Phoenix AUSTRALIA

Traumatic Stress Clinic

THE UNIVERSITY OF MELBOURNE

Plain Language Statement

Melbourne Medical School, Department of Psychiarty,

Faculty of Medicine, Dentistry, and Health Sciences

Project: *Intervention to Manage PTSD, Adjustment Disorder and Comorbidity after Trauma (IMPACT) – Study 1*

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Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research. Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about. Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time.

What is this research about?

This research project is aiming to compare the effectiveness of two psychological treatments that can help individuals who develop posttraumatic stress disorder (PTSD) after experiencing a traumatic event.

Following a traumatic event, most people experience emotional reactions such as feeling anxious and sad for a short period of time, and then find that over time, these feelings reduce. However, some people (about 30%) experience severe, ongoing emotional reactions that develop into emotional disorders such as PTSD. Along with PTSD, some people will experience other emotional disorders at the same time, including anxiety or depression, which may persist if left untreated. Currently, Prolonged Exposure (PE) therapy is considered the gold-standard treatment for PTSD, but a new treatment known as the Unified Protocol (UP) has been suggested as an alternative treatment option for PTSD. Early evidence for UP suggests that it will be successful in treating PTSD, and may have greater psychological benefits than PE. This

study is specifically comparing the effectiveness of UP compared to PE in treating PTSD after a traumatic experience.

This study is known as randomised controlled research. To find out which treatment is best for treating a disorder (such as PTSD), we need to compare different treatments against each other. We can do this by putting people into groups and giving each group a different treatment. To try and make sure the groups are the same, each participant is put into a group by random chance. This means that in this study, participants will be randomly allocated to one of two psychological treatments (UP versus PE). This project is a blind study which means the researchers who have contact with you don't know which group you are in. The study design is to ensure that researchers interpret the results in a fair and appropriate way, and avoids study researchers or participants jumping to conclusions.

What will I be asked to do?

When you called the IMPACT research team to enquire about the project, you will have been given information about the Phoenix Australia Traumatic Stress Clinic (Phoenix Clinic), and been given a Plain Language Statement outlining the intake process prior to providing verbal consent to engage in a 60 minute screening assessment, to identify whether you have developed PTSD following a traumatic event that you experienced. During the intake assessment you will also have been asked questions about other mental health symptoms you may be experiencing, including depression, anxiety and substance use.

If you have been invited and consent to participate in the IMPACT study, you will be randomly allocated to either the UP treatment condition, or the PE treatment condition. Treatment will take place at the Phoenix Clinic at the Royal Melbourne Hospital (Royal Park Campus).

Note: Currently due to social distancing measures related to COVID-19, participation in the IMPACT study is via Telehealth (videoconference) only. This means that treatment will take place over videoconference only (supported by telephone if needed), until social distancing measures are lifted.

Alternatively, if you cannot travel to this location, treatment may be delivered via telehealth or an outreach model may be offered to you if suitable. Telehealth involves video conferencing (audio and video) where you receive your sessions typically from the privacy of your home though your computer (on a program called Zoom). An outreach model is also available where the trained clinician will come to and provide treatment in your home. Once allocated, you will receive 10-weekly sessions of 90-minute face-to-face or telehealth UP or PE treatment, delivered by a trained clinician.

Note: Currently due to social distancing measures related to COVID-19, participation in the IMPACT study is via the telehealth (videoconference) option only (ie. face to face in person and outreach options are not available until social distancing measures are lifted.).

With your consent, the treatment sessions will be audio recorded and reviewed by other clinicians working on the project to monitor and ensure that your sessions are conducted according to protocol. Brief details about each treatment are outlined below:

UP: The Unified Protocol for Transdiagnostic Treatment of Emotional Disorders involves: (a) discussing goals and motivating you to work towards these goals, (b) education about emotional experiences, (c) helping you become more aware of emotions and your reactions to them, (d) dealing with unhelpful thoughts about emotions, (e) changing unhelpful responses to emotions (f) helping you to tolerate difficult emotions and physical feelings and (g) planning for ways to

stay well in the future. UP also involves doing activities during the week that will reinforce each therapy session.

