Protocol Number:	**1.1**
Alfred HREC Number:	**305/17**
Protocol:	**Exercise as a diagnostic and therapeutic tool to prevent cardiovascular morbidity in breast cancer survivors — a randomised trial**
Sponsor:	**Investigator Initiated (Grant applications for funding are pending)**
Principal Investigator	**A/Prof Andre La Gerche**

PRIMARY OBJECTIVES

1) To assess whether novel exercise measures of cardiac function are better than standard assessment with resting ejection fraction at predicting functional capacity (measured as exercise capacity) at 12 months following the initiation of anthracycline-based chemotherapy.

2) To assess whether a 12-month structured, multi-component exercise program initiated at the onset of anthracycline chemotherapy can prevent functional disability

SECONDARY OBJECTIVES

To assess the effects of anthracycline chemotherapy with/without a 12-month structured exercise training program on other indices of cardiac functioning, and additional non-cardiac components of cardiopulmonary fitness, physical function, cognition, fatigue and mood.

Inclusion Criteria

1. Female diagnosed with breast cancer aged 40-75 years
2. Scheduled for anthracycline-based chemotherapy
3. Willing to be randomized to undergo a supervised exercise program or standard of care exercise advice only.

Exclusion Criteria

1. Known structural heart disease (such as symptomatic ischemic heart disease, significant valvular disease or inherited cardiomyopathies
2. Contraindications to undergoing CMR (including the presence of non-MRI compatible breast tissue expanders, pacemaker or other implanted metallic foreign body or device)
3. The presence of any serious contraindication or uncontrolled medical condition that would limit participation in the exercise program
4. An inability to complete questionnaires in English language
5. Significant cognitive impairment

Study Design: Randomised Controlled Trial (100 Subjects)

This will be a 12-month randomised controlled trial, with assessment of primary and secondary outcome measures performed prior to anthracycline-based chemotherapy, 4-weeks following the completion of anthracycline chemotherapy and 12-months from initiating anthracycline-based chemotherapy. Following baseline testing, participants will be randomly allocated to usual care (n=50), or a 12-month structured, multi-component exercise program (n=50).

Please refer to full current approved version of Study Protocol for more information.

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