

**An Integrative Tai Chi (ANITA) Program
For Breast Cancer Patients Undergoing Cancer Therapy:
A Randomized Controlled Feasibility Study**

Participant Information Sheet

Locality:	University of Otago	Ethics committee ref.: 17/STH/96
Principal Investigator:	Dr. Lizhou Liu	School of Physiotherapy, University of Otago
Co-Investigator:	Prof. David Baxter	School of Physiotherapy, University of Otago
Clinician:	Dr. Simone Petrich	Department of Surgical Sciences, Southern DHB
	Dr. Blair McLaren	Oncology Department, Southern DHB
	Dr. Lyndell Kelly	Oncology Department, Southern DHB
Breast Care Nurse:	Ms. Glenys Mitchell	Breast Care Services, Southern DHB
	Ms. Mary Grant	Breast Care Services, Southern DHB
	Ms. Janine Tallentire	Breast Care Services, Southern DHB

Thank you for showing an interest in our project. If you decide to participate, we thank you. If you decide not to take part, there will be no disadvantage to you of any kind, and we thank you for considering our request. If you would like to take part now, but change your mind later, you can pull out of the study at any time without any disadvantage.

This information sheet is to help you to decide if you would like to take part. You do not have to decide today whether to take part. Before you decide, please feel free to talk about it with other people, such as family, whānau, friends, or healthcare providers.

If you agree to take part in this study, please sign the Consent Form on the last page of this document. This document is five pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Why are we doing the study?

Previous research indicates benefits of Tai Chi for the health and wellbeing of breast cancer survivors (who have completed cancer treatment), but there have been no studies that have looked at the benefits of Tai Chi while treatment is still in progress.

We have developed an integrative Tai Chi (ANITA) program (consisting of peer support, health education, and Tai Chi exercise) designed around the specific needs for breast cancer patients undergoing cancer treatment. We would like to see if our ANITA program is practical to run; if patients like it; and if practicing the ANITA program helps patients to manage and improve their symptoms and quality of life during breast cancer therapy.

Who can join the study?

We are looking for people who:

- Have been diagnosed with breast cancer (Stage I, II or III) by the Dunedin Public Hospital;
- Completed breast cancer surgery at least 4 weeks ago;
- Are waiting for, or currently undergoing, cancer therapy including chemotherapy, radiation therapy, and/or hormonal therapy.

You will not be able to take part if you have:

- (1) Engaged in the regular practice of Tai Chi, qigong, or yoga within the past 3 months; or
- (2) A history of severe medical conditions including problems with your heart and/or lungs, liver or kidney disease, or if you suffer from dementia.

What are the start date, end date and sources of funding of the study?

The recruitment will run from August 2017 until the end of July 2018. The New Zealand Breast Cancer Foundation has funded this study.

What would your participation involve?

After you have agreed to take part in the study, you will be randomly placed in one of two groups (selection by chance by a computer):

Group 1- participating in the ANITA program straightaway.

Group 2- participating in a condensed ANITA program at the end of the study.

Please note: You will not be able to choose your group.

You will continue to receive your scheduled cancer treatment at Dunedin Hospital (e.g. chemotherapy, radiation therapy, and hormonal therapy, as directed by your surgeon and oncologist) during the course of the study.

Study timeline:

- **Week 1:** Meet with the Principal Investigator (Dr. Lizhou Liu) at the School of Physiotherapy Clinic, sign the consent form, and fill out questionnaires. This appointment will take approximately 30 minutes. After this appointment, if you are eligible to take part, you will be randomly placed into one of the two groups already mentioned.
- **Week 2-25:** Depending on your group, you will either take part in the ANITA program (as well as continuing with your scheduled cancer treatment), or you will just continue with your scheduled cancer treatment. During this period, you will complete questionnaires at *Week 13 and Week 25*, and post them back to us using prepaid envelopes.
- **Week 26:** Group 1 completes the study, and Group 2 starts a condensed ANITA program.

What is the difference between the two study groups?

Group 1:

- During Week 2-25, you will continue with your scheduled cancer treatment.
- In addition, you will attend a **monthly** peer support group hosted by the Otago/Southland Division of the New Zealand Cancer Society. This group consists of breast cancer patients who have completed cancer therapy and others who are undergoing treatment. The group is intended to be an interactive environment, and provides peer support for you. Furthermore, it serves as a regular social activity and networking opportunity among breast cancer patients.
- You will be invited to attend a 40-minute health education seminar **every second month** at the Otago/Southland Division of the New Zealand Cancer Society. Seminars will be conducted prior to the monthly peer support groups, and provide you with knowledge on post-surgery self-care, nutrition, sleep and fatigue coping, stress management, and social support.
- During Week 2-13, you will attend a 60-minute Tai Chi class at the School of Physiotherapy Clinic, **twice a week**. Everyone in this class has breast cancer, and has completed the surgery. Classes will involve gentle Tai Chi Ruler exercises, with controlled breathing and relaxation techniques. Class times will be

arranged at your convenience to accommodate work and family commitments, and your treatment schedule.

