

Pilates and dance to breast cancer patients undergoing treatment: study protocol for a randomized clinical trial – MoveMama study

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Study protocol

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Abstract

Background: Breast cancer is a global public health issue and the side effects of the clinical treatment can decline the quality of life of these women. Therefore, a healthy lifestyle is essential to minimize the physical and psychological side effects of treatment. Physical activity has several benefits for breast cancer women and Pilates solo and belly dance can be an enjoyable type of physical activity for breast cancer women undergoing clinical treatment. The purpose of the study will be to provide a Pilates solo and a belly dance protocol (3x/16 weeks) for women undergoing breast cancer treatment and compare its effects with the control group. Methods: The participants will be allocated to either the intervention arm (Pilates solo or belly dance classes 3x/week for 16 weeks) or a control group (receipt of a booklet on physical activity for breast cancer patients and maintenance of habitual physical activity routine). The Pilates solo and belly dance classes will be divided into three stages: warm-up and stretching; the main stage and relaxation. Measurements of study outcomes will take place at baseline, post-intervention, 6-, 12- and 24-months (maintenance period). The data collection for both groups will occur with a questionnaire application and tests, covering general and clinical information, primary outcome will be quality of life (EORT QLQ C30 and BR23), secondary outcomes will be physical aspects as cardiorespiratory fitness (6-minute walk test and cycle ergometer), lymphedema (sum of arm circumference), physical activity (IPAQ short version), disabilities of the arm (DASH), range of motion (goniometer test), strength (dynamometer test) and flexibility (sit and reach test) and psychological aspects as depressive symptoms (BECK Inventory), body image (Body Image After Breast Cancer Questionnaire), self-esteem (Rosenberg), fatigue (FACT-F), pain (VAS), sexual function (FSFI) and sleep quality (Pittsburgh Sleep Quality Index). Discussion: In view of the high prevalence of breast cancer among women, the implementation a specific protocol of Pilates solo and belly dance for patients with breast cancer is important considering the needs to improve the quality of life, physical and psychological aspects of their life. Pilates solo and belly dance are two kinds of physical activity that involves mental and body concentration, music, upper limb movements, femininity, and social involvement. An intervention with these two physical activities could offer a choice of supportive care to breast cancer women undergoing treatment to improve quality of life, physical and psychological aspects. Trial registration: ClinicalTrials.gov Identifier: NCT03194997 (registration date: 12 August 2017). Universal Trial Number (World Health Organization): U1111-1195-1623. <https://clinicaltrials.gov/ct2/show/NCT03194997>

Background

Cancer has been considered a global public health issue [1,2]. Among the different types of cancer, breast cancer, specifically, is the most common among women worldwide [1,3]. In the Brazilian context, breast cancer is also considered the most incident type of cancer among women [4]. Following the many advances in breast cancer treatment, there has been an increase in the five-year survival rate from 78% to 87% over the past years in Brazil [4].

Despite the increase in the survival rate, breast cancer is a significant occurrence in a patient's life because of the serious side effects of clinical treatment [5], which compromise her functional capacity [6], and directly affect her quality of life [7]. Living with these symptoms can result in emotional and physical exhaustion for these women [8], so a healthy lifestyle that involves good nutrition and regular physical activity is essential to minimize the psychological and physical side effects of treatment [9].

Considering this context, physical activity after the diagnosis of breast cancer, besides being a protector factor, is also auxiliary to the clinical treatment, minimizing the collateral effects and improving the patients' recuperation [5,9]. The American College of Sports Medicine (ACSM) recommends at least 150 minutes of moderate physical activity or 75 minutes of vigorous activity per week for patients with cancer [10]. Resistance training twice a week is also recommended to improve general physical health [10, 11]. A metanalysis analyze 33 clinical trials regarding the benefits of physical exercise on psychological and physical aspects of women after breast cancer and recommend the physical activity at all treatment stages [12].

Among all the types of physical activity that can relate to the healthcare of women with breast cancer, exercise that involve mind and body can be beneficial for breast cancer women, as Pilates and dance [13, 14, 15]. These two types of activities are pleasant activities [16] that can promote emotional connections [17] and can be considered a moderate physical activity according to the ACSM recommendation.

The Pilates solo includes resistance and stretching exercises, synchronized with breathing and respecting the principles of control, precision, centering, fluidity of movement and concentration [18]. It promotes physical benefits for patients regarding functional capacity and muscle strength [19], and most exercises are performed in a position of dorsal decubitus [20] with control of the speed, precision and movement quality promoting the relaxing of the body [21]. Aspects that are considered consequences of breast cancer treatments, and therefore, their recovery becomes essential.

Dance accompanist with the music promotes movements with awareness of the body rhythms [22]. Belly dance, specifically, is directed only for women and is considered as a form of exercise that associates body and mind through body movements, especially involving the upper limbs, danced to the sound of traditional Arabic music [23, 24]. Because it is a dance that involves the worship of the earth and the woman's uterus, as well as the feminine sensuality [24, 25], it can act in the rescue of femininity, softness and beauty, exploring self-confidence and self-esteem of patients [23]. Because it is a modality that moves the upper limbs, by controlling the arms and using veils, tambourines, vessels, and in this way, it can promote physical benefits, considering the consequences of surgery and treatment which pass through these patients [26].

Both the Pilates solo and dance have been the targets of studies investigating physical exercise in patients after the diagnosis of breast cancer. Clinical trials that address the Pilates solo method demonstrate its benefits in several aspects such as improved quality of life, functional capacity and depressive symptoms after eight weeks [27], benefits in muscle strength, pain and upper limb functionality after eight weeks [19], improvement in external rotation [19] and shoulder abduction in patients

submitted to axillary emptying after 12 weeks of intervention [21] and improvement in shoulder range of motion, quality of life, body image and mood after 12 weeks [14]. None of these studies has published protocols in Pilates solo methods for breast cancer women.

There are several studies in the literature-involving the effects of dance in breast cancer [15, 17, 22, 26, 28-31, 32-34]. However, published protocols for this population have not been identified; only two of these studies are characterized as randomized controlled trials [22, 33]. The modalities investigated include specific dance therapy methods [15, 17, 28-30, 33]; classical ballet and jazz [31]; traditional Greek dance associated with the muscular strength training of the upper limbs [22]; also, the practice of circular dance [32] and ballroom dance for couples [33]. Belly dance is also investigated as a pilot study of our research group, identifying benefits in depressive symptoms, fatigue and quality of life of breast cancer women undergoing treatment and after treatment stage [26].

Thus, it is important to implement a specific protocol of dance and Pilates solo for patients with breast cancer since it has already been positively correlated to the health of women after diagnosis. For this study, belly dance was chosen as the modality of dance included in the protocol, considering the necessity of preserving the femininity of women during the disease [35]. Belly dancing can also address the physical and psychological needs of patients. Furthermore, this type of dance is a form of physical activity that associates the body and mind through movement, particularly involving the upper limbs, to the sound of traditional Arabic music [23-25]. This type of dance can also enhance the emotional aspects of women after the diagnosis of breast cancer since this practice involves expressive movements that facilitate the preservation of femininity, softness, beauty, trust, and security [23]. The Pilates solo was chosen because it favors lymphatic and blood drainage, improves posture, intensifies flexibility, and increases range of motion and muscular strength [36]. When breathing exercises are added, the proposed exercises stimulate the thoracic lymphatic system, and thus, they can promote a reduction in lymphedema, which improves muscle function and consequently improves quality of life [37].

