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Mat Pilates and aquatic aerobic exercises for women with fibromyalgia. A protocol for a randomized controlled blind study

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Abstract

Introduction: Physical exercises have been recommended to improve overall well-being in patients with fibromyalgia, with the main objective to repair the effects of lack of physical conditioning and to improve symptoms, especially pain and fatigue. Although widely recommended and widely known, few studies support the use of the Pilates method as effective for improving the symptoms of the disease, comparing it with other well-founded exercise modalities. This protocol was developed to describe the design of a randomized controlled study with a blind evaluator that evaluates the effectiveness of the mat Pilates method in comparing it with aquatic aerobic exercises for improving pain in women with fibromyalgia.

Methods: Sixty (60) women aged 18 to 60 years with fibromyalgia diagnosis, a score of between 3 and 8 points on the visual analog scale for pain, and who sign the clear and informed consent form will be recruited according to the inclusion criteria. They will be randomized into one of the two intervention groups: (i) Pilates, to perform an exercise program based on the Mat Pilates method; and (ii) aquatic exercise, to participate in a program of aerobic exercises in the swimming pool. The protocol will correspond to 12 weeks of treatment, with both groups performing the exercises with supervision twice a week. The primary outcome will be pain (Visual Analogue Scale for pain). Secondary outcomes are to include impacts related to the disease, functional capacity, sleep quality and overall quality of life. The evaluations will be performed at three moments: baseline, after 6 weeks and 12 weeks of treatment.

Discussion: This is a pioneering study for evaluating the effectiveness of the Mat Pilates method in comparing it with aquatic aerobic exercises with a follow-up of 12 weeks, thus becoming a new contribution to fibromyalgia treatment. In addition, the implementation of the protocol in question may contribute to elucidate the effects of the Mat Pilates method in patients with fibromyalgia, as well as the frequency and adequate duration of exercise to improve symptoms.

Trial registrations: ClinicalTrials.gov Identifier (NCT03149198), May 11, 2017.

Approved by the Ethics Committee of FACISA/UFRN (Number: 2.116.314).

Keywords: Pain, therapeutic exercise, aerobic exercise, Pilates, fibromyalgia.

Strengths and limitations of this study

- Few studies support the use of the pilates method as effective for improving the symptoms of the fibromyalgia.
- This protocol was developed to describe the design of a randomized controlled study with a blind evaluator that evaluates the effectiveness of the mat Pilates method in comparing it with aquatic aerobic exercises for improving pain in women with fibromyalgia.
- We hope that the conclusion of this study contributes to scientific knowledge, providing subsidies for the use of mat pilates as a safe and effective tool in treating FM patients, as well as to help elucidate the best frequency and the adequate duration of exercise for improving the symptoms.

Background

Fibromyalgia (FM) is a syndrome characterized by chronic generalized pain and sleep disorder, fatigue, reduced muscle strength, depression, anxiety, irritable bowel, and other symptoms that cause impairment to quality of life[1-3]. The prevalence of FM in the general population ranges from 0.66 to 4.4%, varying according to the profile of patients evaluated and the study methodology. Most studies indicate that FM is more prevalent in women than in men, at a ratio of 8 to 1, especially in the age group between 35 and 60 years. Studies with adolescent children and special groups are scarce and few are conclusive. A study carried out in Brazil

confirms that fibromyalgia was the second most frequent rheumatic disease in outpatient clinics, only after osteoarthritis[4].

The causes for the onset of this syndrome have not yet been fully elucidated. However, recent scientific research suggests that changes in the metabolism and regulation of certain substances of the central nervous system such as serotonin and noradrenaline can trigger the disease[5].

With a controversial etiopathogenesis, the cause of FM is associated with genetic, environmental and neuromodulatory factors[6]. Many patients with fibromyalgia have high levels of stress and feelings of depression, anxiety and frustration[7]. Patients feel fatigue and physical tiredness with a loss of energy, and decreased strength when performing physical exercises. This fatigue causes a great decrease in quality of life and often prevents performing activities of daily living, thereby reducing productivity in the work environment.

Therefore, physical exercises have been recommended to improve the overall well-being in patients with fibromyalgia, with the main purpose of repairing the effects of a lack of physical conditioning and improving the symptoms, especially pain and fatigue. Valim et al. (2013) report that physical exercises in fibromyalgia are beneficial, low-cost and promote improvement in pain and other symptoms of the disease[8].

The importance of physical exercise for patients with FM is already well described in the literature, in addition to it being a low-cost, safe and efficient intervention as a form of treatment. Exercises have also been shown to be effective in reducing pain and the number of painful points, improving quality of life, mood and other psychological aspects. Although studies show benefits in almost all exercise modalities, further evidence supports the practice of aerobic training[9,10] . Within this perspective, a Cochrane review on aquatic exercises for fibromyalgia showed that aquatic exercises are effective in improving physical well-being, functional capacity, pain, a 37% improvement in muscular strength and improvement in cardiovascular capacity[11].

For some while the Pilates method of exercising has been gaining popularity, being considered one more exercise modality that can be used. This method consists of a system of stretching and strengthening exercises developed by Joseph H. Pilates almost 90 years ago, which employs controlled and precise sets of movements and the use of special equipment. Exercises can also be performed in different positions on the ground on a mat, avoiding excessive impact or pressure on muscles, joints and tissues. The purpose of physical training using the Pilates method is to achieve better functioning of the body based on strengthening the core, a term that refers to the center of the trunk that supports the body. The second major feature of the method are the six basic principles: centralization, concentration, control, precision, breathing, and flow[12].

Although highly recommended and widely known, few studies support the use of Pilates in fibromyalgia. Few studies have evaluated the effects of the method for the treatment of FM patients. In addition, these studies present several methodological flaws that compromise their results and suggest that studies with better methodological design should be conducted with the objective of observing the effectiveness of the Pilates method in treating these patients[13,14]. Therefore, the main objective of this study is to evaluate the effectiveness of the Mat Pilates method in improving pain in women with fibromyalgia, and comparing it with aquatic aerobic exercises. Our hypothesis is that the Mat Pilates method can also bring benefits for improving pain in FM patients, similar to aquatic aerobic exercises.

Methods

Design

Study protocol for a randomized controlled parallel group single-blind trial. This study has been registered (ClinicalTrials.gov Identifier: NCT03149198). Participants will be randomized to perform mat Pilates or aerobic exercises. Allocation to either group (Pilates or aerobic exercises) will be achieved through a computer-generated sequence of random numbers.

The allocation sequence will be created and carried out by a non-interventionist researcher in charge of telephone screening and handling the data obtained in the various assessment sessions.

Figure 1 shows a flowchart of the progress of the various stages of this test. This study was approved by the Ethics Committee of Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi – (FACISA/UFRN) (Number: 2.116.314).

Figure 1.

Participants

Sixty (60) women aged 18 to 60 years, with a clinical diagnosis of fibromyalgia according to the criteria of the American College of Rheumatology[15] and scoring between 3 and 8 points on the visual analogue pain scale (VAS) will be recruited, provided they give their consent after being informed of the study's objectives and procedures. The volunteers will be recruited from the waiting list of patients of the Physiotherapy School Clinic of FACISA/UFRN; in addition, the project will also be announced by radio and local media. After this, a telephone contact will first be made to clarify any questions from the participants, and the first screening for inclusion will be carried out.

Personal data of the participants will be numerically coded and stored in a database, which can only be accessed by the researcher responsible for the randomization and blinding process. Informed consent as well as all study information will be passed on to all participants. Prior to any data collection, participants must sign the clear and informed consent form.

Inclusion criteria:

- Women diagnosed with fibromyalgia according to the American College of Rheumatology classification criteria.
- Aged between 18 and 60 years.
- Reporting pain between 3 and 8 on the VAS.

Exclusion Criteria:

- uncontrolled hypertension
- decompensated cardiorespiratory disease
- history of syncopes or arrhythmias induced by physical exercise
- decompensated diabetes
- serious psychiatric illness

- history of regular exercise (at least 2 times a week) in the last 6 months

- any other condition that makes it impossible for the patient to perform physical exercises.

Research team

This study will involve 5 researchers; 1 researcher responsible for the evaluations; 2 researchers responsible for the interventions (1 for each group); 1 researcher responsible for the interview, initial screening and randomization of participants, and 1 researcher who will perform the statistical analysis.

Randomization and blinding

Participants who are successfully approved for screening and who agree to sign the free and informed consent form will receive a number in a randomization table according to the inclusion order in the study. These numbers will correspond to the Pilates group or aquatic exercise group in which volunteers will be included. This distribution will be performed randomly through the website *randomization.com*. The allocation will be concealed using sealed and opaque envelopes, numbered consecutively. An independent researcher who will not participate in the other study procedures will perform the randomization process. The flow diagram of the study is summarised in Fig. 1.

The researchers responsible for interventions will be blinded to the participants' initial assessments, and the researcher responsible for evaluations will not know the group of each participant.

In addition, data collected during participant evaluations will not be revealed to the researchers responsible for interventions, and participants will be instructed not to disclose their experience and information related to the intervention.

Finally, the researcher responsible for statistical analysis will be blinded. Once the intervention is completed, he/she will receive an Excel data table with all necessary data without identification of the subjects or the groups.

Interventions

Participants in this study will receive 24 treatment sessions (two per week) for 12 weeks. Evaluations will be performed prior to the start of treatment, after 12 sessions and after 24 treatment sessions.

Mat Pilates Exercise Program

The exercise program based on the Pilates method will be carried out on a mat, in the Group Room of the Clinic School of Physiotherapy of the *FACISA/UFRN* in Santa Cruz, RN, Brazil. The room has ample space and air conditioning for better patient accommodation. The exercises will be performed twice a week for 12 weeks. Each session will last about 50 minutes and will be supervised by an experienced Mat Pilates researcher who will be responsible for the intervention in this group. A total of 10 exercises will be performed, which are presented in Table 1. Chart 1 shows the progression of the exercises according to the time.

Chart 1: Exercise progression according to the intervention time

Period	Dose
First month (1st to 8th session)	1 set of 8 repetitions
Second month (8th to 16th session)	2 sets of 10 repetitions
Third month (16th to 24th session)	3 sets of 8 repetitions

Intervention group exercise program

Table 1: Mat Pilates Group Exercise Program

NAME OF THE EXERCISE	DESCRIPTION
1 - SWAN Stretches the anterior trunk chain. Strengthens pectoral, triceps and anterior deltoid muscles.	1 – Lying in the prone position, hands resting in the direction of the shoulders. 2 – Extend the elbows, keeping head aligned with spine, extending/stretching the trunk. 3 – Return to the initial position.
2 – ONE LEG UP-DOWN Strengthens the rectus femoris, iliopsoas and sartorius muscles.	1 – Lying in the supine position, arms outstretched alongside the body. 2 – Raise leg in extension with feet in plantar flexion. 3 – Return to the initial position.
3 – LEG CIRCLES Strengthens the rectus femoris, sartorius, adductor, gluteus medius muscles.	1 – Lying in the supine position, arms outstretched alongside the body and supported on the ground. 2 – Raise leg in extension, with feet in plantar flexion. 3 – Make circles with the leg.
4 – SINGLE LEG STRETCH Strengthens the abdomen, stretches the glutes and the lumbar spine.	1 – Lying in the supine position, flex the right leg by placing the left hand on the right knee and the right hand on the right ankle, flexing as much as possible toward the chest. The left leg will be extended at an angle of 30º. 2 – Slowly switch the leg.
5 – SAW Stretches trunk rotators, the hamstrings and the quadratus lumborum muscle. Strengthens the rectus abdominis, external and internal oblique muscles.	1 – Sitting with the back straight and legs apart at hip width, arms extended and apart at shoulder height. 2 – Slowly from the waist, twist the spine to the left. 3 – Move the right arm toward the left foot and the left arm back at shoulder height. 4 – Return to the initial position and switch sides.
6 – SIDE KICKS: FRONT AND BACK Strengthens the rectus femoris, iliopsoas, sartorius, gluteus medius, gluteus maximus and abdominal muscles in isometry.	1 – Lying straight in lateral decubitus, arm flexed and hand resting under the head. 2 – Keep your upper leg aligned with your hips and slowly bring the extended leg forward. 3 – Return to the initial position.

