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Abstract

Objectives

Impaired executive function, such as impaired decision making and impulsivity, has been identified as an important contributor to the transition from suicidal ideation to suicide attempt. To address the epidemic of Veteran suicide in the United States, we propose to test the feasibility, acceptability, and preliminary effectiveness of a five day transcranial direct current stimulation (tDCS) augmented executive functioning training intervention. This intervention will be delivered to inpatients who have been admitted to the 1K psychiatric unit and deemed to be at hightened suicide risk. The ultimate goal is to reduce future suicide events (ideation, attempts, deaths) and improve quality of life (e.g. social relationships, health resource utilization).

Research Plan and Methods

We propose to test feasibility and acceptability of a five day intervention of ten sessions of tDCS augmented executive function training in a high suicide risk population: Veterans admitted to the 1K psychiatric unit and deemed to be at hightened suicide risk. Inpatients have the highest risk of suicide attempts within the initial weeks following discharge with 50% occurring within 12 weeks of discharge. This suggests that the time prior to hospital discharge could be a critical intervention period. Thirty-eight Veteran inpatients in the 1K Psychiatric unit will be recruited. The five day intervention will be delivered during inpatient stay, prior to discharge. We will collect measures representing multiple domains related to suicidal ideation and behavior, including executive function cognitive performance, and self-report measures of impulsivity, suicidal ideation and behavior, and help seeking. These measures will also be collected at 1 month and 2 months following discharge. Additionally, we will collect longitudinal and daily real-time data on help-seeking, suicide risk, and related factors in the month after discharge using Ecological Momentary Assessment (EMA) and a wearable activity tracker.

Clinical Relevance

Reducing Veteran suicide has been the top clinical priority of the VA for the last few years. However, the total number of suicides among Veterans has continued to increase. There is a critical need for targeted treatments to reduce the risk of suicide in Veterans. Previous research has shown that the transition from inpatient to outpatient care, including the four weeks after discharge from inpatient care is one of the highest risk periods. The low cost, simplicity, and safety of this intervention makes it easy to deliver and scale to clinical settings. If this pilot trial is successful, it would set the stage for a larger trial to test the effectiveness of this intervention for reducing suicide events in a high suicide risk population, and help guide future rehabilitative and treatment approaches.

Background and Significance

Suicide is the tenth leading cause of death overall in the United States, claiming the lives of over 47,000 people per year (Hedegaard et al., 2018). Veterans are particularly vulnerable; the suicide rate for Veterans is 1.5 times the rate for non-veteran adults (VA Office of Mental Health and Suicide Prevention, 2019). Additionally, 10 to 20 times more individuals engage in non-fatal suicidal acts, currently the most predictive risk factor for non-fatal suicide repetition, and for a subsequent completed attempt (Beghi et al., 2013). Suicide continues to rise despite extensive prevention efforts, pointing to the need for new intervention approaches.

Understanding the transition from suicidal ideation to suicidal attempt is critical for developing new interventions. Progress towards more effective suicide prevention is hindered by inadequate knowledge about the transition from suicidal ideation to attempts. The distinction between those who ideate but do not move to action and those who attempt suicide is critical because most individuals with suicidal ideation do not attempt suicide (E. D. Klonsky et al., 2018). Three main theories attempt to characterize the ideation-to-action pathway: Joiner's Interpersonal Theory of Suicide (Van Orden et al., 2010), Klonsky and May's Three-Step Theory (D. E. Klonsky & May, 2015), and O'Connor's Integrated Motivational- Volitional model (IMV) (O'Connor & Kirtley, 2018).

The Interpersonal Theory (Van Orden et al., 2010) posits that exposure to painful and provocative events (PPEs) can lead to habituation to the fear and pain involved in self-inflicted violence, thereby "acquiring" the capability for enacting suicide. PPEs include events such as childhood maltreatment, physical abuse, combat exposure, impulsivity, and previous suicide attempts. The Three-Step Theory incorporates this acquired factor, and proposes two additional categories of variables that contribute to suicide capacity: practical and dispositional (D. E. Klonsky & May, 2015). Practical factors are related to situations such as an individual having knowledge of and access to lethal means, such as a firearm (D. E. Klonsky & May, 2015). Dispositional refers to relevant variables that are driven largely by genetics, such as pain sensitivity (Young et al., 2012), blood phobia (Czajkowski et al., 2011), or impulsivity (Khadka et al., 2014). Finally, the IMV model posits that factors called volitional moderators support the transition from suicidal ideation to suicidal behavior (see **Figure 1**). Volitional moderators include: 1) access to lethal means, 2) planning, 3) impulsivity, 4) fearlessness about death, 5) mental imagery, 6) increased physical pain tolerance, 7) exposure to suicidal behavior and 8) past suicidal behavior (O'Connor & Kirtley, 2018). In the five day intervention window of our proposal, there is little that can be done to alter items 4-8 (yellow and red outlines in Figure 1). Access to means and planning are routinely addressed with firearms assessments and safety planning respectively. This leaves the moderator Executive Function as a potential target for intervention for reducing the transition from suicidal ideation to attempt.

