

Title of Study: PsychArmor Online Training: A Pilot Study

IRB Number: 00021594

Principal Investigator: Dr. Alan Teo
ICF Version Date: 06/24/2021**WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?**

If you become sick or injured, if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), or if you want to otherwise discuss the research study, call the Principal Investigator, Dr. Alan Teo, at (503) 220-8262 extension 52461.

To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at (503) 273-5125, or the VA Regional Counsel at (503) 412-4580.

SUMMARY OF KEY INFORMATION ABOUT THIS STUDY**WHAT AM I BEING ASKED TO DO?**

We are asking you to take part in a research study that is being funded by the Veterans Affairs Health Services Research and Development (HSR&D) service. We conduct research studies to try and answer questions about how to prevent, diagnose, and treat diseases, and how to improve health outcomes for Veterans.

We are asking you to take part in this research study because you are a Veteran who has served on active duty in the U.S. Armed Forces within the past 12 months, or you are a family member or friend of a Veteran.

TAKING PART IN THIS STUDY IS YOUR CHOICE

You can choose to take part or not to take part in this study. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. It's important that you have as much information as you need and that all your questions are answered.

WHY IS THIS STUDY BEING DONE?

This study is being done to answer the following question: What can we learn about the effects of online trainings tailored for Veterans and their friends and family by recruiting and surveying people online? We are doing this study because we want to find out about the helpfulness of these online trainings and we also want to find out about how practical it is to run a study like this entirely online.

WHAT IS THE USUAL APPROACH TO ONLINE TRAININGS?

The usual approach to online trainings for people who are not involved in a study is to seek out trainings on their own. They might find trainings through internet searches or the recommendations of friends, family, or healthcare providers.

WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.

WHAT WILL HAPPEN IF I DECIDE TO TAKE PART IN THIS STUDY?

If you decide to participate, you will be asked to complete a survey, watch a brief online training and complete some follow-up surveys. After your initial participation, you will be invited to complete brief follow-up surveys, once a month for six months. A small subset of participants will also be invited to participate in an

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approximately one-hour long interview about their experience approximately one month after beginning the study.

A detailed description of all procedures that will be done as part of this study is located below in the "What will happen during this study?" section.

WHAT ARE THE RISKS AND BENEFITS OF TAKING PART IN THIS STUDY?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

RISKS

We want to make sure you know about a few key risks right now. We provide additional information in the "What are the risks and possible discomforts from participation?" section.

This study involves collecting identifiable information from you, including your name, email, and phone number, that will be used to send invitations to complete follow-up surveys. In order to send you a survey invitation or reminder by text message, your phone number will be transmitted to Twilio, Inc. You will also be asked to provide your ZIP code and you may be asked sensitive or private questions about things you normally do not discuss. The research team will make every effort to protect your information. However, a loss of privacy could occur.

BENEFITS

You may or may not personally benefit from being in this study. However, by serving as a participant, you may help us learn how to benefit Veterans in the future.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document.

WHAT IS THE PURPOSE OF THIS STUDY?

Military servicemembers who are transitioning to civilian life, as well as their loved ones, often have needs that could be addressed with additional information. Therefore, the purpose of this study is to evaluate online trainings tailored for Veterans and their friends and family and to learn how to more effectively evaluate trainings like these in the future.

WHAT WILL HAPPEN DURING THIS STUDY?

These activities will be done for research purposes and will not be completed if you decide not to take part in the study.

First, you will complete a survey telling us about yourself and some of your opinions. Next you will view an online training video and then answer some survey questionnaires after that. The online training you watch may address preparing finances, using educational benefits, networking, post-traumatic stress disorder, depression, suicidal thoughts, or other related topics. Your initial participation may involve a total of about 45-

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60 minutes of your time. You will then be asked to complete a brief follow-up survey once a month for six months. These follow-up surveys may take approximately 2-15 minutes, depending on the month. We will contact you using your contact information to remind you of these surveys.

A small subgroup of individuals will also be invited to participate in an interview. Should you be interested and decide to participate in the interview, it will last approximately one hour. During the interview we will be taking notes and audio recording the interview. Your interview audio recording may also be sent to a service for transcription. Any identifying information about you will be removed from the transcription.

