PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Study Participant

Plain Language Statement

Date: May 2026

Full Project Title: Co-designing, Evaluating, and Implementing Supportive Care for Endometriosis Full-Trial

Sub-Heading: Trial Participants

Principal Researcher: Prof. Antonina Mikocka-Walus

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Dear Study Participant,
Thank you for considering participation in this study which aims to evaluate the efficacy of supportive care for people living with endometriosis.

Why is this study important?
Endometriosis is a chronic condition in which tissue, similar to tissue lining the uterus, grows on other organs. This leads to scarring and adhesions which cause debilitating pain, menstrual irregularities, and infertility. Endometriosis currently impacts 11% of Australian women and individuals assigned female at birth

Researchers have acknowledged the need for more a holistic management of endometriosis, such as providing e arly, non-surgical interventions.

CoDeEndo is an online modular supportive care program for people living with Endometriosis, which includes 9 different interventions: Mindfulness, Psychoeducation, Relaxation, Physiotherapy, Acceptance and Commitment Therapy, Hypnotherapy, Yoga, Cognitive Behavioural Therapy, and Dietary Education. Modules are comprised of a mix of video, audio, podcasts, and written resources. Participants will have access to all modules throughout the 8 weeks, allowing for observation of natural use. Participants will also be encouraged to practice (repeat) the

modules throughout the 8 weeks. Participants may choose which modules to undertake depending on their unique needs and interests.

Purpose
The purpose of this study is to explore whether CoDeEndo (online modular supportive care program) is effective in improving outcomes such as quality of life, pain, and mental health for people diagnosed with endometriosis. This online intervention can be delivered in a way that adapts to each participant's needs and interests (i.e., by choosing which modules to engage with).

Who can participate?
In order to be considered for the study you will need to:

- Be able to provide proof of endometriosis diagnosis (this can include a letter from a doctor, results of histology, operation reports, ultrasound scan, or any other medical document confirming your diagnosis)
- Reside in Australia
- Be at least 18 years of age
- Be proficient in English
- Not be pregnant
- Have had no endometriosis-related surgery within the last 3 months
- Experience at least mild levels of psychological distress
- Experience no extreme dissociative symptoms
- Not be currently participating in any other trial related to pelvic pain, endometriosis, or hypnotherapy.

You will also be screened for mental health concerns by one of our study psychologists (or provisional psychologist) who will determine your eligibility including cognitive impairment, suicide/self-harm, substance use/dependence, Bipolar I/Bipolar II, Schizophrenia/Psychosis, PTSD, and Borderline Personality Disorder.

How will this study be conducted?
This study will be conducted wholly online. If you decide you would like to be involved in this research project, please provide consent by selecting 'Yes, I do consent' on the form below.

To confirm your eligibility for inclusion in the trial, you will then be automatically redirected to further online screening questions for psychological distress and dissociative symptoms. If you pass further online screening, you will then be automatically redirected to provide evidence of your endometriosis diagnosis. After uploading your evidence of diagnosis, you will be automatically redirected to provide some information about your mental health in preparation for a phone call with one of our study psychologists who will screen for mental health issues as outlined in the section above. This screening process should take no longer than 1-hour to complete. Information collected during the screening process will be kept confidential within the Deakin team unless the psychologist assesses that there is an immediate risk of harm to yourself or someone else, or if a child has experienced or is experiencing harm, or in the case of certain crimes. In such cases, the psychologist may be required to share your personal information with others to fulfil their duty of care and legal obligations.

Once your eligibility is confirmed, you will be provided with a link to register for the CodeEndo trial and will have an equal chance of being randomly allocated to one of 2 study groups: 1) Intervention Group, OR 2) Wait-List Control Group. There is no guarantee which group you will be allocated to. This means that there is an equal chance of being allocated to any group. This process of random group allocation enables researchers to determine whether there are any changes in the symptoms and experiences of one group compared to the other. This study has been designed to ensure the researchers interpret the results in a fair and appropriate way.

Participants who are deemed ineligible for the trial will not be offered counselling by our study psychologists. They will, however, be offered contact with the study team, at no extra cost, and depending on the level of support required, be able to request an additional follow-up phone call from one of the study psychologists to receive further guidance on how and where to seek psychological support, at their own expense.

During your participation in the trial (i.e., the 6 months following randomisation), if we have serious concerns about your wellbeing, we may contact your listed emergency contact person, or your listed General Practitioner (GP) to ensure that you are safe and have access to any necessary support services, OR if you tell us you need immediate support.

