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What is known on physical activity intervention protocols for breast cancer treatment? A scoping review

O que se sabe sobre os protocolos de intervenção de atividade física para o tratamento do câncer de mama? Uma revisão de escopo

Physical activity and breast cancer

Atividade Física e Câncer de Mama

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Author contributions

All authors have contributed to the information or material submitted for publication, and that all authors have read and approved the manuscript. Juliana da Silveira and Vanessa Bellani Lyra were responsible for the conception and design of the study, acquisition, analysis and interpretation of data; Juliana da Silveira, Vanessa Bellani Lyra, Leonessa Boing, Patrícia Severo dos Santos Saraiva and Adriana Coutinho de Azevedo Guimarães participated drafting the article or revising it critically for important intellectual content and final approval of the version to be submitted.

ABSTRACT

Objectives: This study aimed at identifying and characterizing the physical activity and/or physical exercise intervention study protocols for breast cancer treatment. The types, frequency, duration, intensity and timing of the therapeutic intervention with physical activity are highlighted, in addition to showing the results found.

Methods: Based on the guidelines of PRISMA Extension for Scoping Reviews (PRISMA-ScR), a search was carried out in five databases (*Cochrane Library; PubMed Central®; ScienceDirect; Scopus Elsevier and Web of science*). There was no restriction

regarding idiom or year of publication. The studies found were evaluated manually and with the assistance of the Rayyan software by two researchers, blindly and independently. The following keywords were used as a search strategy: 'breast cancer' AND 'physical activity' OR 'physical exercise', AND 'protocol study' OR 'study protocol'. The inclusion criteria comprised study protocols of randomized clinical trials with the intervention of physical activity and/or physical exercise in women undergoing breast cancer treatment and during post-treatment.

Results: 806 articles were found. The duplicates and the ones that did not meet the inclusion criteria were excluded, thus, 17 articles remained for the review. The Cochrane Risk-of-Bias tool was used for the methodological evaluation of the studies classified as having a 'low risk' of bias, which showed methodological rigor. Aerobic exercises, endurance training, dance, Pilates, exercises guided by applications and internet software were highlighted. Moderate intensity exercises were evidenced, with a frequency of three times a week and duration of 30 minutes. The great majority of the women who participated in the interventions were between stages 0 and III of the disease. The study protocols showed improvement with regard to the physical aspects (physical fitness, physical activity level, cognitive function and body composition), and psychological aspects (quality of life, fatigue, depression and anxiety), which reinforces the use of physical activities for this public.

Discussion: Study protocols are essential to provide research transparency, which facilitates the reproducibility and understanding of the interventions, and contributes to scientific advancement.

Impact: This scoping review provides a survey that will help further research on physical activity and/or physical exercise for women with breast cancer.

Keywords: Breast Neoplasms. Clinical Trial Protocol. Complementary Therapies. Exercise.

RESUMO

Objetivos: Este estudo teve como objetivo identificar e caracterizar os protocolos de estudos de atividade física e / ou intervenção com exercícios físicos para o tratamento do câncer de mama. São destacados os tipos, frequência, duração, intensidade e momento da intervenção terapêutica com atividade física, além de mostrar os resultados encontrados.

Métodos: Com base nas diretrizes do PRISMA Extension for Scoping Reviews (PRISMA-ScR), foi realizada uma busca em cinco bases de dados (Cochrane Library; PubMed Central®; ScienceDirect; Scopus Elsevier e Web of science). Não houve restrição quanto ao idioma ou ano de publicação. Os estudos encontrados foram avaliados manualmente e com auxílio do software Rayyan por dois pesquisadores, de forma cega e independente. As seguintes palavras-chave foram usadas como estratégia de pesquisa: ‘câncer de mama’ AND ‘atividade física’ OR ‘exercício físico’, AND ‘protocolo de estudo’ OR ‘protocolo de estudo’. Os critérios de inclusão compreenderam protocolos de estudo de ensaios clínicos randomizados com intervenção de atividade física e / ou exercício físico em mulheres em tratamento para câncer de mama e no pós-tratamento.

Resultados: foram encontrados 806 artigos. Foram excluídas as duplicatas e as que não atenderam aos critérios de inclusão, restando 17 artigos para a revisão. A ferramenta Cochrane Risk-of-Bias foi utilizada para a avaliação metodológica dos estudos classificados como de ‘baixo risco’ de viés, que apresentaram rigor metodológico. Destacaram-se exercícios aeróbicos, endurance, dança, Pilates, exercícios guiados por aplicativos e softwares de internet. Evidenciaram-se exercícios de intensidade moderada, com frequência de três vezes por semana e duração de 30 minutos. A grande maioria das

mulheres que participaram das intervenções encontrava-se entre os estágios 0 e III da doença. Os protocolos de estudo mostraram melhora no que diz respeito aos aspectos físicos (aptidão física, nível de atividade física, função cognitiva e composição corporal), e aos aspectos psicológicos (qualidade de vida, fadiga, depressão e ansiedade), o que reforça o uso de atividades físicas para tal. público.

