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PETER MACCALLUM CANCER CENTRE HUMAN RESEARCH ETHICS COMMITTEE [EC00235]
ETHICAL APPROVAL

Peter Mac No: 23/29
HREC Reference: HREC/92616/PMCC
HREC Approval Date: 29 February 2024

Title: A single-arm feasibility study of a telehealth-based cognitive behavioural therapy program for insomnia in Vietnamese-speaking head and neck cancer survivors

Principal Investigator: Ms Mei Tran

I am pleased to advise that the above project has **received ethical approval** from the Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC). The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2018). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2018), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

Ethical approval for this project applies at the following sites:

Site
Peter MacCallum Cancer Centre

Approved Documents
The following documents have been reviewed and approved:

Document	Version	Date
Protocol	3	21 June 2023
Appendix A Invitation Letter	2	21 June 2023
Appendix B Participant Information Sheet and Consent Form	4	29 June 2023
Appendix C Script for Introducing Study	3	21 June 2023
Appendix D Patient Recruitment Log	1	5 January 2023
Appendix E Case Report Form	1	5 January 2023
Appendix F PROMIS Sleep Disturbance – Short Form 4a	1.0	2 June 2016
Appendix G Restless Legs Screening Tool	--	5 January 2023
Appendix H STOP-BANG Questionnaire	--	5 January 2023
Appendix I Can Sleep Booklet	--	Undated
Appendix J Client Satisfaction Questionnaire CSQ-8	--	Undated
Appendix K Patient Experiences Survey	1	5 January 2023
Data Management Plan	1.0	6 March 2023

Noted Document	Version	Date
Appendix A Invitation Letter – Vietnamese translation	2	21 June 2023
Appendix B Participant Information Sheet and Consent Form – Vietnamese translation	4	29 June 2023
Appendix C Script for Introducing Study – Vietnamese translation	3	21 June 2023
Appendix F PROMIS Sleep Disturbance – Short Form 4a - Vietnamese translation	--	7 June 2023
Appendix G Restless Legs Screening Tool – Vietnamese translation	--	5 January 2023
Appendix J Client Satisfaction Questionnaire CSQ-8 – Vietnamese translation	--	Undated
Appendix K Patient Experiences Survey – Vietnamese translation	1	5 January 2023

Governance Authorisation

Governance Authorisation is required at each site participating in the study before the research project can commence at that site. You are required to provide a copy of this HREC approval letter to the principal investigator for each site covered by this ethics approval for inclusion in the site specific assessment application.

Conditions of Ethical Approval

- You are required to submit to the HREC:
    - An Annual Progress Report (that covers all sites listed on the approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.
    - A comprehensive Final Report upon completion of the project.
- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Safety monitoring and reporting in clinical trials involving therapeutic products November 2016*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005)(ARPANSA Code).

Please note: Template forms for reporting Amendments, Adverse events, Annual/Final reports, etc. can be accessed from: www.petermac.org/research/doing-research-us/ethics-governance.

The HREC may conduct an audit of the project at any time.

Yours sincerely, Dr Dianne Snowden

Digitally signed by Dr Dianne Snowden
Date: 2024.02.29 17:14:20 +11'00'

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