Developing a Mobile Intervention to Reduce Suicidal Cognitions in Veterans

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Study Protocol and Statistical Design

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PROTOCOL TITLE: Developing a Mobile Intervention to Reduce Suicidal Cognitions in Veterans

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Purpose

The goal of this research is to develop, refine, and pilot-test a mobile interpretation bias modification intervention to reduce cognitions that contribute to elevated suicide risk and to assess the impact of reductions in suicide cognitions and hostile interpretation bias on suicide risk and functioning.

Background and Significance

According to the fluid vulnerability theory, suicide risk fluctuates as a function of chronic and acute vulnerability factors.[1] One of the factors that contributes to persistent vulnerability is what is known as a "suicidal belief system".[1] This belief system is made up of several well-studied, cognitive constructs, such as hopelessness[2], thwarted belongingness, perceived burdensomeness [3,4] unlovability, unbearability, and unsolvability[4,5]. Each of these constructs have been associated with suicide-related outcomes.[6] For example, suicide cognitions have been prospectively associated with subsequent suicide attempts among military personnel.[5] In another study, suicide cognitions were stronger predictors of future suicide attempts than current suicidal ideation or prior suicide attempts.[4] In fact, thwarted belongingness, unlovability, and unbearability were uniquely related to prospective attempts over a two-year period, above and beyond other well-established risk factors.[4] Suicide cognitions are conceptualized as enduring, chronic vulnerability factors that predispose individuals to suicidal crises. Therefore, modification of these beliefs may reduce suicidal thoughts and behaviors.

In addition to suicide cognitions, another potentially modifiable risk factor for suicide is anger. Recent research (including from our team) has demonstrated a strong, consistent relationship between anger and suicidal thoughts and behaviors in civilian and veteran samples.[7-9] For example, in a longitudinal, nationally-representative sample, anger was prospectively associated with subsequent suicidal ideation and attempts, even after adjusting for well-established risk factors.[7]

Interpretation bias modification techniques have been used in recent years to modify cognitive biases that cause and maintain psychiatric disorders.[10] Interpretation bias modification is delivered *via* computer, tablet, or smart phone and essentially helps participants to adopt more adaptive interpretational styles through repeated practice. Dr. Dillon has developed an app to deliver her hostile interpretation bias modification intervention with ~10 minute treatment session delivered 5-7 times per week for 4 weeks. The current project will use this paradigm to develop a similar intervention to reduce suicidal cognitions for Veterans. The impact of this intervention as well as the hostile interpretation bias intervention on suicide risk and daily functioning will be examined.

Aims

Aim 1(a). Develop a mobile interpretation bias modification intervention entitled Mobile Intervention for Suicidal Thoughts (MIST) to reduce cognitions that contribute to elevated suicide risk. We will develop content to target cognitive factors that contribute to suicide risk and program this content into a mobile application similar to an existing app developed by the team to target hostile interpretation bias, entitled MIRA.

Aim 1(b). Use a successive cohort design to refine the MIST intervention among Veterans with PTSD, problematic anger, and elevated suicidal ideation. To refine the intervention developed in Aim 1(a), the app will be tested in two cohorts (each $n = 5$) of Veterans with problematic anger, and suicidal ideation. After each cohort uses the MIST application for four weeks, a quantitative and qualitative evaluation will be conducted with each Veteran. Revisions will be conducted before the next cohort is treated. Then, a third cohort ($n = 4$) will be recruited to test a web-based version of the MIST intervention delivered via Qualtrics.

Aim 2. Assess the impact of reductions in suicide cognitions and hostile interpretation bias on suicide risk and functioning. After using the MIST intervention for four weeks, participants will use the MARI intervention for another four weeks. For the duration of the study (all eight weeks of treatment), EMA data will be collected to evaluate the impact of both interventions on suicide risk and daily functioning.

Design

The proposed research project has two aims: 1) to develop and refine the MIST mobile intervention; and 2) to assess the impact of reductions in suicide cognitions and hostile interpretation bias on suicide risk and functioning among Veterans with problematic anger, and elevated suicidal ideation. The project has been designed in order to complete both aims simultaneously. The first step is to develop training scenarios for the MIST intervention. Dr. Dillon has already started developing these scenarios to fit into specific themes of types of cognitions that have been theoretically and empirically linked to suicide: unbearability (*I can't tolerate being this upset*), unlovability (*I am unworthy of love*), unsolvability (*Nothing can solve my problems*), thwarted belongingness (*I do not belong*), perceived burdensomeness (*Others are better off without me*), and hopelessness about the future (*Things will not improve*). Unique scenarios will be developed for 28 treatment sessions (daily sessions for four weeks). When the scenarios have been developed, they will be reviewed by a team of experts (i.e., doctoral level psychologists with experience working with this Veteran population) who will rate them on how relevant they are for the Veteran population. They will also share comments and suggestions for refining these scenarios. Each scenario will be reviewed by at least one expert. Scenarios with low relevance will be revised before inclusion in the app. These are the same procedures used to develop the content for the MARI app.

In order to refine the MIST mobile intervention, a successive cohort design[11] will be used. Successive cohort design utilizes an iterative process for by which psychosocial treatments in the early stages of development are systematically refined and modified. Qualitative and quantitative data collected by providing the treatment to these small

cohorts is used to inform these revisions. Accordingly, we will be refining the treatment approach with two successive cohorts of *n*= 5 Veterans with problematic anger, and elevated suicide risk. After the first cohort uses the application, a qualitative and quantitative evaluation will be conducted. Revisions will then be made based on these evaluations before another cohort of *n* = 5 Veterans is treated. Again, following treatment an evaluation will be completed and further revisions will be made to the treatment. This same method was used successfully to develop the MARI app.

