

Stand Down-Think Before You Drink: An RCT of
a Mobile App for Hazardous Drinking with Peer
Phone Support

NCT05473598

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Information Sheet Template (Waiver of Documentation of Informed Consent)



INFORMATION SHEET FOR "Stand Down – Think Before you Drink: An RCT of a Mobile App for Hazardous Drinking with Peer Phone Support"

You are being invited to take part in a research study that is being funded by the Department of Veteran's Affairs Health Services Research & Development. This study involves the use of a mobile app called "Stand Down" and meeting with a Peer Support Specialist. By doing this study, we hope to learn whether the Stand Down app reduces drinking among Veterans in Primary Care who may engage in hazardous drinking. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

WHY IS THIS STUDY BEING DONE?

We are conducting a research study to increase the accessibility of alcohol-related care for Veterans who engage in hazardous drinking but rarely seek or receive treatment. The purpose of the study is to see if the Stand Down app reduces hazardous drinking among Veteran primary care patients and to also see if Peer Support along with the use of the Stand Down app is more effective than the app alone. Peer Specialists ("Peers") are Veterans who are in recovery from substance use and/or mental health problems and are trained to provide services to other Veterans who are struggling with such problems. Peers can provide Veterans with emotional support, serving as self-care role models and helping Veterans navigate the VA health care system. Peers can meet with you to help with navigating the use of the Stand Down app.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

If you choose to participate, the research study staff will ask you to meet with a member of the research team over the phone, in-person, or by video conference (e.g., VA Video Connect). You will be asked to answer a series of questions and fill out some surveys about your background. You may withdraw from the study at any time, and you may refuse to answer any specific questions. Your name will also not be on any questionnaire or survey to ensure confidentiality. We will ask for your social security number to access your VA medical records only to obtain information on your medical history including the type and amount of health care services you receive from the VA. None of the information collected by the research study team will be shared outside the VA. This will only be accessed by approved members of the study's research team. This session will take about 90 minutes.

After you complete this session, you will be assigned by a computer to one of the 3 groups; you will have approximately a 33% chance of being in the group that receives usual care only, a 33% of being in the group that receives usual care plus use of the Stand Down app, and a 33% of being in the group that receives usual care plus use of the Stand Down app and Peer

Support. Neither you nor the study staff can decide which group you will be assigned to – this is called randomization (like flipping a coin). Regardless to which group you are assigned you will continue receiving care as usual from your primary care team or other VA providers.

The Palo Alto and Syracuse VAs plan to recruit and enroll a total of 274 unique Veterans for the study from the following VA facilities: Palo Alto, San Francisco, Northern CA, Syracuse, Finger Lakes Healthcare System and Puget Sound.

Usual Care

If you are randomized to this condition, you will continue to receive care from your primary care team and other providers in the VA as you and your providers see fit. You will not meet with a Peer or use the Stand Down app, although you may pursue care from a Peer in VA as recommended or requested by your primary care team.

Stand Down

If you are assigned to this condition, you will receive usual care and be provided a unique code and password to access the Stand Down app. Following completion of the baseline phone interview and randomization, a member of the research team will assist patients with downloading the app to their smartphone.

Peer-Supported Stand Down

If you are assigned to this condition you will receive usual care and access to the Stand Down app plus 4 sessions from a Peer over 8 weeks. Sessions can be done in-person, by phone, or by video. Sessions will be bi-weekly, approximately 15 minutes in length, and will focus on using and navigating the app. Some of these sessions may be audio-recorded by the peer and reviewed by their supervisor to ensure that the peer is following the study procedures.

Follow-Up Interviews

Regardless of which group you are assigned to (Usual Care, Stand Down, Peer-Supported Stand Down) you will be contacted for 8-, 20- and 32-week follow-up interviews, which may take place at the VA, over the phone, or by video, whichever is more convenient for you. These interviews will take about 1 hour each, and a member of the research team will ask you a series of questions and to fill out some surveys about your health. Again, you may withdraw from the study at any time and you may refuse to answer any specific questions. Because you may have moved or could be hard to contact when it comes time for these interviews, we ask that participants in the study provide us with some additional ways to find you. We ask that you give us the names, addresses and phone numbers of 3 people who would know your whereabouts, and can be reached to give us this information. We also ask that if you have a probation officer or case manager, that you give us their name and contact information. Regardless of where you are, if we cannot speak to you directly, we will not tell anyone else what the study is about. Research team members will only ask for you, and if necessary, say that the call is about a “health survey”, but nothing more about the subject matter of the study.

