STUDY PROTOCOL OF WATER AND LAND-BASED AEROBIC TRAINING IN BREAST CANCER SURVIVORS: A RANDOMIZED CLINICAL TRIAL

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1. INTRODUCTION

Breast cancer is the type of cancer that mostly affects women in the world. Although physical and psychological side effects accompany cancer and the aggressiveness of the treatment (KLASSEN et al., 2017; PEEL et al., 2014), regular practice of physical exercise is considered a non-pharmacological tool to improve the quality of life of breast cancer survivors (DUNCAN et al., 2017).

Aquatic exercises may present as a possible advantage its multi-component nature. It means that a program involving aerobic exercises performed in water were able to develop improvements not only in cardiorespiratory parameters but also flexibility (BOCALINI et al., 2008), balance (SILVA et al., 2018) and muscle strength, thickness, and quality (ANDRADE et al., 2020; COSTA et al., 2018; KANITZ et al., 2015) in an older population. Such characteristics may be attributed to the water's physical properties, such as drag force and buoyancy, which provide a multidirectional resistance and a higher instability than the land environment during exercises performance (TORRES-RONDA & DEL ALCÁZAR, 2013).

Considering the cardiorespiratory impairments in breast cancer survivors (PEEL et al., 2014), it is verified the importance of studying the effects of periodized and systematized aerobic training programs in this population. In addition, the musculoskeletal losses of breast cancer survivors (KLASSEN et al., 2017) could be minimized with an aerobic training program performed in the aquatic environment. Finally, the water's physical properties may provide an environment that causes well-being and safety, possibly favoring adherence to the program. We aim to analyze the effects of 12 weeks of aerobic training programs in the aquatic and land environments plus health education, compared with a health education program alone, on cancer-related fatigue, physical fitness, mental health, cognition function, pain, and quality of life in breast cancer survivors.

2. METHODOLOGY

The WaterMama trial is a randomized, single-blinded, three-arm, parallel, superiority trial. The study was approved by the Human Research Ethics Committee of ESEF/UFPel (CAAE: 55791222.0.0000.5313). Forty-eight women, ≥18 years of age, who have completed primary treatment and been diagnosed with stage I-III breast cancer are recruited. Participants are randomly allocated on a 1:1:1 ratio to 12-week interventions of aerobic exercise training programs either on the aquatic or land environment two times per week plus health education, or an active-control group receiving health education intervention, once a week.

Participants perform a 12-week training program with two weekly sessions on non-consecutive days. Sessions for both training groups last 60 min (5 min of warm-up, followed by 45 min of exercise and 10 min of stretching) throughout the intervention period. Training intensity is based on Borg's 6-20 Rating of Perceived Exertion (RPE) Scale (BORG, 1990) and training programs have the same intensity periodization, differing only in the training environment. The aquatic training group performs the following water aerobics exercises: stationary running, frontal kick, cross-country skiing, butt kick and jumping jacks. The land training group will perform aerobic training with walking/running exercises in a flat outdoor environment or inside a multi-sport gym, depending on weather conditions.

Control group participants participate in weekly meetings with interactive lectures lasting 45 min. Additionally, each participant receives a self-care booklet containing information about the topics addressed during the meetings. Qualified professionals give lectures on the following topics: 1) fatigue and quality of life ; 2) anxiety and depressive symptoms; 3) body image and sexual function; 4) self-esteem; 5) self-care; 6) sleep; 7) cognitive function; 8) symptoms in the arm and breast; 9) pain and arthralgia; 10) body composition and bone health; 11) eating habits; 12) physical activity. The aquatic and land training groups also receive the booklet and the offer of weekly meetings with the same interactive lectures at different times so that there is no contamination between the other groups.

