of times multiplied by the Brazil's average emergency hospitalization cost due to LBP
Inpatient	Number of times the patient had an inpatient due to LBP	Total number of times multiplied by the Brazil's average inpatient cost due to LBP
Caregiving or companion during emergency or impatient procedures (last 6 weeks)	Number of hours spent during the emergency or inpatient procedures (including transport) due to LBP. The number of hours will be accounted for patients and caregiver/companion (when applicable)	Total number of hours multiplied by the Brazil's overall average salary per hour, stratified by patient and caregiver/companion
Use of drugs (last 6 weeks)	The total consumption of drugs (diary dose multiplied by number of days the patient used each drug)	Total consumption of medication (stratified by each drug) multiplied by the price paid by public health facilities
Indirect costs:		
Work days lost (absenteeism) (last 6 weeks)	Number of work days lost due to LBP	Total number of work days lost due to LBP multiplied by the Brazil's overall average salary per day
Loss of productivity (presenteeism)	Percentage of lost productivity at work when feel LBP	Percentage of lost productivity at work due to LBP multiplied by number of days that feel LBP at work multiplied by the Brazil's overall average salary per day

The use of home-based exercises is considered an effective strategy in the management of CNLBP [18,19,38,40]. Studies have evaluated adult individuals and demonstrated clinically significant improvements in pain intensity and disability compared to other modalities (e.g. non-steroidal drugs, group exercise) [19,38,40]. In Brazil, primary care professionals widely adopt home-based interventions, which are supported by policies and regulations of the Ministry of Health and are considered an essential practice for the management of chronic conditions [45,46].

We will adopt a well-defined protocol for both Pilates and Home-Based Exercise groups, describing the exercise volume and progression. Exercise volume is essential to the gains resulting from exercise; however, it is usually neglected in exercise trials. Volume can be defined by the number of sessions or series/repetitions [47] and, if not controlled, can influence the effects. A familiarisation will be adopted for both groups, allowing control of the unwanted influences of learning effects [48], providing opportunity to clarify any questions regarding the exercises, and aiming for greater adherence. According to Palazzo et al. [49] adherence may be enhanced by adopting strategies that improve patient performance and provide support/adequate communication. Thus, participants of the Home-Based Exercise group will be supervised weekly by text message to encourage compliance. In addition, at the halfway point of the intervention, a face-to-face session will be held to change the exercises and carry out their progression.

One of the limitations of this study might be the relatively small sample size for an economic evaluation. Ideally, economic outcomes are used in the sample size calculation of an economic evaluation alongside an RCT. However, sample size calculations are usually based on primary clinical outcomes. Cost data are skewed and would need larger sample sizes to detect relevant differences than clinical outcomes. Very large sample sizes needed for economic evaluations may be neither feasible nor ethically acceptable. Also, to perform sample size calculations for economic outcomes information on variance parameters of effectiveness measures, cost measures and incremental cost-effectiveness ratios would be needed, many of which are hard to predict a priori. Consequently, trial-based economic evaluations are typically underpowered for economic outcomes. We are aware of this issue and will, therefore, take precision of the cost-effectiveness analysis into account and perform sensitivity analyses to check the robustness of the findings. We are also considering a limitation pertaining.

The analysis of the costs and effects of Pilates versus home-based exercises has not yet been performed. Thus, the comparison may yield results applicable to the decision-making of health system managers.

Disclosure statement

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CHAPTER 5

Paper 2: Effectiveness of Pilates compared with home-based exercises in individuals with chronic non-specific low back pain: randomised controlled trial

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Effectiveness of Pilates compared with home-based exercises in individuals with chronic non-specific low back pain: randomised controlled trial

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Abstract

Objective: To investigate the effectiveness of a Pilates exercise program compared with home-based exercises in individuals with chronic non-specific low back pain.

Design: Randomized controlled trial with a 6-month follow-up.

Setting: Rehabilitation clinic.

Participants: One hundred and forty-five individuals (18-50 years of age) with low back pain for ≥ 12 consecutive weeks were enrolled and randomly allocated in a 1:1 ratio to either Pilates (n=72) or home-based exercise groups (n=73).

Interventions: Method Pilates (Mat Pilates exercises using accessories) versus home-based exercise (postural exercises, muscle stretching and strengthening, and spine stabilization/mobilization), twice a week, for six weeks.

Main outcome measures: Assessments were performed at baseline, post-intervention, and six months follow-up. Outcomes were pain intensity (0 to 10), disability (0 to100), and health-related quality of life (-0.176 1).

Results: At post-intervention, the Pilates group had significantly lower pain intensity (difference= -1.14, 95% CI -2.05; -0.23), less disability (difference= -6.66, 95%CI -11.29; -2.03), and higher health-related quality of life (difference= 0.102, 95%CI 0.054; 0,151) compared to the home-based exercise group. At follow-up, the Pilates group had a significantly higher health-related quality of life (difference= 0.055, 95%CI 0.003; 0.106) compared to the home-based exercise group but there were no significant differences in pain and disability. A significant overall effect of Pilates compared to home-based exercise was found for disability (difference = -4.4, 95%CI -7.6; -1.1), and health-related quality of life (difference = 0.049, 95%CI 0.022; 0.076), but not for pain.

Conclusions: Our findings demonstrated that Pilates was more effective compared to home-based exercise in individuals with CNLBP, but it is uncertain whether these results are clinically relevant.

Clinical trial registration number: NCT03113292.

Keywords: Back pain; Exercise; Pilates; Disability; Quality of life.

5.1. Introduction

One of the most widespread musculoskeletal disorders worldwide is low back pain (LBP), affecting approximately 40% of people at some point in their lives [1]. Defined as persistent pain for more than 12 weeks with no clear cause [2-4], chronic non-specific LBP (CNLBP) is considered one of the most frequent reasons for disability and absenteeism worldwide [2,5]. Individuals with CNLBP often have impaired spinal stability due to reduced neural activation in the stabilizing muscles [6] and coordination impairments [7] and these factors result in deficits in postural control [6].

Exercise therapy has been recognized as beneficial for individuals with CNLBP [8], and is the most commonly prescribed intervention worldwide [9]. Especially, exercise programs prioritizing muscle strengthening [10] and spinal stabilization, such as Pilates [11-15], have gained considerable recognition in recent years and are being used as a first-line treatment option for CNLBP in primary care [16]. Studies have shown promising results on the effectiveness of Pilates in improving pain levels, disability, and quality of life in individuals with CNLBP [11,12,17-19]. In addition, exercise performed at home has been considered as another treatment option for CNLBP as preliminary evidence has shown it to be beneficial for pain relief and functional limitation [20].

Despite the potential benefits of exercise therapies for CNLBP, systematic reviews have highlighted the need for further high-quality evidence regarding the effectiveness of Pilates [15,21,22] and home-based exercise [20]. Furthermore, studies comparing the effectiveness of both exercise therapies are still scarce [23]. Therefore, the aim of this study was to compare the effectiveness of Pilates versus home-based exercise in individuals with CNLBP immediately after interventions and at a 6-month follow-up, in terms of pain intensity, disability, and health-related quality of life. It is hypothesized that Pilates would be more effective than home-based exercise regarding these outcomes.

5.2. Method

5.2.1. Study design

A randomised controlled trial (RCT) with two parallel groups was performed in which Pilates was compared to home-based exercises in individuals with CNLBP with a follow-up of six months. The study was conducted in a clinical setting in the city of Brasilia, Brazil. This study was approved by the Institutional Ethics Committee (protocol n. 2.163.607) and registered at ClinicalTrials.gov (NCT03113292). This RCT was reported according to the CONSORT statement [24].

5.2.2. Setting

The use of exercise therapies for CNLBP in primary care has been implemented by the Brazilian Ministry of Health as a health policy since 2008 [16]. However, Pilates is currently not officially included in the treatment options for CNLBP provided by public primary care services in Brazil.

5.2.3. Participants

Participants were eligible if they met the following criteria: (1) male or female gender (18–50 years of age); (2) CNLBP for more than 12 consecutive weeks before entering the study; (3) not having attended Pilates or physiotherapy interventions for LBP for at least six months prior to enrolment. Participants were excluded if they presented: (1) a history of trauma or fractures of the spine; (2) a diagnosis of spine osteoarthritis, disc herniation, or spondylolisthesis; (3) self-reported referred pain (e.g., visceral, abdominoplasty, appendicitis, abdominal and pelvic surgeries); (4) previous spinal surgery; (5) presence of root symptoms (e.g., sciatica and cauda equina syndrome), classified by the Quebec Task Force [25] as levels 3 and 4; and (6) pregnancy.

5.2.4. Description of the Interventions

Pilates

The Pilates method was supervised by a certified physical therapist. The program consisted of Mat Pilates exercises using accessories (Table 1). In the first two sessions (one week after randomisation), participants received instructions about the method and went through a familiarization process. After the familiarization period, the six-week intervention started. There were 2 sessions per week; sessions were 50 minutes long, with a maximum of 4 participants per session, and included 7 to 10 exercises. For each exercise, two series of 8 to 12 repetitions were adopted, according to the ability of each participant. When required, exercises were adapted and modified individually considering the three difficulty levels used in Pilates: basic, intermediate, and advanced. Exercises were based on Pilates principles, i.e., (1) breathing – coordination of the body during the inspiratory and expiratory phase and deep muscle activation; (2) axial elongation and core control; (3) segmental mobilization and stabilization of the spine; (4) organization of the head, neck, and shoulders; (5) weight-bearing and extremity alignment; (6) movement integration – motor learning with refinement and coordination. The exercises are described in Appendix A.

Home-based exercise

The home-based exercise group was supervised by another physical therapist. Initially, two face-to-face familiarization sessions were held (one week after randomisation). The intervention was based on general exercises (postural exercises, muscle stretching and strengthening, and spine stabilization/mobilization), prescribed twice a week. Participants received a booklet containing the description of the exercises, series and repetitions, and safety issues to be alert for during sessions. The protocol was based on previous studies [26-29]. (Table 1). The expected duration of performing all exercises was around 50 minutes per session (similar to the Pilates group). The progression was held in a face-to-face session. The participants were presented with more challenging exercises variations by changing their body position (e.g., due to variation in arm levers and range of motion). In addition, progression occurred in the absence of postural compensation when performing the minimum number of repetitions. The difficulty level was determined individually. During the intervention, all participants were instructed to complete a printed exercise sheet twice a week to monitor exercise performance, adherence, and to report possible adverse effects. Participants were contacted weekly via email and/or text message (WhatsApp®) for supervision as well as monitoring for possible adverse effects. During the weekly message, the physiotherapist asked about adherence and whether participants performed the exercises as instructed and scheduled (twice a week) and sent messages with reminders about the importance of performing the exercises. Participants of both groups were instructed to take their usual medication, and this information was monitored during post-intervention re-evaluations. The booklet containing the exercises is in Appendix B.

Table 1. Description of the prescribed exercises and progression aims (stages).

Pilates		Home-based exercise	
Aim	**Exercises**	**Aim**	**Exercises**
Stage I	2 weeks	**Stage I**	3 weeks
Stabilization	2 x /week	Warming-up	2x /week
Pain management	2 sets x 8 repetitions (1 min rest interval between sets)	Muscle strength Stretching	3 sets x 10 repetitions (1 min rest interval between sets)
Stage II	2 weeks	**Stage II**	3 weeks
Segmental mobilization	2 x /week	Warming-up	2x /week
	2 sets x 10 repetitions (1 min rest interval between sets)	Muscle strength Stretching	3 sets x 15 repetitions (1 min rest interval between sets)
Stage III	2 weeks		
Dynamic stabilization	2 x /week		
Proprioceptive phase	2 sets x 12 repetitions (1 min rest interval between sets)		

5.2.5. Outcomes measures

Main outcomes measures were pain intensity, disability, and health-related quality of life. Secondary outcome measure was perceived recovery. Participants were assessed at three different moments: baseline; post-intervention (i.e., immediately after the completion of the intervention); and six months post-intervention (follow-up). The following variables were collected at baseline to characterize the study sample: age, gender, Body Mass Index (BMI), kinesiophobia, dynamic balance (Y-Balance test) [30]. Prognosis was assessed using the STartBack Screening Tool (low – good prognosis; medium – less-favourable prognosis; high risk – unfavourable prognosis) [31].

Pain intensity was measured by the Numerical Rating Scale (NRS) [32]. This scale consists on numbers ranging from 0 to 10, where zero is equivalent to no pain and ten to the worst possible pain. Participants were instructed to mark the number representing the intensity of their pain in the last week. Disability was assessed using the Brazilian version of the Quebec Back Pain Disability Scale Questionnaire [33], which investigates the difficulty in performing routine activities through twenty questions. The final score is obtained by summing the responses and ranges from 0 to 100. The higher the score, the greater the level of disability. Health-related quality of life was measured using the validated version of the EQ-5D-3L questionnaire for the Brazilian population. Using the EQ-5D-3L, participants described their health state based on five health dimensions (i.e., mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and three response levels (i.e., no problems, some problems, extreme problems). Subsequently, health states were converted into utility values ranging from -0.176 to 1 (perfect health) using the Brazilian tariffs [34]. For the assessment of perceived recovery, the Global Perceived Effect Scale, which contains a Likert-scale of 11 points, was applied. The scale is divided into categories ranging from -5 ('much worse'), 0 ('no change'), to 5 ('completely recovered') [35].

5.2.6. Randomization and blinding

Participants were recruited at rehabilitation clinics, and at health units located in the city of Brasília. Participants who agreed to participate signed the informed consent, and underwent baseline measurements, after which they were randomly assigned into one of two groups in a 1:1 ratio: (1) Pilates or (2) home-based exercises. For the randomization procedure, we used a random numbers table (Random.com). The allocation was concealed by using opaque and sealed envelopes containing cards with the names of each intervention. This procedure was performed by an independent researcher who was not aware of the aims and study's procedures.

