**PARTICIPANT INFORMATION SHEET**

**HRECS No 2021.260**

 **Study Title:**

**A randomized control trial regarding the efficacy of an app series based on EMDR for PTSD symptoms**

**Investigators: Mark Grant MA, Richard Lau, Jeff Di Nardo Phd.**

# Introduction:

You have been invited to take part in a research study. This is because you have signed up to the online advertisement. The research project is testing a series of new treatment apps for the management of symptoms of Post-traumatic stress disorder (PTSD).

This Participant Information Sheet and Consent Form will tell you about the research project. It explains the purpose of the research, procedures and risks involved. It will also describe the type of information we collect about you, how that information will be used and how it will be shared. By knowing what is involved, it will help you decide if you want to take part in the research. Please read this information carefully.

You can ask questions about anything that you do not understand or would like to know more about by contacting the lead researcher, Mark Grant, at markgra@ozemail.com.au. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor. Participation in this research is completely voluntary. If you do not wish to take part, you don’t have to. You will receive the best possible care whether or not you take part. If you decide you want to take part in the research project, you will be asked to sign the Consent Form and click ‘agree’ to proceed.

By signing and clicking ‘agree’ below, you are telling us that you;

* + Understand what you have read
	+ Consent to take part in the research project
	+ Consent to have the tests and treatments that are described
	+ Consent to use of your personal and health information as described

You will be given a signed and dated copy of this Participant Information Sheet and Consent Form to keep.

# Purpose of the Study:

You are invited to participate in a research study, which is aims to test the efficacy of this series of apps in the management of the four main symptoms/effects of PTSD: anxiety, medically unexplained pain, insomnia, and negative effects on self-confidence.

The proposed duration of the study is 9 month12 (8 weeks of intervention + 3 and 6 month follow-up) online.

# Study Procedures:

You will start with a screening process to help measure the current level of your PTSD symptoms and sleep quality, by completing the PCL-C (PTSD checklist) and Patient Health Questionnaire (PHQ-15). If your results from the assessments fit our study criteria, you will proceed to take part in the next stage. During the next stage of trial, all participants will be divided into either: 50% treatment group or 50% waitlist control group. If you are assigned to the treatment group, you will be given four apps to use for 12 weeks:

* Anxiety Release App
* Overcomingpain App
* Sleep Restore App
* Calm and Confident App

Make use of each or any of the materials, daily, whenever you feel the need for relief from feelings of tension, anxiety, insomnia, pain and/or feelings of inadequacy/insecurity. Please log your daily via the online app use log (any use counts). Each app incorporates sessions of bilateral stimulation sounds combined with guided meditations of calming words and music whenever

If you are assigned to the waitlist control group, you will not receive access to the apps until the end of the study and therefore you do not need to do anything. Regardless of which treatment group you are in, please complete the questionnaires and PTSD checklist at the beginning of the trial and then at three months, 6 months and 9 months (from the beginning of the trial).

Study schedule

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Day 1 | Day 1 – end of 3rd month | End of 3rd month | End of 6th Month | End of 9th Month |  |
| PTSD checklist + 4PHQ-15 | Utilise the treatment apps | PTSD checklist + PHQ-15  | PTSD checklist + PHQ-15 | PTSD checklist + 4PHQ-15 |  |

These apps are normally paid apps, but participants in this study will receive them for free via promo codes which will be supplied for each app. To download these apps, On your iPhone, iPad, or iPod touch, open the App Store app. At the bottom of the screen, tap Today. At the top of the screen, tap the sign-in button or your photo. **Tap "Redeem Gift Card or Code**." If you don't see “Redeem Gift Card or Code,” sign in with your Apple ID. For android devices (eg; Samsung) Open the Google Play app . At the top right, tap the profile icon. Tap **Payments & subscriptions** **Redeem gift code**. Enter the code (s) that were emailed to you when you were accepted for the study. For more information visit <https://www.traumaapps.com/>

# Possible Benefits:

The study seeks to explore the efficacy of the four apps on overall PTSD symptom levels and four of the most common problems associated with PTSD; anxiety, medically unexplained pain, insomnia, and negative effects on self-confidence. It is anticipated that this approach will improve reduce PTSD symptoms and associated problems and give a scientific basis for evaluating the apps as a resource. There may be no benefit to the participant from contributing to this study.

