

Protocol Article





Effect of circular dance compared to lumbar segmental stabilization on nonspecific chronic back pain: randomized controlled trial protocol

Abstract

Background: Circular dance (CD) has been used to improve flexibility, posture, strength and muscle resistance, thereby reducing pain and tension. Lumbar segmental stabilization (LSS) is a therapeutic approach that aims to improve the neuromuscular control, strength and resistance of muscles that provide spinal stability.

Objective: Compare the effect of CD and LSS on pain and functional disability of women with nonspecific chronic low back pain (NCLBP).

Method: The sample will consist of 30 women aged between 35 and 60 years, with nonspecific chronic low back pain and intensity ≥3 points on the Numerical Pain Scale (NPS), divided into 2 groups: 1) CD group: 15 participants; 2) LSS group; 15 participants. Sixteen minutes sessions will be held twice a week for both groups. The primary outcomes will be assessed using the Numerical Pain Scale and Rolland-Morris Disability Questionnaire, and the secondary outcomes by the Beck Depression Inventory, Numerical Anxiety Scale, Global Perceived Effect (GPE) scale, Report of Symptoms and Adverse Events or Side Effects and the SF-36 Quality of Life Questionnaire at pre-treatment and 8, 12 and 24 weeks post-treatment.

Results: It is hoped to obtain results that allow defining the possibility of using CD as a simple alternative to be applied, inexpensive, viable to be used in the public health system, with results equivalent if compared to a treatment already founded in the literature as an effective treatment for chronic back pain. Statistical analysis will be conducted using Statistical Package for the Social Sciences software (SPSS -20.0), applying descriptive and inferential statistics.

Discussion: This study is expected to broaden the use of CD in the national health system as an effective and efficient therapy, which could benefit women with NCLBP to have improved motor functions and emotional aspect of this population as well and ameliorate the quality of life.

Trial registration: Clinicaltrials.gov NCT02807090.

Keywords: back pain, functional disability, quality of life, lumbar segmental stabilization, dance therapy

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Abbreviations: LBP, low back pain; LSS, lumbar segmental stabilization; CD, circle dance; NPS, numerical pain scale; NPS-A, numerical anxiety scale; LSEg, lumbar stabilization exercises group; CDg, circle dance group; BDI, back depression inventory; ANOVA, analysis of variance; SPSS, statistical package of the social sciences; APTA, american physical therapy association; TrA, transversus abdominis; LM, lumbar multifidus; RA, rectus abdominis; IC, iliocostalis; QL, quadratus lumborum; EO, external oblique; IO, internal oblique; SUS, national health system; PNPIC, national policy of integrative and complementary practices; WORD, work related osteoarticular diseases; USP, university of são paulo; UFPB, federal university of paraíba; IMMPACT, initiative on methods, measurement, and pain assessment in clinical trials; sf-36, short form health survey; ADL: activities of daily living; GPTE, global perceived treatment effect; PBU, pressure biofeedback unit; VD, ventral decubitus; DD, dorsal decubitus; PF, pelvic floor: D, diaphragm; EV1, evaluation one; EV2, evaluation two; EV3, evaluation three; EV4, evaluation four; RG, relative gain

Introduction

Chronic musculoskeletal pain affects a large number of individuals worldwide. A recent study showed that low back pain (LBP) was the primary cause of disability when the number of years living with disorders was considered.1 Moreover, it has been most prevalent in musculoskeletal alterations, accounting for 78% of moderate (38%) and intense (40%) pain complaints among users who underwent group treatment for LBP.2 In Brazil, data from the 2016 National Household Sample Survey (PNAD) show that low back pain is the most prevalent among adults.3 Currently, there are a number of treatments for back pain: traditional techniques such as therapeutic exercise4 and nonconventional techniques including Tai Chi Chuan,5 Lian Gong6 and belly dancing.7 Evidence-based LBP treatment guidelines are used in clinical physical therapypractice.^{8,9} The American Physical Therapy Association (APTA)9 classifies low back pain as chronic when patients exhibit symptoms for more than 3 months, and recommends interventions at the primary health care level. Among the exercises





suggested to reduce pain and disability in individuals suffering from sub acute and chronic LBP with compromised motor coordination are strengthening, resistance and trunk coordination exercises (Grade A recommendations),⁹ which the literature also describes as lumbar segmental stabilization exercises, motor control exercises or lumbar multifidus exercise.⁹ Lumbar segmental stabilization (LSS) exercises aim to strengthen deep trunk muscles in order to stabilize the lumbo pelvic region using dynamic stabilization of the spine and trunk neuromuscular training, thereby decreasing the overload on its structures and protecting the facet joints from excessive wear related to activities of daily living.¹⁰

