Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2022 EXP 12775

13 June 2022

Assoc. Professor John Parsons

Level 2, Building 505,
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New Zealand

Tēnā koe Assoc. Professor Parsons

APPROVAL OF APPLICATION

Study title: A tailored iSupport virtual group intervention for Chinese dementia carers living in New Zealand: a pilot randomised controlled trial

I am pleased to advise that your application was **approved** by the Central Health and Disability Ethics Committee (the Committee) with non-standard conditions. This decision was made through the EXP pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Central Health and Disability Ethics Committee is required.

Standard conditions:

- Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
- Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a registry approved by the World Health Organization (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au or https://clinicaltrials.gov/).
- Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Ethics RM. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

- Please amend page 4: replace: "Your identification will not be reported or published in any reports on this study" with: "You will not be able to be identified in any reports, presentations or publications."

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDECs.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through the Ethics Review Manager. Please clearly identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see paragraphs 125 and 126 of the *Standard Operating Procedures for Health and Disability Ethics Committees (SOPs)*.

After HDEC review

Please refer to the *SOPs* for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 13 June 2023.

Participant access to compensation

The Central Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialed. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation.

Further information and assistance

Please contact the HDECs Secretariat at hdecs@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information, as well as

our General FAQ and Ethics RM user manual.

Nāku noa, nā

Mrs Helen Walker

Chair

Central Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Protocol	Phase 2 pilot study protocol 0328 revised	02/05/2022	1
Scientific Peer Review	hdec-peer-review-template-2022 Kathy	02/05/2022	1
Advertisement	Poster FL 0303	02/05/2022	1
PIS/CF	CF FL 0303	02/05/2022	1
PIS/CF	PIS FL 0303	02/05/2022	1
Surveys/questionnaires	SF-12	02/05/2022	1
Surveys/questionnaires	PSS Stress	02/05/2022	1
Data Management Plan	Data management plan 0312	02/05/2022	1
CV for Coordinating Investigator	CV JP	02/05/2022	1
Other	Interview plan -usability 0312	02/05/2022	1
Response to PA Document	CF FL 0525 - tracked version	25/05/2022	2
Response to PA Document	CF FL 0525	25/05/2022	2
Response to PA Document	Cover letter 0525	25/05/2022	1
Response to PA Document	PIS FL 0525 - tracked version	25/05/2022	2
Response to PA Document	PIS FL 0525	25/05/2022	2

Review Document Type	Review Document File Name	Review Document Version Date