Following completion of the second cohort, we will be testing a third cohort (*n*=4) using the web-based version of the MIST intervention delivered via Qualtrics. This intervention will include the same MIST treatment scenarios and EMA questionnaires delivered via Qualtrics links directly to the Veterans' phones.

Procedures: All study procedures can be completed remotely using video conferencing services and mailings to minimize potential COVID-19 exposure. Participant will provide informed consent and HIPAA authorization via mail or with DocuSign where available. At an initial assessment, after establishing that they meet study criteria, they will complete a battery of baseline self-report questionnaires. They will then be instructed on how to complete the MIST treatment sessions and diary entries via their phone through Qualtrics. Four weeks later, each participant will complete a post-MIST interview during which they will provide detailed feedback on their experience using the MIST intervention and some self-report questionnaires. These semi-structured interviews will assess how helpful they found the intervention. They will be asked to elaborate upon what aspects of the intervention they think are most and least helpful and to provide suggestions on how it could be improved. They will also be shown a list of 100 random MIST treatment scenarios and asked to provide feedback and suggestions on the content and wording of these scenarios.

They will then be instructed to complete the MARI treatment sessions and diary entries via Qualtrics for another period of four weeks.

Following the completion of each cohort, quantitative and qualitative data will be analyzed. Based upon results, the intervention structure and content will be revised. The content that will be subject to revisions includes IBM content (e.g., topics and themes of scenarios). After the final cohort is completed, the MIST intervention will be finalized.

Measures: The following self-report measures will be administered at pre-treatment, post-MIST, and post-MARI assessments: *suicide cognitions* will be assessed with the Suicide Cognitions Scale[4], Beck Hopelessness Scale[12], Interpersonal Needs Questionnaire[13]; *hostile interpretation bias* will be assessed with the Word Sentence Association Paradigm-Hostility[14]; *suicide risk* will be assessed with the C-SSRS[15] and the Beck Scale for Suicidal Ideation; *anger* will be assessed with the Dimensions of Anger Reactions[16]; *functioning and quality of life* will be assessed with the Brief Inventory of Psychosocial Functioning (IPF)[17] and WHOQOL-BREF[18]. Participants will also complete the PTSD Checklist for DSM-5, the Patient Health Questionnaire-9, and a

brief questionnaire to assess their self-efficacy at managing suicidal thoughts and anger. On a 1-5 Likert scale they will be asked to rate: “how confident are you with your ability to cope with suicidal thoughts?” and “how confident are you with your ability to cope with anger?”. At the post-MIST and post-MIRA assessments, they will complete the Client Satisfaction Questionnaire.

EMA assessments will also be conducted for the duration of the time that participants are engaged in the MIST and MARI interventions (8 weeks). There will be one random alarm-prompted diary entry during the day and a nightly diary using established procedures from our team.[19,20] The EMA diary will include assessments of: *suicidal ideation*; and *functioning and health related quality of life* using the brief IPF[21] and items from the WHOQOL-BREF[18]. EMA entries will also ask about affect and alcohol and substance use.

Demographics and Background Measures	Time (min)	Baseline	Post-MIST	Post-MIRA
Demographics	2	●		
Traumatic Life Events Questionnaire (TLEQ)	10	●		
Diagnostic Interviews				
Structured Clinical Interview for DSM-5	60	●		
Feasibility and Acceptability Measures				
Participant Recruitment	--	●		
Treatment Retention	--		●	●
Withdrawals	--	●	●	●
App Utilization	--		●	●
Client Satisfaction Questionnaire (CSQ)	5		●	●
Post-MIST Interview	30		●	
Clinical Measures				
Interpersonal Needs Questionnaire (INQ)	5	●	●	●
Suicide Cognitions Scale (SCS)	5	●	●	●
Beck Hopelessness Scale	5	●	●	●
Word Sentence Association Paradigm-Hostility (WSAP-H)	10	●	●	●
Columbia-Suicide Severity Rating Scale	5	●	●	●
Beck Scale for Suicide Ideation	5	●	●	●
Dimensions of Anger Reactions (DAR)	5	●	●	●
Brief Inventory of Psychosocial Functioning	5	●	●	●
WHOQOL-BREF	5	●	●	●
Patient Health Questionnaire-9 (PHQ-9)	5	●	●	●
PTSD Checklist for DSM-5 (PCL-5)	10	●	●	●

Mobile Device Use

Study participants will access the MIST, MARI, and EMA interventions and assessments using their personal mobile devices. They will receive Qualtrics links to access the treatment sessions and EMA diary entries. These data will be collected via the VA instance of Qualtrics.

Risk/Benefit Assessment

Participation is completely voluntary and participants are informed that they are free to refuse to answer any items on the questionnaires or questions from the interview that they do not wish to answer. They are also informed that they are free to decline participation in any procedure and can withdraw from the study at any time. Regarding qualitative data, participants will be informed that all published results will be anonymized, including any mention of city/medical center/clinic to protect the identity of participants.

Potential risks will be minimized by carefully screening potential participants according to the inclusion/exclusion criteria, closely monitoring symptom levels, and following established laboratory procedures. To ensure confidentiality, all records will be identified by the participant's identification number, not by name. All raw hard copy data will be kept in a locked file cabinet in a locked room. Data files will be stored on secure, password-protected computers. Finally, all project staff will complete educational units required by the Durham VAHCS IRB.

While participants may benefit from using the mobile intervention, there are no guaranteed benefits to the individual participant and no immediate benefits of the proposed research to others. There are potential benefits to others from the information generated that potentially will be helpful in increasing reach of treatments to target suicidal ideation and anger and developing more effective interventions for Veterans with suicidal ideation, PTSD, and problematic anger. In our opinion, the anticipated benefits of this study outweigh the potential risks.

Selection of Subjects
We will screen up to 30 participants for the project for a desired total sample size of 14.