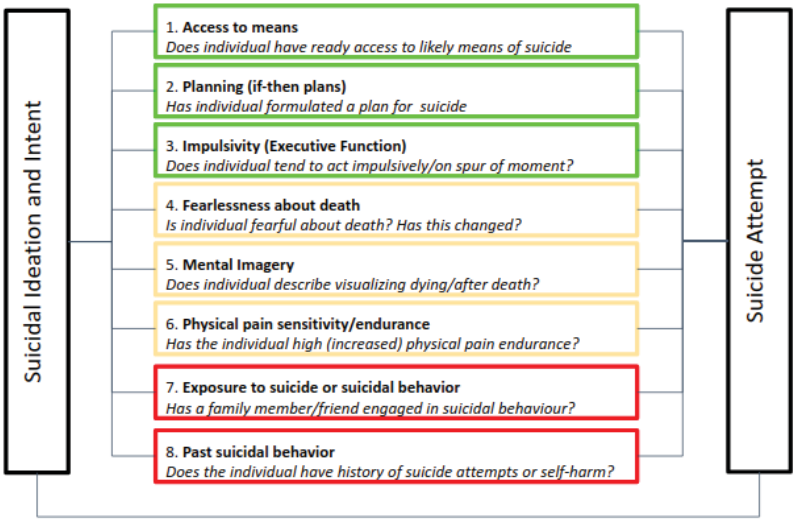


Figure 1. Moderators from Suicidal Ideation to Suicide Attempt from IMV model (adapted from O'Connor & Kirtley, 2018).

Impaired executive function is found in suicide attempters. In the seminal paper formulating the stress-diathesis model, Mann et al. (1999) observed that greater impulsivity and impaired decision making may underlie a generalized propensity to suicidal behavior, and that impulsivity assessment may prove to be more sensitive to predicting suicidal risk than a clinical history. There is evidence that suicide attempters show impaired executive function (Fernández-Sevillano et al., 2021), with impaired performance on tests of cognitive control (Raust et al., 2007), poor problem solving (Pollock & Williams, 2004), and reward/punishment based

learning (Dombrovski et al., 2010), suggesting a deficit in cognitive abilities mediated by frontal cortical brain activity (Raust et al., 2007). Saffer and Klonsky (2017) found that individuals with past-year suicide attempts reported worse executive functioning than those with past-year suicide ideation; a relationship that remained robust after controlling for participant reports of depression, self-efficacy, drug use, or brain injury. Taken together, these results suggest executive function as a potential treatment target. We propose to combine two existing interventions, executive function training and tDCS, to improve executive function.

Combined effects of cognitive training and transcranial direct current stimulation. Cognitive training has been shown to be an effective intervention that improves the core executive functions of inhibitory control (Spierer et al., 2013), working memory (Klingberg, 2010), and cognitive flexibility (Karbach & Kray, 2009). tDCS is a safe, non-invasive brain stimulation technique that applies small amounts of direct current (e.g. 2 mA) to the scalp. tDCS acts through the modulation of cortical excitability and has been demonstrated to have effects on brain networks, behavior, cognition, and learning (Brunelin et al., 2012; V. P. Clark et al., 2012; Fritsch et al., 2010). A growing consensus suggests that tDCS can preferentially enhance ongoing synaptic activity, such as that activated by task performance (Kronberg et al., 2019), in a Hebbian fashion. To improve synaptic efficacy of circuits relevant to executive function, we propose the performance of cognitive exercises during tDCS stimulation.

