

Effect of the Low Pressure Fitness (LPF®) Technique on Diastasis Recti Abdominis in Postpartum Women: Protocol for A Blinded Randomized Clinical Trial

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SUMMARY

Introduction. In the postpartum period, the female body undergoes hormonal, anatomical, and physiological changes that can negatively impact musculoskeletal health and lead to conditions such as Diastasis Recti Abdominis. Low Pressure Fitness (LPF®) has been used in clinical practice; however, there is still no consensus on its effects on the abdominal wall and whether it can effectively reduce diastasis in this population. Therefore, the aim of this study is to evaluate the effects of LPF® on diastasis recti abdominis in this population.

Methods. This is a blinded randomized clinical trial in which 86 volunteers will be randomly allocated to two groups of 43 participants each: control group (Kinesiotherapy) and experimental group (LPF®). The interventions will last for 8 weeks, and outcome measures will include abdominal diastasis, pelvic floor muscle function, trunk resistance, pain, functionality, quality of life, posture, perception of overall effect, and patient expectation with treatment. Statistical significance will be set at 5% with a 95% confidence interval (95%CI).

Conclusions. This protocol was developed to elucidate the effects of LPF® as a treatment for abdominal diastasis in postpartum women compared to traditional treatment methods.

Study registration. Brazilian Clinical Trials Registry (identifier: RBR-3xtxhtz).

KEY WORDS

Muscle diastasis; physical therapy; postpartum period; abdominal rectus; exercise therapy.

INTRODUCTION

Hormonal, anatomical, and physiological variations affect a woman's body during the gravid-puerperal cycle (1). These changes provide a conducive environment for fetal development but can also negatively impact the musculoskeletal health of the female body (1), resulting in conditions such as Diastasis Recti Abdominis (DRA) (2).

DRA is defined as a separation of the two bellies of the rectus abdominis along the midline of the linea alba (3) and occurs most frequently during pregnancy, spontaneously resolving after childbirth in most women (4). However, reported prevalence varies between 60% and 32.5%, at six weeks and 12 months postpartum, respectively (5). Besides being an aesthetic concern for many women, other consequenc-

es associated with DRA include decreased muscle strength (6, 7), impaired abdominal resistance (7), pelvic girdle pain, pelvic floor disorders (8), and low back pain (9).

The American College of Obstetricians and Gynecologists (ACOG) (10) recommends regular exercise during pregnancy and postpartum, in the absence of medical and obstetric complications, for at least three times a week for 30 to 40 minutes (11). In the postpartum period, physical exercise not only helps women regain pre-pregnancy weight but also improves mental health, generates positive feelings, and reduces the incidence of depression (12). Abdominal exercise is generally recommended as an important physiotherapeutic intervention for women with DRA (13). Core stabilization exercises postpartum allow for an average improvement of 35% in the effects of DRA (14); postpartum women also experience significant improvement in quality of life (15).

An alternative treatment technique called Low Pressure Fitness (LPF®) is based on Hypopressive Exercises (HE), which were first described by Caufriez, a physiotherapist (16). According to this author, these exercises relax the diaphragm, decrease abdominal pressure, and reflexively activate abdominal and pelvic floor muscles during diaphragmatic aspiration. The reduction of abdominal pressure obtained through hypopressive technique creates a type I reflex activity in the abdominal wall and pelvic floor muscles with latency of several seconds, which, in the long term, contributes to the strengthening of these muscles (17). Benefits such as improved flexibility of the lumbar and hamstring muscles and postural restructuring have also been suggested (18). The LPF® method also involves a sequence of postures aimed at enhancing the hypopressive effect (19), typically starting in standing and ending in supine positions, passing through kneeling, quadruped, and sitting positions (20).

LPF® has been widely used in treating Pelvic Floor Muscle Dysfunctions (PFMD), such as Urinary Incontinence (UI), and especially in postpartum women with benefits in the pelvic and abdominal regions (19). However, currently, there is still no consensus on the effects of HE on the abdominal wall (21), and there is no evidence that LPF® can effectively influence DRA reduction in postpartum women. This treatment has been widely used and promoted in some countries, although it is strongly recommended that patients be treated only based on theories supported by scientific evidence (22). Therefore, it is necessary for a high-quality randomized controlled trial to be conducted to evaluate the effects of this method before it becomes routine in clinical practice for DRA treatment in postpartum women.