Inclusion/Exclusion Criteria	
Veterans must meet **all** inclusion criteria:	Veterans who meet **any** one of the exclusion criteria will be excluded:
• Report a score of ≥12 on the 5-item Dimensions of Anger Reactions Scale • Can read at least 6th grade level material • Report a score of 1-3 (indicating ideation without intent) on the Columbia-Suicide Severity Rating Scale (C-SSRS) • Are engaged in mental health treatment and regularly attending appointments with a provider (e.g., therapy, counseling, medication management) at least every 3 months.	• Currently in a period of active psychosis or mania. • Current moderate or severe alcohol or substance use disorder, established *via* SCID-5* • Current imminent suicide risk or homicidal ideation requiring immediate intervention.

* SCID-5 interviews will be administered by trained lab personnel who have been trained using standardized training, which consists of review of interview manuals,

training videotapes, and co-rating training with an experienced rater. Across previous studies, interrater reliability based on videotapes of participant interviews has been excellent (kappa = .96).

Subject Recruitment

Participants will be recruited using a Data Access Request Tracker (DART) request to identify Veterans with PTSD diagnoses from Regional and/or Corporate Data Warehouse. Potential participants will be sent an introductory letter that describes the study and informs them that they will be called regarding participation. In the letter, potential participants will be given an "opt-out" number to call in order to decline participation and/or further contact regarding participation. Seven business days after the mailing, Veterans who have not called the toll-free number to decline participation will be contacted by a study team member to request their participation in the research study.

We will also recruit veterans from the Traumatic Stress and Health Laboratory's "Contact Database," IRB #1080; this database contains information about previous lab study participants who have agreed to be contacted about other studies for which they may qualify.

Clinicians in clinics throughout the medical center will be provided information about study eligibility and basic procedures (see brochure), and will be asked to refer potentially eligible veterans. Clinicians have reported that Veterans often indicate that they prefer that their names and contact information be provided directly to study staff. We'd like to make it easy for interested Veterans to get involved in research, while protecting the privacy of those Veterans who are not interested in research. Towards that end, we would like to allow a clinician to refer a participant directly to our clinic by adding the study PI or study coordinator as a co-signer to a note in CPRS in which the clinician has documented that the participant wishes to be contacted about participation.

Any Veteran who contacts or is contacted by the study team will be told that their participation is voluntary, and they may choose not to answer any questions that they find too sensitive. Also, Veterans will be told that their participation will not affect their care at the VA. The study team member will explain the study in detail, including compensation. No study procedures will begin until formal, written informed consent and HIPAA authorization have been obtained.

Study Interventions

Two interventions will be studied in the current project, the MARI and the MIST interventions. The MARI intervention has already been developed by Dr. Dillon (IRB # 2168). The MIST intervention is going to be developed in a similar manner. The interventions will be very similar except for the content of the treatment sessions. Below, we explain the layout of the MARI intervention and then the changes that will be made for the MIST intervention.

MARI Intervention.

The IBM intervention. The IBM treatment works as follows (see Figure 6). Participants are shown ambiguous, anger-relevant scenarios and instructed to imagine themselves in the described situation. For example, "You speak to someone and they do not respond." Next, another sentence appears that offers a benign, non-threatening interpretation of the scenario. For example, the sentence following this particular scenario reads, "This person is unaw_re." The participants fill in the missing letter of the word, forming the word "unaware," and assigning the benign interpretation. This interpretation is then reinforced by requiring the participants to correctly answer "yes" or "no" to a comprehension question (i.e., "Did this person hear you?"). In this example, they must answer "no" to proceed. Across treatment sessions, unique scenarios are presented (i.e., participants do not see the same scenario twice). Scenarios have been developed to capture a wide range of different themes that are likely to be anger-provoking. Themes include: physical aggression, driving situations, irritating traits of others, thinking you are being ignored by others, feeling argued with or criticized, thinking someone is stealing from you, having people block you, thinking that others have hostile feelings, feeling disrespected, thinking that people will not help you, thinking that others do not appreciate you, and thinking that situations are unfair. See Figure 7 for an example of a training scenario in the MARI app.

Figure 6. *IBM Intervention*

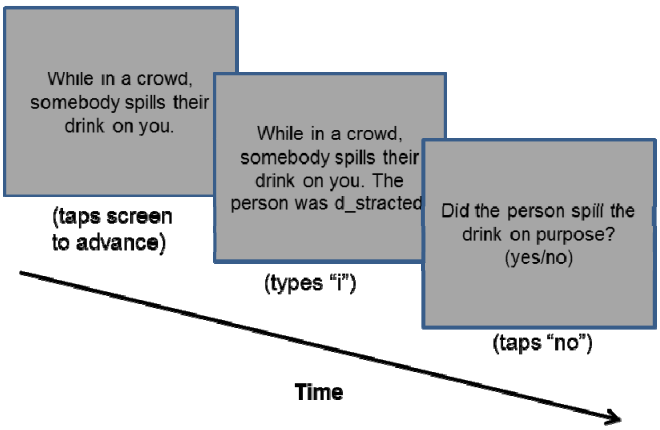
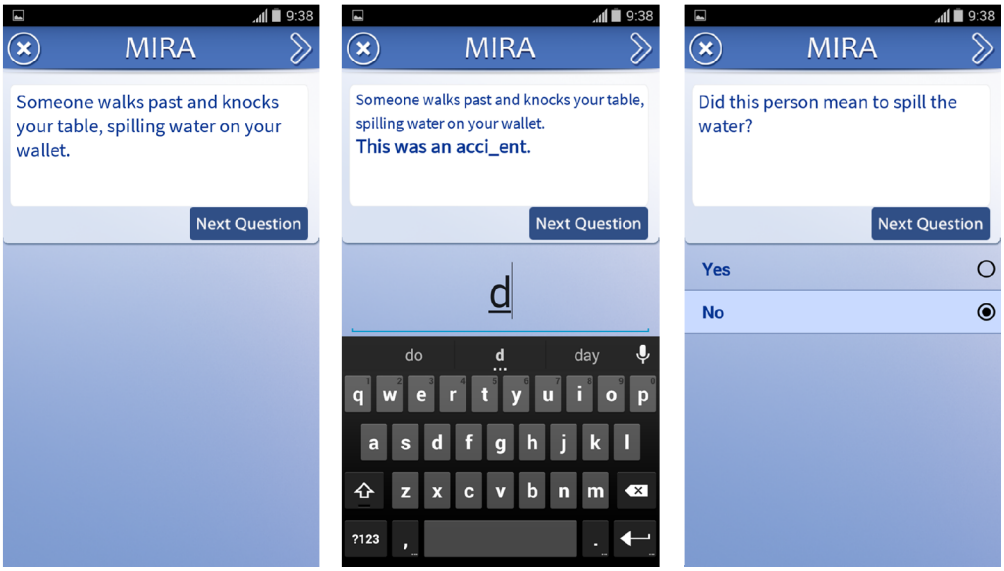


