HUMAN RESEARCH ETHICS APPROVAL

The University of Sydney confirms that this project meets the requirements of the National Statement on Ethical Conduct in Human Research.

Project identifier:	2023/HE000803
Project title:	Active Women over 50: an effectiveness-implementation randomised controlled trial
Application version:	2.02
Chief Investigator:	Professor Anne Tiedemann
Project team:	Miss Courtney West Ms Geraldine Wallbank Dr Juliana Souza de Oliveira Mrs Sandra O'Rourke
Project start date:	20 Dec 2023
Project end date:	20 Dec 2027
Date of issue:	Monday, 14 October, 2024

Project summary

Despite the clear physical and mental health benefits of physical activity, as few as 13% of Australian women aged 45-64 years meet both the physical activity (150 minutes of moderate to vigorous activity per week) and strength (muscle strength twice per week) guidelines. Middle-aged and older adults are a priority for targeted physical activity programs, since physical capacity starts to decline at around age 50. This project aims to test the effectiveness of the Active Women over 50 program (intervention) on physical activity, over 6 months compared with a no intervention wait-list (control), among women aged 50 years and over.

Summary of amendments

We would like to conduct a 12-month follow-up of participants in the intervention group to evaluate the long-term effect of the Active Women over 50 program 6 months after it has been completed. This would involve the intervention participants completing a 12-month survey (the same survey they completed at baseline and 6-months), 12-month impressions survey of the program, and wearing the Actigraph accelerometer for 7 days at the 12-month time-point (same as at baseline and 6-months). Participants in the intervention group would be invited to an additional study follow-up after completing all their 6-month evaluation follow-up measures. They would be provided with a Participant Information Statement (PIS) and consent form informing them about the option to complete an additional study follow-up.

Documents approved

Document type	File name	Document version	Application version
Project description / Protocol	2023_HE000803_v2_01 - AWo50 Protocol_V4_02.10.2024_clean.docx	4	2.02
Other	AWo50_12 month extension notification letter_online_V2_02.10.2024_clean.docx	2	2.02

Other	AWo50_12 month extension notification letter_paper_V2_02.10.2024_clean.docx	2	2.02
Other	AWo50_12 month Follow-up cover letter_online_V2_02.10.2024_clean.docx	2	2.02
Other	AWo50_12 month Follow-up cover letter_paper_V2_02.10.2024_clean.docx	2	2.02
Participant Consent Form (PCF)	AWo50_Consent form Extension_V2_02.10.2024_clean.docx	2	2.02
Participant Information Statement (PIS)	AWo50_PIS_Extension_V2_02.10.2024_clean.docx	2	2.02
Survey or questionnaire	Impressions of AWo50_12 month Intervention_V2_02.10.2024_clean.docx	2	2.02
Survey or questionnaire	Questionnaire_12-month_AWo50_V2_02.10.2024_clean.docx	2	2.02

Conditions of Approval

- Research must be conducted according to the approved proposal.
- An annual progress report must be submitted on or before the anniversary of approval and a final report on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
  - Serious or unexpected adverse events (which should be reported within 72 hours).
  - Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).
- Researchers working on this project must be sufficiently qualified by education, training, and experience for their role, or adequately supervised. Changes to the project team must be reported and approved.
- Researchers must disclose any actual, potential of perceived conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Research data and primary materials must be retained and stored in accordance with relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures, and governance requirements.
- If your research project is a clinical trial and is being sponsored by the University or is to be conducted on a University of Sydney site, you must comply with additional University governance requirements prior to commencing your Clinical Trial.
- The University may conduct audits on approved projects.
- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

Ethics Committee Representative

Chair
On behalf of the University of Sydney

The University of Sydney HRECs are constituted and operate in accordance with the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research (NHMRC). All personnel named on the project should be acquainted with these documents.

Research Integrity & Ethics Administration
Research Portfolio
Level 3, Michael Spence Building (F23)
The University of Sydney
NSW 2006 Australia

T +61 2 9036 9161
E human.ethics@sydney.edu.au
W intranet.sydney.edu.au/ethics

ABN 15 211 513 464
CRICOS 00026A