

Barwon Health Human Research Ethics Committee

ETHICS APPROVAL

Dr Subhadra Evans
221
Burwood Highway
Burwood
VIC
3125
Australia

4 November 2020

Dear Dr Subhadra Evans,

Project Title	A randomised controlled trial comparing yoga, cognitive behaviour therapy and education to improve quality of life and reduce health care costs in endometriosis.
Project ID	65948
Review Reference	HREC/65948/VICBH-2020-232153(v2)
Local Reference Number	

I am pleased to advise that the above project has received ethical approval from Barwon Health Human Research Ethics Committee (HREC).

The HREC confirms that your proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007), and all subsequent updates, and in accordance with the *Note for Guidance on Good Clinical Practice* (CPMP/ICH/135/95), the Health Privacy Principles described in the *Health Records Act 2001* (Vic) and Section 95A of the *Privacy Act 1988* (and subsequent Guidelines).

Participating Sites

Ethical approval for this project applies at the following site(s):

Site	State/Territory
Barwon Health	Victoria
Deakin University	Victoria

Approved Documents

The following documents have been reviewed and approved:

Document Type	File Name	Date	Version
Victorian specific module (VSM)	Victorian Specific Module (VSM)_ERM_PDF	23/07/2020	1
Curriculum vitae	BH ethics CV_OSHea 2020	28/07/2020	1
Curriculum vitae	Barwon_CV_Form_Evans	28/07/2020	1
Curriculum vitae	Watts TransCelerate-Curriculum-Vitae-Form signed	28/07/2020	1
Curriculum vitae	CV_AMW_Barwon	28/07/2020	1
Curriculum vitae	Charlotte Dowding CV	28/07/2020	1
Curriculum vitae	Adrian-Curriculum-Vitae-Form	28/07/2020	1
Participant information and consent form	PISC_Endo_V1	28/07/2020	1
Questionnaire	Semi-structured interviews_V1	28/07/2020	1
Questionnaire	Weekly CBT practice log_V1	28/07/2020	1
Questionnaire	FINAL_Yoga therapy consultation form_Endo study_V1	28/07/2020	1
Questionnaire	Weekly yoga practice log_V1	28/07/2020	1
Questionnaire	Background_V1	28/07/2020	1
Questionnaire	Economic Data Questionnaire_Endo_V1	28/07/2020	1
Questionnaire	BPIshort_V1	28/07/2020	1
Questionnaire	Dass21_V1	28/07/2020	1
Questionnaire	EHP-30_V1	28/07/2020	1
Questionnaire	EQ-5D-5L_V1	28/07/2020	1
Questionnaire	FSI_V1	28/07/2020	1
Questionnaire	MSQ_V1	28/07/2020	1
Questionnaire	PSEQ_V1	28/07/2020	1
Advertising material	Advertisement Flyer_V1	28/07/2020	1
Questionnaire	WERF form_V1	28/07/2020	1
Curriculum vitae	Skvarc-Curriculum-Vitae-Form.pdf_ADW89D6	28/07/2020	1
Curriculum vitae	Marilla cv	29/07/2020	1
Advertising material	Advertisement flyer_V2	08/09/2020	V2
Curriculum vitae	BH ethics_Curriculum-Vitae-Form SK 05092020 printed	08/09/2020	V1
Participant information and consent form	PISC_Endo_V2_unmarked	08/09/2020	V2
PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PISC_Endo_V2	08/09/2020	V2
Protocol	Protocol_Endo_V2_unmarked	08/09/2020	V2
Questionnaire	Background_V2	08/09/2020	V2
Questionnaire	Economic Data Questionnaire_Endo_V2	08/09/2020	V2
Questionnaire	EHP-30_plus_23_V2	08/09/2020	V2
Questionnaire	Health Related Questions_pelvic combined_V2	08/09/2020	V2
Questionnaire	Semi-structured interviews_V2	08/09/2020	V2

Questionnaire	suicide screener	08/09/2020 V1
Questionnaire	FM Survey Questionnaire	08/09/2020 V1
RESPONSE LETTER	Response to BH ethics	08/09/2020 V1
PROTOCOL (TRACKED)	PISC_Endo_V2_tracked	08/09/2020 V2

Research Governance Authorisation

Research governance/site specific assessment (SSA) authorisation must be obtained by each participating site before the research project can commence at that site.

You are required to provide a copy of this HREC approval letter to the principal investigator of each site covered by this ethics approval. A copy must be included in each site's research governance/SSA application.

Conditions of Ethics Approval

1. You are required to submit to the HREC:
 - An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on **DATE/the anniversary of HREC approval**. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the scheduled date. Failure to comply with this requirement may result in suspension of the project by the HREC.
 - A comprehensive Final Report upon completion of the project.
2. Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
3. Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016).
4. Notify the reviewing HREC of your inability to continue as **Coordinating** Principal Investigator.
5. Notify the reviewing HREC of the failure to commence the research project within 12 months of the HREC approval date or if a decision is taken to end the research project at any of the sites prior to the expected date of completion.
6. Notify the reviewing HREC of any matters which may impact the conduct of the research project.
7. If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency *Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes'* Radiation Protection series Publication No.8 (May 2005) (ARPANSA Code).
8. The HREC, authorising institution and/or their delegate(s) may conduct an audit of the research project at any time.

Yours sincerely,

Ms Lisa Fry
Co-Manager REGI Unit
Barwon Health