Date: …….

Participant ID: …….

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Pain and Emotion Therapy Clinical Trial

Prof Sylvia Gustin

1. What is the research study about?

You are invited to take part in this research study. The research study aims to investigate an online emotional recovery skills training for people with chronic pain. We are exploring whether this skills training, called Pain and Emotion Therapy, is beneficial in helping to alleviate pain intensity, distressing thoughts, and feelings likely experienced due to chronic pain. You are invited because you have previously indicated your interest to be part of research exploring chronic pain treatments.

You are no doubt already aware that negative emotions such as worry, stress and low mood are commonly associated with the experience of chronic pain. Experiencing these emotions along with chronic pain can lead to a cycle of worsening pain and difficulties controlling the negative emotions.

Scientists have explored this cycle of worsening pain and difficulties controlling negative emotions and have discovered it may be that changes to the brain resulting from the experience of persistent pain affect a part of the brain which helps people regulate their emotions. In some situations, changes to the brain have shown to be reversible.

By using therapies that target the part of the brain that helps with emotion regulation, it may be possible to break the cycle between worsening pain and difficulties managing negative emotions. Earlier studies have shown that specific skills and techniques in emotion regulation from dialectical behavioural therapy (DBT) help calm the mind and help people more effectively manage negative emotions. Over time there may be a reversal of brain changes affecting emotions, which may result in the experience of chronic pain becoming less burdensome.

2. Who is conducting this research?

The study is being carried out by the following researchers: Professor Sylvia Gustin, Dr Nell Norman-Nott, Dr Negin Hesam-Shariati, Dr Nahian Chowdhury, Annie Butler, Thiago Folly, Lara Alexander, Kevin Chen, and Joshua Rawsthorne at the School of Psychology, UNSW and Neuroscience Research Australia, and by Professor Toby Newton John at University Technology Sydney.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is acceptable for you to take part.

The research study is looking to recruit people who meet the following criteria:

Inclusion criteria:

a) Adults aged 18 years or over.

b) Have access to the internet to participant in the Zoom sessions and have access to a smart phone/ tablet device capable of running the mobile app.

c) Commits to fully participate in the eight sessions and train skills daily using the PaET App.

d) Fluent in speaking and reading English.

e) Persistent or reoccurring pain for at least 3 months (IASP, 2020)

f) Have an average pain rating ≥ 4 out of 10 for the past seven days (Langford et al., 2023)

Participants who meet the following criteria will be excluded from the study.

Exclusion criteria:

a) Diagnosed psychotic and personality disorders (e.g., schizophrenia, borderline personality disorder, bipolar disorder, etc.)
b) Uncontrolled mental health disorder (e.g., persistent depressive disorder).
c) Diagnosis for dementia or neurological condition substantially affecting cognition.
d) At risk of suicide (e.g., recent suicidal ideation, suicide attempt, or current suicide plan).
e) Familiar with dialectical behavioural therapy (e.g. received DBT as an intervention in the past either online or in-person)
f) Planned surgery or substantial medication changes during the trial period.
g) Located outside of Australia.
h) Participated in a prior trial of the same intervention.

4. Do I have to take part in this research study?

Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully and ask questions about anything you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative or friend.
- Consent to participate in this study using the online consent form
- Keep a copy of this Participant Information Statement for your personal records

5. What does participation in this research require, and are there any risks involved?

In this study, we will examine how an emotional skills training program can affect your management and expression of emotions, and changes in the intensity of your chronic pain. The emotional skills training lasts nine-weeks. To measure changes in emotions and chronic pain, we will ask a series of questionnaires lasting approximately 30-40 minutes, before the nine-week skills training, 12, 20 and 52 weeks later.