A trained assessor who was unaware of the group allocation performed the interviews to collect the outcome measures (blind assessor). All outcome measures were self-reported (scales and questionnaires). Statistical analysis was also performed by an evaluator who was blind to the group allocation, by receiving the numerically coded data set (groups/individuals). It was not possible to blind the therapist and participants due to the nature of the intervention. More detailed information can be found in the study protocol [36].

5.2.7. Sample size

The sample size calculation considered a statistical power of 80% and an alpha of 5% to detect differences in pain intensity and disability between the Pilates and Home-Based Exercise groups equivalent to mean differences from previous studies. The mean decrease in pain intensity and standard deviation (SD) of the Pilates group (3.30 ± 2.30) and the home-based exercise group (2.15 ± 1.99) were based, respectively, on data from a previous study [37], and a pilot study. The mean disability and SD were based on a pilot study (8.4 ± 5.6 for the Pilates group and 13.6 ± 13.6 for the home-based exercise group). The calculation demonstrated a required sample size of 126 participants. Assuming a dropout of 15%, we determined that 144 participants were needed (72 participants per group).

5.2.8. Statistical analysis

Analyses were conducted following the intention-to-treat principle. SPSS version 29 software was used. Missing data were imputed using multiple imputation, assuming a completely at random pattern of missing values (MCAR). Variables associated with missing data and outcomes were included in the model (i.e., baseline data). The number of imputed datasets was 5 to reach a fraction of missing information of less than 5%.

The effectiveness analysis was performed using a Linear Mixed Model, in order to estimate the differences between the interventions (Pilates vs home-based exercises) over time (baseline, post-intervention, and 6-month follow-up), in the clinical outcomes of interest. Baseline covariates were included in the model to adjust effect estimates for age, gender, and prognosis.

The Mann-Whitney U test was applied to compare the perceived recovery between intervention groups in the post-intervention and follow-up moment, with significance set at 5%.

5.3. Results

5.3.1. Participants

One hundred and sixty-two subjects were screened for eligibility, and seventeen were excluded (fourteen did not meet inclusion criteria and three declined to participate). One hundred and forty-five subjects were included and randomized. All participants remained in the initially assigned intervention groups and no adverse events were reported (Figure 1). Regarding the dropouts, twenty-three and twenty participants were lost to follow-up in the Pilates group and home exercises group, respectively (Figure 1).

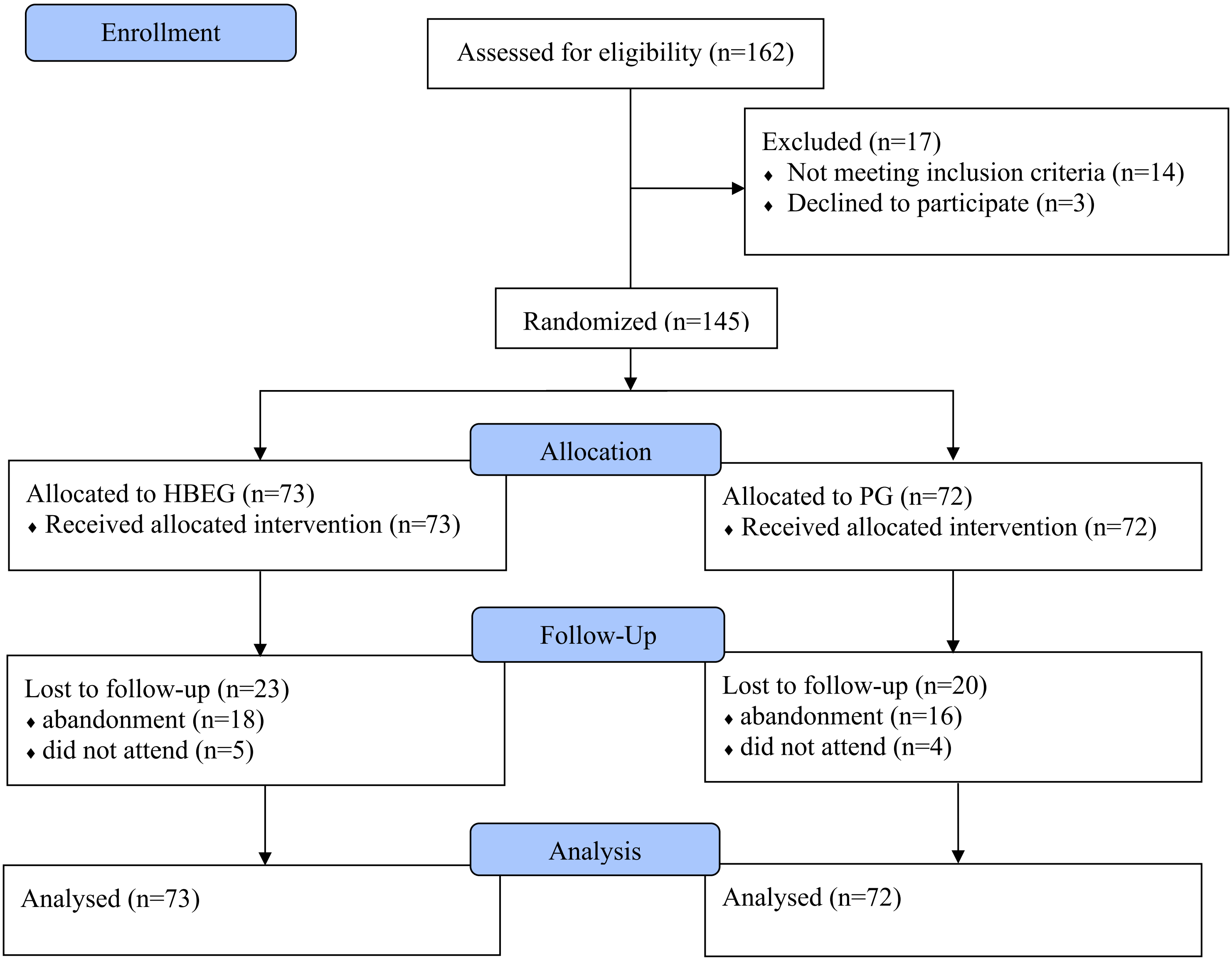

Figure 1. Study flowchart.

The characteristics of the participants at baseline showed no relevant differences (Table 2). During the intervention, over 50% (n=40) of the individuals in the Pilates group successfully attended around 70% of the sessions, while over 50% (n=37) of the participants in the home-based exercise group completed at least 50% of the sessions.

Table 2. Baseline characteristics of the participants.

	PG (*n* = 72)	**HBEG** (*n* = 73)
Age – years; $\bar{X}$ (SD)	35.7 (9)	37.07 (9)
Male – *n* (%)	33 (23)	31 (21)
BMI – kg/m^2; $\bar{X}$ (SD)	26.6 (4)	26.7 (5)
Kinesiophobia (0-100) – $\bar{X}$ (SD)	41.5 (8)	41.2 (8)
YB (score; 0-100) $\bar{X}$ (SD)	58.6 (13)	60.3 (12)
SBST (score; 0-?) $\bar{X}$ (SD)	4.9 (2)	4.6 (2)
SBST (classification) - *n* (%):		
Low risk	23 (32)	23 (31)
Medium risk	20 (28)	26 (36)
High risk	29 (40)	24 (33)

HBEG: Home-based exercise group; PG: Pilates group; $\bar{X}$: mean; SD: standard deviation; BMI: Body Mass Index; SBST: Start-Back Screening Tool; YB: Y-Balance test.

Data for the outcomes measured at baseline, post-intervention, and 6-month follow-up are presented in Table 3. At post-intervention, statistically significant differences were found between Pilates and Home-based exercise group for pain intensity (difference = -1.14, 95% CI -2.05; -0.23), disability (difference = -6.66, 95% CI -11.29; -2.03), and health-related quality of life (difference = 0.102, 95% CI 0.054; 0.151). At follow-up, health-related quality of life was significantly higher in the Pilates group compared to the home-based exercise group (difference = 0.055, 95%CI 0.003; 0.106). The overall effect of Pilates compared to home-based exercise was significantly better for disability (difference = -4.4, 95%CI -7.6; -1.1) and health-related quality of life (difference = 0.049, 95%CI 0.022; 0.076).

The sensitivity analysis showed that there were no relevant differences between the intention-to-treat and complete case analyses. Further information is presented in the Table 3.

Table 3. Sensitivity analysis comparing the results from the intention-to-treat (ITT) and complete-cases (CC) scenarios.

	ITT			CC		
	PG mean (SE)	HBEG mean (SE)	MD (CI 95%)	PG mean (SE)	HBEG mean (SE)	MD (CI 95%)
Pain (cm)						
Baseline	6.5 (0.2)	6.3 (0.2)	0.21 (-0.25; 0.67)	6.5 (0.2)	6.3 (0.2)	0.24 (-0.21; 0.70)
Post-intervention	2.3 (0.3)	3.5 (0.3)	-1.14 (-2.05; -0.23)	2.2 (0.3)	3.5 (0.3)	- 1.4 (-2.2; -0.47)
Follow-up	3.2 (0.4)	3.8 (0.4)	-0.58 (-1.82; 0.66)	3.1 (0.4)	3.9 (0.4)	-.088 (-2.1; 0.32)
overall	-	-	*-0.077 (-0.506; 0.352)*	-	-	*-0.030 (-0.45; 0.39)*
Disability (score)						
Baseline	26.4 (1.5)	29.3 (1.5)	-2.8 (-6.9; 1.2)	26.7 (1.4)	29.8 (1.4)	-3.14 (-7.20; 0.90)
Post-intervention	11.4 (1.5)	18.1 (1.8)	-6.7 (-11.3; -2.0)	10.9 (1.6)	17.3 (1.6)	-6.4 (-10.9; -1.8)
Follow-up	13.0 (1.8)	16.4 (1.7)	-3.4 (-8.2; 1.4)	13.5 (1.9)	16.9 (2.2)	-3.4 (-9.4; 2.6)
overall	-	-	*-4.4 (-7.6; -1.1)*	-	-	*-4.6 (-8.6; -0.55)*
Quality of life (utility)						
Baseline	0.595 (0.014)	0.589 (0.014)	0.006 (-0.033; 0.044)	0.595 (0.014)	0.589 (0.014)	0.006 (-0.33; 0.045)
Post-intervention	0.798 (0.015)	0.696 (0.017)	0.102 (0.054; 0.151)	0.805 (0.015)	0.690 (0.016)	0.115 (0.071; 0.159)
Follow-up	0.759 (0.020)	0.704 (0.019)	0.055 (0.003; 0.106)	0.759 (0.022)	0.683 (0.22)	0.077 (0.016; 0.137)
overall	-	-	*0.049 (0.022; 0.076)*	-	-	*0.047 (0.010; 0.084)*

PG: Pilates group; HBEG: Home-based exercise group; ITT: Intention-to-treat analysis; CC: Complete Case Analysis; MD: Cumulative mean difference; SE: standard error; CI 95%: confidence interval of 95%; Overall effect: mean difference between groups over time.

Within the Pilates group, 88% of the participants provided ratings of 3, 4, and 5 on the perception of recovery scale during the post-intervention phase, while 71% maintained this rating during the follow-up period. In the home-based exercise group, the corresponding percentages were 67% in the post-intervention and 49% in the follow-up phase. Additionally, statistically significant differences were found showing that participants in the Pilates group presented a higher perception of recovery compared with the Home-based exercise group (Table 4). Further information can be found in Table 5.

Table 4. Results on the outcomes measured at baseline, post-intervention, and follow-up.

	PG	**HBEG**	**Mixed model effects**
	mean (SE)	mean (SE)	Between-groups (95%) CI
Pain (cm)			
Baseline	6.5 (0.2)	6.3 (0.2)	0.21 (-0.25; 0.67)
Post-intervention	2.3 (0.3)*	3.5 (0.3)*	-1.14 (-2.05; -0.23)
Follow-up	3.2 (0.4)*	3.8 (0.4)*	-0.58; (-1.82; 0.66)
Overall effect	-	-	*-0.077 (-0.506; 0.352)*
Disability (score)			
Baseline	26.4 (1.5)	29.3 (1.5)	-2.85 (-6.90; 1.19)
Post-intervention	11.4 (1.5)*	18.1 (1.8)*	-6.66 (-11.29; -2.03)
Follow-up	13.0 (1.8)	16.4 (1.7)	-3.43 (-8.23; 1.37)
Overall effect	-	-	*-4.4 (-7.6; -1.1)*
Health-related quality of life (utility)			
Baseline	0.595 (0.014)	0.589 (0.014)	0.006 (-0.033; 0.044)
Post-intervention	0.798 (0.015)*	0.696 (0.017)*	0.102 (0.054; 0.151)
Follow-up	0.759 (0.020)*	0.704 (0.019)*	0.055 (0.003; 0.106)
Overall effect	-	-	*0.049 (0.022; 0.076)*
	median (IR)	median (IR)	
Perceived Recovery			
Baseline	-	-	-
Post-intervention	4 (1)#	3 (2)	-
Follow-up	4 (1.5)#	3 (5.5)	-
Overall effect	-	-	-

PG: Pilates group; HBEG: Home-based exercise group; SE: standard error; CI 95%: confidence interval of 95%; Overall effect: mean difference between groups over time; IR: interquartile range. *Significant differences compared with baseline (P<0.05). #There was difference between the groups.

Table 5. Percentage of perceived recovery reported by the participants.

	Perceived Recovery										
	-5	**-4**	**-3**	**-2**	**-1**	**0**	**1**	**2**	**3**	**4**	**5**
						Post-intervention					
PG	-	-	-	-	-	12.3%	-	-	21.1%	50.9%	15.8%
HBEG	1.9%	-	1.9%	1.9%	-	5.6%	5.6%	16.7%	33.3%	25.9%	7.4%
						Follow-up					
PG	1.9%	7.7%	3.8%	3.8%	1.9%	1.9%	1.9%	5.8%	19.2%	28.8%	23.1%
HBEG	2%	6.1%	12.2%	6.1%	4.1%	14.3%	2%	4.1%	20.4%	20.4%	8.2%

PG: Pilates group; HBEG: Home-based exercise group. Values from the second line represent likert-scale of 11 points: The scale is divided into categories ranging from -5 ('much worse'), 0 ('no change'), to 5 ('completely recovered').