Figure 7. *Example of a Training Scenario in MIRA App*



We will be delivering the intervention daily for 4 weeks. It will include 28 treatments sessions that will each take approximately 10 minutes to complete. Each session will include 42 training scenarios. No scenario will be repeated across these sessions. To this end, 1,176 unique training scenarios have been developed. Scenarios have been reviewed by 9 PTSD experts in the field and

individuals with PTSD to confirm the content is relevant to this patient population. Additionally, the reading level has been assessed using an online readability calculator ("Readability Formulas") and all scenarios are at a 6th grade reading level or less. Qualtrics will time stamp use by the participants so that treatment time and completion for each participant can be calculated.

MIST Intervention

The MIST intervention will be identical to the MARI intervention. The only difference is that the treatment sessions will include the scenarios that are being developed (see Design section) to target suicide cognitions. For example, "You make a mistake." Next, another sentence appears that offers a resolution to the scenario that is incompatible with the suicide cognition being targeted (in this example, unsolvability). The sentence following this particular scenario reads, "It can be fi_ed." The participants fill in the missing letter of the word, forming the word "fixed," and resolving the scenario in a way to change the targeted suicidal cognition. This is then reinforced by requiring the participants to correctly answer "yes" or "no" to a comprehension question (i.e., "Are things permanently damaged?"). In this example, they must answer "no" to proceed.

Staff Readiness to Handle Potential Disruptive Behavior

Principal investigators in the Traumatic Stress and Health Research Laboratory have been working with Veterans with PTSD since the mid-1990s, and much of their clinical and research work has involved providing anger interventions to these Veterans. Our laboratory currently has three other studies in which we provide anger interventions to Veterans with PTSD (IRB #s 1731, 2063, and 2168). Over the course of those studies, we have not had any need to report any disruptive behaviors or contact VA police. Dr. Dillon, recently completed a pilot study of the computer-based hostile interpretation bias intervention (IRB # 2136) and is currently conducting another study of the mobile hostile interpretation bias intervention (IRB # 2168). She has not had any Veterans express anger regarding the intervention.

Senior staff members are well trained in utilization of counseling techniques such as active listening, which helps to minimize the likelihood of angry outbursts. Study staff members are asked to attend levels 2 and 3 of the VA's Prevention and Management of Disruptive Behavior (PMDB) training, which is the VA's workplace violence prevention program. This level of training is the highest offered to VA employees in outpatient settings. Finally, office areas that are used for clinical interventions, interviews, etc. are equipped with panic alarms, and staff are trained in how/when to use the alarms.

Costs and/or Payments to Subjects

The study involves up to three visits. Participants who are screened and found ineligible for the study will receive $40 for their time. Eligible participants will receive $100 for completing the first visit, $50 for completing the post-MIST visit, $25 for providing feedback on the 100 MIST scenarios, and $50 for completing the post-MIRA visit. They will also be paid for completing the EMA monitoring for the 8-week duration of the study.

They will receive $30 for each week that they do the EMA monitoring (8 weeks total) plus a $20 compliance bonus each week that they complete at least 2/3rds of the prompted diaries. Participants can receive up to $625 for completion of the study.

Data and Safety Monitoring
The PI and study staff will be responsible for data safety and monitoring. There will be several ongoing mechanisms for monitoring and reporting of AEs: 1) ongoing participant contact via study personnel, 2) a toll-free number provided to participants to report concerns related to study participation; 3) weekly meetings between the PIs and study personnel. Study-related serious adverse events (SAEs) for participants in this project are not expected, but should they occur, they will be reported to the Durham VA Health Care System Institutional Review Board in accordance with local human protections program guidelines.

The PI will meet at least weekly with study personnel to discuss participants' reactions to the intervention, proper delivery of the intervention, and any adverse events or unanticipated problems. Monthly meetings between the investigators and the project manager will allow for ongoing progress reports, including the number of participants currently involved in the study, attrition rates, and scheduled data collection from participants, as well as notification and review of any AEs. Safety monitoring for AEs will be conducted in real time by the PI and/or project manager. The following information about adverse events will be collected: 1) the onset and resolution of the AE, 2) an assessment of the severity or intensity (use existing grading scales whenever possible), 3) an assessment of the relationship of the event to the study (definitely, probably, possibly or not related), and 4) action taken (e.g., none, referral to physician, start or increase concomitant medication). The PI will determine the severity of the event, will assign attribution to the event, and will monitor the event until its resolution. Any adverse events will be reported to the IRB in accordance with the local Human Research Protection Program's Standards of Practice. All research projects conducted at the Durham VAHCS are required to have yearly IRB review. Reports of non-serious AEs are required as part of these progress reports. Additionally, any changes to the project between review periods must be application by the IRB prior to fielding.