Hence, the aim of this study will be to evaluate the effects of LPF® on diastasis recti abdominis and pelvic floor muscle function in women with postpartum diastasis recti abdominis. The hypothesis is that performing a Hypopressive Exercise program, based on the LPF® protocol, will have an effect on diastasis recti abdominis in postpartum women.

METHODS

Study design

This is a protocol for conducting a blinded randomized clinical trial. The study was registered on the Brazilian Clinical Trials Registry platform (ReBEC) (identifier: RBR-3xtxhtz), and approved by the Research Ethics Committee on Human Beings (CEP) of the Federal University of Rio Grande do Norte (opinion number: 6.192.526 – date of approval: July 20, 2023). The study follows the principles described in the Helsinki Declaration, and participant privacy is considered in accordance with Resolution 466/12 of the National Health Council. Research reporting will follow the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) (23) and will comply with the recommendations of the Checklist Template for Intervention Description and Replication (TIDieR) (24) and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (25). The flowchart is outlined in **figure 1**.

Participants

Eligibility criteria

Primiparous or multiparous women aged 18 or older will be included; who are between 12 weeks to 1 year postpartum; with a BMI of 29 kg/m² or less; who gave birth vaginally to a single fetus after a full-term pregnancy; parity < 4; who have separation of the rectus abdominis muscles > 2 cm and ≥ 2 fingers wide, above, below, or at the level of the umbilical scar; who do not present medical restrictions that prevent participation in the proposed assessments and interventions (cardiorespiratory alterations, such as Systemic Arterial Hypertension (SAH), respiratory (including excessive coughing or sneezing), neurological, and/or musculoskeletal); any form of vulvovaginal pain, pelvic pain, prolapse, or incontinence; lower limb pathology (*e.g.*, fracture, surgery, neoplasia); history of pelvic, abdominal surgery (except cesarean section), smoking, multiple pregnancy; and complications related to the last pregnancy, such as Polyhydramnios and fetal macrosomia.

Postpartum women who are unable to understand and/

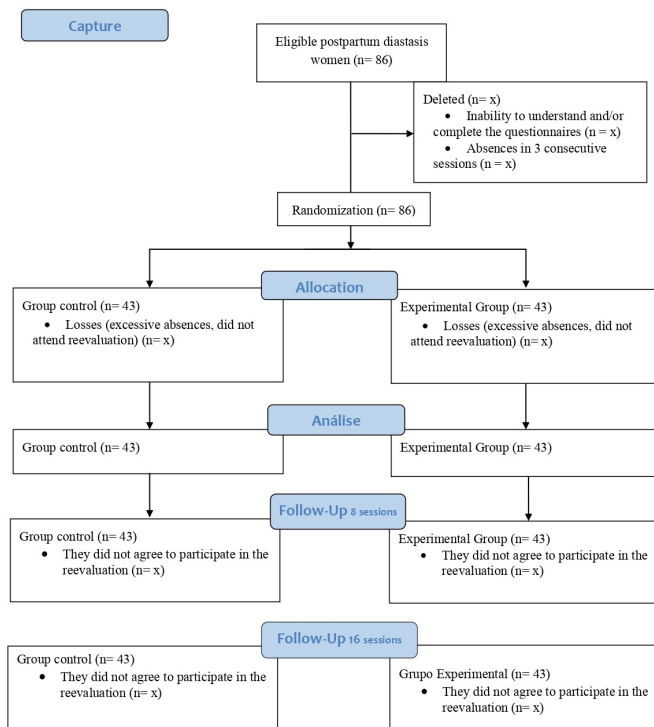


Figure 1. Flowchart of participant distribution, according to CONSORT (23).

or complete the study questionnaires; inability to correctly contract the Pelvic Floor Muscles; who fail to learn to perform the proposed technique; who have uncompensated reflux; and those who have three consecutive absences from the intervention protocol sessions will be excluded.

Randomization

To ensure randomization, participants will be randomly allocated into two groups. The randomization process will be conducted by an independent researcher (A), who will use the website www.randomization.com for randomization and will also be responsible for keeping the participants' codes confidential. To avoid selection bias, the concealed allocation method will use consecutively numbered opaque sealed envelopes, each containing the name of the group to which the participant will belong, which may be: Control Group (CG, kinesiotherapy), or Experimental Group (EG, LPF®).

Blinding

The random allocation of each participant will be revealed to them shortly before the intervention. All participants will be informed about the study's objective of testing two

different treatments for DRA: Kinesiotherapy *versus* Low Pressure Fitness (LPF®).