5.4. Discussion

The aim of this study was to investigate the effectiveness of the Pilates method compared to home-based exercise in individuals with CNLBP on pain intensity, disability, and health-related quality of life. At post-intervention, our findings demonstrated that Pilates resulted in significantly lower pain intensity and disability, and higher health-related quality of life compared to home-based exercise. At 6-month follow-up, we found a significant positive overall effect of Pilates compared to home-based exercise regarding disability and health-related quality of life, but not for pain. However, these differences were not clinically relevant for pain and disability, as the minimum value required to be considered clinically significant is a difference of at least 2 points in the NRS [38-40], and 20 points in the disability scale [38,41]. However, differences in health-related quality of life between groups were clinically relevant (i.e., > 0.03) [42].

Our results are consistent with those from Batibay et al. [23], in which an intervention of Mat Pilates was compared with general home exercises in individuals with CNLBP. The intervention lasted 8 weeks and was supervised only in the Pilates group. Their findings showed that although pain and disability improved in both groups, a greater improvement was reported in the Pilates group. Previous studies conducted by Wajswelner et al. [13] and Mostagi et al. [11] also compared the effectiveness of Pilates with general exercises on individuals with CNLBP during 6 and 8 weeks, respectively, with sessions conducted twice a week and supervised in both the Pilates and general exercise groups. The authors reported that Pilates had similar effects compared with general exercises in improving pain and disability at post intervention and follow-up, and the results were mainly explained by the fact that both interventions were supervised which might explain the similar effects. Moreover, the disability level of the sample at the beginning of the study was not considered high and this may have prevented the detection of clinically relevant effects. This is interesting because in our study, both pain and disability scores improved over time in both groups, though Pilates provided greater improvements. A possible explanation for this finding may be the supervision. Bronfort et al. [43] compared supervised exercises, spine manipulation, and unsupervised home exercises in patients with CNLBP, and demonstrated that supervision explained improvements in strength, pain and disability at the end of treatment, in addition to greater satisfaction during the intervention and follow-up periods. Another study [44] demonstrated that supervised group exercise has been shown to be effective in improving pain intensity, mobility, flexibility, and quality of life in participants with nonspecific chronic low back pain. On the other hand, unsupervised home exercise was effective in similar variables, although with slightly lower effects. In general, the presence of supervision seems to be positive, as it ensures that individuals receive adequate guidance and feedback to perform the exercises correctly [23]. Supervised exercise therapy is recommended as an initial treatment approach in the management of CLBP [45], and has been considered an effective intervention in reducing pain and disability in CNLBP [20,46]. However, the available evidence in favour of supervised versus unsupervised exercise is limited and conclusions derived from current studies lack consistency [44].

Another aspect that might explain our findings was the dose (weekly frequency, duration of sessions and treatment) adopted in our protocol. The duration of 6 weeks of intervention, and with 50-minute sessions applied twice a week was enough to provide significant effects. A previous study investigated the effectiveness of a 12 weeks Pilates intervention in individuals with CNLBP, with two 50-minute sessions per week, and showed similar results, with the greatest change in disability obtained after 6 weeks of Pilates, without any change observed within the group between 6 and 12 weeks [47]. Despite the wide variation and inconsistency of Pilates protocols (duration and frequency of sessions) in clinical trials [48], a recent meta-analysis suggested that the greatest improvements in pain and disability are obtained with at least 1 to 2 sessions per week of Pilates or strength exercises; sessions lasting less than 60 minutes, and 3 to 9 weeks of intervention [49].

Regarding health-related quality of life, we found a significant difference between groups, that also was considered relevant (i.e., > 0.03) [42]. Moreover, these effects were maintained after the intervention period. Hence, Pilates resulted in better quality of life over time, corroborating previous studies with CLBP participants [12,17,23]. As the Pilates sessions were held face-to-face in small groups, it is possible to assume that the social interaction between the participants might explain the better utility provided by the Pilates. This aspect was also considered in a previous study [23]. Furthermore, the utility improvements may also be explained by the decreases in pain and disability, since these two outcomes can affect the quality of life of individuals with CNLBP [23,42].

Furthermore, according to our findings, the majority of individuals who participated in Pilates expressed a sense of near-complete recovery and complete during the post-intervention phase. This perception of recovery remained consistent during the follow-up period. The reported percentages were somewhat higher in the Pilates group in comparison to the home group. These results align with previous research indicating that Pilates yields greater improvements in the overall perception of recovery, particularly following a six-week intervention [12,17].

5.4.1. Implications to clinical practice

Our results provide evidence that Pilates is more effective than home-based exercise for patients with CNLBP. Although both interventions provided benefits, Pilates showed better effects and was safe, i.e., significantly greater improvements in pain, disability, and clinically relevant improvements in quality of life compared with home-based exercise. This is relevant because a recent systematic review suggested that among different types of exercises, Pilates was considered the most effective intervention to improve pain and disability [49]. In addition, another updated systematic review with meta-analysis found that Pilates intervention resulted in a clinically significant improvement in these same outcomes compared with minimal interventions [48]. Both reviews were consistent with our findings, thus, the implementation of Pilates in clinical settings within the healthcare system should be considered by policy makers and decision makers.

5.4.2. Strengths and Limitations

There are several strengths worth mentioning about this study. We used a proper randomization process and concealed allocation to reduce the risk of selection bias. In addition, the statistical analyst was also blind. We implemented intention-to-treat analysis and adopted multiple imputation to mitigate selection bias as a result of dropout. In addition, we made sure to employ the expertise of a certified and experienced Pilates instructor to conduct our Pilates method sessions, and an experienced physical therapist to instruct the home exercises, guaranteeing that the treatment was of the highest quality. Lastly, our sample size was adequate to find a clinically relevant difference and we managed to recruit the intended number of participants [11,13,23].

Notwithstanding, we had some limitations. First, we were not able to collect data of one of the outcomes considered in our designed protocol (i.e., dynamic balance), mostly due to the COVID-19 pandemics which restricted the follow-up assessments of many of our participants. Thus, we decided to use dynamic balance only as a baseline measurement. Secondly, part of our volunteers was also affected by the pandemic, as the last intervention sessions and follow-up measurements were scheduled within the first wave of COVID-19 and lock-down recommendations. Hence, this aspect also influenced to some extent the adherence in the home-based exercise group.

5.5. Conclusion

Our findings demonstrated that Pilates was more effective compared to home-based exercise in individuals with CNLBP, but it is uncertain whether these results are clinically relevant.

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CHAPTER 6

Paper 3: Cost-effectiveness of Pilates versus home-based exercises in individuals with chronic non-specific low back pain: economic evaluation alongside a randomised controlled trial

Manuscript in process of correction and submission

Cost-effectiveness of Pilates versus home-based exercises in individuals with chronic non-specific low back pain: economic evaluation alongside a randomised controlled trial

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Abstract

Objective: To investigate the cost-effectiveness of a Pilates exercise program compared with home-based exercises in individuals with chronic non-specific low back pain.

Design: Economic evaluation alongside a randomised controlled trial.

Setting: Rehabilitation clinic.

Participants: One hundred and forty-five individuals (18-50 years of age) with low back pain for ≥ 12 consecutive weeks were enrolled and randomly allocated in a 1:1 ratio to either Pilates (n=72) or home-based exercise groups (n=73).

Interventions: Method Pilates (Mat Pilates exercises using accessories) versus home-based exercise (postural exercises, muscle stretching and strengthening, and spine stabilization/mobilization), twice a week, for six weeks.

Main outcome measures: Assessments were performed at baseline, post-intervention, and six months follow-up. Three main health outcomes were adopted: pain intensity, disability, and quality-adjusted life years (QALY). The costs included were direct medical costs, direct non-medical costs and indirect costs.

Results: The main contributors to total societal costs were indirect costs in both groups. Costs of lost productivity at work (presenteeism) were higher in PG, however, these differences were not statistically significant between groups. Pilates intervention dominated from a societal perspective, demonstrating to be more effective and less costly for pain, disability and QALY.

Conclusions: Our findings demonstrated that Pilates is cost-effective compared to home-based exercises for improving pain, disability and quality-adjusted live years of individuals with CNLBP in the public health system and societal perspectives.

Clinical trial registration number: NCT03113292.

Keywords: Back pain; Exercise; Pilates; Disability; Economic evaluation;

6.1. Introduction

Chronic non-specific low back pain (CNLBP) is characterized by persistent pain for more than 12 weeks, without an apparent cause [1,2]. This condition is a worldwide health challenge, affecting most adults at some point in their lives [3]. CNLBP is considered one of the main reasons for disability and absence from work [2,4]. In 2015, low back pain accounted for approximately 60.1 million of years-lived with disability in all age groups around the world, and was also associated with increases due to population growth and aging [5].

Around 250 million people are affected by CNLBP each year [6], and about half will seek healthcare [7]. Thus, CNLBP is associated to significant social and economic burden [7,8]. In the United States, expenses related to health services for the treatment of low back pain have increased significantly. In 1997, these costs totaled US$45.9 billion, and in 2004, they reached US$102.6 billion. This represents an annual growth rate of over 12% [9,10]. Specifically, spending on outpatient services for chronic back pain increased 129% from $15.6 billion in 2000 to 2001 to $35.7 billion in 2006 to 2007 [11]. In Brazil, previous studies [8,12] demonstrated that CNLBP accounted for considerable healthcare and societal costs, with productivity losses representing approximately 79% of these costs.

Physical therapy interventions are the first treatment option for many musculoskeletal disorders and therefore play an important role in the management of CNLBP [13,14]. Exercise therapy are widely recommended by international clinical practice guidelines for the treatment of CNLBP, including Pilates [14,15]. Previous studies investigating Pilates exercises have shown benefits in improving pain and disability of individuals with CNLBP [16-20]. Recent systematic reviews also have suggested that, between different types of exercise, Pilates was deemed to be more effective for improving pain and disability [21], resulting in clinically relevant effects compared to minimal interventions [22].

Currently, with the scarcity of financial resources for health worldwide, there is a growing demand for studies that assess the cost-effectiveness of interventions [23]. Thus, it is worth noting that decision makers should rely on cost-effectiveness studies to decide whether or not it is feasible to implement or reimburse new interventions [13]. These analyzes provide information on the financial viability and additional benefits of interventions, aiding informed resource allocation decisions [24]. However, to the best of our knowledge, there are scarce information on the costs and effects of Exercise Therapy focused on the management of CNLBP [25]. Researchers identified the scarcity of such evidence and highlighted cost-effectiveness as a research priority in primary care [26].

Currently, only one clinical trial has been published, which investigated the incremental cost-effectiveness of different weekly Pilates frequencies in individuals with CNLBP [27]. The use of exercise interventions in primary care is a policy of the Brazilian Ministry of Health, and studies have reported the use of Pilates as an intervention strategy [28,29]. This is relevant, as exercise interventions are widely used by health professionals to manage chronic conditions such as CNLBP. However, Pilates is not yet officially included as an intervention in the Brazilian Unified Health System. Therefore, the aim of this study was to investigate the cost-effectiveness of Pilates exercises compared to home exercises in individuals with CNLBP, in terms of pain intensity, disability and quality-adjusted life years (QALY).

6.2. Methods

6.2.1. Study design

An economic evaluation was performed alongside a randomized controlled trial comparing a Pilates exercise program and Home-Based Exercises. The study protocol was registered at ClinicalTrials.gov (NCT03113292) and the protocol paper have been published elsewhere [30]. This trial-based economic evaluation was reported according to the Consolidated Health Economic Evaluating Reporting Standards statement [31].

6.2.2. Setting and location

The study was conducted in a clinical setting in the city of Brasília, Brazil.

6.2.3. Target population

The inclusion criteria were as follows: (1) male or female gender (18–50 years of age); (2) CNLBP for more than 12 consecutive weeks before entering the study; (3) not having attended Pilates or physiotherapy interventions for LBP for at least six months prior to enrolment. Participants were excluded if they presented: (1) history of trauma or fractures of the spine; (2) a diagnosis of spine osteoarthritis, disc herniation, or spondylolisthesis; (3) self-reported referred pain (e.g., visceral, abdominoplasty, appendicitis, abdominal and pelvic surgeries); (4) previous spinal surgery; (5) presence of root symptoms (e.g., sciatica and cauda equina syndrome), classified by the Quebec Task Force [32] as levels 3 and 4; and (6) pregnancy.

After signing the informed consent, participants were randomly assigned into one of two groups: (1) Pilates Exercises (PE) or (2) Home-Based Exercises (HBE). Detailed information about the study design and randomisation procedures can be found elsewhere [30].

6.2.4. Interventions

Pilates Exercises

The PE were supervised by a certified physical therapist, and the program included Pilates exercises with accessories delivered in small groups of up to 4 participants. In the first two sessions, participants received instructions about the method and went through a familiarization process. Following the familiarization period, the six-week intervention started. There were two sessions per week, sessions were 50 minutes long and accommodating a maximum of 4 participants per session. Each session included 7 to 10 exercises, with two sets of 8 to 12 repetitions for each exercise. When required, exercises were adapted and modified individually considering the three difficulty levels used in Pilates: basic, intermediate, and advanced.

Home-Based exercises

The HBE were supervised by another physical therapist. At the beginning, two in-person familiarization sessions were conducted. The intervention consisted of general exercises such as postural exercises, muscle stretching and strengthening, and spine stabilization/mobilization. These exercises were prescribed to be performed twice a week. Participants were provided with a booklet containing detailed descriptions of the exercises, including the recommended series and repetitions, as well as safety precautions to be aware of during the sessions. The difficulty level was assessed on an individual basis. Throughout the intervention, all participants were contacted on a weekly basis via email and/or text message (WhatsApp®) for supervision and to monitor for any possible adverse effects. During the weekly messages, the physiotherapist inquired about participants' adherence to the exercise regimen, specifically if they performed the exercises as instructed and scheduled (twice a week). The physiotherapist also sent reminders emphasizing the importance of consistently completing the exercises. Additionally, participants in both groups were instructed to continue taking their usual medication, and this information was monitored during post-intervention re-evaluations.

