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Facilitating Assessment of At-Risk Sailors Using Technology (FAAST)

VA Eastern Colorado Health Care System

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Project Title: Facilitating Assessment of At-Risk Sailors using Technology (FAAST)
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I. Hypotheses and Specific Aims

Aim 1. Evaluate the efficacy of the Cogito Companion as an upstream suicide prevention intervention.
Hypothesis 1.1. Participants allocated to the Cogito Companion will report significantly fewer episodes of distress and less distress over the course of the study (Outcome Questionnaire-45; OQ-45)[1] compared to those allocated to the Active Control group.
Hypothesis 1.2. Among those with episodes of clinically meaningful distress, those allocated to the Cogito Companion will more rapidly engage in treatment (medical record review and Client Services Receipt Inventory-EU-Revised; CSRI-EU-R)[2] to address such symptoms versus those allocated to the Active Control group.
Hypothesis 1.3. Participants allocated to the Cogito Companion will report significantly fewer episodes of and less severe depressive (Patient Health Questionnaire-9; PHQ-9)[3] and post-traumatic symptoms (Post Traumatic Stress Disorder Checklist-5; PCL-5),[4] and suicide-related thoughts (Beck Scale for Suicide Ideation; BSS, Columbia-Suicide Severity Rating Scale Screener; C-SSRS Screener), as well as overall increased perceived physical/psychological health functioning (Rand 36-Item Health Survey; SF-36)[5,6] over the course of the study compared to those allocated to the Active Control condition.

Aim 2. Evaluate the acceptability and feasibility of the Cogito Companion among military personnel (Sailors).[7]
Aim 2.1. Acceptability of Cogito Companion will evaluate based on participant satisfaction (CSQ), participant engagement in application-related activities (e.g., leaving voice recordings), and time spent on the application.[8] Acceptability refers to the suitability of an intervention from the perspectives of the participants.
Aim 2.2. Feasibility of Cogito Companion will be evaluated based on participant retention and accrual, and number and type (minor, moderate, severe) of technical challenges noted during implementation. Feasibility refers to the ease of implementation.

Exploratory Aim. Identify patterns of distress, depressive symptoms, post-traumatic symptoms, suicide-related thoughts, and perceived physical and psychological health functioning over the course of the study among the entire sample, as well as within the Cogito Companion and Active Control groups.

II. Background and Significance

Research suggests that Naval personnel experience concerning levels of anxiety, stress, and suicidal ideation while deployed.[9] Moreover, the post-deployment period has been shown to be particularly risky in terms of suicidal thoughts and behaviors.[10] Given this, novel, non-stigmatizing, and portable upstream prevention strategies are needed to evaluate behaviors, moods, and symptoms over time, particularly during periods of transition. Whereas regular and frequent monitoring by health diaries can be unreliable, the development of smartphone technology has created accessible means to record, store, display, and monitor (self and other) health information.[11] In specific, technology developed by the Cogito Corporation (Cogito

Companion), and evaluated by members of this research team, has the capability to enable military personnel self-care and facilitate early identification of risk for suicide. However, research is needed to establish evidence for this type of intervention.

Suicide Risk and Periods of Transition. Research suggests that periods of transition are associated with changes in mental health,[12-14] including increased risk for suicidal ideation and behavior.[12,15-19] Additionally, studies have shown that increased risk for death by suicide following a transition is often closely tied to psychosocial stressors, including loss of employment,[19,20] romantic relationships,[20,21] onset of illness, or declines in physical health.[17,22] Timing of transitional periods may also be of import.[23] For example, Warner and colleagues[24] found three time periods of significantly increased risk for suicidality among United States (US) Soldiers over a 15-month deployment cycle. The first period occurred in the second month and was hypothesized to be a result of separation from important social relationships. The second was after six months in theater, which was hypothesized to be related to feelings of isolation after returning from leave. Perhaps most pertinent to this proposed study, the third period was near the end of the Soldier's deployment and thought to be related to exposure to increased stressors on the home front. Highlighting the need for increased focus on the period of transition from military service to Veteran status, the President recently signed an Executive Order entitled, "Supporting Our Veterans During Their Transition from Uniformed Service to Civilian Life".[25] Within the order, the Departments of Defense (DoD), and Veterans Affairs (VA), as well as Homeland Security were directed to develop a plan to ensure that those separating from service receive necessary mental health care. However, current strategies (e.g., Post Deployment Health Assessment) have proven to have limited utility in identifying those whose symptoms develop in the weeks and months following periods of transition (e.g., redeployment to the continental United States [CONUS]).[26] As such, exploration of novel strategies (e.g., smartphone based mobile applications [app]), is indicated.

Historically, suicide prevention efforts have largely focused on individuals known to be at high risk.[27] Although this continues to be an important strategy, efforts are also required "to keep [military personnel] from ever reaching the point of contemplating or attempting suicide", by early identification of increased risk and rapid intervention.[28] To date, limited research has been conducted to evaluate such upstream approaches, particularly among military personnel. Identification of evidence-based upstream interventions is necessary to decrease risk among military personnel during periods of transition.

Smartphone Technology and the Cogito Companion. Smartphone technology can be used to record, store, and monitor (self and other) vital information regarding suicide risk.[19] Specifically, the Cogito Corporation has developed a secure, privacy-compliant mobile app (Cogito Companion). The Cogito Companion was designed to collect and interpret social signals underlying smartphone behaviors via usage, to non-invasively collect, transfer, integrate, analyze, and report objective behavioral measures of psychological distress. Measurements of location, call, and text patterns are fed into machine learning algorithms to compute behavioral measures. These measurements provide proxies for behavioral and cognitive components of depression, mood, and anxiety disorders. Over time, these patterns may provide markers for changes in occupational and social functioning.[29] For example, when a Service member is functioning well, he or she is likely to have a routine level of communication and spend certain hours of the day at home versus at work, or out and about. However, with the onset of mental health symptoms, he/she is more likely to spend increasing amounts of time at home, and limit communication. Adaptive algorithms combine these elements over time to derive behaviorally driven changes in these patterns.