All assessments will be conducted by a single researcher (B) who will not be involved in the interventions and will remain blinded to the treatment groups. The results of the assessments will not be disclosed to the researcher (C) responsible for conducting health education and interventions. Both researchers will be trained beforehand to ensure the standardization of assessments and interventions. The researcher (D) responsible for statistical analysis will not participate in the assessments or interventions and, after the final post-intervention assessment, will receive the data without the subjects or groups being identified.

Procedures and interventions

All participants, after the initial assessment, will undergo an 8-week intervention (26) according to the group allocation. During the 8-week intervention period, both groups will undergo treatment programs twice a week, in-person, at the Physiotherapy Clinic of the Faculty of Health Sciences of Trairi (FACISA/UFRN). Each session will last 30 to 45 minutes (27). The first session in both groups will be dedicated to health education for the participants. Additionally, all women will be asked to perform the exercises daily at home, except on days when there is in-person intervention. Therefore, booklets containing the necessary instructions for performing the home exercises for the week will be provided, and a diary (in digital format) will be sent to track compliance with the protocol at home, with researchers monitoring exercise completion via a messaging app. Participants will be informed about the research procedures, instructed not to engage in any other exercise programs during the study period, and not to use abdominal binders. The initial assessment (baseline) will occur before the start of interventions. Subsequently, participants will be randomized, and treatments will commence. After completing 8 treatment sessions (4 weeks of intervention), all participants will be reassessed, and the protocols will continue. After 16 treatment sessions (8 weeks of intervention), they will undergo a final assessment, completing 2 months of intervention.

Assessments

After screening (-T1), all volunteers will undergo the initial assessment (T0), and will be reassessed after 4 weeks of intervention (T3) and post-intervention (T4) (**figure 2**).

All assessments: assessment form, abdominal diastasis assessment, pelvic floor muscle function, linea alba tone, pain assessment, questionnaires, static and dynamic trunk resistance tests, waist measurement, and posture assess-

| | STUDY PERIOD | | | | | |
|---|--------------|---------------------|------------|-----------------|--|-------------------------------|
| | Enrolment | Baseline assessment | Allocation | Post-allocation | Evaluation after 4 weeks of intervention | Assessment after intervention |
| TIMEPOINT | -T1 | T0 | T1 | T2 | T3 | T4 |
| ENROLLMENT | | | | | | |
| Eligibility Criteria | X | | | | | |
| Informed consent | X | | | | | |
| Allocation | | | X | | | |
| INTERVENTIONS | | | | | | |
| Kinesiotherapy | | | | ●————● | | |
| LPF® | | | | ●————● | | |
| ASSESSMENTS | | | | | | |
| Diastasis – palpation and caliper | | X | | | X | X |
| Pelvic Floor Function | | X | | | X | X |
| Pain | | X | | | X | X |
| Trunk resistance – static and dynamic | | X | | | X | X |
| Functionality – WHODAS 2.0 | | X | | | X | X |
| Quality of life - MAPP-QOL | | X | | | X | X |
| Posture | | X | | | X | X |
| Patient expectation | | X | | | | |
| Perception of the overall effect of treatment – GPE | | | | ●————● | | |

Figure 2. Study Timeline according to SPIRIT Checklist Recommendation.

LPF®: Low Pressure Fitness; WHODAS 2.0: World Health Organization Disability Assessment Schedule; MAPP-QOL: Maternal Postpartum Quality of Life Questionnaire.

ment, will be conducted again at the two reassessments, by the same initial assessors (A), following the same protocol. The Global Perceived Effect (GPE) scale will be applied at both reassessment time points.

Control Group Protocol (CG, Kinesiotherapy)

The control group will perform a set of kinesiotherapeutic exercises (28), including: abdominal crunches, posterior pelvic tilt, Pelvic Floor Muscle Training (PFMT, or Kegel exercises), and Russian twists. Progressions in the number of sets and repetitions of each exercise will be made every two weeks until reaching a total of three sets of 10 repetitions for abdominal and trunk strengthening exercises. The Borg scale will be used to classify perceived effort, with a maximum value of 15 not to be exceeded, and exercise intensity may be adjusted by the patient. For PFMT, the same progression scheme will be applied,

with additional progression of positioning during exercise execution. Initially, 8 maximum voluntary contractions will be performed, each held for 6 seconds, progressing to 3 sets of 8 to 12 contractions (or more) (29). Additionally, 3 rapid contractions will be performed following the sustained contractions.

