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Home-based Cognitive Bias Modification (CBM) for People with Chronic Pain

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in a research study looking at a novel intervention for chronic pain, Cognitive Bias Modification (CBM). CBM has been shown to be helpful in a range of populations including in people with anxiety and depression. However, it has never been tested with a chronic pain sample. We hope that the results of this study will contribute to enhancing future treatments for chronic pain.

You have been invited to participate in this study because you have chronic pain and have responded to an advertisement. This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.
By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

(2) Who is running the study?

The study is being carried out by the following researchers:

- Louise Sharpe, Professor of Clinical Psychology, University of Sydney

Emma Jones is conducting this study as the basis for the Doctor of Philosophy (PhD) degree at The University of Sydney. This will take place under the supervision of Louise Sharpe, Professor of Clinical Psychology.

(3) What will the study involve for me?

If you agree to participate in this study, you will later be asked to agree to the Participant Consent Page.

This study is a double blind, randomised, placebo controlled trial. If you choose to participate in this study, you will firstly be asked to complete a series of questionnaires which will take around 15 minutes. You will also be asked to complete the same questionnaires on two more occasions: one two weeks after the initial survey, and then two weeks after that.

After you have completed the first set of questionnaires, the computer will randomly allocate you into a group, like the flip of a coin. Neither you, nor the researchers will know which group you have been allocated to. Neither you nor the researchers can decide which training you receive – it is completely by chance. There are two groups in this study:

A: Cognitive Bias Modification (CBM)

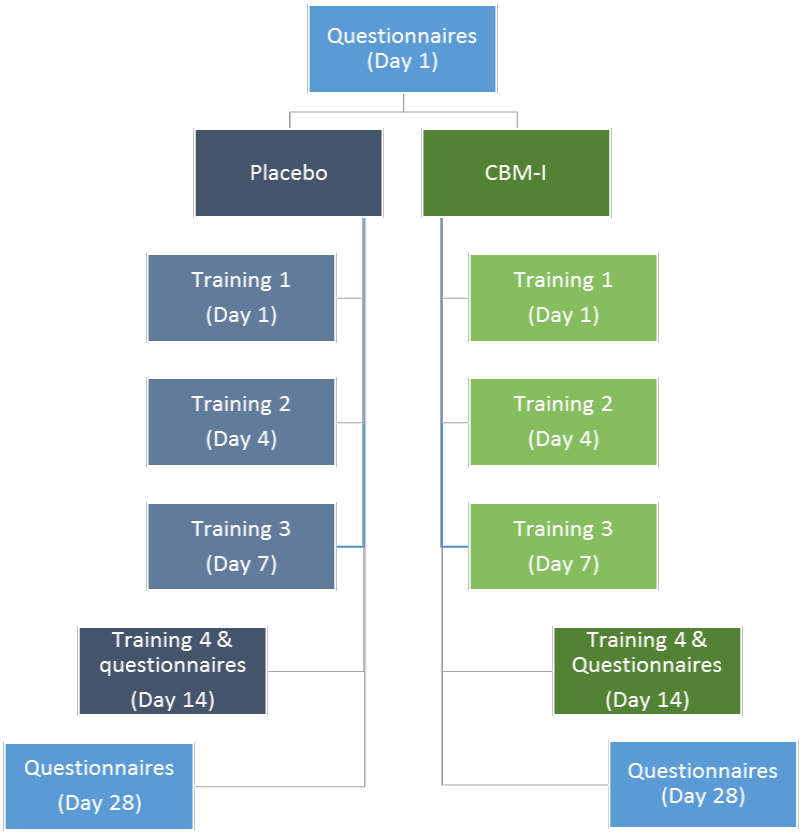
In this condition, participants will be asked to complete one online computer-based training session immediately following completion of the initial questionnaires. They will then be asked to complete another 3 online training sessions over the course of the next 2 weeks, as well as a very brief questionnaire before each training. Each training session will take approximately 10 - 15 minutes to complete.

B: Placebo

Similarly in this condition, participants will be asked to complete one online computer-based training session immediately following completion of the initial questionnaires. They will then be asked to complete another 3 online training sessions over the course of the next two weeks, as well as a very brief questionnaire before each training. Each training session will take approximately 10 - 15 minutes to complete.

