Study Title	Demonstrating the (cost-)effectiveness of a personalised live-remote exercise intervention for cancer survivors using a super umbrella randomised controlled trial: **The LION RCT**
Protocol Number	NL85029.018.23
Sponsor	Cabrini Health
Investigator	Dr Eva M Zopf
Study Coordinator	Dr Eva M Zopf

Treatment Plan

In this international multisite study funded by the European Union and NHMRC, we seek to understand the (cost)-effectiveness of a **personalised, live-remote exercise intervention** (delivered via Zoom) for cancer survivors on Health-Related Quality of Life and treatment-related side-effects. The four side-effects targeted in this study are: 1) fatigue, 2) perceived low physical functioning in daily life, 3) emotional distress (anxiety and/or depressive symptoms), and 4) chemotherapy-induced peripheral neuropathy (CIPN). Novel aspects of this study include 1) the provision of a live-remote exercise intervention, to reduce common barriers to exercise participation: travel time and distance and 2) tailoring of the exercise intervention to patients' main side effect.

Participants will receive a **free 12-week online exercise program (3x/week) tailored to their main side effect** (outlined above). Participants randomised to the intervention group will receive the intervention after the baseline visit and the wait list control participants after the 12-week follow-up visit. In addition to the live-remote exercise training, participants will be provided with an activity tracker (Fitbit), access to an exercise app, and educational material to support exercise participation.

Participants will also receive a **comprehensive assessment of their physical performance and wellbeing**. Assessments include, physical fitness and function testing, body composition measurements, a blood draw, and questionnaires.

The study design and key medical eligibility criteria are included on the following pages. 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

Eligibility criteria

1.	Diagnosed with any type of invasive or hematological cancer and completed their primary cancer treatment. Primary treatment, in this context, includes surgery, radiotherapy, and/or chemotherapy. For patients undergoing endocrine, targeted, or immunotherapy, their treatment must not be scheduled to be discontinued within the next 6 months.
2.	Completed primary treatment with curative intent 3-12 months ago (patient needs to be approached for participation in this timeframe).
3.	Have received systemic chemotherapy (or a stem cell transplantation in case of a hematological malignancy) as part of their primary cancer treatment with curative intent (or remission, without active disease and no expected active treatment within 1 year in case of hematological malignancies).
4.	18 years or older
5.	ECOG (Eastern Cooperative Oncology Group) performance status ≤ 2
6.	Presence of at least one of the following side-effects: fatigue, perceived low physical functioning in daily life, anxiety or depressive symptoms, and/or CIPN (will be assessed with screening questionnaires)
7.	Did not receive chemotherapy as part of treatment for a previous diagnosis.
8.	No evidence of distant metastatic disease (in case of solid tumours)
9.	Not following, or planned to follow, a structured psychological intervention during the intervention period, i.e., cognitive behavioral therapy, or unstable on psychotropic medication
10.	No severe neurologic or cardiac impairment
11.	No uncontrolled severe respiratory insufficiency or dependence on oxygen suppletion in rest or during exercise
12.	No uncontrolled pain
13.	No contra-indication to exercise
14.	No other circumstances that would impede ability to give informed consent or adherence to study requirements

Study design