

Monash University Human Research Ethics Committee

Approval Certificate

This is to certify that the project below was considered by the Monash University Human Research Ethics Committee. The Committee was satisfied that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and has granted approval.

Project ID: 25221

Project Title: An Online, Person-Centred, Multi-Domain Program to Prevent Cognitive Decline: Protocol for a Randomized Controlled Trial

Chief Investigator: Assoc Professor Yen Ying Lim

Approval Date: 10/08/2020 **Expiry Date:** 10/08/2025

Terms of approval - failure to comply with the terms below is in breach of your approval and the Australian Code for the Responsible Conduct of Research.

- 1. The Chief Investigator is responsible for ensuring that permission letters are obtained, if relevant, before any data collection can occur at the specified organisation.
- 2. Approval is only valid whilst you hold a position at Monash University.
- 3. It is responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
- 4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
- 5. The Explanatory Statement must be on Monash letterhead and the Monash University complaints clause must include your project number.
- 6. Amendments to approved projects including changes to personnel must not commence without written approval from MUHREC.
- 7. Annual Report continued approval of this project is dependent on the submission of an Annual Report.
- 8. Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected completion date
- 9. Monitoring project may be subject to an audit or any other form of monitoring by MUHREC at any time.
- 10. Retention and storage of data The Chief Investigator is responsible for the storage and retention of the original data pertaining to the project for a minimum period of five years.

Kind Regards,

Professor Nip Thomson

Chair, MUHREC

CC: Miss Andrea Mills, Ms Alex Lavale, Ms Stephanie Perin, Assoc Professor Matthew Pase, Dr Darshini Ayton, Dr Renata Morello, Dr Chris Barton, Assoc Professor Anna Barker, A/Prof Nawaf Yassi, Dr Rachel Buckley, Prof Paul Maruff, Prof Leonid Churilov, Prof Richard Sinnott, Dr Loren Bruns Jr, Prof Ashley Bush, Prof Amy Brodtmann

List of approved documents:

Document Type	File Name	Date	Version
Consent Form	Healthy Brain Project PICF MHREC 2016.199	24/06/2019	8
Supporting Documentation	BetterBrains intervention participant experience survey	01/04/2020	draft
Supporting Documentation	BetterBrains Social Media Plain Text Templates 27042020 (FINAL)	27/04/2020	1
Supporting Documentation	BetterBrains Medibank Advertisement Text 27.04.2020 (FINAL)	27/04/2020	1
Supporting Documentation	Better Brains Email Advertisement Text OPTION 1 27042020 (FINAL)	27/04/2020	1
Supporting Documentation	Better Brains Email Advertisement Template Text OPTION 2 270420 (FINAL)	27/04/2020	1
Focus Group questions	BetterBrains Focus Group Questions	30/04/2020	draft
Supporting Documentation	BetterBrains Psychoeducation Sample 30042020 (FINAL)	30/04/2020	1

Supporting Documentation	BetterBrains form for Withdrawal of participation	07/05/2020 1
Supporting Documentation	BetterBrains Website Message System	08/05/2020 1
Supporting Documentation	BetterBrains Email SMS App Templates_V1_18.05.2020 (FINAL)	18/05/2020 1
Supporting Documentation	BetterBrains GP Letter (Psychological Risk) 02.06.2020 (FINAL)	02/06/2020 1
Supporting Documentation	BetterBrains Control Group (App) Slides	02/06/2020 1
Supporting Documentation	BetterBrains Intervention Group (App)	02/06/2020 1
Supporting Documentation	BetterBrains_Website Landing Page_020620	02/06/2020 1
Supporting Documentation	BetterBrains Risk Factor Screen, Baseline Assessment Web Slides	02/06/2020 1
Supporting Documentation	BetterBrains Screen Consent Register Web Slides	02/06/2020 1
Supporting Documentation	BetterBrains Control Group (Website)	02/06/2020 1
Supporting Documentation	BetterBrains Intervention Group (Website)	02/06/2020 1
Supporting Documentation	BetterBrains Participant Letter (Psychological Risk) 02.06.2020 (FINAL)	02/06/2020 1
Supporting Documentation	BetterBrains Services Australia Participant Consent Form 16.06.2020	16/06/2020 1
Supporting Documentation	BetterBrains ANZCTR Registration	16/06/2020 1
Supporting Documentation	Protocol	22/06/2020 1
Questionnaires / Surveys	BetterBrains Surveys 17072020	17/07/2020 1
Supporting Documentation	BetterBrains Surveys 17072020	17/07/2020 1
List of data variables	BetterBrains ERM E2 List of Variables 20072020	20/07/2020 1
Consent Form	BetterBrains Group 1 PICF 20072020 TRACKED	20/07/2020 1
Explanatory Statement	BetterBrains Group 1 Explanatory Statement 20072020 TRACKED	20/07/2020 1
Explanatory Statement	BetterBrains Group 2 Explanatory Statement 22072020	22/07/2020 1
Explanatory Statement	BetterBrains Group 3 Explanatory Statement 22072020	22/07/2020 1
Consent Form	BetterBrains Group 2 Consent Forms 22072020	22/07/2020 1
Consent Form	BetterBrains Group 3 Consent Forms 22072020	22/07/2020 1
Supporting Documentation	Project ID 25221 (BetterBrains) Response to Queries Cover Letter 28072020	28/07/2020 1