Higher executive functioning is associated with better quality of life. With regard to functional outcomes and quality of life, evidence shows that executive functions are crucial for success in getting and keeping a job (Bailey, 2007), marital harmony (Eakin et al., 2004), making and keeping friends (Hughes & Dunn, 1998), staying out of jail (Moffitt et al., 2011), and resisting substance abuse (Miller et al., 2011). Conversely, lower quality of life has been associated with higher impulsivity, set-shifting impairment, and impaired decision-making (Chamberlain & Grant, 2019), executive function impairments associated with suicidal behavior. Indeed, lower quality of life (e.g. physical health, psychological health, social relationships, environment) is associated with suicide ideation and attempt (Min & Min, 2015). Two studies (Pien et al., 2016; Wang et al., 2013) following patients receiving follow-up care from hospital suicide prevention programs after a suicide attempt found reduced quality of life reports in those patients who reattempted suicide within 3 months compared with those who did not reattempt (the non-reattempters actually showed higher quality of life scores at followup compared to baseline (Pien et al., 2016)). One study (Marceau et al., 2017) reported the success of a cognitive training intervention incorporating exercises that involved a range of cognitive skills. This cognitive training intervention (twelve 2-hour group sessions across 4 weeks) was administered to a group of inpatients in a women's residential substance use disorder treatment facility (n=23). The cognitive training group showed significantly improved performance on an inhibition task, self-regulation (i.e., impulsivity and self-control), and quality of life post-intervention relative to a treatment as usual group (n=27). These results are promising for the success of an inpatient cognitive training intervention on improving executive function and quality of life, but suggest the need for an accelerated protocol in inpatient environments with shorter stays. In this proposal we use proven executive function training approaches combined with tDCS to enhance brain plasticity and accelerate learning. Additionally, existing research on quality of life relies heavily on retrospective and cross-sectional methods. Given that help-seeking and suicide risk can fluctuate on a daily basis, Ecological Momentary Assessment (EMA) approaches are needed to identify novel ways to increase help-seeking and decrease suicide risk (Sedano-Capdevila et al., 2021). To address this gap, the current study will collect longitudinal and daily real-time EMA data on help-seeking, suicide risk, and related factors after discharge.

In summary, suicide continues to rise despite extensive prevention efforts, pointing to the need for new intervention approaches. Models of suicide intention-to-action and clinical studies point to impaired executive function as an important contributor to the transition from suicidal ideation to suicide attempt. This makes executive function a potential treatment target. We propose to combine two existing interventions, executive function training and tDCS, to improve executive function and quality of life.

Specific Aims

Aim 1: Determine feasibility and acceptability of the tDCS augmented executive function training intervention. Feedback will be obtained from patients and clinical staff through questionnaires, interviews, and debriefs to examine their experience and satisfaction with the intervention and study methods. We will also use participants' performance data to assess engagement with, and ease of use of, the training exercises.
Aim 2: Assess preliminary effects of the intervention on 1) the behavioral treatment target of executive functioning, and 2) reduction in suicide events (ideation, attempts, deaths) and improvement in quality of life. Variability and precision estimates (95% confidence intervals) will be calculated.
Aim 3: Explore between- and within-person variability of cognitive factors (executive function task performance), help-seeking, and suicidal thinking and behavior in the one month post-discharge via in-person visits and daily Ecological Momentary Assessment (EMA).
Aim 4 (exploratory): Explore potential biomarkers of responsiveness to the intervention by collecting resting state electroencephalography (EEG) at pre- and post-intervention in-person visits and at the 1-month and 2-month follow-up. We will examine changes in brain activity measures such as frontal theta-band frequency EEG power - index of reduced impulsivity - from baseline to post-intervention assessments.

Research Design and Methods

This study will be a double-blind, randomized, placebo (sham) controlled feasibility study (see **Figure 2**). Thirty-eight Veteran inpatients in the 1K Psychiatric unit will be recruited. Each participant will be randomly assigned to receive either active or sham tDCS, both paired with executive function cognitive training tasks. Training/tDCS sessions will occur twice a day for five days, for a total of 10 sessions. tDCS (2mA current), with anode over left prefrontal cortex and cathode over right prefrontal cortex, will be applied concurrently with cognitive training. Training/tDCS sessions last approx. 45 min, with tDCS applied during the first 20 min of training. We will collect measures representing multiple domains related to suicidal ideation and behavior, including executive function cognitive performance, resting and stimulus-induced brain activity, and self-report measures of impulsivity, suicidal ideation and behavior, and help seeking. These measures will be collected during their inpatient stay, as well as at the 1 and 2 month followup visits. Additionally, EMA will be collected three times daily for one month following discharge, and participants will also be given a wearable activity tracker.