These exercises are characterized by low-intensity isometry and synchrony of the deep trunk muscles: transverse abdominis (TrA), internal oblique (IO), external oblique (EO), diaphragm (D) and pelvic floor (PF) musclesthat modulate intra-abdominal pressure (IAP).10 LSS is based on two systems: 1) the global: consisting of large torque-producing muscles that act on the trunk without being directly attached to the spine: rectus abdominis, external oblique and the thoracic portion of the iliocostalis lumborum; and 2) the local: formed by muscles directly attached to the vertebrae: lumbar multifidus (LM), transverse abdominis (TrA), posterior fibers of the internal obliques and the quadratus lumborum (QL), which help stabilize spinal segments during dynamic movements, contributing to postural control.⁴ The LM accounts for 2/3 of the increase in segmental stiffness, 10 while the TrAacts primarily in maintaining intra-abdominal pressure (IAP) by providing tension to the lumbar vertebrae through the thoracolumbar fascia (TLF);11 the QL muscle acts as a lateral stabilizer of the lumbar spine.¹²

In addition to the LM and TrA muscles, lumbar stabilization is provided by the diaphragm on the upper portion and the pelvic floor on the lower portion of the trunk, forming a cylinder of deep stabilizing muscles. ^{13,14} Systematic reviews recommend stabilization exercises to treat low back pain. ^{4,15} Chang (2015) concluded that deep trunk muscle strengthening exercises are more effective than resistance training in controlling low back pain. ¹⁵ and Haladay (2013) also reported that stabilization exercises improve pain in individuals with chronic low back pain. ⁴

The benefits of circular dance (CD) may be similar to those of LSS, since it improves body stability, but its effects on chronic LBP are unconfirmed. Circular dance, a low-impact aerobic activity performed in a circle to strengthen social integration and the learning process, aims at improving physical, mental and emotional aspects. It is also used to improve static and dynamic balance, and may also benefit gait. 16,17 It is performed using simple and gentle harmonious movements but can also be intense and energetic. Brazil's national health system (SUS), created in 1988 by the Federal Constitution and one of the largest in the world, guarantees free universal comprehensive care for the entire population.^{18,19} The National Policy of Integrative and Complementary Practices (PNPIC) was approved and implemented in 2006¹⁹ to act in health promotion and disease prevention, and later incorporated circular dance/biodance as therapeutic procedures. The financial support provided has increased the use of CD in treating the population.20

Circular dance can be seen among SUS users as an alternative treatment for a number of disorders. In a study of mastectomized patients, Frison²¹ observed an improvement in quality of life and work

capacity due to a decline in pain and discomfort. Bartilotti et al²² also used CD in a rehabilitation program for workers with work-related osteoarticular diseases (WROD), depression and mood disorders, obtaining a return to work rate of 64%.²² Given that no studies have shown the effectiveness of circular dance in the treatment of chronic low back pain in comparison it with LSS, we hypothesize that CDcould promote and increase functional capacity and reduces the disability in the patients and can be adopted as a regular treatment in the SUS. The primary outcome of this study is to compare the effect of CD and LSS on pain and functional disability in women with nonspecific chronic low back pain. The secondary outcome is to compare the influence of CD and LSS on depression, anxiety, global perceived treatment effect (GPTE), satisfaction at the end of treatment and quality of life after follow-up of 8, 12 and 24 weeks.

Sample and method

Research model

Randomized controlled trial

Inscription and eligibility criteria. The sample will be composed of 30 women with NCLBP for 12 or more weeks¹⁵ who meet the following inclusion and exclusion criteria:

Inclusion treatment:

- I. Women
- II. Age between 35 and 60 years;
- III. Diagnosis of low back pain in accordance with APTA criteria;9
- IV. Nonspecific chronic low back pain for ≥3 months with or without lower extremity irradiation;
- V. Pain intensity ≥ 3 on the Numerical Pain Scale;
- VI. Absence of severe spinal conditions (surgery, fractures, tumors, infections and inflammatory diseases);
- VII. Not being pregnant;
- VIII. Not undergoing physical therapy or opioid-based treatment.

