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Study Protocol

An integrative Tai Chi program for patients with breast cancer undergoing cancer therapy: study protocol for a randomized controlled feasibility study

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ABSTRACT

BACKGROUND: Breast cancer patients experience various side effects during cancer therapy, often resulting in reduced quality of life and poor adherence to treatment. A limited range of proven interventions has been developed to target such side effects. While Tai Chi offers benefits for the health and well-being of breast cancer survivors, the effectiveness of Tai Chi across the treatment continuum has not been evaluated. Improved patient education and support has been suggested as a priority for breast cancer care. This pilot study assesses the feasibility of a randomized controlled trial (RCT) to evaluate the effectiveness of "an integrative Tai Chi" (ANITA) program for breast cancer patients undergoing cancer therapy.

METHODS/DESIGN: This is a single-centre, two-arm feasibility RCT. Twenty-four patients with breast cancer who have undergone surgical treatment will be recruited from the Dunedin Hospital (New Zealand) over a 12-month period (from August 2017 to July 2018). Subject to informed consent, patients will be randomized to receive standard cancer treatment alone or standard cancer treatment plus the ANITA program, consisting of peer support, health education, and Tai Chi Ruler exercise. The program runs alongside the patient's adjuvant cancer therapy, which may include chemotherapy, radiation therapy, antibody treatment, and/or antihormonal therapy. Analysis in this study will focus on process evaluation of participant recruitment, retention, treatment fidelity, acceptability of the program, and occurrence of adverse events. Clinical outcomes (i.e., fatigue, sleep quality, anxiety and depression and quality of life) will be assessed at baseline, and at 12 weeks and 24 weeks post-randomization.

DISCUSSION: Outcomes from this study will inform the feasibility and methodology for a future fully-powered RCT.

TRIAL REGISTRATION: Australian New Zealand Clinical Trials Registry with the identifier ACTRN12617000975392.

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