PROTOCOL

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

Mark Grant MA, Jeff DiNardo, Phd.

Sponsor/s:
none

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Provide brief information

Title:	A randomized control trial regarding the efficacy of an app series based on EMDR for PTSD symptoms
Short Title:	RCT for of Healing Trauma App series
Design:	RCT
Study Centers:	online
Hospital:	n/a
Study Question:	Can apps help PTSD sufferers experience reduced PTSD symptoms
Study Objectives:	To assess the efficacy of a series of apps designed to address the four main symptoms of PTSD; anxiety, medically unexplained pain, insomnia, and negative effects on self-confidence.
Primary Objectives:	Ascertain whether use of 'Healing trauma' App series reduces symptom levels of PTSD.
Secondary Objectives	Ascertain whether use of 'Healing Trauma' app series reduces medically unexplained symptoms. A third objective would be to see if there are any potential risks associated with self-use of

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	apps to manage PTSD symptoms.
Inclusion Criteria:	Diagnosis of PTSD, or symptoms consistent with PTSD as measured by PCL-C and over age 18. May be receiving individual treatment or not.
Exclusion Criteria:	(1) Lack of access to mobile apps; (2) on-going self-harm/suidical or homidical ideation, (3) diagnosis of psychotic or bipolar disorder (4) non-English speakers; (5) diagnosis of dissociative disorder (6) organic mental disorder (7) substance abuse and (8) significant cognitive impairment (eg; severe intellectual disability, dementia).
Number of Planned Subjects:	200
Investigational product:	Healing traumatic stress app series; 1. Anxiety Release App 1. Overcomingpain App 2. Sleep Restore App 3. Calm and Confident App
Safety considerations:	Access to therapist in event of adverse reaction
Statistical Methods:	SPSS statistical software
Subgroups:	

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1. GLOSSARY OF ABBREVIATIONS & TERMS

Abbreviation	Description (using lay language)
EMDR	Eye Movement Desensitization and Reprocessing
app	Computer or mobile phone application
PTSD	Post-traumatic Stress Disorder
MUS	Medically Unexplained Symptoms
RCT	Randomized Control Trial

STUDY SITES

STUDY LOCATION/S

Site	Address	Contact Person	Phone	Email
online	online	Mark Grant		Markgra@ozemail.com.au

INTRODUCTION/BACKGROUND INFORMATION

LAY SUMMARY

The purpose of this study is to evaluate whether a series of mobile apps based on Eye Movement Desensitization and Reprocessing (EMDR) can stimulate reduced symptom levels in individuals experiencing symptoms of PTSD and whether those changes are long-lasting. Although mobile health apps are widely used, there is very little research regarding their efficacy. Participants will be given four mobile apps (for anxiety, medically unexplained symptoms, insomnia and negative effects on self-confidence) together with instructions in how to use them to learn to manage the problems each one addresses. A minimum time commitment of 15 minutes per day will be expected for using one or more of the apps, for one month, with no upper daily time limit.

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INTRODUCTION

Mobile apps are increasingly being used as an adjunct to psychological treatment or a stand-alone self-help resource. Despite PTSD involving multiple symptoms, most PTSD apps are designed as stand-alone resources. The Healing Traumatic Stress app series was developed to help PTSD sufferers cope with four of the most common PTSD symptoms; anxiety, medically unexplained symptoms, insomnia and negative effects on identity. Based on EMDR, each app incorporates a number of tracks comprising guided and unguided bilateral stimulation (BLS), ego-strengthening affirmations, emotional integration exercises and targeted suggestions for symptom management. BLS is a core treatment element of EMDR which has been found to stimulate decreased physiological arousal, relaxation and improved access to positive memories as part of client resourcing (Eloffson 2007, Armano 2019). The latest independent research indicates that BLS is superior at stimulating neuronal pathways involved in fear extinction (Baek *et al*, 2019). This study will seek to determine whether PTSD sufferers can achieve symptom reduction by using these apps and how enduring that reduction is. Participants will be recruited through therapist referral via advertising in professional journals. There is very little research regarding the efficacy of apps for PTSD, let alone their systemic use.