In addition, individual users are prompted by the Cogito Companion to complete standardized psychological measures (see below) and to record short (a few seconds to 10 minute) audio diaries. Using vocal analytics, recordings can be transformed into predictive metrics of depressed mood. Specifically, the recording is analyzed regarding the manner in which people speak, rather than what they say. An analysis of vocal qualities, rather than content, allows the technology to predict depressed mood from short field-based audio recordings, while remaining objective to topic, demographic, or even language spoken. Participants will be asked to enter audio diaries every two weeks, which will be used to produce an additional real-time, longitudinal, and clinically validated measure of depressed mood. Data regarding social signals

underlying smartphone behaviors, as well as from the measures and audio diaries, are displayed in the Clinician Dashboard (see below).

III. **Preliminary Studies/Progress Report:**

Development of Cogito Algorithms. Serving as a contractor to the Defense Advanced Research Program Agency (DARPA), Cogito gathered an extensive dataset of individual trauma survivors' mobile data.[29] With the goal of developing mobile phone behavioral health monitoring for military personnel, the Cogito team ran a 3-month study of 100 participants. The participants, both Veteran and civilian, were enrolled for 12 weeks during which time they each carried a mobile phone equipped with a research app. The research app passively monitored, on an intermittent fixed schedule, probe readings from sensors hardwired into the current generation mobile phone. These sensors included call logs, short message service (SMS) logs, locational pattern changes, acceleration, and battery levels. During the study, participants also filled out weekly self-report metrics around mood disorder symptomatology, left weekly audio diaries, and met with a clinician for a Structured Clinical Interview DSM-IV (SCID-IV)[30] at both intake and exit dates of the study. Cogito used structured machine learning to create models, which took in, as inputs, these raw data streams and predicted the clinical level assessment of symptomatology. Each model outputs a score from 0-100, indicating the probability of presence of the behavioral component of mental health. The model uses a week of data to create a score, and updates on a daily basis. Cogito researchers also met with clinical stakeholders to assess the most useful and actionable means of presenting feedback to patients.

Civilian RCT. Among civilians, a 171 person two-arm randomized clinical trial (RCT) was conducted to compared use of the Cogito Companion to standard care in an integrated behavioral health patient-centered medical home setting.[31] In this National Institute of Mental Health funded clinical trial, the PHQ-9 was the primary outcome. Results showed a statistically significant decrease in this score for patients who received the Companion relative to those who did not. While these findings were not focused on military personnel or upstream suicide prevention, they bolster the hypothesis that Cogito Companion could have a positive effect on improving PHQ-9 outcomes in our study population.

VA Pilot Study. Members of this research team (Brenner, Betthauser, Stearns-Yoder) conducted a pilot study to assess the acceptability and feasibility of Cogito Companion among military Veterans. Participation in the study included a baseline visit, using the mobile app for three months, and one follow-up visit. Participants were sent surveys every two weeks while using the app, and were outreached as needed for clinical concerns or administrative and/or technical issues. One hundred and six Veterans were enrolled in the pilot study, and 85 have completed the study protocol. Initial results support both the feasibility and acceptability of the intervention among Veterans from all cohorts. With an eye towards the population of interest for this proposal, the following data is from Veterans who served in Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn (OEF/OIF/OND; N=53). The vast majority of these individuals reported enjoying using the app with half rating their level of enjoyment as "Yes, a lot", another 43% reporting "Yes, a little", and only 7% reporting "No, not at all". Per the study protocol, acceptability was established apriori as 70% of participants scoring 24 or greater on the Client Satisfaction Questionnaire (CSQ).[8] In this sample, 81% scored above this cut off; thereby suggesting overall acceptability. Qualitatively, OEF/OIF/OND Veterans reported that they liked the ability to self-monitor their symptoms. For example, one participant noted "it allows me freedom to sign in and say what I want when I want or I mean [audio diary], give information I want to or need to when I want to". Another Veteran described, "it just reminded me to take a step back, to breathe. To understand there's always people there that are willing to help you and talk to you". In addition, some participants discussed how specific app functions provided motivation to be more social and active, such as, "it [app] reminded me…of the need to get out of the house on a daily basis. Not just sit and take the pill-pain pills". These data suggest that the intervention will be acceptable to Active Duty Sailors.

IV. Research Methods

A. Outcome Measure(s)

Aim 1. Outcome Questionnaire (OQ-45). The OQ-45 is a psychometrically sounds 45-item measure designed to evaluate key areas of mental health functioning, including symptom distress.[32] It is a widely-accepted tool for identifying, tracking, and measuring behavioral health treatment outcomes.[33]

Client Services Receipt Inventory-EU-Revised (CSRI-EU-R). This is a measure which queries regarding use of inpatient hospital, outpatient hospital, community based-day services, as well as primary and community care contacts. In addition to validating care documented in electronic medical records, it will be will be used to identify care received outside of the MHS.[2] In a recent systematic review of self-report measures, use of this tool was noted as being a valid method for data collection on healthcare utilization.[2]

Patient Health Questionnaire-9 (PHQ-9)*. This is a frequently used and psychometrically sound self-report measure of depression.[3]

Posttraumatic Stress Disorder Checklist 5 (PCL-5)*. The PCL-5 is a self-report measure used to evaluate post traumatic symptom severity.[4] Criteria is based on Diagnostic and Statistical Manual of Mental Disorders-5 criteria.[5] Items are rated on a 5-point Likert scale.