This study protocol describes a randomized controlled trial of Pilates solo and belly dance (3x/week) for women after the diagnosis of breast cancer and compare its effects with the group without intervention. The hypothesis is that the Pilates solo and belly dance protocol will promote improvement in primary (quality of life) and secondary (psychological and physical) outcomes in women after the diagnosis of breast cancer, providing a beneficial activity option for women with breast cancer. Our second hypothesis is that Pilates will improve more physical variables as belly dance will improve psychological variables.

Methods

Study design

This is a single-center prospective, three arm randomized clinical trial to assess the Pilates solo and belly dance effects on the primary outcome quality of life, and secondary outcomes as physical aspects as cardiorespiratory fitness, lymphedema, physical activity, disabilities of the arm, range of motion, strength and flexibility and psychological aspects as depressive symptoms, body image, self-esteem, fatigue, pain,

sexual function, sleep quality of women undergoing clinical treatment of breast cancer. Participants will be randomized into either a Pilates solo intervention group, belly dance intervention group or the control group. This trial is registered at ClinicalTrials.gov with identifier NCT03194997. This study was conducted according to SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents (Supplementary material).

Participants

The study will be realized in the city of Florianopolis – Santa Catarina in Brazil, the participants of the study will be women who received the diagnosis of breast cancer and who are undergoing treatment in the Oncology Research Center (CEPON) at the time of data collection. The study is approved by the Research Ethics Committee in Human Beings (CEPSH) University of Santa Catarina State (UDESC) and for Ethics Committee of Oncologic Research Center (CEPON) by the Protocol No. 2.073.549 on May 19, 2017. Any important protocol modifications will be communicated not only to CEPH but also for the trial participants, trial registries and the journal submitted.

The group will receive an explanation of the stages of the study and after assenting to participation, will sign an informed consent form and then be provide an initial questionnaire for data collection.

Eligibility criteria

The inclusion criteria comprise: Women aged 18 years or older; Clinical stage 0 to III breast cancer; Be in adjuvant treatment with chemotherapy, radiotherapy or hormone therapy in CEPON at any time of the treatment cycle; Receive the release of the oncologist responsible for the practice of physical activity or the Physical Therapy sector of CEPON. Exclusion criteria include the diagnostic of some orthopedic or neurological limitation that prevents the practice of physical activity, as Parkinson disease, Alzheimer's or use of a wheelchair.

Sample size

To calculate the sample size, the method of distinguishing between the means was used, being: $n = (\alpha + \beta) 2 \sigma^2 / d^2$. The values of alpha ($\alpha = 0.05$) and beta ($\beta = 0.80$) were adhered to, which according to the Gauss curve table values of 1.64 and 0.84, respectively, were used. The difference between the means was obtained through the pilot study, and a variable considered for the calculation was a quality of life, in which an average of the difference between all the scales in the pre and post periods was found. This value of the expected selection was 6.15 ± 9.4 . The expected variance (σ^2) was 89.49. At the end of the analysis, after the inclusion of a 30% margin of sample loss, a sample of 19 patients was selected for each group.

Figure 1 shows the flow diagram of the study participants.

Randomization and blinding process

The randomization of the sample will be performed by one of the researchers, who should have access to a list of patients with breast cancer (stage 0 - III) who were in adjuvant treatment with hormone therapy at CEPON in the past three years, with the intention to achieve adequate participant enrolment to reach the target sample size. From this list, a randomization will be held in a website (<http://www.randomization.com>), which will predict the allocation of patients in the three groups: group A: intervention with belly dance; group B: intervention with Pilates solo; group C: control group, who will be invited to maintain their routine activities. The randomization will be stratified for age, dividing the patients between those minors and those over 60 years of age. Considering those older than 60 years of age, according to the Brazilian Statute of the Elderly, established by Law No. 10,741, dated October 1, 2003.

The data from the patients will be maintained only with the principal researcher to protect confidentiality before, during, and after the trial. Since the protocol is difficult to blind for the subjects and the instructors due no proper way to sham physical exercise, all the data analysis will be performed by an external researcher. In this way, at least the data analysis will not receive interference.

Pilates solo intervention

The women allocated to this group will participate in the Pilates solo protocol. The 16-week protocol will be implemented in 60-minute Pilates solo classes, three afternoons a week under supervision of an exercise science professional and a physiotherapist.

The Pilates protocol will be divided in three stages: (1) Warm-up and stretching: Include breathing, imprint and release, hip release, spinal rotation, cat stretch, hip rolls, scapula isolation, arm circles, head nods, elevation and depression of scapulae exercises during warm-up in all sessions.

(2) The main stage: A brief explanation of the purpose of the class will be provided and the exercises will take place as detailed in Table 2. To intensify the protocol, theraband and toning ball exercises will be added to the 10th session, in the 20th will be added the exercise in the arms and from the 24th session the exercise of the spinal rotation will be realized with weight of 1kg. Exercises will be performed according to each patient's ability (principle of sports training) to avoid pain (during and after exercising) and embarrassment associated with possible physical or even psychological and emotional difficulties.

(3) Relaxation: For this stage of the class the patients will be invited to saw on the ball, spine stretch forward on the ball, self-stretching of cervical muscles on the ball (upper trapezius and scalene muscles), and active mobilization of the cervical spine. At the end of each class, a brief discussion will hold on the women's perceptions regarding the objectives discussed in the beginning of class and whether they were achieved, and this data will be recorded by a third researcher to identify whether the participants enjoyed the class and felt that they achieved the objectives of the class.

To control the intensity of the Pilates solo protocol assuring that all the patients experience the same intensity of the intervention and to promote the safety of the practice of physical activity in these breast cancer patients, the heart rate (HR) control will be performed in every session using a Polar pro trainer 5. HR values will be checked in four moments of the class as after the beginning of the class (1), after the warming and stretching (2), after the main stage (3) and at the end of the class (4).

Belly dance intervention

Women allocated to this group will participate in the belly dance protocol. The 16-week protocol will be implemented in 60-minute belly dance classes, three afternoons a week under supervision of an exercise science professional and a physiotherapist.

The classes will be divided into three stages: (1) Warm-up and stretching: The beginning of the class will include songs with up to 80 beats per minute (bpm), thus identified as slow pace. The sequence of movements for this class stage will cover large movements for specific joints, including flexion, extension, abduction, adduction and rotation, initiated by the upper body until it reaches the lower limbs, lasting 10 minutes.

(2) The main stage: A brief explanation of the purpose of the class will be provided (i.e. the theory of dance or the specific step to be developed), followed by the practical part of the technical learning. The aim of this part will be for students to learn the movements of the belly dance technique, to stimulate motor coordination, rhythm, and body awareness, as well as to improve aspects of flexibility and range of motion (ROM) of the upper limbs. The practice of the movements will be explored using individual, pair, or group dynamics, involving movements corresponding to the rhythm of music or the rhythm stipulated for the women. The participants will have the artistic freedom to create their own pattern of movement based on the belly dance technique, while respecting their own body awareness and allowing the expression of feelings. The evolution of the belly dance technique will be applied as outlined in Table 1. For this part of the classes, medium-paced music with up to 120 bpm will be use, as well as fast-paced music with up to 150 bpm. This part of the class will have an average duration of 40 minutes.

