

# Effects of myofascial reorganization associated with kinesiotherapy on chronic pain and functionality of breast cancer survivors: development of a study protocol

*Efeitos da reorganização miofascial associada à cinesioterapia na dor crônica e funcionalidade de sobreviventes de câncer de mama: desenvolvimento de um protocolo de estudo*

Natália de Souza Cunha <sup>1\*</sup>

Larissa Sinhorim <sup>2</sup>

Robert Schleip <sup>3</sup>

Kamilla Zomkowski <sup>2</sup>

Gilmar Moraes Santos <sup>1</sup>

Fabiana Flores Sperandio <sup>1</sup>

<sup>1</sup> Universidade do Estado de Santa Catarina (UDESC), Florianópolis, SC, Brazil

<sup>2</sup> Universidade do Sul de Santa Catarina (UNISUL), Palhoça, SC, Brazil

<sup>3</sup> Ulm University, Guezburg, Germany

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\* **Correspondence:** ndscunha@gmail.com

## Abstract

**Introduction:** Breast cancer is the most common type of cancer among women. Treatments can lead to complications modifying upper limbs movement patterns and generating pain and functionality loss. Kinesiotherapy and myofascial reorganization (MR) have shown positive effects reducing chronic pain and improving upper limbs function. We hypothesize that these techniques can maximize results and reduce treatment time in clinical practice. **Objective:** To develop a study protocol to verify whether MR associated with kinesiotherapy is more effective than isolated kinesiotherapy to treat chronic pain and upper limb dysfunction in breast cancer survivors. **Methods:** Participants will be divided into two groups: intervention group (myofascial reorganization + kinesiotherapy) and sham group (traditional massage + kinesiotherapy). Six treatment sessions (once a week) and three-time assessment will occur. Instruments for assessing pain and functionality will be Visual Analogue Scale, Body Pain Diagram, Disabilities of the Arm, Shoulder and Hand Questionnaire, and goniometry. Statistical analysis will be conducted based on intention-to-treat analysis. To analyze the difference of means between groups, we will use T-Student or U Mann-Whitney test. Repeated measures ANOVA will be used to check treatments effects. Significance level for all tests will be 5%. **Conclusion:** We believe that the developed study protocol will show that MR associated with kinesiotherapy improve chronic pain and upper limbs functionality of breast cancer survivors.

**Keywords:** Breast cancer. Chronic pain. Functionality. Manual therapy. Physiotherapy modalities.

## Resumo

**Introdução:** O câncer de mama é o tipo de câncer mais comum entre as mulheres. Os tratamentos podem levar a complicações, modificando os padrões de movimento dos membros superiores e gerando dor e perda de funcionalidade. A cinesioterapia e a reorganização miofascial (RM) têm demonstrado efeitos positivos na redução da dor crônica e na melhora da função dos membros superiores. A hipótese do presente estudo é que essas técnicas podem maximizar os resultados e reduzir o tempo de tratamento na prática clínica. **Objetivo:** Desenvolver um protocolo para verificar se a RM associada à cinesioterapia é mais eficaz do que a cinesioterapia isolada no tratamento da dor crônica e disfunção do membro superior em sobreviventes de câncer de mama. **Métodos:** As participantes serão divididas em dois grupos: grupo intervenção (reorganização miofascial + cinesioterapia) e grupo sham (massagem tradicional + cinesioterapia). Serão realizadas seis sessões de tratamento (uma vez por semana) e três avaliações. Os instrumentos de avaliação da dor e da funcionalidade serão a Escala Visual Analógica, o Diagrama de Dor Corporal, o Questionário de Deficiências do Braço, Ombro e Mão e a goniometria. A análise estatística será realizada com base na análise de intenção de tratar. Para analisar a diferença de médias entre os grupos, serão utilizados o teste T-Student ou U Mann-Whitney. ANOVA de medidas repetidas será utilizada para verificar os efeitos dos tratamentos. O nível de significância para todos os testes será de 5%. **Conclusão:** Espera-se que a RM associada à cinesioterapia melhore a dor crônica e a funcionalidade dos membros superiores de sobreviventes de câncer de mama.