Withdrawal of Participants
The PI may withdraw participants due to inability, or unwillingness, to complete study procedures or attend appointments.

COVID-19 Temporary Study Procedures
The informed consent process will occur over the phone or via an approved telehealth platform. Potential participants will be mailed the consent and HIPAA authorization, and a study staff member will call them to discuss the consent and HIPAA. Participants will be asked to return the signed consents by mail/UPS.

Study visits will be completed via an approved telehealth platform, with phone as a back-up measure. If the study staff member has access to Audacity via CAG,he/she/they will record the interviews (think-aloud and post-treatment qualitative

interview) directly to the VA secured server (in lieu of videorecording with an external device). If telehealth visits are done using VA's instance of WebEx, audiorecordings will be done to the VA WebEx cloud and moved as soon as possible to the VA secured server. Questionnaires will be completed orally, by mail, and/or via MyHealthyVet.

We would like to ask participants to complete measures related to stress, trauma, and coping strategies during the pandemic. New participants will complete these measures at their first visit, and ongoing participants will complete them at their next study visit. We are adding the CAIR Pandemic Impact Questionnaire (Lang, 2020; https://www.nlm.nih.gov/dr2/CAIR-PIQ_scoring.pdf), and another measure, COVID Core Questions, with variables of interest. If a participant endorses any item marked with an asterisk on the COVID Core Questions measure, we will ask them to complete a PTSD Checklist 5 related to that specific event. Because these are temporary measures to be used only during the COVID-19 pandemic, we have not added them to the consent form. Instead, participants will be informed verbally re: the measures, and will be told that they can refuse to answer them.

Safety Concerns. Study therapists will be informed that prior to beginning interviews participants will need to identify an emergency contact for the participant to be used only in true emergencies (e.g., medical crisis, high risk suicidal ideation). If any participant expresses suicidal or homicidal ideation (SI and HI, respectively), study staff will respond using a standard of practice that has been used successfully in our lab's past telehealth-based trials. The study staff member responsible for the call will be instructed to gather more information from the participant, including information about plan, means, intent, intended victim (in the case of HI) and history of suicidal and homicidal behavior. Any participant who expressed SI will be provided with the suicide hotline number. The participant will be informed that the PI may contact him/her to talk more about his/her SI or HI. The study coordinator will obtain current contact information for the participant and inform the PI, who will contact the participant as necessary to ensure participant safety. In cases of imminent homicidality or suicidality, which are not anticipated, we will seek guidance from the Psychiatric Emergency Clinic on best strategies for follow-up, which could include, but is not limited to, self-presentation at the VA's emergency room with the help of an emergency contact, calling 911, or calling local police for a wellness check.

Study Communication. For any participant who indicates that they are willing to receive study communications via email, we will use Azure to send secure communications to them re: appointment scheduling, missed appointments, etc. Content from the study's IRB-approved letters will be included in the emails.

Data Analysis and Statistical Considerations

Rapid turn-around analysis of the qualitative interviews will be conducted according to methods described by Hamilton.[23] Participant impressions of the MIST app, feedback on the content of the scenarios, usability of the app, perceived strengths and weaknesses, and suggestions for improvement will be compiled and used to make modifications to the app content and design.

Recognizing that it is inappropriate to examine efficacy in a small pilot trial, we will focus on feasibility and acceptability objectives.[24] As appropriate for this stage of treatment development and evaluation, analysis and interpretation will focus on describing the primary outcomes: acceptability of the intervention and feasibility of the trial approach. Additionally, although we will not be able to statistically analyze changes in suicide cognitions and hostile interpretation bias, we will describe the changes including whether they were observed in the expected directions.

Data will be analyzed using SAS. In the event that required SAS modules are not available at VINCI, deidentified data will be moved to Duke University Medical Center for analysis. Any data movement outside the protected VA environment will be accomplished using a VA-issued and owned FIPS-140-2 encrypted thumb drive loaned to a VA study staff member. Data will be stored at Duke on a protected server to which only Dr. Dillon and her study staff have access; data are encrypted at rest.

Multilevel modeling (MLM) will be used to analyze the EMA data. MLM is a technique for analyzing repeated observations of data across multiple individuals. Unlike repeated-measures ANOVA, MLM can incorporate time-varying and time-invariant predictors to model between-person differences in within-person relationships. MLM can also accommodate imbalanced data and unequal variances. To examine the association between app use on suicide risk and functioning (Aim 2), three models will be analyzed in which each of the continuous outcome variables recorded during EMA will be modeled *via* MLM during each of the 4-week intervention periods as a function of frequency of app use.

Privacy, Confidentiality, and Information Security

1. Lists of Data Reviewed and/or Collected for Screening/Recruitment and Conduction of Study:

The Personal Health Information that will be obtained, used, and/or shared for this study includes:

Identifier(s)	Source(s) of Health Information
☒ Names	☐ Medical history & physical exam information
☒ All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code. Describe: Participants' addresses will be collected during the study in order to pay them for participation.	☒ Photographs, videotapes, audiotapes, or digital or other images
☒ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, visit or treatment dates, etc.; and all ages over 89, Describe: Date of participation will be collected. In addition, treatment records, laboratory results, etc.	☐ Biologic specimens (e.g., blood, tissue, urine, saliva). Describe:

Identifier(s)	Source(s) of Health Information
will be collected.	
☒ Telephone numbers	☒ Progress notes
☐ Fax numbers	☒ Diagnostic / Laboratory test results
☒ Electronic mail addresses	☐ Operative reports
☒ Social Security Numbers	☐ Imaging (x-ray, CT, MRI, etc.)
☒ Medical record numbers	☐ Discharge summaries
☐ Health plan beneficiary numbers	☒ Survey / Questionnaire responses
☒ Account numbers	☒ Billing records
☐ Certificate and/or license numbers	☐ HIV testing or infection records
☐ Vehicle identifiers and serial numbers, including license plate numbers	☐ Sickle cell anemia information
☐ Device identifiers and serial numbers	☒ Alcoholism or alcohol use information
☐ Web Universal Resource Locators (URLs)	☒ Drug abuse information
☐ Internet Protocol (IP) address numbers	☒ Mental health (not psychotherapy) notes
☐ Biometric identifiers, including finger & voice prints	☐ Psychological test results
☐ Full-face photographic images and any comparable images	☐ Genetic testing
☐ Any other unique identifying number, linked study ID, characteristic, or code, describe:	☐ Other, describe:

2. Data and/or Specimen Acquisition:

Data for this study will be collected through (*check all that apply*):

☒ Prospective data and/or specimen collection obtained from participants. Provide description of processes: Data will be obtained through self-report questionnaires, semi-structured interviews, and app utilization.

☒ Retrospective data collection and/or specimens obtained from medical chart review/data access. Describe how data will be obtained (e.g., fileman, CDW, etc.): In accordance with a Waiver or Alteration of HIPAA Authorization, names, addresses, telephone numbers, social security numbers, and diagnostic information of potential participants will be obtained from the VA's Regional Data Warehouse.

☐ Retrospective data collection and/or specimens obtained from an IRB-approved data and/or specimen repository. Indicate the repository source including name, VA location, and IRB number: .

Note: for data and/or specimens obtained from a VA approved data repository, a Data Use Agreement (DUA) must be executed prior to obtaining data and/or specimens. See VHA Handbook 1200.12 for further information.

3. Level of Data:

The following level(s) of data will be acquired/maintained for this study (*check all that apply*):

☒ Identified (e.g., names, addresses or other identifiers included)

☒ Coded (direct and/or all identifiers removed, but study code/ID included)
☐ De-Identified (all HIPAA 18 and study ID/code removed):
  ☐ Verified Statistically
    OR
  ☐ Verified by Absence or Removal of HIPAA 18 and study ID
☐ Limited Data Set
☐ Other: Describe:

4. Location of Data and/or Specimens, and Data Retention Plan:

A. Data and/or Specimen Location: Data will be stored electronically in \\VHADURFPC02B\groups1\Nicotine Research\Study Information\Study Logbooks\Kirsten SPRINT and \\VHADURFPC02B\groups1\Nicotine Research\Study Information\Study Databases\Kirsten SPRINT. Data that will be stored electronically include name, address, phone number, social security number, amount of study payment earned, and date of visits (in Study Logbooks location). The study logbook will contain the key connecting PHI and the study identification number. Paper records of data include study consent form and HIPAA authorization (identified), questionnaire responses, and interview notes (coded). Audio recordings will be made using Audacity or WebEx. Any recordings made using WebEx will be transferred from the cloud to the "Study Logbooks" location listed above for long term storage, audio recordings may be moved to an encrypted DVD that is password-protected. Any encrypted DVDs will be stored in a locked filing cabinet in a locked office. Transcriptions from the study interviews will be stored electronically at the Study Logbooks location listed above. Data will also be stored within VA Qualtrics, which is FedRAMP approved for collection and storage of PHI and sensitive information, and has an Authority to Operate (ATO) within VA. Data will be moved from Qualtrics \\VHADURFPC02B\groups1\Nicotine Research\Study Information\Study Databases\Kirsten SPRINT for permanent storage.

☒ Data will be also be placed at the VA Informatics and Computing Interface (VINCI; http://vaww.vinci.med.va.gov/vincicentral/VINCIWorkspace.aspx). The VA Informatics and Computing Infrastructure is a partnership between the VA Office of Information Technology and the Veterans' Health Administration Office of Research and Development. Researchers and operations staff can use VINCI to access data and statistical analysis tools in a virtual working environment through a certified VHA network computer using the VA Intranet or Virtual Private Network (VPN).

B. Data Retention Plan

☒ Research records will be maintained and destroyed according to the National Archives and Records Administration, Records Schedule Number: DAA-0015-2015-0004. Records destruction, when authorized, will be accomplished using the then current requirements for the secure disposal of paper and electronic records. Currently, destruction of research records (see DAA-0015-2015-0004, section 7.6 "Research Investigator Files" for materials included in research records) is scheduled for 6 years after the cut-off (the cut-off is the completion of the research project) and may be retained longer if required by other federal agencies. Records will not be destroyed without pre-notification to the facility records manager.

☐ Other data retention plan, describe:

5. Data Access and Data Recipients: Only members of our DVAMC research team will have access to identifiers and coded data. In order for data analysis to occur using SAS software, a de-identified dataset will be uploaded to VINCI for analysis.

All VA research personnel who have access to VHA records are instructed, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. All study personnel who are VA employees working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. All research staff sign VA Rules of Behavior, and all study staff are up-to-date with VHA Privacy Policy Training and the VA Office of Cyber and Information Security Awareness Training Course. The data security and privacy procedures summarized in that course include logging off or locking the computer when walking away from it; no sharing of access codes, verify codes or passwords; not allowing anyone else to use the computer under one's password; and disposing of sensitive information using VA-approved methods (e.g., shredder bins). Access to study data will be removed for all study personnel when they are no longer part of the research team.

Study visits will either be conducted at the main VA Hospital or at the MIRECC at Croasdaile, based on participant preference and space availability. Data that is transported between the main hospital and Croasdaile offices will be secured in a lockable briefcase.

6. Data and/or Specimen Transportation and/or Transmission for all data and/or specimens involved in the study:

I. ☐ Data and/or specimens will not be transported or transmitted outside of Durham VAMC environment.

II. ☐ Data and/or specimens will be transported BETWEEN sites that are under the auspices of the Durham VA Medical Center.

