Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2024 EXP 19143

11 April 2024

Mr Sarfaraz Alam

School of Physiotherapy, 325 Great King Street
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9054
New Zealand

Tēnā koe Mr Alam

APPROVAL OF APPLICATION

Study title: Effect of manual therapy on selected biomechanical outcomes of gait in people with knee osteoarthritis

I am pleased to advise that your application was **approved** by the Southern 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 Southern 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 correct the typo in the following sentence on page 1 of the PISCF: 'Biomechanics during gait implies (sic) to analysis of movement...'
- Please delete 'your' from 'you have pain in your one knee' in the advertisements and on page 2 of the PISCF.
- Please rewrite the following section of the PISCF in lay language: 'on the following landmarks: posterior superior iliac spine (PSIS), anterior superior iliac spine (ASIS), lateral thigh, medial and lateral epicondyle femur, lateral shank cluster, medial and lateral malleolus, dome of calcaneus, 2nd metatarsal base, base of 5th metatarsal, and head of 1st metatarsal'. Exact anatomical positions are not required.

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 11 April 2025.

Participant access to compensation

The Southern 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

Mr Dominic Fitchett

Chair

Southern Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Protocol	A3- Protocol	16/02/2024	1.0
Scientific Peer Review	B12-HDEC-Independent peer-review	16/02/2024	1.0
Scientific Peer Review	B12-HDEC peer-review- Response from PI	16/02/2024	1.0
Evidence of Consultation	C6-Research consultation with Maori	16/02/2024	1.0
Advertisement	D7-Advertisement	16/02/2024	1.0
PIS/CF	D10-Participant information sheet-consent form	16/02/2024	1.0
Surveys/questionnaires	E3.3-Quality of Life questionnaire-Subset of KOOS4	16/02/2024	1.0
Data Management Plan	G5-HDEC-data management plan	16/02/2024	1.0
CV for Coordinating Investigator	H3-Coordinating investigator CV	16/02/2024	1.0
Protocol	Appendix D-ANZCTR - ongoing registration	16/02/2024	1.0
Data Management Plan	HDEC-data management plan-MARKED	02/04/2024	version 2.0
Data Management Plan	G5 HDEC-data management plan-version 2.0	02/04/2024	version 2.0
Advertisement	D 7 Advertisement-version 2.0	02/04/2024	version 2.0
Advertisement	2-Advertisement flyer-version 1.0	02/04/2024	version 1.0
Advertisement	3-Webpage study recruitment- version 1.0	02/04/2024	version 1.0
PIS/CF	Participant information sheet -marked-version 2.0	02/04/2024	version 2.0
PIS/CF	D10 Participant information sheet consent form -version 2.0	02/04/2024	version 2.0
Protocol	Updated protocol-MARKED. version 2.0	02/04/2024	version 2.0
Protocol	A3 protocol-version 2.0	02/04/2024	version 2.0
Response to PA Document	Cover letter	02/04/2024	version 1.0

Document Type	File Name	Date	Version
Scientific Peer Review	B12 HDEC Independent peer-review-version 2.0	02/04/2024	version 2.0

Review Document Type	Review Document File Name	Review Document Version Date