IRB Use Only
Approval Date: July 10, 2019
Expiration Date: December 12, 2019

Title of Study: Online and Mobile Mindfulness Intervention to Reduce Distress in Veterans

Consent Form

What is this research about?

The purpose of this study is to evaluate whether learning and practicing mindfulness techniques can improve trauma-related distress in Veterans with PTSD. Participants in this study will be randomized to one of 2 possible groups. Both groups will participate in assessment procedures. If you are assigned to Group 1, you will complete an assessment and then you will receive a mobile phone app with information and exercises about mindfulness. You will also be mailed or emailed information about how to best make use of the mobile phone app. If you are assigned to Group 2 you will complete an assessment, and then you will be mailed or emailed information about how to find other resources for PTSD, but you will not receive the mobile phone app until 60 days later. At that time (two months or 60 days after first assessment), both Groups 1 and 2 will take a second assessment and then Group 2 will begin their first download and use of the phone app. Groups 1 and 2 will be asked again to complete an assessment at the end of a second 60-day period (2 months). Total participation time is 16 weeks or 4 months. This allows us to compare groups and differences in terms of use and outcome.

We use a random selection process to determine who goes into Group 1 and Group 2. The term “randomized” means that which group a participant receives will not be based on any characteristic or behavior of the participant but will be determined solely by chance like the roll of a dice, so you have a 1 in 2 (or 50%) chance of being assigned to either one of the two groups. You will only be able to participate in the group to which you are assigned at the beginning, until the waiting period is over. Participants will have access to the Mindfulness Coach mobile phone app or other information about mindfulness resources and will be asked questions about their experiences using the app. We expect to enroll 200 participants in this study.

What is expected of me?

If you wish to participate in this study, you must select “Yes” at the end of this form. The alternative is not to participate in the study. Total study time is estimated at 2-3 hours over approximately 4 months, although you may use the mobile phone app as little or as long as you like. All of the assessments will be completed online. You may be asked to also take part in a brief telephone interview to better understand your experiences with the smart phone app. You will be asked to do the following:

1) Groups 1 and 2 will be asked to complete a baseline assessment of computerized questionnaires prior to downloading the app and directly after completing this consent form, agreeing to participate in the study and being randomly assigned to a group. This baseline assessment will ask you questions about your thoughts and feelings related to PTSD and how you've coped with any stress associated with PTSD. You have the right to refuse to answer any questions. We anticipate that it will take you between 30 and 45 minutes to complete the baseline assessment, depending on how quickly you can read, understand, and respond to the online survey. This assessment will remain the same at all assessment time points.

2) After the initial assessment, Group 1 will download and use the app. Group 2 will be given other resources about PTSD and will be placed into a 60-day waiting period before receiving download instructions to begin use the app. Both groups, at their designated times, will be given information about how to download the phone application and all participants (Both groups 1 and 2) can try/use the app for as little or long as you like. Your use of specific parts of the app will be stored, time stamped, monitored, and saved on a secure server. The amount of time you spend using the app is entirely up to you. Again, if you are in Group 1, you will receive that app after completing the initial assessment. If you are in Group 2, you will receive the app 60-days after consent and your first assessment.

3) Complete follow-up assessments. All participants, both Groups 1 and 2, will be assessed at follow up time points. If you are in Group one, you will be asked to complete a second assessment 8 weeks after downloading the app. If you are in Group 2, you will be asked to complete a second assessment 8 weeks after your first assessment and then you will receive the app. Both Groups will be asked to complete a third and final assessment 8 weeks after the second assessment. Each survey is expected to take 30-45 minutes to complete. You have the right to refuse to answer any questions.

4) Some participants will be asked to complete a brief telephone interview. These participants will be randomly selected, 8-12 weeks after downloading the app, to take part in a telephone interview about their experiences using the app. If you are invited to participate in the interview, you will be contacted by telephone to arrange a time to meet with a research assistant by phone. The interview will not be recorded, but the research assistant will take notes based on your comments. You may choose to not take part in the interview.

Do you understand the purpose of this research and what is expected of you as a participant?

- ❍ Yes
- ❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 493-5000, 1, 2, extension 27358.

What are my responsibilities as a participant in this study?

As a participant in this study, your responsibilities include:

- Follow the instructions of the investigator and study staff.
- Complete your web assessments as instructed.
- Download the phone app at the designated times and use as you determine.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- If you schedule an appointment to talk with a research assistant (e.g., for the brief telephone interview), please keep the appointment if at all possible because it can be very difficult to schedule and coordinate these calls.
- If it is necessary to miss an appointment, please contact research study staff to reschedule as soon as you know you will miss the appointment.

Do you understand this list of the participant's responsibilities?

❍ Yes

❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 493-5000, 1, 2, extension 27358.

What are the possible risks or discomforts?