Discussão: Os protocolos de estudo são essenciais para dar transparência à pesquisa, o que facilita a reprodutibilidade e compreensão das intervenções e contribui para o avanço científico.

Impacto: esta análise de escopo fornece uma pesquisa que ajudará em pesquisas futuras sobre atividade física e / ou exercícios físicos para mulheres com câncer de mama.

Palavras-chave: Exercício. Neoplasias da mama. Protocolo de Ensaios Clínicos. Terapias complementares.

1. Introduction

Breast cancer has been considered the most common type of cancer in women worldwide since 2018. That year it accounted for more than 24% of the total cancer cases diagnosed in the female world population, with approximately 2.1 million new cases, in addition to also being identified as the fifth cause of cancer death¹. Current evidence suggests physical activity practice as an alternative therapy^{2,3}, which provides health benefits for women undergoing breast cancer treatment or during post-treatment; moreover, such activities can be significantly associated with these women postoperative stage⁴.

Therefore, randomized clinical trials that investigate interventions with physical activity in women with breast cancer have been shown to be effective in improving

fatigue.⁵⁻⁷, quality of life^{5,8,9}, decreased body mass index (BMI) and body weight⁵, increased muscle endurance⁵, muscle strength^{10,11}, decreased symptoms of depression and anxiety^{6,7,9}, improvement in shoulder range of motion^{9,10}, sleep disorders¹², body image¹², pain¹³ and cardiorespiratory fitness^{11,13}.

The search in the databases (*PubMed Central*®; *Cochrane Library*; *Web of science* - main collection, *Scopus Elsevier* e *ScienceDirect*) showed that the international literature has published studies on physical activity and chronic diseases since 1983 with the investigation by Metzner et al¹⁴. Such study suggested that the practice of physical activity contributes to reduce the risks of chronic diseases. Regarding study protocols, one of the first findings dates from 1955 with the study by Sakheim¹⁵ that aimed at validating a study protocol in a psychiatric hospital. Only in 1989, with the investigation by Dickhuth et al¹⁶ the study protocols started to associate physical activity.

The fact that the publication of study protocols provides transparency to research¹⁷ is notorious, in addition to reducing publication bias¹⁸. When published, such protocols become significant research instruments, since they help in the reproducibility of interventions by other researchers and contribute to the scientific community to identify what has been produced in a given area¹⁷. However, despite their benefits, not all clinical trials are concerned with publishing the physical activity intervention protocols that have worked as an instrument.

In this sense, by mapping the scenario of randomized clinical trials protocols that include physical activity for women with breast cancer, the present scoping review can contribute with new perspectives of interventions for the professionals in the area. In addition, this review is intended to collaborate for the improvement in physical and mental health of women with breast cancer through complementary therapies. Thus, this scoping review aimed at identifying and characterizing the physical activity and/or

physical exercise intervention study protocols for breast cancer treatment. The types, frequency, duration, intensity and timing of the therapeutic intervention with physical activity were highlighted, in addition to showing the results found.

2. Methods

Protocol

The present scoping review is based on the guidelines of PRISMA Extension for Scoping Reviews (PRISMA-ScR)¹⁹. The guiding question was formed according to PICOS acronym: what are the characteristics of the physical activity and/or physical exercise intervention protocols for breast cancer treatment?

Search strategy

A search was performed in five databases: *Cochrane Library*; *PubMed Central*®; *ScienceDirect*; *Scopus Elsevier* and *Web of science* - main collection. The descriptors are shown in Table 1. All the titles and abstracts found in the electronic search were manually assessed by two researchers (JS, VBL), blindly and independently, from January to February 2021. Such researchers are members of a Brazilian laboratory referred to as *Laboratório de Pesquisa em Lazer e Atividade Física – LAPLAF/CNPq* (Leisure and Physical Activity Research Laboratory). The Rayaan software (Intelligent Systematic Review) was also used to assist in the selection of references. The discrepancies were resolved by a third researcher (ACAG). The reference lists of all the relevant articles were examined to identify other eligible studies.

Table 1. Complete electronic database search strategy

Terms	Descriptors
#1 Breast cancer	Breast cancer
#2 Intervention	Physical activity OR Physical exercise
#3 Study	Protocol study OR Study protocol
Combination	#1 AND #2 OR #3 OR

Eligibility criteria

The eligibility criteria for the studies were defined according to PICOS acronym by considering the population, intervention, comparison, outcome and study design (Table 2). Some randomized clinical trials carried out with adult women (≥ 18 years old) undergoing breast cancer treatment and during post-treatment were eligible for this review.