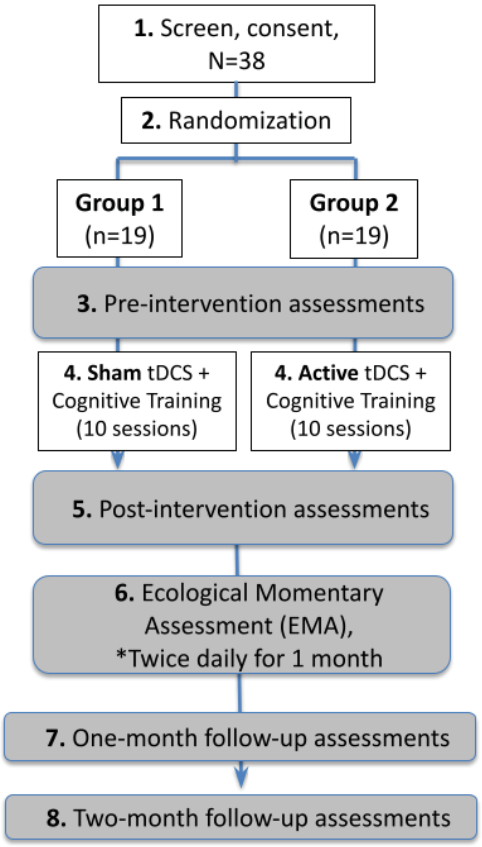


Figure 2. Consort diagram detailing study design

Safety of the intervention will be assessed using a treatment side effect questionnaire collected after each treatment session. Our safety criteria will be that there are no more than moderate side effects in the active tDCS condition (Brunoni et al., 2011). Feasibility and acceptability will be demonstrated by 1) successful recruitment of 15 participants per year into the study, 2) a retention rate of 80% at the two month follow-up assessment, 3) 70% of subjects tolerating the intervention (able to complete ⅔ of treatment sessions), and 4) 70% of subjects completing at least ⅔ of the twice-daily EMA surveys. Outcome measures will compare changes in executive function (e.g. impulsivity), clinical symptomatology (e.g. suicidal ideation, depression), and quality of life (e.g. social participation, help-seeking) from pre- to post-intervention. Variability and precision estimates (95% confidence intervals) will be calculated to inform future planned studies. Feasibility and success of contacting participants at one and two

month in-person follow-up sessions, as well as the durability of the effects of intervention on outcome measures at these time points and across the daily EMA surveys, will be assessed.

Stimulation

We will use the Neuroelectrics Starstim or Taskflow tDCS systems, both wireless multi-channel transcranial current stimulators. The devices communicate with a computer via Bluetooth which controls the device and monitors impedance and delivered current. A 2 mA current will be administered via two saline-soaked surface sponges (25 cm^2), placed in a neoprene head cap with marked locations based on the 10-10 EEG system. The anodal electrode will be placed over the left frontal cortex and the cathode over the right frontal cortex. Periods of tDCS stimulation will last 20 minutes and will be completed concurrently with cognitive training (see **Figure 3** for timeline of an intervention session). For sham stimulation, the electrodes will be placed at the same positions as for active stimulation, but current will be ramped down immediately after the initial 30 s ramp up period and then ramped up and down again at the end of the 20 minute period. Thus, participants receiving sham stimulation will receive current only during the up-down ramps at the beginning and end of the sham stimulation period. This procedure has demonstrated effectiveness in preventing subjects from recognizing experimental vs. control conditions.

Recruitment

This study will recruit 38 Veterans who have been admitted to the Minneapolis VA Inpatient Psychiatric unit. Regular meetings to identify and consult on participant recruitment will take place with Mary Jo Jensen, Nurse Manager of the 1K Inpatient Psychiatric unit, and David Holewinski, Program Manager of the Suicide Prevention program. The Suicide Prevention program tracks all Veterans receiving services at the Minneapolis VA who have attempted suicide. Per discharge data from FY2010-2020, 40-50 Veterans discharge from the inpatient unit per month. For those patients admitted following a suicide attempt, the Suicide Prevention program conducts telephone follow-up within 48 hours of discharge, mental health evaluations in the week following discharge, and face-to-face evaluations within 2 weeks of discharge (Britton et al., 2017).

Participants will be Veterans (18-75 years old) of any era or military background. Our target sample size is 30. We will plan to enroll 38 participants, to account for an assumed 20% rate of attrition.

Randomization Procedures

Following enrollment in the study, participants will be randomized to either active or sham tDCS. Random permuted blocks will be used to ensure equal treatment numbers at equally spaced points in the sequence of patient assignment. This will be maintained by the study statistician to keep study personnel blinded.

Inclusion Criteria

Participants will be included if they are 1) currently admitted and housed in the MVAHCS Inpatient Psychiatric Unit, 2) at a heightened risk for suicide (defined as a positive screen on the VA Comprehensive Suicide Risk Evaluation (CSRE) at intake and/or a suicide attempt within the previous 12 months), 3) between the ages of 18 to 75, and 4) able to complete procedures and tasks.

