



# EXHIBIT STUDY

Study Title	The effects of exercise in patients with melanoma undergoing immune checkpoint inhibitor immunotherapy – <b>the EXHIBIT Study</b>
Protocol Number	V1.7 08/09/2025
Sponsor	Australian Catholic University
Principal Investigator	Dr Eva M Zopf
Study Coordinator	Megan Doherty

In this study, we are investigating whether **exercise concurrent with immune checkpoint inhibitor treatment is safe and feasible for patients with melanoma**. We are also interested in the effects of exercise for these patients on a variety of other outcomes.

All participants in the study will receive **standard medical care, a Fitbit activity tracker, resistance bands, and comprehensive assessments** free of charge throughout their immunotherapy treatment. Assessments include physical fitness and functioning tests, body composition measurements, blood draws, and questionnaires.

In addition, participants allocated to the **exercise group will receive a free exercise program, including an individualised exercise prescription and support from an exercise professional**. The individualised prescription will be designed in accordance with national and international guidelines for best practice in exercise prescription for people with cancer, involving a combination of aerobic and resistance exercises, and will follow a step-down approach:

- **Phase 1** (adjuvant: baseline to 12 weeks; neo-adjuvant: baseline to pre-surgery (up to 12 weeks)): two supervised and one unsupervised exercise session per week.
- **Phase 2** (adjuvant: 13 to 24 weeks; neo-adjuvant: immunotherapy re-initiation to 12 weeks post-immunotherapy re-initiation): one supervised and two unsupervised exercise sessions per week.
- **Phase 3** (25 to 52 weeks, or until scheduled ICI treatment completion): home-based exercise program plus monthly check-in calls.

The study design and key 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) 9230 8268 or [ExerciseOncology@acu.edu.au](mailto:ExerciseOncology@acu.edu.au)

**To refer a patient, please either:**

- email patient details to [ExerciseOncology@acu.edu.au](mailto:ExerciseOncology@acu.edu.au)
- complete the referral form
- complete the online referral form (via link below or QR code):  
<https://redcap.link/fjsvqtvd>





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## Key eligibility criteria

•	Diagnosed with cutaneous melanoma (stages II/III).
•	Scheduled to receive immune checkpoint inhibitor immunotherapy (or has received only one dose)
•	ECOG (Eastern Cooperative Oncology Group) performance status $\leq 2$ : <ul style="list-style-type: none"> <li>○ ECOG 0: Fully active, able to carry on all pre-disease performance without restriction.</li> <li>○ ECOG 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.</li> <li>○ ECOG 2: Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.</li> </ul>
•	$\geq 18$ years of age
•	Able to read, speak and understand English
•	Does <u>NOT</u> have stage IV disease.
•	Is <u>NOT</u> receiving treatment for another cancer (excluding non-melanoma skin cancer)
•	Has <u>NOT</u> received $> 1$ dose of ICI immunotherapy
•	Does <u>NOT</u> have any contraindications for exercise (e.g. serious active infection, severe neurological or cardiac impairment)
•	Is <u>NOT</u> pregnant

## Study design