PE: Prolonged Exposure involves helping you to gradually address the difficult memories of your traumatic experience, as well as any situations you may be avoiding because of the traumatic experience. In a supportive and controlled fashion, PE involves: (a) learning about common reactions after a traumatic experience, (b) learning breathing retraining to help manage anxiety, (c) creating a list of avoiding situations, (d) engaging in imaginal PE, which involves describing the traumatic event you experienced, with guidance from the trained clinician and (e) planning for ways to stay well in the future. PE also involves doing *in vivo* activities during the week, which involves confronting avoided situations in a graded fashion.

Assessments

Before beginning treatment, you will be asked to complete a set of questionnaires that will assess the psychological symptoms that you are currently experiencing. The questionnaires will take approximately 30 minutes to complete in total, and you will have the option to complete it in hardcopy, or via an online form. You will also be invited for an assessment, during which you will be asked to answer some questions about your PTSD symptoms. The interview will take approximately 60-90 minutes to complete, and you will have the option to complete this interview via telephone or face-to-face. However, if you are receiving treatment via telehealth, this assessment will be done by videoconferencing (Zoom) in order to assist with any technical issues. **Note: Currently, due to social distancing measures related to COVID-19, all interviews will be done via the telehealth (videoconference) or telephone only.**

During this first assessment, you will also meet with a member of the trial team who will explain the mobile phone-based task that occurs between the first assessment and the first meeting with your clinician. You will be asked to download an application on your smartphone to complete (1) a set of randomly triggered twice daily surveys and (2) surveys that you can enter anytime when you experience intrusions. During this 25-30 minute meeting, you will get assistance downloading the mobile application on to your smartphone, go through the surveys that you'll answer, and have the chance to answer questions that you might have. The surveys usually take less than five minutes to complete and ask questions about how you deal with your emotions. This is done to get an idea of what strategies you are already using in your daily life to manage your emotions. You'll be invited to complete the same set of surveys again at the end of treatment, which will help researchers understand how the type of treatment impacts how we manage our emotions.

Your first session is an assessment where you will meet your treating clinician who will ask you about your traumatic event in order to record a three minute re-telling of the event. You will be invited to listen to this recording at the beginning of your second and fourth session, then again at your final treatment session. While you are listening to the recording, we will measure your heart rate and skin conductance, using a small non-invasive sensory. This is done to get an objective measure of your response to treatment, and will help researchers investigate if they can predict which treatment will be more beneficial for people based on how they physiologically respond during the retelling of their traumatic event. This aspect of the treatment will <u>not</u> be undertaken if you are receiving your treatment via telehealth.

If you are participating in telehealth treatment, in your first session, you and your clinician will develop a Telehealth Management Plan (TMP), which will include you providing two contacts that are close by, as nominated support persons. These individuals may be contacted in

emergency situations where the clinician is unable to reach you. If required, a safety plan will also be developed at this session.

After you have completed the course of treatment that you have been allocated to (UP or PE), we will contact you at certain time points to conduct telephone assessments and complete questionnaires (similar to those you were asked to complete before treatment). Telephone assessments are conducted to identify the severity of your PTSD symptoms (and possible anxiety/depressive symptoms), and will take approximately 1.5 hours to complete. They will occur after you complete treatment (i.e., after the 10-week period), and at a follow-up period of 6 and 12-months after treatment completion. As mentioned above, you will also be asked to complete a set of questionnaires which assess the level of psychological symptoms that you are experiencing, how you view these symptoms, and how you are managing them, as well as your current quality of life. The questionnaires will be sent to you by post or you can complete them online, and will take approximately 30 minutes to complete. These questionnaires will be completed at approximately the same time points as the telephone assessments.

What are the possible benefits?

We cannot guarantee that you will receive any benefits from this research. However, early evidence shows that UP is beneficial for treating PTSD. Additionally, PE is one of the most effective treatments available for PTSD. As such, possible benefits may include improvement in symptoms of PTSD, anxiety or depression. You will be reimbursed with a $25 Coles/Myer voucher after you have completed the 6 and 12-month follow-up assessment.

Potential benefits of the research for the wider community include improving the effectiveness of psychological treatments for PTSD. Specifically, this research has the potential to offer individuals with PTSD a choice of evidence-based treatments for PTSD, not just limited to the gold-standard PE treatment.

What are the possible risks?