Interviews with those from the App-only or Peer-Supported Stand Down conditions

If you were randomized to either the Peer-Supported Stand Down condition or the app-only condition, you may be asked to complete an extra phone interview to share your thoughts and experiences using the app, your phone meetings with a Peer (if applicable), and ways to improve the program. The interview will take approximately 30 minutes and will be conducted by phone. You will be paid \$25 for the interview. We will ask that this final interview be audio-recorded in order to transcribe and code the interview. Your identity will not be made known. The information from this interview will be transcribed into a written version that can be studied by the researchers. The transcription will be performed by a professional VA medical transcription agency specifically chosen for this study. You may refuse to participate in this interview portion of the study and still take part in the rest of the study.

Your safety will be monitored by the project staff throughout your time in this study. If at any time the research study members believe that you pose a danger to yourself or others, the researchers will need to break confidentiality, which includes making a report to the proper authorities and/or providing additional help to you as dictated by VA regulations and state law.

If you agree to participate, you may withdraw from the study at any time, and you may refuse to answer any specific questions. All information will be confidential and used only for the purposes of the research study. You may contact the site PI or a research assistant with any questions at any time. We will tell you if we learn of new information that could change your mind about taking part or continuing in this research study.

ARE THERE ANY RISKS OR DISCOMFORTS?

Any procedure has possible risks. The procedures in this study may cause all, some, or none of the risks listed. Rare, unknown, or unexpected risks also may occur. Nonetheless, precautions will be taken to further reduce any risks to you in this study. Specifically, you are encouraged to have any questions answered and concerns addressed to your satisfaction prior to being asked to provide consent.

It is possible that a few of the questions asked of you (e.g., those inquiring about stressful life circumstances; alcohol and drug use; mental health symptoms) may cause you some discomfort. However, such questions should not cause you any more discomfort than the questions that are typically asked of other Veterans who receive primary or specialty care in the VA. These questions are not anticipated to cause you any harm.

ARE THERE ANY BENEFITS?

You will not benefit directly from being in this study. Your participation may benefit others in the future by contributing to the researchers' understanding of alcohol use among Veterans.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Records will be kept locked in filing cabinets, on computers protected with passwords, only study staff will have access to this information.

- Information about study participants may be discussed at meetings with the other sites, but you will not be identified by name.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you by name or any other information.

We will ask for your social security number to access your VA computer records to obtain information on your medical history including the type and amount of health care you receive from the VA. If you choose to not share your Social Security Number you will not be able to participate in this study; however, this decision will not affect your medical care or eligibility for services. The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, or our local Research and Development Committee may look at or copy portions of records that identify you.

In attempting to contact you, the research assistant will explain to any other person whom they reach that s/he is trying to locate you regarding a health survey. We will not include your name on any interview forms. Instead, these documents will be given ID numbers that are not linked to you. The list that contains names, contact information, and ID numbers will be kept on computer files that can only be seen by project staff, and all data with personal information will be stored in locked file drawers.

This informed consent will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others as dictated by VA regulations and state law. This form does not prevent you or a member of your family from releasing data about yourself or your involvement in this study, if you so choose.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

Regardless of your assignment to Usual Care, Stand Down, Peer Supported Stand Down, you will be asked to complete an initial interview with research staff shortly after you agree to participate in the study (in-person, by phone, or by video conference) and three follow-up interviews (in-person, by phone, by video conference, or by mail) 8, 20, and 32 weeks later. You will receive \$50 after completion of each of these interviews. If you are selected to take part in the phone interview to share your thoughts and experiences using the app and/or meeting with a Peer, you will receive \$25 after completion of that interview. Research staff (Research Assistants and Project Manager) will have access to personally identifiable information (PII) in order to provide payment. In addition, your social security number will be needed to provide you with these payments. You will be paid by direct deposit or debit card within 4-6 weeks.

WHO CAN I TALK TO ABOUT THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY: [SITE LEVEL INFORMATION TO BE ADDED]

AFTER HOURS: VA Crisis Communications Line at 1-800-273-8255

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 Local Site Principal Investigator [TO BE ADDED]. You may contact him at [TO BE ADDED]. You should also contact him at any time if you feel you have been hurt by being a part of this study. You may also contact your local VA patient advocate [TO BE ADDED].

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll free at 1-877-254-3130.