6.2.5. Study perspective and time horizon

In this trial-based economic evaluation, we calculated incremental cost-effectiveness ratios for the primary outcomes pain and disability, as well as cost-utility rates, from both societal and public health perspectives. In the public health perspective, the analysis considered only the costs of health services provided by the public health system. This includes healthcare costs associated with consultations, medications, examinations, hospitalizations, and professional fees. In the societal perspective, expenses with private medical assistance, costs incurred by patients related to transportation and support from caregivers (when applicable), as well as indirect costs related to absenteeism and presenteeism, were included. The time horizon was less than one year, and consisted of six weeks of intervention with additional six months of follow-up. Therefore, discounting of costs and effects was not required.

6.2.6. Choice of health outcomes

Three main health outcomes were adopted: pain intensity, disability, and quality-adjusted life years (QALY).

The burden of low back pain, which is the leading cause of years lost to disability worldwide, is increasing [33]. Currently, low back pain is one of the main causes of disability worldwide [2, 34]. Therefore, pain and disability are relevant outcomes to this population. Moreover, QALY are commonly employed as a concise measure of health in economic evaluations. By considering the effects of interventions on both the quantity and quality of life [35], QALY enables decision-makers to assess and compare the effectiveness and cost-effectiveness between interventions across different health conditions [36].

6.2.7. Outcomes

Health outcomes

Data on pain, disability, and quality of life (utility) were collected through questionnaires at baseline, 6-week post-intervention, and at 6-month follow-up.

Pain intensity was measured by the Numerical Rating Scale (NRS) [37]. This scale consists on numbers ranging from 0 to 10, where zero is equivalent to no pain and ten to the worst possible pain. Participants were instructed to mark the number representing the intensity of their pain in the last week. To assess disability, we adopted the Brazilian version of the Quebec Back Pain Disability Scale Questionnaire [38]. This questionnaire consists of twenty questions that explore the level of difficulty individuals experience when performing their routine activities. The total score ranges from 0 to 100, with higher scores representing a worst disability.

To assess health-related quality of life, we used the Brazilian validated version of the EQ-5D-3L questionnaire. This questionnaire enabled participants to describe their health state across five dimensions, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Participants could choose from three response levels, indicating whether they experienced no problems, some problems, or extreme problems in each dimension. Subsequently, these health states were converted into utility values on a scale ranging from 0 to 1, with 1 representing perfect health, using the specific conversion method applicable to the Brazilian context [39]. To calculate QALY, the utility values obtained were employed using the area under the curve method (i.e., the duration of a health state is multiplied by the utility related to that health state) [35]. This method involves multiplying the duration of a specific health state by the corresponding utility value associated with that state.

Cost outcomes

To obtain the economic data, a questionnaire was applied to participants at baseline, post-intervention, and follow-up. Participants reported the frequency and amount of items used in the past 6 weeks. The costs included were healthcare costs (intervention costs, health consultation, emergency and hospital admissions, home health care and medication costs), other costs (transportation to appointments, medications, emergency, and travel costs) and indirect costs (presenteeism and absenteeism). The detailed description is presented in Table 1.

The costs were extracted from national available databases: (i) for drug costs, the Health Price Bank, publicly available by the Ministry of Health (http://bps.saude.gov.br/); (ii) for medical consultations, exams and hospitalizations, the average cost paid by the Ministry of Health to public health services, available on the TABNET/DATASUS website (http://datasus.saude.gov.br); (iii) for indirect costs related to absenteism and presenteism, the hourly cost was considered based on the average wage earnings reported by the participants. All costs were expressed in national currency (R$), with reference to the year 2020.

6.2.8. Statistical analysis

All analyses were performed according to the intention-to-treat using RStudio version 4.2.1. Missing cost and effectiveness data were imputed using multiple chained equation imputation (MICE). Variables associated with missingness and outcomes, as well as potential confounders, were included in the imputation model for all baseline variables including costs and utility. To account for the skewed distribution of costs, predictive mean matching within the MICE procedure was used. The number of imputed datasets was increased until the fraction of missing information was less than 5%, resulting in five imputed datasets [40]. The complete imputed datasets were analysed separately and the estimates were grouped using Rubin's rules [41].

Differences in costs and effects between treatment groups at 6-month follow-up were estimated using SUR (seemingly unrelated regression). Costs are generally not normally distributed, thus the joint uncertainty around differences in costs and effects was estimated using Bias-corrected accelerated bootstrapping with 5000 replications. Incremental cost-effectiveness ratios (ICERs) were calculated by dividing the difference in costs (i.e., total societal costs and total healthcare costs) between groups by the difference in effects. Sensitivity and uncertainty analysis around ICERs was shown by plotting bootstrap cost-effect pairs on cost-effectiveness plans [42]. Cost-effectiveness acceptability curves (CEAC) were also estimated, showing the probability of Pilates (new intervention) being more cost-effective compared to home exercises for a range of willingness to pay thresholds (WTP). In the analysis, the WTP of Brazil was used, defined as one GDP (Gross Domestic Product) per capita (approximately R$40.000/QALY gained, in 2022) [43].

The effect outcome for pain and disability was multiplied by -1 in the cost-effectiveness analysis (CEA) to allow correct data interpretation in the CE-plane.

6.2.9. Sensitivity analysis

A probabilistic sensitivity analysis (PSA) with 5,000 bootstrapping samples was performed including all randomized participants (intention-to-treat analysis - ITT) considering the health system and societal perspective, for pain, disability and QALY outcomes.

6.2.10. Patient and public involvement

No participant was involved in the planning and development of this study. We plan to share the study findings with all participants and make them accessible to the general public via popular science articles and social media.

Table 1. Description of the cost items that were included in the economic evaluation

	Definition	Calculation
Healthcare costs		
Intervention costs	Total cost of each intervention (professional hourly rate, adherence, and material cost)	Number of sessions performed by the participant (adherence) multiplied by the value of the Physiotherapy session made up of the interventions adopted plus the cost of the materials used in the sessions
Consultations (last 6 weeks)	Number of consultations due to LBP, by a health professional	Number of consultations multiplied by the value reimbursed by the Ministry of Health, by health professional
Emergency hospitalization (last 6 weeks)	Number of times the patient was hospitalized in an emergency facility due to LBP	Total number of times multiplied by the number of hours the emergency care lasted multiplied by the hourly rate based on the ASR by the participant
Hospital admissions	Number of times the patient had an inpatient due to LBP	Total number of times multiplied by the Brazil's average inpatient cost due to LBP
Home health care (last 6 weeks)	Home health care for LBP	Value of the home care session multiplied by the number of sessions
Medication costs (last 6 weeks)	The total consumption of drugs (diary dose multiplied by number of days the patient used each drug)	Total consumption of medication (stratified by each drug) multiplied by the price paid by public health facilities
Transport (last 6 weeks)	Number of displacements for consultation, emergencies and get drug due to LBP	Total number of displacements by type of transport used
Commute cost - caregiving or companion during consultations (last 6 weeks)	Number of hours spent during the consultation (including transport) due to LBP. The number of hours will be accounted for patients and companion/ caregiver (when applicable)	Transportation value added to the value of time lost by the participant (number of hours multiplied by the hourly rate based on the ASR by the participant) plus the value of time lost by the companion/caregiver (when applicable)
Indirect costs		
Loss of productivity (presenteeism)	Percentage of lost productivity at work when feel LBP	Hourly rate based on ASR by participant multiplied by number of hours worked per day multiplied by 45 days (6 weeks) multiplied by percentage of reported lost productivity divided by 100
Work days lost (absenteeism) (last 6 weeks)	Number of working hours lost due to LBP	Hourly rate based on the ASR by the participant multiplied by the number of hours spent in the emergency room

LBP: Low back pain; ASR: Average salary reported.

6.3. Results

In total, 145 patients were included in the randomized trial. Of the included individuals, 72 were allocated to Pilates Exercises (PE) and 73 to Home-Based Exercises (HBE). Table 2 shows that there were no clinically relevant differences in baseline characteristics between groups.

Table 2. Baseline characteristics of the participants.

	PE (n = 72)	HBE (n = 73)
Demographics		
Age, years $\bar{x}$ (SD)	35.7 (8.6)	37.0 (9.0)
Sex, female, n (%)	39.0 (26.9)	42.0 (28.9)
BMI kg/m^2; $\bar{x}$ (SD)	26.5 (4.0)	26.7 (4.8)
Educational level, n (%)		
Low	5.0 (3.4)	6.0 (4.1)
Middle	36.0 (24.8)	36.0 (24.8)
High	31.0 (21.4)	31.0 (21.4)
Pain $\bar{x}$ (SD)		
Pain score (NRS 0-10)	6.6 (1.8)	6.2 (1.5)
Disability $\bar{x}$ (SD)		
Disability score (0-100)	27.5 (16.5)	29.0 (16.9)
Quality of life $\bar{x}$ (SD)		
EQ-5D-3L utility score (0-1)	0.587 (0.13)	0.596 (0.15)

PE: Pilates exercises; HBE: Home-based exercises; $\bar{x}$: mean; SD: standard deviation; n: number of participants; BMI: Body Mass Index; NRS: Numeric Rating Scale; EQ-5D-3L: EuroQol Five Dimension Scale;

Effectiveness outcomes

There were no statistically significant differences between groups in pain (mean difference -0.67, 95% CI -1.87 to 0.53) and disability (mean difference -3.07, 95% CI -8.07 to 1.92). There were statistically significant differences between groups for QALY at follow-up. The QALY was significantly higher in the Pilates group compared to the home-based exercise group (mean difference 0.046, CI 95 % 0.022 to 0.070) (Table 3).

Cost outcomes

The main contributors to total societal costs in both groups were lost productivity costs (indirect costs: R$2062.88 in PE and R$1503.11 in HBE) and Commute costs (R$175.39 in PE and R$79.82 in HBE) as presented in Table 3.

The total healthcare costs were R$175 and R$184 for Pilates and Home-Based Exercises, respectively. The total societal costs were R$2.238 for Pilates and R$1.687 for the Home-Based Exercises (Table 3).

Among the healthcare costs, the highest share were transportation to pick up medication (R$49.66 in PE and R$45.16 in HBE) and transportation costs. For the intervention costs, there were statistically significant differences showing higher costs in the HBE (mean difference R$7.66; 95% CI R$1.83 to R$13.23). Costs associated with presenteeism were the major contributor to indirect costs in both groups (R$2.062 in PE and R$1.497,23 in HBE). PE had higher presenteeism costs (mean difference R$-564.77; 95% CI R$-1.754,11 to R$631.38) (Table 3).

Table 3. Multiply imputed mean effects and costs by group and mean difference at 6 months follow-up. Data are presented as mean (standard error: SE).

	PE (n = 72)	**HBE (n = 73)**	**Mean difference* (95% CI)**
Effects			
Pain	3.25 (0.12)	3.76 (0.08)	-0.50 (-1.42 to 0.45)
Disability	13.62 (0.27)	16.47 (0.07)	-2.84 (-7.68 to 2.10)
QALY gained	0.468 (0.001)	0.431 (0.001)	0.037 (0.013; 0.059)
Costs			
Healthcare costs			
Intervention	25.96 (0.10)	33.62 (0.26)	7.66 (1.83 to 13.23)
Consultations	6.19 (0.70)	4.79 (0.93)	-1.39 (-5.56 to 2.66)
Emergency	0.54 (0)	0.69 (0)	0.14 (-1.30 to 1.80)
Hospital admissions	0	0	0
Home health care	0	0	0
Medication	0.90 (0.18)	0.39 (0.24)	-0.50 (-2.73 to 0.80)
Other costs			
Transport for consultation	17.18 (1.84)	16.80 (0.76)	-0.38 (-15.02 to 15.87)
Transport for medication	49.66 (2.52)	45.16 (4.13)	-4.50 (-32.72 to 23.64)
Emergency transport	0.44 (0)	3.25 (0)	2.81 (-0.50 to 16.02)
Commute cost	74.48 (9.40)	79.82 (6.26)	5.33 (-69.98 to 85.52)
Total healthcare costs†	175.39 (13.20)	184.56 (11.41)	9.16 (-91.31 to 123.68)
Indirect costs			
Presenteeism	2062.00 (112.79)	1497.23 (227.30)	-564.77 (-1754.11 to 631.38)
Absenteeism	0.87 (0)	5.87 (0)	5 (-1.14 to 29.48)
Total indirect costs‡	2062.88 (112.79)	1503.11 (227.30)	-559.77 (-1770.25 to 639.11)
Total societal costs§	2238.27 (124.79)	1687.67 (238.00)	-550.60 (-1810.99 to 731.63)

*Cost and effect differences at six months follow-up were estimated using seemingly unrelated regression analyses [44].
Effect data at six-month follow-up and cost data are the sum of post-intervention and follow-up time points. Costs are presented in Brazilian reais (R$). PE: Pilates exercises; HBE: Home-based exercises; QALY: quality-adjusted life-years.
Healthcare costs: Intervention: sum of session costs and costs of exercise materials; Consultations: consultations with health professional – physiotherapist and/or physicians; Emergency: costs of emergency visit in the last 6 weeks; Hospital admissions: hospital stay costs in the last 6 weeks; Home health care: home health care costs in the last 6 weeks; Medication: costs of using physician-prescribed drugs for non-specific chronic low back pain.
Other costs: Transport for consultation: cost of transport used to go to consultations with health professional; Transport for medication: transport costs to buy medicines; Emergency transport: transport costs used to go to hospital emergency; Commute cost: transport cost + participant's lost time cost + companion's lost time cost (when applicable). The cost of travel was calculated when the participant went to a consultation and was not on sick leave (absence from work);
Indirect costs: Absenteeism: costs of absenteeism from work activities (hospital emergency visits); Presenteeism: costs of working while suffering from health complaints (lost productivity).
†The sum of healthcare costs and other costs.
‡The sum of absenteeism and presenteeism costs.
§The sum of total healthcare costs and total indirect costs.