**Palavras-chave:** Câncer de mama. Dor crônica. Funcionalidade. Terapia manual. Modalidades de fisioterapia.

## Introduction

According to the World Health Organization (WHO), breast cancer is the most commonly diagnosed cancer.<sup>1</sup> Breast cancer treatments can lead to several complications: scar adhesions, tissue fibrosis, reduced range of motion (ROM), reduced upper limb muscle strength, and pain.<sup>2</sup> These factors, alone or in combination, change the upper limbs movement patterns and might lead to chronic pain and reduced functionality, affecting these women quality of life and daily living activities.<sup>2-4</sup>

Chronic pain after breast cancer surgery is one of the most common complaints, with a prevalence ranging from 20% to 68%.<sup>5-7</sup> Different mechanisms might be involved (nociceptive, neuropathic, central sensitization, and/or allodynia) and can make chronic pain treatment a challenge in clinical practice.<sup>8</sup> Due to chronic pain mechanisms complexity and multifactorial nature, there is no consensus in literature about the best therapeutic modality to treat this condition in women after breast cancer,<sup>9</sup> which intrigues researchers and clinicians.

Another common complication after breast cancer surgery is the reduced upper limb function, with a prevalence rate of over 50%.<sup>2,10,11</sup> Some factors are associated with worsening of upper limb function, such as pain intensity and characteristics, reduced shoulder flexion and abduction ROM, and decreased upper limb muscle strength.<sup>11</sup>

Literature suggests chronic pain treatment should be based on multidisciplinary approach involving pain education, psychopharmacological and physical therapy interventions.<sup>12</sup> Techniques like kinesiotherapy, stretching, strengthening, and neuromuscular control exercises can increase mobility and reduce shoulder pain.<sup>9</sup> Also, kinesiotherapy has shown positive effects for reducing chronic pain and increasing upper limbs functionality.<sup>9,12</sup> On the other hand, more than one intervention can be effective for the same symptom and these effects depend not only on the intervention type, but also on how and when it is applied.<sup>9</sup> The type, frequency, intensity, and ideal exercises duration are still not clear enough, as well as their effects in combination with other modalities in the treatment of the same symptoms.<sup>9,13</sup> Thus, two techniques association might lead to greater benefits.

Myofascial reorganization (MR) is a method of myofascial manual therapy which emphasizes: (i) diagonal pressure; (ii) shear loading; (iii) tensile loading; (iiii) compressive loading in the myofascial tissue. It aims to influence receptors in the fascia, contributing to changes in local fluid dynamics, capillary constriction and increased local blood flow, restoring normal integrity of treated tissue.<sup>14</sup> Thus, MR may reduce pain and improve body structures mobility and function.<sup>15-17</sup> In addition, manual contact is safe and reduces costs,<sup>18</sup> given the wide clinical applicability. Although current evidence indicates the effectiveness of interventions in fascial system, there are scarce high-quality methodological articles with large sample sizes,

requiring new studies to understand the role of available techniques.<sup>19</sup>

As there is insufficient information and no consensus on optimal chronic pain management and upper limb functionality among breast cancer survivors, we hypothesize that by combining benefits of two therapies we can maximize results and reduce treatment time in clinical practice. Therefore, this study aims to develop a study protocol to verify whether MR associated with kinesiotherapy is superior to isolated kinesiotherapy in chronic pain treatment and upper limb dysfunction in breast cancer survivors.

## Methods

This study was approved by the Ethics Committee on Research with Human Beings (CEPSH) of the Universidade do Estado de Santa Catarina (UDESC), under CAAE protocol 10420519.7.0000.0118, and has been registered on the Clinical Trials platform under the protocol NCT04084600.