Exclusion treatment:

- Experiencing pain or discomfort in the lumbar region that impedes treatment continuation and a formal request to withdraw from the study;
- II. Being involved in a labor dispute;
- III. Absent from 4 consecutive treatment sessions.

Ethics committee

This project was approved by the Research Committee of the Faculty of Medicine of the University of São Paulo (USP) under protocol no. 118/2016 and CAAE no. 55131916.7.0000.0065. The study will be conducted at the following facilities: 1) Clinical School of Physical Therapy of the Federal University of Paraíba - UFPB, 2) LauroWanderley University Hospital; 3) Center for Integrative Practices and Human Equilibrium (CPICS), Paraiba state, Brazil. It is registered under clinical trials (www.clinicaltrials.gov) under protocol no. NCT02807090.

Procedure

Participants diagnosed with chronic low back pain will be recruited from the waiting list at the School Physical Therapy Clinic, LauroWanderley University Hospital of the Federal University of Paraíba (UFPB) and CPICS. Moreover, posters, pamphlets and television media will be used to call volunteers for the study to the general population. After telephone screening, potential participants will be interviewed for initial assessment. At initial assessment, a duly trained physical therapist (blind assessor) will:

- Collect personal and sociodemographic data and anamnesis, including history of associated diseases, signs and symptoms, and conduct specific examinations;²³
- II. Next, measurement instruments will be applied to determine pain intensity(Numerical Pain Scale-NPS)in line with "Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials" guidelines (IMMPACT);²⁴
- III. Functional Disability Rolland-Morris Disability Questionnaire;^{26,27}
- IV. Depression and Anxiety–Beck Depression Inventory BDI,²⁸ anxiety level using the Numerical Anxiety Scale – NAS;²⁹
- V. Global Perception— using the Global Perceived Effect (GPE) scale in order to determine whether the participant perceives treatment progress;^{26,30} and

- VI. Satisfaction Level– applying the Report of Symptoms and Adverse Events or Side Effects.³¹
- VII. Quality of Life- Brazilian version of the Quality of Life Questionnaire (SF-36);²⁵

The questionnaires will be in the form of an interview in order to minimize comprehension problems and errors in filling out the instrument. The LSS group will be tested in the Physical Therapy Department of LauroWanderley University Hospital by a physical therapist with clinical experience, and the CD group at the Center for Integrative Practices and Human Equilibrium (CPICS) by the same physical therapist and a professional experienced in circle dance denominated the "Focuser", who maintains the "Focus" and leads the activity so that participants feel the importance of the moment and can open creative processes through the dance.³²

Randomization

After participants have given their informed consent, they will be randomly assigned to groups using www.randomization.com software. Group allocation will be concealed in consecutively number sealed opaque envelopes. An independent researcher who did not participate in the other procedures will conduct the randomization process.³³ Subjects will be assigned to two groups: 1) CD group: where they will perform choreographed movements together (CDg n=15). 2) LSS group (LSSg n=15), where a series of individual exercises will be developed according to the attached study flowchart (Figure 1).

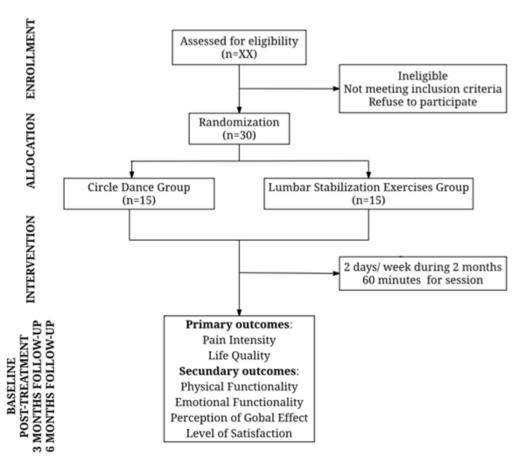


Figure I Study Flowchart.

Outcome measures

All the instruments that will be used have been validated for Brazilian Portuguese.

Primary outcome

Pain

Pain intensity will be assessed by the Numerical Pain Scale – NPS, an 11-point scale (0-10)in which 0 indicates "no pain" and 10 "the most intense pain experienced" in the last seven days. Scores between 0 and 3 are classified as "mild pain", between 4 and 7 "moderate pain" and between 8 and 10 "intense pain".