7 – THE HUNDRED Strengthens the abdominal, oblique, transverse and rectus femoris muscles.	1 – Lying in the supine position, elbow extended with the shoulder, hips and knees at 90°. 2 – Knee extension at approximately 45°. Slight bending of the trunk (removing the shoulder blades from the mat) and chin toward chest. 3 – Return to the initial position.
8 – PELVIC LIFT ON THE BALL Strengthens the gluteus maximus, biceps femoris, semitendinosus, semimembranosus, gastrocnemius, and quadriceps femoris muscles. Mobilizes the spine.	1 – Lying in the supine position, legs flexed at 90°, with heels on the ball. 2 - Raise the hips from the mat, extending the legs. 3 – Return to the initial position.
9 – SIT-UPS ON THE BALL Strengthens rectus abdominis and external oblique muscles.	1 – Lying in the supine position holding the ball over the head and legs at a 45°. 2 – Bring the ball toward the legs and hold it. 3 – Return to the initial position.
10 – STRETCHING ON THE BALL Stretching and muscle relaxation.	1 – Lying in lateral, ventral and dorsal decubitus on the ball.

Aquatic Aerobic Exercise Program

The aerobic exercise program will be carried out at the therapeutic swimming pool of the Physiotherapy School Clinic at the *FACISA/UFRN* in Santa Cruz, RN. The pool is heated (30^{o}C), which provides better effects to the proposed treatment.

The exercises will be performed twice a week for 12 weeks. Each session will last about 50 minutes and will be supervised by an experienced researcher responsible for the intervention in this group.

Patients will always be instructed to perform the exercise according to their current conditioning and increase the intensity according to their perception of exertion (Borg scale). The program is best described in Table 2.

Table 2: Aquatic aerobic exercises group exercise program.

TIME	EXERCISE
5 min – Warm-up.	1 - Walking in a clockwise circle at a slow pace. 2 - Walking in a counterclockwise circle at a slow pace. 3 - Walking with abduction/adduction in the horizontal plane of the upper limbs at a fast pace. 4 - Walking with knee flexion and alternating hip flexion and hand on opposite knee at a fast pace.
30 min – Aquatic aerobic exercises.	1 - Rapid tiptoe walking (2 laps in the pool) 2 - Fast walking on the heels (2 laps in the pool). 3 - Quick lateral marching (2 laps in the pool). 4 - Circles against the turbulent water flow. 5 - Rhythmic waist circles using pool noodles and floaters. 6 - Rhythmic movement of upper and lower limbs.
5 min – Cool-down.	1 - Walking in a clockwise circle at a slow pace. 2 - Walking in a counterclockwise circle at a slow pace. 3 - Walking with abduction/adduction in the horizontal plane of the upper limbs at a slow pace. 4 - Walking with knee flexion and alternating hip flexion and hand on the opposite knee at a slow pace. 5 - Respiratory exercises of diaphragmatic pattern.

Evaluations

During the baseline measurement, the following descriptive characteristics will be collected: gender, age, weight, height, current occupation. The chronology of the evaluation of the primary and secondary outcome measures is shown in Table 3.

Primary outcome measures

The Visual Analogue Scale for pain is the main result of this study and will be used for the intensity of pain. Participants will mark the intensity of their pain on the VAS consisting of a 100-mm long horizontal line, which is anchored by the classifications of "no pain" at the left end (score 0) and "worst pain imaginable" rightmost (score 10), asking the participant for the most intense pain episode perceived while doing daily activities. The VAS has demonstrated the ability to detect changes in pain, establishing a minimal clinically significant difference at 2.5 cm[16].

Secondary outcome measures

1. Impact related to the disease: the evaluation will be performed using the FIQ (*Fibromyalgia Impact Questionnaire*), a questionnaire that assesses anxiety, depression and physical performance in fibromyalgia. The translated version adapted for the Brazilian population will be used[17].
2. Functional capacity:
   - *"Timed Up and Go test"* (TUG), a functional test consisting of getting up from a chair without the aid of the arms, walking a distance of three meters, turning around and walking back. At the start of the test, the patient should have his or her back resting on the back of the chair. The patient then receives the "go" command to perform the test and they are timed from the command voice until the moment they rest their back on the chair again[18,19] .
   - *Six-minute Walk Test* (6MWT), although this test was developed to evaluate the physical capacity of patients with cardiopulmonary diseases, it has also been used (with some adaptations) to measure the walking performance of patients with motor difficulties. The test will be performed on a 20-meter marked gymnasium track away from other people. The patients will be instructed to walk the entire distance, being

able to interrupt the test if they do not feel able to continue[19].

3. Assessment of sleep quality:

   - *Pittsburgh Sleep Quality Index* – the Brazilian Portuguese version (PSQI-BR) will be used to evaluate the subjective quality of sleep. This questionnaire consists of nineteen items grouped into seven components, which are scored on a scale from 0 to 3. The components are: (1) subjective quality of sleep; (2) sleep latency; (3) duration of sleep; (4) habitual sleep efficiency; (5) sleep disorders; (6) use of medication for sleep; and (7) daytime dysfunction. The values corresponding to respondents' responses for each component are summed up to give an overall PSQI score, which ranges from 0 to 21. Scores between 0-4 indicate good sleep quality, while 5-10 scores indicate poor quality, and above 10 indicate sleep disturbance[20].
   - *Epworth Sleepiness Scale* version in Brazilian Portuguese (ESS-BR) will be used to measure the possibility of dozing off. The questionnaire consists of eight daily situations where the probability of dozing off is graded on a scale from zero (no probability of dozing off) to three (very likely to doze off). At the end, the scores are summed up to generate a total score ranging from 0-24, where an individual above 10 points is characterized with excessive drowsiness[21].

4. Overall quality of life: will be assessed by the *Short Form-36 Health Survey*, a quality of life questionnaire, translated into Portuguese, containing 36 questions. The result is given in 8 domains: functional capacity, limitation by physical aspects, pain, general health status, vitality, social aspects, mental health and emotional aspects, with scores ranging from 0-100 in each domain, in which 100 is the best health state and 0 the worst health state[22].

Table 3 Chronology of primary and secondary outcome measures

Results	Baseline	6 week	12 week
Primary			
VAS	✓	✓	✓
Secondary			
FIQ	✓	✓	✓
TUG	✓	✓	✓
6MWT	✓	✓	✓
PSQI-BR	✓	✓	✓
ESS-BR	✓	✓	✓
SF-36	✓	✓	✓

VAS= *Visual Analogue Scale* for pain, FIQ= *Fibromyalgia Impact Questionnaire*, TUG= *Timed Up and Go test*, 6MWT= *Six-minute Walk Test*, PSQI-BR= *Pittsburgh Sleep Quality Index* – the Brazilian Portuguese version, ESS-BR= *Epworth Sleepiness Scale* version in Brazilian Portuguese, SF-36= *Short Form-36 Health Survey*.

Training of researchers

A series of training stages prior to starting the study will be implemented for the assessment and treatment intending to protocolize the actions carried out in the study. In these training stages, treatment techniques and measuring will be practiced in order to reach a consensus among the involved researchers.

Statistical issues

Sample size calculation

The sample size was calculated based on the pain variable in order to find a difference of ± 2.5 points between the intervention groups on the visual analog pain scale - VAS [16], with a standard deviation of 2.5 points[23]. A sample of 60 participants is required (30 in each group) in order to achieve a statistical power of 90% with a 5% alpha, and considering a loss rate of 20%.

The sample calculation was performed for the ANOVA repeated measures statistical test with interaction between groups. Gpower3.1 software was used for the calculation.

Statistical analysis

The analysis will be descriptive for all outcomes included in the study, expressing quantitative outcomes with their mean ± standard deviation and qualitative outcomes with their absolute value, percentage and 95% confidence intervals.

Data will be analyzed by SPSS software. The chi-square test will be used to observe associations between the qualitative variables. After observing the normal distribution and homogeneity of the variances of the quantitative variables by means of the kolmogorov-Smirnov test and the Levene test, respectively, the Student's t-test (for variables with normal distribution) or the Mann-Whitney test (for variables with a non-normal distribution) will be used to perform a comparison of the means. Estimates of average effect (differences between groups) for all variables will be calculated using the ANOVA mixed model. This analysis model incorporated the intervention groups (Pilates and aquatic exercise), time (baseline, 6 weeks and 12 weeks) and the group × time interaction. When a significant F value is found, the Bonferroni post-hoc test will be applied in order to identify the differences. An intention-to-treat analysis will be used to assess the response to intervention, with the last evaluation carried forward when necessary. The size of the effect between the groups for the variables that present intergroup differences can be calculated at some point, with a respective 95% confidence interval. The level of statistical significance adopted will be 5%. The analysis will be performed by an independent researcher.

Discussion

This protocol will be carried out for a randomized single-blind clinical trial, in order to investigate whether mat Pilates produces similar beneficial effects to aquatic aerobic exercises in reducing pain and disability in woman with fibromyalgia. With the conclusion of the study, we

hope to test the following null hypothesis: "There is no difference in pain and disability for participants undergoing treatment with Pilates or with aquatic aerobic exercises".

Patients with FM experience fatigue[24] and physical tiredness, with loss of energy, and decreased power/strength when performing physical exercises. Fatigue leads to a great decrease in quality of life and often prevents performance of activities of daily living, thereby reducing productivity in the workplace. Thus, physical exercises, and especially aerobic ones[25], have been recommended to improve overall well-being in patients with fibromyalgia, with the main purpose of repairing the effects of a lack of physical conditioning, and especially improving symptoms regarding pain and fatigue.

A recent Cochrane review on aerobic exercise in fibromyalgia concluded that, when compared to control, moderate quality evidence indicates that aerobic exercise is likely to improve quality of life, and poor quality evidence suggests that aerobic exercise may slightly decrease pain intensity, slightly improve physical function, and lead to a slight difference in fatigue and stiffness[26].

Regarding aquatic aerobic exercises, a meta-analysis[27] found good results for aquatic therapy (hydrotherapy) with a duration of over 20 weeks; however, in our study we will use aquatic exercises with an aerobic purpose, rather than just aquatic physiotherapy. *Deep water running* is an aquatic aerobic conditioning technique that has shown to be as beneficial as aerobic exercise on land, however with advantages related to emotional aspects in patients with fibromyalgia[28]. A systematic review carried out by Bidonde et al. (2014) concluded that the evidence of low to moderate quality in relation to the control suggests that aquatic training is beneficial for improving well-being, symptoms and fitness in adults with fibromyalgia. Low quality evidence suggests that there are benefits of aquatic and land exercise, except for muscle strength (low quality evidence favoring land exercises) and also that no serious adverse effects were found[11].

A recent protocol on aquatic exercise *versus* land exercises to treat balance and pain in women with fibromyalgia was published, showing the interest of the researchers in deepening knowledge on the subject, since more well-designed studies are still necessary. However, our aquatic aerobic exercise program differs from the one used in this study due to the fact that it has the objective of working on more aspects related to balance and proprioception in water[29]. The Pilates method is currently well known and highly recommended by doctors and health professionals with the aim of improving pain, posture, stretching and strengthening of the body as a whole. Patients with fibromyalgia are frequently recommended to perform physical exercises to improve the fibromyalgia symptoms, in which Pilates represents an important option to be considered. However, few studies have evaluated the effects of the method for the treatment of FM patients. In addition, these studies present several methodological flaws that compromise their results, suggesting that studies with better methodological design should be conducted with the objective of observing the effectiveness of the Pilates method in treating these patients[13,14].