There are a number of steps involved in applying and participating in this study as follows:

1. Screening and Consent

We have some criteria that need to be met to determine study eligibility. In order to evaluate whether you may be eligible for the study we ask, if you are interested in participating, that you complete a screening process. The screening process is divided into two steps, (1) online screening, and (2) phone screening. The online screening is self-completed by you on the internet and will take approximately 5 minutes. The online screening will ask for your personal details (e.g., name, phone number) and details about your chronic pain condition and current medical status (e.g., pain rating score and current pain medication). The second step in the screening process is a phone call (approximately 20 minutes) with a member of our research team to answer some additional questions

about your chronic pain (e.g., is your pain related to a specific incident), your current treatment plan (e.g., physio) and to clarify with you the details and expectations of the trial (e.g., working internet connection and a smart device). If, at any stage in the screening process (online or phone), based on your responses we are unable to take you in the trial you will be notified by phone or email of this outcome. If we are not able to take you in the study, the information provided by you (e.g., your contact details and details about your chronic pain condition) will be deleted unless you have indicated by checking the box during the online screening that you would like us to retain your details to be contacted about participating in trials in the future. If you select for your details to be retained by us, they will be stored securely on our password protected servers at UNSW.

2. Informed Consent

If eligible to participate in this trial, you will be asked to carefully review the informed consent form located in Section 13 of this document. If after having read and understood what it means to participate in this trial and you are interested in participating, we will ask you complete the informed consent form using an online form. You will then be able to start the trial.

3. Randomisation

After consenting to participate in the study you will be randomly assigned (like the toss of a coin) to receive either the “treatment”, or “treatment-as-usual”. You have equal chance of being assigned to either group. You will be contacted by a member of the research team to advise you of what group you are allocated to. Details of what to expect in the each of the groups is listed under intervention.

4. Intervention

Treatment Group: If you are allocated to the treatment group, you will be asked to complete the emotional recovery skills training (Pain and Emotion Therapy). This therapy includes a total of eight sessions (including an introductory and concluding session), delivered to you over the internet, approximately every 7 days across eight weeks. The sessions will run for around 60 minutes and will be delivered by at least one therapist over the internet using the video conferencing platform Zoom. For security, Zoom sessions will only be accessible to invited participants accessible via password which will be provided to you via email. The zoom sessions may be recorded. This will allow the researchers to check the consistency of the content delivered by the therapist during the session to ensure the adherence to the protocols we have developed for this skills training.

For the duration of the eight weeks, and for one week after the concluding session, you will have continued access to a mobile app which we will ask you to access on your own smart device (e.g., iPhone) with your own secure password and username. We are capturing usage information, such as how much time on average is spent using the app every day) but will not capture any identifiable information, such as you name, and will not be able to see individual usage information within the app.

See below an example schedule of the skills training sessions and web app access across the nine weeks:

Week	Weekly Online Pain and Emotion Therapy Sessions via Zoom	Pain and Emotion Therapy app accessed on a smart device (e.g., iPhone)
Week 1	Introductory Session (60 min)	Continued access to the Pain and Emotion Therapy app from Week 2 onwards
Week 2	Session 1 (60 min)	
Week 3	Session 2 (60 min)	
Week 4	Session 3 (60 min)	
Week 5	Session 4 (60 min)	
Week 6	Session 5 (60 min)	
Week 7	Session 6 (60 min)	

Week 8	Concluding Session (60 min)
Week 9	*No session*

Prior to the study commencing, participants in the treatment group will be asked to install Zoom (if it is not already on your computer). From Week 2 you will be asked to set up the Pain and Emotion Therapy app to your smart phone, tablet or computer. We will provide instructions on how to complete this installation and set-up, and a member of the research team will be available for you to call if you have questions.

Each participant in the treatment group will also receive worksheets in a manual either in hard copy (print) or in PDF (electronic) format to be referred to during the Zoom sessions and to facilitate homework.

At the end of the study, participants in the treatment group will have the option to continue to have the Pain and Emotion Therapy app on their smart phone, computer, or tablet device for ongoing usage.

Treatment as Usual Group: In the treatment-as-usual group, treatment options can be any of those offered by your regular healthcare professionals that you would normally choose to see in the community. In other words, in this group your treatment will not be determined by the study or funded by it. The role of being in this group is very important to the study because the outcomes gained by this group set the bar to know whether Pain and Emotion Therapy is any better or not. At the end of the study (after you have completed the questionnaires at 52-weeks) if you would like to access part of the skills training we can give you access to the app with self-paced training modules on your smart phone, computer, or tablet device, and will give you electronic access to the worksheets.