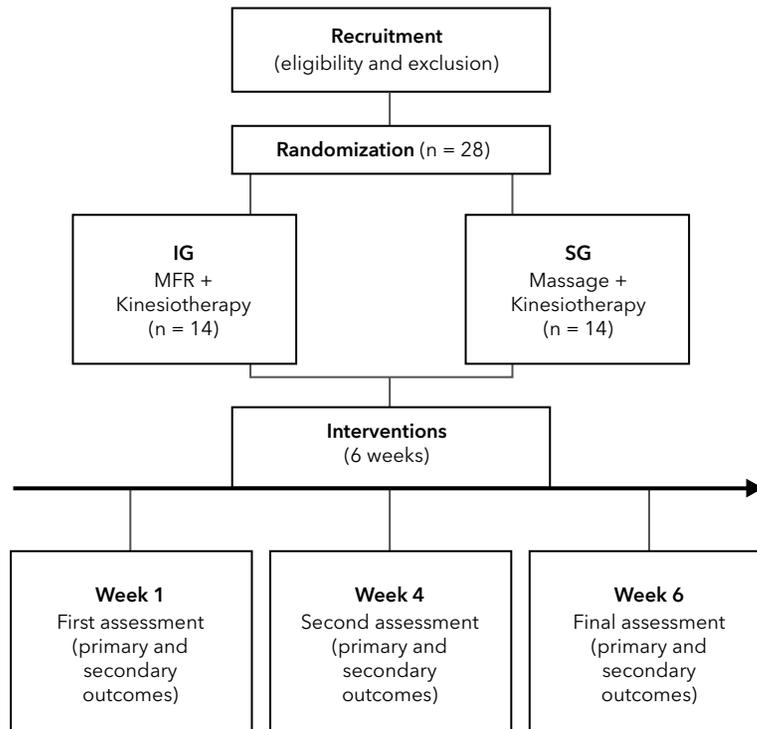
## Study design

The study described in this protocol will be a double blind randomized controlled clinical trial (assessor and patient), parallel in two groups (IG - intervention group; and SG - sham group), organized according to the flowchart below (Figure 1). The protocol was developed according to the SPIRIT (Standard Protocol Items: Recommendations for International Trials) checklist, 2013.

All participants who agree to be part of the study will make the initial evaluation after signing the Informed Consent Form.

## Setting and recruitment procedures

Data collection will be carried out in a reserved room at the Physiotherapy School Clinic of UDESC, in Florianópolis, Brazil. Women will be recruited by our research group through folders, banners, social media, and in person at the College of Health and Sport Science (CEFID) of UDESC.



**Figure 1** - Study flowchart.

Note: IG = intervention group; SG = sham group; MFR = myofascial reorganization.

### Randomisation and blinding procedures

Participants will be randomly assigned to the IG or SG groups. Randomization will be carried out when recruitment procedures were finished through a random numerical sequence generated on Randomizer.org, in blocks, with an allocation rate of 1:1. Participants allocation will be hidden in sequentially sealed, numbered opaque envelopes prepared before the study starts. A researcher, who will not be involved in the other trial stages, will be responsible for randomization and allocation procedures. There will be three researchers responsible for assessments and they will not have access to participants allocation. The physiotherapist responsible for the interventions will not participate in assessments or participants allocation.

### Participants

The sample will be composed of women who meet the following inclusion criteria: (1) age over 18 years; (2) have undergone breast cancer surgery; (3) have completed chemotherapy and/or radiotherapy; (4) present pain in the affected upper quadrant of the surgery for at least three months, with a minimum score of four-cm on the visual analogue scale (VAS) in the last week; (5) present a score of at least 30 in the DASH questionnaire (Disabilities of the arm, shoulder and hand).

Participants who present one of the following criteria will be excluded: (1) difficulty in understanding the Portuguese language to answer the questionnaires; (2) bilateral surgery for the treatment of breast cancer; (3) palliative care; (4) pregnant women; (5) use of analgesic and/or anti-inflammatory drugs; (6) rheumatic diseases; (7) history of orthopaedic surgery in the upper limbs; (8) have undergone physiotherapy treatment for less than 30 days.

### Initial assessments

Women who agree to join the study will sign a Free Informed Consent Form and will be notified of the possibility to withdraw from the research at any stage. All participants personal identification data will be preserved according to national health council resolution, considering the possibility of results scientific dissemination. None of the participants will receive financial support to participate in the research.