Experimental Group (EG, Low Pressure Fitness (LPF®))

In the second session of the first week, participants will be trained according to the technical principles of LPF® as described by Rial and Pinsach, which include: maintaining correct posture with adequate muscle contraction; maintaining axial and cervical elongation; activation of the scapular waist, expiratory apnea, and self-massage for diaphragm release. The latter will be performed before all sessions (19). In the second week, women will be taught to perform Hypopressive Exercises (HEs) by performing a slow diaphragmatic inspiration followed by full expiration and, after glottic closure, a gradual contraction of the abdominal wall muscles with superior displacement of the diaphragm dome (diaphragmatic aspiration) according to Caufriez’s instructions (1997) (17). Then, the intervention protocol will be applied with the performance of hypopressive exercises in all postures, where a hypopressive maneuver (expiratory apnea) will be performed for each hypopressive posture after three respiratory cycles. Three repetitions will be performed for each posture. The respiratory rhythm and exercises will be guided by the instructor, who will supervise correct execution (30). As the weeks progress, there will be a gradual progression of postures.

Primary outcome

Diastasis measurement

Diastasis will be assessed in two ways: using the Boissonnault technique (31) and with a caliper (32), both with the patient in a supine position with flexed knees. For palpation, participants will be asked to flex the upper trunk until the scapulae are off the bed. Three locations along the linea alba will be evaluated: at the level of the umbilicus and 4.5 cm above and below it. The spacing between the rectus abdominis muscles will be measured by palpating the widths of the fingers. For evaluation with the caliper, the measurement locations will be the same as those evaluated previously. Therefore, the Inter-Recti Distance (IRD) will also be assessed with the abdominal muscles contracted, with the participant performing the same movement again and sustaining it while the examiner palpates the medial borders of the rectus abdominis muscle bellies and positions the internal measur-

ing tips of the caliper perpendicular to the direction of the muscles. Significant Diastasis Recti Abdominis (DRA) will be considered present when there is a separation exceeding 2 cm between the medial borders of these muscles (33), and if the palpated separation at any of the three mentioned locations along the linea alba is ≥ 2 finger-widths wide or if a protrusion along the linea alba is observed even if the palpated separation is < 2 finger-widths or cm wide (34).

Secondary outcomes

Evaluation of pelvic floor

The assessment of the Pelvic Floor Muscles (PFM) will be performed by observation and also through bidigital vaginal palpation. The index and middle fingers will be inserted 2-3cm into the vagina with the palmar side directed toward the caudal part of the vagina (35). During the observation of PFM contraction, the researcher will observe involuntary and voluntary movement of the perineum; involuntary movement will be observed upon request for a forced cough; voluntary movement will be observed after the verbal command “squeeze your vaginal muscles as if you were holding urine”; in both situations, the movement will be classified as: downward, perineal retraction, and no movement (35).

The assessment of PFM function will be done using the letters P, E, R, and F from the PERFECT scheme (36), where power (P) represents strength; endurance (E) refers to the time of contraction sustainability; repetitions (R) indicate how many repetitions the patient can perform with the same force and contraction time; fast (F) indicates how many fast contractions the patient can perform with the same force. The Modified Oxford Scale, which considers variations from 0 to 5, where 0 represents the absence of contraction and 5 a strong compression associated with elevation of the examiner’s fingers, will be used to grade Power/force of contraction. Participants will rest for 1 minute between requested contractions during the evaluation.

Pain intensity

Presence of pain in the abdomino-lumbo-pelvic complex associated with DRA of the participants will be investigated. Firstly, abdominal pain during the upper trunk flexion movement in supine position will be evaluated (as described previously). Subsequently, examination of the lumbar spine will be performed (flexion/extension movements, lateral rotations, lateral flexions, and the Lasegue test). Then, tests dedicated to the pelvic girdle will be conducted: Posterior Pelvic Pain Provocation Test (P4) and active straight

leg raise test (ASLR). Pain will be quantified separately using the Numerical Rating Scale (NRS), which contains an 11-point numerical assessment (0-10), with “no pain” and “worst imaginable pain” as anchors (37).

