

Study Title: Facilitating Assessment of At-Risk Sailors using Technology (FAAST)

Principal Investigator: [REDACTED]

COMIRB No: [REDACTED]

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You are being asked to be in this research study because you are an Active Duty Sailor.

If you join the study, you will answer questions about your thoughts, feelings, and physical and mental health symptoms on the MyCAP/REDCap smartphone app. A study team member will explain monitoring and outreach processes. Within the app, you will be asked to provide your mobile phone number and email address for study outreach purposes. You will also be asked to provide phone numbers for personal (e.g., spouse, friend) and/or provider contacts in case you cannot be reached during the study. Then you will be randomized to download either the Cogito Companion smartphone app or the MyCAP/REDCap smartphone app for three months. The Cognito Companion smartphone application is a medical experimental device not approved by the FDA. Randomization is a method similar to tossing a coin. You will not be able to choose your assigned group. You will also answer survey questions on the app every two weeks. At the end of the study period (after using the app for three months), you will receive a survey link to your email address to answer survey questions. During the study you will be asked about your thoughts and feelings, as well as medical care that you are receiving. Information regarding medical services may also be obtained from existing records.

For those randomized to the Cogito Companion app, the Cogito Companion app will gather behavioral information from voice recordings and mobile phone usage and analyze this data in real time. The app on the phone will be recording data about your use of your phone. The application will use a combination of global positioning system (GPS), wireless fidelity (WIFI), and cell tower data to record your approximate location. It will create anonymous numbers to represent the phone numbers of the people you call. The app will record when you send and get SMS/MMS (commonly referred to as text messages). It will create anonymous numbers to represent the phone numbers of the people you call and text with. The app will record how you use the mobile app including how frequently it is used and which features of the app you choose to view or click. This data will be analyzed using methods developed by the Cogito Corporation to evaluate how you are doing. The Cogito Corporation will provide members of the research team with summary data scores about your mood, level of stress, and general well-being. Members of the study team will review the summary data scores, and your survey responses, and will contact you if concerns regarding safety are identified. The Cogito Corporation will also share information regarding your use of the app, as well as other data collected with the study team.

The application will prompt you to leave audio diaries. These audio recordings are free form single channel audio recordings about how your day is going or about how you are feeling. We will not listen to what you say. We will analyze vocal qualities of the recordings. You will be asked to complete audio diaries every other week.

The Cogito Companion app will never record the names of people in your contact list, what is said in phone calls, what is said in SMS/MMS, or any details on any other apps that are used on their phone, including but not limited to email, web browsing, Facebook, financial management applications, or any medical or mental health apps.

For those randomized to the MyCAP/REDCap condition, information will be presented on the REDCap HIPAA-compliant web-based platform that is hosted by the University of Colorado, Anschutz Medical Campus.

Study team members will also monitor information received from Cogito and MyCAP/REDCap each business day and outreach participants based upon their scores. Study team members may also contact participants who are not responding to surveys or based on data that suggests they may be having technical difficulties with the applications.

This study is designed to learn more about using a mobile application (app) on your smartphone.

Possible discomforts or risks include being asked to answer questions that make you feel uncomfortable or upset. You may feel frustrated or tired while completing the questionnaires. If this happens, you may pause or stop the study. You can also decline to answer any questions you do not feel comfortable answering. There are several safeguards built into the online survey to help monitor and manage this risk. You may also call the Military Crisis Line, emergency services, or the study team if you have significant concerns at any point during this study. There may be other risks the researchers have not thought of.

This study is not designed to benefit you directly.

Every effort will be made to protect your privacy and confidentiality by storing records about you in password-protected or user-restricted files protected by the University of Colorado, Anschutz Medical Campus and VA electronic security systems. Only members of the research team will have access to these data.

Some things we cannot keep private. If you indicate that you are going to physically hurt yourself, we have to report that to your mental health provider or emergency services. If you indicate you are going to physically hurt someone else, we have to report this to local authorities, command, and/or your mental health provider.

This research is being paid for by the Department of Defense, Military Suicide Research Consortium.

There is no cost to you for participation in this study. You may be paid to be in the study. You will be paid \$30.00 for monthly cell phone data usage for each month you participate in the study. You will be paid up to a total of \$90.00. All payments may be made via a MasterCard debit type card called a "ClinCard" that is provided by Greenphire. Your funds will be available to you via this card usually within 24 hours following your scheduled visit or completion of study tests (possible exceptions are weekends or holidays). Greenphire and its Customer Support members may be provided with your name, social security number and date of birth for the purposes of payment only. You will be able given the ability to check the balance on your Greenphire debit card throughout the study. Instructions and terms of use will be included with the card upon your enrollment in the study. We may also ask for your mailing address to send you a replacement card, if applicable. If you leave the study early, or if we have to take you out of the study, you will be paid only for the parts you have completed. It is important to know that payments for participation in a study are taxable income.

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

You have a choice about being in this study. You do not have to be in this study if you do not want to be. If you have questions, you can call the study's Principal Investigator, [REDACTED]. You can call and ask questions at any time. If [REDACTED] is unavailable when you call, please leave a message and she will return your call as soon as possible.

You may have questions about your rights as someone in this study. If you have questions, you can call COMIRB (the responsible Institutional Review Board) at [REDACTED].