

# TOPS trial: Treatment of Post-Cancer Fatigue Study

ACTRN12611000338965

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Status	RECRUITING
Sponsor	University of NSW
Enrollment	100 participants

## Plain Language Summary

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This study is testing a 12-week program designed specifically for people who feel very tired (fatigue) even after finishing treatment for breast or bowel cancer. This type of tiredness — called post-cancer fatigue — is different from ordinary tiredness and can seriously affect your daily life. The program combines exercise guidance from an exercise physiologist with psychological support, including help with sleep, concentration, and mood. Half of participants receive the full program, and half receive a self-guided booklet explaining the same principles.

You may be eligible if:

- You are 18 to 70 years old
- You have finished treatment for breast or colon cancer at least 3 months ago but no more than 12 months ago
- You are experiencing significant fatigue that is reducing your activity levels
- You have no signs of cancer coming back
- You have no other medical or mental health conditions that explain your fatigue

You may NOT be eligible if:

- You cannot speak, read, or understand English well enough
- You have significant other health conditions that prevent you from exercising
- Your doctor does not approve your participation
- You are unable to attend face-to-face sessions

Talk to your doctor about whether this trial might be right for you.

## Key Eligibility Criteria

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### Inclusion (6)

- report clinically significant fatigue (i.e. 'SOMA positive' status on the SPHERE questionnaire);
- be at least 18 years of age;
- have completed adjuvant therapy for cancer at least three months prior;
- be free of co-morbid medical or psychiatric conditions which explain ongoing fatigue, or preclude participation in an exercise/activities program (e.g. organ dysfunction such as cardiac, renal or liver disease);
- be free of clinical or laboratory evidence of cancer recurrence;
- ... and 1 more (see full listing online)

### Exclusion (4)

- they are unable to adequately speak or understand or read English;
- they have significant co-morbid conditions precluding participation;
- their primary physician declines their participation on clinical grounds;
- are unable to attend the face-to-face sessions of the program.

## Locations (1 total)

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NSW, Australia  
<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12611000338965>

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