Cost-effectiveness analysis

Data on the overall results of the cost-effectiveness analysis are presented in Table 4. It is worth noting that point estimates may slightly differ from the mean effects presented in Table 3, due to the probabilistic nature of estimates used for both analyses.

From a societal perspective, pain outcomes demonstrated that ICER indicate that a 1-point reduction in pain was, on average, associated with savings of R$761 for Pilates (i.e., less expensive, and more effective) in relation to HBE. For disability, the ICER indicates that a 1-point reduction in disability was, on average, associated with savings of R$168 for PE (i.e., less expensive, and more effective) in relation to HBE. For QALY, PE was also dominant over HBE with ICER indicating that 1 QALY gained was associated with savings of R$11,076 for Pilates (Table 4).

From a healthcare perspective, pain outcomes demonstrated that ICER indicate that a 1-point reduction in pain was, on average, associated with a cost of R$10 for PE (i.e., more expensive and more effective) compared to HBE. For disability, the ICER indicates that a 1-point reduction in disability was associated with a cost of R$2 for PE (i.e., more expensive, and more effective) in relation to HBE. For QALY, Pilates was also the most expensive and most effective intervention, with the ICER indicating that 1 QALY point gained was associated with a cost of R$158 for PE compared to HBE (Table 4).

Table 4. Outcomes for the cost-effectiveness analysis (Brazilian real R$)

Outcome	ΔC (95% CI)*	ΔE (95% CI)†	ICER‡	CE plane NE	SE	SW	NW
Societal perspective							
Pain	-510.22 (-2262.16; 1241.72)	-0.67 (-1.87 0.53)	761.43	18%	69%	7%	6%
Disability	-517.46 (-2288.54; 1253.60)	-3.07 (-8.07; 1.92)	168.33	20%	69%	8%	3%
QALY (0-1)	-511.68 (-2279.38; 1256.02)	0.046 (0.022; 0.070)	-11076.21	24%	76%	0%	0%
Healthcare perspective							
Pain	7.35 (-0.96; 15.66)	-0.67 (-1.87 0.53)	-10.77	84%	3%	0%	13%
Disability	7.36 (-0.97; 15.69)	-3.07 (-8.07; 1.92)	-2.34	86%	3%	0%	10%
QALY (0-1)	7.37 (-0.94; 15.69)	0.046 (0.022; 0.070)	158.61	97%	3%	0%	0%

*Uncertainty around cost differences estimated using the non-parametric bootstrap.
†Overall effect over time.
‡The ICER presented was computed using the unrounded values for cost and effect.
QALY: quality-adjusted life-year; ΔC: difference in costs between the two groups; ΔE: difference in effectiveness outcome between the two groups; ICER: incremental cost-effectiveness ratio; CE plane: cost-effectiveness plane; NE: North-East Quadrant; SE: South-East Quadrant; SW: South-West Quadrant; NW: North-West Quadrant;
The effect outcome for pain and disability was multiplied by -1 in the cost-effectiveness analysis to allow correct data interpretation in the CE-plane.

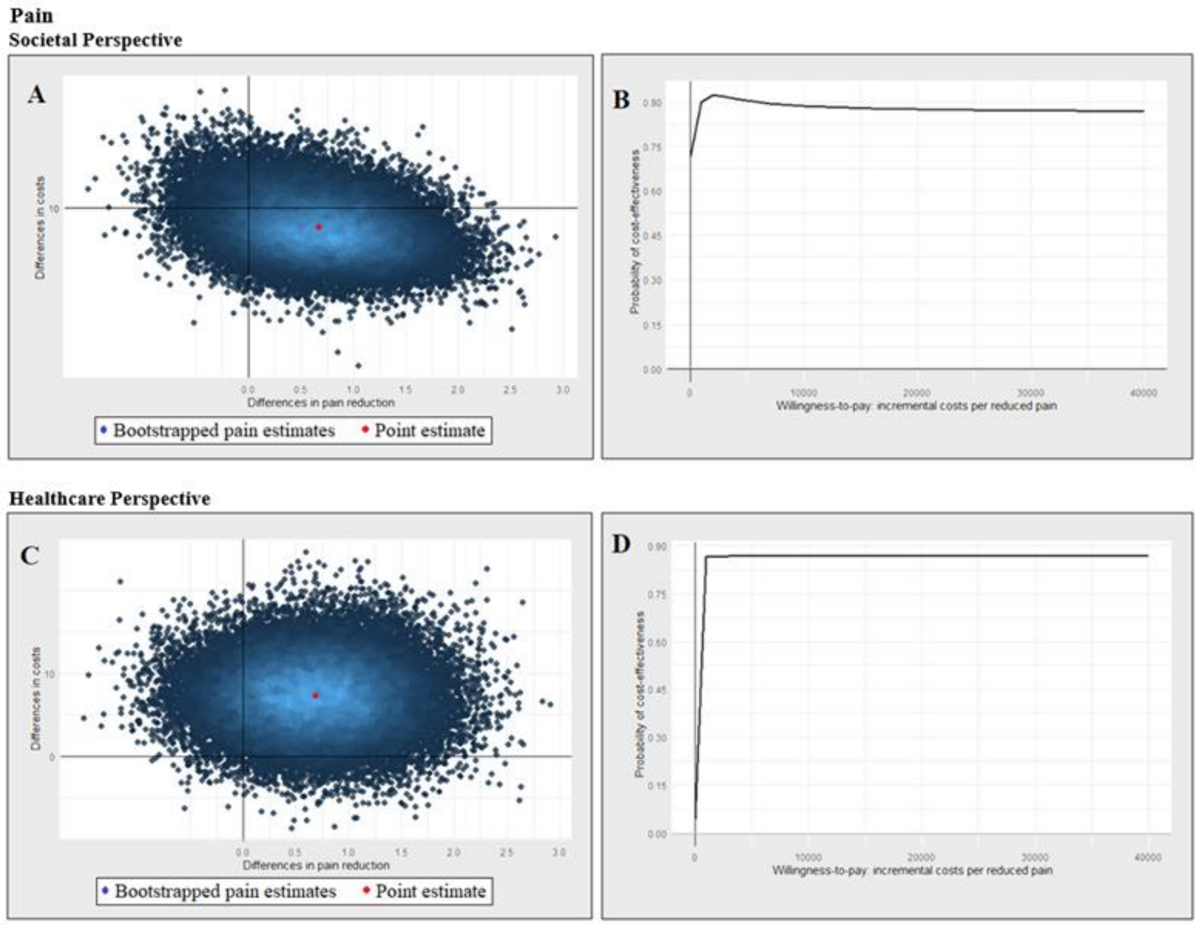
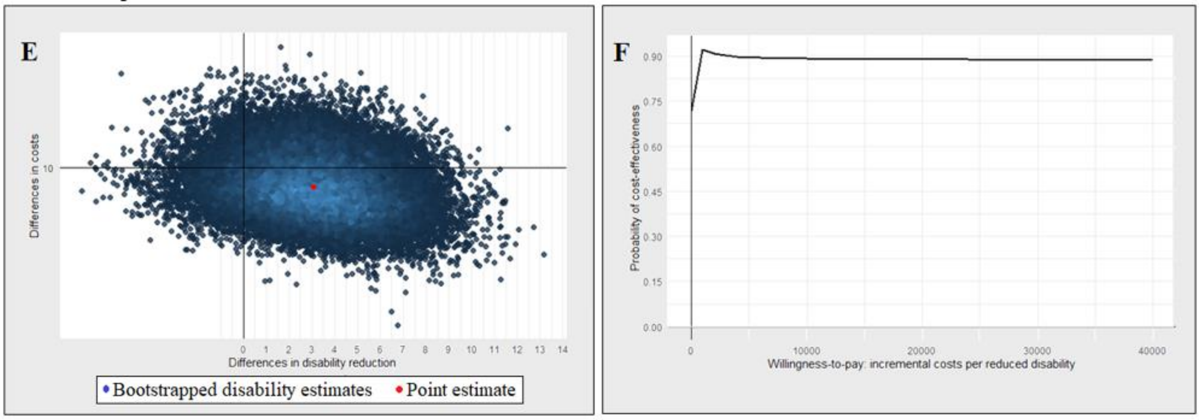


Figure 1. Cost-effectiveness planes and cost acceptability curves from a societal and healthcare perspective comparing the Pilates with home-based exercises. (1) Cost-effectiveness plane (CE plane) showing the incremental cost-effectiveness ratio point estimate (ICER, red dot) and the distribution of the 5.000 replications of the bootstrapped cost-effective pairs (blue dots). (2) Cost-effectiveness acceptability curve (CEAC) indicating the probability of Pilates being cost-effective compared with home-based exercise (y-axis) for different willingness-to-pay (WTP) thresholds per unit of effect gained or reduced (x-axis).

Pain: (A) CE plane for pain from a societal perspective showing that most of bootstrapped cost-effect pairs were in the South-East quadrant, demonstrating that Pilates was more effective and less costly compared to home-based exercise. (B) CEAC for pain from a societal perspective indicating a probability of Pilates being cost-effective compared with home-based exercises of around 0.70 at a WTP of R$0/point of pain reduction, and 0.88 at a WTP of R$20.000/point of pain reduction. (C) CE plane for pain from a healthcare perspective showing that most of the bootstrapped cost-effect pairs were in North-East quadrants, where Pilates was more costly and more effective compared with home-based exercises. (D) CEAC for pain from a healthcare perspective indicating a probability to 0.85 of Pilates being cost-effective compared with home-based exercises with a WTP is approximately R$2,000/point of pain reduction.

Disability

Societal Perspective



Healthcare Perspective

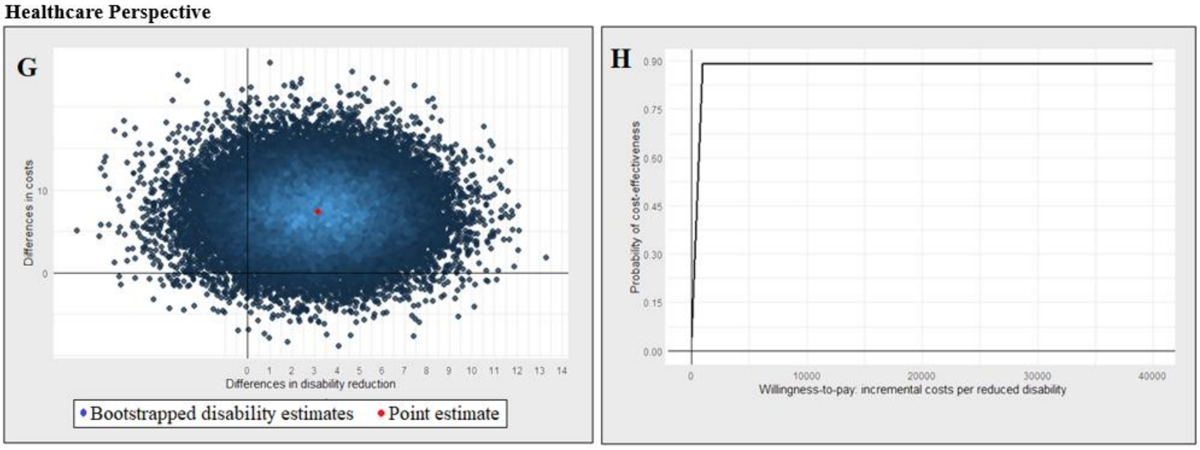


Figure 2. Cost-effectiveness planes and cost acceptability curves from a societal and healthcare perspective comparing the Pilates with home-based exercises. (1) Cost-effectiveness plane (CE plane) showing the incremental cost-effectiveness ratio point estimate (ICER, red dot) and the distribution of the 5.000 replications of the bootstrapped cost-effective pairs (blue dots). (2) Cost-effectiveness acceptability curve (CEAC) indicating the probability of Pilates being cost-effective compared with home-based exercise (y-axis) for different willingness-to-pay (WTP) thresholds per unit of effect gained or reduced (x-axis).

Disability: (E) CE plane for disability from a societal perspective showing that most of bootstrapped cost-effect pairs were in the South-East quadrant, demonstrating that Pilates was more effective and less costly compared to home-based exercises. (F) CEAC for disability from a societal perspective indicating a probability of Pilates being cost-effective compared with home-based exercises was around 0.90 at a WTP of R$2.000/point of disability reduction. (G) CE-plane for disability from a healthcare perspective showing that most of the bootstrapped cost-effect pairs were in the North-East quadrant, i.e., where Pilates had higher costs but had more effective. (H) CEAC for disability from a healthcare perspective indicating probability to 0.90 of Pilates being cost-effective compared with home-based exercises with a WTP is approximately R$1.500/point of disability reduction.