Beck Scale for Suicidal Ideation (BSS)* is the self-report version of the Beck Scale for Suicide Ideation.[34] Concurrent validity (comparing patient and psychiatrist ratings) was reported as .90 ($p < .001$) and internal reliability was similarly high ($\alpha = .93$)[34]

Rand 36-Item Health Survey is a 36-item psychometrically sound quality of life outcome-measure that yields perceived physical and mental health functioning summary scores.[35]

The Columbia-Suicide Severity Rating Scale (C-SSRS) Screener is a screening measure, administered by a clinician or electronically, that assesses for suicidal ideation and attempt behavior based on established definitions.[36] The C-SSRS screener assesses intensity of suicidal ideation, specifically asking about frequency, duration, intrusiveness, controllability, and deterrents, as well as suicide-related behavior, such as actual attempts and aborted attempts.

Aim 2. Client Satisfaction Questionnaire (CSQ). The CSQ is an eight-item questionnaire with adequate reliability and validity, which has frequently been used to evaluate standard community mental health care.[8,37] Items are scored on a Likert-type scale where '1' indicates the lowest degree of satisfaction and '4' the highest.

General. MSRC Standard Demographic Form. Information will be gathered on topics such as participant age, gender, race/ethnicity, education, military service, and combat exposure.

University of Washington Risk Assessment Protocol-Revised (UWRAP). The UWRAP will be used during clinical outreach phone calls to facilitate risk identification. The UWRAP has been recommended by National Institute of Mental Health and has been used in over 20 years of research.[38,39]

Self-Help Mobile Application Survey. The study team will develop a brief survey to identify applications that military personnel may use for mental health and wellness, and may include brief items such as the purpose of the app, and estimated amount of time (i.e., minutes) they interacted with these mobile apps. Participants will be specifically asked about mHealth Tools developed by the National Center for Telehealth & Technology), as well as any additional apps (free text field).[40] Some examples include: the Virtual Hope Box, Breathe2Relax, and the T2 Mood Tracker. Those in the experimental arm will complete this survey at the beginning and end of the study. Participants allocated to the Active Control arm will respond to these survey questions every two weeks.

MSRC Common Data Elements (CDEs). The Military Suicide Research Consortium's (MSRCs) questionnaire includes shortened measures of the following: current and past suicide risk, lethality and intent of past suicide attempts, hopelessness, thwarted belongingness, anxiety sensitivity, posttraumatic stress disorder symptoms, traumatic brain injury, insomnia, and alcohol abuse. All studies funded by MSRC are required to include the CDEs in their assessment protocol.

COVID-19 Questionnaire. The brief self-report asks participants about the impact of the COVID-19 pandemic and stressors related to the pandemic.[48] Questions are also taken from the Fear of Illness and Virus Evaluation (FIVE) form.[49]

Additional Data Sources. Mobile Apps. In addition to data obtained from the measures outlined above, data from those allocated to the Cogito Companion group will be captured via the mobile app including: the number of phone calls made and received, and the length of those calls; the number of text messages sent and received; how frequently the mobile app is used; and which features of the app the participant chooses to view.

For those in the Active Control arm, MyCAP data will be captured regarding app usage and information accessed (e.g., links to wellness apps) using the Self-Help Mobile Application Survey developed by the study team (see description above, as well as measures pushed regarding their mental health. Measures demarcated with an * above will be sent every two weeks (see Figure 1 below).

Technical Challenges (Implementation Data). For those in both groups, data will also be collected regarding technical challenges faced by participants such as: forgotten passwords; no individual model scores; and, not completing biweekly surveys. Moreover, for individuals in both conditions, we will capture information regarding research staff outreach (Administrative, Clinical).

Military Health System (MHS) Data. Study participant medical usage (including medical and mental health) data (e.g., dates of visits, hospitalizations), Current Procedural Terminology [CPT Codes], International Classification of Diseases codes, Ninth Revision and Tenth Revision [ICD-9/10]) will also be obtained from the MHS.42 This will include information regarding all visits to a MHS facility during and 1 month post the study period (a total a four months). Likely data systems of interest include the MHS Data Repository (MDR)/Military Health System Mart (M2), as well as the Mental Health Research File.[42]

B. Description of Population to be Enrolled

Inclusion Criteria. 1) Member of the Navel Surface or Aviation Forces; 2) Age: 18-55 years at the time of enrollment; 3) History of at least one deployment with return to permanent station within the past 36 months, or stationed outside the Continental United States with permanent change of station (PCS) to the Continental United States within the past 36 months, or any PCS move within the past 36 months or on initial command duty assignment; 4) Ability to provide verbal and electronic informed consents; 5) Ownership of smartphone; and 6) Willingness to use smartphone and personal data plan to participate.

Exclusion Criteria. 1) Having an iPhone (until the Cogito Corporation releases the iOS version of the Cogito Companion app).

C. Study Design and Research Methods

Recruitment. Dr. Werbel (Naval Captain, Co-Investigator on grant) will work with US Fleet Forces Command to identify units viable for participation. Members of such units may be serving on larger (e.g., Aircraft Carrier, ~5000 Sailors) or smaller (e.g., Destroyers, ~300 Sailors) vessels. Post-unit identification, Dr. Werbel will work with commanding officers to facilitate recruitment efforts, in terms of identifying vessels/Sailors. Members of this research team may present information to potential participants. This could occur on the participating vessels and/or identified military locations. Potential in-person options to inform potential participants regarding the study may range from recruitment on-board vessels during redeployment (recruitment and enrollment tables on ships) to pier-side post-leave during redeployment procedures/all-hands meetings to approximately 36 months post-redeployment.