<u>If you are allocated to the placebo group and wish to complete the CBM training, it will be made available to you when you complete the study.</u>

A diagram of the study flow follows:



(4) How much of my time will the study take?

The study will be conducted over 4 weeks in total. The first stage of the study is estimated to take up to 45 mins. The three subsequent training sessions are estimated to take you 10 - 15 minutes each. The initial follow-up set of questionnaires are estimated to take up to 30 minutes, while the second follow-up set of questionnaires two weeks after are estimated to take up to 15 minutes. Therefore, your total maximum participation in hours across 4 weeks would be 2.5 hours

(5) Who can take part in the study?

We welcome any participant who is experiencing chronic pain (ongoing pain for more than 3 months). To participate in this study, you must be able to use the computer for simple typing, and you must have access to the internet over the course of the 3 week period. You also must be fluent in English. This is because the training is all delivered online and requires a good understanding of the written content.

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by responding to the email from which you were sent the link to this study.

If you decide to withdraw from the study, we will not collect any more information from you. Please let us know at the time when you withdraw what you would like us to do with the information we have collected about you up to that point. If you wish, your information will be removed from our study records and will not be included in the study results, up to the point that we have analysed and published the results.

(7) Are there any risks or costs associated with being in the study?

We do not foresee any risks associated with participation in this study. There is no evidence that the questionnaires in the study will cause distress nor that the training involved in this study would pose a risk to you. However, should you become distressed at any point throughout the duration of your participation in the research, we would urge you to contact Emma Jones. You can find her details in section 12 of this document. Further, if your answers to the questionnaires indicate you are experiencing high levels of distress, the research team will contact you via telephone.

The only cost associated with being in the study is the time you give up to participate in the research project, for which we are very grateful.

(8) Are there any benefits associated with being in the study?

We are very grateful that you're willing to participate in this research. As a show of our appreciation for your time, we are pleased to be able to offer a donation of $5 to the advocacy group for every person who completes the study. Thanks to your help, we believe this project will be important in helping to better understand chronic pain. We also believe the results of this study may inform future treatments for chronic pain.

(9) What will happen to information about me that is collected during the study?

All information that you provide in the questionnaires, training and email contact is **strictly confidential**. Electronic records will be kept on a password protected server owned by the University of Sydney that is only accessible to members of the research team. Qualtrics, an external online survey host, will be used for initial data collection. Your survey responses are also password protected and again, only accessible by the research team. All electronic records will be stored for a minimum of 20 years, as required by law. In the interest of transparency, fully anonymised data may be stored indefinitely for the purposes of open-access practice.

Distribution of training sessions and follow-up questionnaires over the 8 day study period will be managed using the email address that you responded to the initial advertisement with. Your email address will be used for the sole purpose of distributing the training sessions and questionnaires. Similarly, we will only contact your via telephone if you have indicated high levels of distress in the questionnaires and we are concerned for your safety. After you have completed the study, you will not receive any contact from the research team, unless you have elected to receive a summary of the findings via email after the project is complete or if you have indicated you would be happy to take part in future research. The team will delete the email address we created to manage survey distribution after completion of our project. Therefore, your email address will not be stored longer than the study duration.

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study finding may be published, but you will not be individually identified in these publications.

(10) What will happen to my treatment when the study is finished?

As previously mentioned, if you are allocated to the placebo group and wish to complete the CBM training, it will be made available to you at the completion of your involvement in the study. If you are allocated to the CBM group, you will already have completed the relevant treatment in this study.

(11) Can I tell other people about the study?

Please don't talk to other people who are likely to participate in the study (i.e. have chronic pain), as it may affect their responses.

(12) What if I would like further information about the study?

When you have read this information, Emma Jones will be available to discuss it with you further and answer any questions you may have. Also, if you would like to know more at any stage during the study, please feel free to contact her.

Emma Jones, Registered Psychologist and PhD Candidate, University of Sydney
Phone (02) 9351 4257 or email usydpainstudy@outlook.com

(13) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by electing so either in the initial survey or in the follow-up questionnaire at the completion of the project. This feedback will be in the form of a one page summary via email. You will receive this feedback after the study is finished.

(14) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney *[INSERT* protocol number once approval is obtained*].* As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)