The risks associated with this study are that answering questions on some of the questionnaires used in this study may provoke mild feelings of frustration, sadness, or anxiety. You have the right to refuse to answer any question that makes you feel uncomfortable on any of the questionnaires. In addition, you may feel uncomfortable revealing certain personal information, but your responses will remain strictly confidential and will only be reported when combined with data from other study participants. We do not intend to disclose this information.

Do you understand the possible risks, discomforts, and inconveniences, as we have described them?

❍ Yes

❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 493-5000, 1, 2, extension 27358.

Will I benefit from the study?

We cannot and do not guarantee or promise that you will receive any benefits from this study. However, you may enjoy using the mobile app and find it to be helpful in learning more about mindfulness. We hope to benefit science through the results of this study.

Do you understand that there is no evidence yet that you will directly benefit from this study?

❍ Yes

❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 493-5000, 1, 2, extension 27358.

What are my alternatives to being in this study?

The alternative to being in this study is to not participate in this study.

Will I get paid?

Participants will receive a Target gift card in the amount of $20 for completing the online assessment and successfully downloading the mobile app. Participants will also receive a $20 Target gift card for completing the follow-up assessment at 8 weeks (and after downloading the app for Group 2), and another $20 Target gift card for completing the third and final survey 8 weeks later. If you are invited to take part in the brief telephone interview, you will receive a fourth $20 Target gift card. In order to provide compensation we will ask for your home address.

Do you understand what form the compensation will be in, when the compensation will be given to you, and the information we will need to collect in order to provide compensation?

❍ Yes

❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 493-5000, 1, 2, x.27358.

Will I have to pay anything?

You will not have to pay anything to be in this study, although there may be costs incurred if from your voice/data provider (e.g., Verizon Wireless, AT&T, etc.) if you receive and use a mobile app for this study, depending on the type of data plan you have. Because we are collecting information about how participants use the mobile app in this study, the app transmits small amounts of data (8-20kb per use) that could increase your data charges in some cases. Participants of this study must have access to an iPhone or Android phone for 6 months and phone access in order to be contacted by study staff.

Do I have to be in this study?

If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. If you want to end your participation in the study you should tell the investigator or study staff. You can do this by calling the principal investigator at (650) 493-5000, 1, 2, extension 27358.

Do you understand that refusing to participate will not have a negative impact on you?

❍ Yes

❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 493-5000, 1, 2, extension 27358.

Can I change my mind later and stop being in this study?

Participants can withdraw from the study at any time without penalty or loss of benefits they may be entitled.

Do you understand that you may withdraw from the study any time without losing the benefits you are otherwise entitled to?

❍ Yes

❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 493-5000, 1, 2, extension 27358.

It is possible that, based on information gained from this study, the researchers may have serious concerns (relating to matters such as severe depression, physical abuse, etc.) about your health and/or safety; in such a case, the researchers may withdraw you from the study and/or contact you and provide a referral for your care. If the investigators had reason to believe that your life or that of another was in immediate danger, the investigators would, by law, be required to contact 911 and disclose enough information about you in order to ensure your safety. Furthermore, the investigator may withdraw you from the study for one or more of the following reasons:

- Failure to follow the instructions of the investigators and/or study staff.
- The investigators decide that continuing your participation could be harmful to you.
- You need treatment not provided in this study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

Do you understand the reasons why the investigators may withdraw you?

❍ Yes

❍ No

Please re-read the information above as necessary. If you still do not understand the information presented, please contact us at (650) 493-5000, 1, 2, extension 27358.

Will my information be protected from the public?

We will keep your name and all the information you tell us in this study confidential. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, email, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General, may have access to your information.

Who can I talk to if I have questions about the research, problems related to the study or if I think I've been hurt by being a part of the study?

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the principal investigator, Dr. Jason Owen (phone number: (650) 493-5000, 1, 2, then x23478). You should also contact him at any time if you feel you have been hurt by being a part of this study.

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, and would like to speak someone independent of the research team please contact the Stanford Institutional Review Board (IRB) at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Use of Your Individually Identifiable Health Information (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care. Indicating your agreement to this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

- Personal identifiers that include name, email address, and mailing address

- Demographic items, such as age, gender, race
- Your responses to survey (i.e., assessment) items
- Your use of the mobile phone app

Disclosure:
The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by agreeing to this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information:

The Office of Human Research Protections in the U.S. Department of Health and Human Services

Note: Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.

Access to your Individually Identifiable Health Information created or obtained in the course of this research:

While this study is being conducted, you will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION:
If you indicate your authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

Jason Owen, Ph.D.
VA Palo Alto Health Care System (NC-PTSD)
795 Willow Road, Bldg. 334
Menlo Park, CA 94025

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

Expiration:
Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:
Expire at the end of the research study**.**

By selecting "Yes" below, I acknowledge that I have read and understood this consent form, and that I wish participate in this study.

- ❍ Yes
- ❍ No

Note: Please print a copy of this form for your records.