To facilitate remote recruitment, information regarding the study may be provided to Sailors via email or text, or flyers posted around ships/bases. Although distribution of such information may occur via military personnel, responses to such information (e.g., interest in enrollment) will only be directed to members of the study team. In terms of remote recruitment, Sailors can express interest in the study by calling the study team or completing a short recruitment survey in REDCap. The survey will collect name, phone number, and best day/time to contact the Sailor regarding next steps.

Consent. Once interest has been noted, potential participants will be asked to provide verbal consent either in person, over the phone, or via a secure and approved video connection

platform (e.g., VA Video Connect, Zoom) to: 1) confirm eligibility and complete informed consent and baseline measures on the MyCAP/REDCap (Research Electronic Data Capture) smartphone app and/or web-based service 2) be randomized; 3) download either the Cogito Companion smartphone app (Experimental) or the MyCAP/REDCap smartphone app and/or web-based service (Active Control); and 4) complete baseline measures. Further information regarding MyCAP/REDCap (https://projectmycap.org/ or https://redcapinfo.ucdenver.edu/) is provided below.

Sailors will be provided with written and/or electronic consent materials. That is, Sailors will be provided with a written copy and/or an electronic copy(ies) of the consent materials. Consent will be obtained via MyCAP/REDCap. This will be facilitated and observed by the team members. During this process, Sailors will be asked to confirm that they have read consent materials and received a written and/or electronic version of consent materials. During the study visit, members of the research team will also explain monitoring processes, and outreach procedures. Such procedures will be initiated in the event that the study team receives technical or clinical data suggesting that such a contact is warranted (more information to be provided below). Participants will be asked to provide the study team with multiple phone numbers via MyCAP/REDCap or in written format for personal (e.g., spouse, friend) and/or provider contact in case the participant cannot be reached during a clinical monitoring outreach call (see below for clinical monitoring procedures).

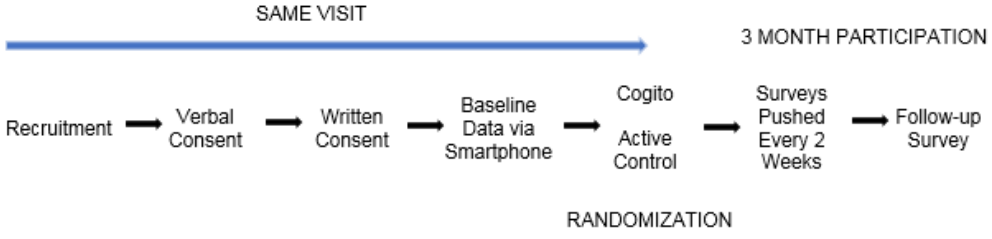
Randomization will be stratified by gender, force (Surface versus Aviation), and smartphone type (i.e., Android, iPhone [once the iOS version is released]). Initially, only those with Android platform smartphones will be recruited. Once either application is assigned and/or downloaded, a member of the study team will provide the Sailor with the information to login (e.g., tokens). Participants will be provided with study team contact information, for any technical assistance while using the assigned modality, as well as information regarding monthly reimbursement for cell phone data usage ($30 per month). They will all be provided with Military/Veterans Crisis Line Contact information, and may be provided with additional resources (e.g., local resources). All payments may be made via a MasterCard debit type card called a “ClinCard” that is provided by Greenphire. Funds are usually available via this card within 24 hours following the scheduled payment date (possible exceptions are weekends or holidays).

Authorization. All required elements of informed consent will be provided on MyCAP/REDCap, including information regarding the purpose of the study, what to expect if participating, possible risks and discomforts, who is paying for the study, the voluntary nature of participating, whom to contact with questions, information regarding the privacy of participants’ information, and exceptions to confidentiality. We will request a Waiver of Documentation of Consent and a HIPAA Waiver to facilitate conducting this study.

Study Design. Randomized Controlled Trial (RCT), with up to 1,418 individuals being allocated to Experimental (Cogito Companion) or Active Control (MyCAP) based on stratified randomization tables. Randomization will be stratified by gender, force (Surface, Aviation), and smartphone model (Android, I-Phone [once the iOS version is released]), as Cogito algorithms differ based on smartphone platforms. Data is also being collected (feasibility/acceptability) to inform future implementation.

Study Procedures. Upon confirming interest in participating in the study, a member of the research team will obtain verbal informed consent and confirm eligibility. Electronic consent will be provided via MyCAP/REDCap. Baseline measures will be administered via MyCAP/REDCap. Military personnel will then be randomized to the Cogito Companion group (Experimental) or the Active Control (MyCAP) group.

Figure 1. Study Procedures



Biweekly (every other week) post-consent, study measures will be pushed to participants via the mobile apps (Cogito Companion, MyCAP). Post-completion of measures at the end of the study period (Follow-up Survey), participants will be provided with a link (MyCAP/REDCap). See Figure 1 for an outline of study procedures, and Table 1 for proposed measures and administration schedule.

Table 1. Measures and Administration

Measure	Domain	Baseline	During Intervention (Biweekly)	Follow-up Survey
Beck Scale for Suicidal Ideation (BSS)	Suicidal ideation	X	X	X
Client Satisfaction Questionnaire (CSQ)	Satisfaction with intervention			X
Client Services Receipt Inventory-EU-Revised (CSRI-EU-R)	Health care utilization	X	X	X
Columbia-Suicide Severity Rating Scale (C-SSRS) Screener	Suicidal ideation and behavior	X	X	X
MSRC Common Data Elements				X
MSRC Standard Demographic Form	Demographics	X		X
Outcome Questionnaire (OQ-45)	Psychological Distress	X	X	X
Patient Health Questionnaire-9 (PHQ-9)	Depression	X	X	X
Posttraumatic Stress Disorder Checklist 5 (PCL-5)	PTSD	X	X	X
Rand 36-Item Health Survey	Quality of life	X	X	X
Self-Help Mobile Application Utilization Survey	Use of readily available Apps	X*	X**	X*
COVID-19 Questionnaire		X	X	X

*All study participants; **Those allocated to the Active Control arm only

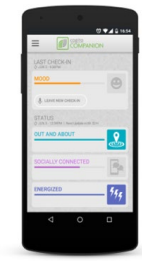


Figure 2. Participant View

Random Allocation and Concealment. Randomization to the Experimental or Active Control arms will be stratified by gender, force, and smartphone model. The block randomization schemes, using random block sizes of 2, 4, and 6, will be produced by Dr. Forster using Statistical Analysis System (SAS) PROC PLAN with a specified seed, prior to any recruitment. To ensure concealed allocation, participants will be designated by an identification number.

