

Plain Language Statement

Melbourne Medical School, Department of Psychiatry,
Faculty of Medicine, Dentistry, and Health Sciences and Faculty of Medicine,
Dentistry, and Health Sciences

Project: Intake Process for the Phoenix Traumatic Stress Research Clinic

Responsible Researchers: **IMPACT:** Professor Meaghan O'Donnell
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Other Researchers:

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Introduction

Thank you for your interest in the Phoenix Traumatic Stress Research Clinic (Phoenix Clinic). The following few pages will provide you with further information about the Phoenix Clinic and what is involved in the intake process for the current research trials within the clinic. This will assist you in deciding if you would like to take part in the intake process, and subsequently, the clinical trials at the Phoenix Clinic. Please take the time to read this 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 in the intake process, you can also stop at any time.

What is this research about?

The Phoenix Clinic runs trials of new, innovative treatments that are based on the latest science and evidence, in order to improve mental health treatments for people who have experienced traumatic stress and trauma-related mental health problems. As we are a treatment research facility, the treatments we offer are aimed at improving knowledge in the treatment of posttraumatic mental health conditions. The Phoenix Clinic is staffed by qualified specialist trauma mental health clinicians, led by Professor Meaghan O'Donnell, an internationally recognised expert in trauma.

We run a number of psychological treatment trials and treatment is available free of charge to eligible individuals. The Phoenix Clinic offers treatment for individuals who have experienced a trauma in their lifetime – this could be events such as an experience of an assault, a motor vehicle or work accident, exposure to critical incidents and occupational risks, a physical injury, traumatic birth or grief experience, natural disaster, war related experience, or trauma experienced as a child.

The current research trials that are operating at the Phoenix Clinic are outlined below. You will be provided with more information about these studies during the intake process and can request the Plain Language Statement for individual studies at any time. More information including downloadable links to the Plain Language Statement and Consent Forms for these studies can be found at: [link to be inserted here].

IMPACT: Intervention to Manage PTSD, Adjustment disorder and Comorbidity after Trauma (*University of Melbourne Ethics ID: 1853047.1*)

The IMPACT Trial is investigating whether two psychological treatments for posttraumatic stress disorder (PTSD), prolonged exposure and the unified protocol for emotional disorders, can help improve PTSD symptoms and quality of life.

BDNF: Effect of acute intensive exercise and brain derived neurotrophic factor (BDNF) on treatment response to exposure therapy in posttraumatic stress disorder (*University of Melbourne Ethics ID: 1954422.3*)

The BDNF Trial investigates whether aerobic exercise can improve the effectiveness of prolonged exposure therapy for treating PTSD. All participants will receive prolonged exposure therapy while some participants also completing an aerobic exercise intervention and others completing gentle stretching with prolonged exposure.

What will I be asked to do?

Should you agree to participate, the intake process will help to establish eligibility for current studies at the Phoenix Clinic. The trials will be described in detail by the research team and you will have the opportunity to ask questions before, during, or after the intake process. Enrolment into specific trials will be based on a combination of preference and eligibility. Eligibility will be assessed during the intake process, which is outlined below:

1. During an initial contact, a Phoenix Clinic staff member will provide an overview of the clinic and the current trials. At this stage, you will be asked broad questions regarding the traumatic or stressful event(s) you have experienced and the mental health symptoms you are experiencing. If suitable, an intake assessment will be booked and this Plain Language Statement will be sent to you via email or post, in order for you to read and familiarise yourself with prior to the intake assessment.
2. Intake assessment: an intake officer will conduct the telephone intake assessment to determine eligibility into the current trials. This telephone intake will last for approximately 60 minutes, and will involve:

- a. Answering any questions you have regarding the Phoenix Clinic or from this Plain Language Statement.
 - b. Verbal consent to conduct the intake assessment will be sought from you and audio recorded. You will also be asked if we can audio record the mental health assessment component of the intake (i.e., where we ask you about your symptoms of PTSD, depression, anxiety). This recording is a routine part of our research to check that the interviewers are asking the questions in a standard way. If you do not want to be audio recorded please let the interviewer know.
 - c. The intake assessment will be conducted which will include demographic questions, a brief description of the traumatic or stressful experience, a semi-structured assessment of your current mental health symptoms, your mental health and treatment history, any risk of harm to yourself and others, physical health history, description of medication prescriptions, and other information relevant to your participation in the treatment trials.
3. Following your intake assessment, the intake officer will discuss your assessment with other members of the team, which includes our consultant psychiatrist, at which stage, a determination will be made regarding your eligibility for receiving treatment at the Phoenix Clinic, as well as a recommendation for the most suitable research trial. If you have a preference for one trial over the other, this will also be considered in the recommendation.
4. You will be contacted within one to two weeks of your intake call, either with a decision regarding your eligibility or a request for further information (from yourself or your current health professionals if required e.g. General Practitioner, psychologist, or psychiatrist). If we request to contact any health professionals as part of the intake process, you will be asked to provide written consent via email.
 - a. If you are eligible: The next steps of enrolling into a specific trial will be outlined and a Plain Language Statement and Consent Form for the trial will be sent to you.
 - b. If you are not eligible for any of our studies: We will aim to facilitate referrals and provide feedback from the intake assessment that may assist with you receiving treatment or support elsewhere. This typically can include a referral to your doctor or other psychological or health support service.

What are the possible benefits?

We cannot guarantee that you will be eligible for the research trials offered through the Phoenix Clinic or that you will receive any benefits from being involved in the research. Potential benefits from being involved in the intake process following eligibility may be enrolment into one of the Phoenix Clinic treatment trials where you may experience an improvement in your mental health symptoms.

What are the possible risks?

By consenting to take part in the Phoenix Clinic's intake process, you are consenting to the research team determining your eligibility into one of the clinic's trials. This does not guarantee that you will be eligible or that you will receive treatment at the Phoenix Clinic. If you are not eligible for the trials at the Phoenix Clinic, we will discuss with you your options for referral for treatment that is/are considered suitable for you.

If you participate in the Phoenix Clinic intake process, you will be asked to speak about your memory of your trauma experience(s) and associated symptoms. Some people may find it distressing to talk about their traumatic event experiences. This distress is quite normal and usually dissipates afterwards. You can stop or pause the intake assessment at any stage and the intake officer will assist you in managing your distress. All Phoenix Clinic intake officers are trained to assist in managing any distress caused by the intake process. If your distress persists, after discussion with you, we may decide to contact your other treating health professionals to help manage your distress. We will always discuss this with you first and seek your consent. **It is natural for some distress to occur when talking about trauma experiences, but if your distress persists, you can contact your GP or Lifeline on 13 11 14.**

Do I have to take part?

No. Participation in the intake process and assessment is completely voluntary. You are able to withdraw at any time. If you decide to withdraw before, after, or during the intake process, please notify a member of the research team. If you withdraw following your intake assessment, your personal and health information collected through the Phoenix Clinic will be kept to ensure the results of the research can be measured properly.

Will I hear about the results of this project?

If you proceed with the intake process and are deemed eligible to participate in one of the research trials, results of the studies 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 intake process, you are also giving consent for us to use your de-identified 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. Your individual data will be stored in locked cabinets or password protected electronic files at Phoenix

Australia within a locked room. Personal identifying information will be kept separate from data from structured assessments. The audio recordings of your verbal consent provided for telephone screening purposes and of the semi-structured mental health assessment will be stored on a password protected computer in a locked room at Phoenix Australia, with access restricted to the research team only. All hard copies of data gathered during this study will be scanned and stored electronically, and hard copies will be securely destroyed. In accordance with National Health and Medical Research Council guidelines, electronic data will be securely disposed of seven years after the publication of this study or any future studies using this data. De-identified information gathered throughout the intake process will be shared with members of the Phoenix Clinic staff during weekly meetings in order to determine eligibility.

With your consent, relevant clinical information may be communicated to your treating health professionals to provide them with information relating to your involvement in the intake process in order to determine eligibility into the trials.

Information you provide to the research team and Phoenix Clinic staff during the intake process will be treated confidentially. If any serious risk to you or another person is identified during the intake process we may need to break confidentiality in order to keep you and others safe. This may involve contacting your next of kin, your GP, health professionals or other mental health services. When possible we will always discuss this with you first.

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 more information about the Phoenix Clinic, please contact the Responsible Researcher, Professor Meaghan O'Donnell on 03 9035 55989 or visit <https://www.phoenixaustralia.org/expertise/research/clinic/>.

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.