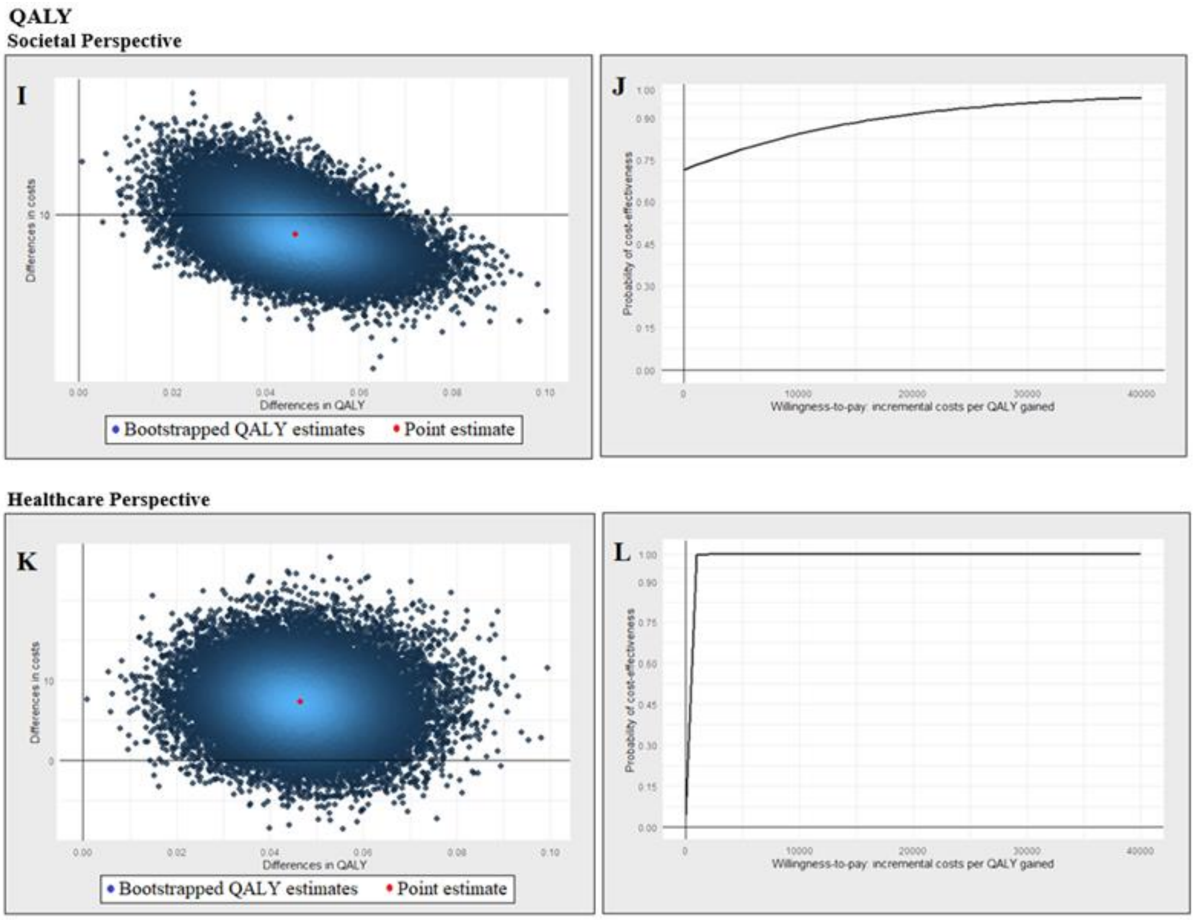


Figure 3. Cost-effectiveness planes and cost acceptability curves from a societal and healthcare perspective comparing the Pilates with home-based exercises. (1) Cost-effectiveness plane (CE plane) showing the incremental cost-effectiveness ratio point estimate (ICER, red dot) and the distribution of the 5.000 replications of the bootstrapped cost-effective pairs (blue dots). (2) Cost-effectiveness acceptability curve (CEAC) indicating the probability of Pilates being cost-effective compared with home-based exercise (y-axis) for different willingness-to-pay (WTP) thresholds per unit of effect gained or reduced (x-axis).

QALY: (I) CE plane for QALY from a societal perspective showing that most of the bootstrapped cost-effect pairs were in the South-East quadrant, demonstrating that Pilates was more effective and less costly compared to home-based exercises. (J) CEAC for QALY from a societal perspective indicating a probability of the Pilates being cost-effective around 0.75 for different WTP thresholds per QALY gained. (K) CE-plane for QALY from a healthcare perspective showing that most of the bootstrapped cost-effect pairs were in the North-East quadrant, i.e., where Pilates had higher costs and had more effective. (L) CEAC for QALY from a healthcare perspective indicating that the probability of Pilates being cost-effective compared with home-based exercise reached 1 with a WTP of approximately R$2.000/per QALY gained. This probability holds for different WTP thresholds per QALY gained.

6.4. Discussion

Our findings showed that the total healthcare costs were R$175 and R$184 for Pilates and Home-Based Exercises, respectively. The total societal costs were R$2.238 for Pilates and R$1.687 for the Home-Based Exercises.

Cost-effectiveness analyses showed that, from a societal perspective, Pilates was the dominant intervention i.e., more effective, and less costly for pain, disability and QALY. From the healthcare perspective, our findings showed that Pilates was more costly and more effective for all outcomes, and considered cost-effective at a WTP of R$40.000 per unit of improvement.

6.4.1. Comparison with previous studies

Currently, the cost-effectiveness of Pilates exercises has been evaluated in a previous study comparing different doses of Pilates to an advice (booklet) in the treatment of individuals with CNLBP from a societal perspective [27]. Accordingly, Pilates performed three times a week was considered the preferred option with a probability of being cost-effective of 0.78 with a WTP of £20,000 per QALY gained, and 0.85 at £30,000 per QALY gained. However, Pilates exercises were not deemed to be cost-effective compared to advice (booklet) for pain intensity and disability [27]. In contrast, our findings showed that, from a societal perspective, Pilates exercises performed twice a week were cost-effective for pain, disability, and QALY, compared to Home-Based Exercises. Moreover, our analyses demonstrated Pilates exercises provided savings of around R$11,076 per QALY gained. The probability of Pilates being cost-effective was 0.70 with a WTP of R$0 and 0.90 at R$20,000 per QALY gained.

From the perspective of the health system, our study showed that Pilates was more effective and more costly for the three outcomes compared to home-based exercises. However, the probability of Pilates being cost-effective from a health system perspective reaches 1 with a WTP of approximately R$2,000 per QALY gained, and this probability holds for different thresholds of WTP per QALY gained. These are high (maximum) probabilities and are within the willingness-to-pay threshold defined for Brazil [43].

Systematic reviews investigating the cost-effectiveness of conservative treatments for low back pain, including exercise interventions, reported conflicting results [25, 45-48]. Two reviews found that exercise therapy, among other treatments, was considered cost-effective compared to usual care in individuals with subacute and chronic non-specific low back pain [45, 47]. However, other systematic reviews highlighted inconsistencies and high heterogeneity in the costs and effects within the included studies. Hence, the authors recommended caution due to inconclusive evidence [25, 46, 48].

6.4.2. Strengths and Limitations

The strengths of this trial include the random assignment of patients, concealed allocation and the analysis based on intention to treat. Another strong point is that this study is the first to provide evidence on the analysis of cost-effectiveness of Pilates compared to home-based exercise for treating patients with non-specific chronic low back pain. In addition, we conducted a cost-effectiveness analysis from a societal perspective, including all relevant costs for decision-making (intervention cost, health care utilization, informal care and lost productivity costs) [36]. We also performed sensitivity analyses to assess the robustness of our results, which demonstrated similar results compared to the main analyses.

As limitations, our findings might not be generalized to health systems in other countries, since these systems adopt different usual practices and have different payment systems. Another possible limitation was the percentage of dropouts in the 6-month reassessment (follow-up). However, we adopted the multiple imputation method to deal with missing data. Multiple imputation is widely recognized as the most valid method for dealing with missing data [49].

6.4.3.Conclusion

Our findings suggest that Pilates is cost-effective compared to home-based exercises for improving pain, disability, and quality-adjusted live years of individuals with CNLBP in the public health system and societal perspectives.

Acknowledgments

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Conflict of interest statement

The authors have no conflicts of interest to declare.

CHAPTER 7

Final considerations

7.1. Key findings and clinical and management implications

This thesis provided important results for management and clinical practice. Our results provide evidence that Pilates is more effective than home exercises for patients with CNLBP. Although both interventions provided benefits, Pilates showed better effects and was safe, i.e., significantly greater improvements in pain, disability, and clinically relevant improvements in quality of life compared with home-based exercise. Furthermore, our findings suggest that Pilates is cost-effective compared to home-based exercises for improving pain, disability, and quality-adjusted life years of individuals with CNLBP from public health system and societal perspectives.

These findings can be considered in the process of implementing truly effective and cost-effective interventions. Therefore, the implementation of Pilates as a treatment option for CNLBP in clinical settings within the healthcare system should be considered by policy makers and decision makers.

7.2. Suggestions for future studies

Clinical trials present a unique chance to collect cost and effect data in a prospective manner, thus allowing the assessment of cost-effectiveness in physiotherapeutic interventions. Therefore, we strongly recommend physical therapy researchers to assess the cost-effectiveness of their interventions whenever possible, regardless of effectiveness results. In doing so, researchers can effectively explore the relationship between costs and effects, ultimately assisting in making informed decisions and potentially implementing interventions that are not only effective, but also economically viable.

CHAPTER 8

Other productions linked to the thesis

Manuscript published - Brazilian Journal of Pain (BrJP)

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ORIGINAL ARTICLE

Is kinesiophobia associated with disturbances in dynamic balance in individuals with chronic non-specific low back pain?

A cinesiofobia está associada a distúrbios de equilíbrio dinâmico em indivíduos com dor lombar crônica não-específica?

Marina Cardoso de Melo Silva[1], Caroline Ribeiro Tottoli[1,2], Katharina Mascarenhas[1], Yara Andrade Marques[1], Aline Martins Toledo[1], Rodrigo Luiz Carregaro[1,2]

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Abstract

Background and objectives: Chronic non-specific low back pain is a disabling condition that has a high worldwide prevalence. The aim of the study was to investigate the association between deficits in dynamic balance, age and body mass index (BMI), and kinesiophobia, as well as to establish a comparison between men and women.

Methods: A cross-sectional study with 145 individuals between 18 and 50 years of age with non-specific chronic low back pain. Sociodemographic data were collected, and dynamic balance was assessed using the Y-Balance Test. The Tampa Scale was used to assess kinesiophobia. A linear regression was applied to investigate the association between kinesiophobia and a set of predictor variables (balance, gender, BMI). Men and women were compared using the Student's t-test (kinesiophobia and dynamic balance).

Results: The overall mean kinesiophobia score was 41.3. The Y-Balance Test mean for the right and left lower limb, respectively, was 59.4 and 59.5. An association was found between kinesiophobia and two predictors: balance and BMI (R2:6.8%). No significant differences were found between gender for kinesiophobia (42.1 for women and 40.3 for men). However, women had worse dynamic balance compared to men (mean reach of 56.1 versus 63.5, respectively; $p<0.05$).

Conclusion: Kinesiophobia was found to be associated with disturbances in dynamic balance and BMI of individuals with non-specific chronic low back pain. However, the model explained a small variation in kinesiophobia. Women showed worse dynamic balance compared to with men.

Keywords: Chronic pain, Low back pain, Postural balance, Age and gender distribution.

Introduction

Low back pain (LBP) is defined as pain between the 12th thoracic vertebra and above the upper gluteal fold, with or without irradiation to the lower limbs [1,2]. It is worth noting that LBP can increase health care and social costs, mainly due to treatment and productivity losses [3,4]. Chronic low back pain (CLBP) is one of the main causes of absenteeism in Brazil [4] , and it is one of the four main conditions that impose increases in years of life lived with disability in the world [5].

Disability related to CLBP is multifactorial and associated with cognitive, emotional, environmental and social factors [1,6-8]. Increased age and body mass index (BMI) are associated with increases in the prevalence of CLBP, and individuals aged between 50 and 59 years old have an approximately eight times higher risk of having CLBP when compared to individuals between 20 and 29 years [9].

Despite the biopsychosocial causal model, it should be noted that individuals with LBP have relevant physical manifestations, such as postural control deficits [10]. In this sense, postural control is characterized by the ability to maintain or return the body to a state of balance, and it depends on mobility and the ability to stabilize [11,12]. Individuals with CLBP may present movement instability and less muscle strength when compared to individuals without LBP [11,13,14]. A study [11] has shown that individuals with a history of LBP showed deficits in dynamic balance even after pain was resolved, which may increase the risk of recurrences. This aspect is relevant, because proprioceptive alterations in individuals with CLBP may cause postural balance disturbances [15-17].

In this context, kinesiophobia is characterized by irrational and debilitating fear of movement, arising from the belief of vulnerability to injury. However, other conditions, such as poor self-perception of health, pain intensity, depression, and anxiety may also be associated with kinesiophobia [7,18,19]. A previous study showed that quality of life, physical and social function, and pain were negatively associated with increased kinesiophobia scores in individuals with CLBP [19]. Thus, the hypothesis is that such changes could cause a gradual decrease in mobility and, consequently, a reduction in activity and participation in this population. However, although the balance deficit is a clinical manifestation of individuals with CLBP, it is not clear whether there is an association with the fear of moving, and whether there are considerable differences between men and women. In this sense, understanding the association between kinesiophobia and possible balance deficits is relevant, because individuals with musculoskeletal pain may develop the fear that certain movements cause painful episodes and/or a recurrence of injury [20]. Individuals with LBP can develop avoidance behaviors and the belief that movements are linked to pain and, therefore, avoid movement, limiting their mobility [20].

Therefore, the objective of the present study was to investigate whether kinesiophobia is associated with a set of predictors in individuals with non-specific CLBP. Secondarily, the study aimed to compare kinesiophobia scores and dynamic balance between men and women.

Methods

A cross-sectional observational study, characterized by the investigation of baseline data from a randomized controlled trial [21]. Data collection was conducted in a clinical setting between March 2019 and January 2020. The study was reported according to the recommendations of STROBE (Strengthening the Reporting of Observational Studies in Epidemiology Statement) [22].

Participants were recruited through social media announcement and calls in the community and rehabilitation clinics. Participants were included according to the following criteria: 1) young adults, male and female, aged between 18 and 50 years old; 2) residents of Brasília and administrative regions; 3) presenting a non-specific CLBP condition for more than 12 consecutive weeks.

The sample size calculation is presented in detail in another study, which indicated a total sample of 144 participants [21]. The sample size calculation has considered a statistical power of 80% and confidence interval of 95% to detect differences in pain intensity and disability between Pilates and home exercises. Standard deviation and mean pain intensity for Pilates was based on a previous study (3.30±2.30) and for home exercise on a pilot study (2.15±1.99). Standard deviation and mean disability were based on a pilot study (8.4±5.6 for Pilates and 13.6±13.6 for home exercise). The calculation indicated a sample size of 126 participants. Assuming a 15% dropout rate, it was determined that 144 participants would be needed (72 per group) [21]. After being included in the study, all participants underwent anamnesis.