- During Week 14-25, you will practice the Tai Chi Ruler exercise at home **twice per week**, on days and at times of your choice. You will receive a CD containing exercise music to facilitate your home practice.
- You will complete questionnaires on Week 1, 13, and 25.

Group 2:

- During Week 2-25, you will continue with your scheduled cancer treatment.
- You will complete questionnaires on Week 1, 13, and 25.
- In Week 26, you have the option to attend a weekend Tai Chi Ruler workshop, which will teach you the Tai Chi Ruler practices given to Group 1. You will receive a CD containing exercise music to facilitate your future home practice of the Tai Chi Ruler exercise. You will be invited to join the monthly peer support groups and weekly health education seminars held by the Otago/Southland Division of the New Zealand Cancer Society.

Who will teach the Tai Chi Ruler class?

Dr. Lizhou Liu will teach the Tai Chi Ruler classes. Lizhou is a trained Tai Chi instructor with two years' experience leading Tai Chi classes for people with chronic health issues and post-surgery.

What are the possible benefits and risks to you of participating?

Benefits:

Potential benefits of taking part in this study may include decreased fatigue, reduced stress, and improved sleep quality and quality of life during the cancer treatment and beyond.

Risks and discomfort:

We do not expect any risks to you from participating, as we have designed this study especially for breast cancer patients undergoing cancer treatment. This means you can take part in the classes according to how you feel on the day, and may sit down and rest during class at any time.

What will happen if you are injured in the study?

If you are injured in this study, which is highly unlikely, you may be eligible for compensation from ACC. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

What are the rights of participants in the study?

Refusal or withdrawal of participation:

Your participation is purely voluntary. You may withdraw from the project at any time and without any disadvantage of any kind.

Participant information confidentiality:

Your health information in the study will be kept confidential by using a random ID number. All data will be stored securely on password-protected servers, and all hard copies will be stored in a locked cabinet in the School of Physiotherapy for 10 years after the project and discarded thereafter according to the University of Otago research policy. Only the members of the research team have access to the data, and they take the responsibility for secure storage of data.

What will happen after the study ends, or if you pull out?

During your participation in the study, there is no charge for the Tai Chi Ruler class at the School of Physiotherapy Clinic. If you choose to continue with the instructor-led classes at the School of Physiotherapy Clinic when your part in the study is finished, the usual charges will apply. Alternatively, you may continue with the exercise regime at home on individual basis, as you will be given a CD containing practice music for the Tai Chi Ruler exercise. This CD will help you to perform the home exercise program for the 12 weeks when you are taking part in the study.

Data information and use:

Data acquired from this study will be used for a report for the New Zealand Breast Cancer Foundation as well as for publications in health-related journals. Your anonymity will be preserved in all publications. The published study will be available in the University of Otago Library (Dunedin, New Zealand).

Data collected during this study may be useful for future research, subject to future ethical approval. If you are happy for us to use your de-identified data in this way, please tick the relevant box on the Consent Form.

Request for more information:

If you have any more questions about participation in the study, you may contact the Principal Investigator:

Dr. Lizhou Liu
School of Physiotherapy, University of Otago
Phone: (03) 479 5694
Email: lizhou.liu@otago.ac.nz

If you have any questions, concerns or complaints about the study once you have enrolled, you can contact:

Professor David Baxter
School of Physiotherapy, University of Otago
Phone: (03) 479 7411
Email: david.baxter@otago.ac.nz

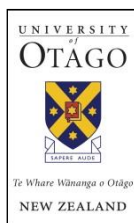
If you want to talk to someone who is not involved with the study, or ask for independent Maori health support, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Thank you again for your interest in our study



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Consent Form for Participants

Declaration by participant:

I have read, or have had the information read to me, and I understand the Participant Information Sheet. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

I know that:-

1. My participation in the study is voluntary.
2. I am free to withdraw from the study at any time without any disadvantage.
3. I may not choose which group I go in.
4. I am aware that I should continue to receive my scheduled cancer treatment at the Dunedin Hospital during the course of the study.
5. My participation in this study is confidential; no data that could identify me will be used in any reports or publications from this study.

I allow the research team to obtain my medical records from the Southern DHB: Yes No

I consent to my de-identified data being used in future research, subject to ethical approval: Yes No

I hereby consent to take part in this study: Yes

I wish to have a copy of the study results: Yes No

If yes, please indicate your preference to receive your results: By email By post

Participant's name: _____

Signature: _____

Date: _____