Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2021 FULL 11846

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Ms Zara Mansoor

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Tēnā koe Ms Mansoor

APPROVAL OF APPLICATION

Study title: Tuning in to Teens in Aotearoa New Zealand: Evaluating a programme for parents of young adolescents in child adolescent mental health services (CAMHS).

I am pleased to advise that your application was **approved** by the Southern Health and Disability Ethics Committee (the Committee) with non-standard conditions. This decision was made through the Full Review pathway.

Summary of resolved ethical issues

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

1. The Committee commended the researcher for having addressed the comments from the previous HDEC review to a high standard.
2. The Committee and researcher discussed the fact that Part I of the study will inform Part II. The Committee noted that they can only approve Part I of the study. Part II will need to be submitted as a substantial amendment to the study once the protocol has been developed.
3. The Committee queried how confidentiality will be managed in the group workshops. The researcher responded that informing the participants of the confidentiality risks will be part of the informed consent, and at the beginning of the workshops the importance of privacy and confidentiality and the associated risks will be discussed.
4. The Committee noted the $150 reimbursement per participant in part I of the study, commenting that this is quite high, especially for children. The researcher responded that this is because participants in part I of the study are involved in co-design, which means they are being used for their expertise. Therefore, they are being paid a market rate for their expertise. Furthermore, the researcher noted that it is important that children are not underpaid on the basis of age. She noted that participants in part II will be paid $20, which is reimbursement for their time rather than expertise, because they are filling out a questionnaire rather than contributing to co-design.
5. The Committee queried the consent process and whether the young people and parents will be consented together or separately. The researcher responded that this will be dependent on the personal preference of the children, as to whether they want a parent or support person with them through the consenting process. The researcher confirmed they will ensure the young participants to not feel pressured to participate.
6. The Committee queried how clinical care will be distinguished from research within the study, to ensure there is a separation of roles between researchers and clinicians. The researcher responded that the initial recruitment will not be coming from the participants' care team.
7. The Committee noted the study title 'Tuning in to Teens' is not relevant for many of the participants, as the age group is 10-14. The researcher noted the difficulty in changing the study title across their documentation but will consider use a more appropriate lay title for participant-facing documentation. However, the programme is called Tuning in to Teens which is a trademark protected title so reference to the programme cannot be changed.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee which require addressing by the Researcher are as follows.

1. In the demographic questionnaire, please correct the spelling of 'Niuean'.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. The Committee noted a printing error in the PISCF and asked the researcher to check / correct for this if necessary.
2. Please check for lay language. For example, participants may not know what co-design means. Please explain what co-design means before starting to use this term widely in the PISCF.
3. On the first page of the PISCFs, please include researcher name and locality, and ethics approval number, version numbers and date at the bottom.
4. Please modify each CF to clarify throughout the document whether it is the participant *assenting* or *consenting*, or the parent/guardian/researcher consenting for the *child's* participation, or for their *own* participation in the study. Please ensure that there are separate and distinct forms for each scenario. Ensure that each sheet has a place to sign. Please refer to parents or guardians rather than caregivers.

Part I of the study was approved by consensus subject to the non-standard conditions below. Please submit Part II of the study as an amendment once the

protocol has been developed.

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 Committee is required.

Standard conditions:

- Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
- Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a registry approved by the World Health Organization (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au or https://clinicaltrials.gov/).
- Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Ethics RM. 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.

Non-standard conditions:

- please address all outstanding ethical issues raised by the Committee
- please update the PIS/CF, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, paras 7.15 – 7.17).*

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDECs.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through the Ethics Review Manager. Please clearly identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see paragraphs 125 and 126 of the *Standard Operating Procedures for Health and Disability Ethics Committees (SOPs)*.

After HDEC review

Please refer to the *SOPs* for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 22 December 2022.

Participant access to compensation

The 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.

Further information and assistance

Please contact the HDECs Secretariat at hdecs@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information, as well as our General FAQ and Ethics RM FAQ.

Nāku noa, nā

Mr Anthony Fallon

Chair

Southern Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix B: statement of compliance and list of members

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Non-Review Document	Decline letter HDEC		
Scientific Peer Review	Peer review for TINT		
Scientific Peer Review	22-006 Mansoor review		
Evidence of Consultation	Maori consultation letter		
Advertisement	Study flyer and invites		
Surveys/questionnaires	Appendix - measures		
Evidence of CI Indemnity	NZCCP Certificate with proof of MPS membership		
CV for Coordinating Investigator	Zara Mansoor CV Sept 2021		
Covering Letter	Cover Letter		
PIS/CF	PIS & CFs		
Data Management Plan	Data management plan TINT 1.3	25/11/2021	1.3
Protocol	TINT study protocol v1.5	26/11/2021	1.5
Assent form	Assent forms	26/11/2021	

Appendix B: Statement of compliance and list of members

Statement of compliance

The Southern 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 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Mr Anthony Fallon (Chair), Mrs Helen Walker (Acting Chair) Mr Dominic Fitchett, Dr Sarah Gunningham, Associate Professor Mira Harrison-Woolrych, Ms Amy Henry, Dr Patries Herst (co-opted non-lay member from the Central HDEC), Dr Kate Parker (co-opted non-lay member from the Northern A HDEC).

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).

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