Trunk Static and Dynamic Endurance Test

Three core endurance tests will be conducted: the trunk flexor endurance test and bilateral side plank tests. In the first static test, participants will sit with their knees bent at 90° on the bench for the trunk flexor endurance test, with their feet fixed. They will then cross their hands in front of their chest and initially lean on the 60-degree trunk support until the evaluator pulls the trunk support 3 cm backward. Participants must then maintain the posture for as long as possible, and the time will be recorded in seconds. The test will be stopped when the subject’s inclined posture is lost or when their back touches the support. In the static bilateral side plank tests, participants will lie on their side on the same surface as the previous test, raising their trunk with their knees extended. They will place one foot in front of the other, with hips raised, and support the body weight only with the elbow. The test will be stopped when the side lying posture is lost or when the buttocks touch the bench (or platform) (38). For the dynamic endurance test, the participant will be instructed to perform the same movement as the static trunk flexor endurance test, except that the movement will be repeated as many times as possible at a rate of approximately once every 3 seconds. The test will be stopped if the lower angles of the scapula cannot be lifted from the bench. Five-minute rests will be taken between tests for recovery and to avoid fatigue.

Postural evaluation

Posture will be assessed in orthostatism by capturing photographic images of the participants, totaling 4 photos in the following views: anterior, left lateral, posterior, and right lateral views. For photographic recording of the anterior and posterior views, they will be instructed to keep the upper limbs relaxed, positioned laterally to the trunk, with elbows extended and palms facing forward, and looking at the horizon; for the right and left lateral views, they should keep the elbow flexed at 90°. Participants will be instructed to wear only underwear for adequate visualization of body segments. Anatomical landmarks will be marked as the anterior superior iliac spine and posterior superior iliac spine, with 15 mm diameter Styrofoam balls affixed with double-sided tape to the participants’ bodies. Photographic records will be taken in the same room, with a white background, adequate lighting, and using the same cell phone.

Postural Assessment Software (PAS/SAPO) will be used to analyze the images (39).

Questionnaires

Functionality will be assessed using the World Health Organization Disability Assessment Schedule (WHODAS) 2.0, designed to measure activity functioning and participation in daily life activities over the past 30 days. The results provide a functioning profile within domains, and the overall score will be used for the study. WHODAS 2.0 total scores can range from 0 to 100, with higher numbers indicating greater impairment in daily functionality. The 36-item version validated for the Portuguese language by Silveira *et al.* (2017) (40) will be used.

Quality of life will be assessed using the Maternal Postpartum Quality of Life Questionnaire (MAPP-QOL), which has good reliability (total Cronbach's alpha was 0.89 in the Portuguese version). The MAPP-QOL consists of 40 items and two parts (satisfaction and importance), and scores are calculated by weighting each satisfaction response with its paired importance response. QOL scores range from 0 to 30, with higher scores indicating higher QOL. The version validated for the Portuguese language by Oliveira MF (2014) (41) will be used.

Patient expectation

A Likert scale will be used to assess patient expectations regarding the treatments to be performed, with the following question: "With the treatment you will receive, do you think you will:" and possible responses: 1) worsen significantly, 2) worsen slightly, 3) neither improve nor worsen, 4) improve slightly, and 5) improve significantly.

Perception of global treatment effect

The patient's perception of the global treatment effect will be assessed only for the diastasis outcome using the Global Perceived Effect Scale (GPE) at the end of treatments. The GPE is a direct scale of patient self-perception when the intervention is performed. It is a 9-point Likert scale ranging from 1 ("extremely better") to 9 ("extremely worse"), where lower scores represent patients who are better and higher scores represent those who worsened after the start of treatment compared to the onset of their symptoms. The version validated for the Portuguese language by Oliveira *et al.* (2014) (42) will be used.

Participant and public involvement

The volunteers will not be involved in the design of this study but will collaborate in the development of the

research stages. However, after the completion of the study, the results may be reported to women through conversations and lectures to present the effects found in the studied variables.

Study viability

The study's feasibility will be measured based on the following aspects: technique safety and adverse effects; patient comfort; retention rate, and protocol adherence. Technique safety will be evaluated by monitoring the emergence of any complaints (such as pain or discomfort) during the technique. Patient comfort will be assessed qualitatively by the researcher and patients, and a question will be asked to investigate the presence or absence of discomfort. Retention strategies will include encouraging patients to attend in-person sessions and weekly encouragement to complete home exercises via a messaging app. The retention rate will be the ratio of total participants who completed the 16 sessions to the total participants who started the interventions. Adherence strategies for participants will be the same as those used for retention, and the adherence rate to in-person sessions will be the ratio of the number of fully completed sessions to the number of sessions attended by the participant. Reasons for participants not completing the sessions will be recorded. Adherence to home exercises will be monitored with weekly records filled out by the patient and reviewed by the therapist responsible for treatment to ensure protocol completion accuracy.

