Study Title	Physical exercise during neoadjuvant chemotherapy for breast cancer as a means to increase pathological complete response rates: the randomized Neo-ACT trial
Protocol Number	2.1
Sponsor	Cabrini Health / Karolinska Institute, Sweden
Investigator	Dr Eva M Zopf
Study Coordinator	Dr Eva M Zopf

Treatment Plan

In this study, we seek to understand whether exercise concurrent to neoadjuvant chemotherapy (NACT) can improve pathological complete response (pCR) in breast cancer patients.

Secondary aims are to evaluate long-term disease-related outcomes (i.e., overall survival, relapse-free and distant metastasis-free survival), patient-reported outcomes (health-related quality of life, level of functioning), cancer treatment-related toxicities (i.e., cardiovascular toxicity, cognitive dysfunction, chemotherapy completion rates) and physiological outcomes (muscle strength, cardiorespiratory fitness, device-measured physical activity.

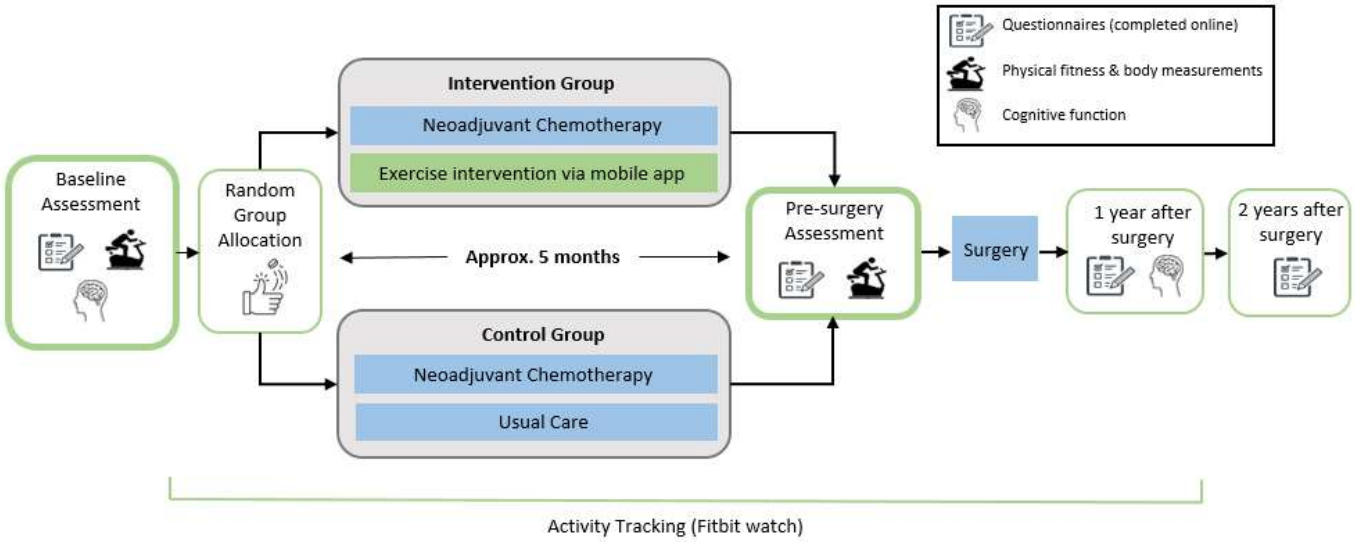
Participants randomized to the exercise group will complete a total of 120 minutes of home-based exercise sessions per week from initiation of NACT to surgery (approx. five months). The exercise program is delivered via a mobile app (Vitala). Participants will also be supported by pre-recorded and supervised live-remote (via Zoom) exercise sessions. All exercise sessions include resistance training and high intensity interval training. Participants randomized to the control group will continue with routine care and receive general information about the benefits of physical activity. Both groups will receive an activity monitor (Fitbit) and the control group will receive access to the Vitala app after the study.

All participants will receive a comprehensive assessment of their physical performance and wellbeing before and after chemotherapy (but before surgery). Assessments include, physical fitness and function testing, body composition measurements, blood draws, and questionnaires.

The study design and key medical eligibility criteria are included below. Please note further inclusion criteria will be checked by the research team.

If you have any questions or would like further details about the study, please feel free to contact the research team via (03) 9508 1866 or exerciseoncology@cabrini.com.au

To refer a patient, please email patient details to exerciseoncology@cabrini.com.au or complete the REDCap referral form via: https://research.cabrini.technology/redcap/surveys/?s=8P9F4YLKE9EYXTJF



Inclusions

1.	Diagnosed with primary invasive breast cancer cT1-T3 cN0-2
2.	Scheduled for NACT and surgery with curative intent
3.	Tumour subtype (ER, HER2) available before initiation of NACT
4.	≥ 18 years of age
5.	There are no circumstances that would impede ability to give informed consent

Exclusions

1.	Bilateral invasive breast cancer
2.	Pregnancy or breast-feeding
3.	The presence of musculoskeletal, neurological, respiratory, metabolic or cardiovascular conditions that may prevent safe completion of the exercise and testing demands of the trial
4.	Unable to read, speak or understand English (and no one who can help with interpretation)