ACE Trial: Advanced Cancer and Cachexia Exercise Trial

Chief Principal Investigator: Dr Eva Zopf, Exercise Scientist, Cabrini Cancer Institute

Study Overview:

Cancer cachexia is a multifaceted syndrome characterised by the ongoing loss of skeletal muscle mass. Cachexia may impact up to 80% of individuals with advanced cancer. In addition to negatively impacting quality of life, cachexia may worsen physical function, increase symptom burden, and reduce overall survival.

The ACE Trial: Advanced Cancer & Cachexia Exercise Trial is a two-arm randomised controlled trial that aims to test the feasibility and potential mediating effect of an 8-week supervised tele-exercise intervention relative to usual care (waitlist control) in people with cancer cachexia.

The trial is aiming to enrol **56 patients** across Melbourne, including Cabrini Hospital.

Who is this study for?

Inclusion criteria:

- Adults ≥18 years
- A diagnosis of locally advanced or metastatic cancer
- Body mass index (BMI) <30 kg/m^2
- Australia-modified Karnofsky Performance Status ≥70
- Weight loss >5% within the past 6 months, or weight loss >2% and BMI <20 kg/m^2, or weight loss >2% and the presence of sarcopenia evaluated using dual-energy X-ray absorptiometry scans

Exclusion criteria:

- Expected survival <3 months
- Receiving parenteral nutrition or enteral nutrition via feeding tube
- Less than four weeks post-surgery or scheduled to undergo surgery within the trial period
- Full time reliance on mobility aids including a walker or wheelchair for all day-to-day activities
- Contraindication to exercise as determined by treating medical physician
- Inability to read and communicate in English

What does participation involve?

Study Assessments: All participants are required to complete three in-person assessments at baseline, 2-months, and 4-months. Assessments are performed at the Australian Catholic University (115 Victoria Parade, Fitzroy VIC 3065). Assessments include body composition measurements, physical function testing, a blood draw, and questionnaires. Participants are also asked to complete questionnaires at 1-month. Participants have the option of completing a telehealth consultation in lieu of in-person assessments, based on their preference and proximity to the Australian Catholic University.

Tele-exercise Intervention: The intervention is an 8-week, virtually supervised exercise program delivered via Zoom. The intervention will be led by exercise physiologists who have experience working with individuals with cancer. The intervention will be delivered one-on-one or in small group-based settings (maximum of four people per session) based on the number of participants enrolled.

To carry out the tele-exercise program, participants will be mailed an instructional handout to help them operate the videoconference application and elastic bands to perform specific strength exercises at home. Exercise sessions are performed 3-days per week and last between 30-40 minutes per session. Sessions will be individually tailored and progressed only as tolerated by the participant.

A 1kg bag of protein-dense oral nutritional supplement will also be provided to all participants and they will be advised to consume one serving following each exercise session (~30g of protein).

Usual Care (Waitlist Control) Group: Participants in the usual care group will not take part in the exercise intervention for the first 8-weeks of the research trial. After 8 weeks, participants will be offered the study's supervised tele-exercise intervention (i.e. exact same intervention outlined above).

How to Refer:

Complete the ACE Trial referral form or send patient contact details directly to:

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