(3) Relaxation: This stage will be developed from slow-moving practices, with music up to 80 bpm, usually the same songs used in the initial warm-up and stretching. With heart-rate normalization, this part will last 10 minutes. At the end of each class, a brief discussion will hold on the women's perceptions regarding the objectives discussed in the beginning of class and whether they were achieved, and this data will be recorded by a third researcher to identify whether the participants enjoyed the class and felt that they achieved the objectives of the class.

Verification of the songs' rhythm was performed by measure the beats per minute (bpm), according to the ballroom dance protocol used in the study by Braga et al (2015) [38]. The songs will be categorized in

groups: slow (up to 80 bpm), medium (up to 120 bpm), and fast (up to 150 bpm). The performance score was calculated using the bpm Detector Pro application.

To control the intensity of the belly dance protocol assuring that all the patients experience the same intensity of the intervention and to promote the safety of the practice of physical activity in these breast cancer patients, the heart rate (HR) control will be performed in every session using a Polar pro trainer 5. HR values will be checked in four moments of the class as after the beginning of the class (1), after the warming and stretching (2), after the main stage (3) and at the end of the class (4).

Control group

Women allocated in this group will be asked to continue their routine activities during the 16-week intervention period. They will be contacted every two months by telephone. It will be also offered to this group three meetings during the 16 weeks of intervention, the first meeting will focus on stretching exercise to develop at home, a second meeting will be about self-esteem and the last meeting will be about prevented of lymphedema. These meetings will occur with the purpose of promoting to these women talking and sharing experiences with other women with breast cancer and make sure that they also receive health educational information, as they will not receive the exercise intervention in the first phase of the study. These meetings were an exigence of the Ethics Committee of the CEPON, hospital that will take place the study in Brazil to ensure that the control group also receive possible benefits of the study. Likewise, this strategy can improve the adherence of the control group as they will feel as a group and make social binds.

Both groups, experimental (Pilates solo and belly dance) and control group, will receive after the 16 weeks of intervention an explanatory booklet on the benefits of practicing physical activity after the breast cancer diagnosis, as well instruction on the prevention of lymphedema. As a strategy to improve adherence of the subjects on the trials, all the patients will be invited to social meetings, groups in social medias, thematic classes according with specific dates (E.g Carnival, Easter, Halloween, Christmas), and receive a T-shirt from the Project at the first meeting. Additionally, direct contact with the subjects that miss a class will occur via SMS and phone calls. These activities are planned to make the subjects feel familiar with the trial environment. For the 2-year follow up the intervention and control group will be invited to a physical activity program organized by the university. They will also be contacted through social media and SMS once in a month to motivate the practice of physical activity and to remind of future data collections. After the end of the study besides the publication in academic journals the main results will be presented at the Hospital in Brazil and shared with the patients in brochure format.

Figure 1 presents the participant selection process and the execution of the steps of the protocol.

Assessment

Primary outcome measure

The main aim of the study is to evaluate the impact of 16-week Pilates solo and belly dance protocol on quality of life change ($\geq 2\%$ of the baseline scores) in breast cancer patients undergoing clinical treatment. The quality of life is the primary outcome at all time points of the study, namely baseline, right after intervention, 6-month, 12-month and 24-month after intervention. The quality of life will be the primary outcome since it involves all the physical and psychological aspects of the life of breast cancer women. Therefore, the maintenance collection will take place considering the modification in quality of life and other outcomes that the Pilates solo and belly dance intervention can promote in these women.

The primary outcome quality of life will be investigated by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30 (EORTC QLQ-C30) [39]. This instrument was created by European Organization for Research and Treatment of Cancer (EORTC) in 1986, and this is the third version. Validated to cancer population by Michels; Latorre; Maciel (2013) [40], with Cronbach alpha of 0.72 for health global scale, 0.86 for functional scale and 0.81 for symptomatic scale.

The instrument consists of 30 questions, being multidimensional and self-applied, its objective is to evaluate the quality of life in patients with cancer in the last four weeks. It presents five functional scales (physical, functional, emotional, social and cognitive), a scale on global health status, three symptom scales (fatigue, pain and nausea/vomiting) and six additional symptom items (dyspnea, appetite, constipation, diarrhea and financial difficulties). The answers are presented in the form of Likert scale following the classification: 1 – Not at all, 2 – A little, 3 – Quite a bit and 4 – Very much. The only exception applies to the global health scale. This is composed of two questions that ask the patient to rate both their health and their quality of life in the last week, in a grade of 1 to 7. In this case, 1 would be a poor quality of life and 7 a good quality of life.

The EORTC QLQ-C30 is complemented by specific cancer modules. In this study, the breast cancer module - QLQ BR-23, validated for the Portuguese language by Michels, Latorre and Maciel (2013) [40], with a Cronbach alpha of 0.78 and 0.83 will be used. The QLQ BR-23 consists of 23 questions incorporated into multi-item scales. It measures the functional scales (body image, sexual functioning, sexual enjoyment and future perspective) and symptom scales (systemic therapy side effects, arm symptoms, breast symptoms and upset by hair loss). Classifications are also in the range of 0 to 100, where values closer to 100 for the functional scale indicate better patient functionality, and values closer to 100 for the symptom scales range show higher presence of symptoms.

Other outcome measures

As secondary outcomes will be evaluated the physical and psychological variables associated with the quality of life. The physical outcomes are cardiorespiratory fitness, functional capacity, lymphedema, disabilities of the arm, range of motion, strength, flexibility and physical activity. In addition, the psychological outcomes are depressive symptoms, pain, fatigue, body image, self-esteem, sexual function and sleep quality.

Cardiorespiratory fitness

To assess the cardiorespiratory fitness, an submaximal incremental exercise test (85% of maximum heart rate - HRmax) will be performed using a cycle ergometer (Lode Excalibur Sport, Groningen, the Netherlands). The protocol will start with a power of 20W, and in every 3 minutes, 15W will be added, until the patient reaches 85% of his HRmax, which will be identified through the equation $(207 - 0.7 * \text{age})$ [41]. In the initial three minutes of the test, the patient will be asked to remain in a rest position, accommodated in the cycle ergometer, to identify the values of resting heart rate and oxygen consumption. Patients will be asked to maintain the rotation per minute (RPM) of the cycle ergometer always above 60 RPM. Expiratory gases and flow volume will be collected during the test and analyzed by calibrated metabolic system (Quark CPET Ergo, Cosmed, Rome, Italy) to provide measurements of oxygen consumption. The heart rate will be monitored by a POLAR mark frequency and will be observed within the first three minutes of the test and at the end of each minute of the three-minute test stages. Also, every three minutes, the patient will be questioned about her perception of the exercise, through the Subjective Perception Scale of Effort - Borg Scale 6-20 points [42]. This scale ranges from six to 20 points, where the sixth position would be the perception of "very easy" and 20 the "exhaustive".

The 6-minute walk test measures the distance a person can travel on a flat, rigid surface in six minutes. It's main objective is to determine the tolerance to exercise and oxygen saturation during a submaximal exercise [43]. Patients are asked to walk at their own pace as fast as possible during the six minutes, being allowed to walk slowly, stop and / or rest when necessary, and return to walking when they feel fit.