III. ☐ Data and/or specimens will be transmitted to other VA sites using the following method(s):

A. Data

☐ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted disk (encryption is optional).

☐ Data are coded or contain identifiers and thus will be sent

☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional).

☐ Specimens are coded or contain identifiers and thus will be sent via VA-authorized carrier with tracking.

☐ Other, describe:

IV. ☒ Data and/or specimens will be transported to non-VA/VHA sites (e.g., academic affiliates, laboratories, etc.) using the following method(s):

A. Data

☒ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted CD.
☐ Data are coded or contain identifiers and thus will be sent via <chose method of transfer such as FIPS 140-2 encrypted CD or FIPS 140-2 encrypted hard drive/flash drive> using VA—approved carrier with tracking.
☐ Data are coded or identified and will be uploaded to sponsor website using electronic case report form (eCRF) <insert information including sponsor name and URL and the encryption the site uses.>
☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional) or will be hand-delivered by research study personnel. Specify method of delivery:
☐ Specimens are coded and thus will be sent via VA-approved carrier with tracking or will be hand-delivered by research study personnel. Specify method of delivery:

In accordance with the HIPAA and the Privacy Act, for any coded or identifiable data or specimens released from the Durham VAMC (with the exception of Limited Data Sets), an Accounting of Disclosure (AOD) will be maintained (e.g., in a database or spreadsheet) that includes the participant's name, date of the disclosure, description of the nature of the Individually Identifiable Information (III) disclosed, purpose of each disclosure, and the name and address of the person/agency to whom the disclosure was made.

C. ☐ Local DVAMC memorandum "Authorization to Use, Process, Store, or Transmit VA Sensitive Information Outside VA Owned or Managed Facilities" has been pre-filled out for each study team member who may transport the data and/or specimens off-site. This (these) forms are included with the IRB materials.

D. ☐ Containers (e.g., briefcase, bin) are labeled with the following notice (label placed on the outside of container) in accordance with VHA Directive 6609:

NOTICE!!!
Access to these records is limited to: AUTHORIZED PERSONS ONLY. Information may not be disclosed from this file unless permitted by all applicable legal authorities, which may include the Privacy Act; 38 U.S.C. §§ 5701, 5705, 7332; the Health Insurance Portability and Accountability Act; and regulations implementing those provisions, at 38 C.F.R. §§ 1.460 – 1.599 and 45 C.F.R. Parts 160 and 164. Anyone who discloses information in violation of the above provisions may subject to civil and criminal penalties.

7. Risk Mitigation Strategies:

☒ Data are fully de-identified (stripped of HIPAA 18 and study ID/code) before being shared outside of Durham VAMC.
☐ Specimens are fully de-identified (stripped of HIPAA 18 and study ID/code before being shared outside of Durham VAMC.

☒ Direct identifiers will be maintained separately from data and or specimens by using a code to "identify" subjects. In a separate database (i.e., a "linking" or "cross-walk" database) this code will be linked to identifying subject information.
☐ Other, specify:

8. Suspected Loss of VA Information:
Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported according to VA policy. All incidents regarding information security/privacy incidents will be reported to the ISO and PO within 1 hour of acknowledgement of issue and done so using the VHADUR Research Events Report e-mail group (VHADURResearchEventReport@va.gov).

9. Reporting of Results:
☒ Reporting of results, such as in scientific papers and presentations, will never identify individual subjects. Data will be presented in aggregate and individual-level data will not be published.
☐ Other results reporting plan, describe:

10. Future Use of Data:
☐ Data will be retained for future use. This is described elsewhere in the protocol and is noted in the HIPAA authorization.
- ☐ Future Use of data is optional (i.e., not required by the research subject).
- ☐ Future Use of data is required for participation in the study.

☒ No future use of data is currently planned.

11. Use of Mail Merge Technology
☒ Mail merge programs will be used to generate letters and/or address labels for mailings to potential or already enrolled research subjects. The study team is aware that to reduce risk of mail merge related privacy incidents, use of mail merge programs requires a 25% accuracy check to verify that (potential) research subject name and mailing address are properly "matched". If discrepancies are found, a 100% accuracy check is required before letters may be mailed.

12. Use of Non-Standard Software
☒ I do NOT intend to use any new specialized software (i.e. Software that's not already approved OR installed) in this study.

☐ I intend to use specialized software that has not already been installed and it has been approved for use by the VA Technical Reference Model (TRM) Group.
(Note: All new software must be approved by TRM before it can be installed on VA systems.)

☐ I intend to use previously installed software on my VA computer.

13. Use of Cloud Computing Services

☐ Cloud computing services will NOT be used in this study.

☒ Cloud computing services WILL be used in this study as described below and have been approved nationally by the VA Chief Information Officer (CIO). (Note: ONLY cloud computing services that have been approved nationally may be used.) If telehealth study visits are performed using VA's instance of WebEx, the visits may be audio-recorded to the VA's WebEx cloud, as has been previously approved by VA.