Functional disability

Functional disability will be quantified by the Rolland-Morris Disability Questionnaire, composed of 24 questions related to activities of daily living (ADL), where each affirmative answer corresponds to 1 point and the final score is the sum of the values obtained. Values close to zero indicate fewer limitations, those above 14 points show functional disability and those near 24 points represent a severely compromised spine. ^{26,27}

Secondary outcomes

Depression

Depression will be determined by the Beck Depression Inventory (BDI), composed of 21 items whose intensities vary from 0 to 3; the higher the score the greater the depressive symptoms.²⁸

Anxiety

The Numerical Anxiety Scale (NAS) will be used to measure anxiety. It consists of an 11-point scale (0-10) where 0 indicates "no anxiety" and 10 the "most intense anxiety" experienced in the last seven days.²⁹

Global perceived treatment effect

The Global Perceived Effect (GPE) scale assesses the patient's perceived treatment-related recovery, comparing pre- and post-treatment symptoms. Scores vary between -5 ("extremely bad"), 0 ("no change") and +5 ("completely recovered"), whereby the higher the score, the greater the recovery.^{26,30}

Symptoms and adverse effects

The Report of Symptoms and Adverse Events or Side Effects describes possible complications during the sessions. It will include the spontaneous report of symptoms and/or events resulting from the procedures adopted. Next, participants will be asked to classify the certainty of their complaints according to a 5-point Likert scale, where 1 represents "not certain" and 5 "completely certain".³¹

Quality of life

Quality of life will be assessed by the SF-36 (Medical Outcomes Study 36 – Item Short – Form Health Survey), a generic assessment instrument containing 36 items, divided into the following 8 domains: 1) functional disability; 2) physical aspects; 3) pain; 4) general health; 5) vitality; 6) social aspects; 7) emotional aspectsand 8) mental health. The maximum score is 100 points (calculated using the Raw Scale), where 0 corresponds to the worst and 100 the best general health status.²⁵

Interventions

The interventions that will be used involve two different activities for participants with nonspecific chronic low back pain. Both will include 16 one-hour sessions performed twice a week. The CD group will have 15 participants and the LSS group individual sessions.

Lumbar segmental stabilization group (LSS)

At both assessment and the first session, participants will be instructed to fast for 2 hours before the start of the procedures (including water), empty their bladder before the test, and not engage in any abdominal exercise the day before. Initially, participants will be informed about the basic anatomic/biomechanical aspects of the spinal muscles and the LSS technique. Next, quantitative assessment of the deep core stability muscles (TrA and LM) will be carried out using a Chattanooga 9296 stabilizer pressure biofeedback unit - PBU (San Diego, USA).34 For the TrA test in ventral decubitus (VD), the subjects will lie on a gurney with the pressure bag of the PBU below the abdomen and the navel at the center of the bag, which will be inflated with air up to a baseline pressure of 70 mmHg. They will be asked to hold a contraction of the abdominal wall on the following command: "Contract your lower abdominal muscles without moving your spine or pelvis and hold it for 10 seconds". Pressure should decrease between 6 and 10 mmHg.

For the TrA test, in dorsal decubitus (DC), the participants lie on the gurney, the pressure bag is placed longitudinally to the spine on the opposite side of the leg that is raised during the test and filled to a baseline pressure of 40mmHge.Subjects will be instructed to contract the abdominal wall on the following command: "Contract your lower abdominal muscles controlling the position of the spine while raising your leg without moving your spine or pelvis, and hold this position for 10 seconds" The test will be deemed satisfactory if the pressure remains at 40 mmHg, but if this values increases or decreases, TrA contraction will be considered unsatisfactory. 10 Assessment of the LM will be in ventral decubitus (VD) for the muscle activation test. The muscle will be palpated bilaterally to compare loss of muscle consistency at each level of the lower back region. The command will be: "push" your muscles against the therapist's fingers without moving your spine or pelvis and hold the contraction while breathing normally". 10