Sample size calculation

The sample size was calculated based on a previous study (43), where the sample consisted of 60 postpartum women, 2 months after delivery. The following parameters were inputted into the G*Power software to calculate the final sample size for this study: alpha error = 0.05, power = 80%, number of groups = 2, and number of measurements = 8. Thus, the sample size per group will be 39 participants. However, a possible sample loss of 10% per group (approximately 4 individuals) will be considered. Therefore, we will consider 43 participants per group, reaching a final sample of 86 postpartum women.

Statistical analysis

The Statistical Package for the Social Sciences (SPSS®) version 21.0 will be used for data analysis. Bootstrapping technique (44) will be employed to adjust quantitative variables to the assumption of parametric distribution. Thus, all data will be presented as mean and standard deviation to facilitate result interpretation.

Descriptive statistics using mean and standard deviation (for quantitative variables) and absolute and relative frequencies (for categorical variables) will be used to characterize the sample regarding sociodemographic and clinical aspects.

To assess the effects of the proposed interventions and compare outcome variables between groups and over time, Analysis of Variance (ANOVA - 2 groups \times 2 measurement moments) will be used. If the assumption of variance equality is not met, Welch correction will be applied. An intention-to-treat analysis will be conducted to ensure the effects of randomization, so that prognostic factors are evenly distributed in both groups.

Measures with 95% confidence intervals (CI), F statistics, and effect size, η^2 (eta squared), will be presented. Effect sizes will be defined as small ($\eta^2 = 0.01$), medium ($\eta^2 = 0.06$), and large ($\eta^2 = 0.14$) based on benchmarks suggested by Cohen (45). A test will be considered significant if $\eta^2 > 0.01$ and P-values < 0.05 .

DISCUSSION

The objective of this study was to describe the protocol of a clinical trial on the effects of the LPF[®] method on diastasis recti abdominis (DRA). The modifications in the inter-recti distance during the performance of different abdominal exercises are partially known, especially in primiparous and multiparous women (46, 47). However, it is still necessary to understand the effects of LPF on abdominal diastasis, pelvic floor, and trunk when compared to the execution of kinesiotherapeutic exercises. EH were originally described by Caufriez for the preventive treatment of pelvic floor dysfunctions after pregnancy. Recently, studies have reported new evidence on the effects of these exercises on postpartum women, such as abdominal diastasis, trunk circumference, mechanical properties of abdominopelvic tissues (48), and morphology of the linea alba (49). However, to date, no randomized controlled clinical trials or well-defined protocols have been reported on the use of the LPF[®] method itself for outcomes such as abdominal diastasis, pelvic floor muscle function, pain, functionality, trunk endurance, quality of life, posture, global effect perception, and expectation of postpartum women undergoing treatment.

Given the use of LPF[®] in clinical practice for the treatment of various conditions, it is necessary to investigate the real effect of the method on abdominal diastasis, as well as defined parameters of use. Therefore, this study will serve as a method to guide the first randomized clinical trial with blinded assessors and concealed allocation to evaluate the impact of an EH program based on the LPF[®] method on the

condition in postpartum women. In addition, limitations of the study include the impossibility of blinding participants and the physiotherapist responsible for the application of treatment protocols.

Ethics

The volunteers will be recruited through the dissemination of the research project on local radio, visits to Basic Health Units (UBS), social media, and the waiting list of the Physiotherapy Clinic of FACISA/UFRN. They will be contacted initially by phone to clarify doubts and undergo the first screening for inclusion. If eligible, volunteers will be informed about the objectives and procedures of the study and must indicate in writing, by signing the Informed Consent Form (ICF), their agreement to participate in the research. The anonymity of the volunteers will be respected and guaranteed, ensuring their privacy regarding the data collected during the research as regulated by Resolution 466/12 of the National Health Council.

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DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

CAAL, VPSS: conceptualization, writing – review & editing. EBC, MGS, MENM, ENER, CCOC: formal analysis. TLM, ABFN: methodology. ABFN: data curation, writing – original draft. ABFN, CAAL, VPSS: supervision.

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CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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