

BMJ Open Design, development and randomised controlled trial protocol of a smartphone-delivered version of 'SOLAR' for emergency service workers to manage stress and trauma

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Introduction Emergency service workers are routinely exposed to stress and trauma, and there is a need to address mental health symptoms early to prevent chronic impairment and/or psychiatric disorder. Digital health innovations mean that face-to-face psychosocial interventions can now be delivered remotely, which is particularly appealing to populations who have strong preferences for digital delivery, such as emergency service workers. This two phase study aims to first adapt the Skills for Life Adjustment and Resilience (SOLAR) programme into a smartphone application ('app'), and then evaluate the effectiveness of this new app.

Methods and analyses First, focus groups and codesign activities with mental health professionals and emergency service workers will be conducted to develop and test the prototype smartphone version of SOLAR (ie, SOLAR-m). Second, a multicentre randomised controlled trial will investigate the effectiveness of the new app, compared with an active control app, in reducing symptoms of anxiety and depression (primary outcome), as well as other indicators of mental health and work performance. Firefighters from one of the largest urban fire and rescue services in Australia who are currently experiencing distress will be invited to participate. After screening and baseline assessment, 240 will be randomised to receive either SOLAR-m or the control app for 5 weeks, with measurements pre, post and 3-month follow-up. Analyses will be conducted within an intention-to-treat framework using mixed modelling.

Ethics and dissemination The current trial has received ethics approval from the University of Melbourne Human Research Ethics Committee (2021-20632-18826-5). Study results will be disseminated through peer-reviewed journals and conferences, with a focus on how to expand the new app to other trauma-affected populations if proven effective.

Trial registration number ANZCTR12621001141831.

INTRODUCTION

In recent years, attention has turned to how to best meet the psychosocial needs of individuals exposed to traumatic or stressful events

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This large trial will be the first to evaluate the efficacy of a smartphone delivered version of a brief, scalable, evidence-based, trauma-informed intervention.
- ⇒ The trial will target firefighters in one of the world's largest urban fire service with preferences for digitally delivered mental health resources.
- ⇒ The study will include codesign to ensure the newly developed smartphone version of the intervention is highly acceptable and feasible to the target population.
- ⇒ The study will include telephone facilitation to support uptake and usage of the smartphone application.
- ⇒ The trial design is limited by a 3-month follow-up period.

who are experiencing persistent adjustment and subclinical mental health problems, but do not meet diagnostic criteria for a psychiatric disorder. These individuals often have significant levels of distress and impairment, despite not meeting full threshold criteria for psychiatric disorders, and are at risk of development of disorder if recovery is not achieved.¹ While work has focused on developing preventative strategies for this population,² a gap remains at the subclinical level for brief, scalable, evidence-based, trauma-informed interventions. The Skills for Life Adjustment and Resilience (SOLAR) programme was developed by an international collaboration of experts in trauma and postdisaster mental health. An iterative expert consensus process was undertaken to address this gap in treatment provision.³ Pilot testing of the SOLAR programme in natural disaster survivors experiencing stress and trauma showed it is feasible, acceptable, safe

and beneficial in reducing psychological symptoms and impairment.^{3 4} Further work involving a cultural adaptation of SOLAR for individuals residing in the South Pacific affected by natural disasters indicates that the programme is flexible and adaptable to a wider range of populations experiencing stress and trauma.⁵

Individuals employed in high-risk organisations, defined as those in which trauma exposure is routinely experienced as part of the job role, such as ambulance personnel, firefighters, police, military personnel and healthcare workers in emergency settings, are at greater risk of psychosocial difficulties. Research indicates that individuals in high-risk organisations have higher rates of psychological distress, post-traumatic stress disorder (PTSD), depression and anxiety compared with the general community.⁶ As a result, workplace mental health and well-being strategies for these high-risk organisations are encouraged to consider mental health across a continuum and develop strategies that address mental health and well-being at the subthreshold level.⁷

Innovations in digital health have led to a revolution in psychiatry and delivery of mental healthcare. Previous research indicates that smartphone-delivered mental healthcare is feasible, acceptable and effective in populations characterised by high trauma exposure.² While there is a plethora of smartphone apps to manage aspects of mental health, many lack an evidence base. There is a recognised gap for digital health solutions that deliver evidence-based, trauma-informed approaches specifically designed to manage the emotional consequences of trauma exposure.⁸ The aim of this study is to develop the first smartphone version of the SOLAR programme, which has been culturally adapted to meet the needs of emergency service workers who are exposed to high levels of stress and trauma, and then test whether it is effective in reducing distress symptoms, relative to a comparator app.

METHODS

Patient and public involvement

This study will be conducted in two phases. First, we will adapt the face-to-face psychosocial programme SOLAR for a smartphone application. Second, we will test this application in a randomised controlled trial (RCT).

Phase 1: conversion of the programme

This phase of this project will adapt the psychosocial intervention SOLAR into a smartphone version for emergency service workers. This adaptation process will involve the following:

1. Review the literature for current approaches to digital health and mental health in emergency service workers. Eligible studies will include observational and experimental designs that designed and evaluated digital mental health approaches in emergency service workers and other high-risk occupations exposed to stress and trauma (ie, healthcare workers and military and

veteran populations), and data around preferred content delivery methods, session length usage and types of interactivity will be extracted.

2. Collaborative design and content mapping by SOLAR content experts, web designers and app developers.
3. Three focus groups consisting of 4–8 mental health experts and emergency service workers to collect design and content data, which allows us to incorporate end-user feedback on the initial design concept and an app wireframe prototype.
4. End-user pilot testing of the app (beta version) and finalisation with 5–10 firefighters.

The goal of this phase of the project is to understand the ways in which SOLAR, traditionally a programme delivered face to face by trained, non-specialist providers (ie, 'coaches'), can be translated into a self-guided digital health programme, as well adapted to meet the specific needs and preferences of emergency service workers.

Phase 2: RCT

Phase 2 will be a two-arm, parallel group, 1:1, triple-blind, superiority RCT evaluating the effectiveness of SOLAR-m in reducing symptoms of distress in emergency service workers. The RCT will be conducted online, with recruitment occurring in Australian fire stations. Assessments will occur at baseline (time 1; T1), 7–9 weeks after baseline and intervention (time 2; T2) and 3-month follow-up (time 3; T3). The RCT will open for recruitment in July 2022, and recruit for 18 months.

Eligibility

Eligibility criteria are: having an Apple-operating or Android-operating smartphone, being currently employed by the partner fire and rescue organisation, being aged over 18 years, self-identifying as currently experiencing distress or having difficulty managing strong emotions, and scoring >7 on the Kessler Psychological Distress Scale (K6).⁹ Participants who have significant levels of distress (ie, score ≥ 19 on the K6) will be encouraged to seek a more intensive form of mental health treatment through usual referral pathways. However, if a participant chooses not to seek alternative treatment, they can still participate in the study.

Interventions

SOLAR-m

For the purpose of blinding, all participants will download the same app, but the content visible to them will vary according to the group to which they are randomised. Participants in the SOLAR-m group will receive access to the SOLAR-m version of the app. On first entering the app, they will provide information for app personalisation (ie, enter a preferred name or nickname, set preferred frequency and timing of notifications), then complete the initial introductory module. After this, they can work through the remaining seven modules (see [table 1](#)) at their own pace. These are delivered using animations, videos, interactive activities, skill rehearsal scheduling,

Table 1 Components of each module in SOLAR-m

Module 1	Welcome to SOLAR introduces participants to the programme
Module 2	Healthy body, healthy mind explains the interdependency of physical and mental health, and provides tips for improved nutrition, alcohol use, sleep and exercise.
Module 3	Managing strong emotions offers behavioural and cognitive strategies for managing stress and other overwhelming feelings, including understanding your symptoms of stress, and mindfulness and relaxation activities.
Module 4	Living the life you value helps participants to identify the life areas and activities they value and build a plan to incorporate these activities into their daily life.
Module 5	Managing healthy relationships explains how stress can impact relationships, presents strategies for effective communication and dealing with conflict, and provides ways to make time for relationships in times of stress.
Module 6	Getting control over your thoughts provides participants with skills to manage rumination/worry, including mindfulness, short-term distraction, putting worries aside until a prescribed time, effective problem solving and, when appropriate, accepting that a situation cannot be changed.
Module 7	Coming to terms with difficult experiences is an expressive writing activity that focuses on processing distressing events from the past or present.
Module 8	Planning for the future summarises the programme and prompts participants to create a personalised plan for maintaining resilience in the future that includes those skills and activities they have found most useful during the SOLAR programme.

SOLAR, Skills fOr Life Adjustment and Resilience.

progress monitoring and notifications. The app is designed to give users the impression of being guided through the app by their selected chosen virtual ‘coach’. Users can choose from one of two highly credentialed mental health professionals whose identity and experience is introduced in the initial module. Prescribed audio that is embedded on each screen is relayed in the voice of the user’s selected virtual coach.

The SOLAR programme comprises therapeutic elements drawn from evidence-based treatments for individuals experiencing trauma-related mental health problems. These elements include psychoeducation about healthy living, information about maintaining healthy relationships and managing conflict in relationships, values-based behavioural activation, arousal and affective management, expressive writing to emotionally process stress or traumatic experiences, and skills associated with managing worry and rumination (see O’Donnell for a more in-depth description of targeted mechanisms of action).³ Most modules focus on behavioural skill development alongside psychoeducation, with one module focusing primarily on cognitive strategies.

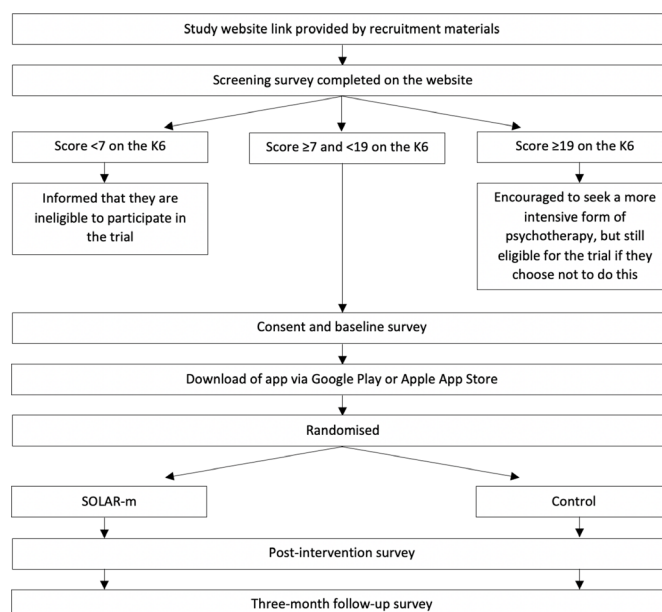
Control app

Participants who receive the control version of the app will receive access to a custom-designed app for emergency service workers. The app will provide daily mood monitoring; psychoeducation about the benefits of mood monitoring, mental health and high-risk occupations, and common mental health problems; and crisis referral support. Participants will be prompted to record their mood between one to three times per day for the 5-week period. Participants are able to review their mood over the past month based on the data they have entered into the app. Mood monitoring is a common component of digital health interventions and has been shown to be effective in improving distress and symptoms of anxiety and depression.¹⁰ This active comparator has been chosen to ensure that estimates of the treatment effect of the SOLAR intervention are not overestimated, as would be the case if a waitlist comparator were used.

Previous research indicates that an external facilitation model maximises engagement with mental health apps.¹¹ Thus both groups will receive optional access to weekly telephone contact with a SOLAR programme facilitator, for the 5 weeks of the app programme. The facilitator will offer support and assistance with the participant’s progression through the programme. Telephone facilitators will be paraprofessionals who have some formal training in mental health (eg, postgraduate psychology students). They will be required to undergo structured training, use a facilitator guide and be supervised by a psychologist in weekly group supervision sessions throughout the study.

Participant timeline

The participant timeline is shown in figure 1. Potential participants will be assessed for eligibility through the study website, which will screen for distress (≥ 7 on the K6). Participants with low levels of distress (< 7 on the K6) who do not meet the criteria for inclusion, will be informed


Figure 1 Flow chart showing the participant timeline.

they are ineligible via the study website. Eligible participants will provide written informed consent, complete the baseline survey, and then be given instructions on how to download the study app. Once downloaded, they will be randomised to receive either the SOLAR-m or the control version of the study app. Participants will be given access to the study app for 5 weeks, and will then be contacted to complete the postintervention survey. Participants can continue to use the version of the app they were allocated to after this time and will be evaluated again at a 3-month follow-up assessment.

Sample size

Sample size was determined based on detecting a small-to-moderate effect size in the intervention group at post-treatment. This is based on prior research using SOLAR, and previous evidence that smartphone-delivered interventions tend to have smaller effective sizes relative to traditional interventions.¹⁰ In order to detect a 0.4 difference in effect size with 0.80 power and an alpha of 0.05, a sample size of 200 will be required. To account for attrition (20%), the sample size was inflated to 240.

Recruitment

A variety of recruitment strategies will be used to engage potential participants.

1. The study will be advertised to emergency service personnel who are employees of the partner organisation at local information seminars.
2. Emails will be sent from the emergency service worker organisation notifying employees of the trial.
3. Advertisements will be placed throughout the targeted locations, social media (Facebook, website, Twitter) and in newsletters.

Allocation

Participants will be randomly assigned to one of two groups using in-built app software, programmed to use a simple randomisation sequence that allocates participants in a 1:1 ratio. Trial participants, outcome assessors, and trial statisticians will be blinded to participants' assignment to interventions. There are no circumstances in which unblinding would be necessary. To minimise lost to follow-up and missing data, facilitators will use text messages and email to prompt participants to complete their follow-up assessments. The follow-up assessments are intentionally brief and will be disseminated through text messages to facilitate access and ensure ease of completion.

Safety protocol

Safety of participants will be supported in two ways. First, both versions of the app contain crisis support details that can be used at any time. Second, participants who report distress to a telephone facilitator will be directed by that facilitator to further support as appropriate (eg, a general practitioner or local emergency department). A report of distress will not be considered ground for immediate modification or cessation of participation in the trial, but

participants are able to choose to withdraw from the study at any time. Study staff will continually monitor for and record adverse events when or if they arise.

Outcomes

The primary outcome is change in mean depression and anxiety symptoms from preintervention (T1) to postintervention (T2). Secondary mental health and well-being outcomes include: change in mean scores of PTSD, work-family conflict (WFC), work health and performance from preintervention (T1) to postintervention (T2 and T3). Other outcomes include: treatment expectations (at T1), and treatment adherence (T2).

Distress symptoms will be measured using the Hospital Anxiety and Depression Scale (HADS).¹² The HADS is a 14-item transdiagnostic measure that assesses a range of anxiety and depressive symptoms. Items are rated on a response-scale with four alternatives ranging between 0 and 3. The total score range is between 0 and 42.¹³

Post-traumatic stress symptom severity will be measured using the PTSD Checklist for the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (PCL-5),¹⁴ a psychometrically sound self-report rating scale for assessing the 20 DSM-5 symptoms of PTSD.¹⁵ Respondents rate each item from 0 ('not at all') to 4 ('extremely') to indicate the degree to which they have been bothered by that particular symptom. A total score is computed by adding the 20 items.

WFC will be assessed using the WFC scale, which contains two three-item abbreviated measures based on an earlier multidimensional measure of WFC.¹⁶ This abbreviated version is internally consistent, has exhibited good test-retest reliability, and was systematically related to measures of role stressors, work-family balance and well-being outcomes.¹⁷ Respondents rate each item from 1 ('strongly disagree') to 5 ('strongly agree'). Items 1-3 are summed to determine the WFC scale score. Items 4-6 are summed to determine the family-to-work conflict subscale score. The range for each subscale is 3-15, and high scores indicate higher levels of conflict.

Measures of work performance will be obtained using the Health and Work Performance Questionnaire, a self-report survey designed to estimate the workplace costs of health problems as measured by reduced job performance, sickness absence and work-related accidents/injuries.¹⁸ Work performance will be measured using three items (performance items A10, A11, A12) and two additional items pertaining to past month sickness absence (days absent, days absent for mental health reasons) and past 6 months week-long sickness absence (weeks absent, weeks absent for mental health reasons).

Treatment adherence will be measured using app metadata, including rates of completion of the app modules and other data usage metrics.

Statistical analyses

All data will be analysed using Mplus. The level of significance for all statistical tests will be set at $\alpha=0.05$.

Demographic differences and baseline mental health symptoms will be compared between groups to check for differences. Data will be analysed on an intention-to-treat basis. Missing data will be handled using a range of suitable techniques including full information likelihood, multiple imputation and, where power and missing data patterns afford, listwise deletion.

Data collection and management

Screening for eligibility will occur through the study website, after which eligible participants are directed to the online survey software to complete the first assessment. Text messages or emails will be used to link to subsequent assessments. A data monitoring committee is not deemed necessary for this study given that only minimal risks to participants are anticipated. Data will be held by the principal investigators and can be made available on request.

Ethics and dissemination

The University of Melbourne Human Research Ethics Committee (HREC) has approved this study (protocol number: 2021-20632-18826-5). Any changes to the protocol will be submitted to the HREC as an ethical amendment and will be updated in the ANZCTR. Informed consent to participate in the trial will be obtained electronically from all participants. This consent will be extended, such that participants will allow use of deidentified data in future research that is closely related to the aims of this study. Data will be kept confidential by deidentifying it and utilising a study ID for each participant. Identifying participant information will be password protected and stored separately from the rest of their data. The study will be run centrally from Phoenix Australia, so only Phoenix Australia researchers will have access to the file containing identifiable information. Survey data will be collected via REDCap which is managed by Phoenix Australia and stored on Phoenix Australia, University of Melbourne computers using a VPN (Virtual Private Network) and secured by password access. Meta-data and data analytics from the study app will be stored on the Cloud Firestore database, which allows data to be stored securely on the cloud in Google's Australian data centre. From there, app data will be downloaded on demand using a purpose-built admin portal that only Phoenix Australia researchers named on this application have access to. The results of this study will be disseminated for publication in peer-reviewed journals and the key findings will be presented at national and international conferences. Authorship of these publications will be determined based on contribution to study design, data collection, analysis and interpretation of data and writing of the manuscript.

DISCUSSION

This study will be the first to adapt the face-to-face, evidence-based, psychosocial intervention known as SOLAR into a smartphone app, and trial that app for

efficacy in reducing distress associated with stress and trauma exposure. The original programme leveraged non-professional Coaches, who were trained to deliver the content and support users. In order to transfer this programme to a smartphone format, through code-sign, the app version of SOLAR will continue to provide facilitation through both virtual and human telephone support. This study extends new developments in the field of digital mental health that are focused on adapting effective mental health interventions for specific populations to improve relevance and engagement.¹⁹ Previous research has established that low engagement in mental health apps may be due to poor usability and lack of user-centric design. Therefore, a key focus of this study is to collaboratively adapt the SOLAR programme using code-sign principles to meet the specific needs of emergency service workers. This approach adds to a growing body of evidence that helps guide the adaptation of existing mental health interventions and subsequent evaluation for specific populations.^{2 19 20} The findings from this study can be used for future adaptations of the SOLAR programme.

Furthermore, this study will provide evidence around delivering digital mental health interventions to high stress and trauma exposed occupational groups. Evidence shows that occupations at risk of stress and trauma, such as emergency service workers, and veteran and military populations are at greater risk of developing mental health issues, and also present with high levels of stigma around help-seeking, as well as having non-traditional working schedules.²¹ Digital mental health solutions help bridge these barriers to traditional mental healthcare.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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