References

1. Rudd, M.D. Fluid Vulnerability Theory: A Cognitive Approach to Understanding the Process of Acute and Chronic Suicide Risk. In: Ellis, T.E., ed. *Cognition and suicide: Theory, research, and therapy*: American Psychological Association; 2006:355–68.
2. O'Connor, R.C., Smyth, R., Ferguson, E., Ryan, C. & Williams, J.M. (2013). Psychological processes and repeat suicidal behavior: a four-year prospective study. *J Consult Clin Psychol,* 81, 1137-43. PMCID: PMC3933214.
3. Chu, C., Buchman-Schmitt, J.M., Stanley, I.H., Hom, M.A., Tucker, R.P., Hagan, C.R., Rogers, M.L., Podlogar, M.C., Chiurliza, B., Ringer, F.B., Michaels, M.S., Patros, C.H.G. & Joiner, T.E. (2017). The interpersonal theory of suicide: A systematic review and meta-analysis of a decade of cross-national research. *Psychol Bull,* 143, 1313-45. PMCID: PMC5730496.
4. Bryan, C.J., David Rudd, M., Wertenberger, E., Etienne, N., Ray-Sannerud, B.N., Morrow, C.E., Peterson, A.L. & Young-McCaughon, S. (2014). Improving the detection and prediction of suicidal behavior among military personnel by measuring suicidal beliefs: an evaluation of the Suicide Cognitions Scale. *J Affect Disord,* 159, 15-22.
5. Bryan, C.J., Rozek, D.C. & Khazem, L.R. (2020). Prospective Validity of the Suicide Cognitions Scale Among Acutely Suicidal Military Personnel Seeking Unscheduled Psychiatric Intervention. *Crisis,* 41, 407-11.
6. Bryan, C.J.H., J. A. (2019). The Structure of Suicidal Beliefs: A Bifactor Analysis of the Suicide Cognitions Scale. *Cognitive Therapy and Research,* 43, 335-44.
7. Dillon, K.H., Van Voorhees, E.E. & Elbogen, E.B. (2020). Associations between anger and suicidal ideation and attempts: A prospective study using the National Epidemiologic Survey on Alcohol and Related Conditions. *J Psychiatr Res,* 122, 17-21. PMCID: PMC7010536.
8. Wilks, C.R., Morland, L.A., Dillon, K.H., Mackintosh, M.A., Blakey, S.M., Wagner, H.R., Workgroup, V.A.M.-A.M. & Elbogen, E.B. (2019). Anger, social support, and suicide risk in U.S. military veterans. *J Psychiatr Res,* 109, 139-44.
9. Hawkins, K.A. & Cougle, J.R. (2013). A test of the unique and interactive roles of anger experience and expression in suicidality: Findings from a population-based study. *The Journal of Nervous and Mental Disease,* 201, 959-63.
10. Menne-Lothmann, C., Viechtbauer, W., Höhn, P., Kasanova, Z., Haller, S.P., Drukker, M., van Os, J., Wichers, M. & Lau, J.Y. (2014). How to boost positive interpretations? A meta-analysis of the effectiveness of cognitive bias modification for interpretation. *PloS One,* 9, e100925.
11. Epstein, E.E., McCrady, B.S., Morgan, T.J., Cook, S.M., Kugler, G. & Ziedonis, D. (2007). The successive cohort design: A model for developing new behavioral therapies for drug use disorders, and application to behavioral couple treatment. *Addictive Disorders & Their Treatment,* 6, 1-19.
12. Beck, A.T., Steer, R.A. (1993). *Manual for the Beck Hopelessness Scale*. San Antonio, TX: Psychological Corporation.

13. Van Orden, K.A., Cukrowicz, K.C., Witte, T.K. & Joiner, T.E. (2012). Thwarted belongingness and perceived burdensomeness: construct validity and psychometric properties of the Interpersonal Needs Questionnaire. *Psychol Assess,* 24, 197-215. PMCID: PMC3377972.
14. Dillon, K.H., Allan, N.P., Cougle, J.R. & Fincham, F.D. (2016). Measuring hostile interpretation bias: the WSAP-hostility scale. *Assessment,* 23, 707-19.
15. Posner, K., Brent, D., Lucas, C., Gould, M., Stanley, B., Brown, G., ... & Mann, J. . (2008). *Columbia-suicide severity rating scale (C-SSRS)*. New York, NY: Columbia University Medical Center.
16. Novaco, R.W. (1975). Dimensions of Anger Reactions. *Irvine, CA: University of California*.
17. Bovin, M.J., Black, S.K., Rodriguez, P., Lunney, C.A., Kleiman, S.E., Weathers, F.W., Schnurr, P.P., Spira, J., Keane, T.M. & Marx, B.P. (2018). Development and validation of a measure of PTSD-related psychosocial functional impairment: The Inventory of Psychosocial Functioning. *Psychol Serv,* 15, 216-29.
18. Group, W. (1998). Development of the World Health Organization WHOQOL-BREF quality of life assessment. The WHOQOL Group. *Psychol Med,* 28, 551-8.
19. Dillon, K.H., Glenn, J.J., Dennis, P.A., LoSavio, S.T., Cassiello-Robbins, C., Gromatsky, M.A., Beckham, J.C., Calhoun, P.S. & Kimbrel, N.A. (2021). Anger precedes and predicts nonsuicidal self-injury in veterans: Findings from an ecological momentary assessment study. *J Psychiatr Res,* 135, 47-51.
20. Beckham, J.C., Calhoun, P.S., Dennis, M.F., Wilson, S.M. & Dedert, E.A. (2013). Predictors of lapse in first week of smoking abstinence in PTSD and non-PTSD smokers. *Nicotine Tob Res,* 15, 1122-9. PMCID: PMC3646653.
21. Kleiman, S.E., Bovin, M.J., Black, S.K., Rodriguez, P., Brown, L.G., Brown, M.E., Lunney, C.A., Weathers, F.W., Schnurr, P.P., Spira, J., Keane, T.M. & Marx, B.P. (2020). Psychometric properties of a brief measure of posttraumatic stress disorder-related impairment: The Brief Inventory of Psychosocial Functioning. *Psychol Serv,* 17, 187-94.
22. Lewis, Z.H., Swartz, M.C. & Lyons, E.J. (2016). What's the point?: a review of reward systems implemented in gamification interventions. *Games for Health Journal,* 5, 93-99.
23. Hamilton, A. Qualitative methods in rapid turn-around health services research. *VA HSR&D National Cyberseminar Series: Spotlight on Women's Health* 2013.
24. Leon, A.C., Davis, L.L. & Kraemer, H.C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research,* 45, 626-29.