Adherence to treatment is something very important to be reported, mainly in interventions for chronic musculoskeletal disorders[30]. We hope that the volunteers in our study will have good adherence to treatment, considering that the heated pool is a stimulating invitation for relaxation and that Pilates is a popular, famous and still relatively high-cost technique in our reality, thus we believe that our intervention will be well accepted.

In view of the above, we hope that the conclusion of this study contributes to scientific knowledge, providing subsidies for the use of mat pilates as a safe and effective tool in treating FM patients, as well as to help elucidate the best frequency and the adequate duration of exercise for improving the symptoms.

Abbreviations

FM: fibromyalgia; FACISA/UFRN: Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi; VAS: Visual Analogue Scale; FIQ: Fibromyalgia Impact Questionnaire; TUG: Timed Up and Go test; 6MWT: Six-minute Walk Test: PSQI-BR: Pittsburgh Sleep Quality Index – the Brazilian Portuguese version; ESS-BR: Epworth Sleepiness Scale version in Brazilian Portuguese; SF-36: Short Form-36 Health Survey.

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Availability of data and material

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Authors' contributions

CAAL and MCS lead the study design and design and planned the statistical analysis. TTXN, VPSS and RTJC have made substantial contributions to the design and design of the study. CAAL, MCS, TTXN, VPSS and RTJC reviewed the manuscript critically and gave final approval for publication.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi – (FACISA/UFRN) with registration code 2.116.314. The ethical principles agreed in the Declaration of Helsinki will be respected for all study procedures. Respect for individuals will be insured and their autonomy will be maintained. Participants will be informed of the study objectives, its risks and benefits. Participants will be free to abandon the study at any time without the obligation of giving any explanation. Participants must sign the informed consent before the study begins. This study protocol is registered in ClinicalTrials.gov (a U.S. National Institutes of Health service) with the identifier NCT03149198, published on 11th May, 2017.

Figure Legend: Fig. 1 Flow diagram of the study

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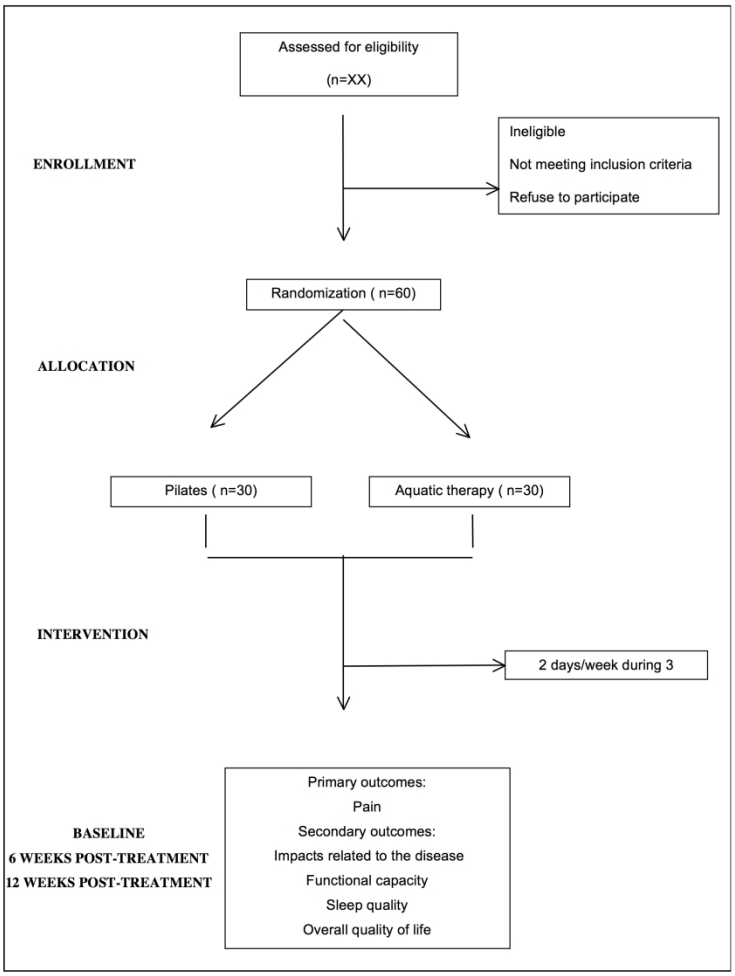

Fig. 1 Flow diagram of the study

Fig. 1 Flow diagram of the study

UFRN - FACULDADE DE CIÊNCIAS DA SAÚDE - FACISA

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação da efetividade do método pilates em solo no tratamento de mulheres com fibromialgia da cidade de Santa Cruz, RN. Um estudo controlado, randomizado e cego.

Pesquisador: Marcelo Cardoso de Souza
Área Temática:
Versão: 2
CAAE: 67834617.1.0000.5568
Instituição Proponente: Faculdade de Ciências da Saúde do Trairí
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.116.314

Apresentação do Projeto:

Exercícios físicos têm sido recomendados para melhorar o bem-estar global em pacientes com fibromialgia, com objetivo principal de reparar os efeitos da falta de condicionamento físico, e melhorar os sintomas especialmente a dor e a fadiga. Embora muito recomendado e amplamente conhecido, poucos são os estudos que suportam o uso do método pilates como efetivo na melhora dos sintomas da doença. Objetivo: Avaliar a efetividade do método pilates em solo na melhora da dor em mulheres com fibromialgia da cidade de Santa Cruz, RN. Metodologia: Este é um estudo controlado e randomizado, com avaliador cego, onde serão avaliadas 60 pacientes com diagnóstico de fibromialgia divididas em dois grupos. O grupo intervenção, realizará um programa de exercícios baseados no método pilates em solo e o outro, considerado grupo controle, participará de um programa de exercícios aeróbios na piscina. Ambos os grupos realizarão os programas de exercícios supervisionados 2 vezes por semana, por um período de 12 semanas. Os instrumentos de avaliação utilizados serão a EVA (escala visual de dor); questionário FIQ – Fibromyalgia Impact Questionnaire; a capacidade funcional pelo teste “Timed Up and Go” e teste de caminhada de 6 minutos; a qualidade de sono pelo Índice de Qualidade de Sono de Pittsburgh (PSQI-BR) e a ESS-BR (Escala de Sonolência de Epworth); por fim a qualidade de vida geral pelo SF-36.

Endereço: Rua Trairi S/N
Bairro: S/B **CEP:** 59.200-000
UF: RN **Município:** SANTA CRUZ
Telefone: (84)3291-2411 **E-mail:** cep@facisa.ufrn.br

Objetivo da Pesquisa:

OBJETIVO GERAL

Avaliar a efetividade do método pilates em solo na melhora da dor em mulheres com fibromialgia da cidade de Santa Cruz, RN.

OBJETIVOS ESPECÍFICOS

Avaliar a efetividade do método pilates em solo na melhora da:

• capacidade funcional em mulheres com fibromialgia da cidade de Santa Cruz, RN.

• qualidade de vida em mulheres com fibromialgia da cidade de Santa Cruz, RN.

• qualidade do sono em mulheres com fibromialgia da cidade de Santa Cruz, RN.

Avaliação dos Riscos e Benefícios:

O pesquisador apresenta os riscos e benefícios da pesquisa, bem como seus riscos com a respectiva forma de minimiza-los.

Comentários e Considerações sobre a Pesquisa:

O projeto apresenta temática interessante e relevante para área da pesquisa, estando condizente com o nível de abrangência, buscando avaliar a efetividade do método pilates em solo na melhora da dor em mulheres com fibromialgia da cidade de Santa Cruz, RN.

Considerações sobre os Termos de apresentação obrigatória:

Todos os termos obrigatórios estão presentes.

Recomendações:

Nada a referir.

Conclusões ou Pendências e Lista de Inadequações:

Todas as pendências foram atendidas totalmente.

Considerações Finais a critério do CEP:

1. Apresentar relatório parcial da pesquisa, semestralmente, a contar do início da mesma.

2. Apresentar relatório final da pesquisa até 30 dias após o término da mesma.

3. O CEP FACISA deverá ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo.

4. Quaisquer documentações encaminhadas ao CEP FACISA deverão conter junto uma Carta de Encaminhamento, em que conste o objetivo e justificativa do que esteja sendo apresentado.

5. Caso a pesquisa seja suspensa ou encerrada antes do previsto, o CEP FACISA deverá ser comunicado, estando os motivos expressos no relatório final a ser apresentado.

6. O TCLE deverá ser obtido em duas vias, uma ficará com o pesquisador e a outra com o sujeito

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de pesquisa.

7. Em conformidade com a Carta Circular nº. 003/2011CONEP/CNS, faz-se obrigatório a rubrica em todas as páginas do TCLE pelo sujeito de pesquisa ou seu responsável e pelo pesquisador.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_899030.pdf	23/05/2017 14:31:41		Aceito
Outros	CARTAaoCEPpilates.doc	23/05/2017 14:31:23	Marcelo Cardoso de Souza	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLEmodificado.doc	22/05/2017 10:19:06	Marcelo Cardoso de Souza	Aceito
Projeto Detalhado / Brochura Investigador	projetoICmodificado.pdf	22/05/2017 10:18:48	Marcelo Cardoso de Souza	Aceito
Outros	CartaAnuencia.pdf	10/04/2017 20:24:53	Marcelo Cardoso de Souza	Aceito
Folha de Rosto	folharostopilates.pdf	10/04/2017 14:41:05	Marcelo Cardoso de Souza	Aceito
Outros	CONFIDENCIALIDADE.doc	09/04/2017 10:34:31	Marcelo Cardoso de Souza	Aceito
Outros	Compromissoetico.doc	09/04/2017 10:33:22	Marcelo Cardoso de Souza	Aceito
Outros	ficha_cep.doc	09/04/2017 10:32:50	Marcelo Cardoso de Souza	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

SANTA CRUZ, 13 de Junho de 2017

Assinado por:
Thaiza Teixeira Xavier Nobre
(Coordenador)

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3,4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	6
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8,9,10,11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	12
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	14
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Mat Pilates and aquatic aerobic exercises for women with fibromyalgia. A protocol for a randomized controlled blind study

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Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Rheumatology
Keywords:	fibromyalgia, Pilates, aquatic aerobic execises, Chronic pain

Mat Pilates and aquatic aerobic exercises for women with fibromyalgia. A protocol for a randomized controlled blind study

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Abstract

Introduction: Physical exercises have been recommended to improve overall well-being in patients with fibromyalgia, with the main objective to repair the effects of lack of physical conditioning and to improve symptoms, especially pain and fatigue. Although widely recommended and widely known, few studies support the use of the Pilates method as effective for improving the symptoms of the disease, comparing it with other well-founded exercise modalities. This protocol was developed to describe the design of a randomized controlled study with a blind evaluator that evaluates the effectiveness of the mat Pilates method in comparing it with aquatic aerobic exercises for improving pain in women with fibromyalgia.

Methods: Sixty (60) women aged 18 to 60 years with fibromyalgia diagnosis, a score of between 3 and 8 points on the visual analog scale for pain, and who sign the clear and informed consent form will be recruited according to the inclusion criteria. They will be randomized into one of the two intervention groups: (i) Pilates, to perform an exercise program based on the Mat Pilates method; and (ii) aquatic exercise, to participate in a program of aerobic exercises in the swimming pool. The protocol will correspond to 12 weeks of treatment, with both groups performing the exercises with supervision twice a week. The primary outcome will be pain (Visual Analogue Scale for pain). Secondary outcomes are to include impacts related to the disease, functional capacity, sleep quality and overall quality of life. The evaluations will be performed at three moments: baseline, after 6 weeks and 12 weeks of treatment.

Ethics and dissemination: This is a pioneering study for evaluating the effectiveness of the Mat Pilates method in comparing it with aquatic aerobic exercises with a follow-up of 12 weeks, thus becoming a new contribution to fibromyalgia treatment. In addition, the implementation of the protocol in question may contribute to elucidate the effects of the Mat Pilates method in patients with fibromyalgia, as well as the frequency and adequate duration of exercise to improve symptoms.

