

12 April 2018

Ms Virginia Eggleston
St Georges Cancer Care Centre
Private Bag 4737
Christchurch 8014

Dear Ms Eggleston

| | |
|------------------------|--|
| Re: Ethics ref: | 18/NTB/36 |
| Study title: | A Randomised Control Trial Comparing the Effects of Mindfulness and Exercise on Psychological and Physical Wellbeing in People with Cancer During and After Treatment. |

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

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

- Adjustment to Participant Information Sheet, Consent Form and the advertisement have been made as requested.

If a new application:

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 Northern B 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 clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However <https://clinicaltrials.gov/> is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.
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 **11 April 2019**.

Participant access to ACC

The Northern B 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 Kate O'Connor
Chairperson
Northern B Health and Disability Ethics Committee

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

Appendix A
Documents submitted

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|---|----------------|------------------|
| Protocol: Consent | 2 | 26 March 2018 |
| Protocol: Information Sheet | 2 | 26 March 2018 |
| Protocol: Protocol | 1 | 19 February 2018 |
| Protocol: Recruitment Flyer/advertising | 2 | 26 March 2018 |
| Evidence of scientific review: Peer review | 1 | 19 February 2018 |
| Survey/questionnaire: Demographic Questionnaire | 1 | 19 February 2018 |
| Survey/questionnaire: T1 Pre Assessment Questionnaire | 1 | 19 February 2018 |
| Survey/questionnaire: T2,T3 and T4 Questionnaire | 1 | 19 February 2018 |
| Survey/questionnaire: MDASI Questionnaire | 1 | 19 February 2018 |
| Survey/questionnaire: FFMQ-SF | 1 | 19 February 2018 |
| Protocol: 6 minute walk Test description | 1 | 19 February 2018 |
| Protocol: Sit to stand test description | 1 | 19 February 2018 |
| Protocol: SOZO description | 1 | 19 February 2018 |
| Protocol: Mindfulness Structure | 1 | 19 February 2018 |
| Protocol: Exercise Structure | 1 | 19 February 2018 |
| Protocol: Take Home Exercises | 1 | 19 February 2018 |
| Survey/questionnaire: Mindfulness Homework Sheet | 1 | 19 February 2018 |
| Survey/questionnaire: Exercise Homework Sheet | 1 | 19 February 2018 |
| CV for CI: CV | 1 | 19 February 2018 |
| Application | NA | |
| Response to Request for Further Information | NA | |

Appendix B Statement of compliance and list of members

Statement of compliance

The Northern B 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 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

| <i>Name</i> | <i>Category</i> | <i>Appointed</i> | <i>Term Expires</i> |
|----------------------------|---|------------------|---------------------|
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 24/07/2015 | 24/07/2018 |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 20/05/2017 | 20/05/2020 |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 |

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>