Research Integrity & Ethics Administration
Human Research Ethics Committee

Tuesday, 17 July 2018

Dr Shantel Duffy
Central Clinical School: Office; Faculty of Medicine and Health
Email: shantel.duffy@sydney.edu.au

Dear Shantel

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

After consideration of your response to the comments raised your project has been approved.

Approval is granted for a period of four years from **17 July 2018** to **17 July 2022**

Project Title: **CogStep Phase 2.0: Evaluation of a 12-week combined psycho-education and home-based exercise program on dementia risk, mood, health knowledge, cognition, sleep, metabolic markers and brain connectivity in older adults with cognitive difficulties.**

Project No.: 2018/437

First Annual Report Due: 17 July 2019

Sites Approved: Brain and Mind Centre, 100 Mallett Street, Camperdown NSW 2050.

Authorised Personnel: Duffy Shantel; Broadhouse Kathryn; Burrows Claire; Clemson Lindy; Dixon Kahala; Jeon Yun-Hee; LaMonica Haley; Leung Isabella Hoikei; Mowszowski Loren Rina; Naismith Sharon; Rahmanovic Alena; Skinner Bradley; Tran Bonnie; West Stacey;

Documents Approved:

Date Uploaded	Version number	Document Name
12/07/2018	Version 2	Cogstep2.0_EligibilityPhoneScreening_V2
12/07/2018	Version 2	Cogstep2.0_EligiblityScreenConfirmation_V2
12/07/2018	Version 2	Cogstep2.0_Phone_Eligibility_V2
12/07/2018	Version 2	CogStep2.0_PIS_V2
12/07/2018	Version 2	CogStep2.0_Protocol_V2
10/07/2018	Version 1	CogStep2.0_Provisional_Eligibility_REDCap
10/07/2018	Version 2	Cogstep2.0_ExerciseSheet_ALL_V2
26/06/2018	Version 1	Cogstep2.0_RedCap_Questionnaires
26/06/2018	Version 1	Cogstep2.0_RedCap_Nutrition_Questionnaire
03/05/2018	Version 1	Cogstep2.0_Psychoed_Workbook_PartB_V1
03/05/2018	Version 1	CogStep2.0_Marketing-A4-Poster_V1
02/05/2018	Version 1	Cogstep2.0_Psychoed_Workbook_PartA_V1
02/05/2018	Version 1	CogStep2.0_Adverse-Event-Form_V1

02/05/2018	Version 1	CogStep2.0_Adverse-Summary-Report-Form_V1
02/05/2018	Version 1	CogStep2.0_Advertisement_V1
02/05/2018	Version 1	CogStep2.0_Clinical-Trials-HREC-CV_V1
02/05/2018	Version 1	Cogstep2.0_ClinicalReviewSheet_V1
02/05/2018	Version 1	Cogstep2.0_Distress_Protocol_V1
02/05/2018	Version 1	Cogstep2.0_DistressChecklistReport_V1
02/05/2018	Version 1	Cogstep2.0_Control-ContactMessages_V1
02/05/2018	Version 1	CogStep2.0_Participant_Revocation of Consent_V1
02/05/2018	Version 1	CogStep2.0_Responding-to-self-harm-or-distress_V1
02/05/2018	Version 1	CogStep2.0_Participant_Questionnaire_V1
02/05/2018	Version 1	CogStep2.0_Serious-Adverse-Events-Form_V1
02/05/2018	Version 1	CogStep2.0_SleepDiary-Email_V1
02/05/2018	Version 1	Cogstep2.0_SleepDiary-REDCap_V1
02/05/2018	Version 1	Cogstep2.0_WeeklyChecklist_V1
02/05/2018	Version 1	CogStep2.0_ExerciseWorkbook-Skeleton_V1
02/05/2018	Version 1	Cogstep2.0_ExitInterview_V1
02/05/2018	Version 1	Cogstep2.0_MonitoringCalls_ScriptResponseSheet_V1
02/05/2018	Version 1	CogStep2.0_Participant_ConsentForm_V1

Special Conditions of Approval for Clinical Trials

- **This letter constitutes ethical approval only.** This project cannot proceed at any site until the necessary research governance authorisation is obtained. If your study is sponsored by the University or is to be conducted on a University of Sydney site you may need to comply with additional University governance requirements prior to commencing. Please contact the Clinical Trials Governance Office at clinical-trials.research@sydney.edu.au

- Clinical Trials must be registered on a clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE). For trials conducted in Australia or New Zealand registration should be on the Australian New Zealand Clinical Trial Registry before recruitment of the first subject (http://www.anzctr.org.au/).

- A trial to be conducted under the Clinical Trials Notification (CTN) scheme should not commence until it has been notified to the Therapeutic Goods Administration (TGA). If your study is sponsored by the University please contact Clinical Trials Governance to arrange submission of your CTN.

Condition/s of Approval

- Research must be conducted according to the approved proposal.

- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and on completion of the project.

- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
  - Serious or unexpected adverse events (which should be reported within 72 hours).
  - Unforeseen events that might affect continued ethical acceptability of the project.

- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).

- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.

- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.

- Data and primary materials must be retained and stored in accordance with the relevant legislation and University guidelines.

- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures and governance requirements.

- The Ethics Office may conduct audits on approved projects.

- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

Please contact the Ethics Office should you require further information or clarification.

Sincerely

Dr Helen Mitchell
Deputy Chair
Human Research Ethics Committee (HREC 1)

cc. Clinical Trial Governance (only where relevant)

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007) and the NHMRC's Australian Code for the Responsible Conduct of Research (2007).