Trial registrations: ClinicalTrials.gov Identifier (NCT03149198), May 11, 2017.

Approved by the Ethics Committee of FACISA/UFRN (Number: 2.116.314).

Keywords: Chronic pain, therapeutic exercise, aerobic exercise, Pilates, fibromyalgia treatment.

Strengths and limitations of this study

- Pilates is a very recommended exercise concept for women with fibromyalgia, but there is little evidence of high quality for their use.

- It is important to compare a mode known as pilates with another type of exercise, the aerobic exercise, this time performed in the water.

- It is necessary that new exercise interventions for fibromyalgia be tested and compared so that they can be recommended based on evidence.

- It is difficult to perform a double-blind study with exercises, since the participant knows what exercise is performing.

Background

Fibromyalgia (FM) is a syndrome characterized by chronic generalized pain and sleep disorder, fatigue, reduced muscle strength, depression, anxiety, irritable bowel, and other symptoms that cause impairment to quality of life [1-3]. The prevalence of FM in the general population ranges from 0.66 to 4.4%, varying according to the profile of patients evaluated and the study methodology. Most studies indicate that FM is more prevalent in women than in men, at a ratio of 8 to 1, especially in the age group between 35 and 60 years. Studies with adolescent children and special groups are scarce and few are conclusive. A study carried out in Brazil confirms that FM was the second most frequent rheumatic disease in outpatient clinics, only after osteoarthritis [4].

The causes for the onset of this syndrome have not yet been fully elucidated. However, recent scientific research suggests that changes in the metabolism and regulation of certain substances of the central nervous system such as serotonin and noradrenaline can trigger the disease [5].

With a controversial etiopathogenesis, the cause of FM is associated with genetic, environmental and neuromodulatory factors [6]. Many patients with FM have high levels of stress and feelings of depression, anxiety and frustration [7]. Patients feel fatigue and physical tiredness with a loss of energy, and decreased strength when performing physical exercises. This fatigue causes a great decrease in quality of life and often prevents performing activities of daily living, thereby reducing productivity in the work environment.

Therefore, physical exercises have been recommended to improve the overall well-being in women with FM, with the main purpose of repairing the effects of a lack of physical conditioning and improving the symptoms, especially pain and fatigue. Valim et al. (2013) report that physical exercises in FM are beneficial, low-cost and promote improvement in pain and other symptoms of the disease [8].

The importance of physical exercise for women with FM is already well described in the literature, in addition to it being a low-cost, safe and efficient intervention as a form of treatment. Exercises have also been shown to be effective in reducing pain and the number of painful points, improving quality of life, mood and other psychological aspects. Although studies show benefits in almost all exercise modalities, further evidence supports the practice of aerobic training [9,10]. Within this perspective, a Cochrane review on aquatic exercises for FM showed that aquatic exercises are effective in improving physical well-being, functional capacity, pain, a 37% improvement in muscular strength and improvement in cardiovascular capacity [11].

For some while the Pilates method of exercising has been gaining popularity, being considered one more exercise modality that can be used. This method consists of a system of stretching and strengthening exercises developed by Joseph H. Pilates almost 90 years ago, which employs controlled and precise sets of movements and the use of special equipment. Exercises can also be performed in different positions on the ground on a mat, avoiding excessive impact or pressure on muscles, joints and tissues. The purpose of physical training using the Pilates method is to achieve better functioning of the body based on strengthening the core, a term that refers to the center of the trunk that supports the body (rectus abdominus, transverse abdominus, erector spinae, diaphragm and pelvic floor muscles). The second major feature of the method are the six basic principles: centralization, concentration, control, precision, breathing, and flow [12].

Although highly recommended and widely known, few studies have evaluated the effects of the method for the treatment of women with FM. In addition, these studies present several methodological flaws that compromise their results and suggest that studies with better methodological design should be conducted with the objective of observing the effectiveness of the Pilates method in treating these patients [13,14]. Therefore, the main objective of this study is to evaluate the effectiveness of the Mat Pilates method in improving pain in women with FM, and comparing it with aquatic

aerobic exercises. Our hypothesis is that the Mat Pilates method can also bring benefits for improving pain in women with FM, similar to aquatic aerobic exercises. The secondary objectives of the study are to compare the impact of disease, functionality and performance, sleep quality and quality of life in women with FM who perform two different modalities of exercise.

Methods

Design

Study protocol for a randomized controlled parallel group single-blind trial. This study has been registered (ClinicalTrials.gov Identifier: NCT03149198). Participants will be randomized to perform mat Pilates or aerobic exercises. Allocation to either group (Mat pilates or aquatic aerobic exercises) will be achieved through a computer-generated sequence of random numbers. The allocation sequence will be created and carried out by a non-interventionist researcher in charge of telephone screening and handling the data obtained in the various assessment sessions.

Figure 1 shows a flowchart of the progress of the various stages of this test. This study was approved by the Ethics Committee of Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi – (FACISA/UFRN) (Number: 2.116.314).

Participants

Sixty (60) women aged 18 to 60 years, with a clinical diagnosis of FM according to the criteria of the American College of Rheumatology [15] and scoring between 3 and 8 points on the visual analogue pain scale will be recruited, provided they give their consent after being informed of the study's objectives and procedures. The volunteers will be recruited from the waiting list of patients of the Physiotherapy School Clinic of FACISA/UFRN; in addition, the project will also be announced by radio and local media. After this, a telephone contact will first be made to clarify any questions from the participants, and the first screening for inclusion will be carried out.

Personal data of the participants will be numerically coded and stored in a database, which can only be accessed by the researcher responsible for the randomization and blinding process. Informed consent as well as all study information will be passed on to all participants. Prior to any data collection, participants must sign the clear and informed consent form.

Inclusion criteria:

- Women diagnosed with FM according to the American College of Rheumatology classification criteria.
- Aged between 18 and 60 years.
- Reporting pain between 3 and 8 on the VAS.

Exclusion Criteria:

- uncontrolled hypertension
- decompensated cardiorespiratory disease
- history of syncopes or arrhythmias induced by physical exercise
- decompensated diabetes
- serious psychiatric illness
- Primarily Systemic Exertion Intolerance Disease
- thyroid issues
- obesity
- history of regular exercise (at least 2 times a week) in the last 6 months
- any other condition that makes it impossible for the patient to perform physical exercises.

Research team

This study will involve 5 researchers; 1 researcher responsible for the evaluations; 2 researchers responsible for the interventions (1 for each group); 1 researcher responsible for the interview, initial screening and randomization of participants, and 1 researcher who will perform the statistical analysis.

Patient and Public Involvement

The main question of the study was developed to answer a gap in the literature on the comparison of different modalities of physical exercises for the treatment of fibromyalgia, although no participant in the study was involved so far. At the end of the study, the results will be disseminated to the participants in the form of a lecture and fellowship, showing the effects found in the studied variables. If superiority of one modality is found over the other, it will be offered and guaranteed to the participants.

Randomization and blinding

Participants who are successfully approved for screening and who agree to sign the free and informed consent form will receive a number in a randomization table according to the inclusion order in the study. These numbers will correspond to the Pilates group or aquatic exercise group in which volunteers will be included. This distribution will be performed randomly through the website *randomization.com*. The allocation will be concealed using sealed and opaque envelopes, numbered consecutively. An independent researcher who will not participate in the other study procedures will perform the randomization process. The flow diagram of the study is summarised in Fig. 1.

The researchers responsible for interventions will be blinded to the participants' initial assessments, and the researcher responsible for evaluations will not know the group of each participant.

In addition, data collected during participant evaluations will not be revealed to the researchers responsible for interventions, and participants will be instructed not to disclose their experience and information related to the intervention.

Finally, the researcher responsible for statistical analysis will be blinded. Once the intervention is completed, he/she will receive an Excel data table with all necessary data without identification of the subjects or the groups.

Interventions

Participants in this study will receive 24 treatment sessions (two per week) for 12 weeks. Evaluations will be performed prior to the start of treatment, after 12 sessions and after 24 treatment sessions.

Mat Pilates Exercise Program

The exercise program based on the Pilates method will be carried out on a mat, in the Group Room of the Clinic School of Physiotherapy of the *FACISA/UFRN* in Santa Cruz, RN, Brazil. The room has ample space and air conditioning for better patient accommodation. The exercises will be performed twice a week for 12 weeks. Each session will last about 50 minutes and will be supervised by an experienced Mat Pilates researcher who will be responsible for the intervention in this group. A total of

10 exercises will be performed, which are presented in Table 1. Chart 1 shows the progression of the exercises according to the time.

Chart 1: Exercise progression according to the intervention time

Period	Dose
First month (1st to 8th session)	1 set of 8 repetitions
Second month (8th to 16th session)	2 sets of 10 repetitions
Third month (16th to 24th session)	3 sets of 8 repetitions

Intervention group exercise program

Table 1: Mat Pilates Group Exercise Program

NAME OF THE EXERCISE	DESCRIPTION
1 - SWAN Stretches the anterior trunk chain. Strengthens pectoral, triceps and anterior deltoid muscles.	1 – Lying in the prone position, hands resting in the direction of the shoulders. 2 – Extend the elbows, keeping head aligned with spine, extending/stretching the trunk. 3 – Return to the initial position.
2 – ONE LEG UP-DOWN Strengthens the rectus femoris, iliopsoas and sartorius muscles.	1 – Lying in the supine position, arms outstretched alongside the body. 2 – Raise leg in extension with feet in plantar flexion. 3 – Return to the initial position.
3 – LEG CIRCLES Strengthens the rectus femoris, sartorius, adductor, gluteus medius muscles.	1 – Lying in the supine position, arms outstretched alongside the body and supported on the ground. 2 – Raise leg in extension, with feet in plantar flexion. 3 – Make circles with the leg.
4 – SINGLE LEG STRETCH Strengthens the abdomen, stretches the glutes and the lumbar spine.	1 – Lying in the supine position, flex the right leg by placing the left hand on the right knee and the right hand on the right ankle, flexing as much as possible toward the chest. The left leg will be extended at an angle of 30º. 2 – Slowly switch the leg.
5 – SAW Stretches trunk rotators, the hamstrings and the quadratus lumborum muscle. Strengthens the rectus abdominis, external and internal oblique muscles.	1 – Sitting with the back straight and legs apart at hip width, arms extended and apart at shoulder height. 2 – Slowly from the waist, twist the spine to the left.

	3 – Move the right arm toward the left foot and the left arm back at shoulder height. 4 – Return to the initial position and switch sides.
6 – SIDE KICKS: FRONT AND BACK Strengthens the rectus femoris, iliopsoas, sartorius, gluteus medius, gluteus maximus and abdominal muscles in isometry.	1 – Lying straight in lateral decubitus, arm flexed and hand resting under the head. 2 – Keep your upper leg aligned with your hips and slowly bring the extended leg forward. 3 – Return to the initial position.
7 – THE HUNDRED Strengthens the abdominal, oblique, transverse and rectus femoris muscles.	1 – Lying in the supine position, elbow extended with the shoulder, hips and knees at 90°. 2 – Knee extension at approximately 45°. Slight bending of the trunk (removing the shoulder blades from the mat) and chin toward chest. 3 – Return to the initial position.
8 – PELVIC LIFT ON THE BALL Strengthens the gluteus maximus, biceps femoris, semitendinosus, semimembranosus, gastrocnemius, and quadriceps femoris muscles. Mobilizes the spine.	1 – Lying in the supine position, legs flexed at 90°, with heels on the ball. 2 - Raise the hips from the mat, extending the legs. 3 – Return to the initial position.
9 – SIT-UPS ON THE BALL Strengthens rectus abdominis and external oblique muscles.	1 – Lying in the supine position holding the ball over the head and legs at a 45°. 2 – Bring the ball toward the legs and hold it. 3 – Return to the initial position.
10 – STRETCHING ON THE BALL Stretching and muscle relaxation.	1 – Lying in lateral, ventral and dorsal decubitus on the ball.

