

Online general exercise management program for patients with breast cancer-related lymphoedema: a protocol for a pilot randomised controlled trial

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Key words

Breast cancer-related lymphoedema, general exercise management, online intervention, randomised controlled trial, self-care adherence

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Abstract

Background: Breast cancer-related lymphoedema (BCRL) requires a lifetime commitment to self-care.

Aims: This is a study protocol for a pilot parallel-group, randomised controlled trial, which will assess the effectiveness of an online version of the general exercise management programme for patients with BCRL.

Methods: Sixty patients will be recruited through online advertisements and randomly allocated to either an intervention or control group. The intervention group will be provided with an educational programme on standard self-care for BCRL as well as the general exercise management programme, while the control group will receive only the self-care education programme. Both groups will participate in a 6-month online programme, perform daily self-checks and participate in monthly small-group sessions. All participants, session facilitators and a statistical analyst will be blinded to group allocation.

Anticipated Results: The primary expected outcome is a reduction of BCRL symptoms, and the secondary outcomes are health-related quality of life and self-care adherence improvements.

Conclusions: The findings will inform further investigation in a phase III trial.

Breast cancer-related lymphoedema (BCRL) is a chronic condition affecting approximately 29.8% of breast cancer survivors (Shen et al 2024). BCRL symptoms typically include arm swelling, pain and various physical discomforts that affect daily activities (Shen et al, 2024). These symptoms significantly impact a patient's long-term quality of life (QOL) (Ramirez-Parada et al 2023). Managing BCRL requires a lifetime commitment to self-care, but many patients find it challenging to maintain such a commitment (Fu et al, 2023).

Complete decongestive therapy is the most common recommended approach for improving health-related QOL and managing lymphoedema (Rangon et al, 2022, JLS, 2024). Complete decongestive therapy consists of skin care, exercise, compression therapy and daily self-care

education, including weight management. Exercise has been shown to have benefits for BCRL patients (Lin et al, 2023, Ali et al, 2021, Hasenoehrl et al, 2020) and the clinical practice guidelines published by the Japanese Lymphedema Society in 2024 (JLS, 2024) also recommend exercise as part of the treatment plan for BCRL. In this guideline (JLS, 2024), several studies of various exercises are included (Wang et al, 2023, Kilbreath et al, 2020, Pirincci et al, 2023, Pasyar et al, 2019). Despite the importance of exercise, existing Japanese guidelines often lack specific recommendations regarding the type, frequency and duration of exercise, making it difficult for healthcare providers to instruct patients on specific methods.

Although high-frequency exercise programmes have been reported to reduce the severity of symptoms (Lian et al, 2024),

only 14.2% of lymphoedema treatment facilities in Japan implement exercise therapy (Ishii et al, 2021), which may explain poor patient adherence. Furthermore, the complexity of self-care, as well as the various costs associated with practicing it, place a considerable burden on both patients and caregivers, often resulting in low adherence and worsening of the conditions (Lytvyn et al, 2020). Patients must be provided with education on practical and feasible self-care in order to encourage adherence.

We previously reported the benefits of a 10-minute holistic self-care programme for BCRL patients (Arinaga et al, 2019), which included: a modified Radio Taiso No. 1 (a calisthenics programme that has long been practiced in Japan) (Japan-Post-Insurance), gentle arm exercises with deep breathing (Moseley et al, 2005), central lymphatic drainage and skin care using modified

traditional lymphatic drainage techniques (Arinaga et al, 2019).

The control group continued with the usual care as recommended by their respective hospitals over a 6-month period. In our programme, Radio Taiso was modified to be performed at half the speed of the original for BCRL patients, in order to prevent damage to contracted muscles or surgical scars, reduce peripheral movement of lymphatic fluid caused by centrifugal force and enhance muscle strength by maintaining muscle tension for a longer duration.

The intervention group showed significant reductions in relative hand oedema volume and improvements in most BCRL symptoms compared to the control group, who showed improvements only in pain and coldness. While the programme was beneficial, the effects of its individual components were not evaluated separately.

Online interventions have shown benefits in lymphoedema management and patient recruitment (Brøgger-Mikkelsen et al, 2020).

Aims

This study aims to evaluate the efficacy of an online general exercise management (GEM) based on modified Radio Taiso, plus standard self-care education compared to standard self-care education only, focusing on BCRL symptoms, health-related quality of life and self-care adherence.

Methods

Participants

Sixty participants (30 in each group) in Japan, who will have self-confirmed their eligibility as detailed in the following criteria, will be recruited using Online advertisements [Figure 1].

Inclusion criteria

- Adults aged 18 years or older
- History of breast cancer surgery
- Persistent BCRL symptoms (e.g., swelling of the upper extremity on the surgery side) for at least 3 months post-treatment
- Ability to understand study materials and complete online questionnaires
- Access to the internet and ability to attend monthly online sessions

Exclusion criteria

- Current recurrence of breast cancer or

presence of other cancers

- History of radiotherapy or chemotherapy within the last 6 months, or plans to undergo either during the study period
- Current infection, inflammation or deep vein thrombosis in the arm on the surgery side
- Difficulty responding to online questionnaires

Timeline

The study will be conducted from August 2024 to March 2028, including enrolment and follow-up periods.

