

PLAIN LANGUAGE STATEMENT AND CONSENT FORM



TO: Study Participant

Plain Language Statement

Date: July 2025

Full Project Title: Randomised e-Hypnotherapy for Chronic Pelvic Pain Study – (REST)

Sub-Heading: Trial Participants

Principal Researcher: A/Prof. Subhadra Evans

Associate Researcher(s): Prof. Antonina Mikocka-Walus (Deakin University), Prof. Adrian Esterman (University of South Australia), Prof. Matthew Fuller-Tyszkiewicz (Deakin University), A/Prof. Simon Knowles (Swinburne University of Technology), Prof. Jane Andrews (University of Adelaide), A/Prof Nikki McCaffrey (Deakin University), Ms Katherine Stanley (Endo Help Foundation), Dr Anna Klas (Deakin University), Prof. Thierry Vancaillie (University of NSW), Dr Marilla Druitt (Deakin University), Dr Kathryn McLeod (Deakin University), Dr Katherine Brain (University of Newcastle), Mr Eric O (Deakin University), Mr Drew Aras (Western Alliance Health Science Centre), Dr Tiffany Brooks (University of South Australia), Ms Anna Bassili (Deakin University), Mr Luke Barisic (Deakin University), Dr Leesa van Niekerk (University of Tasmania), Mr Chatpakorn Prasertsung (Deakin University), Dr Susan Chesterman (Deakin University), Ms Jessica Bowring (Deakin University), Ms Colette Naude (Deakin University), Ms Lily Blake (Deakin University), Mr Yao Coitinho (Deakin University), Dr David Skvarc (Deakin University), Charlotte Dowding (Deakin University), Samantha De Araugo (Deakin University), Anabelle Webster (Deakin University), Emily Dwyer (Deakin University), Lillijana Murphy (Deakin University), Aditi Waghela (Deakin University), **Lisa Seberry** (Deakin University), Dr Shannon Bennetts (Deakin University), Daniel Romano (Deakin University).

Dear Study Participant,

Thank you for considering participation in this study which aims to evaluate the efficacy of e-Hypnotherapy for people living with chronic pelvic pain.

Why is this study important?

Chronic pain affects more than 3.2 million Australians, costing the country \$73.2 billion annually and is inadequately treated. Specifically, Chronic Pelvic Pain Syndrome affects as many as 25% of those assigned female at birth and 18% of those assigned male at birth and involves intermittent or constant pain between the hips and naval area. Chronic pelvic pain (CPP) can be highly disabling and can severely impact the mental health, sexual function, and quality of life of those diagnosed. To support the well-being of people with CPP, psychological approaches are recommended, but their effectiveness is yet to be established.

One psychological approach is hypnosis, a state of consciousness involving focused attention, and enhanced capacity for suggestion. Hypnosis has been shown to outperform other psychological approaches when it comes to improving chronic pain. Though not regarded as a replacement for medical care, hypnosis is a complementary approach that can enhance pain education, improve pain and quality of life, has few side effects and can be cost-effective. Hypnosis can be delivered either face-to-face or via telehealth (for example pre-recorded hypnotherapy).

Purpose

The purpose of this study is to explore whether e-Hypnotherapy (pre-recorded hypnotherapy) is effective in improving pain and other biopsychosocial outcomes for people living with chronic pelvic pain. This is a world-first innovation, as our online intervention can be delivered in a way that more closely mirrors how hypnosis is

experienced face-to-face, where participants are provided with options for their hypnosis experience and can choose based on their preferences (i.e. choose your own adventure).

Who can participate?

In order to be considered for the study you will need to:

- Have self-reported chronic/persistent pelvic pain for at least 3 months.
- Not identify as female*
- Reside in Australia.
- Be at least 18 years of age.
- Be proficient in English.
- Not pregnant, nor seeking to become pregnant.
- Have had no pelvic area surgery within the last 3 months.
- Have had no engagement in hypnotherapy within the last 6 months.
- Experience at least mild levels of pain.
- Experience at least mild levels of psychological distress.
- Experience no extreme dissociative symptoms.
- Not be participating in any other clinical trials.

***Note:** We have reached our recruitment target for women in this study as part of our previous recruitment drive. This phase of the study is now closed, but given that we were unable to recruit many men or gender diverse participants, we have re-opened the study to focus specifically on improving the gender diversity of the trial. This is important for the reasons identified in the “Why is this study important?” section above, given that Chronic Pelvic Pain syndrome commonly affects people from all genders, not just women.