After the first session, the 15 remaining sessions will be divided into 3 phases (cognitive, associative and automatic) according to the LSS technique (Table 1). In the cognitive phase we propose training the isolated voluntary contraction of stabilizer muscles with the use of the PBU in order to promote recruitment awareness.In the associative phase, we suggest an association between lower and upper limb movements, and in the automatic phase between active and continuous movements, performed in a circuit.¹⁰ After executing each exercise participants will rest for twice the time the contraction was held during the test (1:2).36 Subjects will be instructed to maintain their ADL and not engage in any other physical activity during this time. They will be reassessed at each training session and, if possible, reallocated to a higher level. Fatigue or being out of breath, as reported by the participant or perceived by the physiotherapist, in addition to the adequate execution of the exercise, will be considered before increasing the task. If these signs are present the exercise will not be increased. Subjects will be shown pictures of the shape and anatomical arrangement of the TrA, LM, PF and diaphragm muscles in order to facilitate the specific exercises.10

Table I LSS protocol

Phases	Exercise description	Series / duration / interval
Cognitive	I. Positioning: Dorsal decubitus (DD), knees flexed and feet flat on the gurney. Command: "contract your abdomen" (associated with forced expiration and holding their breath).	2 series, each series with 10 repetitions 10s contraction, 15s rest 1min 30s between series
	Evolutioni) Without holding their breath	2 series, each series with 10 repetitions 10s contraction, 15s rest 1min 30s between series
	Evolution ii) Without holding their breath, increasing the time	2 series, each series with 10 repetitions 15s contraction, 15s rest 1min 30s between series
Associative	I. Positioning: DD, knees flexed and feet flat on the gurney. Command: "contract your abdomen" and forced expiration associated with:	3 series, each series with 10 repetitions 15s contraction, 20s rest2min between series
	 i) Continuously and alternately sliding their heels along the gurney; ii) Alternating one arm with the contralateral leg (LL), raising them off the gurney and moving them constantly; iii) Hip bridge exercise; iv) 4-point positioning, alternating and raising one arm and the contralateral leg off the gurney. 	
Automatic	I. Positioning: Dynamic (Circuit)Command: "contract your abdomen" and forced expiration associated with:	3 Circuits Each circuit with 3 repetitions for each exercise (a, b, c), 60s contration; 60s rest; 2min rest at the end of the 3 repetitions of each exercise (a, b, c)
	i) Ist Circuit: Exercise a) moving from DD to a sitting position; Exercise b) moving from the sitting (in a chair) to the standing position; Exercise c) stepping up and down once;	
	ii) 2nd Circuit: Exercise a) stepping up and down once; Exercise b) moving from the sitting (in a chair) to a standing position and running on the spot; Exercise c) sitting on a Swiss ball and raising the arms 90 degrees while the researcher moves the ball from one side to the other;	
	iii) 3rd Circuit: Exercise a) jumping back and forth over three obstacles; Exercise b) squatting with the Swiss ball placed between the spine and the wall; Exercise c) sitting on the Swiss ball raising one arm and the contralateral leg at the same time, while the researcher moves the ball from one side to the other.	

Table 2 Circle dance protocol

Stages	Procedures	Time
Reception/ Harmonization	I) Position: Sitting and/or standing in a circle holding hands; 2) Command: a) close your eyes; b) engage in reflective meditation (relax the mind); c) breathe slowly; d) connect with the present ("here and now").	
Reflection	I) Position: Sitting and/or standing; 2) Action: a) The "focuser" asks each one of the group how they are feeling (The answers are limited to one word); b) He or she then reads a positive message or short fable.	
Warm-up/ stretching	I) Position: Sitting and/or standing; 2) Action: a) stretch your arms and legs; 3) Command: a) "touch the ceiling with your hands"; b) "extend your arms in front of your heart"; c) "extend your arms behind your back; d) "rotate your shoulders forward and backward"; e) "walk on tiptoes"; f) "walk on your heels"; g) "walk with your feet turned in"; h) "walk with your feet turned out"; i) "with your back against the wall, grab your right knee with both hands and lift your leg towards your abdomen; k) "rotate your right thigh outward and inward"; l) "rotate your left thigh outward and inward".	
Circular Dance	1) Position: Sitting and/or standing in the circle; 2) Action: ask what the circle means; the delimitations of the center of the circle and the area around it that the subjects can use, moving forward, backward, to the right and to the left.	5min
Choreographies	1) Position: Sitting and/or standing in the circle; 2) Action: practice the sequence of steps established for the dance selected and its meaning.	10mir
Performing the repertoire	1) Position: Sitting and/or standing in the circle; 2) Action: execute the sequence of steps established by the dance selected.	25min
Conclusion	1) Position: Sitting and/or standing in the circle; 2) Action: relax and resume normal breathing; 3) Command: a) "breathe normally"; b) "say a word that reflects what you are feeling".	5 min