Randomisation and blinding

Participants will be randomly assigned in a 1:1 ratio to either the intervention group or control group using block randomisation with computer-generated random numbers. In this study, participants, small-group session facilitators, and statistical analysts will be blinded to group assignments to minimise bias.

Interventions

Both groups will participate in a 6-month online programme featuring standard self-care education based on the recent guidelines (JLS, 2024) and research, including videos and texts on BCRL knowledge, skin care, exercise, compression therapy, weight management, and other self-care practices. All participants will complete daily self-care checklists and attend monthly online small-group sessions facilitated by trained staff to share experiences and receive support.

Control group

Participants will have access to the standard self-care education programme website only.

Intervention group

In addition to the above standard self-care education, the intervention group will receive access to the GEM programme. This program is based on Radio Taiso No. 1 (Japan-Post-Insurance) and is adapted for BCRL patients by reducing movement speed by half for therapeutic purposes (Arinaga et al, 2019).

Primary outcome to be assessed

This is the rate of change in the total BCRL symptom score from baseline to 6 months. The symptoms of BCRL will be

assessed using an online self-completed questionnaire consisting of 11 items that were selected based on previous literature (Keeley et al, 2010, Launois et al, 2002). The questionnaire has been validated for face validity by breast surgeons, dermatologists, and breast cancer nursing researchers (Arinaga et al, 2019). Symptoms in the affected upper limb will be self-reported using a seven-point semantic differential scale, ranging from 0 (none) to 6 (very severe). The total score will range from 0 to 72, with higher scores indicating a greater severity and number of symptoms.

Secondary outcomes to be assessed

Secondary outcomes will be evaluated at baseline, 1 week, 1 month, 3 months, and 6 months using an online questionnaire.

This will include:

1. Individual BCRL symptom scores
2. Health-related QOL using the validated Japanese SF-8 (Fukuhara and Suzukamo, 2014) instrument.
3. Self-care adherence measured by daily performance of skin moisturizing (three-times daily), exercise (twice daily for intervention group), weight monitoring, and compression therapy (when prescribed), with scores: 0 (not performed), 1 (performed 1–2 times/week), 2 (performed 3–5 times/week), and 3 (performed almost every day)
4. Self-perceived effectiveness and burden of self-care rated on a 7-point semantic differential scale ranging from 0 (none) to 6 (very much)
5. Daily time spent on self-care activities
6. Adverse events

Sample size calculation

Sample size calculation is based on previous pilot studies (Basha et al, 2022, Whitehead et al, 2016). Using an effect size of 0.4, 80% power, and a two-sided 5% alpha level, we determined that 60 participants (30 per group) would be needed, including a 20% allowance for potential dropout.

Data collection and analysis

Primary outcome analysis

The primary outcome will be analysed using the FAS. The analysis will focus on the change in total BCRL symptom scores from baseline to 6 months. The difference in mean scores between the intervention and control groups will be tested using Welch's t-test or the Wilcoxon rank-sum test, as

