Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2023 FULL 15152

14 April 2023

Mrs Shirley Harris

PO Box 4345, 72 Oxford Terrace
Christchurch
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New Zealand

Tēnā koe Mrs Harris

APPROVAL OF APPLICATION

Study title: Mastery of breathlessness in Chronic Obstructive Pulmonary Disease after an eight-week mindful breathing intervention. A feasibility study

I am pleased to advise that your application was **approved** by the Northern B 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 Northern B 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 clarify on what basis the ten persons undertaking the follow-up interview will be "chosen". Could participants elect for this themselves using an option box on the Consent Form?
- In the 'what will participation involve' section please be clear that the assessment visits can be conducted in the participant's home, or another suitable location.
- health information must be kept for at least 10 years not 7 years, please amend.
- Māori cultural support, not health support, please amend.

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 14 April 2024.

Participant access to compensation

The Northern B 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

Ms Kate O'Connor

Chair

Northern B Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Surveys/questionnaires	HADS score		
Surveys/questionnaires	St Georges respiratory questionnaire		
Evidence of Consultation	Bev Burrell 25 March 2019	28/03/2019	one
PIS/CF	participant-information-sheet-consent-form-template-v3.0july2022 PR final	31/07/2022	3
Surveys/questionnaires	Shirley Harris semi-structured interview guide MW comments	20/12/2022	1
Scientific Peer Review	S Harris review 29.11.2022 final	31/01/2023	
CV for Coordinating Investigator	Academic CV updated October 2019	02/02/2023	
Protocol	Harris research protocol JJ 9.1.93	17/02/2023	one
Data Management Plan	UoA_DMP-template_v04	17/02/2023	1
Covering Letter	Cover letter for ethics	17/02/2023	1
Surveys/questionnaires	Day and Date daily diary	17/02/2023	1
Surveys/questionnaires	five facet mindfulness	17/02/2023	1
Surveys/questionnaires	MRC-301121-1959MRCBreathlessnessScale	17/02/2023	1
Surveys/questionnaires	THE COPD SELF efficacy scale	17/02/2023	1

Review Document Type	Review Document File Name	Review Document Version Date