Treatment Arms. Experimental. Those allocated to Experimental arm will have access the Cogito Companion for a three-month period post-consent. Passive data collection will also occur during this period. As a secure, privacy-compliant mobile app, the Cogito Companion facilitates the non-invasive collection, transfer, integration, analysis, and reporting of objective behavioral indicators (Figure 2). The Cogito mobile sensing platform passively gathers behavioral information through an individual's normal smartphone usage. Measurements of location, call, and text patterns are recorded. These raw

Figure 3. Clinician Dashboard

measurements, which number in the tens of thousands per week, are fed into Cogito's algorithms to compute validated behavioral indicators. These indicators are presented as model scores in the Clinician Dashboard, which will be used to facilitate monitoring of behavioral changes (Figure 3). Further information regarding this process will be provided below and in Human Subjects Recruitment and Safety Procedures. Participants may also monitor their own behavioral changes overtime (Figure 3). Individual users will also be prompted to record an "audio diary" using the mobile app via their smartphone. An analysis of vocal qualities, rather than content, will produce a model score, which is provided to users and the research team. Participants will also be able to subjectively rate their mood at the time of the recording. Reminders to complete these "audio diaries" will occur biweekly, on an alternating schedule with the biweekly surveys. Nonetheless, participants will be able to leave as many "audio diaries" as they would like during the three-month period.

Clinical Research Staff Outreach – Cogito Group. Clinically-trained research team members will monitor the Clinician Dashboard each business day one time per day (excluding federal holidays and weekends). Clinical monitoring may include the review of responses for the following: the PHQ-9, BSS, C-SSRS Screener, and individual model scores derived by Cogito app algorithms. Lack of data may also prompt a clinical outreach. Further information regarding risk identification and clinical monitoring will also be provided below.

PHQ-9 Monitoring. Clinical team members will review PHQ-9, item 9 "Thoughts that you would be better off dead or of hurting yourself in some way."[3] A response of 2 (more than half the days) or 3 (nearly every day) will prompt a clinical outreach call to the participant. A response of 1 (several days) will be considered for a clinical outreach call in conjunction with other Dashboard data and/or surveys.

BSS Monitoring. Clinical team members will review the BSS screening items (items 1-5). Any response of "2" on items 1- 4, will prompt a clinical outreach call.

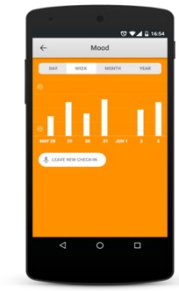


Figure 4. Health-Related Feedback

C-SSRS Screener Monitoring. Clinical team members will review responses to the C-SSRS and conduct outreach based upon recent and/or current suicidal ideation and/or suicidal or self-harm behaviors. Specifically, we will outreach if the participant positively endorses thinking about how they may kill themselves, have had thoughts of killing themselves with intention of acting on these thoughts, and/or if they've started to work out details of how to kill themselves.

Using the same clinical thresholds described above, the Cogito app will send an automatic notification to the participant regarding their scores, as well as resources (e.g., Military and Veterans Crisis Line, Military OneSource, Military Health System provider contact information [individualized data entered by participant or study team]).

Cogito Model Score Monitoring. Model scores are presented both in number and color format (Figure 4). Red indicates scores 39 or below, yellow indicates scores between 40 and 79, and green indicates scores between 80 and 100. The higher the score, the "healthier" the individual's behaviors. Any drastic daily change in score (+/- change of 20) and/or two scores less than 20 may prompt a clinical outreach call.

Active Control. Participants randomized to the Active Control group will download MyCAP and have access to resources housed within this app for a three-month period post-consent. Participants will be provided information regarding the mHealth Tool apps, and provided basic information on how to download the apps. As noted above, participants will be provided biweekly surveys as listed in Table 1. Participants will get one notification when surveys are available. If surveys are not completed, participants may be sent a reminder to complete the surveys via MyCAP automatic reminder or the in-app messaging feature.

Clinical Research Staff Outreach – Active Control. Clinically-trained research team members will monitor the MyCAP dashboard each business day one time per day (excluding federal holidays and weekends); however, outreach will solely be based on survey data or lack thereof.

Similar to the Cogito group, the Active Control group will receive the PHQ-9, BSS, and C-SSRS Screener surveys biweekly. If participants' responses on the PHQ-9, BSS and/or the C-SSRS Screener meet the clinical threshold described above, they will receive an outreach call, as well as automatic notification from MyCAP with resources (e.g., Military and Veterans Crisis Line, Military OneSource, and Military Health System provider contact information [individualized data entered by participant or study team]). Lack of responses to surveys may also prompt clinical outreach. Further information regarding risk identification and clinical monitoring will be provided below.