BACKGROUND INFORMATION

Post-traumatic stress disorder (PTSD) is a mental health condition which can develop after experiencing or witnessing threatening or horrific events such as childhood sexual or physical abuse and adult trauma such as terrorism, domestic violence, rape and assault. Survivors of workplace bullying, life-threatening health problems and medical mishaps (including birth trauma), are also more likely to develop symptoms of PTSD (Deatrich et al, 2016, Fishbain et al, 2017, . The symptoms of PTSD include increased physiological arousal (difficulty relaxing), hypervigilance (feeling anxious and "on-edge"), re-experiencing (nightmares and flashbacks) and avoidance of reminders the traumatic event. PTSD is often associated with problems such as insomnia, anxiety, depression and medically unexplained symptoms (Kuhn & Owen, 2020, Wright et al, 2021, Fishbain *et al*, 2017, Gupta, 2013). Medically unexplained symptoms are one of the most common-comorbid problems with PTSD symptoms preceding pain in 66.5% of cases (Hauser, 2013). PTSD is associated with possibly the highest frequency of ill-defined medical symptoms among all psychiatric disorders (Andreski *et al.*, 1998). The relationship between co-morbid problems and PTSD is thought to be bidirectional; e.g.; anxiety disrupts sleep, poor sleep contributes to somatic problems; somatic problems increase the sense of powerlessness and defectiveness that PTSD sufferers feel and so on. Insomnia is thought to be most responsible for MUS associated with PTSD (Wright *et al*, 2021)

PTSD is usually treated via face-to-face psychotherapy in the form of trauma-focused CBT, exposure therapy and EMDR (WHO, 2013, Watkins et al, 2018). However, treatment is also often supplemented by self-help strategies in the form of books, audio relaxation (Redding et al, 2008) and now mobile apps (Kuhn & Owen, 2020, Wasil *et al,* 2021). The term m-health is used to refer to "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices … and other wireless devices (WHO, 2011). Mobile apps are thought to offer access to convenient, inexpensive, in-the-moment interventions for symptom management, particularly for those unable to access treatment, and augment outcomes for clients already in treatment (Kuhn & Owen, 2020, Goreis *et al,* 2020).

According to a recent estimate there are over 325,000 health apps, approximately 10,000 of which are for mental health (Kuhn & Owen, 2020, Wasil *et al,* 2021). Usage of health apps is growing with a recent study finding that 25% of adults in the US reported having used a health app (Statistica, 2019). Like self-help books and audio recordings, Mobile apps constitute a therapeutic

resource for individuals who may not be able to afford or access treatment, or to supplement treatment for individuals already receiving therapy (Shen et al, 2015, Cernvall et al 2018). A recent research review identified 555 mobiles apps for PTSD, predominantly based on Cognitive Behavior Therapy. Most of these apps focus on affect and mood regulation through mindfulness meditation, breathing exercises, and behavioral activation (Sanders et al, 2020). Other elements include psycho-education, problem-solving skills and symptom-tracking. Many of the apps are designed to be used in conjunction with treatment. There were 25 apps based on EMDR (Marotta-Walters et al, 2018). The key features of apps based on EMDR are the incorporation of bilateral stimulation (BLS), psychoeducation about trauma, EMDR, and the AIP model, and emotional regulation strategies (Marotta-Walters et al, 2018, Grant, 2014). BLS is a defining element of EMDR which has been found to stimulate decreased physiological arousal, relaxation and improved access to positive memories as part of client resourcing (Eloffson 2007, Armano 2019). The latest independent research indicates that BLS is superior at stimulating neuronal pathways involved in fear extinction (Baek et al, 2019). Most of the EMDR apps are designed to be used as an adjunct to EMDR therapy, but the Healing Trauma App series are designed to be suitable for symptom management. In a review of EMDR apps that was written before the series had been published in its entirety, Anxiety Release was found to be suitable for symptom management (Marotta-Walters et al, 2018).

