Queensland Government

Metro South Health

Research

Enquiries to: Metro South Human Research Ethics Committee
Telephone: 07 3443 8049
Our Ref: HREC/2019/QMS/53077 (SR)
Email: MSH-Ethics@health.qld.gov.au

Dr Daniel Harvie
The Hopkins Centre
Menzies Health Institute QLD
Griffith University QLD 4222

Dear Dr Harvie,

HREC Reference: HREC/2019/QMS/53077
Protocol title: Altering body image in chronic low back pain using virtual reality: a proof of concept randomised controlled trial

Thank you for submitting the above research protocol to the Metro South Human Research Ethics Committee for ethical and scientific review. This protocol was first considered by the Human Research Ethics Committee (HREC) at the meeting held on 1st October 2019.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the Hospital Health Service Chief Executive (CE) or Delegate of that site has been obtained.

A copy of this approval must be submitted to the Research Governance Office(r)/Delegate of the relevant institution with a completed Site Specific Assessment (SSA) Form for authorisation from the CE or Delegate to conduct this research at the Princess Alexandra Hospital.

If this study currently receives grant funding, please remember to forward a copy of this approval letter to the relevant Grants Office of the Administering Institution(s) for the grant.

I am pleased to advise you that the research protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* and ethical approval has been granted. The documents reviewed and approved include:

Document	Version	Date
HREA submitted via Ethical Review Manager (ERM)	2	24/10/2019
CVs for Investigators (7)		n.d.
PICF		08/09/2019
Protocol		12/09/2019
Questionnaire (via Lime Survey)		12/09/2019

Data Management Plan: Participant data spreadsheet		12/09/2019
Data Management Plan: Participant details spreadsheet		12/09/2019
Response Letter		12/09/2019
Research Data Management Plan		26/09/2019

This HREC approval is valid from 30/10/2019 until 30/10/2024.

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect continued ethical acceptability of the protocol.
2. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review. Major amendments should be reflected in revised study documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Hard copies of the revised documents and the cover letter, with *tracked changes*, must also be submitted to the HREC office as per standard HREC SOP.
3. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.
4. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
5. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) should be submitted electronically (track changes) and in hard copy (final clean copy) to the HREC Coordinator. These should include a cover letter from the Principal Investigator or Study Co-ordinator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.
6. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
7. The Coordinating Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
8. If you require an extension for your study, please submit a request for an extension in writing outlining the reasons. Note: One of the criteria for granting an extension is the compliance with the approval's conditions including submission of progress reports.
9. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/

Please note that the Metro South HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

Should you have any queries about the HREC's consideration of your protocol please contact Ethics Secretariat on 07 3443 8049.

The Metro South HREC wishes you every success in your research.

Yours sincerely,

A/Prof Scott Campbell
Chair
Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Metro South Research
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