The studies should investigate interventions that included physical activities and/or physical exercise for breast cancer treatment. The abstracts and full texts were available from January to February, 2021. There was no restriction regarding the idiom or the year of publication.

The researchers (JS and VBL) carried out the searches on the databases mentioned and, then, they systematized the organization of the articles selected according to the title and abstract. Those that did not meet the objectives of the study were excluded. After this screening, the articles were read in full, so that the selection process of the ones that would be included in this study was completed (Figure 1).

Table 2. Inclusion and exclusion criteria of the studies

Inclusion criteria	Exclusion criteria
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P	<i>Participants</i>	Women undergoing breast cancer treatment and during post-treatment.	Not having a diagnosis of breast cancer
I	<i>Intervention</i>	Any practice of physical activity, physical exercises or body practice with face-to-face intervention and/or call center	Use of complementary drugs
C	<i>Comparasion</i>	Comparison between groups (control group with intervention group or two intervention groups)	No comparison between two groups
O	<i>Outcome</i>	Protocols of physical activity and/or physical exercise for women with breast cancer	Studies without registration of the protocol on the randomized clinical trials platforms.
S	<i>Study</i>	Study protocols of randomized clinical trials.	Systematic or literature reviews, case studies, pilot studies, dissertations, theses, book chapters, abstracts shown at conferences, supplements or editors' comments.

The variables evaluated

After searching for the studies to be included in the present scoping review, those that addressed physical activity and/or physical exercise protocols for the treatment and post-treatment of women with breast cancer were selected. Thus, the following variables were investigated: study protocols, breast cancer and physical activity and/or physical exercise.

Study protocols

Study protocols provide guidelines for research performance, in addition to being a basis for recording and facilitating the evaluation itself²⁰. These are studies that establish detailed steps and sequences so that an investigation can then be carried out by answering both, the questions that are sought according to the purposes and any other questions that may arise.²¹.

Breast cancer

Breast cancer is characterized by an uncontrolled growth of abnormal breast cells²² and it is the type of cancer with the highest incidence among women worldwide²³. The first articles published on this theme date from the 1880s, with the study by Snow²⁴, and in 1889 with the study by Cheyne²⁵. Currently, there is an increasing number of studies related to breast cancer, with more than 500,000 articles in the databases. Such investigations have been in evidence since the 1960s with clinical trials²⁶⁻²⁸, which increasingly intensified and deepened the search for early diagnosis and types of treatment with the purpose of improving the quality of life of these women.

Physical activity and/or physical exercise

Physical activity is defined as any body movement produced by skeletal muscles that require energy expenditure²⁹. According to Krebs, Berling-Ernst, Halle³⁰ physical activity represents a therapy option and support for cancer patients. There are studies related to the practice of physical activity and/or physical exercise during the treatment and post-treatment of cancers^{29,31,32}, especially breast cancer, which recommend at least 150 minutes of moderate-to-vigorous physical activity per week³³.

Data extraction

The analysis and discussion of the study protocols was carried out by extracting the data referring to the authors, year of publication, journal, country where the study was carried out, number of citations according to the Web of Science base (until February 7, 2021), number of databases, search period and whether the 27-item PRISMA checklist

was followed (yes or no). In addition, the objectives, total sample size, intervention groups, control group, age, the location where the study was carried out, the variables investigated (physical and psychological ones), particularities of the intervention with physical activity, duration, number and frequency of the sessions, and duration of the intervention were scored.

Study quality and risk of bias

The Cochrane Risk-of-Bias tool was used³⁴ in order to assess the methodological quality of the studies. The following criteria were evaluated: (1) random sequence generation, (2) allocation sequence hiding, (3) the participants and researchers' masking, and (4) selective reporting. The masking items regarding the evaluation of the outcomes, as well as the incomplete data were not included in the study, since study protocols do not show intervention results. The researchers' judgment (JS, ACAG) on the review was rated as low, unclear, or as having a high risk of bias.

3. Results

Studies included

806 articles were found in the first database search, that is, 290 in Science Direct, 46 in Web of Science, 87 in Scopus, 170 in Cochrane and 213 in PubMed. 102 duplicate articles were excluded. After reading the titles and abstracts, 686 articles were excluded for not meeting the inclusion criteria, besides being characterized as another type of study or for investigating individuals with other diseases. Thus, 18 articles remained to be read in full and, after doing so, one article was excluded.

Therefore, 17 articles were included in this scoping review, all of them characterized as study protocols with randomized clinical trials³⁵⁻⁵¹.