There are few risks associated with involvement in this project. However, it is important to note that all effective psychological interventions have the potential to cause distress to some degree – as this is part of the process of "working through" the traumatic experience. The prospect of confronting your memory of the traumatic event during PE treatment especially may seem frightening to you, however you will learn skills to manage distress, and any distress you experience will reduce during the sessions. While no evidence suggests that the psychological treatments being offered are detrimental, the study researchers will arrange for appropriate support in the event that you become upset or experience any distress (or unusual) symptoms. If you are in UP or PE and you reach the end of your treatment and feel as though your overall symptoms have not improved, you are free to speak to your GP about accessing other types of psychological treatment. With your consent, we can write a letter to your GP outlining your involvement in the study, and your desire for further referral.

Can I have other treatments during this project?

You may continue to take antidepressants and other medications during this study. If you are allocated to either UP or PE you cannot receive any other psychological treatments.

Are there alternatives to participation?

Before participating in the IMPACT project, you may discuss options such as psychological interventions or medications with a healthcare worker (for example, a hospital doctor or your

GP). In many cases, the intervention offered in this study will be similar to that you would receive from a private psychologist.

Do I have to take part?

No. Participation is completely voluntary. You are able to withdraw at any time. If you decide to withdraw, please notify a member of the research team. They will inform you if there are any health risks or special requirements linked to withdrawing. After you withdraw, your personal and health information collected through the study will be kept to ensure the results of the research can be measured properly. If you do not want your personal and health information to be kept for the study's purposes, please tell a member of the research team once you withdraw.

Will I hear about the results of this project?

Results of this project will be published and presented in a variety of forums including reports, media, peer review publications, and other public forums. A brief report containing a summary of the project's findings will be uploaded to the Phoenix Clinic's website for you to access when the study has finished.

What will happen to information about me?

Any information about your identity will remain confidential, and all data will remain de-identified. We plan to publish the results from the study in scientific journals. All published information will be group data only, therefore individual information will not be identified. It is possible that we may use the data collected in this study for future research with similar aims to improve the mental health of people impacted by traumatic experiences. In consenting to this study, you are also giving consent for us to use your data for future research which would be subject to approval from a Human Research Ethics Committee.

Only the researcher team will have access to your personal information. Most information will be stored electronically on Phoenix Australia, University of Melbourne computers using the VPN (Virtual Private Network) and secured by password access. For any participants consenting to telehealth treatment, all information will be kept electronically. Any hard copy information or data will be stored in locked cabinets at Phoenix Australia.

All electronic data will be set with access restricted to the research team only and stored on a password protected computer. This data will be attached to a unique identifying code and no personal identifying information will be attached to electronic data. Personal identifying information attached to the unique code will be kept in a separate database with no electronic data attached. This includes, data collected from the questionnaires you complete; the audio recordings of your verbal consent provided for the intake assessment and when consenting into the IMPACT trial; and audio recordings of assessment and treatment sessions. The assessment and treatment session recordings are optional and you are asked for your consent for this on the consent form.

Both hard copies and electronic copies of data gathered during this study will be securely disposed of 7 years after the publication of this study or any future studies using this data.

As you will be receiving psychological treatment in this study, it will be important that your local doctor be advised of your involvement in this research project. We will send a letter to your GP to notify them of your involvement if you provide consent for us to do so. Any correspondence to other health professionals will require your consent.

If you are accessing treatment via telehealth, your assessments and therapy will be held via Zoom, a high quality video and audio online conferencing tool for desktops, laptops, and

smartphones/tablets. Zoom is an easy to use and common videoconferencing platform chosen by many health practitioners. The IMPACT Trial has chosen Zoom as its platform for its security credentials and ease of use, however videoconferencing content in Zoom is not end-to-end encrypted. As with many online conferencing platforms over the internet, this means 100% privacy cannot be guaranteed. We have put in place strategies in order to increase the security of your information including: clinicians will require a University of Melbourne login and password to host the meeting; and participants will also require a unique password to join the meeting. More information regarding the security of Zoom, is found: https://zoom.us/security.

How can I access my information?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

What happens if I am injured as a result of participating in this project?

If you suffer an injury as a result of your participation in this research project, please contact the research staff. Hospital care and treatment will be provided by the public health care system (Medicare) at no cost to you if you are eligible for Medicare benefits and elect to be treated as a public patient.

Who is funding this project?

This project has been funded by the National Health and Medical Research Council of Australia (NHMRC).

Where can I get further information?

If you would like more information about the project, please contact the Responsible Researcher, Professor Meaghan O'Donnell on 03 9035 5599.

Who can I contact if I have any concerns about the project?

This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: HumanEthics-complaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.