Study Groups:
Intervention Group: Participants randomised to this group will be provided with a website link to access the online intervention. The intervention will run for 8 weeks and includes 9 self-directed video or audio modules (with a number of sub-modules). Participants will have access to all 9 modules at all times and be able to choose which modules they would like to engage with. We also encourage participants to practice (repeat) modules. This means participants could spend as little as 5-minutes to several hours per week on each intervention. Participants will also receive weekly reminders to access the intervention.

Waitlist Control Group (WLC): Participants randomised to this group will go on a waitlist and be offered the online intervention at the end of their time in the study (6 months post group allocation).

Study Team Contact: A member of our study team will contact participants via phone call in weeks 1, 4 and 8 to check in regarding participants' experience of the intervention. We may send participants study-related materials in the mail (e.g., a study fridge magnet).

Please note: All participants will continue their usual medical care.

Follow-up Commitment:
All participants in both the intervention group and the WLC group will be asked to provide follow-up information as described below:

Questionnaires: Participants will be asked to complete 3 online questionnaires at baseline (before the intervention), 8 weeks (after the intervention), and 6 months later. These questionnaires will take approximately 45-minutes to complete. An example of a question you will be asked is: "Do you have diarrhea during your period?". After the completion of each questionnaire, participants will receive a $10 gift voucher via email to thank them for their time and input, therefore participants can receive a total of $30 if they complete all 3 questionnaires. Participants will also be asked to complete brief (5-minute) questionnaires weekly throughout the duration of the 8-week trial period (no gift vouchers will be provided for the 5-minute questionnaires).

Interviews:

Only participants in the intervention group will be asked to provide follow-up information as described below:

Interviews: A smaller group of participants will be invited to participate in a series of follow-up individual interviews at 8 weeks and 6 months later. Interviews will be conducted via Zoom or phone and will be approximately 45 minutes in length. Each interview will be conducted by a trained researcher who will ask questions and guide the conversation. This is to provide feedback about the intervention, for example, "Thinking back to your time participating in the intervention, what do you think were the most significant changes you experienced?". Each interview will be recorded for later transcription and analysis. After the completion of each interview, participants will also receive a $50 gift voucher via email to thank them for their time and input, therefore participants can receive a total of $100 if they complete all 2 interviews.

Healthcare Usage:

You will also be asked for voluntary consent for the study team to access your healthcare usage data from Services Australia. This data does not include your medical history, only the health services you have used and/or medications purchased (Medicare Benefits Schedule and Pharmaceutical Benefits Scheme). You can choose to allow the study team to access both, either or none of this data. You can still participate in the study without consenting to this data access. But by agreeing it will help us to accurately compare the health service use of participants who take part in the different study interventions and control group.

You will be asked to sign a separate consent form authorising the study to access your Commonwealth health information provided by Services Australia; see the separate Services Australia Participant Information Document and Participant Consent Form.

Services Australia is not involved in this research other than to provide the information that you have consented to the release of, should you decide to participate in this study. Services Australia has confirmed that this research and any associated documents have received approval from a Human Research Ethics Committee

(HREC) that is registered with and operates within guidelines set out by the National Health and Medical Research Council (NHMRC).

Risks of the study
We do not anticipate any lasting risks to your health or wellbeing as a result of participating in this study. However, researchers acknowledge participating in an intervention trial or answering study questionnaires may make some people feel uncomfortable or emotional. Some common risks with engaging in hypnotherapy, relaxation or mindfulness can also include sleepiness, disorientation/confusion, headache/dizziness, or some psychological distress. Further risks associated with participating in yoga or physiotherapy movements can include overexertion or injury. If, at any stage of this study, you feel concerned, please do not hesitate to contact the study team, at no extra cost, via email at codeendo@deakin.edu.au . You may also like to discuss your health with your GP or medical specialist, at your own expense, or contact services such as Lifeline on 13 11 14 or Beyond Blue on 1300 22 4636.

Please remember your participation is voluntary and you may withdraw from the study at any time without consequence by completing the withdrawal of consent form. If you decide to withdraw, please let us know if you would like your already collected study data withdrawn as well (please note this is only possible prior to the time of data analyses).

Benefits of the study
We cannot guarantee or promise that you will receive any benefits from participating in this research. You may find that the techniques you learn or the education you receive positively benefit your health, including quality of life and other important outcomes such as pain or mental health. This project may also benefit the wider endometriosis community, as it is likely to provide necessary data to design better psychological treatments to support the well-being of people with endometriosis.