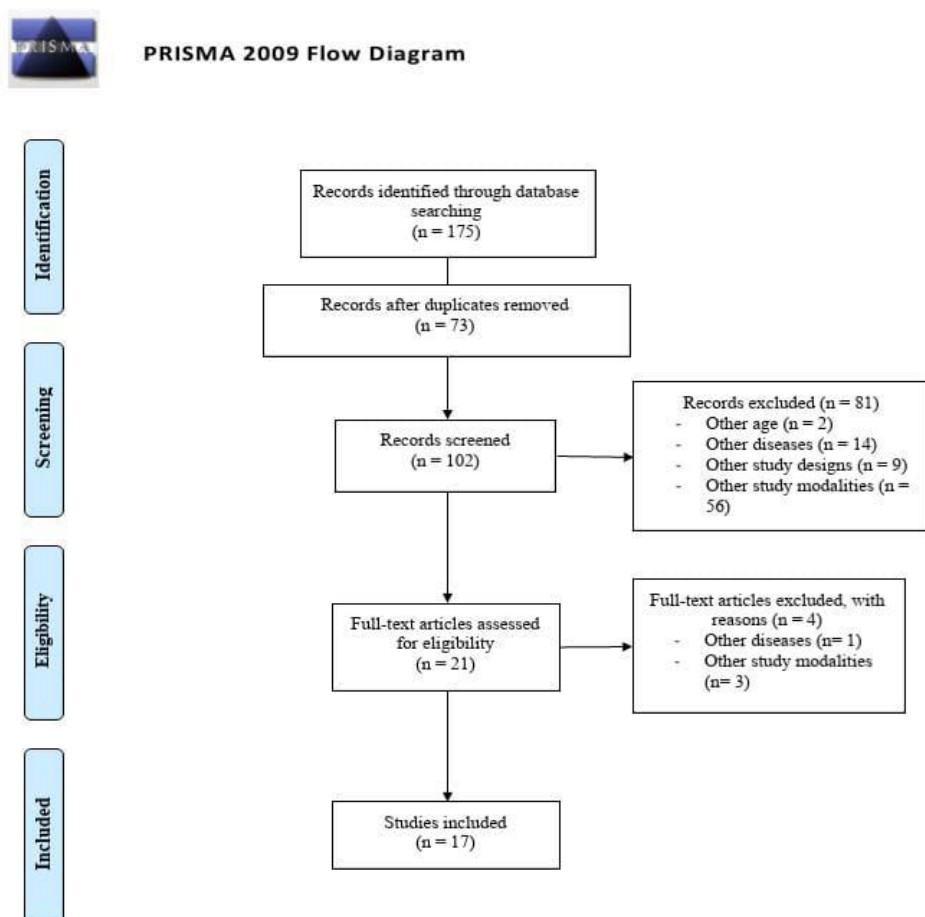


Figure 1 - Flowchart of the study selection strategy according to PRISMA model

Participants

The study participants comprised women diagnosed with breast cancer^{34,35,36,37,39,41-45,46-49}, metastatic breast cancer⁵⁰, overweight or obese women with breast cancer⁴⁸ and elderly women with breast cancer³⁵. The age criterion varied from being over 18 years old^{36,40,42-46,50,51}, between 18 and 65⁴⁰, 18 and 75^{47,49}, 19 and 70⁴⁵, 20 and 59⁴¹, 30 and 75⁴², 40 and 75⁴⁶, and, finally, 65 and 70 years old³⁵.

The women were between stages 0 and III of the disease^{36,37,47-49,51,38-45}; some of them with metastasis or severe cancer^{35,50}. One study did not show the disease stage of the participants⁴⁶.

Regarding treatment, some studies included women undergoing treatment, such as chemotherapy, radiotherapy or adjuvant therapies^{35–37,39,41,44,47,49}; some who had completed adjuvant chemotherapy and radiotherapy therapies^{40,43,48}, in addition to a study in which the individuals received neoadjuvant therapy⁴²; four studies included women scheduled to undergo chemotherapy^{38,45,46,51} and one study did not specify the treatment period of the female participants⁵⁰.

Overview

Considering the studies included, the oldest are the ones by Carayol et al⁴⁷ and Schmidt et al³⁸, in addition to other more recent investigations, that is, the ones by Andersen et al³⁵, Boing et al³⁶, Pudkasam et al³⁷, Smith-Turchyn et al³⁹, Foulkes et al⁴⁶, and Meier-Girard et al⁵⁰. The impact factor of the journals varied from 1.552⁴⁰ to 3.150^{45,46,51}. Out of the 17 articles found, only twelve were mentioned in the Web of Science, with one^{36,38,41}, two^{45,46,51}, four⁴², five⁴⁰, six⁴³, seven⁴⁴, eighth⁴⁸ and twelve⁴⁷ citations until April 12, 2021.

Regarding the locations where the studies were performed, nine of them were developed in Europe, that is, Spain⁴⁰, Holland⁴², Denmark³⁵, Italy⁴⁸, United Kingdom⁴⁹, France⁴⁷, Germany^{51,38}, and Switzerland⁵⁰; three investigations were carried out in North America, more specifically in the United States⁴⁴ and Canada^{45,39}, one in South America, in Brazil³⁶, two in Oceania, specifically in Australia^{37,46}, and two in Asia, in China⁴³ and Japan⁴¹.