Aquatic Aerobic Exercise Program

The aerobic exercise program will be carried out at the therapeutic swimming pool of the Physiotherapy School Clinic at the *FACISA/UFRN* in Santa Cruz, RN. The pool is heated (30^{o}C), which provides better effects to the proposed treatment.

The exercises will be performed twice a week for 12 weeks. Each session will last about 50 minutes and will be supervised by an experienced researcher responsible for the intervention in this group.

Patients will always be instructed to perform the exercise according to their current conditioning and increase the intensity according to their perception of exertion (Borg scale). The program is best described in Table 2.

Table 2: Aquatic aerobic exercises group exercise program.

TIME	EXERCISE
5 min – Warm-up.	1 - Walking in a clockwise circle at a slow pace. 2 - Walking in a counterclockwise circle at a slow pace. 3 - Walking with abduction/adduction in the horizontal plane of the upper limbs at a fast pace. 4 - Walking with knee flexion and alternating hip flexion and hand on opposite knee at a fast pace.
30 min – Aquatic aerobic exercises.	1 - Rapid tiptoe walking (2 laps in the pool) 2 - Fast walking on the heels (2 laps in the pool). 3 - Quick lateral marching (2 laps in the pool). 4 - Circles against the turbulent water flow. 5 - Rhythmic waist circles using pool noodles and floaters. 6 - Rhythmic movement of upper and lower limbs.
5 min – Cool-down.	1 - Walking in a clockwise circle at a slow pace. 2 - Walking in a counterclockwise circle at a slow pace. 3 - Walking with abduction/adduction in the horizontal plane of the upper limbs at a slow pace. 4 - Walking with knee flexion and alternating hip flexion and hand on the opposite knee at a slow pace. 5 - Respiratory exercises of diaphragmatic pattern.

Evaluations

During the baseline measurement, the following descriptive characteristics will be collected: gender, age, weight, height, current occupation. The chronology of the evaluation of the primary and secondary outcome measures is shown in Table 3.

Primary outcome measures

The Visual Analogue Scale (VAS) for pain is the main result of this study and will be used for the intensity of pain. Participants will mark the intensity of their pain on the VAS consisting of a 100-mm long horizontal line, which is anchored by the classifications of “no pain” at the left end (score 0) and “worst pain imaginable” rightmost (score 10), asking the participant for the most intense pain episode perceived

while doing daily activities. The VAS has demonstrated the ability to detect changes in pain, establishing a minimal clinically significant difference at 2.5 cm [16].

Secondary outcome measures

1. Impact related to the disease: the evaluation will be performed using the FIQ (*Fibromyalgia Impact Questionnaire*), a questionnaire that assesses anxiety, depression and physical performance in FM. The translated version adapted for the Brazilian population will be used [17].
2. Functional capacity:
   - *"Timed Up and Go test"* (TUG), a functional test consisting of getting up from a chair without the aid of the arms, walking a distance of three meters, turning around and walking back. At the start of the test, the patient should have his or her back resting on the back of the chair. The patient then receives the "go" command to perform the test and they are timed from the command voice until the moment they rest their back on the chair again [18,19].
   - *Six-minute Walk Test* (6MWT), to measure the walking performance of patients . The test will be performed on a 20-meter marked gymnasium track away from other people. The patients will be instructed to walk the entire distance, being able to interrupt the test if they do not feel able to continue [19].
3. Assessment of sleep quality:
   - *Pittsburgh Sleep Quality Index* – the Brazilian Portuguese version (PSQI-BR) will be used to evaluate the subjective quality of sleep. This questionnaire consists of nineteen items grouped into seven components, which are scored on a scale from 0 to 3. The components are: (1) subjective quality of sleep; (2) sleep latency; (3) duration of sleep; (4) habitual sleep efficiency; (5) sleep disorders; (6) use of medication for sleep; and (7) daytime dysfunction. The values corresponding to respondents' responses for each component are summed up to give an overall PSQI score, which ranges from 0 to 21. Scores between 0-4 indicate good sleep quality, while 5-10 scores indicate poor quality, and above 10 indicate sleep disturbance [20].

- *Epworth Sleepiness Scale* version in Brazilian Portuguese (ESS-BR) will be used to measure the possibility of dozing off. The questionnaire consists of eight daily situations where the probability of dozing off is graded on a scale from zero (no probability of dozing off) to three (very likely to doze off). At the end, the scores are summed up to generate a total score ranging from 0-24, where an individual above 10 points is characterized with excessive drowsiness [21].

4. Overall quality of life: will be assessed by the *Short Form-36 Health Survey*, a quality of life questionnaire, translated into Portuguese, containing 36 questions. The result is given in 8 domains: physical functioning, role physical, role emotional, bodily pain, vitality, mental health, social functioning, and general health, with scores ranging from 0-100 in each domain, in which 100 is the best health state and 0 the worst health state [22].

Table 3 Chronology of primary and secondary outcome measures

Results	baseline	6 week	12 week
Primary			
VAS	✓	✓	✓
Secondary			
FIQ	✓	✓	✓
TUG	✓	✓	✓
6MWT	✓	✓	✓
PSQI-BR	✓	✓	✓
ESS-BR	✓	✓	✓
SF-36	✓	✓	✓

VAS= *Visual Analogue Scale* for pain, FIQ= *Fibromyalgia Impact Questionnaire*, TUG= *Timed Up and Go test*, 6MWT= *Six-minute Walk Test*, PSQI-BR= *Pittsburgh Sleep Quality Index* – the Brazilian Portuguese version, ESS-BR= *Epworth Sleepiness Scale* version in Brazilian Portuguese, SF-36= *Short Form-36 Health Survey*.

Training of researchers

A series of training stages prior to starting the study will be implemented for the assessment and treatment intending to protocolize the actions carried out in the study. In

these training stages, treatment techniques and measuring will be practiced in order to reach a consensus among the involved researchers.

Statistical issues

Sample size calculation

The sample size was calculated based on the pain variable in order to find a difference of ± 2.5 points between the intervention groups on the visual analog pain scale - VAS [16], with a standard deviation of 2.5 points [23]. A sample of 60 participants is required (30 in each group) in order to achieve a statistical power of 90% with a 5% alpha, and considering a loss rate of 20%. The sample calculation was performed for the ANOVA repeated measures statistical test with interaction between groups. Gpower3.1 software was used for the calculation.

Statistical analysis

The analysis will be descriptive for all outcomes included in the study, expressing quantitative outcomes with their mean ± standard deviation and qualitative outcomes with their absolute value, percentage and 95% confidence intervals.

Data will be analyzed by SPSS software. The chi-square test will be used to observe associations between the qualitative variables. After observing the normal distribution and homogeneity of the variances of the quantitative variables by means of the kolmogorov-Smirnov test and the Levene test, respectively, the Student's t-test (for variables with normal distribution) or the Mann-Whitney test (for variables with a non-normal distribution) will be used to perform a comparison of the means. Estimates of average effect (differences between groups) for all variables will be calculated using the ANOVA mixed model. This analysis model incorporated the intervention groups (Pilates and aquatic exercise), time (baseline, 6 weeks and 12 weeks) and the group × time interaction. When a significant F value is found, the Bonferroni post-hoc test will be applied in order to identify the differences. An intention-to-treat analysis will be used to assess the response to intervention, with the last evaluation carried forward when necessary. The size of the effect between the groups for the variables that present intergroup differences can be calculated at some point, with a respective 95% confidence interval. The level of statistical significance adopted will be 5%. The analysis will be performed by an independent researcher.

Discussion

This protocol will be carried out for a randomized single-blind clinical trial, in order to investigate whether mat Pilates produces similar beneficial effects to aquatic aerobic exercises in reducing pain and disability in women with FM. Secondary outcomes are to include impacts related to the disease, functional capacity, sleep quality and overall quality of life. With the conclusion of the study, we hope to test the following null hypothesis: "There is no difference in pain and disability for participants undergoing treatment with Mat Pilates or with aquatic aerobic exercises".

Women with FM experience fatigue [24] and physical tiredness, with loss of energy, and decreased power/strength when performing physical exercises. Fatigue leads to a great decrease in quality of life and often prevents performance of activities of daily living, thereby reducing productivity in the workplace. Thus, physical exercises, and especially aerobic ones [25], have been recommended to improve overall well-being in women with FM, with the main purpose of repairing the effects of a lack of physical conditioning, and especially improving symptoms regarding pain and fatigue.

A recent Cochrane review on aerobic exercise in fibromyalgia concluded that, when compared to control, moderate quality evidence indicates that aerobic exercise is likely to improve quality of life, and poor quality evidence suggests that aerobic exercise may slightly decrease pain intensity, slightly improve physical function, and lead to a slight difference in fatigue and stiffness [26].

Regarding aquatic aerobic exercises, a meta-analysis [27] found good results for aquatic therapy (hydrotherapy) with a duration of over 20 weeks; however, in our study we will use aquatic exercises with an aerobic purpose, rather than just aquatic physiotherapy. *Deep water running* is an aquatic aerobic conditioning technique that has shown to be as beneficial as aerobic exercise on land, however with advantages related to emotional aspects in patients with fibromyalgia [28]. A systematic review carried out by Bidonde et al. (2014) concluded that the evidence of low to moderate quality in relation to the control suggests that aquatic training is beneficial for improving well-being, symptoms and fitness in adults with fibromyalgia. Low quality evidence suggests that there are benefits of aquatic and land exercise, except for muscle strength (low quality evidence favoring land exercises) and also that no serious adverse effects were found [11].

A recent protocol on aquatic exercise *versus* land exercises to treat balance and pain in women with fibromyalgia was published, showing the interest of the researchers

in deepening knowledge on the subject, since more well-designed studies are still necessary. However, our aquatic aerobic exercise program differs from the one used in this study due to the fact that it has the objective of working on more aspects related to balance and proprioception in water [29]. The Pilates method is currently well known and highly recommended by doctors and health professionals with the aim of improving pain, posture, stretching and strengthening of the body as a whole. Women with FM are frequently recommended to perform physical exercises to improve the FM symptoms, in which Pilates represents an important option to be considered. However, few studies have evaluated the effects of the method for the treatment of women with FM. In addition, these studies present several methodological flaws that compromise their results, suggesting that studies with better methodological design should be conducted with the objective of observing the effectiveness of the Pilates method in treating these womens [13,14].

Adherence to treatment is something very important to be reported, mainly in interventions for chronic musculoskeletal disorders [30]. We hope that the volunteers in our study will have good adherence to treatment, considering that the heated pool is a stimulating invitation for relaxation and that Pilates is a popular, famous and still relatively high-cost technique in our reality, thus we believe that our intervention will be well accepted.

In view of the above, we hope that the conclusion of this study contributes to scientific knowledge, providing subsidies for the use of physiotherapy as a safe and effective tool in treating women with FM,, as well as to help elucidate the best frequency and the adequate duration of exercise for improving the symptoms.

Abbreviations

FM: fibromyalgia; FACISA/UFRN: Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi; VAS: Visual Analogue Scale; FIQ: Fibromyalgia Impact Questionnaire; TUG: Timed Up and Go test; 6MWT: Six-minute Walk Test: PSQI-BR: Pittsburgh Sleep Quality Index – the Brazilian Portuguese version; ESS-BR: Epworth Sleepiness Scale version in Brazilian Portuguese; SF-36: Short Form-36 Health Survey.

Acknowledgements

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Funding

Not applicable.

Availability of data and material

Not applicable.