D. Description, Risks and Justification of Procedures and Data Collection Tools

Risk and Benefits. The primary benefit of this trial is facilitating knowledge regarding the early identification of risk and intervention among Naval personnel. During the study period, participants may become upset or frustrated with technology associated with the mobile application itself, or during administration of the interviews or questionnaires. Possible breaches of confidentiality may occur, though risks will be minimized as outlined below. The research may also involve unforeseeable risks.

Safety Monitoring. *Procedures for Minimizing Risk.* Training. Members of the research team will receive training on risk assessment, crisis management, and regulatory reporting requirements. Clinical team members will receive additional training about clinical monitoring via the Cogito and MyCAP apps, using developed tools (e.g., clinical decision-tree).

Risk Identification and Clinical Monitoring. Informed consent materials (which will be stored within the apps and available for participant download) will contain statements explaining mandatory reporting requirements for information regarding intention to harm self or others. During the informed consent process, all participants will provide multiple phone numbers for personal and/or provider contact in case we are unable to reach the participant during a clinical monitoring outreach call. All participants will be monitored during the study period. Specifically, clinical monitoring will occur via responses to the PHQ-9, BSS, C-SSRS, and for the Cogito group, the Cogito Model Scores. Participants may be outreached in two ways. First, if participants meet the clinical threshold on the PHQ-9, BSS and/or the C-SSRS, they will receive an automatic notification via Cogito Companion or MyCAP smartphone applications with crisis resources. Second, clinical team members will contact participant via phone using the following steps.

Initial Data Assessment. Clinical team members will have clinical decision-tree handouts for both groups to help guide decision making. Once a clinical team member has determined the need for clinical outreach, the team member will call the participant. The study team will outreach the participant first, and if the participant does not answer, the study team may proceed to contact the personal and/or provider contacts the participant listed during the consent process.

Clinical Outreach Calls. At the beginning of the call, a locator form will be completed to document the physical location and contact information of the participant in case of imminent risk. The participant may be asked for permission to collect contact information for the participants' mental health or health provider, and/or a secondary contact person for additional safety outreach. Next, the team member will let the participant know that information gathered from the app indicated that the participant may be at increased risk and prompted a check on the participant. During the call, the team member will assess the participant's urge to harm themselves or others, and suicidal intent using the UWRAP.[38] Additional information may be gathered including coping strategies, reasons for living, and assessment of physical/mental health symptoms that may be eliciting suicidal ideation, intent, and/or a plan. Referral assistance to treatment providers (DoD/VA) may also be provided. All information gathered during the clinical call, as well as app monitoring data, will be used to determine level of risk and appropriate action steps to be taken. Three risk levels will be used: 1) imminent acute risk; 2) increased acute risk; or 3) no perceived increased acute risk.

Imminent Acute Risk. Clinical team members, Dr. Betthauser, the PI, or their designee will stay on the telephone with the participant while another team member immediately calls 911, or the appropriate emergency service to initiate an on-site rescue if such action is clinically indicated.

Increased Acute Risk. If a participant appears to be at increased but not imminent risk of suicide, the clinical team member will provide the participant with crisis resources and encourage use, as well as referrals for treatment. Increased clinical monitoring and continued clinical outreach will occur following this contact until the participant is determined to be at No Perceived Increased Acute Risk.

No Perceived Increased Acute Risk. If a participant appears to be at No Perceived Increased Acute Risk with respect to the platform data and suicide risk assessment, the clinical team member may provide crisis resources and referral information, as indicated.

All participants will be informed that they will continue to be monitored via these platforms over the course of their participation in the study. Each clinical outreach, including steps taken during the outreach call, will be documented per study-specific standard operating procedures (SOPs) and reviewed with Drs. Betthauser and Brenner.

Documentation of Risk. Notes from the call and responses to the UWRAP will be documented in electronic study "note to file" for the respective participant for each clinical outreach call. Drs. Betthauser and Brenner will be informed of the clinical call and will sign off on each note to file. Each note to file will be saved electronically in the participant's study folder for reference and documentation during active participation in the study. Note to file information may be shared with participant's mental health and/or health providers, with the permission of the participant, or with emergency responders in the case of clinical action for those at imminent risk. Data regarding clinical outreach calls will be compiled. After Action Reviews (AARs) will be conducted following the clinical outreach and these events and forms will be reviewed during clinical and administrative team meetings and with the PI.

Administrative Monitoring and Outreach. Clinical team members also will assess the need for administrative outreach. Administrative outreach most generally will be initiated based on a lack of data being collected. Common issues include: participants' limited internet connectivity; low frequency of text messaging behaviors; changes in app permission (e.g., location permission); and, lack of responses to surveys or incomplete surveys. In most cases, such issues will be noted by Clinical Team Members who will provided this information to the Research Coordinator and/or Assistant, who will make the administrative outreach calls. These administrative calls will be documented in an administrative log maintained by the study team for tracking purposes. Study team contact information will also be provided in both apps, should the participant encounter any administrative issues. The study team will be the primary contact for resolving any administrative or technical issues related to use of the application.

Clinical & Administrative Consultation Reviews. Dr. Betthauser (clinical) and Ms. Stearns-Yoder (administrative) will provide ongoing consultation to members of the research team. They will maintain notes regarding these meetings and will review such notes with the PI.

Reporting. Any adverse event will be reported to the local Institutional Review Board by the PI within 5 days and will be reported to the Safety Monitor and MSRC as indicated.

Data Management Plan. Minimizing risks pertaining to data security will be achieved by employing safeguards). Initially, all data collected via Cogito or REDCap will be stored on the secure server and behind the firewall at CU-AMC. Files will be user-restricted and/or password-protected so that only members of the research team can access the data. Data in electronic form created by the study team will be limited data sets and stored in password protected Word documents, Excel spreadsheets and/or ACCESS databases within a restricted access folder behind the firewall at CU-AMC. A master list of participant names and phone number will be kept in a password-protected electronic file, password known only to an authorized member of the research team as designated by the PI. A separate research identification number spreadsheet will be kept and will include the participant's names and an assigned unique research identification number (UID) in a password-protected electronic file, known only to the authorized research team members. All data in paper format or original documents containing sensitive information will be stored in locked filing cabinets in the Department of Physical Medicine & Rehabilitation, in administrative offices at CU-AMC.