Assessments will be conducted by three different physiotherapists, blinded and properly trained. Initially, in a face-to-face interview, a sociodemographic and clinical-surgical form will be fulfilled. Sociodemographic items include: name, age, education, marital status, ethnicity, living habits, physical activity, limb dominance, gynaecological history, gestational history and family income. For clinical-surgical aspects, type of breast cancer, cancer side, type of surgery, date of diagnosis, lymph node resection, other previous treatments and complications reported will be assessed.

### Outcomes

Assessments will take place in three stages: just before the first treatment session (week 1), immediately after four treatment sessions (week 4), and at the end of the last treatment session (week 6). The primary outcome will be pain intensity and frequency measured by the VAS and the Body Pain Diagram (BPD). The secondary outcome will be upper limbs functionality by DASH and ROM, identified by the mean of the goniometry values.

VAS is a valid and reliable scale, widely used to identify pain intensity.<sup>20,21</sup> It consists of a numbered line from 0 to 10, 0 being no pain and 10 being the worst pain imaginable. BPD is a graphic representation of a woman's body in anterior, posterior and lateral view, created by Zomkowski et al.,<sup>22</sup> in order to identify the site and frequency of pain. In this diagram, women should mark their principal pain areas at the moment with an X. For the frequency analysis of pain location, the BPD will be segmented into five areas: anterior trunk, posterior trunk, lateral trunk, affected upper limb, and unaffected upper limb.

DASH will be used to assess the disabilities and physical symptoms of the upper limbs. It was created in Canada in 1996<sup>23</sup> and translated and validated in Brazil in 2005.<sup>24</sup> It is a 30-item questionnaire that assesses physical disabilities and upper limbs symptoms in a wide variety of musculoskeletal disorders. The score is a Likert scale ranging from one to five and the total score goes from 0 to 100, where higher scores represent higher physical disabilities and upper limbs symptoms. The questions refer to the last week and the items in the questionnaire are categorised into the domains: physical function, symptoms and social function.

For goniometry, a plastic manual goniometer with two adjustable arms will be used, which has proved to be

a valid and reliable tool.<sup>25</sup> The active ROM of the shoulder joint will be objectively measured in flexion, abduction, internal and external rotation movements. Participants will be positioned according to Marques,<sup>26</sup> and will perform two repetitions of each movement; the mean of these measures will be considered for the analysis of the results.

### Interventions

Participants will undergo six treatment sessions once a week for six weeks, each lasting 40 minutes. The sessions will be conducted individually in a reserved room with adequate lighting and air conditioning

adjusted to a temperature of approximately 23 °C. The interventions will be applied by a physiotherapist with previous experience and practice in this protocol. The interventions proposed for each group are described in more details below:

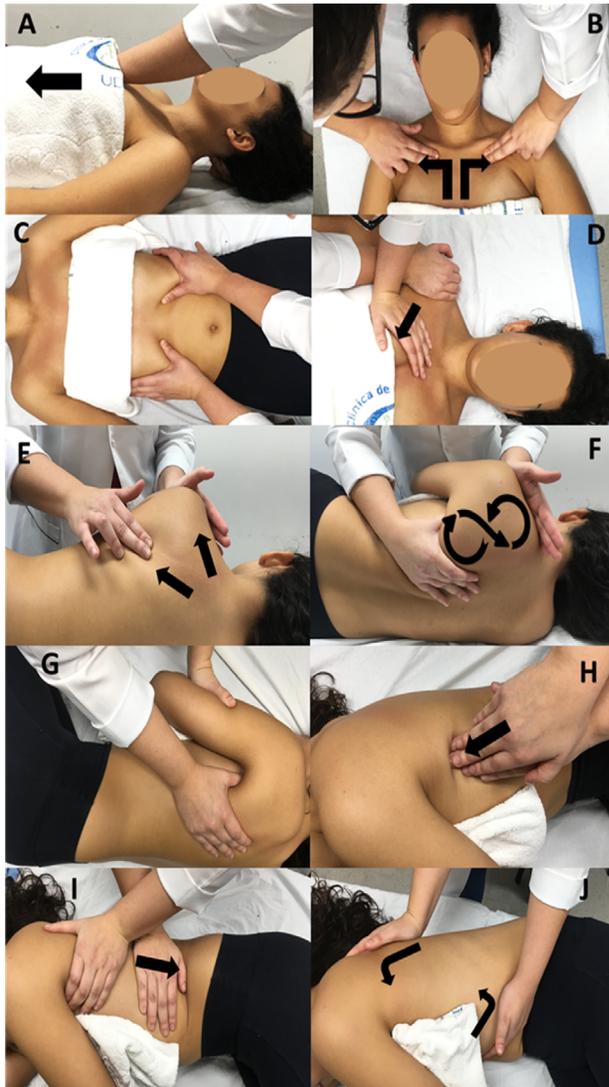
#### *Intervention group*

First, a 20-minute MR protocol will be conducted using an adapted approach described in Sinhorim et al.<sup>14</sup> The techniques will be applied emphasizing shear loading, tensile loading and compressive loading, as shown in Table 1 and Figure 2.

**Table 1** - Description of myofascial reorganization protocol for breast cancer survivors

Techniques sequence	Techniques description
A. Sternal region	Participant: supine position with knees bent. Therapist: standing in front of the participant's head. Technique: the therapist fixes one hand in the region of the nuchal ligament and the other hand over the sternum, making a smooth and progressive caudal pressure towards the stretcher (1 minute).
B. Anterior ribcage region	Participant: supine position with knees bent. Therapist: standing in front of the participant's head. Technique: the therapist performs pressure and sliding from the xiphoid process, passing through the sternum, the infra clavicular region and ending at the acromion (6 times).
C. Diaphragm reorganization	Participant: supine position with knees bent. Therapist: standing beside the stretcher, in front of the participant's pelvis. Technique: the therapist performs pressure and sliding from the xiphoid process to the lower borders of the last ribs (6 times).
D. Pectoralis major	Participant: supine position with knees bent. Therapist: standing beside the stretcher, in front of the participant's chest. Technique: the therapist fixes one hand on the humerus and applies pressure towards the sternum with the other hand (1 minute).
E. Scapular region 1	Participant: lateral position, without pillow and with 90° of knee and hip flexion. Therapist: standing beside the stretcher, in front of the participant's abdomen. Technique: therapist performs pressure and sliding on the medial and upper border of the scapula (6 times).
F. Scapular region 2	Participant: lateral position, without pillow and with 90° of knee and hip flexion. Therapist: standing beside the stretcher, in front of the participant's abdomen. Technique: therapist departs the scapula from the ribcage and performs scapular mobilization in eight (1 minute).
G. Scapular region 3	Participant: lateral position, without pillow and with 90° of knee and hip flexion. Therapist: standing beside the stretcher, in front of the participant's abdomen. Technique: the therapist places the thumb in the region of teres minor muscle and applies sustained pressure (1 minute).
H. 45° Lateral trunk	Participant: lateral position, without pillow and with 90° of knee and hip flexion. Therapist: standing beside the stretcher, in front of the participant's posterior thorax. Technique: therapist with hands overlapped at 45° with the lateral region of the participant's thorax, performs pressure between the 6th and 8th ribs towards the stretcher and shoulder of the participant (1 minute).
I. Lateral trunk region	Participant: lateral position, without pillow and with 90° of knee and hip flexion. Therapist: standing beside the stretcher, in front of the participant's posterior thorax. Technique: therapist positions one hand on the upper thorax and the other on the lower thorax, the upper hand remains fixed and the lower one moves in a caudal direction (1 minute).
J. Thorax reorganization	Participant: lateral position, without pillow and with 90° of knee and hip flexion. Therapist: standing beside the stretcher, in front of the participant's posterior thorax. Technique: therapist places one hand on the anterior region of the last ribs and the other hand in the region of the inferior angle of the scapula, applying twisting pressure in a cranial direction (1 minute).