5. Benefits of the intervention

While there is no guarantee of therapeutic benefit from receiving Pain and Emotion Therapy, in a prior trial we discovered that this skills training therapy improved the emotional problems often experienced with chronic pain and helped to reduce pain intensity. As with many research studies there is a burden of taking part (e.g., time commitment to do the therapy), and possible risks but we expect these to be mild and of minimal likelihood to occur (see Section 6 for more details about risks and discomforts associated with this trial). When effectiveness, discomforts, and risks are all considered we expect that Pain and Emotion Therapy is at least as beneficial as other standard treatments for chronic pain (e.g., psychoeducational programs for chronic pain). There is a possibility that participation in this trial will be without benefit to participants regardless of whether they receive Pain and Emotion Therapy or treatment-as-usual.

6. Questionnaires

Participants in both the treatment and treatment-as-usual groups will be asked to complete a series of questionnaires at the start of the study, 12-, 20- and 52 weeks later. The questionnaires will ask you about your pain severity, the specific qualities of your pain, the interference of pain in different aspects of your life, the psychosocial effects, your wellbeing, and sleep quality. The questionnaires will take approximately 30-40 minutes to complete. You will be asked to complete the questionnaires at home online using your computer. Participants in the treatment group will also be asked to complete a semi-structured interview with a member of the research team by phone or by Zoom. The semi-structured interview will ask open ended questions about the experience of Pain and Emotion Therapy and the changes observed during the course of the intervention.

7. Optional consent to Access Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data

In addition to the main study consent, we will also invite participants in the in both the treatment and treatment-as-usual groups to sign a **separate consent form from Services Australia**. This optional form gives us permission to access information from your **Medicare Benefits Schedule (MBS)** and **Pharmaceutical Benefits Scheme (PBS)** records through Services Australia. Please see the separate Services Australia Participant Consent Form and Participant Information Document.

If you choose to give this consent, we will use existing records to understand the types of healthcare services you've used (like visits to doctors or other health professionals) and any prescription medicines you've received, both before and after the intervention. This will help us better understand whether the treatment reduces the need for pain-related healthcare and medications.

Any information collected will be treated with strict confidentiality. It will be securely stored, used only for research purposes, and accessed only by authorised members of the research team.

Providing this consent is entirely optional. We will completely understand and respect your choice if you choose not to allow access to your MBS and PBS data. You can still take part in all other parts of the study. 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).

6. What are the risks and possible benefits to participation?

In most research studies there are possible side effects. In the current study the potential risks are mild and of minimal likelihood to occur. Nevertheless, we do ask that you are aware of the following possible side effects that you may experience. If they should be a concern to you, we ask that you talk with a member of the research team (email: neurorecoveryresearch@unsw.edu.au; phone/text: 0490802397 (business hours).

Risks and discomforts:

- The aim of Pain and Emotion Therapy is to enable participants to better appraise and express emotions which are impacted by the effect of chronic pain on their lives. On exposure to this information, a very small minority of people may experience temporary and transient increases in distress. If distress does occur, please let us know and contact a source of support (e.g., your regular health professional/ general practitioner or call a mental health service such as Beyond Blue)
- There may be some discomfort in terms of fatigue by attending up to eight hours of Zoom sessions over the course of the intervention. To mitigate this, sessions will be spaced evenly throughout the intervention period with one per week over eight weeks, with sufficient time between sessions and breaks as necessary. We will also ask you to have a glass or bottle of water with you during the Zoom sessions to stay hydrated.
- Questionnaires may contain questions that are upsetting or uncomfortable in nature. You may refuse to answer any question that makes you feel uncomfortable, and skip to the next question, or you may stop immediately.

Benefits

We cannot guarantee or promise that you will receive any benefits from this research; however, there is some evidence from our previous studies that Pain and Emotion Therapy may improve the emotional problems often experienced with chronic pain and it may reduce pain intensity.

This study may help the researchers learn things that may help other people in the future with chronic pain.

Additional Costs and Reimbursements

There are no costs associated with participating in this research project.

Pain and Emotion Therapy, including the zoom sessions, app, and handbook, will be provided at no cost during the trial, and the app will be provided for ongoing usage following the completion of the trial.