All the studies were registered on clinical trial registry platforms, that is, *Clinical Trial*^{35,36,50,52,38–40,42,44,45,47,48}, Chinese Clinical Trial Registry (ChiCTR)⁴³, UMIN Clinical Trial Registry (UMIN-CTR)⁴¹, German Clinical Trials Register (GermanCTR)⁵¹ and Clinical Trials Registry from Australia and New Zealand^{37,46}.

Control and comparison groups

Considering the studies selected, 15 had a control group^{35,36,48,49,51,39,41–47}. The approaches of the control groups included usual and routine care^{35,36,39,42,43,45–47,49}; general health advice and guidelines for reducing body weight⁴⁸; in addition to the provision of a device to monitor physical activity and physical exercise practice⁴¹; active control (CoordiFit)⁵⁰; guidance on physical exercises for postoperative recovery and breast cancer treatment⁴⁴; supervised myofascial release training three times a week⁵¹, and guidelines for performing aerobic activity and taking at least 10,000 steps per day⁴⁰.

Among the studies selected, 2 of them had a comparison group^{37,38}. The approaches of the comparison groups comprised immediate intervention group and a late intervention group, with self-directed physical activity³⁷; a progressive endurance training program, and a supervised program in muscle relaxation training³⁸.

Interventions

Type of interventions with physical activity and/or physical exercise

Physical activity and/or physical exercise interventions in study protocols vary from home walking⁴⁹, walking and supervised exercises^{35,46}, aerobic and strength/endurance exercises^{38,40,42,45}, eurythmy and coordfit therapy⁵⁰, Pilates and belly dance³⁶; supervised exercises, exercises guided by applications and/or internet software and use of watches to monitor the activity^{39,41}; internet software and Qigong⁴³, self-directed exercises³⁷, rehabilitation exercises⁴⁴, high-intensity interval training (HIIT)⁵¹, personalized exercises and a diet program⁴⁷, besides motivational meetings, diet and the use of watches to monitor the activity⁴⁸.

Duration of the interventions with physical activity and/or physical exercise

The duration of the interventions ranged from 12 weeks^{35,38,40,41,43,49}, 16 weeks³⁶, 20 weeks⁵⁰, 24 weeks^{42,48}, 12 to 24 weeks⁴⁵, 12 to 18 weeks⁵¹, 26 weeks⁴⁷ and 48 weeks³⁹. A study was carried out in three phases, that is, 12 weeks, 14 weeks and 26 weeks⁴⁶, and another one did not provide the duration of the intervention⁴⁴.

Frequency of physical activity and/or physical exercise interventions

The frequency proposed for the interventions varied from 1 to 3 times a week^{35,36,51,38-40,42,43,45,46,50}, 4 to 5 times a week^{47,49}, 6 meetings divided into 6 months^{41,48}, and two studies did not provide the frequency according to which the interventions occurred^{37,44}.

Duration of the physical activity and/or physical exercise interventions

The duration of each intervention session ranged from 20 to 25 minutes⁵¹, 20 to 40 minutes per session⁴⁵, 30 minutes per session^{35,39,41,43,49}, 30 to 45 minutes per session⁴⁷, 45 minutes per session⁵⁰, 30 to 60 minutes⁴⁶, 60 minutes per session^{36,38,40,48}, 60 to 120 minutes per session⁴². Two studies did not provide the session duration of the interventions^{37,46}.

Intensity of physical activity and/or physical exercise interventions

The intensity of the interventions varied from light⁴⁰, light to moderate^{35,50}, moderate^{37-39,47,48}, light to vigorous⁵¹, and moderate to high/vigorous^{42,45}. Six studies did not show the intensity of the interventions^{36,41,43,44,46,49}.

Professionals who performed the physical activity and/or physical exercise interventions

The interventions were performed by Physical Education professionals or professionals who worked with physical exercise^{39,40,45,47}, in addition to physiologists⁴⁶, physiotherapists^{35,42-44}, Physical Education professionals and/or physiotherapists^{36,38}, clinical staff (doctor, physiotherapist, Physical Education professional, nurses)^{41,48}, therapists or specialists in eurythmy⁵⁰ or by the researcher himself⁴⁹, one per application³⁷. An article did not specify the professionals⁵¹.

The locations where the physical activity and/or physical exercise interventions were carried out

Interventions were carried out at universities^{38,42,45,46}, hospitals^{35-37,43,47,51}, at home^{41,49,50}, at physiotherapy clinics and at home⁴⁴; city hall exercise rooms⁴⁰, research center,³⁹ at home and in the presence of support groups⁴⁸.