Authors' contributions

CAAL and MCS lead the study design and design and planned the statistical analysis. HJAS, TTXN, VPSS and RTJC have made substantial contributions to the design and design of the study. HJAS, CAAL, MCS, TTXN, VPSS and RTJC reviewed the manuscript critically and gave final approval for publication.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi – (FACISA/UFRN) with registration code 2.116.314. The ethical principles agreed in the Declaration of Helsinki will be respected for all study procedures. Respect for individuals will be insured and their autonomy will be maintained. Participants will be informed of the study objectives, its risks and benefits. Participants will be free to abandon the study at any time without the obligation of giving any explanation. Participants must sign the informed consent before the study begins. This study protocol is registered in ClinicalTrials.gov (a U.S. National Institutes of Health service) with the identifier NCT03149198, published on 11th May, 2017.

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Figure 1: Flow diagram of the study

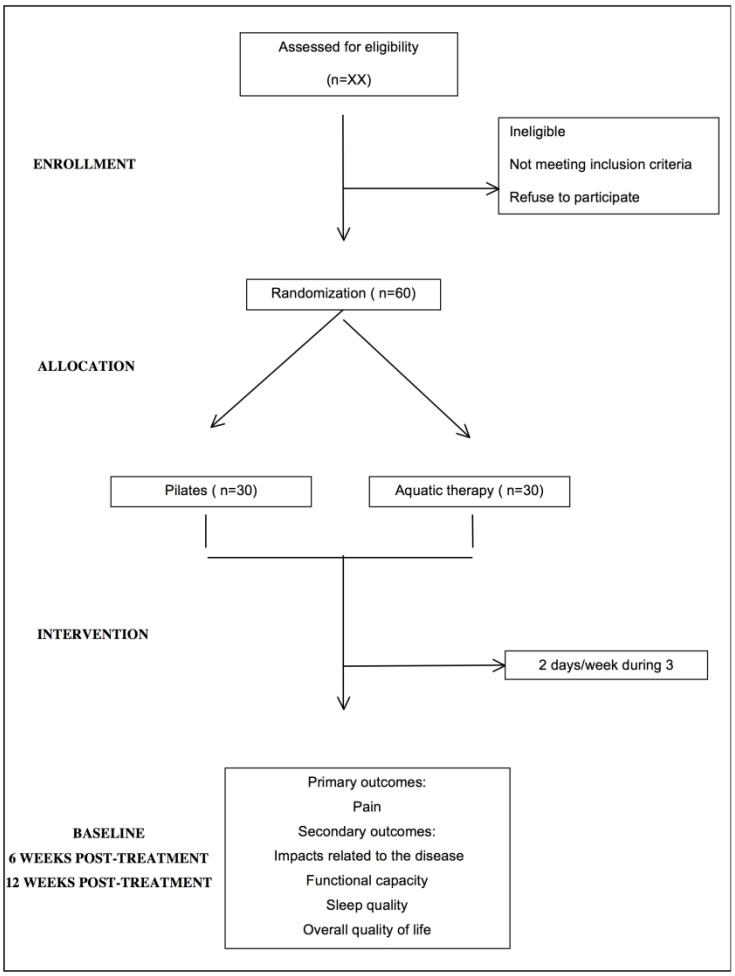

Fig. 1 Flow diagram of the study

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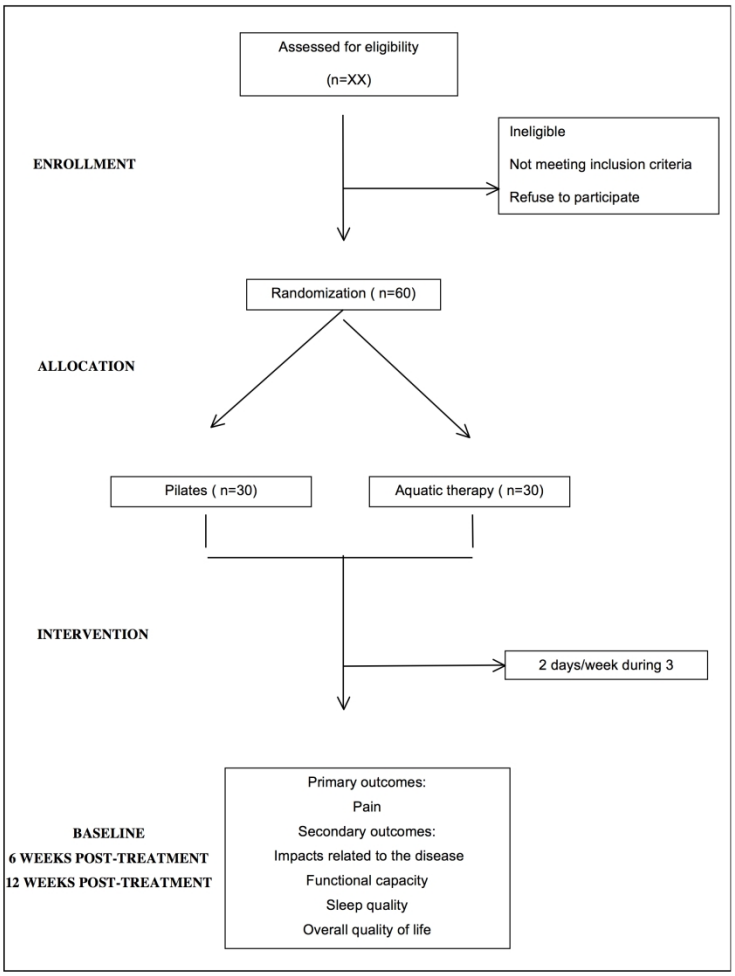
209x296mm (300 x 300 DPI)



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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	2	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2	Trial identifier and registry name. If not yet registered, name of intended registry
	N/A	All items from the World Health Organization Trial Registration Data Set
Protocol version	8	Date and version identifier
Funding	N/A	Sources and types of financial, material, and other support
Roles and responsibilities	1	Names, affiliations, and roles of protocol contributors
	1	Name and contact information for the trial sponsor
	1	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	1	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	3	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	3	Explanation for choice of comparators
Objectives	5	Specific objectives or hypotheses
Trial design	5	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes		
Study setting	5	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	6	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	7	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	7	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	N/A	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	N/A	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	10	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	7	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	12	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	7	Strategies for achieving adequate participant enrolment to reach target sample size
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	6	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	6	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	N/A	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	6	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	6	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	12	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	12	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	N/A	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	12	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	12	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	12	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	N/A	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	N/A	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	N/A	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	N/A	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	16	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	16	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	16	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	N/A	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	16	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	16	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	N/A	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	N./A	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	N/A	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	N/A	Authorship eligibility guidelines and any intended use of professional writers
	N/A	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	N/A	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	N/A	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Mat Pilates and aquatic aerobic exercises for women with fibromyalgia. A protocol for a randomized controlled blind study

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Mat Pilates and aquatic aerobic exercises for women with fibromyalgia. A protocol for a randomized controlled blind study

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Abstract

Introduction: Physical exercises have been recommended to improve overall well-being in patients with fibromyalgia, with the main objective to repair the effects of lack of physical conditioning and to improve symptoms, especially pain and fatigue. Although widely recommended and widely known, few studies support the use of the Pilates method as effective for improving the symptoms of the disease, comparing it with other well-founded exercise modalities. This protocol was developed to describe the design of a randomized controlled study with a blind evaluator that evaluates the effectiveness of the mat Pilates method in comparing it with aquatic aerobic exercises for improving pain in women with fibromyalgia.

Methods: Sixty (60) women aged 18 to 60 years with fibromyalgia diagnosis, a score of between 3 and 8 points on the visual analog scale for pain, and who sign the clear and informed consent form will be recruited according to the inclusion criteria. They will be randomized into one of the two intervention groups: (i) Pilates, to perform an exercise program based on the Mat Pilates method; and (ii) aquatic exercise, to participate in a program of aerobic exercises in the swimming pool. The protocol will correspond to 12 weeks of treatment, with both groups performing the exercises with supervision twice a week. The primary outcome will be pain (Visual Analogue Scale for pain). Secondary outcomes are to include impacts related to the disease, functional capacity, sleep quality and overall quality of life. The evaluations will be performed at three moments: baseline, after 6 weeks and 12 weeks of treatment.

Ethics and dissemination: This protocol has been approved by Ethics Committee of FACISA/UFRN (Number: 2.116.314). Data collection will begin after approval by the ethics committee. There will be prior contact with the women, at which time all the information about the study and objectives will be presented, as well as resolution No. 466/2012 of the National Health Council of Brazil of the year 2012, which provides guidelines and regulatory standards for research involving human beings. Participants must sign the informed consent form before the study begins.

Trial registrations: ClinicalTrials.gov Identifier (NCT03149198), May 11, 2017.

Keywords: Chronic pain, therapeutic exercise, aerobic exercise, Pilates, fibromyalgia treatment.

Strengths and limitations of this study

- This is a pioneering study for evaluating the effectiveness of the Mat Pilates method in comparing it with aquatic aerobic exercises with a follow-up of 12 weeks.
- In addition, implementation of the protocol in question may contribute to elucidate the effects of the Mat Pilates method in women with fibromyalgia, as well as the frequency and adequate duration of exercise to improve symptoms.
- It is important to compare an exercise mode known as pilates with another type of exercise, namely aerobic exercise, this time performed in the water, as little evidence of high quality for its use exists.
- It is necessary that new exercise interventions for fibromyalgia be tested and compared so that they can be recommended based on evidence.
- It is difficult to perform a double-blind study with exercises, since the participant knows what exercise is performing.

Background

Fibromyalgia (FM) is a syndrome characterized by generalized chronic pain and sleep disturbance, fatigue, reduced muscle strength, depression, anxiety, mood disorders, irritable bowel and other symptoms that negatively impact quality of life [1-3]. The prevalence of FM ranges from 0.66 to 4.4% being more frequent in women than in men, in the proportion of 8 to 1, especially in the age group between 35 and 60 years. In Brazil, FM was considered the second most frequent rheumatic disease in outpatient clinics after osteoarthritis [4].

The causes for the onset of this syndrome have not yet been fully elucidated. However, recent scientific research suggests that changes in the metabolism and regulation of certain substances of the central nervous system such as serotonin and noradrenaline can trigger the disease [5].

With a controversial etiopathogenesis, the cause of FM is associated with genetic, environmental and neuromodulatory factors [6]. Many patients with FM have high levels of stress and feelings of depression, anxiety and frustration [7]. Patients feel fatigue and

physical tiredness with a loss of energy, and decreased strength when performing physical exercises. This fatigue causes a great decrease in quality of life and often prevents performing activities of daily living, thereby reducing productivity in the work environment.

Therefore, physical exercises have been recommended to improve the overall well-being in women with FM, with the main purpose of repairing the effects of a lack of physical conditioning and improving the symptoms, especially pain and fatigue. Valim et al. (2013) report that physical exercises in FM are beneficial, low-cost and promote improvement in pain and other symptoms of the disease [8].

The importance of physical exercise for women with FM is already well described in the literature, in addition to it being a low-cost, safe and efficient intervention as a form of treatment. Exercises have also been shown to be effective in reducing pain and the number of painful points, improving quality of life, mood and other psychological aspects. Although studies show benefits in almost all exercise modalities, further evidence supports the practice of aerobic training [9,10]. Within this perspective, a Cochrane review on aquatic exercises for FM showed that aquatic exercises are effective in improving physical well-being, functional capacity, pain, a 37% improvement in muscular strength and improvement in cardiovascular capacity [11].

For some while the Pilates method of exercising has been gaining popularity, being considered one more exercise modality that can be used. This method developed by Joseph H. Pilates includes stretching and strengthening exercises with controlled and precise movements that can use special equipment or even on the ground. The purpose of physical training using the Pilates method is to improve body functioning based on core strengthening, a term that refers to the center of the trunk supporting the body (rectus abdominus, transverse abdomen, erector spine, diaphragm, and pelvic floor muscles) . The six basic principles of the method are: centralization, concentration, control, precision, respiration, and flow [12].