Prize Draw

Participants in both groups who have completed all components of the trial may choose to enter a prize draw to receive one of five $200 Gift cards. To notify us of your request to be entered into the draw, you must check a box to consent to be entered into the draw when completing this informed consent form.

The draw will be conducted following the completion of the trial (circa 2029). Participants that do not complete the study will not be eligible for entry into the draw. Gift cards will be posted to the five winners.

7. What are the alternatives to taking part in the research?

You do not have to participate in this study to be treated for the psychological and physical aspects of your chronic pain. Participation in this study is entirely voluntary. If you decide to not participate, your regular doctor or health care provider may be able to provide other available treatments. This includes medications such as antidepressants, or opioids, or could be other treatments including psychotherapy, physiotherapy, and activities such as exercise. We do not require you to change your current medication or treatment regimen if you decide to participate. You can use online treatments and web apps for chronic pain without being in the study, but they will not be the online emotional skills training intervention used in this study.

8. What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using information about you for the research study. All the information collected from you for the study will be treated confidentially, and only the researchers named above will have access to it. Your data will be kept for 15 years after the project's completion. No personnel other than the researchers will have access to the research documents.

We will download data entered electronically by you and save it in a password protected database on a secure server at UNSW. This data will not be associated with any participant identifying information as all data will be coded with the participant's unique identifier code.

All data for use in journal publications and presentations will be de-identified.

For each Pain and Emotion Therapy app session, the following will be automatically recorded: when you started and finished, which modules you accessed and how you responded. This recorded data will be sent to a secure server over the internet. No personally identifiable participant information is received or stored by the app, the database, file server, or any connected system at any time. Only the trial researchers will be able to view the recorded data for all participants as a group within the app.

The Pain and Emotion Therapy sessions will be delivered via the video conferencing platform, Zoom. These sessions will be recorded to ensure adherence to the treatment protocol. Recordings will be saved on a password protected secure server at UNSW. Recorded sessions will be only available for the researchers. To ensure cybersecurity and prevent potential hacking into the Zoom sessions, access to the Zoom sessions will be password protected. Moreover, the waiting room function within Zoom will be utilised meaning that the therapist will need to give each participant access to the session.

Hard copy data, will be stored securely within locked fireproof cabinets in the School of Psychology, UNSW. It will be kept in separate files/cabinets to those containing participant details and trial identification numbers. Only approved researchers will have access to this information.

Permission to use your data for future research projects

We would like to store the de-identified data collected from you with the intention to share it with other interested researchers and use it in future research projects. Some medical journals in which we may seek to publish the study findings require that we provide access to this de-identified data to interested researchers.

If you consent to participate in this study the research team will store your data in a secure databank. The data will not contain any of your personal details and you cannot be identified from this information, nor any of the information linked to you.

The researchers listed on page 1 of this document will ensure that your data is stored and managed appropriately and according to the relevant privacy laws. The researchers will share only your de-identified data with other interested researchers and only once these projects have received separate ethics approval from a Human Research Ethics Committee.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the UNSW Privacy Management Plan.

9. How and when will I find out what the results of the research study are?

The research team intend to publish and/ report the results of the research. All Information will be published in a way that will not identify you. If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

10. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form', which is accessible online via contacting a member of the research team, provided at the end of this document, or you can ring the research team and tell them you no longer want to participate. Please tell the research staff if you are thinking about stopping or decide to stop. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney. If you decide to leave the research study, the researchers will not collect additional information from you. However, the researchers may ask you for an optional exit interview to understand your experience in the study and reason to withdraw. You may decline to have this interview. You can request that any identifiable information collected be withdrawn from the research project.

11. What if I have a complaint or any concerns about the research study and will I receive compensation if suffer any injuries or have complications?