Outcomes assessed in the study protocols

Physical and psychological outcomes were assessed. All the study protocols proposed to evaluate the female participants in the baseline and post-intervention periods. Some studies included evaluations in the middle of the intervention, on the 6th week³⁵, 15th week⁴⁷, 8th and on 14th weeks⁵⁰, and on the 12th week³⁷. Some investigations included follow-up assessments, that is, 24 weeks after the intervention³⁵, 6 months after the intervention⁵¹, 6, 12 and 24 months after the intervention³⁶, 24 and 36 weeks after the intervention⁴¹, 6 and 12 months after the intervention^{39,44}, 12 and 18 months after the intervention⁴⁷, 12 and 24 months after the intervention⁴⁸, and 18 months after the intervention⁴².

Physical outcomes assessed in the physical activity and/or physical exercise protocols

The physical outcomes assessed in the protocol studies are shown in Figure 2. More specifically, they included physical fitness^{36,38-43,45}, physical function^{35,41,46}, body composition^{35,40,47,48}, total, regional and mineral bone body composition⁴⁶, physical activity level^{36,41,44-48}, functional status⁵⁰, muscle strength^{36,39,46}, flexibility³⁶, inflammatory biomarkers^{35,51}, hospitalization³⁵, survival³⁵, upper limb mobility^{40,44}, arm, shoulder and hands function^{36,40,44}, range of motion³⁶, lymphedema^{36,40,44}, pain^{44,50}, work performance⁴², memory⁴⁹, brain function⁴⁵, executive function⁴⁹, attention⁴⁹, spatial visual skills⁴⁹, cognitive function^{38,45,46,49,51}, self-perceived cognitive performance⁵¹, food intake/diet⁴⁶⁻⁴⁸, health condition⁴⁸, use of health services³⁹, biological assessments⁴¹, neutrophilic levels⁵¹, cardiac reserve⁴⁶, cardiac structure and function⁴⁶, central vascular stiffness⁴⁶, blood pressure⁴⁶, sedentary behavior⁴⁶, side effects related to cancer⁵¹ and immune function³⁷.



Figure 2. Physical outcomes assessed

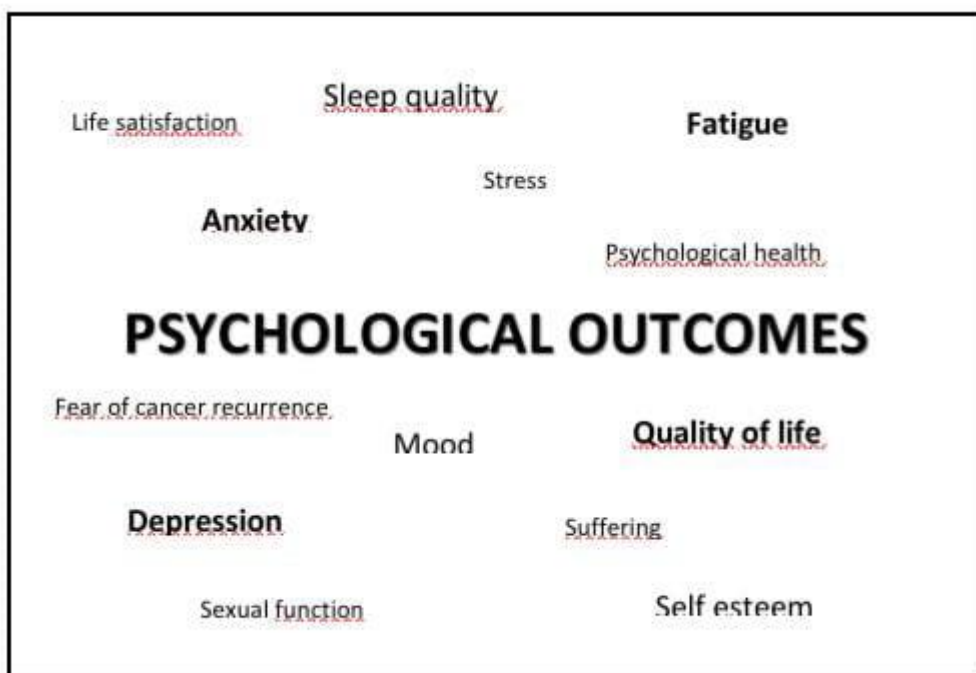


Figure 3. Psychological outcomes assessed

Psychological outcomes assessed in the physical activity and/or physical exercise protocols

Figure 3 shows the psychological variables evaluated, that is, quality of life^{35,36,45,46,48,50,37-44}, welfare³⁵, fatigue^{36,38,40-42,46,47,49,50}, anxiety^{37,42,47,49,50}, depression^{36-38,40-42,47,49,50}, stress³⁷, mood^{46,49}, self-esteem^{36,49}, body image³⁶, sexual function³⁶, sleep quality^{36,41,50}, suffering⁵⁰, life satisfaction⁴⁰, psychological health⁴⁵ and fear of cancer recurrence⁴¹.