Lymphedema

The evaluation of lymphedema will be developed by calculating the arm volume, performed by measuring the circumferences of both upper limbs, at five points distributed along the arm and forearm: at 21 cm and 11.5 cm above the olecranon; to 7.5 cm, 14 cm and 24 cm below the olecranon. The circumference will be obtained, with the patient sitting, keeping the arm in abduction, flexed forearm and hand resting on the chest. These measures are used to calculate the approximate volume of the five truncated cones formed at the points of circumference measurements. The sum of these five parts gives the total limb volume [44].

Disabilities of the arm

Evaluated through the Disabilities of the Arm, Shoulder and Hand (DASH) scale developed by Hudak et al. (1996) [45] and translated and validated for Brazil by Orfale et al. (2005) [46]. This instrument was developed to assess the disability and symptoms of single or multiple upper limb disorders. It contains 30 questions, involving activities of daily living, symptoms of pain, tingling and stiffness and questions about social factors, work, sleep and self confidence. Used in other studies with patients with breast cancer [19].

Range of motion

To verify the range of motion, evaluations of flexion, abduction, and external rotation of the shoulder according to previous studies with breast cancer patients [47], using the digital goniometer (Absolute Axis 360°). The protocol used by Marques (2003) [48] to perform the range motion assessment will be performed. The shoulder flexion movement will be performed with the subject lying down, the flexion movement will be performed with the palm facing medially parallel to the sagittal plane, the fixed arm of the goniometer will be placed along the axillary line of the trunk and the movable arm is placed on the lateral surface of the humerus body facing the lateral epicondyle. For abduction the individual must be seated. When performing the abduction movement, the palm of the hand will face anteriorly parallel to the frontal plane, the fixed arm of the goniometer should lie on the axillary line and posterior to the trunk and the movable arm on the posterior surface of the arm of the individual. In order to perform the external rotation, the position of the individual and the goniometer are the same, the individual will lie in the dorsal position and the shoulder will be in an abduction of 90°, with the elbow flexed at 90° and the forearm in supination. The arm of the goniometer lies in the olecranon and the movable arm over the posterior region of the forearm directed to the third finger of the hand.

Strength of the upper limb

The muscle strength of the upper limb on both arms will be measured by the Chatillon® portable digital dynamometer, which can measure overall appendicular muscle strength and all body segments [49]. This equipment provides the value of the peak of isometric maximum force exerted by the evaluated segment, and for this it requires a generation of fast force, that does not fatigue the muscle. The maximum force generated is registered in Newtons. The muscle groups responsible for flexion, extension, abduction, adduction, internal rotators and external rotators of the shoulder will be evaluated. The dynamometer will be placed over the specific location and patients will be asked to perform force against the equipment for up to five seconds. Each muscle group will be evaluated three times, and the mean value of these evaluations will be used [50], with a thirty second interval between the tests, and bilaterally. In all cases, the patients will be instructed before the start and during the repetitions, on the specific position.

Flexibility

"Sit and Reach" test, which allows assessing the flexibility of the coxo-femoral joint [51]. The Sit and Reach box should be supported on a wall, and for evaluation the patient is asked to keep the knees extended, bare feet resting Sit and Reach box, and hands overlapped on the horizontal surface of the box. It should perform an anterior flexion of the spine, keeping the head between the arms, without flexing the knees, revealing a pause in the moment it reaches the maximum of the dotted line. Three replicates are performed, and it is considered the best mark among the three.

Physical activity

The physical activity level will be investigated through the International Physical Activity Questionnaire (IPAQ - short version) [52]. The Brazilian validation and reproducibility were performed by Matsudo (2001) [53] and had significant Spearman correlation and high reproducibility ($\rho = 0.69 - 0.71$: $p < 0.01$) and

validity, of 0.75 observed in comparison to the instrument Computer Science & Applications (CSA). It consists of six items that seek to verify the number of times the subject has practiced at least 10 continuous minutes of walking, moderate and vigorous physical activity, in the last week, in diverse involvements, namely, labor, domestic, leisure, recreational and sports. After completing the questionnaire, the participants can be classified into: Sedentary; Insufficiently Active; and Very Active. The IPAQ also addresses the sitting time of individuals, on weekdays and on weekends. There are two specific questions that ask: (1) How much time in total do you spend sitting on a weekday; and (2) How much time in total do you spend seated during on a weekend day; Data are presented in minutes per week and minutes per week.

Depressive symptoms

Investigated using the Beck Depression Inventory (BDI), that is a self-report questionnaire originally developed by Beck et al. (1961) [54]. It was validated in Brazil [55] and factorially validated for cancer patients, indicating a Cronbach alpha of 0.82 [56]. Contains 21 multiple-choice objective questions related to depressive symptoms, in detail: sadness, pessimism, feeling of failure, dissatisfaction, guilty feelings, punishment feelings, self-dislike, self-criticism, suicidal thoughts, crying, irritability, withdrawal from family or friends [56]. Each question provides four response options, ranging from zero to three (0-3). The sum of the scores of each question provides a total score, ranging from zero to 63, and the closer to 63, the greater the presence of depressive symptoms, indicating a high degree of depression, and the greater the proximity to the zero greater absence of depressive symptoms.

Pain

The Visual Analogue Scale (VAS) will be used. VAS is a one-dimensional measure for assessing pain intensity. Composed of a 10 cm line, with anchors at both ends, at one end of the line is marked "no pain" and the other "worst pain imaginable". The magnitude of the pain is indicated by marking the line and a ruler is used to quantify the measurement on a scale of 0-100mm [57].

Fatigue

Investigated by the Functional Assessment of Cancer Therapy-Fatigue instrument (FACT-F). Validated in Brazil [58] showing an internal consistency of 0.91 for fatigue, and 0.92 for the total FACT-F and the total Cronbach's alpha 0.92. It is a self-report instrument aimed at patients with cancer that includes 13 items related to the perception of fatigue. Individuals will be asked to respond to each item with a score of 0 to 4, where 0 to 4, where 0 = not at all, 1 = a little bit, 2 = somewhat, 3 = quite a bit, and 4 = very much. In the total score the possible interval is between 0 and 52, being that, a higher score indicates a level of less perceived fatigue.

Body image

Addressed by the Body Image After Breast Cancer (BIBCQ) questionnaire originally developed in Canada [59] which was translated, validated and culturally adapted in Brazil [60] with values of Cronbach's alpha

for detailed internal validity for each scale, namely, vulnerability (0.77), body stigma (0.86), concerns about the body (0.83), transparency (0.80), concerns about the arm (0.67) and limitations (0.72). This instrument aims to evaluate the body image after the diagnosis of breast cancer and can provide information related to the perceptions and attitudes regarding the side effects of breast cancer in the life of these patients. The BIBCQ is a questionnaire considered self-applicable, in which each item can be answered using the Likert scale. It consists of 44 questions divided into six scales, namely: vulnerability, body stigma, limitations, concerns about the body, transparency, and concerns about the arm. In the end, the higher the score reaches, more compromised is the patient body image.