If you suffer any injuries or complications as a result of this research project, you should contact the research team or your GP as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

Complaints Contact

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
Ethics Reference Number	iRECS8841

12. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details

Name	*Dr Nell Norman-Nott*
Position	*Clinical Trial Manager*
Telephone	*+61 490 802 397*
Email	*n.normannott@unsw.edu.au*

Name	*Dr Annie Butler*
Position	*Research Assistant*
Telephone	*+61 490 802 397*
Email	*a.*butler*@unsw.edu.au*

Name	*Prof Sylvia Gustin*
Position	*Chief Investigator*
Telephone	*+61 490 802 397*
Email	*s.gustin@unsw.edu.au*

Support Services Contact Details

If at any stage during the study you become distressed or require additional support from someone not involved in the research please call:

Name/Organisation	*LifeLine*
Telephone	*13 11 14*
Name/Organisation	*B*eyond Blue
Telephone	*1300 22 4636*
Name/Organisation	*Healthdirect*
Telephone	*1800 022 222*

13. Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study
- ☐ I have thoroughly read the Participant Information Statement.
- ☐ I understand the purposes, study procedures (including the randomisation procedure and the time commitments to complete the assessments at baseline, 12-, 20-and 52-week assessment timepoints) and risks of the research described in the study.
- ☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members.
- ☐ I consent for my de-identified data to be stored in a secure databank for the purpose of this research study.
- ☐ I understand that I will be given the option to sign a separate Services Australia consent form to allow access to my Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data. This information will be used to help evaluate the effectiveness of the treatment. I understand that providing this consent is optional, and that I can still take part in all other parts of the trial if I choose not to give this consent.
- ☐ I understand that the Pain and Emotion Therapy sessions and the Semi Structured Interviews are on Zoom and that these will be video recorded to ensure adherence with the treatment protocol and for transcription purposes, with recordings saved on the password protected secure server at UNSW.
- ☐ I understand that when using the Pain and Emotion Therapy App, information about usage will be recorded and stored on a secure server.
- ☐ I have had an opportunity to ask questions, and I am satisfied with the answers I have received.
- ☐ I understand that I will be provided with a signed copy of this document to keep

If you would like to receive a copy of the study results via email, please complete your contact details. We will use these details only for this purpose.

Name:

Phone:

Email address:

Optional participant consent:

- ☐ I give my consent for my de-identified data to be stored in a secure databank and shared with other interested researchers for use in future research projects as described in section 8 of this document.
- ☐ I give my permission to be contacted for future studies about chronic pain.
- ☐ I consent to being contacted by the HREC approved research staff about potential participation in media events.
- ☐ If at the end of the study I choose to access the Pain and Emotion Therapy app for ongoing personal use, I understand that this is given with no further support from the researchers and access may be removed at any time in the future.
- ☐ I consent for my details to be entered into the competition draw for an opportunity to receive one of five $200 gift cards.

Name:

Postal Address:

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	REVIEW COPY ONLY - NOT FOR SIGNATURE
Date	

Please provide details of your primary health care provider (GP/Medical Centre) in case of emergencies

Name of GP (please print)	
Name of Medical centre you attend if you don't have a regular GP (please print)	REVIEW COPY ONLY - NOT FOR SIGNATURE
Telephone	

Participant Emergency Contact

Please provide the details of one person whom we may contact in the event of an emergency.

Full name:	
Relationship:	REVIEW COPY ONLY - NOT FOR SIGNATURE
Phone:	
Email:	

Declaration by Researcher*

☐ I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	REVIEW COPY ONLY - NOT FOR SIGNATURE
Date	

***An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.**

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with the University of New South Wales and Neuroscience Research Australia. I understand that I may be contacted for an optional exit interview about my experience in the trial and reasons for withdrawing.

Please select one of the following:

- ☐ I am withdrawing my consent to take part in any further parts of this research and give permission for the research team to keep and use the data already collected about me for the purposes of this study.
- ☐ I am withdrawing my consent and request that any identifiable information collected about me for this study be removed. I understand that data which has already been analysed, published, or cannot be linked to my identity cannot be withdrawn from the research.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	REVIEW COPY ONLY - NOT FOR SIGNATURE
Date	

The section for Withdrawal of Participation should be forwarded to:

Chief Investigator Name	*Prof Sylvia Gustin*
Email	*s.gustin@unsw.edu.au*
Phone	*0490802397*
Postal Address	*BioLink Building, Level 1* *The University of New South Wales* *Sydney NSW 2052 Australia*