Exclusion criteria

Participants will be excluded if they 1) are unable to provide informed consent as determined by the Modified Dysken Tool, 2) have moderate/severe cognitive impairment as determined by the Mini-Mental State Examination (score ≤ 27), 3) have contraindications for tDCS (history of seizures, metallic cranial plates/screws or implanted device, history of eczema on scalp), 4) do not have a smartphone or device with internet connection to complete EMA surveys, or 5) have been involuntarily committed.

Inclusion of Women and Children

Women and minorities will be included in this study.

Informed Consent Process

Prior to completing any study assessments, voluntary informed consent will be obtained in accordance with MVAHCS IRB guidelines. The consent session will take place in a private office in the Inpatient Psychiatric unit at the MVAHCS. At the consent session, the principal investigator, research coordinator, and/or other trained research staff will explain the study to participants including the assessments, risks, benefits, confidentiality, and compensation. Research staff will emphasize that the study is voluntary and their decision to participate will not influence their clinical care or VA benefits. Participants will be allowed as much time as needed to review the consenting documents and ask any questions before making the decision to participate.

Participants must be able to provide voluntary informed consent to be enrolled in this study. Indications of lack of capacity to consent include:

- Potential participant has severe cognitive disorder that does not allow him or her to ask understandable questions or to answer the questions on the Modified Dysken Tool.
- Potential participant is unable to maintain attention during the consent process long enough to perceive the individual points in the consent form.
- Potential participant cannot ask questions or respond sufficiently to indicate agreement.
- Potential participant is unable to articulate an understanding of the research.

To ensure comprehension of the information provided in the consenting documents, participants will be asked to complete the Modified Dysken Tool and correctly answer 7 out of 10 questions. Participants who are unable to correctly answer 7 out of 10 questions will be offered remedial teaching and the Dysken will be re-administered. If a participant is unable to correctly answer 7 out of 10 questions after remedial teaching, they will be excluded from the study. Once study staff have determined that the participant understands the consenting documents, they will be asked to sign the Informed Consent and HIPAA Authorization Forms. After consent and HIPAA paperwork is completed, participants will be provided with signed copies of the paperwork.

When participants are called to schedule follow-up appointments, they will be reminded about the voluntary nature of the study, the procedures that will take place, and the duration of the visit, and they will be given time to ask any questions that may arise. The principal investigator will be consulted regarding participants reporting new health symptoms that may affect cognition during the course of the study to determine if reassessment is needed.

No participant will be under legal commitment at the time of their consent or during their participation in the study.

Sessions

Baseline Inpatient Session

Participants will provide voluntary informed consent and sign the HIPAA Authorization form before beginning any study procedures. After consent is obtained, participants will complete assessments of clinical symptomatology, functional outcomes, and cognitive executive functioning (see Table of Assessments below). This session during their inpatient stay is expected to last approximately 2 ½ hours.

Stimulation/Training Sessions

Stimulation/Training intervention sessions will occur twice per day for five days (**10 total sessions**) while participants are residing in 1K. The two daily sessions will be separated by ≥ 2 hours. Prior to and after each stimulation visit, participants will complete the Symptom Rating Questionnaire to assess for any side effects. If the session is occurring on 1L while the patient is admitted as an inpatient, participants will also complete an Inpatient EMA Questionnaire (part of the EMA Battery) before tDCS intervention. During tDCS (active or sham), participants will complete cognitive training tasks. Each session is expected to last approximately 60 minutes.

If a participant is discharged such that they cannot complete the 10 sessions of the intervention while an inpatient, they will be asked to return to the MVAHCS to complete the remaining intervention sessions. If this is not possible, or they do not return for these in-person sessions, we will note the number of sessions that they did complete and use this information as appropriate in any analyses (e.g. as a covariate).

Mid-Intervention-Assessment Session

Following the fifth Intervention session, participants will complete a subset of the assessments of clinical symptomatology, functional outcomes, and cognitive executive functioning that were completed during the Baseline Inpatient Session (see Table of Assessments below). These assessments may occur immediately following the fifth Stimulation/Training session, or may occur the following day, depending on the participant's schedule. This session is expected to last approximately 70 minutes.

Post-Intervention Session

Following the final Stimulation/Training session, participants will complete a subset of the assessments of clinical symptomatology, functional outcomes, and cognitive executive functioning that were completed during the Baseline Inpatient Session (see Table of Assessments below). These assessments may occur immediately following the final Stimulation/Training session, or may occur the following day, depending on the participant's schedule. This session is expected to last approximately 70 minutes.

Follow-Up Sessions

The follow-up sessions will occur in-person at the MVAHCS approximately 1 and 2 months after the participant is discharged from their inpatient stay. During the follow-up sessions, participants will complete the same assessments as during their Baseline Inpatient Session (see Table of Assessments below). These visits are expected to last approximately 1 hour and 45 minutes each. If a participant cannot return to the MVAHCS for an in-person follow-up (the preferred method of assessment), they will first be offered the opportunity to conduct the follow-up assessment via VA Video Connect, then by phone, instead of in-person.