You will also be screened for mental health concerns by our study psychologist (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. Please note that if you become pregnant at any point during the study, you must communicate this to the research team, and you may be withdrawn from the study.

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 pain, psychological distress, and dissociative symptoms. If you pass further online screening, you will then be automatically redirected to provide some information about your mental health in preparation for a phone call with our study psychologist 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 REST trial and will have an equal chance of being randomly allocated to one of 3 study groups: 1) Intervention Group #1, OR 2) Intervention Group #2, OR 3) 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.

Please note, participants who are deemed ineligible for the trial during the screening process will not be offered counselling by our study psychologist. They will, however, be offered contact with the study team and depending on the level of support required, be able to request an additional follow-up phone call from the study psychologist to receive further guidance on how and where to seek psychological support.

Study Groups:

Intervention Groups #1 and #2: Participants randomised to these groups will be provided with a website link to access the online intervention. The intervention will run for 7 weeks and includes 7 self-directed audio modules

(as well as an extra pain education video). Although participants will have access to all 7 modules at all times, we encourage participants to complete 1 module a week for the 7-weeks. We also encourage participants to practice (repeat) modules. This means participants could spend as little as 40-minutes to several hours per week on each intervention. Participants will also receive weekly reminders to access the intervention.

Waitlist Control Group: Participants randomised to this group will go on a waitlist and be offered the e-Hypnotherapy intervention at the end of their time in the study (12 months post group allocation).

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

Follow-up Commitment:

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

Questionnaires: Participants will be asked to complete 4 online questionnaires at baseline (before the intervention), 7-weeks (after the intervention), 6-months, and 12-months. These questionnaires will take approximately 45 minutes to complete. An example of a question you will be asked is: "Please rate your pain at its worst in the last 24 hours". After the completion of the 7-week questionnaire, participants will receive a \$20 gift voucher via email to thank them for their time and input. Participants will also receive a \$10 voucher after completion of the following questionnaires (6-month and 12-month). Therefore participants can receive a total of \$40 if they complete all 4 questionnaires. Participants will also be asked to complete brief (5-minute) questionnaires weekly throughout the duration of the 7-week trial period (no gift vouchers will be provided for the 5-minute questionnaires). In addition to the vouchers, we may also send participants study-related materials (e.g. fridge magnets with the study logo) at certain points in throughout the study.

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).

Only participants in the intervention groups 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 interviews at 7-weeks, 6-months, and 12-months later. Interviews will be conducted via Zoom on a one-to-one basis and will be approximately 45 minutes in length. Each interview will be run by a facilitator who will ask questions and guide the discussion. 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 \$30 gift voucher via email to thank them for their time and input, therefore participants can receive a total of \$90 if they complete all 3 interviews.

Study Team Contact: A member of our study team will contact participants via phone call in weeks 3 and 7 to check in regarding participants' experience of the intervention.

Risks of the study

We do not anticipate any lasting risks to your health or well-being as a result of participating in this study. However, researchers acknowledge participating in psychological therapy or answering study questionnaires may make some people feel uncomfortable or emotional. Some common risks of engaging in hypnotherapy also include sleepiness, disorientation/confusion, headache/dizziness, or some psychological distress. If, at any stage of this study, you feel concerned, please do not hesitate to contact the study team via email at reststudy@deakin.edu.au. You may also like to discuss your health with your GP or medical specialist, 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 pain and other important outcomes such as quality of life or mental health. This project may also benefit the wider CPP community, as it is likely to provide necessary data to design better psychological treatments to support the well-being of people with CPP.

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) 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, email and phone number) will be stored in a separate file. Once the interview recordings have been transcribed, they 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.

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 mediated access repository, during the publication process. De-identified data may also be made available to future research groups who wish to perform secondary analyses (i.e., systematic review/meta-analysis) 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 \$1,302,624 over five years; this will cover design, development, resource production, advertising, evaluation, and implementation of the REST 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 mediated access repository during the publication process. Participants are invited to contact the researchers should they wish to obtain a summary of the results.

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 reststudy@deakin.edu.au or contact the principal investigator Associate Professor Subhadra Evans at:

Phone: +61 3 9244 6270

Email: subhadra.evans@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 [2024-080].

Thank you for your time.



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Consent Form

Date: July 2025

Full Project Title: Randomised e-Hypnotherapy for Chronic Pelvic Pain Study – (REST)

Reference Number: [2024-080]

- 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.

Please also provide details of your emergency contact's details (we may contact this person if we are unable to reach you and have concerns about your well-being):

Their Name: _____
Relationship To You: _____
Email Address: _____
Phone Number: _____

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.