# Possible Risks:

We do not foresee any risks from participation in this study but please let us know if you have any concerns. Please make your treating GP and other treating doctors aware of your participation in this study.

In the event that this study aggravates your existing PTSD symptoms or identifies previously undiagnosed PTSD symptoms, we advise you to consider the following support:

1. Contact the lead researcher, Mark Grant at; markgra@ozemail.com.au or phone: 0402122173.

1. If he is unavailable contact; Ana Grant at; analuzgra@ozemail.com.au or ph 0425391216
2. If she is unavailable contact Jo Sheedy at; josheeds2014@gmail.com
3. Contact your last therapist or current treating professional.
4. Contact Lifeline on 13 11 14
5. Alternatively seek help from an EMDR-trained therapist; You can locate EMDR therapists in Australia via the ‘find a therapist’ facility on the website of EMDR Association of Australia; <https://emdraa.org/find-an-emdr-therapist/>

# Voluntary Participation/Right to Refuse or Withdraw:

You are not obligated to participate in this study. If you do not wish to participate, your normal treatment plan will be followed. If you decide to participate in the study and later feel that you no longer wish to be part of it, you can withdraw from the study at any time.

# Confidentiality:

Your records relating to this study and any other information collected will be kept confidential as per Australian Law and will not impact your employment or any claim for compensation. However, staff participating in your care, and other agencies authorised by law, may inspect the records related to the study. In the event you are admitted to hospital as a result of an adverse effect resulting from this study, your treating doctor may require access to your study records.

Your identity will not be revealed, and your confidentiality will be protected in any reviews and reports of this study which may be published. Your treating Doctor/s will not be notified of your participation in this study.

Only the researchers will have access to the raw data you provide and your data will not be used in any other projects. The data and information you have provided will be securely disposed of after 5 years.

# Costs

Some of the tests or treatments used in this study may be part of standard care used to maintain your health even if you did not take part in the study. You will be responsible for the cost of this standard care in the usual way (health insurance, Medicare and your personal contribution depending on your circumstances). All study-related material will be provided at no cost to you.

# Illness or Injury

We do not foresee any potential risks associate with this study. If, as a result of being in this study, you become ill or are injured, please immediately contact the investigators and seek appropriate assistance.

# Termination of the Study

This research project may be stopped for a variety of reasons, include the following:

* Unacceptable side effects,
* illness arising from study trial, and;
* Voluntary drop out.

# Results of Project

Upon completion of the study, you will be sent a summary report of the results and further directions of the research via email newsletters with your consent. This report will contain aggregated data. Your identity and responses will not be identified.

# Consent

Prior to the beginning of the study, these apps will provide you with all information regarding the nature and purpose of the research study and its risks/benefits. You will be given the opportunity to discuss these by contacting us through email before giving consent. You are free to withdraw anytime by sending a signed copy of the withdrawal form via email (see email addresses below).

#  Privacy, protection of and access to data

The study will gather certain personal information about you. Your study profile and substantive data will be handled under a study ID separated from your identified data. This ID will be held securely and separately. They allow substantive data to be re-associated with the identifying data during dissemination of data or under specific conditions listed below.

Your data will be stored on a cloud-based google drive for a period of 5 years and will be accessed by the primary researchers and co-researchers listed above. Any personal data associated with the use of the apps is subject to the normal risks associated with cloud storage of mobile app data, common to apps in general. At the end of this storage period your data will be electronically destroyed on the database. Unless required by law, only your doctor, the study team will have access to data which identifies you by name or from which your identity is otherwise apparent or can be reasonably ascertained.

1. **Conflict of interest**

The lead researcher Mark Grant MA is also the creator of the apps. Independence of the implementation of the interventions and analysis of the results will be maintained through independent third party delivery and monitoring of the study.

1. **Further information**

If you have any questions and/or would like more information about the study you may contact the lead investigator, Mark Grant, at; markgra@ozemail.com.au

# Advice and Information

If you have any further questions regarding this study, please do not hesitate to contact

**Mark Grant MA** at **sleeprestore00@gmail.com**.

All study participants will be provided with a (digital) signed and dated copy of the Participant Information Sheet and Consent Form for their personal records.