Ecological Momentary Assessment (EMA)

Participants will be asked to complete three brief surveys each day on their phone for 30 days after discharge from inpatient treatment. Each survey is expected to require 5-10 minutes to complete.

Table of Assessments

Table 1 below outlines the visits and assessments administered at each visit. Full descriptions of the assessments are located in the “Assessments” section of the protocol.

Activity	Details	Session						Length (mins)
		Inpatient				Post-discharge		
		Baseline	Intervention	Mid-intervention	Post-intervention	1 mo	2 mo	
Consent & HIPAA	Regulatory	X						15
Mini-Mental State Exam	Assessment of cognitive capacity for inclusion	X						10

	Intervention							
tDCS (or sham)	Intervention		X					45 each session
Training exercises	Computerized cognitive training exercises (see **Table 2** for details)		X					
tDCS Symptom Rating Questionnaire	Side effect rating questionnaire (self-report)		X					2
	Clinical Symptomatology							
Suicide Risk Battery	Military Suicide Research Consortium (MSRC) Common Data Elements, battery of self-report measures of suicide risk factors	X				X	X	25
Abbreviated Suicide Risk Battery	Shortened version of the MSRC Common Data Elements, battery of self-report measures of suicide risk factors			X				10
Beck Depression Inventory, 2nd Ed.	Self-report measure of depression symptoms (Beck, Steer, Ball, et al., 1996)	X		X	X	X	X	5
Beck Anxiety Inventory	Self-report measure of anxiety symptoms (Beck, Epstein, et al., 1988)	X		X	X	X	X	5
General Help Seeking Questionnaire	Measure of help-seeking intentions and behaviors	X			X	X	X	5
Endorsed and	Measure of beliefs about help-seeking	X					X	< 5

Anticipated Stigma Inventory								
UPPS-P	Impulsive Behavior Scale	X		X	X	X	X	5
	Functional Outcome							
NIH Toolbox Functional & Quality of Life assessment	Questionnaire to assess quality of life with regard to cognitive, social, emotional, and behavioral abilities (Cella et al., 2012)	X			X	X	X	10
Keele Assessment of Participation	Measures participation in multiple domains of daily life (Wilkie et al., 2005)	X				X	X	5
Pittsburgh Sleep Quality Index	Assesses sleep quality and disturbances (Buysse et al., 1989)	X			X	X	X	5
Difficulties in Emotion Regulation Scale-16	Self-report measure of emotion dysregulation (Hallion et al., 2018)	X		X	X	X	X	5
	Executive Function							
Information Sampling Task	Task assessing reflection impulsivity	X		X	X	X	X	10
Groton Maze Learning Task	Task assessing spatial working memory, learning efficiency, and error monitoring	X		X	X	X	X	10

Delay Discounting Task	Task assessing the relationship between a reward and the time it takes to receive it	X		X	X	X	X	5
GoStop Impulsivity Task	Task measuring response inhibition	X		X	X	X	X	5
	Brain Activity							
Resting EEG	Assess neural dynamics	X			X	X	X	10
	Ecological Momentary Assessment							
Ecological Momentary Assessment (EMA) Battery	Repeated sampling of participants' behaviors and experiences in real time					Three times daily for 30 days post-discharge		3-5 min/ day
GoStop Impulsivity Task (shortened)	Task measuring response inhibition					Three times daily for 30 days post-discharge		30sec-1 min/ day
Information Sampling Task (shortened)	Task assessing reflection impulsivity					Three times daily for 30 days post-discharge		1-2 min/ day
5-Trial Delay Discounting Task	Task assessing the relationship between a reward and the time it takes to receive it					Three times daily for 30 days post-discharge		30sec-1min/ day
Grid Trails AB Task	Task measuring executive functioning					Three times daily for 30 days post-discharge		1-2 min/ day

Missed Visits Procedure

The assessment schedule may shift based on participant, investigator, study staff, and resource availability. Missed visits during the course of stimulation/training will be accounted for by resuming intervention on the next available workday. The missed visit will be added to the end of the participant's intervention schedule so that all participants receive 10 stimulation/training sessions.

Equipment
Participants will be provided with or asked to use the following equipment during the study: personal smartphone and internet connection, and wearable activity tracker. Participants will be asked to use their personal smartphone and internet connection for EMA data collection. Participants will return the activity tracker to the study team at the last follow up visit upon completion of the study, or at the time of discontinuation or withdrawal from the study.