Quality of the study protocols

In general, the study protocols were classified as having a ‘low’ risk of bias in most of the items assessed. Only one study had a ‘high’ risk of bias classification³⁹, and there were two ‘unclear’ studies^{47,53} concerning the random sequence generation item. Five

studies^{39,42,47-49} showed an ‘unclear’ classification with regard to the allocation sequence hiding. Considering the participants and researchers’ masking, three studies^{42,48,49} were classified as having an ‘unclear’ classification. Twelve studies^{35,36,50,51,37,38,40,41,43-46} showed a ‘low risk’ of bias in all items, which points to a more detailed methodological rigor.

4. Discussion

This scoping review aimed at identifying and characterizing the physical activity and/or exercise intervention study protocols for breast cancer treatment by highlighting the types, frequency, duration, intensity and timing of the therapeutic intervention with physical activity, in addition to showing the outcomes found. Seventeen protocol studies met the inclusion criteria adopted in this scoping review, which configured a group of randomized clinical trials registered on official platforms. Considering this universe, the evidence with regard to the risk of bias was adapted, since protocol studies do not show the results. The study protocols followed the standards of the SPIRIT checklist²⁰; thus, after being assessed, such studies were shown to have a low risk of bias because they clearly showed a random sequence generation, allocation sequence hiding, the participants and researchers’ masking, as well as selective reports, which are in accordance with Cochrane Risk-of-Bias tool³⁴.

Characterization of physical activity and/or physical exercises

The types of physical activity and/or physical exercises found in the study protocols included in this scoping review comprised aerobic exercises, endurance training, dance and Pilates, and exercises guided by applications and Internet software. This shows a wide range of modalities that have been investigated in the context of breast

cancer. Thus, these study protocols provided a series of intervention options, which outlines possibilities and structure, in addition to providing a basis for further randomized clinical trials. Some studies have previously investigated some of these modalities, such as aerobic and endurance exercises, which have been shown to be viable and safe in the literature for women undergoing breast cancer treatment^{54,55}. The results found in the randomized clinical trials by Paulo et al¹², García-Soidán et al⁵⁶, and Sweeney et al⁵⁷, showed significant improvement in strength, flexibility, musculoskeletal improvement, body composition, reduction of side effects regarding breast cancer treatment, besides improving the quality of life and emotional level of these women after interventions with aerobic and endurance exercises.

Regarding the interventions with walking, the study protocols have shown that it can be an effective training to improve cardiorespiratory fitness, physical performance, in addition to being a safe and beneficial intervention for women who have lymphedema due to breast cancer^{58,59}. Walking also stands out for being an accessible physical activity with a low cost and that can be used as a means of dislocation⁶⁰, which makes it an interesting option in low and middle income countries. The exercises provided by a High Intensity Interval Training (HIIT), in turn, are suggested in the study protocols by Tsuji et al⁴¹ and Oberste et al⁵¹. This new modality has also been addressed for breast cancer patients during chemotherapy with positive effects⁶¹.

Two study protocols assessed in this scoping review included interventions through dance^{36,50}. Others, such as the ones by Loo et al⁶² and Ho et al⁶³ showed that dance practice enabled to achieve an increased physical activity in breast cancer survivors. The quality of life was also improved by increasing vigor and reducing problems associated with obesity, and reducing stress and pain in these women. Considering the interventions with Pilates, the study by Eyigor et al⁶⁴ showed that such a

method is a safe and effective exercise for breast cancer patients, since it enables the improvement of functional capacities, fatigue, quality of life and helps to reduce depression. According to the results shown in the study by Alpozgen et al⁶⁵, Pilates also provided improvement in pain, muscle strength, besides being effective as a rehabilitation exercise for women with breast cancer. Thus, this method can be considered an alternative treatment for this public.

Current modalities seen in the protocols, that is, exercises performed at home with interventions using electronics, such as watches to monitor physical activity, internet software and smartphone applications, have been encouraged for providing changes in living standards, especially considering the pandemic and relocation of professional activities for home-office. In other previously studies, such as that by Dong et al¹⁰, the findings of an intervention based on combined exercises of an internet software showed positive effects on muscle strength and quality of life in patients during breast cancer postoperative period. Galiano-Castillo et al⁶⁶ indicated a physical exercise program that uses an Internet software, through which it was possible to improve and maintain the quality of life of breast cancer patients, as well as to reduce pain and fatigue, and improve muscle strength, which resulted in improved functionality related to daily activities. These strategies, such as the use of online tools and the fact that the interventions are carried out at home, can be adequate alternatives to assist both, researchers and participants, since they provide a larger network for a great number of participants. The current moment, with the recommendations for staying at home, has led us to increase the demand for digital tools, in addition to raising people's awareness on how much these methods can be explored. It would not be possible to carry out the interventions without such tools. Problems related to the capability of some software, the lack of skills to use the applications, difficulties in accessing the Internet and a possible lack of interest by the

participants are likely to be limitations. However, these strategies can work as a useful tool in changing behavior, besides facilitating and bringing the researchers and participants closer together⁶⁷.

