

Interim project report to Breast Cancer Australia

Project Title: Randomised controlled trial of exercise in patients with upper-limb lymphoedema

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Brief Overview of Project, including significance:

The project aimed to investigate the role of exercise for women who have upper-limb lymphoedema following treatment for breast cancer. There have been numerous studies involving women with breast cancer and exercise, with this work demonstrating that participation in exercise brings with it physical and psychosocial advantages. However, typically, women with lymphoedema have been excluded from this work for fear of exacerbating the condition. Preliminary evidence exists to suggest that exercise neither causes nor exacerbates lymphoedema and that limiting exercise has the potential to deny women an important strategy to improve well-being, physical functioning and hence quality of life. This work was designed to broaden our understanding of the role exercise can play in the treatment and management of upper-limb lymphoedema.

Through use of local physiotherapists known to treat women with lymphoedema, the Lymphoedema Association of Queensland, phone calls following study advertisements in local papers and our own database of women with lymphoedema following breast cancer, 332 women were sent information about the study. While the response rate was 52% (n=172), the nature of the study made it difficult

for women to participate. Eligibility criteria included:

- being diagnosed with unilateral lymphoedema following treatment for breast cancer,
- currently experiencing lymphoedema,
- completed treatment for breast cancer at least 6 months prior,
- aged less than 75 years,
- having a good understanding of written and verbal English,
- being available to travel to the Royal Brisbane and Women's hospital twice per week (during work hours) for eight weeks, and then once per week for four weeks, to enable participating in group supervised exercise,
- and willingness to be randomly assigned to the exercise or control group.

Of the 59 women who met all eligibility criteria, 32 (54%) provided consent to participate. Following baseline screening of lymphoedema status, women were then randomly assigned to the exercise or control group (16 women per group). The intervention period was completed at the end of July, while the post-intervention testing session was completed mid-August. The final 3-month follow-up testing session is scheduled in late October and early November.

Data are being analysed for all women with group comparisons being made. While the key outcome variable of interest is lymphoedema status, we will also be assessing changes in fatigue, self-report upper body function, depression and quality of life (known key issues for women with lymphoedema).

Ultimately, the results from this study will be used to quantify the short- and longer-term effects of participating in a mixed-type, moderate-intensity, supervised exercise program on lymphoedema status. In addition, the study will significantly contribute to the current state of the literature (or lack there of) regarding exercise prescription advice for these women. Consequently, it will allow more realistic disclosure regarding lymphoedema prevention or management, while help develop recommendations for optimizing physical therapy in consultation with prevailing care.

Progress to date:

As indicated above, the intervention has been completed. To date, study adherence has been excellent with no drop-outs as a consequence of group allocation, all 16 women in the exercise intervention successfully completed the intervention and all 32 women have participated in the pre- and post-intervention testing sessions, with all women's final testing session already scheduled.

While there were reports of changes in lymphoedema symptoms in 5 of the exercising women, clinical assessment midway through the exercise intervention indicated that lymphoedema status was improving for 4 out of 5 of these women and remaining stable for the other woman.

Data entry for information collected during the first and second testing sessions has been completed. We are currently in the process of completing data cleaning and will then move onto data analysis (comparing changes in lymphoedema status between the control and exercise groups). The expected outcomes from the continued data collection, entry, cleaning and analysis include:

Academic:

- submission of manuscript to Breast Cancer Research and Treatment (IF:4.643)
- Submission of 3 abstracts for oral presentation at the International Lymphoedema Congress (Shanghai, China, 2007) covering:
 - Lymphoedema – challenges and clinical implications of intervention research
 - Randomised controlled trial of exercise in women with lymphoedema following breast cancer
 - Exercise and women with upper-limb lymphoedema – the psychosocial effects
- As a consequence of the recruitment approach used in this study, we've developed key relationships with the health professionals involved in treating women with lymphoedema in South-East Queensland.
- Human Movement Studies undergraduate students (n=5) underwent their 3rd year practicum experience by being involved in the data collection sessions and exercise intervention, raising awareness of the condition within a health professional setting.

Community:

- Recruitment for the work led to advertorials regarding lymphoedema in local and regional newspapers throughout Queensland, raising awareness of the condition in the community.
- News article was published in the Royal Brisbane and Women's paper
- All women participating in the study, as well as their partners, friends and family, have been invited to an information evening, scheduled for 9 November at 6.00pm. During this session, the results of the study will be discussed as what we currently know and don't know about lymphoedema prevention and treatment.
- Once the data analysis has been complete, we will send out another news press highlighting the findings of the work, in the hope that the story will be picked up by various media groups.

Future plans:

Upon completion of the final data collection session, we will submit a final report to the Cancer and Bowel Research Association.

Results from this study are being used as pilot study data to inform the development of a multi-centre (involving Queensland, New South Wales and Western Australia) project grant application that will be dealing with issues surrounding the integration of a formal lymphoedema assessment into the routine clinical care of women with breast cancer, as well as assessment of various treatment options for women who develop lymphoedema. Grant applications will be submitted to the National Health and Medical Research Council and the National Breast Cancer Foundation.