

Monash University Human Research Ethics Committee
Approval Certificate

This is to certify that the project below was considered by the Monash University Human Research Ethics Committee. The Committee was satisfied that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and has granted approval.

Project ID: 39672
Application Type: HREC Review
Project Title: Changing the Focus: Facilitating engagement in physical activity for people with dementia in a local community - A feasibility study
Chief Investigator: Professor Keith Hill
Approval Date: 14/09/2023
Expiry Date: 14/09/2028

Terms of approval - failure to comply with the terms below is in breach of your approval and the *Australian Code for the Responsible Conduct of Research*.

1. The Chief Investigator is responsible for ensuring that permission letters are obtained, if relevant, before any data collection can occur at the specified organisation.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash letterhead and the Monash University complaints clause must include your project number.
6. Amendments to approved projects including changes to personnel must not commence without written approval from MUHREC.
7. Annual Report - continued approval of this project is dependent on the submission of an Annual Report.
8. Final Report - should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected completion date.
9. Monitoring - the project may be subject to an audit or any other form of monitoring by MUHREC at any time.
10. Retention and storage of data - The Chief Investigator is responsible for the storage and retention of the original data pertaining to the project for a minimum period of five years.

Kind Regards,

Professor Nip Thomson

Chair, MUHREC

CC: Assoc Professor Michele Callisaya, Professor Terry Haines, Assoc Professor Natasha Brusco, Dr Angel Lee, Dr Christina Ekegren, Dr Angel Lee, Dr Amelia Crabtree, Dr Claudia Meyer, Dr Morag Taylor, Dr Katherine Lawler, Professor Pazit Levinger, Associate Professor Susan Hunter, Associate Professor Dawn Mackey, Associate Professor Elissa Burton

List of approved documents:

Document Type	File Name	Date	Version
Questionnaires / Surveys	Data collection surveys_M0_M6_M12	26/07/2023	1
Supporting Documentation	Cognitive Capacity Checklist	26/07/2023	1
Supporting Documentation	Physical activity and falls diary	26/07/2023	1
Supporting Documentation	Email invitation to ex referrers and providers for Changing the Focus	09/08/2023	1
Supporting Documentation	Email invitation_PWD and carers_Changing the Focus	09/08/2023	1
Supporting Documentation	Flyer_carers and people with dementia_Changing the focus	09/08/2023	1
Supporting Documentation	Flyer_ex referrers and providers_Changing the Focus	09/08/2023	1

Document Type	File Name	Date	Version
Supporting Documentation	Script for contacting ex referrers and providers for Changing the Focus	09/08/2023	1
Supporting Documentation	Script for invitation_PWD and carers_Changing the Focus	09/08/2023	1
Supporting Documentation	Social Media_Changing the Focus_pwd and carers	09/08/2023	1
Supporting Documentation	Social Media_Changing the Focus_referrers and exercise providers	09/08/2023	1
Explanatory Statement	ES_Changing the Focus_Exercise providers	09/08/2023	1
Explanatory Statement	ES_Changing the Focus_Referrers	09/08/2023	1
Consent Form	Consent form_Changing the Focus_carers	09/08/2023	1
Consent Form	Consent form_Changing the Focus_Ex providers	09/08/2023	1
Consent Form	Consent form_Changing the Focus_pwd able to consent	09/08/2023	1
Consent Form	Consent form_Changing the Focus_pwd unable to consent	09/08/2023	1
Consent Form	Consent form_Changing the Focus_Referrers	09/08/2023	1
Supporting Documentation	1 month interview schedule for exercise referrers	09/08/2023	1
Supporting Documentation	6 month interview schedule for exercise providers	09/08/2023	1
Supporting Documentation	6 month interview schedule for people with dementia and carers	09/08/2023	1
Supporting Documentation	Exit interview schedule for people with dementia and carers	09/08/2023	1
Supporting Documentation	Telephone or video call help sheet	09/08/2023	1
Supporting Documentation	Week 3_second home visit help sheet	09/08/2023	1
Supporting Documentation	Research protocol_Phase 2_Changing the Focus project_V1	09/08/2023	1
Explanatory Statement	ES_Changing the Focus_carers-V2	08/09/2023	2
Questionnaires / Surveys	Scales and tests for Changing the Focus home visits	08/09/2023	1
Supporting Documentation	Letter of response to MUHREC	08/09/2023	1
Explanatory Statement	ES_Changing the Focus_pwd-V2	08/09/2023	2