Immediately after MR protocol, participants will undergo a 20-minute kinesiotherapy protocol. This protocol was created based on previous studies,<sup>9,27-29</sup> and consists of stretching, strengthening, control, and stabilization exercises of shoulder complex, according to Table 2 and Figure 3.



**Figure 2** - Myofascial reorganization protocol for breast cancer survivors.

Note: A - Sternal region; B - Anterior ribcage region; C - Diaphragm reorganization; D - Pectoralis Major; E - Scapular region 1; F - Scapular region 2; G - Scapular region 3; H - 45° Lateral trunk; I - Lateral trunk region; J - Thorax reorganization.

**Table 2** - Description of the kinesiotherapy protocol for breast cancer survivors based on stretching, strengthening, control and stabilization of shoulder complex

Exercises sequence	Exercises description
1. Stretches	Seating, participants will stretch pectoral, levator scapulae, trapezius and latissimus dorsi. Each position will be held for 1 minute and 30 seconds.
2. Codman's pendulum exercise	Participants will stand with torso flexed over hips at 90° and one arm hanging in a 60° to 90° flexion or abduction position in the scapular plane. Participants will perform circling movements for 1 minute and 30 seconds. Dumbbells up to 1 kg will be used.
3. Scapular mobilization	Participants will stand, face the mirror and perform scapular adduction, abduction, elevation and depression movements. 1 set of 10 repetitions for each movement.
4. Shoulder flexion and abduction	Participants will stand, close to the wall, performs flexion and abduction movements in the scapular plane, sliding her hands along the wall. 1 set of 10 repetitions for each movement.
5. Shoulder elevation with dumbbells	Participants will stand, performs scapular elevation and depression with arms parallel to the body holding dumbbells. 2 sets of 10 repetitions. Dumbbells up to 1 kg will be used.
6. Seated chest press with dumbbells	Participants will be seated with upper limbs in 90° of shoulder flexion and full elbow extension, with pronated forearms, will bring the dumbbells towards the chest performing elbow flexion. 2 sets of 10 repetitions. Dumbbells up to 1 kg will be used.
7. Diagonal patterns exercises	Diagonal D1 flexion: participants will sit, start with shoulder extended, abducted, and internally rotated and end with shoulder flexed, adducted, and externally rotated. Diagonal D2 flexion: participants will sit, start the exercise with shoulder extended, adducted, and internally rotated and end with shoulder flexed, abducted, and externally rotated. 2 sets of 10 repetitions for each diagonal. Dumbbells up to 1 kg will be used.
8. Full can exercise	Participants will stand up, perform shoulder abduction with the elbows extended in the scapular plane, the humerus in external rotation and the thumbs pointing upwards, holding dumbbells. 2 sets of 10 repetitions. Dumbbells up to 1 kg will be used.
9. Scapular stabilization exercise	Participants will stand with shoulders flexed at 90° and hands on the wall, and will perform scapular abduction and adduction keeping hand contact with the wall and elbows extended. 2 sets of 10 repetitions.



**Figure 3** - Kinesiotherapy protocol for breast cancer survivors.

Note: 1 - Stretches; 2 - Codman's pendulum exercise; 3 - Active scapular mobilization; 4 - Shoulder flexion and abduction; 5 - Shoulder elevation with dumbbells; 6 - Seated chest press with dumbbells; 7 - Diagonal patterns exercise; 8 - Full can exercise; 9 - Scapular stabilization exercise.

### *Sham group*

SG will start intervention receiving a traditional massage, in regions different from those covered by the IG. The surface smoothing technique will be used, based on Domenico and Wood's classical massage concept.<sup>30</sup> Smooth, rhythmic and circular movements will be made with all the palmar surface, in order to minimize major fascial changes. Traditional massage will last 20 minutes. In the first ten minutes, the participant will stay in dorsal decubitus position and receive the technique in the abdominal region. In the last ten minutes, the participant will adopt the lateral decubitus to receive the massage in the lumbar region. After the traditional massage, the participant will perform the same kinesiotherapy protocol described above, during 20 minutes.