Compensation
Due to the time commitment, as well as potential costs of transportation and lost wages during time of participation at follow-up sessions, participants will be compensated. Compensation for study sessions will be delivered according to the following schedule: Participants will be paid $25 following the Baseline Inpatient Session, and $50 following the Post-Intervention Session. They will also be paid $0.50 for each of the 90 EMA surveys (3 per day for 30 days = $45) completed, and a $1 per day bonus if they complete two EMA surveys each day ($30). Finally, they will be paid $75 following successful completion of the study ($30 after attending the 1-month and $45 after attending the 2-month follow-up visits). The maximum amount of compensation that participants can receive is $225. Participants will be paid via debit card or electronic funds transfer according to VA OR&D policy.

Data Collection Procedure
Enrolled participants will be tracked using randomly-assigned, unique participant ID numbers. Data will be collected and stored using the participant ID number. During analyses, only de-identified data will be used or reported.

The following data will be obtained from electronic records with consent: date of initial admission to inpatient hospitalization (to determine treatment length), basic demographics (age, gender, ethnicity/race, marital status, rank, years of service, combat history), Coronavirus Disease 2019 (COVID-19) history, current and past mental health treatment, current and past mental health diagnosis, and current psychotropic medications.

Self-report assessments will be collected via the VA Research Electronic Data Capture (REDCap) system on the VA Intranet, on paper forms, or electronically on a study computer not connected to the VA or UMN networks. VA REDCap data will be stored there using only a study identifier without PHI. Paper or standalone computer data will be entered manually or transferred via a VA-issued Iron Key USB drive into a password-protected database behind the MVAHCS firewall.

EEG data will be collected on a password-protected study computer without network connection (VA or UMN). After EEG data collection is complete, VA-issued Iron Keys will be used to transfer the data into a password-protected database behind the MVAHCS firewall. After the data is transferred, it will be removed from the study computer. Cognitive functioning assessments will be collected on a password-protected study computer with UMN network connection. Tasks will be collected via a secure, password-protected, study-specific server located at: cnc2.med.umn.edu. Random, unique participant ID numbers will be entered into the website for data collection. No PHI or identifying information will be entered into the website.

Activity tracking data will be collected via a smartphone-connected, wrist-worn tracker (Garmin Vivosmart 4) and affiliated application (Garmin Connect) that participants will access on their personal smartphones (instructions will be provided to participants by the research team and participants will access the app independently). Activity data will be transmitted via Bluetooth to the affiliated app and transferred to a HIPAA-complaint server (cnc2.med.umn.edu) at the University of Minnesota where it will be stored and analyzed.

Cognitive Training Exercises
Cognitive training occurs on a laptop computer and consists of 8 exercises selected to (1) place demands on the executive function system (e.g., working memory, behavioral inhibition, decision making, and set-shifting),

(2) adapt to challenge the participant's current ability level, and (3) provide ongoing feedback. During each 45-minute stimulation/training period, 5 of the 8 available tasks (**Table 2**) will be randomly selected and participants will train for approximately 9 minutes per task in a randomly selected order. Cognitive training will be concurrent with tDCS, in both the active and sham tDCS groups, during intervention sessions (**Figure 3** illustrates the timeline for one intervention session). Cognitive training tasks will be collected on a password-protected study computer with UMN network connection (no VA network connection). Tasks will be collected via a secure, password-protected, study-specific server located here: cnc2.med.umn.edu. Random, unique participant ID numbers will be entered into the website for data collection. No other PHI or identifying information will be entered into the website. We will use a set of cognitive training exercises developed in the lab using JavaScript and the jspsych library (de Leeuw, 2015). The exercises are stored on our application server which allows study staff to select the exercises and difficulty level for each session for each subject. During a session, the selected exercises for a subject are automatically downloaded to the study laptop. All responses and timing for each keystroke are recorded and uploaded to the server allowing the detailed examination of each training exercise. We developed this platform so that we would have fine-grained control over all aspects of the training exercises as well as access to the timing and performance data. Our cognitive training platform is currently being used for our Brain Initiative award (1RF1MH116987-01).