It was also identified that the interventions were mainly proposed to work with moderate intensity exercises, which corroborates with Spence et al³³ who recommended physical activity for breast cancer patients at least 150 minutes per week, as proposed in the randomized clinical trial studies by Ligibel et al⁶⁸, Arem et al⁶⁹ and Mijwel et al⁷⁰. Lack of information regarding the intensity of the interventions was one of the limitations of some study protocols. These recommendations should be suggested by the researcher so that benefit is proven, in addition to facilitating subsequent implementation and performance of other intervention study protocols.

Physical and psychological outcomes

The physical outcomes most found in the study protocols comprised the physical conditions and limitations of women with breast cancer, such as decreased function of the upper limb⁷¹, decreased range of motion and muscle strength¹⁹, and cardiovascular consequences⁷². In almost all studies, the limiting factors related to the disease were investigated, given that there is a concern with the return of these women to daily activities. Thus, the Disabilities of the Arm, Shoulder and Hand (DASH) test, the Sitting-rising test in 30 seconds (30s - SRT) and the 6-minute walk test (6MWT) were the instruments most often used by the studies assessed. These instruments have a low cost and are fast to be applied.

The consequences of the treatments considering the conditions or psychological health of the women undergoing treatment and during post-treatment of breast cancer can lead to problems of anxiety, depressive symptoms, fatigue, and sexual dysfunction. Thus,

there is a great concern with quality. In view of this, several studies show quality of life as their main outcome, followed by depression and anxiety, which are possibly more often addressed due to the worrying factors related to the disease⁷³.

Regarding the instruments used, it is noteworthy that there is a wide range of possibilities, which makes later comparisons between studies difficult. Regarding quality of life, for example, which was shown to be the main outcome in most study protocols, the instruments used included the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30), EuroQol Five-dimensional Instrument (EQ-5D-5L), and the Functional Assessment of Cancer Therapy - Breast (FACT-B). All of them are validated and used in studies on cancer patients. The Hospital Anxiety and Depression Scale (HADS) is one of the most used instruments to assess depression and anxiety.

Conclusions

The study protocols showed different possibilities of intervention through physical activity and/or physical exercise; however, some have limitations due to the lack of information, such as intensity, frequency or timing of the sessions, which are necessary for a better use of these interventions. It should be highlighted that the first study protocol found in this scoping review dates from 2013, which shows that previous clinical trials did not have protocol publications, and that the practice of publishing study protocols is still expanding. Not all scientific journals accept this type of study, and some authors of randomized clinical trials choose not to publish their protocols.

Considering the study protocols included in this scoping review, a range of interventions with different modalities of physical activity and/or physical exercise was found, that is, endurance training, aerobic exercises, dance, Pilates, HIIT, Qigong, and

activities by using technologies, such as software and applications and/or watches to monitor physical activity. The frequency of interventions ranged from one to five times a week, lasting from 12 to 48 weeks, in a low-to-vigorous intensity. Regarding the disease stages, the study protocols mainly included stages between 0 and III. Considering the treatment period, the women were mainly undergoing chemotherapy, radiotherapy or other adjuvant therapies. Physical fitness, physical activity level, cognitive function and body composition were the main outcomes seen. Quality of life, fatigue, depression and anxiety were the psychological outcomes that stood out the most.

Even considering this range of modalities, more study protocols are necessary so that research transparency is obtained, in addition to facilitating the reproducibility and understanding of interventions. These protocols, on the other hand, provide tools to assist in further research and contribute to the advancement of scientific knowledge.

Impact Statement

The present study provides insight into the characteristics of study protocols with randomized clinical trials by showing which protocols might be more suitable for a given study, as well as which instruments are most used for obtaining physical and psychological outcomes. The survey carried out and shown in this scoping review will help further research that involves physical activity and/or physical exercise for women with breast cancer.

Contribuintes

All authors have contributed to the information or material submitted for publication, and that all authors have read and approved the manuscript. Juliana da Silveira and Vanessa Bellani Lyra were responsible for the conception and design of the study, acquisition, analysis and interpretation of data; Juliana da Silveira, Vanessa Bellani Lyra, Leonessa Boing, Patrícia Severo dos Santos Saraiva and Adriana Coutinho de Azevedo Guimarães participated drafting the article

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Interest conflicts

The authors declare no conflict of interest, financial or otherwise. Study results are presented clearly, honestly and without falsification or improper data manipulation.

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