Dynamic balance was evaluated by the Y-Balance Test (YBT). This test was performed in unipodal support, with the purpose of measuring the reach of lower limbs in three directions: anterior (A), posterolateral (PL), and posteromedial (PM). The data were normalized by the size of each individual's lower limb [23]. The test was applied using a wooden structure composed of a fixed base with three poles that allow movements in the A, PL, and PM directions. Each pole has a mobile base that is moved by the limb contralateral to the supporting limb. Three measurements were taken for each limb, in each direction. In the test interpretation, the farther the reach, the better the dynamic balance. The test result was calculated as a percentage using the following equation:

$$\text{Composite Score} = \frac{(A + PL + PM)}{(3 \text{ x limb length})} \text{ x } 100$$

The Tampa scale, translated and validated for Brazilian Portuguese, measured kinesiophobia [24]. The scale evaluates the excessive, irrational and debilitating fear of performing movements, and it is composed of a self-administered questionnaire with 17 questions. Each question has four possible answers: "totally disagree", "partially disagree", "partially agree" and "totally agree". To obtain the final score, it is necessary to invert the scores of questions 4, 8, 12, and 16, with the minimum score being 17 points and the maximum 68. The higher the final score, the higher the degree of kinesiophobia.

The study was approved by the Institutional Ethics Committee, CAAE: 64255917.7.000, and the participants were invited to participate by signing the Free and Informed Consent Term (FICT).

Statistical analysis

Data were analyzed using the SPSS version 25.0 software. Initially, the normality assumptions were verified using the Shapiro-Wilk test, indicating normality of the kinesiophobia and balance variables. The age and BMI variables (scores) were non- -parametric.

Data were analyzed descriptively through mean and standard deviation, median and interquartile range, and frequency measures (%). For the non-parametric variables, the 95% confidence interval was estimated using the bootstrapping procedure with 1000 samples. Regarding the participants' BMI description, the individuals were classified as eutrophic (18.5-24.9 kg/ m^2), overweight (25-29.9 kg/m^2), and obese (greater than or equal to 30 kg/m^2) [25].

A multiple linear regression analysis was performed to estimate the association between the kinesiophobia score (dependent variable) and a set of predictors (independent variables), including only continuous variables with normal distribution. Predictors were dynamic balance measure (reach distance in cm), gender (reference category: female) and BMI classifications (dummy variable, considering eutrophic as the reference). The collinearity and homoscedasticity assumptions were confirmed in the exploratory analysis, respectively, through analysis of the correlation matrix and measures of tolerance and variance inflation factor (VIF), and analysis of the residuals. The model fit was verified by the AIC (Akaike's information criterion).

In order to compare the kinesiophobia score and the dynamic balance measurement between men and women, the Student's t test for independent samples was applied. The significance level was set at 5% ($p<0.05$), with a 95% confidence interval.

Results

Table 1 presents the data of the participants characterization. The study included 145 individuals, 81 women (55.9%) and 64 men (44.1%).

Table 2 presents the data regarding the regression analysis. Kinesiophobia was found to be explained by a set of two significant predictors (YBT performance and BMI classified as obese). The remaining predictors were not significant and did not contribute to the model (Table 2).

The data showed that increases in kinesiophobia were associated with decreased reach on the YBT (worse performance) and obese individuals showed decreased kinesiophobia scores compared to eutrophic individuals.

Table 1. Characteristics of the study's participants, stratified in female and male genders. Data are presented by mean (standard deviation) for parametric variables (kinesiophobia and YBT) and median and interquartile range (BMI and age)

	General		Female		Male	
		CI95%		CI95%		CI95%
Age (years)	38.0 (15.0)	36.0 - 39.0	38.0 (17.5)	35.0 - 41.0	37.0 (12.8)	34.0 - 39.0
BMI (kg/m²)	28.7 (13.4)	27.1 - 30.5	29.2 (13.1)	26.9 - 31.7	27.9 (14.5)	26. - 31.7
BMI (n - %*)						
Eutrophic (18.5-24.9 kg/m²)	37 (25.5)	-	21 (25.9)	-	16 (25.0)	-
Overweight (25-29.9 kg/m²)	44 (30.4)	-	24 (29.6)	-	20 (31.2)	-
Obese (≥30 kg/m²)	64 (44.1)	-	36 (44.5)	-	28 (43.8)	-
Kinesiophobia (17-68)	41.3 (8.2)	39.6 - 42.7	42.1 (8.1)	40.2 - 43.9	40.3 (8.3)	38.3 - 42.4
Composite YBT (%)						
Right side	59.4 (12.9)	57.3 - 61.5	56.1 (11.5)	53.5 - 58.6	63.5 (14.5)	59.9 - 66.7
Left side	59.5 (12.3)	57.5 - 61.5	56.1 (11.1)	53.7 - 58.6	63.4 (12.6)	60.2 - 66.5
YBT between R/L	59.4 (12.3)	57.4 - 61.5	56.3 (11.1)	53.9 - 58.8	‡63.4 (12.7)	60.2 - 66.5

BMI = body mass index; YBT = Y-Balance Test; 95%CI = 95% confidence interval.
*Percentage value in reference to the total of each column; ‡Significant difference compared to women: $p<0.01$.

Table 2. Data regarding the regression analysis between kinesiophobia (dependent variable) and the gender, body mass index (BMI), and dynamic balance (composite YBT) predictors

Kinesiophobia R: 0.261 R^2: 0.068	Coefficient		CI95%		p-value
	B	SE	LB	UB	
Intercept	52.99	4.01	45.07	60.93	-
Gender					
Male	-0.71	1.41	-3.49	2.08	0.615
Female‡	-	-	-	-	-
IMC:					
Overweight	-3.14	1.83	-6.76	0.47	0.087
Obese	-4.01	1.75	-7.47	-0.54	0.024
Normal‡	-	-	-	-	-
Composite YBT	-0.14	0.06	-0.26	-0.03	0.017

YBT = Y-Balance Test; B = parameter estimate coefficient; SE = standard error; 95%CI = 95% confidence interval; LB = lower bound; UP = upper bound. ‡Reference categories in the model.

As presented in table 1, the comparison between men and women showed that kinesiophobia scores were similar (mean difference of 1.8 and 95%CI [-0.9; 4.5]; p>0.05). However, the study found that women had a lower reach on the YBT, indicating worse balance compared to men (mean difference of -7.03 and 95%CI [-10.94; -3.13]; p<0.01).

Discussion

The present results showed that a lower reach on the YBT and the obese category were associated with kinesiophobia. Nevertheless, such findings should be analyzed with caution, considering that the shared variance was only 6.8% (R2). Furthermore, women presented lower reach scores on the YBT compared to men.

Additionally, increased kinesiophobia was found to be associated with worse dynamic balance, confirming the initial hypothesis of the study. However, the comparison with previous studies shows that this association is still conflicting. For example, authors [26] have verified a significant association between kinesiophobia and mobility and balance disorders in elderly people with LBP. On the other hand, another study [27] has showed that there were no differences between dynamic balance and the degree of kinesiophobia in economically active individuals with chronic pain. Another study showed [28] that, although there was no correlation between kinesiophobia and dynamic balance, a good proprioceptive ability was considered beneficial for individuals with pain, as it could decrease the generalized fear of the condition.

It is worth noting that previous studies [11,29] have shown reduced reach on the YBT in individuals with LBP when compared to individuals without pain. Thus, it is possible to assume that the fear of moving may be a factor that influences dynamic balance, considering the apprehension when performing dynamic tasks. However, the present study's findings must be interpreted with caution, considering that the regression model explained only 6.8% of the variation in the participants' kinesiophobia. According to study [30], such findings could be explained by the fact that pain has a greater impact on balance, on the other hand, their data showed that fear of pain during movement seems not to be enough to change body sway.

Another factor that could explain the present findings is self- -efficacy, which is a predictor of recovery and is related to the psychosocial sphere and physical performance of individuals with LBP [31]. Authors [31] have shown that individuals with LBP who had a lower level of self-efficacy had greater pain intensity, lower torso range of motion, and worse postural stability.

The second significant predictor in the regression model was the BMI category classified as obese. Obese individuals had a decrease of approximately 4 points in the kinesiophobia scale when compared to eutrophic individuals. Although authors [32] had also shown an association between Kinesiophobia and BMI, their findings indicated that obese individuals had higher Kinesiophobia scores when compared to non-obese individuals.

Similarly, another study [33] showed that high BMI, age above 45 years, and sleep disorders can be considered as propensity factors for the development of LBP. However, a study [34] opposes these interpretations, as its findings have shown that increased age and obesity did not have a direct impact on the occurrence of LBP, but were considered as factors that make it difficult to perform some activities of daily life and can prolong the recovery time of these individuals. This aspect must be considered, since it is supposed that a 4-point difference in the kinesiophobia scale is not clinically relevant. Indeed, a previous study carried out with individuals with LBP in Italy who underwent rehabilitation showed that the minimally important change in the total score of the Tampa scale was approximately of 5.5 points [35].

It is worth highlighting that the biopsychosocial model advocates that LBP is multifactorial and complex, and depends on the interaction of several factors. Thus, it is important to emphasize that the fear of moving can be explained by factors other than BMI. Considering this complexity of associations, it is recommended that further research should be designed using comprehensive scientific theory-based models, such as the use of Directed Acyclic Graphs (DAG) associated with structural equation modelling [36].

Significant differences in YBT reach between men and women were found, indicating worse dynamic balance in women. The study [37] investigated differences between men and women with nonspecific CLBP in postural control and the association between pain, disability, and fear of moving. Overall, the study found no considerable differences between men and women for the variables investigated. Nevertheless, the findings showed that women had a slower reaction time compared to men. In addition, greater pain intensity was associated with longer reaction time and lower speed only in women37. These findings suggest that women have a worse strategy for pain coping, which may reflect the dynamic balance disorders. This aspect is relevant, because the study [38] showed that, among the population investigated, women with higher pain intensity had a higher degree of kinesiophobia, disability, fatigue and problems in daily activities, such as carrying materials.

However, it is worth noting that, from the perspective of the comparison performed in the present study, a difference of approximately 7% was found between the performance of women compared to men in the YBT. Therefore, it is important to ponder that such a difference is not clinically important and that other factors should be considered. For example, the disability assessment of individuals contextualized by the International Classification of Functioning, Disability and Health (ICF) [39] showed that activity and participation domains, such as maintaining body position, carrying objects, and changing body position, were the most affected. Furthermore, the findings showed that gender had a greater influence in certain activities, such as women's restrictions in home activities [39]. Also, another study [40] observed that, when women with chronic pain have the same pain intensity as men, they have a better activity level, pain acceptance and social support, while men have greater kinesiophobia and mood disorders.

The absence of a group of participants without LBP is one limitation of the present study. This reference group would have favoured a better comprehension about the impact of the presence of pain on the analysed variables.

Conclusion

The present study showed that kinesiophobia had an association with dynamic balance disorders and BMI in individuals with nonspecific CLBP. However, the model explained a small variation in kinesiophobia and interpretations need to be made with caution. From a clinical point of view, the present findings show that the assessment of dynamic balance and kinesiophobia are relevant, but also complementary, and other variables should be considered. Additionally, it was found that women with LBP had worse dynamic balance when compared to men, which suggests the need for specific interventions in this population.

CHAPTER 9

Societal contributions

9.1. Abstracts published in Annals

IASP Virtual World Congress on Pain, 2021

Carregaro, Rodrigo Luiz; Silva, E.N; Toledo, AM; Tottoli, Caroline Ribeiro; van Tulder, Maurits. **Do Sociodemographic and Socioeconomic Variables Predict the Days Off Work and Lost Productivity Costs due to Low Back Pain? A Brazilian Cost-Of-Illness Study Between 2015-2016**. In: IASP 2021 Virtual World Congress on Pain, 2021, Amsterdam. Anais do IASP Congress, 2021. v. 1.

19ª Jornada Científica do Hospital Universitário de Brasília, 2020

SILVA, M. C. M. ; VIEIRA, D.; Tottoli, Caroline Ribeiro; Toledo, AM; Carregaro, Rodrigo Luiz. **O medo de se movimentar tem relação com um déficit de equilíbrio em indivíduos com dor lombar crônica não-específica?** In: 19ª Jornada Científica do Hospital Universitário de Brasília (HUB-UnB), 2020, Brasília. Anais da 19ª Jornada Científica do Hospital Universitário de Brasília. Brasília: HUB-UnB, 2020. v. 1.

19ª Jornada Científica do Hospital Universitário de Brasília, 2020

SOARES, Gabriel C. C.; SILVA, T. G.; Tottoli, Caroline Ribeiro; Marques, YA; Toledo, AM; Carregaro, Rodrigo Luiz. **Caracterização da limitação na atividade e participação de indivíduos com dor lombar crônica não-específica**. In: 19ª Jornada Científica do Hospital Universitário de Brasília (HUB-UnB), 2020, Brasília. Anais da 19ª Jornada Científica do Hospital Universitário de Brasília. Brasília: HUB-UnB, 2020. v. 1.

19ª Jornada Científica do Hospital Universitário de Brasília, 2020

Ribeiro, Tais Dias; SILVA, T. G.; Tottoli, Caroline Ribeiro; Marques, YA; Toledo, AM; Carregaro, Rodrigo Luiz. **O pilates é eficaz comparado a exercícios domiciliares na melhora da capacidade de movimento de indivíduos com dor lombar crônica não-específica?**. In: 19ª Jornada Científica do Hospital Universitário de Brasília (HUB-UnB), 2020, Brasília. Anais da 19ª Jornada Científica do Hospital Universitário de Brasília (HUB-UnB). Brasília: HUB-UnB, 2020. v. 1.