Self-esteem

The Self-Esteem Scale (EAR) developed by Rosenberg (1965) [61] will be used. This scale was validated for the population with cancer [62], and in Brazil [63]. It also received a validation review [64] with Cronbach alpha of 0.90. It is a one-dimensional measure consisting of ten statements related to a set of feelings of self-esteem and self-acceptance that determine the global self-esteem. The total scale score varies from 10 to 40 points, and the following form is used as categorization: (1) satisfactory or high self-esteem, those that presented a score greater than 31 points; (2) mean self-esteem, those that resulted in their total score between 21 and 30 points; and (3) unsatisfactory or low self-esteem, those with scores lower than 20 points. It is understood in this way, that the greater the value reached by the woman on the scale the better her self-esteem.

Sexual function

Evaluated by the Female Sexual Function Index (FSFI) with cross-cultural validation [65], revealing a Cronbach alpha of 0.96. Also validated internationally for patients with breast cancer [66] with Cronbach alpha of 0.70. This questionnaire consists of 19 questions, grouped into six areas: desire, excitement, lubrication, orgasm, satisfaction and pain. The sexual function score, at the end of the analysis, can vary from two to 36 points, considering that the higher the score obtained, the better the sexual function of the woman.

Sleep quality

Evaluated by the Pittsburgh Sleep Quality Index. Validated [67] with Cronbach alpha 0.76. This instrument is composed of seven sleep-related areas: subjective quality, latency, duration, habitual efficiency, disturbances, use of sleeping medication and daytime sleepiness. Scores range from zero to 21 and correspond to overall sleep quality. In the end, scores up to five determine a good sleep quality and scores greater than five points distinguish poor sleep quality.

Descriptive and control variables

The descriptive and control variables were divided into clinical variables (cancer stage, characteristics of treatment, previous clinical treatment, characteristics of surgical intervention, mammary reconstruction, date of surgery, presence of lymphedema, physiotherapy and other diseases), sociodemographic

variables (age, education, marital status, economic level and occupation) and anthropometric measures (height and body mass). The descriptive and control variables will be acquired by self report.

The variables of the study regarding the Pilates solo and belly dance protocol are present in Table 3 and in Figure 2.

Insert Table 3 and Figure 2.

Data collection

Data will be collect using an interview format and physical tests. The principal investigator of the study, who received previously training, will conduct a 50-minute interview. The questionnaire will cover general and clinical information, quality of life and psychological variables. The physical variables will be investigated by the specific tests. All data collection will be administered before the beginning of the intervention (baseline collection) and right after the conclusion of the program (post-intervention collection), also, 6-month, 12-month and 24-month after intervention (maintenance collection). (See Figure 1). The maintenance collection will take place considering the health behavioral change that the belly dance and Pilates solo intervention can promote in breast cancer women.

For control group, data collection will be conduct using the same questionnaire and tests applied to the intervention group, with data on general and clinical information, quality of life, physical and psychological variables. The collection will be schedule with the participants and will take place at the same intervals as for the experimental group, before the start of the intervention (baseline collection) and after completion (post-intervention collection) by the same principal investigator, also, 6-month, 12-month and 24-month after intervention (maintenance collection). All the data collection of intervention and control group will occur at Santa Catarina State University.

Patients that discontinue intervention or control group that did not show for meeting, will be collect as well and analyzed as intention to treat group. During the intervention and data collection the researchers will collect spontaneously feedback from the patients to guarantee that the study will not have any adverse events.

Statistical Analysis

First, a spreadsheet will be created using the Excel 2016, from which the data will be transfer to SPSS version 20.0 for the analysis. Descriptive statistics (mean, standard deviation, and percentage) for the characteristics of the sample will be compute. To investigate the relationship between general and health information in the control and experimental groups, Chi-Square or Fisher's exact tests will be used. To analyze differences in the experimental and control groups in the baseline, post intervention, and in the maintenance periods, a two-way ANOVA with repeated measures and Sydak comparison tests will be conduct. Confounders variables will be considered in the analyses, as type of treatment, type of surgery, age and weight status. The analysis will occur according to the protocol and to intention to treat, meaning

that all the patients will be evaluated according to the randomization process. For handle with missing data it will be used the multiple imputation method. The significance level will be set at 5%.

Discussion

We presented a 16-weeks Pilates solo and belly dance protocol for women after breast cancer diagnosis. In the context of breast cancer, the benefits of physical activity are established in the literature. The systematic reviews reported improved quality of life and cardiorespiratory capacity and reduced fatigue after practice of physical exercise during breast cancer treatment [12, 68-70]. Considering the context, the proposal of this study is present a protocol of Pilates solo and belly dance (3x/week) for women after the diagnosis of breast cancer and compare its effects with the group without intervention, considering that these are two kinds of activities that valorize mind and body, and can bring to different outcomes and benefits for breast cancer women [71].

Dance can represent both psychotherapeutic treatment and a form of physical activity, based on body awareness, expression, and acceptance, to facilitate physical, emotional, cognitive, and spiritual integration [17]. Moreover, through the socialization context promoted by dance, benefits are revealed in relation to decreased feelings of loneliness and misunderstandings with others [30]. Pilates as well, was created by Joseph Pilates as a method based on Eastern mind-body-spirit theories combined with Western theories, according to the following six principles: centralization, control, concentration, fluidity, breathing, and precision [71]. Its practice provides shoulder and pelvis stability and improves posture, stretching capacity, muscular strength, and mind-body connection [36].

In a systematic review of dance and breast cancer published by our group, we identified dance as a viable alternative of adjuvant treatment for patients who have passed through breast cancer, as well as claiming that it can promote psychological benefits and improve strength and range of motion of the upper limbs [73]. In this scenario, studies involving dance and breast cancer may involve specific dance therapy methods [15, 17, 28-30, 33]; traditional dance techniques, such as classical ballet and jazz [31]; the practice of traditional Greek dance associated with the training of the upper limbs [22]; as well as circular dance [32] and ballroom dance [33]. However, none of these studies presented published protocols, demonstrating the importance of a belly dance protocol for women after the diagnosis of breast cancer. And further publication of a belly dance protocol will improve the possibility of generalization of the study, assuring the external validity.

The use of the Pilates method in patients with breast cancer was evaluated by a systematic review of four studies and determined that the method implies an improvement in patients' range of motion, pain and fatigue [74]. Other evidences related to the benefits of the Pilates method for the health of these women reported improved quality of life, reduced pain and fatigue, decreased lymphedema, and increased upper limb functionality [21, 27, 37, 75]. These studies published on Pilates interventions but there is no protocol study for women with breast cancer. Also further publication of a Pilates solo protocol will improve the possibility of generalization of the study, assuring the external validity.

Methods of dance therapy are generally similar, taking advantage of subjective approaches to the perceptions of body and movement fluency in relation to feelings [15, 17, 28-30, 33]. These methods can comprise the use of conscious walks and drives, verbal feedback, exploration of specific body parts, different movement intensities (light and slow to energetic and active), and work in pairs [28]. These studies have shown positive results in relation to psychological and physical aspects of women after the diagnosis of breast cancer. However, they do not include the validation of a protocol, which, therefore, does not allow the study to be replicated by other researchers and does not indicate the frequency, duration, or intensity of the movements, as well as the beats per minute of the music used.