To facilitate data analysis aggregate de-identified datasets may be stored at the Rocky Mountain Regional VA Medical Center. Files will be user-restricted and/or password-protected so that only members of the research team can access the data. All VA data in electronic form will be limited data sets and stored in password protected Word documents, Excel spreadsheets

and/or ACCESS databases within a restricted access folder on the VA shared drive and on the secure server and behind the VA firewall. The secure VA servers are located in a secure room and are backed up nightly.

Cogito. Cogito servers and centralized hardware are locked down both physically and electronically. Networking infrastructure is done through a series of access-controlled devices, which restrict access of outside presences and protect inside resources. Datasets are stored on encrypted volumes or under systems with full disk encryption, as appropriate. Data are encrypted and backed-up externally. Data access is granted under least privilege. Cogito is fully equipped with an internal system for project management and documentation of non-PII (personally identifiable information) research materials. This system is fully backed-up and accessible by all employees, both on and off-site. The computing infrastructure has automated monitoring capacities to alert Cogito engineering for downtime, data anomalies, security risks, and directed attacks. End-point data will be validated and confirmed by members of the research team. Cogito has secured Federal Wide Assurance (FWA) for the Protection of Human Subjects. All participants assigned to the Cogito group will be provided a unique research identification "token." Cogito Corporation will provide the research team with a list of unique tokens prior to study recruitment. Authorized members of the research team will distribute the Cogito token at the time of enrollment to participants assigned to this group. The research team will keep a password-protected list of the assigned Cogito token and the participant's unique research identification number (UID). Cogito Corporation will transfer de-identified data via encrypted Word documents and/or Excel spreadsheets to authorized members of the research team via email at CU-AMC.

REDCap. The University of Colorado Anschutz Medical Campus (AMC) REDCap platform is a highly secure, nationally-utilized data management system, and it is housed within the highly-secure environment on the AMC. MyCAP is an app developed for use within REDCap. MyCAP allows research study participants to access and respond to surveys on their mobile devices. The app is protected by a 6-digit passcode chosen by the participant, and data are stored in an encrypted database. Participants' survey responses are synchronized with the REDCap database. All participants assigned to the Active Control group will be provided a unique MyCAP research identification number (ID). A member of the study team will obtain a list of unique MyCAP ID prior to study recruitment. Authorized members of the research team will distribute the MyCAP ID at the time of enrollment to participants assigned to this group. The research team will keep a password-protected list of the assigned MyCAP ID and the participant's unique research identification number (UID). Authorized members of the research team will have secure access to MyCAP/REDCap data, and all data will be transferred and stored securely in a user-restricted study folder, saved on the VA server behind the VA firewall (see below).

Clinical & Administrative Outreach Data. All clinical and administrative outreach data will be kept using the participant's assigned UID and protected as described above.

Military Health System Data. Data management and security for military health information will be stored securely in accordance with the Guide for DoD Researchers on Using MHS Data, as well as protections in accordance with 32 CFR219, DoDI 3216.02 and other applicable Federal laws, regulations, and DoD policies.[43,44]

E. Potential Scientific Problems

Participant recruitment and retention may be a potential scientific concern; however, we have initial support from Naval command to recruit onboard an aircraft carrier (~5000 Sailors) and attached Striker units. The PI and Dr. Werbel will continue to work with Naval command to ensure ongoing recruitment support and planning.

Technological issues with Android and/or iPhone platforms with the assigned study arms (Active or Control) may occur. The study team has pilot data that assists in problem-solving these concerns quickly. Cogito Corporation will have dedicated staff to assist with any Cogito Companion technological issues as they arise. The study team will monitor MyCAP issues and work closely with REDCap staff at the University in a timely manner. Issues will be documented and reviewed as part of Aim 2 and appropriate amendments may occur with consistently identified issues.

While 21% attrition is expected and the statistical methods proposed below are equipped to handle data that are missing at random, characteristics of participants who drop out of the study will be compared to those who do not and if there is differential dropout by group or it is plausible, based on characteristics of those who did drop out, that the missingness is related to the primary outcome of interest, additional methods aimed at accounting for nonignorable dropout will be employed where possible.

F. Data Analysis Plan

Power Analysis. Power is calculated for the two primary hypotheses assessing episodes of distress and distress over the course of the study. We will recruit 1418 participants and expect approximately 33% to decline participation resulting in 950 participants randomized to either the Cogito Companion or Active Control groups, stratified by gender, force and phone type. Assuming 21% attrition, it is expected that 750 participants will complete the entire protocol. While the analysis will include all participants who are randomized, power is based on 750 completed (375 per group). Power to address episodes of distress was estimated using the Poisson regression procedure in Power and Sample Size (PASS) v13. An episode of distress is defined as an OQ-45 total score of ≥ 64 with each participant having a maximum of 6 possible episodes (every 2 weeks for weeks 2-12 of the study, inclusive). We wish to detect a 15% difference in the number of episodes of distress over the 3-month study period, and we assume a two-sided test and a significance level of 0.025 to control for the two primary tests (number of episodes and overall distress). If the Active Control mean response rate is 3.5 (i.e., number of episodes in the 3-month study period) we will have 97% power to detect a 15% difference. For Active Control response rates of 3, 2.5, 2 and 1.5, power is then 94%, 89%, 81% and 68%, respectively. For the second primary hypothesis, we will calculate the Area Under the Curve (AUC) using an estimate statement within a linear mixed model described below. We wish to demonstrate that the Cogito Companion is superior to Active Control by a margin of at least 14 points (minimally clinically significant difference, translates to an AUC difference of 84). Using the Superiority by a Margin procedure in PASS v13, 375 participants per group provides 90% power to demonstrate superiority, assuming a true difference of ≥18.7 points (AUC difference of 112.2) with a significance level of 0.025.