In this study, some people will receive one training and some people will receive a different training. This is a randomized study. That means you can't choose which of the two trainings you will receive. That will be decided by chance (like tossing a coin, heads could mean you get one training and tails that you get the other). You have a 50/50 chance of getting either training.

The study team will not know which training you received. The study is done this way because sometimes knowing which intervention you received can change the results of the study.

WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?

In addition to the risks described above in the Summary of Key Information About This Study, "What are the risks and benefits of taking part in this study?" section, the following risks could occur if you choose to take part in this study.

Some of these questions may seem very personal or upsetting to you. You may refuse to answer any of the questions.

In order to pay you for your time participating in this study, we may need to collect additional identifying information such as your social security number, banking account information, or mailing address. To process some forms of payment (e.g. electronic gift cards), some of this information (e.g. name and email address) may need to be shared over the internet with an outside party processing the transaction, which may increase the risk of a breach in confidentiality. Providing this additional identifying information would be optional but we may not be able to pay you without it. A breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft, future job status, plans to have a family, relations with your family, parental rights or responsibilities, or status in the community, or could result in embarrassment. However, the research team will make every effort to protect your private health information and guard against any loss of privacy.

If you participate in an interview as part of this study and you indicate that you are suicidal, we may call the VA National Suicide Prevention Hotline and provide them with your name and phone number so they can follow up with you.

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HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

Identifiers related to you (i.e. information that can identify you) will be used in this research study and will include: your ZIP code, name, email address, and phone number. Contact identifiers will be used to communicate information about the study.

In the future, identifiers may be removed from the data, and de-identified information about you may be used for future research studies (not part of this study) without additional informed consent obtained from you. This means the people working on future research studies will not be able to identify who you are.

All other parties, including employers, insurance companies, personal physicians and relatives, will be refused access to the information, unless you provide written permission or unless otherwise required by law.

The study surveys are completed in a database called REDCap. The REDCap database is password protected and maintained by the Oregon Clinical & Translational Research Institute (OCTRI) at Oregon Health & Science University (OHSU). A study ID number will be created for you, which will help to separate your survey responses from any identifying information. Your email address and phone number will be stored in this database, so that you may be sent the links to the follow-up surveys. The database will collect your responses to questions. By agreeing to participate, you give permission for this data to be maintained by OCTRI, which will be responsible for maintaining the security and confidentiality of the transferred data.

By agreeing to participate, you give permission for the transfer of a copy of your survey responses to OHSU's instance of Box.com. Alan Teo will be responsible for maintaining the security and confidentiality of the transferred data. OHSU have ownership of your research data for this research study. All original research records, both hard copy and electronic, will be maintained at the VAPORHCS in accordance with current records retention requirements. Any information shared outside the VA may no longer be protected under federal law. Research records may be reviewed and/or copied by the sponsor.

If you are invited and decide to participate in an interview, an audio recording will be made of this interview. You will be asked for your consent for participation in the recording at the start of the interview. By agreeing to participate, you authorize the use of the audio recording for research purposes. All research-related audio recordings will be held in accordance with the VA records control schedule.

Mandatory reporting of suspected child, elder, or vulnerable adult abuse. Under Oregon Law, suspected child, elder or vulnerable adult abuse must be reported to appropriate authorities.

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Possibility of Disclosure and Notice of Privacy Practices.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. The Notice of Privacy Practices available online at http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3048).

If you are a non-Veteran or a Veteran not enrolled in VHA health care, please refer to the above linked VA Notice of Privacy Practices to better understand how we will protect your information.

WILL I BE TOLD ABOUT ANY STUDY RESULTS?

The results of your participation will not be made available to you because the results will be general and not relate directly to you and/or your medical care.

WILL I BE PAID FOR PARTICIPATING?

You will receive compensation valued at \$20 after completing your first follow-up survey. You will receive an additional compensation valued at \$20 at the completion of this study. If you also participate in the interview, you will receive compensation valued at \$25 after completion of the interview. If you do not complete the study, you will not be paid. To provide you this compensation, we may need to collect additional identifying information from you.

WHAT DO I NEED TO DO TO DROP OUT (WITHDRAW) AFTER I AGREE TO PARTICIPATE?

To withdraw, you may simply stop participating or inform a study team member by calling (503) 220-8262, extension 52457 or emailing us at PORPsychArmorStudy@va.gov.

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