The belly dance protocol presented in this study addresses a form of dance that has predetermined movements and specific techniques and was developed following a specific progression to the correct learning model. In this sense, belly dance was chosen as the model for the intervention protocol for being an enjoyable practice that involves an intimate relation between movement and emotion. Also preserves the female identity and awakens a spontaneous body language, with beneficial movements that respect the individuality of each practitioner. Belly dance is also characterized as a practice that offers intense movement of the upper limbs [23-25], which directly benefits women; addressing limitations caused by the disease, such as the development of lymphedema and decreased range of motion. A pilot study was developed by the research group itself and has been shown to be an effective possibility for interventions with breast cancer patients [26], in the pilot study the intervention was only performed for 12 weeks, often twice weekly and with 60 minutes of duration per session, but already demonstrated benefits in breast cancer on quality of life, depressive symptoms and fatigue. Also, the adherence was 78,6% (IC95%: 71.3 - 85.9).

The Pilates intervention protocol presented here has not been yet performed in women with breast cancer, and it is of great relevance as an adjuvant therapy in the treatment of these women. The protocol was developed to achieve the great benefits reported in the international literature, including improvement in quality of life and reduction in the physical and psychological effects of adjuvant breast cancer treatment. In addition, this protocol influences and encourages the practice and maintenance of physical activity after treatment, as the practice of physical activity reduces the risk of breast cancer recurrence [76]. The exercises include stretching of the upper and lower limbs, upper limb mobility, and strengthening of the upper and lower limbs and abdomen, with consideration and respect for each patient's limit and most exercises are performed in the supine position, avoiding impact to the joints.

The time of intervention of 16 weeks for this protocol was chosen considering the pilot study [26] and the systematic review of breast cancer and dance [73] and Pilates [74]. The pilot study of 12 weeks showed psychological benefits to breast cancer women, and the classes were developed in 24 sessions. Therefore, to improve physical and psychological aspects in this protocol it was decided to explore the double of sessions, leading to a 48 sessions protocol, in 16 weeks. In the systematic review of dance and breast cancer it was demonstrated that interventions were performed with a range of three to 24 weeks, with one to three sessions a week and one to three hours per session. It was also observed that most of the studies identified in the systematic review about Pilates and breast cancer had their interventions with

a total duration of eight weeks, frequency of three times weekly and sessions of 45 to 60 minutes [74]. Thus, as average of these findings we also propose 16 weeks with three 60-min sessions per week.

Due to the lack of a systematic and specific protocol for patients with breast cancer and the importance of acting with adjunctive treatment, a Pilates solo and a belly dance intervention protocol was developed to improve quality of life, as well as to mitigate the psychological and physical outcomes of women after breast cancer diagnosis. For being two kinds of physical activity that is known worldwide, there is the possibility of application in other locations. Finally, Pilates solo and belly dance are characterized as important physical activity option for this population that can minimize the side effects of the disease and its treatment, assisting in the patients' recovery.

Trial Status

Protocol version: 1 Date: May 17, 2019

Active recruitment: January 2019, Enrolling by invitation.

Recruitment will be completed at July, 2019.

Declarations

Ethics approval and consent to participate

The study is approved by the Research Ethics Committee in Human Beings (CEPSH) University of Santa Catarina State (UDESC) and for Ethics Committee of Oncologic Research Center (CEPON) by the Protocol No. 2.073.549 on May 19, 2017. Any important protocol modifications will be communicated not only to CEPH but also for the trial participants, trial registries and the journal submitted. It will be obtained written informed consent from all participants in the study.

Consent for publication

Not applicable.

Availability of data and materials

Data are available on request to the authors.

Competing interests

The authors declare that they have no competing interests.

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for the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Author's contributions

LB conceived of the study, initiated the study design, developed the methodology, commented on initial drafts of the manuscript; TBF conceived of the study, initiated the study design, developed the methodology, commented on initial drafts of the manuscript; MCSV initiated the study design, developed the methodology; GSP initiated the study design, developed the methodology, commented on initial drafts of the manuscript; JM initiated the study design, developed the methodology, commented on initial drafts of the manuscript; FFS initiated the study design, commented on initial drafts of the manuscript; AB initiated the study design, commented on initial drafts of the manuscript; FB initiated the study design, commented on initial drafts of the manuscript; MD initiated the study design, commented on initial drafts of the manuscript; ACAG initiated the study design, commented on initial drafts of the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1. Sixteen-week (48 sessions) of Pilates solo protocol for women after breast cancer diagnosis. (Florianopolis - SC, Brazil - 2018)

Week	Session	Description of the activity
1	1	Explanatory Session: What is Pilates, the basic principles of Joseph Pilates: breathing, centering, control, precision, fluency, and concentration. Clarify the positions: positioning of the pelvis, positioning of the rib cage, stabilization and movement of the shoulder girdle and positioning of the head and cervical spine
	2 and 3	Single leg stretches, obliques (with feet flat on the floor), scissors, obliques roll, one leg circle, side kick, preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1kg.
2	4	Single leg stretches, obliques (with feet flat on the floor), scissors, obliques roll, one leg circle, side kick, preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1kg, single leg extension e roll up.
	5 and 6	Half roll back (with over ball in the lumbar spine), roll up (pressing the magic circle with your hands), single leg stretch (with over ball between the shoulder blades), one leg circle (with TheraBand around the thigh with both knees flexed), preparation shoulder bridge tightening the over ball between the knees and performing simultaneously exercises of biceps with weight of 1kg, hell squeeze prone (pressing magic circle on ankles), side kick, spine twist.
3	7	Half roll back (with over ball in the lumbar spine), roll up (pressing the magic circle with your hands), single leg stretch (with over ball between the shoulder blades), one leg circle (with TheraBand around the thigh with both knees flexed), preparation shoulder bridge tightening the over ball between the knees and performing simultaneously exercises of biceps with weight of 1kg, hell squeeze prone (pressing magic circle on ankles), side kick, spine twist.
	8 and 9	Half roll back, single leg stretches, double leg stretches, preparation shoulder bridge (with feet on top of the ball), top leg abduction, top leg circles, staggered legs, both legs together.
4	10	Half roll back, obliques (with your feet on the floor, tightening the over ball and extending the lower member to the side of the rotation of the trunk), double leg stretch, scissors (with over ball in sacral region), preparation shoulder bridge (with feet on top of the ball), top leg circles, both legs together.
	11 and 12	Obliques roll (with magic circle the knees), hundred (with feet on the floor), obliques (with your feet on the floor and tightening the over ball between the knees, jack knife, both legs together e lateral flexion.
5	13	Obliques roll (tightening magic circle between knees), hundred (with feet on the floor), jack knife, top leg abduction (with the lower limbs within the magic circle), top leg circles, staggered legs (with the lower limbs within the magic circle).
	14 and 15	Roll up (with TheraBand on feet), slow double leg stretch, double leg stretch, preparation shoulder bridge (with feet on top of the ball), preparation shoulder bridge (with feet on top of the ball and performing extension and flexion of the knees), side kick (with ankle weights).
6	16	Hundred (with the feet on the floor), roll up (with TheraBand on feet), rolling like a ball, saw, preparation shoulder bridge (with feet on top of the ball), preparation shoulder bridge (with feet on top of the ball and performing extension and flexion the knees), double leg kick.
	17 and 18	Single leg stretches, obliques, roll over, preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1kg, hell squeeze prone (with magic circle on our ankles) and spine stretch forward with pressing the magic circle with your hands.

