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A phase III, multi-state, randomised controlled trial evaluating the addition of exercise or compression therapy to best-practice usual breast cancer care to prevent breast cancer-related lymphoedema: The ACHIEVE trial protocol

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Introduction: Breast cancer-related lymphoedema (BCRL) is a prevalent condition associated with lifelong physical, psychological and social burden, and lower quality of life. The primary aim of this trial is to determine if adding exercise therapy or compression therapy to usual care can prevent BCRL. Secondary aims evaluate effects on patient-reported outcomes and the cost-effectiveness of preventive strategies.

Methods: This multi-state, phase III, single-blind, parallel-group (1:1:1), randomised controlled trial will recruit adults with a first diagnosis of breast cancer who are at high risk of BCRL. Participants will be randomised to usual care, usual care plus exercise therapy, usual care plus compression therapy. 660 participants are needed to detect a 10% absolute difference in 12-month BCRL incidence between groups (α=0.05, β=0.2, 10% drop-out). BCRL incidence will be assessed using bioimpedance spectroscopy, circumferences, tissue dielectric constant and validated self-report measures, applying predetermined diagnostic thresholds. Secondary outcomes include patient-reported outcomes of symptoms, function, quality of life, mental health and physical activity as well as intervention cost-effectiveness. Usual care includes prospective surveillance (lymphoedema assessments of the upper-limb, postoperative lymphoedema education including risk reducing strategies and shoulder function rehabilitation). Exercise therapy (behaviour-change counselling and individualised prescription of aerobic and resistance training targeting 150 minutes per week) and compression therapy (provision of individually-fitted compression garments for daily wear) will be delivered through fortnightly calls over a 6-month period. Primary and secondary outcomes will be assessed at baseline, 3-, 6-, 12-, 24-months, and 5 years post-randomisation.

Results: Study ethics approval is under review. Study protocol will be registered on the Australian New Zealand Clinical Trial Registry (ANZCTR). Findings will be disseminated via peer-reviewed publications and national/international conferences.

Conclusion: This trial will determine the efficacy and cost-effectiveness of incorporating exercise therapy or compression therapy into best-practice usual breast cancer care for BCRL prevention.

Keywords

Breast Cancer-related Lymphoedema, Prevention, Exercise trial, Compression

Conflict of Interest & Ethical Approval

yes

Abstract submitters declaration

yes

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