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:	2024/HE000347
Project title:	Implementation of the Choose to Move Program in Sydney Australia
Application version:	0.03
Chief Investigator:	Professor Anne Tiedemann
Project team:	Mr Daniel Cheung Ms Sandra O'Rourke
Sites approved:	Share
Project start date:	20 Sep 2024
Project end date:	19 Sep 2028
Date of issue:	Friday, 20 September, 2024

Project summary

Choose to Move (CTM) is a 3-month program that provides motivation and support to adults aged 50 and over to become more physically active and socially connected. CTM was designed in Canada and has shown to successfully increase physical activity, mobility and reduce social isolation in older adults. The purpose of this study is to adapt this program to suit adults aged 50 and over living in Sydney who are particularly inactive and not well supported by existing programs. This will be through a process of adaptation (co-design implementation strategies to adapt the program for older adults in Sydney), program implementation and delivery (build organisation capacity, support delivery partners on implementation and deliver 3-month intervention) and evaluation (describe and assess implementation strategies used to achieve 'best fit' and to measure CTM program benefits for various health outcomes to the older person).

Documents approved

Document type	File name	Document version	Application version
Recruitment or advertising material	ChooseToMove (redcap survey) V1 dated 19.07.2024.pdf	1	0.01
Survey or questionnaire	Choose to Move Activity Coach Feedback Survey V1 31.07.24.docx	1	0.02
Participant Consent Form (PCF)	CTM_Consent Form Participants_V2_02.09.2024_Clean.docx	2	0.03
Recruitment or advertising material	Choose to move flyers V2 2.9.24.pdf	2	0.03
Participant Information Statement (PIS)	CTM_PIS_Participants_V2_02.09.24_Clean.docx	2	0.03
Project description / Protocol	Choose to Move Protocol V3 02.09.2024_Clean.docx	3	0.03

Procedure or other study tools	CTM_ScreeningTool_V1_19.07.24_Final.docx	1	0.01
Survey or questionnaire	CTM_3Mth Survey V1_19.07.2024_Final.docx	1	0.01
Survey or questionnaire	CTM_6Mth Post program Survey V1_19.07.2024_Final.docx	1	0.01
Survey or questionnaire	CTM_BaselineSurvey V1_19.07.2024_Final.docx	1	0.01
Survey or questionnaire	CTM_Demographic Form_V1_19.07.2024.docx	1	0.01
Survey or questionnaire	CTM_ Get Active Form_V1_19.07.2024.docx	1	0.01
Survey or questionnaire	CTM_ Get Active Form_V2_02.09.2024_Clean.docx	1	0.03
Survey or questionnaire	CTM_ Get Active Form_V2_02.09.2024_Track changes.docx	1	0.03
Procedure or other study tools	CTM_SPPB V1_19.07.2024_Final.docx	1	0.01
Procedure or other study tools	CTM_tracking checklist for research manager V1 dated 7.8.24.docx	1	0.02
Survey or questionnaire	CTM_GM1_TellMeAboutYourself_V1 dated 9.8.24.pdf	1	0.03
Recruitment or advertising material	Choose to Move_social media recruitment text_V1_19.07.2024.docx	1	0.01
Participant Consent Form (PCF)	CTM_Consent Form_Activity Coach V2_02.09.2024_Clean.docx	2	0.03
Other	CTM_GM2_PhysicalActivity_Slides_V1.pptx	1	0.03
Participant Information Statement (PIS)	CTM_Consent Form_Delivery Partner Organisations_V1_07.08.2024.docx	1	0.03
Participant Information Statement (PIS)	CTM_PIS_Activity Coach V1_07.08.24_Final.docx	1	0.02
Participant Information Statement (PIS)	CTM_PIS_Delivery Partner Organisations_V1_07.08.24_Final.docx	1	0.02
Other	CTM_Information session_handout V1 19.7.24.docx	1	0.01
Interview or focus group plan	Interview Guide for Activity Coaches_CTM_V1_31.07.2024.docx	2	0.02
Interview or focus group plan	Interview guide for Organisation _CTM _V1 31.07.2.docx	1	0.02
Survey or questionnaire	Choose to Move organisation Feedback Survey V1 31.7.24.docx	1	0.02
Interview or focus group plan	Participants Interview guide_CTM_V1_31.07.2024.docx	1	0.01
Survey or questionnaire	Participants Impressions of CTM_V1_31.07.2024.docx	1	0.01

Conditions of Approval for Clinical Trials

This letter constitutes ethical approval only. This project cannot proceed at any site until the necessary research governance authorisation is obtained.

- If your study is 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 at each site. Please contact Research Portfolio Clinical Trials Support at clinical-trials.research@sydney.edu.au.
- Clinical Trials must be registered on a clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE). For trials conducted in Australia or New Zealand registration should be on the Australian New Zealand Clinical Trial Registry before recruitment of the first subject (http://www.anzctr.org.au/).
- If your trial is to be conducted under the Clinical Trials Notification (CTN) or Clinical Trials Approval (CTA) schemes should not commence until it has been notified to the Therapeutic Goods Administration (TGA).

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.

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