HREC APPROVAL

4 December 2023

Dr Anjali Khushu
Head Aged Care Medicine
Peninsula Health
2 Hastings Road
FRANKSTON VIC 3199

Dear Dr Khushu

Changing the focus: Facilitating engagement in physical activity for people with dementia in a local community:
A feasibility study

HREC Reference Number: HREC/102657/PH-2023

SSA Reference Number: SSA/102657/PH-2023

Thank you for submitting the above project which was first considered by the Peninsula Health Human Research Ethics Committee (HREC) on Wednesday 18 October 2023 in accordance with the National Statement on Ethical Conduct in Human Research (2007 updated 2018). Following further review of requested clarifications and application amendments, I am pleased to advise that approval to commence has now been granted.

The documents reviewed and approved at Peninsula Health are listed below:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application:	Version 2	HREC/102657/PH-2023
SSA Application:	Version 1	HREC/102657/PH-2023
Protocol:	Version 1.1	23 October 2023
VSM:	Version 1	29 November 2023
Explanatory Statement:		
People with Dementia Interviews:	Version 3	26 October 2023
People with Dementia Feasibility:	Version 3	26 October 2023
Carers Interview:	Version 3	26 October 2023
Carers Feasibility:	Version 3	26 October 2023
Exercise Providers:	Version 1	9 August 2023
Referrers:	Version 2	26 October 20
Consent Forms:		
People with Dementia Able to Consent:	Version 2	26 October 2023
People with Dementia Unable to Consent:	Version 2	26 October 2023
Carers:	Version 2	26 October 2023
Referrers:	Version 2	26 October 2023
Exercise Providers:	Version 1	9 August 2023
Flyers:		
People with Dementia and Carers:	Version 1	9 August 2023
Referrers and Exercise Providers:	Version 1	9 August 2023
Questionnaire:	Version 1	26 July 2023

Invitation:		
People with Dementia and Carers:	Version 1	9 August 2023
Referrers and Exercise Providers:	Version 1	9 August 2023
Social Media People with Dementia and Carers:	Version 1	9 August 2023
Social Media Referrers and Exercise Providers:	Version 1	9 August 2023
Script for People with Dementia and Carers:	Version 1	9 August 2023
Script for Contacting Referrers and Exercise Providers:	Version 1	9 August 2023
Other:		
Cognitive Capacity Checklist:	Version 2	26 October 2023
Physical Activity and Falls Diary:	Version 1	9 August 2023
Scales and Tests for Changing The Focus Home Visits:	Version 1	9 August 2023
Week 3 Second Home Visit Help Sheet:	Version 1	9 August 2023
Telephone or Video Call Help Sheet:	Version 1	9 August 2023
1 Month Interview Schedule Exercise Providers:	Version 1	9 August 2023
6 Month Interview Schedule Exercise Providers:	Version 1	9 August 2023
6 Month Interview Schedule People with Dementia and Carers:	Version 1	9 August 2023
Exit Interview Schedule for People with Dementia and Carers:	Version 1	9 August 2023
Monthly Running Cost Data Collection:	Version 1	9 August 2023

Please note the following requirements of the Peninsula Health HREC:

1. The principal investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - any serious or unexpected adverse events
 - unforeseen events that might affect continued acceptability of the project.
2. Proposed changes to the research protocol, conduct of the research, or research completion date will be provided to the Human Research Ethics Committee (HREC) for review in the specified format.
3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
4. The principal investigator will provide an annual report to the HREC and at completion of the study a final report, in the specified format.

Should you have any queries about the consideration of your project please contact Ms Lee-Anne Clavarino, Manager, Office for Research. Details of review processes and guidelines are available on the Peninsula Health website <http://www.peninsulahealth.org.au/research-and-education/human-research-ethics-and-governance/>.

Please quote the Peninsula Health Project Number in all correspondence.

The Committee wishes you every success in your research

Yours sincerely



Lee-Anne Clavarino
Manager Office for Research

When publishing:

Ensure you list your Peninsula Health appointment as well as academic affiliations. For further information, see Authorship Policy.