Analysis Plan. All analyses will assume a two-sided test of hypothesis, a significance level of 0.05 (unless otherwise indicated) and will be run in SAS v9.4 or higher, or R v3.3 or higher. To check randomization, demographic and clinical characteristics will be compared between groups using t-tests, chi-square tests or nonparametric tests, as appropriate. If any variable is found to be significantly different between the groups and is also plausibly associated with an outcome, it will be considered as potential confounders in the models described below.

Aim 1. To address the hypothesis regarding episodes of distress first using Poisson regression will be used to model the number (response rate) of episodes of distress as a function of group (0=Active Control, 1=Cogito), any potential confounders, and an offset of log (time) to account for varying lengths of follow-up. If the deviance is estimated to be >1.5, Negative Binomial regression will be used instead, incorporating the same variables. The parameter estimate associated with the group variable will be exponentiated, providing an estimate of the ratio of response rates between the groups and will be reported with a 97.5% confidence interval (CI). To address the hypothesis regarding distress over the course of the study, a linear mixed-effects model will be employed with longitudinal OQ-45 scores as the dependent variable and group, potential confounders, and an interaction between group and time (using either natural cubic B-spline transformations on time or polynomial transformations on time) as independent variables. These transformations will also be applied to the random time effects so that individual trajectories can be calculated. Akaike's Information Criterion will be used to determine which model provides the best fit (both between the B-spline/polynomial models and within them). Once a final model is determined, the difference in AUC will be calculated and between groups and compared to the clinically meaningful AUC difference of 84 using a one-sided test. Here the null hypothesis is that $AUC_{AC} - AUC_{Cogito} \geq 84$, and the alternative hypothesis is that $AUC_{AC} - AUC_{Cogito} < 84$. The estimated difference will be reported with the one-sided 97.5% CI. For hypothesis 1.2, a Kaplan-Meier estimate will be used to compare the median time to treatment engagement

between the groups and each median will be reported with 95% CIs. Treatment engagement is operationalized as a visit with any medical or mental health provider in which a mental health related ICD code is identified. and will be determined by medical record review. Additionally, the total number of mental health visits calculated from the CSRI-EU-R will be modeled using a Poisson or Negative Binomial regression model to estimate the difference in number of visits between the groups over the course of the study. The model will be set up similarly to the OQ-45 model. Hypothesis 1.3 is similar to hypothesis 1.1 such that we wish to look at episodes of depressive symptoms (PHQ-9), post-traumatic symptoms (PCL-5) and suicide-related thoughts (BSS) as well as severity of each over the course of the study. We also wish to look at perceived physical and psychological health functioning (RAND SF-36) over the course of the study. The methods employed to address hypothesis 1.1 will be utilized to estimate the difference in number of episodes of each outcome (excluding the SF-36) as well as the difference in AUC for each outcome. Zero-inflated negative binomial regression will be considered for the BSS if a large proportion of the participants do not exhibit suicidal thoughts and transformations will be considered for the AUC BSS analysis, given that it is likely to be highly skewed. Cutoffs for episodes of depressive/post traumatic symptoms, and suicidal thoughts are ≥10 (PHQ-9),[45] ≥33 (PCL-5),[46] and ≥2 (BSS),[47] respectively.

Aim 2. We will assess the proportion of participants who find the Cogito Companion acceptable, defined as ≥ 70% of participants scoring ≥ 24 on the CSQ. The proportion of Cogito Companion participants with a CSQ score of ≥24 will be calculated with a 95% CI. Additionally, the proportion of participants engaging in activities will be reported with a 95% CI as well as the median (range) amount of time spent on the application. Feasibility will be measured by the proportion of Cogito Companion participants who complete treatment and reasons for termination will be examined.

Exploratory Aim. To explore patterns of distress experienced by participants over the course of the study, individual OQ-45 curves modeled in Aim 1 will be qualitatively clustered into groups based on visual inspection of the trajectory patterns. Once distinct patterns are identified and labeled, baseline demographic and clinical characteristics of participants in each pattern will be summarized and reported. This will be performed for the entire sample, as well as within each group. This is considered a hypothesis generating aim. This analysis will be repeated for the PHQ-9, PCL-5, BSS and SF-36.

G. Summarize Knowledge to be Gained

Establishing the efficacy of the Cogito Companion has direct military relevance aligned with Leaderships' desire to promote wellness and help-seeking behaviors, as well as prevent suicide-related behaviors among Naval personnel during the redeployment home following a stressful forward operating mission. Importantly, this upstream intervention (the Cogito Companion) has the potential to facilitate identification of those transitioning (e.g., redeployment, permanent change of station, separation) whose risk may: 1) not be easily identified immediately post-deployment; 2) and/or may increase secondary to intra- and inter-personal stressors during the reintegration period. Identifying and engaging such individuals in treatment using traditional methods has proven to be challenging. Based on consumer preferences, technology is finding its way into the health arena. Identifying means by which technology can be used to evaluate risk identification is imperative. Specifically, evidence-based, portable, and non-pathologizing interventions, which capitalize on Active Duty Service Member comfort with technology, are necessary to prevent suicide among members of this high-risk cohort. Importantly, project aims also align with the MSRC objective of “fund[ing] … clinical trial … research with high value to the MSRC,” aimed at promoting help-seeking behavior and preventing suicide.

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