How will your privacy and confidentiality be protected?
Information collected as part of this research project will be accessible to members of the research team only. Deakin University will be the data custodian, and all information gathered will be kept confidential and stored electronically on secure servers at Deakin University, in Australia, following university guidelines. All data will be re-identifiable, this means that your identifiable information (e.g., name, phone number, email, home address) will not be recorded together with your data. Instead, your data will be allocated and stored using a unique ID, and only the research team will be able to match your identifiable information to your unique ID. Identifiable information (e.g., name, phone number, email, home address) will be stored in a separate file. Once the interview recordings have been transcribed, their video format will be destroyed. In any report, publication, or presentation, the research findings associated with this study will be provided in such a way that you cannot be identified. The data collected in this study will be stored for 15 years from the study's final report and subsequently destroyed as per the Deakin University guidelines. Please note that any information you share is confidential, except where disclosure is required by law.

Electronic gift cards: As part of your participation, you will receive reimbursement in the form of an electronic gift card. To access this gift card, you will need to register with Prezzee, which requires sharing personal information in the form of your name and email address as this is necessary for them to be able to deliver the electronic gift card. This information will be managed by Prezzee in accordance with their privacy policy. If you are not comfortable with using your main email address for this, you may also like to consider setting up a specific email account for the purpose of receiving your gift card. If you prefer not to share your details with an external provider, please inform the research team to discuss alternative reimbursement options.

Potential future uses of study data: If required by the journal for publication of the study, the de-identified data file containing analyses and results, may be submitted to the journal publisher. Study data may also be shared in a de-identified form, with an open or controlled access storage system, during the publication process. De-identified data may also be made available to future research groups who wish to perform secondary analyses following completion of the current study. Please note, that we will not be sharing qualitative data transcriptions obtained from interviews with participants, given the potential for participants to be able to be identifiable through quotes. Data may also be used by future research projects that are an extension, closely related to, or in the same general area of research as this study. Such as future honours students, post-graduate students, or members of the wider research group. Any re-use of the study data, however, will be subject to review and approval by relevant ethics committees.

Monitoring of study conduct and declaration of interest
This project will be monitored by senior staff members of Deakin University. There are no conflicts of interest to report, however, the study is being supported by the Australian Government with a grant totalling $1,473,436 over five years; this will cover design, development, resource production, advertising, evaluation, and implementation of the CodeEndo program.

Dissemination
It is anticipated that the results of this study will be published and/or presented in different forums. No identifiable information collected from you will be shared, published and/or presented. Study data will be used by Deakin University for analyses and report writing and results may be presented at conferences and published in peer-review journals, or form part of a PhD thesis. The findings may also be published on the websites and social media platforms of relevant chronic pain organisations and networks. Study data may also be shared in a de-identified form with an open or controlled access storage system during the publication process. Participants will be emailed a summary of trial results, with all identifiable information removed at the completion of the trial.

Further information, queries or any problems
If you require further information or if you have any questions concerning this project, you can contact us at codeendo@deakin.edu.au or contact the principal investigator Professor Antonina Mikocka-Walus at:
Phone: +61 3 9246 8575
Email: antonina.mikockawalus@deakin.edu.au

Complaints
If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

The Human Research Ethics Office
Deakin University
221 Burwood Highway
Burwood, Victoria, 3125
Telephone: +61 3 9251 7129
Email: research-ethics@deakin.edu.au.

Please quote project number [2024-157].

Thank you for your time.

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Study Participant

Consent Form

Date: May 2026

Full Project Title: Co-designing, Evaluating, and Implementing Supportive Care for Endometriosis Full-Trial

Reference Number: 2024-157

- I have read and I understand the Plain Language Statement.
- I understand the purposes, procedures, and risks of the research described in the Plain Language Statement.
- I have had an opportunity to ask questions, and I am satisfied with the answers I have received.
- I understand that (if selected) interviews will be video/audio recorded for transcription.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.
- I have been given the opportunity to download a copy of the Plain Language Statement and Consent Form to keep.

Click here to download a copy of the Plain Language Statement and Consent Form

By checking the box below consent to all of the above statements:

- ☐ Yes, I do consent to participate in this research study.
- ☐ No, I do not consent to participate in this research study.

Would you like to be informed about future research projects conducted by our group?

- ☐ Yes, I would like to be informed of future research projects.
- ☐ No, I would not like to be informed of future research projects.

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Study Participant

Withdrawal of Consent Form

(To be used for participants who wish to withdraw from the project)

Date: May 2026

Full Project Title: Co-designing, Evaluating, and Implementing Supportive Care for Endometriosis Full-Trial

Reference Number: 2024-157

I wish to withdraw from participation in the research project titled: Co-designing, Evaluating, and Implementing Supportive Care for Endometriosis Full-Trial

I understand that such withdrawal will not affect my routine care or my relationships with the researchers or Deakin University.

□ Yes, I wish to withdraw my consent

- OPTIONAL: Provide reason for withdrawing consent:_____
- Name: _____
- Surname:_____
- Date of Birth:_____

Do you give researchers permission to use information collected from you, as part of the analysis for this study?
□ Yes □ No