In terms of their application to the most common symptoms of PTSD, most CBT apps focus on anxiety management, two address PTSD-related insomnia, (insomnia coach and CBT-I) but none address MUS associated with PTSD. Anxiety is a common symptom of PTSD (Ref); sleep disturbance is a part of hypervigilance (Ref); medically unexplained symptoms are a well-documented consequence trauma exposure (Roelofs & Spinhoven, 2007); negative alterations in cognition and their impact of identity and self confidence are also well-documented symptoms of PTSD (Wright et al, 2021,)

As of 2019 there were only four RCT studies of PTSD apps, three involving PTSD coach (Kuhn & Owen, 2020). The results showed modest effects, not necessarily maintained at follow-up (Kuhn *et al*, 2017). Goreis et al (2020) metanalysis found a PTSD app produced small to moderate effect size for reduction of PTSD and depressive symptoms in a sample of 209 PTSD sufferers. Although many apps were found to be of high quality, most lacked scientific research. Individual apps for insomnia, chronic pain or anxiety, fail to recognize the overlap between these problems and PTSD.

With the exception of the Healing traumatic stress app series, all of the EMDR apps are designed as an adjunct to EMDR therapy.

The Healing PTSD series consists of four apps which address four of the most common symptoms associated with PTSD, anxiety, medically unexplained symptoms, insomnia and negative effects on identity. This series consists of; Anxiety Release, Overcoming Pain, Sleep Restore and Calm and Confident. These apps were developed by Mark Grant with no outside funding. While depression and dissociation are also strongly correlated with PTSD (van der Kolk et al, 1996, Flory & Yehuda, 2015, Carlson et al, 2012), it was felt that having more than four apps would be cumbersome and that these issues could be addressed indirectly through the emotional regulation and self-awareness exercises incorporated in the existing four apps. These apps were designed to be used outside of treatment and hypothesized to have tangible benefits, but not to act as a substitute for face-to-face treatment. Apart from a single case-study report regarding the use *of Anxiety Release based on EMDR* to resolve Carpal Tunnel Syndrome, there is no research regarding the efficacy of EMDR-based apps (Grant 2014). Based on EMDR, each app incorporates

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a number of tracks comprising guided and unguided bilateral stimulation (BLS), ego-strengthening affirmations, emotional integration exercises and targeted suggestions for symptom management. The inclusion of BLS and the coupling of that with cognitive and sensory stimulus (accessing positive memories, positive affirmations, music) and sensory monitoring forms the rational for defining these apps as based on EMDR.

This study seeks to investigate whether a series of apps which separately target four of the main symptoms associated with PTSD, based on EMDR, can help PTSD sufferers experience reduced symptoms and whether these reductions can be enduring.

The target audience of this research are PTSD sufferers in the community who are not be receiving out-patient treatment. This study will help answer the question of whether a targeted series of mobile apps a) help PTSD sufferers achieve reduced levels of symptoms and b) how enduring any reductions achieved are.

STUDY OBJECTIVES

HYPOTHESIS
That mobile apps based on EMDR can help reduce symptoms of anxiety and MUS in persons suffering from PTSD symptoms.

STUDY AIMS
This study aims to evaluate whether a series of apps, which target four of the key effects of PTSD, can reduce overall PTSD symptoms. Secondary outcomes will be to evaluate any changes in MUS following use of these apps. An additional aim is to evaluate any potential risks associated with self-management of symptoms using apps in this population.

OUTCOME MEASURES

The primary outcome being measured is PTSD symptoms, as measured by the PCL-5 (Blevins et al, 2015). The PCL-5 is a 20-item questionnaire, corresponding to the *DSM-5* symptom criteria for PTSD. With the exception of MUS the PCL-5 captures DSM-5 levels of PTSD symptomatology such as anxiety, sleep disturbance, (Cluster E) and general well-being (cluster D).

Secondary outcomes are MUS as measured by the PHQ-15 (Kocalevent et al, 2013). High levels of somatization have been found in PTSD sufferers (Wright et al, 2021). The PHQ-15 is a self-report questionnaire comprising 15 items. Each of the fifteen items on the PHQ-15 is rated on a 3-point Likert scale ranging from 'not bothered at all' to 'bothered a lot' (Kroenke et al, 2002). The total score is continuous and can range from 0 to 30, it can also provide a categorical measure of somatic symptom severity. A total score of 0–4 indicates minimal somatic symptom severity, 5–9 indicates low, 10–14 indicates medium, and 15–30 indicates high symptom severity. The PHQ-15 is well validated and has a sensitivity of 78% and a specificity of 71% for a DSM-IV diagnosis of somatoform disorder in a primary care setting using a cutoff of 3 or more severe somatic symptoms over the preceding 4 weeks (van Ravesteijn et al, 2009). Furthermore, internal consistency is good (Cronbach's alpha = 0.80).

cales; distress, anxiety, depression and somatization. The items are worded as questions similar to those that can be asked in everyday primary care practice. The reference period is "the past

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week". For example, item 26 reads "During the past week, did you feel easily irritated?". The 4DSQ does not contain any positive affect questions, nor any other "reversed" worded questions. The response categories are also worded as normal answers to clinical questions: "no", "sometimes", "regularly", "often", "very often or constantly". In order to arrive at scale scores, the responses are scored as 0 for "no", 1 for "sometimes" and 2 for the other response categories, and the item scores are summated to scale scores. The Distress scale contains 16 items and has a score range of 0–32, the Depression scale contains 6 items and has a range of 0–12, the Anxiety scale contains 12 items and has a range of 0–24, and the Somatization scale contains 16 items and has a range of 0–32

STUDY DESIGN

STUDY TYPE & DESIGN & SCHEDULE

This controlled, two-arm, randomized (1:1) trial will evaluate the efficacy of the healing effects of PTSD series to reduce PTSD symptoms in a community sample of trauma survivors with PTSD (adults aged 18 or above). After completing an eligibility online screen, individuals who score 35 or above on the PTSD Checklist (PCL-5) and consent will complete a baseline assessment and then be randomized to group 1: using a series of PTSD app condition, or group B: a waitlist control group. Each individual will be reassessed at post-intervention (1 month) and a follow-up (3 months later, or 6 months after completing baseline) by completing the same set of online assessments to measure PTSD symptoms across all stages. Self-reported PTSD symptoms in the form of non-identifiable data will be collected via online questionnaires provided to participants. All data collection, treatment and assessment procedures will be conducted through online questionnaires, managed and stored electronically for a period of 5 years post study closure (see section 11). The investigators predict that those using the healing effects of PTSD app series will demonstrate improved symptom management and a significant and sustained reduction in PTSD symptoms, compared to the waitlist control group.

STUDY TABLE

	Assessment/ Procedure	Screening	Post-intervention (3 months)	Follow-up (6 months)	Follow-up (12 months)
Procedures	**Informed Consent**	x			
	Demographic Information	x			
	PCL-C questionnaire	x	x	x	x
	4DSQ	x	x	x	x

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STANDARD CARE AND ADDITIONAL TO STANDARD CARE PROCEDURES

Standard Care Procedures			Additional To Standard Care		
Procedure	**Time/Visit**	**Dosage/ Volume**	**Procedure**	**Time/Visit**	**Dosage/ Volume**
Anxiety Release App	Daily	-	-	-	-
Overcomingpain App	Daily	-			
Sleep Restore App	Daily	-			
Calm and Confident App	Daily	-			

RANDOMISATION

This research will employ the Study Randomiser software (www.studyrandomizer.com) wherein both the researcher and study coordinator can create, and utilise, one account to send out weblinks to the respective study participants. Both the researcher and study coordinator would update the online questionnaires into the software by filling out a form, with details regarding the research. As such, the aforementioned software will automatically randomise the participants into the distinct categories, whilst maintaining their privacy by allocating each candidate a numerical participant ID which prevents selection bias and insures against accidental bias- during the analysis phase of this research. Nevertheless, the researchers can still access data regarding the number of participants enrolled in the study through the "dashboard" feature, and the groups they are allocated to.

STUDY METHODOLOGY

The design of the present study is a parallel-group randomized controlled trial comprised of: (1) a 4-week mobile app treatment arm and (2) a 4-week control group (no treatment) arm. Participants will be randomly allocated by the computer program (see section 6.3) to ensure blindness of the investigators. Half of the participants to be allocated to the treatment group and the other half to the control group with no provision of the treatment apps. The proposed intervention (4 mobile apps) is available on Apple app store for iPhone devices and Google Play Services for android devices. Users will be directed to use contents of all apps at least once a day, for example before bed and whilst they sleep.

Screening will be conducted after consent as the process may involve the collection of sensitive data such as information about being on worker's compensation and/or having sleep apnea and the use of psychotropic medication.

The screening process will include the materials used in baseline, during and follow-up assessment on participants' PTSD symptoms and sleep quality (see section "assessment

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measures" below), delivered in the format of online questionnaires. Those who meet criteria will proceed to be invited to participate in the experiment trial. They will be given one month to decide. Self-report measures of sleep quality, sleep behaviours, PTSD symptoms and medication use will be obtained in all participants at baseline, immediate post-intervention, 3 months post-intervention and 6 months post-intervention. Participants allocated to the waitlist control group will be provided the full version of sleep restore app and treatment materials upon completion of the study. All data collection, treatment and assessment procedures will be conducted through online surveys and managed electronically.

Assessment measures

All assessment material will be provided in the form of online questionnaires that require an internet browser which can be used/found on any device. These questionnaires aim to assess PTSD symptoms and stress factors that are affecting sleep and whether or not the user might be suffering from a medical sleep disorder such as sleep apnea or restless leg syndrome. Subjects will be advised to seek professional help through email if they report positive in the above conditions.

PTSD Checklist

The PCL-5 is a validated self-report scale for the assessment of PTSD symptoms, with a total of 20 items on a 5-point scale correspond to DSM-5 symptoms of PTSD. Checklist scores range from 0 to 80, with a score of 31-33 being the cut-off indicative of probable a diagnosis of PTSD and higher scores indicating a higher severity of PTSD symptoms. (Blevins et al, 2015, Bovins et al, 2015, Wortman et al, 2016).

Four-Dimensional Symptom Questionnaire (4DSQ)

The 4DSQ is a self-report questionnaire to assess distress, depression, anxiety and somatization. The questionnaire aims to differentiate between normal distress and psychiatric disorders.

Treatment conditions

Anxiety Release App

The Anxiety Release App incorporates brain training exercises, guided anxiety management sessions and bilateral stimulation material in audio and video formats. The purpose is to stimulate the brain with bilateral stimulation (alternating audio and/or visual stimuli), which captures attention processes and diverts emotional resources. It is predicted that the exercises would help release anxiety using sensory and auditory bilateral stimulation.

Overcomingpain App

The Overcomingpain app is designed to decrease medically unexplained pain associated with trauma. This app comprises 20 sessions incorporating a mix of BLS, pain-relieving imagery and suggestions and behavioral exercises divided into three playlists targeting mental and emotional dimensions of chronic pain;

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1. Mental Healing strategies,

2. Sensory Healing strategies and

3. Stress Management. created by the author before the era or mobile apps.

This app is based on a CD called 'Pain Control based on EMDR', created by the author before the era of mobile apps.

Sleep Restore App

The Sleep Restore app was developed to specifically address the effects of traumatic stress which lead to insomnia, namely: trouble falling asleep, night-waking, hypervigilance, worry, nightmares and feelings of lack of safety. Based on the response collected from each participant in the online assessment, the Sleep Restore app will automatically generate a unique meditation playlist from 18 sessions of pre-installed guided EMDR-based treatment materials including: BLS (natural sounds, music and story reading), individually designed to address the different effects of stress. Materials will be available immediately after completion of baseline assessments. Participants will be instructed to utilize these materials whenever they experience trouble falling asleep. They will also be encouraged to revisit the app more often in order to unlock extra treatment materials.

Calm and Confident App

The Calm and Confident app incorporates guided meditations. BLS and ego-enhancing suggestions to stimulate decreased tension, relaxation and increased confidence. In addition to decreasing stress, this app aims to facilitate a relaxed state of well-being in the listener. The 10 tracks include session targeting stress and anxiety relief, emotional integration and self-worth. This app is based on a CD of the same name, created by the author before the era or mobile apps.

Waitlist control condition

The waitlist control condition will consist of only monitoring PTSD symptoms and anxiety, MUS, sleep and self-confidence using the assessment measures during assessment periods at baseline, immediate post-intervention, 3- and 6-months post-study. Participants will not be provided any treatment materials or feedback until the end of study.

Treatment condition summary

	Sleep Restore (bilateral stimulation)	Waitlist control
Treatment content	Anxiety Release App Overcomingpain App Sleep Restore App Calm and Confident App	N/A [advised that full treatment would be provided upon completion]
Duration	(Minimum of) 8 weeks	N/A
Delivery	Online mobile app	N/A

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context		
Assessment content	PTSD checklist + Sleep questionnaire at: - Baseline - Follow-up - 3 months post-treatment - 6 months post-treatment	PTSD checklist + Sleep questionnaire at: - Baseline - Follow-up - 3 months post-treatment - 6 months post-treatment

STUDY POPULATION

RECRUITMENT PROCEDURE

Study participants will be recruited through internet postings (i.e. Facebook, email call-outs to trauma therapists) and promotion online on a voluntary participation basis. Context of the study, inclusion criteria and exclusion criteria will be provided in the recruitment material for reference. Study participants (both treatment and control group) will include individuals who have been diagnosed with PTSD and complain of symptoms of PTSD such as anxiety, MUS and insomnia based on responses to the screening questionnaires.

INCLUSION CRITERIA

Study participants will be recruited through online postings and promotion to the general public within Australia and internationally. Study participants will include individuals who; (1) have clinical levels of symptoms of PTSD at the time of self-report screening based on responses to the PCL-5 checklist and/or; (2) Experience of sleeping problems (e.g. trouble falling asleep, night-waking, lack of restorative sleep) as evaluated the Sleep condition indicator (SCI) criteria for Insomnia; (3) English-speaking male or female PTSD sufferers above the age of 18. The study is open to people of all races and gender.

EXCLUSION CRITERIA

Exclusion criteria will be: (1) Lack of access to mobile apps; (2) on-going self-harm/suidical or homidical ideation, (3) diagnosis of psychotic or bipolar disorder (4) non-English speakers; (5) diagnosis of dissociative disorder (6) organic mental disorder (7) substance abuse and (8) significant cognitive impairment (eg; severe intellectual disability, dementia). Diagnosis of sleep apnea will be recorded into medical condition history but the subject will not be excluded from the trial. Participants involved in worker-compensation claims or who are subject to concurrent stressful events will not be excluded, but cases will be noted as a variable given the stressful nature of the circumstance. Children and young individuals (under 18years of age) will be excluded from this research as they do not possess legal authority to give consent to the study, and they most likely require very different treatment approaches compared to emergency workers, which are beyond the scope of this study.

CONSENT

Participation is entirely voluntary. Prior to entering into the study, prospective participants

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(both patients and therapists) will be informed of their ability to withdraw at any given time, without a reason. The process will be conducted through an online consent form delivered through email, once participants sign up for the study. The online form will include an information sheet regarding the content of the experiment and the participant's involvement in the study. Respondents will have to click 'agree', on the consent page followed by their electronic signature in full name to imply consent, in order to participate. If they click 'decline' then they will be thanked for their time and subsequently redirected out of the online form. The Information Sheet will also explain that withdrawal from the study will prevent them from accessing the study material, but that if they withdraw following commencement of the study, they will be allowed to retain the treatment resources (Healing Trauma app series).

PARTICIPANT SAFETY AND WITHDRAWAL

RISK MANAGEMENT AND SAFETY

We do not foresee any specific risks from participation in this study. All participants will be advised to contact the primary investigator and cease use of the apps in the unlikely event they experience any adverse responses. The primary investigator will provide immediate one-to-one assistance and on-going referral if necessary.

HANDLING OF WITHDRAWALS

Participants will be allowed to withdraw from the study at any time, without a reason. They will be informed of their ability to withdraw prior to entry into the study. Data collected from withdrawn participants will not be included nor used as valid study data, but will be labelled withdrawn and stored and destroyed in accordance to data security and handling strategy (see section 11).

REPLACEMENTS

Withdrawn participants will be replaced in the study via the same recruitment process as described in section 7.1.

STATISTICAL METHODS

SAMPLE SIZE ESTIMATION & JUSTIFICATION

Data analysis will be carried out under 80% power to detect a medium effect size at $P = .05$ using SPSS statistical software. These criteria implied a proposed sample size of 80, randomised half to the treatment group and the other half to the waitlist control group.

POWER CALCULATIONS

See section 9.1

STATISTICAL METHODS TO BE UNDERTAKEN

All tests will be run using 2-sided tests of significance, with $P < 0.05$ considered statistical significance. Repeated-measures ANOVA will be carried out on assessment measures collected at baseline, immediate post-treatment, 3- and 6-months post-treatment for both conditions.

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Analysis of covariance (to control for baseline score) will be conducted to test differences at baseline and post-treatment. Paired t-tests will be conducted for the treatment group to compare baseline results to post-treatment data.

STORAGE OF BLOOD AND TISSUE SAMPLES

DETAILS OF WHERE SAMPLES WILL BE STORED, AND THE TYPE OF CONSENT FOR FUTURE USE OF SAMPLES

No blood or tissue samples from participants will be collected nor used for the purpose of this study.

DATA SECURITY & HANDLING

DETAILS OF WHERE RECORDS WILL BE KEPT & HOW LONG WILL THEY BE STORED

All data collection, treatment and assessment procedures will be conducted through online questionnaires, which will be managed, and stored, electronically for a period of 5 years post study closure. Participants' responses on online questionnaires will be numerically coded and analysed as group data. Furthermore, the software *Study Randomiser* is a secured application which stores all data in a protected database that is backed up every day, thus ensuring that no information regarding the study nor the participants are leaked. Access to the data will be provided to: Primary Investigator (Mark Grant) - to monitor process of the study and for analysis purposes; The study co-ordinator (Richard Lau) - monitoring of participation status and administrative purposes such as mail out of survey and data entry.

CONFIDENTIALITY AND SECURITY

All electronic data will be stored on an online database (Google Drive) secured by user names and passwords accessible only to the primary investigator and co-ordinator (named above) to enable secure and confidential collection, storage and maintenance of the research data for this study. The database is legally owned by Google and located on an online server, registered independently for the research. Participants will not have access to any data until the dissemination of project outcomes. They will be provided their own data together with the disseminated report. This process ensures confidentiality and secure storage of all the research data. Study data will be destroyed by electronically deleting all relevant files on the online database (described above) containing participant information and activities. All participants (including control group) will continue to have access to the trial intervention (the respective apps) for an unlimited time for zero costs as the apps are already developed.

ANCILLARY DATA

Data such as videos, photographs and images (if any collected) will be stored on the online database (Google Drive) mentioned above for a period of 5 years post study closure secured by

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user names and passwords accessible only to the primary investigator and co-ordinator (named above) to enable secure and confidential collection, storage and maintenance of the research data for this study.

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APPENDIX

List of Attachments included:

Document Name	Version Number	Date (e.g. 18 January 2012)
PCL-C checklist – Google form	1	13 July 2021
4DSQ – online form	1	13 July 2021

1. PCL-C CHECKLIST

PTSD checklist (PCL-C)

Below is a list of problems and complaints that individuals may have in response to stressful life experiences. Please read each one carefully, check the corresponding box to indicate how much you have been bothered by that problem in the last month.
*Required

1. User ID *

2. 1. Repeated, disturbing memories, thoughts, or images of a stressful experience from the past. *
   Mark only one oval.
   1 2 3 4 5
   Not at all ◯ ◯ ◯ ◯ ◯ Extremely

3. 2. Repeated, disturbing dreams of a stressful experience from the past. *
   Mark only one oval.
   1 2 3 4 5
   Not at all ◯ ◯ ◯ ◯ ◯ Extremely

4. 3. Suddenly acting or feeling as if a stressful experience were happening again (as you were reliving it) *
   Mark only one oval.
   1 2 3 4 5
   Not at all ◯ ◯ ◯ ◯ ◯ Extremely

5. 4. Feeling very upset when something reminded you of a stressful experience from the past. *
   Mark only one oval.
   1 2 3 4 5
   Not at all ◯ ◯ ◯ ◯ ◯ Extremely

6. 5. Having physical reactions (e.g. heart pounding, trouble breathing, or sweating) when something reminded you of a stressful experience from the past. *
   Mark only one oval.
   1 2 3 4 5
   Not at all ◯ ◯ ◯ ◯ ◯ Extremely

7. 6. Avoid thinking about or talking about a stressful experience from the past or avoid having feelings related to it. *
   Mark only one oval.
   1 2 3 4 5
   Not at all ◯ ◯ ◯ ◯ ◯ Extremely

8. 7. Avoid activities or situations because they remind you of a stressful experience from the past. *
   Mark only one oval.
   1 2 3 4 5
   Not at all ◯ ◯ ◯ ◯ ◯ Extremely

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9. 8. Trouble remembering important parts of a stressful experience from the past. *

Mark only one oval.

	1	2	3	4	5	
Not at all	◯	◯	◯	◯	◯	Extremely

10. 9. Loss of interest in things that you used to enjoy. *

Mark only one oval.

	1	2	3	4	5	
Not at all	◯	◯	◯	◯	◯	Extremely

11. 10. Feeling distant or cut off from other people *

Mark only one oval.

	1	2	3	4	5	
Not at all	◯	◯	◯	◯	◯	Extremely

12. 11. Feeling emotionally numb or being unable to have loving feelings for those close to you *

Mark only one oval.

	1	2	3	4	5	
Not at all	◯	◯	◯	◯	◯	Extremely

17. 16. Being "super alert" or watchful on guard. *

Mark only one oval.

	1	2	3	4	5	
Not at all	◯	◯	◯	◯	◯	Extremely

18. 17. Feeling jumpy or easily startled. *

Mark only one oval.

	1	2	3	4	5	
Not at all	◯	◯	◯	◯	◯	Extremely

13. 12. Feeling as if your future will somehow be cut short. *

Mark only one oval.

	1	2	3	4	5	
Not at all	◯	◯	◯	◯	◯	Extremely

14. 13. Trouble falling or staying asleep *

Mark only one oval.

	1	2	3	4	5	
Not at all	◯	◯	◯	◯	◯	Extremely

15. 14. Feeling irritable or having angry outbursts. *

Mark only one oval.

	1	2	3	4	5	
Not at all	◯	◯	◯	◯	◯	Extremely

16. 15. Having difficulty concentrating. *

Mark only one oval.

	1	2	3	4	5	
Not at all	◯	◯	◯	◯	◯	Extremely

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2. 4DSQ

	Yes	No
During the past week, did you suffer from:		
1. dizziness or feeling light-headed?		
2. painful muscles?		
3. fainting?		
4. neck pain?		
5. back pain?		
6. excessive perspiration?		
7. palpitations?		
8. headache?		
9. a bloated feeling in the abdomen?		
10. blurred vision or spots in front of your eyes?		
11. shortness of breath?		
12. nausea or an upset stomach?		
13. pain in the abdomen or stomach area?		
14. tingling in the fingers?		
15. pressure or a tight feeling in the chest?		
16. pain in the chest?		
17. feeling down or depressed?		
18. sudden shock for no reason?		
19. worry?		
20. disturbed sleep?		
21. indefinable feelings of fear?		
22. listlessness?		
23. trembling when with other people?		
24. anxiety or panic attacks?		
During the past week, did you feel:		
25. tense?		
26. easily irritated?		
27. frightened?		
28. that everything is meaningless?		
29. that you just can't do anything anymore?		
30. that life is not worth while?		
31. that you can no longer take any interest in the people and things around you?		
32. that you can't cope anymore?		
33. that you would be better off if you were dead?		
34. that you can't enjoy anything anymore?		
35. that there is no escape from your situation?		
36. that you can't face it anymore?		
During the past week, did you:		
37. no longer feel like doing anything?		
38. have difficulty in thinking clearly?		
39. have difficulty in getting to sleep?		
40. have any fear of going out of the house alone?		
During the past week:		
41. did you easily become emotional?		
42. were you afraid of anything when there was really no need for you to be afraid? (for instance animals, heights, small rooms)		
43. were you afraid to travel on busses, trains or trams?		
44. were you afraid of becoming embarrassed when with other people?		
45. did you ever feel as if you were being threatened by unknown danger?		
46. did you ever think "If only I was dead"?		
47. did you ever have fleeting images of any upsetting event(s) that you have experienced?		
48. did you ever have to do your best to put aside thoughts about any upsetting event(s)?		
49. did you have to avoid certain places because they frightened you?		
50. did you have to repeat some actions a number of times before you could do something else?		

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