The CD group will be conducted by the researcher with good experience in CD. The group will consist of an average of 15 regular participants with low back pain and study subjects who will take part in only16 sessions. These individuals will be assessed 8, 12 and 24 weeks after the final session. The group will be presented with simple to more complex choreographies. In order for the choreographies to evolve, 50% of participants will have to be able to execute them in a coordinated and harmonious fashion. The difficulties in executing the steps reported by participants will be considered in the choreographic evolution assessed at each session. The CDs used will be those described in the literature, as follows: a) contemporary dances (ex: Circular/Brazil), b) traditional (ex: Shalom Salam/Israel), c) ethnic (ex: Dikanda/Poland) and d) Findhorn Foundation (ex: Banish Misfortune/Scotland).

Statistics

Sample size calculation

Sample size was calculated to find a difference of 2.5 points between the groups on the pain intensity scale with a standard deviation of 2.5 points. The sample was calculated using G* Power 3.1.0 software and the procedures followed Beck's recommendations³⁵ to estimate sample size. A power of 0.9 was adopted a priori, considering a significance level of 5%; correction coefficient of 0.5; nonsphericity correction of 1; and effect size of 0.25. A total "n" of 30 subjects (15 per group) was calculated, based on 4 measures per group (repeated measures). This analysis was conducted to reduce the likelihood of type II error and determine the minimum number of individuals required for this investigation. Thus, the sample size will be sufficient to provide 90.3% of statistical power, with sample loss of 15%.

Statistical analysis

The data will be analyzed in Statistical Package for the Social Sciences software (SPSS - Version20.0), using descriptive and inferential statistics. Initially, data normality (Shapiro-Wilk) and homogeneity of variances (Levene) will be verified and, depending on adherence to normality, the following tests will be used: repeated measures ANOVA (parametric data), followed by Bonferroni's post hoc test or Friedman's ANOVA (nonparametric data), for intra and intergroup analysis, with a 95% confidence level for all the comparisons. The groups will be compared pre-treatment (EV1), post-treatment (EV2: 8 weeks), andthree (EV3: 12 weeks) and six months(EV4: 24 weeks) after treatment. The relative gain (Gr_i) will correspond to the gain patients obtain from treatment in relation to how much they could have improved, which will be calculated as follows:

 $GR_i = (Before_i - After_i) \times 100$ $Before_i - Min (variable)$

Where Min (variable) represents the lowest possible value of the variable under study.³⁶

Results

We hope that we will be able to obtain consequent data that allow us to choose circular dance as a simple alternative treatment to be trained by regular people in the community and that can be applied inexpensively and quite widely among individuals suffering from chronic back pain. Lumbar stabilization exercises a traditional treatment well founded in the literature, which have good evidence of therapeutic effectiveness, could have results similar to the use of circular dance, we could confirm the viability of this alternative treatment for the group of patients who suffer chronically from back pain.

Discussion

We believe that there will be convincing results to allow a wide discussion on the perspectives of using circular dance as a simple and inexpensive method in comparison to the exercises of re-education of the intrinsic musculature of the lumbothoracic region. Primary outcomes will be prioritized, but due importance should be given to secondary outcomes, since this study is exploratory and comparative with treatment already in use in clinical practice. All the aspects of the chronic back pain will be considered as result to take in account.

Conclusion

The primary objective of this study is to compare the effect of CD and LSS exercises on pain and functional disability in women with nonspecific chronic low back pain, and the secondary objective is to compare the effect of CD and LSS on depression, anxiety, global perceived treatment effect, satisfaction at the end of treatment and quality of life. Assessments will occur before and after interventions as well as 3 and 6 months after the sessions. This study is expected to broaden use of CD, thereby benefitting women with nonspecific chronic low back pain in Brazil's national health system.

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Authors' contributions

JMB*¹, HHS², MSV³, ACP⁴, RAC⁵ were responsible for the study design.

Conflicts of interest

The authors declare that there are no conflicts of interest related to this manuscript.

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