The study outcomes are assessed at baseline and post-intervention (weeks 0 and 13). The primary study outcome is cancer-related fatigue assessed by the Piper Fatigue Scale. A set of clinically relevant secondary outcomes for breast cancer survivors was established. Cardiorespiratory fitness is determined by peak oxygen consumption (VO_{2peak}) obtained by incremental tests on a treadmill. The maximal dynamic strength of knee extensors is determined in the one-repetition maximum (1RM) test, while the dynamic muscular endurance is determined from the maximum number of repetitions performed with 60% of the 1RM load. Functional tests (i.e., arm curl, 30s-chair stand, 8-ft up-and-go, sit-and-reach chair, back scratch, 6-min walk) are performed according to the procedures proposed by RIKLI & JONES (1999). The muscle thickness and muscle quality of the quadriceps femoris are measured from images obtained by ultrasonography. Cognitive function is measured by Functional Assessment of Cancer Therapy – Cognitive Function – Version 3 (FACT-Cog-v3), Trail Making Test (TMT) – A and B, and Controlled Oral Word Association Test (COWAT). Depressive and anxiety symptoms are measured by the Hospital Anxiety and Depression Scale (HADS), and pain assessment is measured by the Brief Pain Inventory (BPI-B). Finally, the quality of life is measured by the Functional Assessment of Cancer Therapy-Breast (FACT-B). Data regarding secondary outcomes are presented as group means at the measurement time points.

Generalized Estimating Equations and post hoc test of Bonferroni will be used for comparison between time points and groups.

3. RESULTS AND DISCUSSION

Study recruitment and data collection are expected to begin in the second half of 2022 due to the sanitary conditions imposed by COVID-19 made it impossible to start the study before. The WaterMama Study is strengthened in the attempt to understand the effects of programs of physical exercise performed in different environments to expand the knowledge related to water-based exercises for breast cancer survivors, minimizing adverse effects from the disease and treatment. We believe in the potential

of water-based exercises to counteract the side effects of the treatment, considering that training in this environment may positively impact the musculoskeletal system of women breast cancer survivors beyond the benefits on the cardiorespiratory system. This hypothesis is based on previous studies that have already demonstrated that aerobic training programs in the aquatic environment were efficient to increase strength, thickness, and muscle quality in older women due to the multidirectional resistance offered by the drag force in water (ANDRADE et al., 2020; COSTA et al., 2018; KANITZ et al., 2015).

In addition, we highlight that most women breast cancer survivors use hormonal therapy, which comprises among their adverse effects the joint pain and other musculoskeletal disorders (RUNOWICZ et al., 2016). Exercises performed in the aquatic environment have an apparent weight reduction of around 70 to 80% in women of different age ranges and body composition when they are immersed up to the xiphoid process depth. This characteristic is essential because this reduction promotes support of load substantially lower, resulting in a very attenuated ground reaction force during water-based exercises performance (ALBERTON et al., 2013). Therefore, some types of water-based exercise may be more easily performed than on land by this population, with higher osteoarticular safety. In addition, this type of program may be more pleasant, generating greater well-being, with implications for greater adherence to its practice throughout life compared to other types of exercise programs.

Another point to emphasize is that recent studies reported that the current scenario of the COVID-19 pandemic caused a significant reduction in the physical activity levels and increase in the body mass of breast cancer survivors (GURGEL et al., 2021), as well as generating psychosocial and emotional disorders (SWAINSTON et al., 2020;) as a result of social isolation. Our research group showed that women breast cancer survivors maintained the related-cancer fatigue levels after 12 weeks of a physical exercise program remotely supervised in the first months of the pandemic (PINTO et al., 2020). Accordingly, the search for alternative exercise programs that provide benefits in parameters of fatigue, physical fitness, mental health, and quality of life emerges for women who have completed the primary treatment for breast cancer in stages I-III, and that can be performed safely for this population after the control of the pandemic.

Finally, we hope that the results of the present study can strengthen the idea that a physical exercise is a non-pharmacological tool for recovery and health promotion after primary treatment of breast cancer, especially in the aquatic environment, since the literature addressing this type of exercise is scarce (CANTARERO-VILLANUEVA et al., 2013; CUESTA-VARGAS et al., 2014, FERNÁNDEZ-LAO et al., 2013; LINDQUIST et al., 2015).

4. CONCLUSIONS

So far, it has not been possible to draw conclusions from the present study.

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