Although highly recommended and widely known, few studies have evaluated the effects of the method for the treatment of women with FM. In addition, these studies present several methodological flaws that compromise their results and suggest that studies with better methodological design should be conducted with the objective of observing the effectiveness of the Pilates method in treating these patients [13,14]. Therefore, the main objective of this study is to evaluate the effectiveness of the Mat

Pilates method in improving pain in women with FM, and comparing it with aquatic aerobic exercises. Our hypothesis is that the Mat Pilates method can also bring benefits for improving pain in women with FM, similar to aquatic aerobic exercises. The secondary objectives of the study are to compare the impact of disease, functionality and performance, sleep quality and quality of life in women with FM who perform two different modalities of exercise.

Methods

Design

Study protocol for a randomized controlled parallel group single-blind trial. This study has been registered (ClinicalTrials.gov Identifier: NCT03149198). Participants will be randomized to perform mat Pilates or aerobic exercises. Allocation to either group (Mat pilates or aquatic aerobic exercises) will be achieved through a computer-generated sequence of random numbers. The allocation sequence will be created and carried out by a non-interventionist researcher in charge of telephone screening and handling the data obtained in the various assessment sessions.

Figure 1 shows a flowchart of the progress of the various stages of this test. This study was approved by the Ethics Committee of Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi – (FACISA/UFRN) (Number: 2.116.314).

Participants

Sixty (60) women aged 18 to 60 years, with a clinical diagnosis of FM according to the criteria of the American College of Rheumatology [15] and scoring between 3 and 8 points on the visual analogue pain scale will be recruited, provided they give their consent after being informed of the study's objectives and procedures. The volunteers will be recruited from the waiting list of patients of the Physiotherapy School Clinic of FACISA/UFRN; in addition, the project will also be announced by radio and local media. After this, a telephone contact will first be made to clarify any questions from the participants, and the first screening for inclusion will be carried out.

Personal data of the participants will be numerically coded and stored in a database, which can only be accessed by the researcher responsible for the randomization and blinding process. Informed consent as well as all study information will be passed on

to all participants. Prior to any data collection, participants must sign the clear and informed consent form.

Inclusion criteria:

- Women diagnosed with FM according to the American College of Rheumatology classification criteria.
- Aged between 18 and 60 years.
- Reporting pain between 3 and 8 on the VAS.

Exclusion Criteria:

- uncontrolled hypertension
- decompensated cardiorespiratory disease
- history of syncopes or arrhythmias induced by physical exercise
- decompensated diabetes
- serious psychiatric illness
- Primarily Systemic Exertion Intolerance Disease
- thyroid issues
- obesity
- history of regular exercise (at least 2 times a week) in the last 6 months
- any other condition that makes it impossible for the patient to perform physical exercises.

Research team

This study will involve 5 researchers; 1 researcher responsible for the evaluations; 2 researchers responsible for the interventions (1 for each group); 1 researcher responsible for the interview, initial screening and randomization of participants, and 1 researcher who will perform the statistical analysis.

Patient and Public Involvement

The main question of the study was developed to answer a gap in the literature on the comparison of different physical exercise modalities for treating fibromyalgia, although no participant in the study has been involved so far. The results will be

disseminated to the participants in the form of a lecture and fellowship at the end of the study, presenting the effects found in the studied variables. If one modality is proven to be superior over the other, it will be offered and guaranteed to the participants.

Randomization and blinding

Participants who are successfully approved for screening and who agree to sign the free and informed consent form will receive a number in a randomization table according to the inclusion order in the study. These numbers will correspond to the Pilates group or aquatic exercise group in which volunteers will be included. This distribution will be performed randomly through the website *randomization.com*. The allocation will be concealed using sealed and opaque envelopes, numbered consecutively. An independent researcher who will not participate in the other study procedures will perform the randomization process. The flow diagram of the study is summarised in Fig. 1.

The researchers responsible for interventions will be blinded to the participants' initial assessments, and the researcher responsible for evaluations will not know the group of each participant.

In addition, data collected during participant evaluations will not be revealed to the researchers responsible for interventions, and participants will be instructed not to disclose their experience and information related to the intervention.

Finally, the researcher responsible for statistical analysis will be blinded. Once the intervention is completed, he/she will receive an Excel data table with all necessary data without identification of the subjects or the groups.

Interventions

Participants in this study will receive 24 treatment sessions (two per week) for 12 weeks. Evaluations will be performed prior to the start of treatment, after 12 sessions and after 24 treatment sessions.

Mat Pilates Exercise Program

The exercise program based on the Pilates method will be carried out on a mat, in the Group Room of the Clinic School of Physiotherapy of the *UFRN*/*FACISA* in Santa Cruz, RN, Brazil. The room has ample space and air conditioning for better patient accommodation. The exercises will be performed twice a week for 12 weeks. Each session will last about 50 minutes and will be supervised by an experienced Mat Pilates

researcher who will be responsible for the intervention in this group. Table 1 shows the progression of the exercises according to the time. A total of 10 exercises will be performed, which are presented in Table 2.

Table 1: Exercise progression according to the intervention time

Period	Dose
First month (1st to 8th session)	1 set of 8 repetitions
Second month (8th to 16th session)	2 sets of 10 repetitions
Third month (16th to 24th session)	3 sets of 8 repetitions

Intervention group exercise program

Table 2: Mat Pilates Group Exercise Program

NAME OF THE EXERCISE	DESCRIPTION
1 - SWAN Stretches the anterior trunk chain. Strengthens pectoral, triceps and anterior deltoid muscles.	1 – Lying in the prone position, hands resting in the direction of the shoulders. 2 – Extend the elbows, keeping head aligned with spine, extending/stretching the trunk. 3 – Return to the initial position.
2 – ONE LEG UP-DOWN Strengthens the rectus femoris, iliopsoas and sartorius muscles.	1 – Lying in the supine position, arms outstretched alongside the body. 2 – Raise leg in extension with feet in plantar flexion. 3 – Return to the initial position.
3 – LEG CIRCLES Strengthens the rectus femoris, sartorius, adductor, gluteus medius muscles.	1 – Lying in the supine position, arms outstretched alongside the body and supported on the ground. 2 – Raise leg in extension, with feet in plantar flexion. 3 – Make circles with the leg.
4 – SINGLE LEG STRETCH Strengthens the abdomen, stretches the glutes and the lumbar spine.	1 – Lying in the supine position, flex the right leg by placing the left hand on the right knee and the right hand on the right ankle, flexing as much as possible toward the chest. The left leg will be extended at an angle of 30º. 2 – Slowly switch the leg.
5 – SAW Stretches trunk rotators, the hamstrings and the quadratus lumborum muscle.	1 – Sitting with the back straight and legs apart at hip width, arms extended and apart at shoulder height.

Strengthens the rectus abdominis, external and internal oblique muscles.	2 – Slowly from the waist, twist the spine to the left. 3 – Move the right arm toward the left foot and the left arm back at shoulder height. 4 – Return to the initial position and switch sides.
6 – SIDE KICKS: FRONT AND BACK Strengthens the rectus femoris, iliopsoas, sartorius, gluteus medius, gluteus maximus and abdominal muscles in isometry.	1 – Lying straight in lateral decubitus, arm flexed and hand resting under the head. 2 – Keep your upper leg aligned with your hips and slowly bring the extended leg forward. 3 – Return to the initial position.
7 – THE HUNDRED Strengthens the abdominal, oblique, transverse and rectus femoris muscles.	1 – Lying in the supine position, elbow extended with the shoulder, hips and knees at 90°. 2 – Knee extension at approximately 45°. Slight bending of the trunk (removing the shoulder blades from the mat) and chin toward chest. 3 – Return to the initial position.
8 – PELVIC LIFT ON THE BALL Strengthens the gluteus maximus, biceps femoris, semitendinosus, semimembranosus, gastrocnemius, and quadriceps femoris muscles. Mobilizes the spine.	1 – Lying in the supine position, legs flexed at 90°, with heels on the ball. 2 - Raise the hips from the mat, extending the legs. 3 – Return to the initial position.
9 – SIT-UPS ON THE BALL Strengthens rectus abdominis and external oblique muscles.	1 – Lying in the supine position holding the ball over the head and legs at a 45°. 2 – Bring the ball toward the legs and hold it. 3 – Return to the initial position.
10 – STRETCHING ON THE BALL Stretching and muscle relaxation.	1 – Lying in lateral, ventral and dorsal decubitus on the ball.

Aquatic Aerobic Exercise Program

The aerobic exercise program will be carried out at the therapeutic swimming pool of the Physiotherapy School Clinic at the *FACISA/UFRN* in Santa Cruz, RN. The pool is heated (30ºC), which provides better effects to the proposed treatment.

The exercises will be performed twice a week for 12 weeks. Each session will last about 50 minutes and will be supervised by an experienced researcher responsible for the intervention in this group.

Patients will always be instructed to perform the exercise according to their current conditioning and increase the intensity according to their perception of exertion (Borg scale). The program is best described in Table 3.

Table 3: Aquatic aerobic exercises group exercise program.

TIME	EXERCISE
5 min – Warm-up.	1 - Walking in a clockwise circle at a slow pace. 2 - Walking in a counterclockwise circle at a slow pace. 3 - Walking with abduction/adduction in the horizontal plane of the upper limbs at a fast pace. 4 - Walking with knee flexion and alternating hip flexion and hand on opposite knee at a fast pace.
30 min – Aquatic aerobic exercises.	1 - Rapid tiptoe walking (2 laps in the pool) 2 - Fast walking on the heels (2 laps in the pool). 3 - Quick lateral marching (2 laps in the pool). 4 - Circles against the turbulent water flow. 5 - Rhythmic waist circles using pool noodles and floaters. 6 - Rhythmic movement of upper and lower limbs.
5 min – Cool-down.	1 - Walking in a clockwise circle at a slow pace. 2 - Walking in a counterclockwise circle at a slow pace. 3 - Walking with abduction/adduction in the horizontal plane of the upper limbs at a slow pace. 4 - Walking with knee flexion and alternating hip flexion and hand on the opposite knee at a slow pace. 5 - Respiratory exercises of diaphragmatic pattern.

Evaluations

During the baseline measurement, the following descriptive characteristics will be collected: gender, age, weight, height, current occupation. The chronology of the evaluation of the primary and secondary outcome measures is shown in Table 4.

Primary outcome measures

The Visual Analogue Scale (VAS) for pain is the main result of this study and will be used for the intensity of pain. Participants should mark the intensity of their pain in the VAS that consists of a horizontal line 100 mm long, where 0 means "no pain" and 10 "worst pain imaginable", where the participant reports the most intense pain episode during the daily activities. The difference considered clinically significant for improvement in pain is change in the scale by 2.5 cm [16].

Secondary outcome measures

1. Impact related to the disease: the evaluation will be performed using the FIQ (*Fibromyalgia Impact Questionnaire*), a questionnaire that assesses anxiety, depression and physical performance in FM. The translated version adapted for the Brazilian population will be used [17].
2. Functional capacity:
   - *"Timed Up and Go test"* (TUG), a functional test consisting of getting up from a chair without the aid of the arms, walking a distance of three meters, turning around and walking back. At the start of the test, the patient should have his or her back resting on the back of the chair. The patient then receives the "go" command to perform the test and they are timed from the command voice until the moment they rest their back on the chair again [18,19].
   - *Six-minute Walk Test* (6MWT), to measure the walking performance of patients. The test will be performed on a 20-meter marked gymnasium track away from other people. The patients will be instructed to walk the entire distance, being able to interrupt the test if they do not feel able to continue [19].
3. Assessment of sleep quality:
   - *Pittsburgh Sleep Quality Index* – the Brazilian Portuguese version (PSQI-BR) will be used to evaluate the subjective quality of sleep. This questionnaire consists of nineteen items grouped into seven components, which are scored on a scale from 0 to 3. The components are: (1) subjective quality of sleep; (2) sleep latency; (3) duration of sleep; (4) habitual sleep efficiency; (5) sleep disorders; (6) use of medication for sleep; and (7) daytime dysfunction. The values corresponding to respondents' responses for each component are summed up to give an overall PSQI score, which ranges from 0 to 21. Scores

between 0-4 indicate good sleep quality, while 5-10 scores indicate poor quality, and above 10 indicate sleep disturbance [20].