ACSM's 66th Annual Meeting, Orlando/FL, 2019

Tottoli, Caroline Ribeiro; Marques, YA; Mascarenhas, KCS; Medeiros, Lais; Costa, IMS; Silva, EO; Silva, E.N; Martins, WR; Carregaro, Rodrigo Luiz. **Comparison Between Pilates And Home-exercises On Health-related Outcomes In Individuals With Chronic Low Back Pain**. In: ACSM's 66th Annual Meeting, 2019, Orlando/FL. Medicine & Science in Sports & Exercise, 2019. v. 49. p. S93.

ACSM's 66th Annual Meeting, Orlando/FL, 2019

Carregaro, Rodrigo Luiz; Tottoli, Caroline Ribeiro; Marques, YA; Mascarenhas, KCS; Medeiros, Lais; Costa, IMS; Silva, EO; Silva, E.N; Martins, WR; **Do Pilates And Home-exercises Improve Balance And Kinesiophobia Of Individuals With Low Back Pain?**. In: ACSM's 66th Annual Meeting, 2019, Orlando/FL. Medicine & Science in Sports & Exercise, 2019. v. 49. p. S93.

1º Congresso da REBRATS, Brasília/DF, 2019

Carregaro, Rodrigo Luiz; Silva, E.N; Tottoli, Caroline Ribeiro; van Tulder, Maurits; **Custos diretos e indiretos da dor lombar no Brasil entre 2012-2016**. In: 1º Congresso da REBRATS, 2019, Brasília/DF. Anais do 1º Congresso da REBRATS, 2019. v. 1.

Abstract sent to REBRATS, 2023:

Caroline Ribeiro Tottoli; Ângela Jornada Bem; Everton Nunes da Silva; Judith E. Bosmans; Maurits van Tulder; Rodrigo Luiz Carregaro. **Cost-utility of Pilates versus home-based exercises in individuals with chronic non-specific low back pain: economic evaluation alongside a randomised controlled trial**

9.2 Media interviews and commentary

Tottoli, Caroline Ribeiro; Carregaro, Rodrigo Luiz; Ribeiro, Tais Dias. **SUS faz uso excessivo de exames de imagem no diagnóstico de problemas na coluna, revela artigo**. 2019.
Disponível em: https://www.unbciencia.unb.br/biologicas/63-fisioterapia/622-artigo-revela-uso-excessivo-de-exames-de-imagem-no-brasil-para-diagnostico-de-problemas-na-coluna

Tottoli, Caroline Ribeiro; Carregaro, Rodrigo Luiz; Projeto inédito da UnB pesquisa formas de tratar a dor lombar. 2019.
Disponível em: https://www.youtube.com/watch?v=EJdQJh0Ixso

9.3 Participation in the Group CONSCiência@

Extension project composed of professors and students of the Physiotherapy course at the University of Brasília (UnB Campus - Ceilândia). This action was aimed at contributing to a portion of the population, which was affected by the social and home isolation imposed by health measures to face COVID-19. Through social media, content on health education practices and physical exercises at home were made available, as a strategy for coping with the pandemic imposed by COVID-19.

Development of didactic or instructional material - Scientific information for the population:

Tottoli, Caroline Ribeiro; Custódio, Luciana A; Pasinato, Fernanda; **Carregaro, Rodrigo Luiz**. Recomendações de exercícios físicos para dor lombar. 2020.

Tottoli, Caroline Ribeiro; Custódio, Luciana A; Pasinato, Fernanda; **Carregaro, Rodrigo Luiz**. Recomendações de exercícios físicos para cervicalgia. 2020.

Tottoli, Caroline Ribeiro; Beda, J.; **Carregaro, Rodrigo Luiz**. Dor na lombar há mais de três meses. 2020.

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Contextualization

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Paper 1: Effectiveness and cost-effectiveness of Pilates versus home-based exercises in individuals with chronic non-specific low back pain: randomised controlled trial protocol

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Paper 3: Cost-effectiveness of Pilates versus home-based exercises in individuals with chronic non-specific low back pain: economic evaluation alongside a randomised controlled trial

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Paper: Is kinesiophobia associated with disturbances in dynamic balance in individuals with chronic non-specific low back pain?

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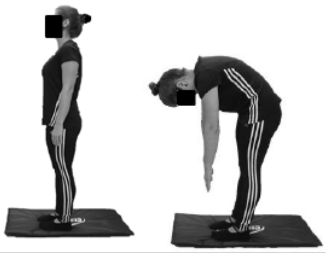
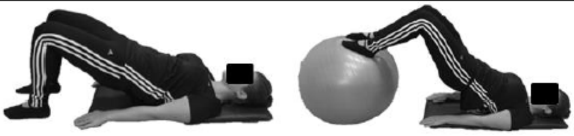
APPENDICES

Appendix A. Description of Pilates Group exercises

EXERCÍCIO	OBJETIVO	DESCRIÇÃO	IMAGEM
Arm Arcs	Mobilidade cintura escapular; mover MMSS sem mudar a posição do tronco	DD, CN, estabilização de coluna com dissociação de MMSS	
Bent Knee Opening	Mover MMII sem mudar a posição do tronco para estabilidade com forças rotacionais	DD, CN, estabilização de coluna com dissociação de MMII	
Sidelying	Alinhamento e estabilidade do tronco em DL, mobilidade do quadril mantendo a CN enquanto move uma perna	DL, CN; - Expire, flutue a perna paralela ao colchonete; inspire e balance a perna para frente, tronco em alinhamento neutro; expire e balance a perna para trás, contraia a parede abdominal, tronco neutro	
Dead Bug & Femur Arcs	Mover MMII sem mudar a posição do tronco; mobilização do quadril, fortalecimento abdominal	DD, CN, estabilização de coluna com dissociação de MMII	
Quadruped Series	Mover membros sem mover o tronco; melhora estabilidade e mobilidade do quadril, organização e mobilidade de ombro	Em quatro apoios, estabilização de coluna com dissociação de MMSS e MMII	
Single Leg Stretch	Coordenação, fortalecimento abdominal e mobilidade do quadril	DD, coluna lombar em imprint; estabilização de tronco em flexão com dissociação de MMSS e MMII	
Prone Press Up	Fortalecimento e mobilidade torácica em extensão; fortalecimento de MMSS e organização de ombros em prono	DV, inicia em coluna neutra; mobilização de coluna em extensão com apoio das mãos ao lado do peito; direcionar cotovelos para trás	
			
Sidekick	Estabilidade e mobilidade de quadril; organização de ombros; estabilidade de coluna com diminuição da base de suporte	DL, estabilização de tronco lateral com dissociação de MMII	
Leg Pull Front	Descarga de peso; fortalecimento de coluna, abdome e glúteos	DV, estabilização de tronco e dissociação de MMII com alinhamento e descarga de peso em MMSS	

Stanging Roll Down	Mobilidade da coluna em flexão a partir da cabeça e da pelve; alongamento de isquiotibiais	Em pé, mobilização de coluna em flexão com mãos em direção ao chão – retomar para coluna neutra	
Spine Stretch	Mobilidade da coluna em flexão e flexibilidade de isquiotibiais	Sentado, mobilização de coluna em flexão; manter MMSS na altura dos ombros	
Pelvic Clock	Mobilidade pélvica e da coluna, consciência corporal	Inicia-se em CN, DD, a pelve leva à flexão, extensão e rotação da coluna sem flexão lateral	
			
Bridging	Mobilidade do quadril, da coluna de forma segmentada (articulação segmentar) e consciente; fortalecimento cadeia posterior e quadril	DD, mobilizar coluna a partir da pelve - Inspire para alongar a coluna, expire para afastar gradualmente o corpo do colchonete, inspire em uma longa linha diagonal e então expire para rolar para baixo voltando para a posição inicial	
The Hundred	Fortalecimento abdominal, coordenação e ritmo, promove circulação e aquece através da respiração	DD, coluna lombar em imprint; estabilização de tronco em flexão com dissociação de MMSS e MMII	
Mermaid	Mobilidade da coluna em flexão lateral, rotação, rotação com flexão e alinhamento dos ombros	Sentado, mobilização de coluna em flexão lateral e rotação	
Book Openings	Estabilidade e mobilidade torácica; alinhamento e mobilidade de ombros	DL, estabilização de tronco e mobilização torácica em rotação com dissociação de MMSS	

			
Swan Dive I	Mobilidade e fortalecimento da coluna em extensão; fortalecimento e consciência do centro em extensão; mobilidade do quadril em extensão e fortalecimento de MMSS	DV, mobilização de coluna em extensão; estender tronco até extensão completa de cotovelos	
Swimming	Fortalecimento de coluna em extensão; mobilidade de quadril e ombros	DV, estabilização de coluna em extensão com dissociação de MMSS e MMII	

			
Dart	Fortalecimento e mobilidade de coluna torácica em extensão; organização de ombros em prono	DV, mobilização de coluna em extensão com MMSS estendidos ao longo do corpo	
Saw	Mobilidade de coluna em rotação; organização de ombros e flexibilidade de isquiotibiais	Sentado, mobilização de coluna em rotação com dissociação de MMSS	

			
Single Leg Kick	Fortalecimento de coluna em extensão; organização de ombros e MMII	DV, estabilização de coluna em extensão com dissociação de MMII	
Side To Side	Mobilidade da coluna em rotação, mobilidade das costelas e postura	DD, coluna lombar em imprint; - Alongue braços e tronco; Inspire para rolar a pelve e pernas para o lado; mantenhas as escápulas no colchonete; expire para retornar para posição inicial	

Assisted Roll Up	Fortalecimento abdominal e mobilidade da coluna a partir da cabeça	DD, CN – para subir mova a partir da cabeça em flexão e para descer a partir da pelve - Inspire puxando as pernas em direção ao peito; expire empurrando as pernas contra as mãos para rolar para cima até estender os braços	

Appendix B. Booklet delivered to participants of the Home-based Exercise Group

FASE I

PROTOCOLO DE EXERCÍCIOS TERAPÊUTICOS PARA LOMBALGIA

Grupo de Pesquisa: "Avaliação e Intervenção em Fisioterapia"

UnB

ORIENTAÇÕES GERAIS

Para iniciar os exercícios:

- Use roupa confortável
- Beba água durante os intervalos
- Escolha um local arejado
- Controle a respiração durante todos os exercícios: puxe o ar pelo nariz e solte pela boca

AQUECIMENTO

1 – Sentar e levantar;
2 – Elevação de perna alternada;
3 – Caminhada estacionária.

Escolha um tipo de aquecimento e o realize durante 30 segundos, descansando por 15 segundos após a execução. Repita a instrução 6 vezes.

FORTALECIMENTO

1. Braços estendidos, subir tronco com mãos em direção aos joelhos

3x10 repetições

2. Retirar um braço de cada vez estendido, e depois uma perna de cada vez

2x10 repetições

3. Mãos na testa, subir cabeça, tronco, mãos e cotovelos ao mesmo tempo

10 repetições/ 10-15 seg

4. Subir quadril e coluna em direção ao teto

3x10 repetições

FASE I

PROTOCOLO DE EXERCÍCIOS TERAPÊUTICOS PARA LOMBALGIA

Grupo de Pesquisa: "Avaliação e Intervenção em Fisioterapia"

UnB

ALONGAMENTO

5. Estenda os joelhos, depois desça a cabeça e tronco com as mãos em direção aos pés

Manter 1 minuto

6. Gire as pernas para um lado e olhe para o lado contrário

Manter 15 segundos

7. Cruze uma perna sobre a outra e abrace o joelho

Manter 30 segundos

8. De joelhos, leve o tronco a frente

Manter 30 segundos

9. Apoiar em uma parede e abrir as pernas por completo com joelhos estendidos

Manter 30 segundos

10. Estender a perna e levar em direção à outra, inclinando o pé para dentro

Manter 30 segundos

FASE II

PROTOCOLO DE EXERCÍCIOS TERAPÊUTICOS PARA LOMBALGIA

Grupo de Pesquisa: “Avaliação e Intervenção em Fisioterapia”

ORIENTAÇÕES GERAIS

Para iniciar os exercícios:

- Use roupa confortável
- Beba água durante os intervalos
- Escolha um local arejado
- Controle a respiração durante todos os exercícios: puxe o ar pelo nariz e solte pela boca

AQUECIMENTO

1 – Sentar e levantar;
2 – Elevação de perna alternada;
3 – Caminhada estacionária.

Escolha um tipo de aquecimento e o realize durante 30 segundos, descansando por 15 segundos após a execução. Repita a instrução 6 vezes.

FORTALECIMENTO

1. Braços estendidos, subir tronco com mãos em direção aos joelhos

3x15 repetições

2. Retirar um braço de cada vez estendido, e depois uma perna de cada vez

2x15 repetições

3. Mãos na testa, subir cabeça, tronco, mãos e cotovelos ao mesmo tempo

10 repetições/ 15-20 seg

4. Subir quadril e coluna em direção ao teto

3x15 repetições

FASE II

PROTOCOLO DE EXERCÍCIOS TERAPÊUTICOS PARA LOMBALGIA

Grupo de Pesquisa: “Avaliação e Intervenção em Fisioterapia”

FORTALECIMENTO

5. Suba uma perna e a segure com as mãos atrás do joelho. Desça a outra perna com o joelho flexionado

3x15 repetições

6. Movimente uma perna de cada vez . E depois, um braço de cada vez estendido.

3x15 repetições

FASE II

PROTOCOLO DE EXERCÍCIOS TERAPÊUTICOS PARA LOMBALGIA

Grupo de Pesquisa: "Avaliação e Intervenção em Fisioterapia"

UnB

ALONGAMENTO

7. Estenda os joelhos, depois desça a cabeça e tronco com as mãos em direção aos pés

Manter 1 minuto

10. De joelhos, leve o tronco a frente

Manter 30 segundos

8. Gire as pernas para um lado e olhe para o lado contrário

Manter 15 segundos

11. Apoiar em uma parede e abrir as pernas por completo com joelhos estendidos

Manter 30 segundos

9. Cruze uma perna sobre a outra e abrace o joelho

Manter 30 segundos

12. Estender a perna e levar em direção à outra, inclinando o pé para dentro

Manter 30 segundos