

HUMAN RESEARCH ETHICS COMMITTEE

15 April 2024 Doctor Guoyan Yang NICM Health Research Institute

Dear Guoyan,

Project Title: "Tai Chi-based Stress Reduction Program for students in higher education settings: A pilot clinical trial"

HREC Approval Number: H15903

Risk Rating: Greater Than Low Risk (Moderate)

I am pleased to advise the above research project meets the requirements of the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018).

Ethical approval for this project has been granted by the Western Sydney University Human Research Ethics Committee. This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018).

Approval of this project is valid from 15 April 2024 until 15 April 2025.

This protocol covers the following researchers:

Guoyan Yang, Erin Mackenzie, Janet Conti, Emily Hielscher, Byeongsang Oh, Moin Uddin Ahmed, Md. Nazmul Huda, Albert Yeung, Carolyn Ee, Marcus Henning

All researchers named on this application must ensure that conflicts of interest are recorded on the University's Conflict of Interest Register.

<u>Approved Documents</u>

A list of documents appears on page 2 of this letter.

Summary of Conditions of Approval

- 1. A progress report will be due annually on the anniversary of the approval date
- 2. A final report will be due at the expiration of the approval period.
- 3. Any amendments to the project must be approved by the Human Research Ethics Committee prior to being implemented. Amendments must be requested using the HREC Amendment Request Form.
- 4. Any serious or unexpected adverse events involving participants must be reported to the Human Research Ethics Committee via the Human Ethics Officer as a matter of priority.
- 5. Any unforeseen events that might affect continued ethical acceptability of the project should also be reported to the Committee as a matter of priority.
- 6. Consent forms are to be retained within the archives of the School or Research Institute and made available to the Committee upon request.
- 7. The Chief Investigator or Principal Supervisor must notify the HREC if the project is discontinued before the expected completion date, with reasons provided.
- 8. Approval is only valid while you hold a position or are enrolled at Western Sydney University. You will need to transfer your project or seek fresh ethics approval from your new institution if you leave Western Sydney University.





9. The research must comply with the National Statement requirement 3.1.7 which states that any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform [ICTRP] on the World Health Organisation website) before the recruitment of the first participant.

10. Project specific conditions:

There are no specific conditions applicable.

This letter constitutes ethical approval only. The Chief Investigator is responsible for obtaining any additional approvals required to conduct the research.

Please quote the HREC reference number and title as indicated above in the subject line on all future correspondence related to this project. All correspondence should be sent to humanethics@westernsydney.edu.au as this email address is closely monitored.

The Western Sydney University HREC Terms of Reference, membership and standard forms are available from https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics

The Western Sydney University HREC wishes you every success in your research.

Yours sincerely

Associate Professor Gabrielle Weidemann

Presiding Member,

G. Weicker

Western Sydney University Human Research Ethics Committee

H15903 15 April 2024

00. H15903 More Information required

01. GY00022 v1 03 - Project Description R1 clean version

01a. GY00022_v1_03 - Project Description_R1_track change

02. GY00022 v1 03 - Output Form

03. GY00022_v1_03 - Albert_COI

03. GY00022_v1_03 - COI Declaration_M Ahmed_signed_010224

03. GY00022_v1_03 - COI Declaration_sample_EH

03. GY00022_v1_03 - COI Declaration_sample_Janet

03. GY00022_v1_03 - COI Declaration_sample_MAH

03. GY00022_v1_03 - COI-Carolyn

03. GY00022_v1_03 - COI-Erin

03. GY00022_v1_03 - Nazmul_COI

03. GY00022_v1_03 - WSU_Byeongsang Oh_Sigature

04. GY00022_v1_03 - S11_Recruitment script_R1 - Clean

04. GY00022_v1_03 - S11_Recruitment script_R1

05. GY00022_v1_03 - S2_Participant_Information_Sheet_R1 - Clean

05a. GY00022_v1_03 - S2_Participant_Information_Sheet_R1





H15903 15 April 2024

06. GY00022_v1_03 - S4_Screening survey_DASS 21

06. GY00022_v1_03 - S5_Questionnaires

06. GY00022_v1_03 - S6_Adverse events
06. GY00022_v1_03 - S7_Lifestyle behaviour change
06. GY00022_v1_03 - S8_Confidentiality Agreement_workshop

06. GY00022_v1_03 - S9_iHealth Patient Guide
06. GY00022_v1_03 - S10_Interview Guide - 20Feb
06. GY00022_v1_03 - S12_Intervention outline
07. GY00022_v1_03 - rdmp