Health and Disability Ethics Committees
Ministry of Health
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01 September 2015

Dr Harry McNaughton
Neurology Department, CMU
Wellington Hospital
Riddiford St
Private Bag 7902
Wellington 6021

Dear Dr McNaughton

Re:	**Ethics ref:**	**15/CEN/115**
	Study title:	Self-directed rehabilitation RCT after stroke: a practical, low cost programme. The Taking Charge after Stroke (TaCAS) Study

I am pleased to advise that this application has been ***approved*** by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- Dr McNaughton introduced the study. It is a randomised controlled trial of a novel communication intervention for people after they have experienced a stroke. The intervention has been tested before in Maori and Pacific People populations and has been shown to be effective. Therefore, Maori and Pacific Peoples are excluded from the current study. This study is for non-Maori who survive a stroke and who aren't discharged from hospital. Dr McNaughton explained that 15-20 percent of stroke sufferers die in hospital and 15 percent are discharged.
- The Take Charge intervention acknowledges that it is common after stroke to be overwhelmed by such a life changing event. The intervention encourages people to become who they are and take charge of their journey after experiencing a stroke. A focus is placed on who the person is rather than on physical goal setting, such as walking 10 metres in a certain timeframe. Dr McNaughton advised that this type of goal setting has been found not to be effective in transforming people's lives after stroke. The intervention is cheap, and has been found to be very practical and generalizable.
- The research team will recruit only participants who can give informed consent. The committee noted that there may be people who following a stroke, can understand verbal information but who might struggle to read and asked whether there is an alternative way of getting information to them. Dr McNaughton noted that aphasia following stroke is always a challenge and that he has set the bar that a person will need to understand the information that is in the document and

with family/caregiver help can express that they understand. No one will consent on behalf of participants in this study.
- Dr McNaughton explained that in the hospital setting clinicians will be asked to consider whether a person has the ability to understand the information and if not or if the clinician determines that it would be very close they won't refer a patient. Once a patient is referred then the research team will organise a visit and further assess whether a participant will be able to enter the study. The committee noted that it is important that people who are reading impaired but can understand verbal information are included as the benefit could be great.

The committee requested the following changes to the participant information sheet and consent forms:

- Page 3, 'Could this research be stopped unexpectedly?': please remove this paragraph as it is not relevant for this type of study and could be confusing for participants.
- Page 3: the committee noted the information given that a participant's GP will be told about their participation in the study as they may need to contact GPs if new medical problems develop after discharge from hospital or if the research team is unable to contact the participant for final assessments. The committee requested that more specific information is given here about what might happen. For example, high blood pressure and heart rate are critical in this respect.
- Page 4 under the heading 'Will the information collected be confidential?': please replace the words "NZ Multi Regional ethics committee" with the Central Health and Disability Ethics Committee.
- Pages 6 and 7: please review the statements and only include yes/no statements for those that are truly optional.
- Page 6: please remove the interpreter box as there will be no Maori or Pacific Peoples in this study.
- Page 6: please remove the statement "I know who to contact if I have any side effects from the study".
- Page 7, last bullet point: please remove the words "I understand".

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 Central Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. 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.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 27 August 2016.

Participant access to ACC

The Central 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 trialled. 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 (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Mrs Helen Walker
Chairperson
Central Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
CV for CI: CV Dr Harry McNaughton	1	02 August 2015
CVs for other Investigators: CV Dr John Gommans	1	02 August 2015
CVs for other Investigators: CV Dr Geoff Green	1	02 August 2015
CVs for other Investigators: CV Dr Matire Harwood	1	02 August 2015
CVs for other Investigators: CV Prof Mark Weatherall	1	02 August 2015
CVs for other Investigators: CV Assoc Prof William Taylor	1	02 August 2015
CVs for other Investigators: CV Dr Carl Hanger	1	02 August 2015
CVs for other Investigators: CV Dr Anna Ranta	1	02 August 2015
Survey/questionnaire: Six month Outcome form	Six month v2	02 August 2015
Survey/questionnaire: 12 month outcome form	12 month v2	02 August 2015
Evidence of scientific review: HRC letter confirming successful application and funding	1	27 May 2015
Take Charge Session sheet	v2	02 August 2015
Survey/questionnaire: Baseline assessment form	Baseline v2	02 August 2015
PIS/CF: Patient Info and consent form	v4	02 August 2015
Protocol: Protocol	v5	01 August 2015
Covering Letter: Cover letter	v1	10 August 2015

Appendix B
Statement of compliance and list of members

Statement of compliance

The Central Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008712) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*	*Present on 25/08/2015?*	*Declaration of interest?*
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Yes	No
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	01/07/2015	01/07/2018	No	No
Dr Melissa Cragg	Non-lay (observational studies)	01/07/2015	01/07/2018	No	No
Dr Peter Gallagher	Non-lay (health/disability service provision)	01/07/2015	01/07/2018	Yes	No
Mrs Sandy Gill	Lay (consumer/community perspectives)	01/07/2015	01/07/2018	Yes	No
Dr Patries Herst	Non-lay (intervention studies)	01/07/2012	01/07/2015	Yes	No
Dr Dean Quinn	Non-lay (intervention studies)	01/07/2012	01/07/2015	Yes	No
Dr Cordelia Thomas	Lay (ethical/moral reasoning)	19/05/2014	19/05/2017	Yes	No

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz