



EXPLANATORY STATEMENT

Project ID: 40515

Project title: Couple HOPES Australia

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Dear Prospective Participant,

You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via couplehopesaustralia@monash.edu.

Participation in this research is voluntary. If you do not wish to take part, you do not have to.

This is a student project, which will be undertaken as part of a PhD (Clinical Psychology) in the School of Psychological Sciences, Monash University.

What is the aim and purpose of this research?

This study is a clinical trial evaluating an evidence based online intervention developed in Canada, called Couple HOPES. Couple HOPES is designed to improve PTSD symptoms and enhance relationship satisfaction. You can find out more about the intervention, here: couplehopes.med.monash.edu

First responders are at an increased risk of developing PTSD, which can significantly impact their lives and relationships. Their intimate partners or spouses can also be affected by PTSD and may need support as they navigate changes within the relationship.

Our aim is to understand whether Couple HOPES is effective at improving the health and wellbeing of first responders with symptoms of PTSD and their partners who may be experiencing caregiver burden. We are also interested in couples views regarding whether it is an acceptable approach and how it might be tailored to the Australian context.

A consumer advisory group of first responders with PTSD and partners have helped to shape this study to ensure it is relevant and tailored to the first responder community. The results obtained from this study will help us to develop more effective ways of supporting couples living with PTSD.

Why were you invited for this research?

You were invited to participate in this research because you are a current or veteran Paramedic, Firefighter or Police Officer with clinically significant symptoms of post-traumatic stress disorder (PTSD), or are a partner of this person.

To participate, you will need access to high speed internet, be able to complete the modules together as a couple, and be willing to have coaching sessions video recorded. This study is not appropriate for couples where both partners have symptoms of PTSD, where there is current or a history of intimate partner violence within the relationship, or if one or both partners are experiencing elevated suicide risk.

Participation in this study does not require you to stop any existing medication, treatment or interventions for PTSD or their relationship. If you feel you need support, we encourage you to contact your GP or mental health professional to discuss options.

We welcome any first responders who are active, on leave or have retired from their role.

Possible benefits

This study is the first in Australia to trial an online guided self-help intervention that supports first responders and their partners to recover from PTSD and enhance their relationship satisfaction. Insights will help inform policy makers seeking new and innovative approaches to support first responders with PTSD and their partners, and guide future optimisation of the program for an Australian population.

You will have FREE access to the Couple HOPES program which may help you to decrease symptoms of PTSD and enhance relationship satisfaction. Screening questionnaires completed before you start the study may also reveal health-related information, which will be conveyed to you as soon as possible.

What does the research involve?

Participation in all aspects of the research study will take 5 months, and involve:

- Meeting with one of the research team via Zoom to discuss your eligibility
- Random allocation to receive either immediate or delayed access to Couple HOPES
- Completion of 7 Couple HOPES modules, including practice assignments between sessions and attending coaching sessions with your coach
- Completing 7 online surveys, each approximately 15-20 minutes in duration
- Participation in an online interview via Zoom (optional)

When you register your interest, you will complete a brief survey to see if you and your partner might be eligible to participate. You will then be invited to a meet with a researcher via Zoom to further discuss your eligibility. You will have an opportunity to discuss this explanatory statement with the researcher and decide whether you would like to participate. If you decide to take part in this study, you will be asked to sign a consent form, which will be kept by the researcher for the project records. It is important to note that this study involves the participation of both you and your partner. If your partner does not consent, you will not be able to participate in this study. Once you have signed the consent form, you will complete an online survey about your mental health and relationship to confirm your eligibility for this study.

Eligible couples will then be randomly assigned (by chance) together to one of 2 groups:

- **Immediate access to Couple HOPES, OR**
- **Delayed access to Couple HOPES.**

If you are allocated to receive immediate access to Couple HOPES, you will begin Couple HOPES right away, followed by a 3-month follow-up period. If you are allocated to receive delayed access to Couple HOPES, you will start Couple HOPES 2-months after beginning the study, followed by a 1-month follow-up. These two groups are visualised in the image below (see figure 1).

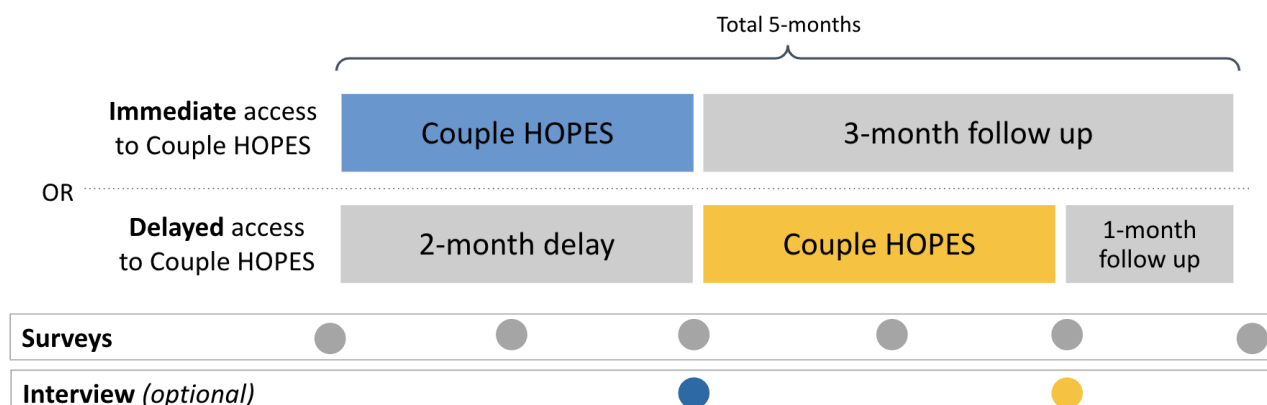


Figure 1: The stages involved in Immediate access to Couple HOPES, and Delayed access to Couple HOPES.

Couple HOPES

Couple HOPES is an evidence-based, online self-help intervention for couples, which was developed by researchers and psychologists in Canada to improve PTSD and relationship satisfaction. The program consists of 7 online learning modules each taking approximately 30 minutes to complete. Modules are completed together, and include videos with educational content, skill building exercises, and brief practice assignments. You will also be asked to continue to practice the skills learnt within the module, between sessions. Before each module, you and your partner will complete a brief survey about PTSD symptoms and relationship satisfaction. These results will be shared with your partner, and you will have the opportunity to discuss progress together.

During the program, you will also be supported by a coach who is also a provisionally registered psychologist enrolled in a postgraduate training program. They will help you make the most of the program by helping you overcome any barriers you encounter and keep an eye on how you are doing in terms of your symptoms. They will also send you reminders and prompts via email and/or text throughout the program. Your coach will meet with you both via Zoom after completing modules 1, 3, 5 and 7, with one additional meeting for you to book on a week of your choice. Coaching sessions will be video recorded via Zoom, and will be kept confidential.

You will also receive reminders to complete home practice via an external text service called SMS Broadcast.

Delayed Access and Follow-up Period

By delaying access for some couples, we can compare outcomes of those who have completed Couple HOPES with those who have not yet started it. This comparison helps us determine whether Couple HOPES has an effect on the health and wellbeing of couples.

The follow-up period allows us to understand the long-term impact of the program, and whether improvements found as a result of completing Couple HOPES are maintained over time.

During the delay and follow-up periods, we encourage you to continue your standard care practices as usual. We will be in touch once a month and ask that you complete a survey regarding your mental health and wellbeing.

Surveys, Interview and Other Data

Once you start the study, you will both be asked to complete a survey once a month, asking about PTSD, your health and wellbeing, and your relationship. There are 6 surveys in total, with the first one being completed before you are allocated to a group, and the last survey completed at the end of the follow-up period. You will also be asked to complete an additional short survey regarding your expectations of the intervention following your first coaching session.

Once you have completed Couple HOPES, you and your partner will be invited to participate in an optional interview seeking your feedback and experience of the program. The interview will take 45-75 minutes and will be held online using Zoom. The interview will be video recorded so that it can be transcribed and analysed as part of the study.

Further, every aspect of your participation has the potential to generate data. For example, completing pre-module surveys, practice assignments and even logging onto the platform itself can generate data. This is useful because this information can tell us how couples engage with the module content over time.

How much time will it take?

Participation in all aspects of the study will take approximately 11-12 hours in total over a period of 5 months.

Each Couple HOPES module and coaching session takes approximately 30 minutes to complete. You are encouraged to practice the skills you learn on a daily basis. How much time you spend on practice assignments between modules is up to you, however the more time you spend the more you will get out of the program. In addition, each online survey will take between 15-20 minutes to complete, and the online interview is expected to take 45-75 minutes of your time.

Inconvenience / discomfort

Participation in this study may involve some minor discomfort. Some survey questions relate to symptoms of PTSD, mood and other anxiety disorders, illicit drug use, domestic violence and overall health functioning, which might be uncomfortable to answer. You have the right to skip any questions or choose not to participate in an interview. If you ever feel uncomfortable or unsafe, you are encouraged to inform the study researchers or your coach. All personal information you provide will remain confidential.

Coaching sessions will be video recorded. These video files are securely stored during the study, and are only accessed by the coach, their supervisor, and the research team to ensure that the sessions have been delivered properly and you are receiving the best possible support. Some people feel uncomfortable about being recorded on video or audio. This is a normal response, and the discomfort usually goes away (or decreases) over time.

If you wish to speak to someone about any mental health issues, please contact your GP or mental health provider to discuss options. You can also contact one of the following mental health services for further information, to discuss your concerns, or obtain a referral for treatment if necessary:

Lifeline: 13 11 14

Beyond Blue: <https://www.beyondblue.org.au/get-support/get-immediate-support>

Payment

You and your partner will receive access to Couple HOPES at no charge. Individuals who participate in an interview regarding their experience of the program will receive \$50.

You can withdraw from the research at any time

Participation in this study is entirely voluntary and you are under no obligation to participate. If you choose to participate, you may withdraw from the study at any time. Please note that if you withdraw from the study early, while any data already provided cannot be destroyed, it will be kept confidential.

This study requires both you and your partner to participate. Therefore, if your partner withdraws from this study you will not be able to participate further in this study.

Privacy and Confidentiality

Your privacy is important to us. To preserve participant confidentiality, any identifiable information such as your name, email address and emergency contact information will be kept separate from the data you provide as part of this study. You will be allocated a research participant number which will be used in place of your name or other identifying information.

Your sessions with a coach will remain confidential, except where they may be required by law to disclose your information without written permission. These are if your coach holds a reasonable belief that you are in danger of harming yourself or others, if your information is subpoenaed by the Courts, or if your coach forms a belief on reasonable grounds that a child is in need of protection from physical injury or sexual abuse.

Quotes will be used to help illustrate and explain key themes in the data, however care will be taken to ensure those that are selected are not identifiable. Transcription of interview audio-files may be completed with the support of an external transcription service. A confidentiality agreement will be signed by the third party transcription service before audio data is shared. Recordings will be provided in a de-identified form, except where you may provide identifiable information during the interview.

If you would like to accept the offer of the \$50 payment as thanks for participating in an interview, your name may need to be provided to the Monash finance team for auditing purposes.

For further information about how Monash University handles personal information, refer to the Research Data Protection and Privacy Collection Statement and Data Protection and Privacy Procedure on the Monash University website, or contact our Data Protection and Privacy Office at dataprotectionofficer@monash.edu.

Storage of data

Couple HOPES is securely hosted on Monash University servers located in Australia.

All study information and data will be securely stored in a secure and restricted computer database for a period of 15 years. Any potentially identifiable data, such as names and contact details, will be kept in a separate section of the database. Access to the study data will be restricted to authorised researchers solely involved in this project, with specific roles assigned for access control.

All data will be permanently deleted and destroyed 15 years after the completion of the study.

Use of data for other purposes

The data you have contributed may also be used in future research. Only de-identified data will be eligible for use in other projects, contingent upon obtaining the necessary ethics approval.

Results

Data generated in the process of completing the intervention, such as pre-module surveys and practice assignments, will be made available to both partners to support shared understanding of each other's experience. No other individual data will be shared with participants.

If you would like to be informed of the aggregate research findings, we will record your interest at the completion of the study. The aggregated findings of the study will be published in a thesis, journal articles and reported at conferences.

Concerns or Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Chancellery Building D,
26 Sports Walk, Clayton Campus
Research Office
Monash University VIC 3800

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Thank you,

Dr Alexander Wolkow