7	19	Hundred (with the feet on the floor and tightening magic circle between knees), single leg stretches, roll over, preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1kg, shoulder bridge and spine stretch forward with pressing the magic circle with your hands.
	20 and 21	Side bend with knees supported, hundred (with hip and knees flexed 90°), scissors with over ball in the sacral region, obliques roll (with weight of 1kg), sing leg extension (with 1kg ankle weights), jack knife.
8	22	Hundred (with hip and knees flexed 90°), obliques roll (with weight of 1kg), lateral flexion, sing leg extension (with 1kg ankle weights), jack knife and hip twist with supported ribs.
	23 and 24	Roll up tightening magic circle, hundred (with hip and knees flexed 90°), obliques, slow double leg stretch, preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1kg, one leg kick with 1kg ankle weights, breast stroke with weight of 1kg, side kick with 1kg ankle weights and lateral flexion.
9	25	Roll up tightening magic circle, hundred (with hip and knees flexed 90°), roll up with weight of 1kg, slow double leg stretch, roll over, preparation shoulder bridge performing simultaneously exercises of biceps with weight of 2kg, one leg kick with 1kg ankle weights, side kick with 1kg ankle weights and lateral flexion.
	26 and 27	Hundred (with hip and knees flexed 90° and magic circle on our ankles), double leg stretch, open leg rocker, scissors in air, teaser (with feet flat on the floor), seal, preparation shoulder bridge with feet on top of the ball and performing simultaneously exercises of biceps with weight of 1kg and spine stretch forward.
10	28	Hundred (with hip and knees flexed 90° and magic circle on our ankles), double leg stretch, scissors in air, teaser (with feet flat on the floor) swimming, hip twist (with the ball between the ankles performing knee flexion and extension), side kick kneeling, preparation shoulder bridge with feet on top of the ball and performing simultaneously exercises of biceps with weight of 1kg, twist with knees on the floor, spine stretch forward.
	29 and 30	Hundred, side bend, obliques roll with weight of 1kg, side bend, spine twist, swimming with weight of 1kg, top leg abduction with 1kg ankle weights, top leg circles with 1kg ankle weights.
11	31	Hundred, side bend, scissors with over ballin sacral region, side bend, spine twist, swimming with weight of 1kg, top leg abduction with 1kg ankle weights, top leg circles with 1kg ankle weights.
	32 and 33	Half roll back, roll up, obliques, bicycle in air, teaser (with feet flat on the floor), side kick kneeling with 1kg ankle weights, one leg circle with 1kg ankle weights, staggered legs with 1kg ankle weights, both legs together with 1kg ankle weights and lateral flexion.
12	34	Shell stretch, half roll back, roll up, obliques, teaser (with feet flat on the floor), one leg circle 1kg ankle weights, staggered legs 1kg ankle weights both, legs together with 1kg ankle weights and lateral flexion.
	35 and 36	Scissors in air, hundred (with magic circle on our ankles), single leg stretch, teaser (with feet flat on the floor), rolling like a ball, swan dive (with hands supported without elevation of lower limbs), preparation shoulder (performing simultaneously exercises of biceps with weight of 1kg), shoulder bridge and side kick with 1kg ankle weights.
13	37	Teaser (with feet flat on the floor), hundred, double leg stretches, open leg rocker, swimming, side kick kneeling, preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1kg, one leg circle with 1kg ankle weights, staggered legs with 1kg ankle weights.
	38 and	Hundred, scissors with over ball in the sacral region, obliques roll (with weight of 1kg),

	39	swimming, lateral flexion, sing leg extension with 1kg ankle weights, side kick with 1kg ankle weights, shoulder bridge.
14	40	Hundred, single leg stretches, obliques, roll over, preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1kg, shoulder bridge, hell squeeze prone (with magic circle on our ankles), spine stretch forward (with hands on top of the magic circle performing a pressure) and swimming.
	41 and 42	Half roll back, roll up, obliques, rolling like a ball, bicycle in air, one leg circle with 1kg ankle weights, staggered legs with 1kg ankle weights, both legs together with 1kg ankle weights and shoulder bridge.
15	43	Hundred, roll up, slow double leg stretch, double leg stretch, breast stroke, saw, preparation shoulder bridge (with feet on top of the ball), preparation shoulder bridge (with the feet on the ball performing extension and flexion of the knees) and double leg kick with 1kg ankle weights.
	44 and 45	Hundred, side bend, scissors with over ball in the sacral region, obliques roll with weighing 1kg, preparation shoulder bridge with the feet on the ball performing simultaneously exercises of biceps with weight of 1kg, top leg abduction with 1kg ankle weights and top leg circles with 1kg ankle weights
16	46	Scissors in air, teaser (with feet flat on the floor), hundred (with magic circle on our ankles), single leg stretch, bicycle in air, rolling like a ball, swan dive with the hands supported without elevation of lower limbs, one leg circle with 1kg ankle weights, staggered legs with 1kg ankle weights, preparation shoulder bridge with the feet on the ball performing simultaneously exercises of biceps with weight of 1kg.
	47 and 48	Hundred, double leg stretches, breast stroke, rolling like a ball, saw, preparation shoulder bridge (with feet on top of the ball), preparation shoulder bridge (with the feet on the ball performing simultaneously exercises of biceps with weight of 1kg) and single leg stretch with 1kg ankle weights.

Source: Made by the authors. Warm up - Classes 2 to 7 - breast stroke preparation (hand by hips) and preparation abdomen; Classes 8 to 22/ 38 to 40/ 43 and 47 - breast stroke preparation (hand by shoulders) and preparation abdomen; Classes 23 to 37/ 41 and 42/ 44 to 46 - breast stroke preparation (hands under forehead) and preparation abdomen; Class 48 - breast stroke preparation (hand by shoulders) and preparation abdomen (with over ball between the knees).

Table 2. Sixteen-week (48 sessions) of belly dance protocol for women after breast cancer diagnosis. (Florianopolis - SC, Brazil - 2018)

	Session 1	Session 2	Session 3
	Slow songs (Up to 80 bpm)	Slow songs (Up to 80 bpm)	Slow songs (Up to 80 bpm)
	Medium songs (Up to 120 bpm)	Medium songs (Up to 120 bpm)	Medium songs (Up to 120 bpm)
	Fast songs (Up to 150 bpm)	Fast songs (Up to 150 bpm)	Fast songs (Up to 150 bpm)
1	Belly dance presentation	Belly dance presentation	Belly dance presentation
2	Loosening of hips	Loosening of hips	Pendulum and side hit
3	Pendulum and side hit	Movements and steps sequence	Pendulum and side hit with displacement
4	Pendulum and side hit with displacement	Undulations and round	Movements and steps sequence
5	Undulations and round	Undulations and round with displacement	Movements and steps sequence
6	Undulations and round with displacement	Egyptian basics and twist	Movements and steps sequence
7	Egyptian basics and twist	Shimis and variations	Shimis and variations
8	Displacements, rotations, and use of space	Displacements, rotations, and use of space	Movements and steps sequence
9	Study of Arabic Dabke folklore	Study of Arabic Dabke folklore	Movements and steps sequence
10	Dance pitcher	Dance pitcher	Movements and steps sequence
11	Dance Tambourine	Dance Tambourine	Movements and steps sequence
12	Study of Arabic Khalije folklore	Study of Arabic Khalije folklore	Movements and steps sequence
13	Dance with the veil	Dance with the veil	Movements and steps sequence
14	Study of Arabic Dabke folklore	Dance Tambourine	Study of Arabic Khalije folklore
15	Dance with the veil	Movements and steps sequence	Displacements, rotations, and use of space
16	Review of all the movements	Review of all the movements	Review of all the movements

Source: Made by the authors. bpm: beats per minute.