- *Epworth Sleepiness Scale* version in Brazilian Portuguese (ESS-BR) will be used to measure the possibility of dozing off. The questionnaire consists of eight daily situations where the probability of dozing off is graded on a scale from zero (no probability of dozing off) to three (very likely to doze off). At the end, the scores are summed up to generate a total score ranging from 0-24, where an individual above 10 points is characterized with excessive drowsiness [21].

4. Overall quality of life: will be assessed by the *Short Form-36 Health Survey*, a quality of life questionnaire, translated into Portuguese, containing 36 questions. The result is given in 8 domains: physical functioning, role physical, role emotional, bodily pain, vitality, mental health, social functioning, and general health, with scores ranging from 0-100 in each domain, in which 100 is the best health state and 0 the worst health state [22].

Table 4 Chronology of primary and secondary outcome measures

Results	baseline	6 week	12 week
Primary			
VAS	✓	✓	✓
Secondary			
FIQ	✓	✓	✓
TUG	✓	✓	✓
6MWT	✓	✓	✓
PSQI-BR	✓	✓	✓
ESS-BR	✓	✓	✓
SF-36	✓	✓	✓

VAS= *Visual Analogue Scale* for pain, FIQ= *Fibromyalgia Impact Questionnaire*, TUG= *Timed Up and Go test*, 6MWT= *Six-minute Walk Test*, PSQI-BR= *Pittsburgh Sleep Quality Index* – the Brazilian Portuguese version, ESS-BR= *Epworth Sleepiness Scale* version in Brazilian Portuguese, SF-36= *Short Form-36 Health Survey*.

Training of researchers

A series of training stages prior to starting the study will be implemented for the assessment and treatment intending to protocolize the actions carried out in the study. In these training stages, treatment techniques and measuring will be practiced in order to reach a consensus among the involved researchers.

Statistical issues

Sample size calculation

The sample size was calculated based on the pain variable in order to find a difference of ± 2.5 points between the intervention groups on the visual analog pain scale - VAS [16], with a standard deviation of 2.5 points [23]. A sample of 60 participants is required (30 in each group) in order to achieve a statistical power of 90% with a 5% alpha, and considering a loss rate of 20%. The sample calculation was performed for the ANOVA repeated measures statistical test with interaction between groups. Gpower3.1 software was used for the calculation.

Statistical analysis

The analysis will be descriptive for all outcomes included in the study, expressing quantitative outcomes with their mean ± standard deviation and qualitative outcomes with their absolute value, percentage and 95% confidence intervals.

Data will be analyzed by SPSS software. The chi-square test will be used to observe associations between the qualitative variables. After observing the normal distribution and homogeneity of the variances of the quantitative variables by means of the Kolmogorov-Smirnov test and the Levene test, respectively, the Student's t-test (for variables with normal distribution) or the Mann-Whitney test (for variables with a non-normal distribution) will be used to perform a comparison of the means. Estimates of average effect (differences between groups) for all variables will be calculated using the ANOVA mixed model. This analysis model incorporated the intervention groups (Pilates and aquatic exercise), time (baseline, 6 weeks and 12 weeks) and the group × time interaction. When a significant F value is found, the Bonferroni post-hoc test will be applied in order to identify the differences. An intention-to-treat analysis will be used to assess the response to intervention, with the last evaluation carried forward when necessary. The size of the effect between the groups for the variables that present intergroup differences can be calculated at some point, with a respective 95% confidence

interval. The level of statistical significance adopted will be 5%. The analysis will be performed by an independent researcher.

Discussion

This protocol will be carried out for a randomized single-blind clinical trial, in order to investigate whether mat Pilates produces similar beneficial effects to aquatic aerobic exercises in reducing pain and disability in women with FM. Secondary outcomes are to include impacts related to the disease, functional capacity, sleep quality and overall quality of life. With the conclusion of the study, we hope to test the following null hypothesis: "There is no difference in pain and disability for participants undergoing treatment with Mat Pilates or with aquatic aerobic exercises".

Women with FM experience fatigue [24] and physical tiredness, with loss of energy, and decreased power/strength when performing physical exercises. Fatigue leads to a great decrease in quality of life and often prevents performance of activities of daily living, thereby reducing productivity in the workplace. Thus, physical exercises, and especially aerobic ones [25], have been recommended to improve overall well-being in women with FM, with the main purpose of repairing the effects of a lack of physical conditioning, and especially improving symptoms regarding pain and fatigue.

A recent Cochrane review on aerobic exercise in fibromyalgia concluded that moderate quality evidence exists indicating that aerobic exercise is likely to improve quality of life when compared to control, and poor quality evidence suggests that aerobic exercise may slightly decrease pain intensity, slightly improve physical function, and lead to a slight difference in fatigue and stiffness [26].

Regarding aquatic aerobic exercises, a meta-analysis [27] found good results for aquatic therapy (hydrotherapy) with a duration of over 20 weeks; however, in our study we will use aquatic exercises with an aerobic purpose, rather than just aquatic physiotherapy. *Deep water running* is an aquatic aerobic conditioning technique that has shown to be as beneficial as aerobic exercise on land, however with advantages related to emotional aspects in women with fibromyalgia [28]. A systematic review carried out by Bidonde et al. (2014) concluded that the evidence of low to moderate quality in relation to the control suggests that aquatic training is beneficial for improving well-being, symptoms and fitness in adults with fibromyalgia. Low quality evidence suggests that there are benefits of aquatic and land exercise, except for muscle strength (low quality

evidence favoring land exercises) and also that no serious adverse effects were found [11].

A recent protocol on aquatic exercise *versus* land exercises to treat balance and pain in women with fibromyalgia was published, showing the interest of the researchers in deepening knowledge on the subject, since more well-designed studies are still necessary. However, our aquatic aerobic exercise program differs from the one used in this study due to the fact that it has the objective of working on more aspects related to balance and proprioception in water [29]. The Pilates method is currently well known and highly recommended by doctors and health professionals with the aim of improving pain, posture, stretching and strengthening of the body as a whole. Women with FM are frequently recommended to perform physical exercises to improve the FM symptoms, in which Pilates represents an important option to be considered. However, few studies have evaluated the effects of the method for the treatment of women with FM. In addition, these studies present several methodological flaws that compromise their results, suggesting that studies with better methodological design should be conducted with the objective of observing the effectiveness of the Pilates method in treating these women [13,14].

Adherence to treatment is something very important to be reported, mainly in interventions for chronic musculoskeletal disorders [30]. We hope that the volunteers in our study will have good adherence to treatment, considering that the heated pool is a stimulating invitation for relaxation and that Pilates is a popular, famous and still relatively high-cost technique in our reality, thus we believe that our intervention will be well accepted.

In view of the above, we hope that the conclusion of this study contributes to scientific knowledge, providing subsidies for the use of physiotherapy as a safe and effective tool in treating women with FM, as well as to help elucidate the best frequency and the adequate duration of exercise for improving the symptoms.

Abbreviations

FM: fibromyalgia; FACISA/UFRN: Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi; VAS: Visual Analogue Scale; FIQ: Fibromyalgia Impact Questionnaire; TUG: Timed Up and Go test; 6MWT: Six-minute Walk Test: PSQI-BR: Pittsburgh Sleep Quality Index – the Brazilian Portuguese version; ESS-BR: Epworth Sleepiness Scale version in Brazilian Portuguese; SF-36: Short Form-36 Health Survey.

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Availability of data and material

Not applicable.

Authors' contributions

CAAL and MCS lead the study design and design and planned the statistical analysis. HJAS, TTXN, VPSS and RTJC have made substantial contributions to the design and design of the study. HJAS, CAAL, MCS, TTXN, VPSS and RTJC reviewed the manuscript critically and gave final approval for publication.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi – (FACISA/UFRN) with registration code 2.116.314. The ethical principles agreed in the Declaration of Helsinki will be respected for all study procedures. Respect for individuals will be insured and their autonomy will be maintained. Participants will be informed of the study objectives, its risks and benefits. Participants will be free to abandon the study at any time without the obligation of giving any explanation. Participants must sign the informed consent before the study begins. This study protocol is registered in ClinicalTrials.gov (a U.S. National Institutes of Health service) with the identifier NCT03149198, published on 11th May, 2017.

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Figure 1: Flow diagram of the study

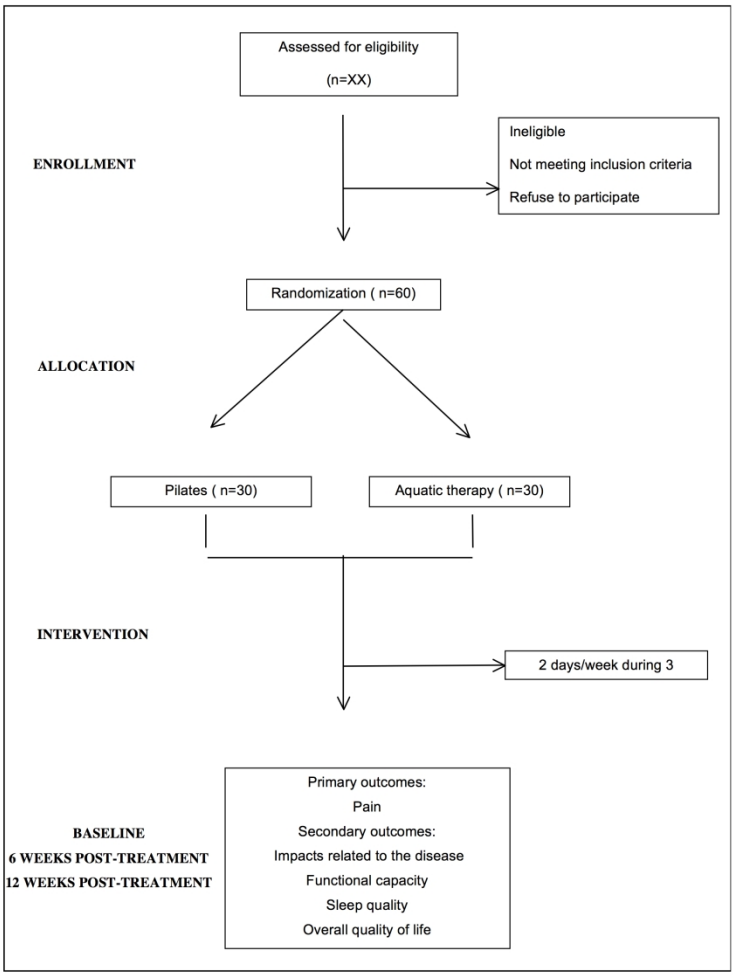

Fig. 1 Flow diagram of the study

Fig. 1 Flow diagram of the study

209x296mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	2	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2	Trial identifier and registry name. If not yet registered, name of intended registry
	N/A	All items from the World Health Organization Trial Registration Data Set
Protocol version	8	Date and version identifier
Funding	N/A	Sources and types of financial, material, and other support
Roles and responsibilities	1	Names, affiliations, and roles of protocol contributors
	1	Name and contact information for the trial sponsor
	1	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	1	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	3	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	3	Explanation for choice of comparators
Objectives	5	Specific objectives or hypotheses
Trial design	5	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting	5	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	6	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	7	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	7	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	N/A	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	N/A	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	10	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	7	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	12	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	7	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	6	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	6	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	N/A	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	6	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	6	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	12	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	12	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	N/A	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	12	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	12	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	12	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	N/A	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	N/A	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	N/A	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	N/A	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	16	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	16	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	16	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	N/A	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	16	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	16	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	N/A	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	N./A	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	N/A	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	N/A	Authorship eligibility guidelines and any intended use of professional writers
	N/A	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	N/A	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	N/A	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.