### Sample size calculation

Sample calculation was performed using the G-Power® 3.1 software. Variable used was pain intensity in the VAS. Calculation was based on the detection of a 3-point difference between the groups.<sup>31</sup> Considering a power of 80% and  $\alpha$  of 5%, we estimated 14 participants per group.

### Statistical analysis

Statistical analysis will be conducted based on intention-to-treat analysis. Data will be organised in Excel® (version 2010) and then analysed in SPSS® (Statistical Package for Social Sciences, version 20.0) software. Shapiro-Wilk will be used to check the data normality. Sample characterization will be presented by descriptive statistics. To check the difference between means, the T-Student test or the U-Mann-Whitney test will be used, according to data normality. To verify treatments effects, analysis of variance (ANOVA) for repeated measurements will be used, considering two factors (two-way): time (week 1, week 4, and week 6) and group (IG and SG). Significance level adopted for all tests will be 5%.

### Discussion

This study evaluated effects of MR associated with kinesiotherapy on chronic pain treatment and upper limb dysfunction in breast cancer survivors. By using stretching, strengthening and neuromuscular control exercises, kinesiotherapy has been shown to be effective, playing a central role in the rehabilitation process.<sup>12</sup> Whereas MR, by acting on myofascial tissue through stretching, manual pressure and sliding techniques, has shown good results in the treatment of chronic pain and upper limb dysfunctions after breast cancer surgery.<sup>16,17,32</sup>

It is possible that through manual therapy, stimulation of intrafascial sympathetic afferents can trigger changes in the global autonomic nervous system tone, as well as in local circulation and extracellular matrix hydration.<sup>33</sup> Therefore, we believe that associating a MR protocol with kinesiotherapy, we can maximize results, reducing pain and increasing functionality after breast cancer. In this way, we will be able to provide these women with a faster return to socio-labour activities, which has a positive impact on their quality of life.

In a recent systematic review with meta-analysis, it was found that manual therapy decreased the intensity of chronic musculoskeletal pain among breast cancer survivors, however, studies were scarce, with small sample size and low methodological quality.<sup>19</sup> Therefore, during the development of our study, we seek to reduce these gaps by describing and illustrating each of the techniques and using a simple and clear methodology. Furthermore, by adding SG, on one hand we will allow participants of both groups to have the same time of individual treatment with the therapist touch, reducing possible biases. On the other hand, therapists touch can be considered therapeutic by physical and psychological mechanisms,<sup>34</sup> which can make it difficult to identify a difference between groups.

Finally, chronic pain in breast cancer survivors may involve different mechanisms (nociceptive, neuropathic and/or central sensitization).<sup>8</sup> However, randomized clinical trials investigating chronic pain in breast cancer survivors usually do not consider pain mechanisms to address treatment.<sup>35</sup> By associating kinesiotherapy with MR, we can work on more than one mechanism in the same session, maximizing the results. Therefore, if the association of MR with kinesiotherapy prove to have superior effects than isolated kinesiotherapy, we can suggest that pain mechanisms might also be considered when developing a treatment programme for chronic pain of breast cancer survivors.

The study presents some limitations. Due to the proposed interventions nature, responsible therapist for implementing treatment cannot be blinded. In addition, if the intervention will be replicated in other rehabilitation centers, it should only be performed by physiotherapists with experience in MR, which eventually restricts its use. On the other hand, kinesiotherapy protocol allows for greater flexibility, as it can be adapted even for group care, enabling greater reproducibility.

## Conclusion

In conclusion, the association of MR with kinesiotherapy will hopefully generate an improvement in chronic pain and functionality of breast cancer survivors. Thus, we believe that MR technique can be routinely included in clinical practice since the early stages of rehabilitation process.

## Acknowledgments

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## Authors' contributions

NSC, LMBS, KZ and FFS were responsible for the study conceptualization; NSC, KZ, GMS and FFS, for the methodology. NSC conducted the investigation, while FFS conducted and supervised the whole project. The original draft was written by NSC and LMBS; review and editing were performed by RS and FFS.

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