Table 3. Study assessments.

Outcomes	Instruments	Visits					
		Baseline	Post intervention	3-month	6-month	12-month	24-month
<i>Primary</i>							
Quality of life	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30 (EORTC QLQ - C30) and Specific for Breast Cancer (EORTC QLQ-BR23)	√	√	√	√	√	√
<i>Other outcomes</i>							
<i>Psychological</i>							
Depressive symptoms	Beck Depressive Inventory (BDI)	√	√	√	√	√	√
Pain	Visual Analogue Scale (VAS)	√	√	√	√	√	√
Fatigue	Functional Assessment of Cancer Therapy-Fatigue (FACT-F)	√	√	√	√	√	√
Body image	Body Image After Breast Cancer (BIBCQ)	√	√	√	√	√	√
Self-esteem	Rosenberg Self-Esteem Scale	√	√	√	√	√	√
Sexual function	Female Sexual Function Index (FSFI)	√	√	√	√	√	√
Sleep quality	Pittsburgh Sleep Quality Index	√	√	√	√	√	√
<i>Physical</i>							
Cardiorespiratory fitness	Cyclo-ergometer 6-minute walk test	√	√	√		√	√
Lymphedema	Sum of the arm circumference	√	√	√	√	√	√
Physical activity	International Physical Activity Questionnaire (IPAQ - short version)	√	√	√	√	√	√
Disabilities of the arm	Disabilities of the Arm, Shoulder and Hand (DASH)	√	√	√	√	√	√
Range of motion	Goniometer Test	√	√	√	√	√	√
Strength	Dynamometer Test	√	√	√	√	√	√
Flexibility	Sit and Reach Test	√	√	√	√	√	√

Source: Made by the authors.

Figures

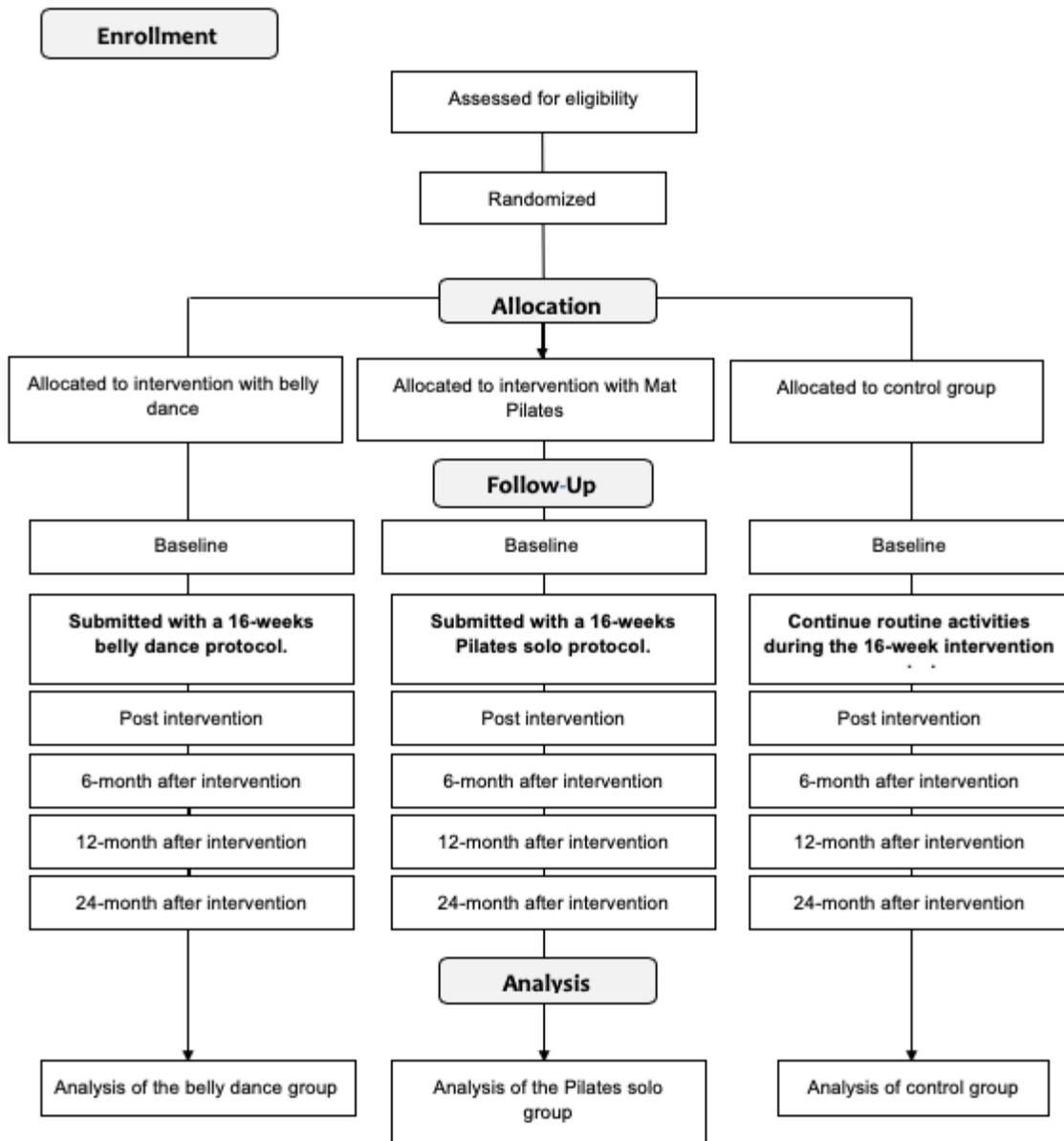


Figure 1

Flow diagram of the study participants according to CONSORT 2010.

TIMEPOINT**	STUDY PERIOD								
	Enrolment	Allocation	Treatment (16 weeks)				Follow up		
			t_0			t_1	t_2	t_3	t_4
ENROLMENT:									
Eligibility screen	X								
Informed consent	X								
Allocation		X							
INTERVENTIONS:									
<i>[Pilates intervention]</i>									
<i>[Dance intervention]</i>									
<i>[Control group]</i>									
ASSESSMENTS:									
<i>[Primary outcome - Quality of life]</i>			X			X	X	X	X
<i>[Second outcomes - Psychological variables - Depressive symptoms; Pain; Fatigue; Body image; Self-esteem; Sexual function; Sleep quality]</i>			X			X	X	X	X
<i>[Second outcomes - Physical variables- Cardiorespiratory fitness Lymphedema; Physical activity; Disabilities of the arm; Range of motion; Strength; Flexibility]</i>			X			X	X	X	X

Source: According to SPIRIT 2013 Statement: Defining Standard Protocols Items to Clinical Trials.

Figure 2

Template of recommended content for the schedule of enrolment, interventions, and assessments.

Supplementary Files

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- [supplement1.doc](#)