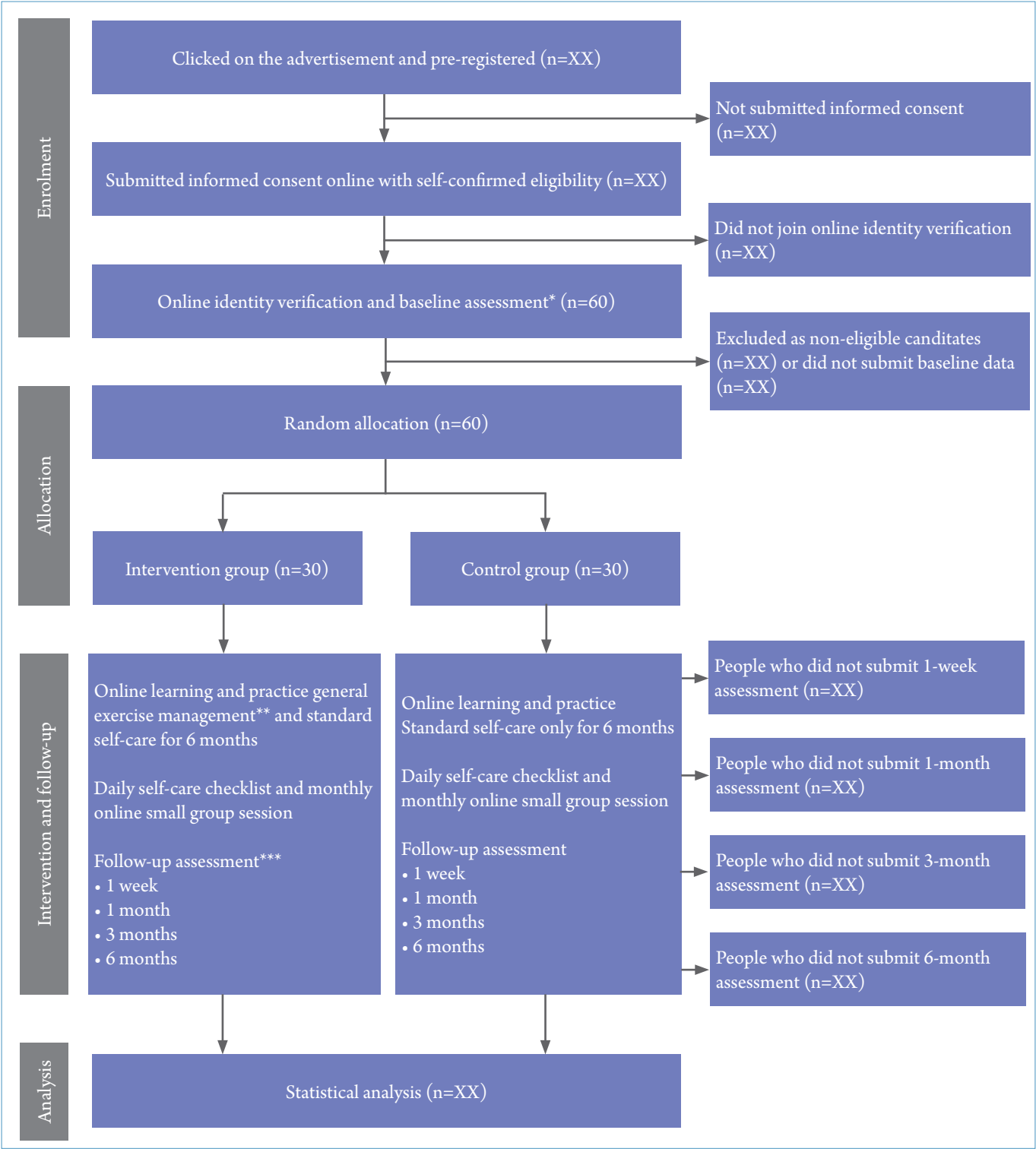


Figure 1. Flow diagram of articles included in this systematic review.

*Age, BMI, types of surgery, side of surgery, arm dominance, time since surgery, history of adjuvant therapy, duration of breast cancer-related lymphoedema (BCRL), triggers for BCRL, history of cellulitis, BCRL self-care education, exercise education, exercise practice, BCRL symptoms, health-related quality of life, self-care adherence.

**A modified version of Radio Taiso No. 1, which will be performed at half the speed of the original, designed for BCRL patients to promote controlled limb movement, prevent muscle damage and improve lymphatic drainage.

***Exercise practice, BCRL symptoms, health-related quality of life, self-care adherence.

appropriate. $p < 0.05$ will be considered statistically significant.

Secondary outcome analysis

For continuous variables, group comparisons will be performed at each time point (baseline, 1 week, 1 month, 3 months and 6 months) using Welch's t-test and the Wilcoxon rank-sum test. For categorical variables, Fisher's exact test will be used for group comparisons. To address multiple comparisons, adjustments will be made using Holm's method.

For longitudinal data, multivariate analyses will be conducted using a linear mixed-effects model.

Additional analyses

Summary statistics will be calculated for all variables, with continuous data presented as mean (standard deviation) and categorical data as frequencies (%). Adverse events will be documented and compared between groups. Sensitivity analyses will include per protocol set analysis and multiple imputation for missing data. Outliers will be included in the primary analysis, with sensitivity analyses conducted if necessary.

Discussion

This phase II trial aims to evaluate the online GEM programme for BCRL patients, based on modified Radio Taiso, a widely recognized Japanese calisthenics programme. The GEM programme's cultural familiarity and simplicity may enhance self-care adherence. Additionally, the online delivery of the intervention addresses the accessibility challenges often faced by patients with lymphoedema, particularly those in rural or underserved areas.

The results of this study will provide foundational data for the planning of a phase III trial. Furthermore, the online format offers a cost-effective solution that can be easily expanded to reach more patients, addressing the challenges of in-person care, particularly during global health crises, such as the COVID-19 pandemic.

Potential limitations of this study include the reliance on self-reported outcomes and variability in participants' engagement with the online platform. Additionally, the use of online recruitment may introduce selection

bias, as only participants with internet access will be eligible. Future studies should incorporate a more objective method to assess changes in lymphoedema symptoms and increase the sample size. It will also be essential to disseminate the effectiveness of the GEM programme to a broader range of BCRL patients, who must maintain lifelong self-care for lymphoedema, and to the healthcare providers who support them, as the programme is designed to be simple and suitable for long-term implementation.

Declaration of Interest

All authors declare that they have no competing financial interests.

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