Table 2. Executive Function Training Exercises

Task	Domain	Description	Levels
Restaurant Rush	Working Memory (Visual)	An n-back memory task involving keeping track of orders (pictures of food) in a restaurant.	17
Crime Busters	Working Memory (Spatial)	An n-back memory task involving keeping track of spatial locations on a map where fictional crimes have occurred.	16
BART	Ambiguous Decision Making	Inflate a virtual balloon as large as possible without bursting it. The more pumps, the more points that are gained, but a greater likelihood that the balloon will pop.	n/a
Sailing by the Stars	Context processing, Working memory, Inhibitory Control	A dot pattern expectancy task where players must memorize response rules to specific stimuli sequences. Stimuli are constellations in the night sky.	6
Nebula 9	Inhibitory Control	A flanker task themed as a space navigation challenge. Players must focus on guiding arrow to steer the spaceship to safety while ignoring irrelevant arrows and other visual distractors.	11
Dungeon Crawler	Inhibitory Control	A flanker task themed as an epic fantasy quest. Players engage in combat with monsters by following the guiding arrow as direction for where to aim their weapon, while ignoring irrelevant arrows and other visual distractors.	14
Scuba Dive!	Cognitive Flexibility	A cognitive flexibility task where the context is a scuba dive and there are fish, plants, rocks in different patterns	10
Reversal Learning	Cognitive Flexibility, Inhibitory Control	Correct response contingency changes after some number of trials. Players must adjust their response accordingly.	n/a

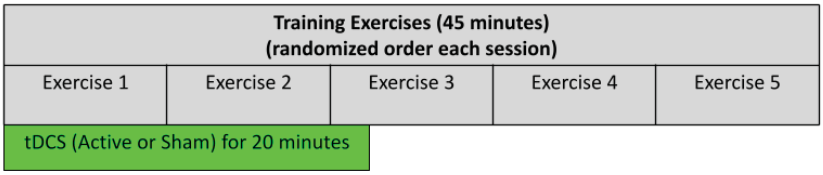


Figure 3. Timeline of a single Intervention session. The 5 Training Exercises will be presented in randomized order during each session. tDCS is applied for 20 minutes at the start of the session.

<u>Ecological Momentary Assessment (EMA)</u>
Participants will complete EMA surveys using either the mPRO app or VA Qualtrics. mPRO requires participants to download the app to their device. If a participant cannot or does not agree to download mPRO, they will be able to use Qualtrics. For mPRO, prior to discharge, Veterans will be asked to download the mPRO app on their mobile device from the Apple App store or Google Play Store. mPRO is a research app designed and distributed by VA for use in VA research, developed by Dr. Eric Kuhn at the Palo Alto VA, VA National Center for PTSD, Dissemination & Training Division. Participants will be provided with verbal and paper instructions on how to access and use the app to complete questionnaires. They will be given a login alpha-numeric string code that will allow us to track individual participant data (login code will be different from Subject ID). Data will be uploaded using VA encrypted connections to the Minneapolis VA servers behind the VA firewall. Only de-identified data will be transmitted or stored.

Also, veterans will be given the option of using Qualtrics to complete the EMA surveys. Qualtrics enables accessible and user-friendly collection of patient-reported outcome survey data for research studies using remote procedures. Study participants are sent a link to a Qualtrics survey by email or text message, and can complete their survey on any internet-connected device with an internet browser. Qualtrics is accredited by FedRAMP, a government-wide initiative to protect sensitive data in federal agencies, ensuring gold standard

security for data collected through Qualtrics. Further information can be found at https://qualtrics.com/platform/fedramp. Researchers will access participant data using the Qualtrics dashboard, and all data will be identified through a numeric participant code only. Only approved members of the research team have access to the secure dashboard. Research team members will export participant data from the dashboard directly to secure VA research servers.

After discharge from inpatient treatment, Veterans will report on current experiences (i.e., signal-contingent monitoring) and to report on experiences during the day since last assessment (i.e., interval-contingent monitoring) on their phone using mPRO or Qualtrics. We will send two daily prompts to participants' phones in the morning and evening. By default, participants will only be contacted from 8am to 8pm and participants will be able to set a custom "survey availability window" and will not be contacted outside of that window. If participants report elevated suicidal intent in their daily assessment (>8 out of 10 in suicidal intent) via daily diary, they will receive a prompt to contact the Veteran Crisis Line and a list of options for managing their distress, including coping skills and other emergency numbers (e.g., 911). This information is consistent with skills/resources already reviewed with Veterans by MH clinicians on 1K and during the suicide risk assessment conducted at baseline. Study staff will review the mPRO or Qualtrics dashboard three times daily to identify Veterans who reported elevated suicidal intent (see Suicide Risk Safety Procedures for details).

Assessments

Mini-Mental State Exam

The Mini-Mental State Exam (MMSE) is a widely used test of cognitive function. It includes tests of orientation, attention, memory, language, and visual-spatial skills (Folstein et al., 1975).

Suicide Risk Battery

Suicide risk factors will be assessed using Military Suicide Research Consortium (MSRC) Common Data Elements (CDEs), a brief psychometrically sound assessement capturing a broad range of suicide risk factors (Ringer et al., 2018). Select items from empirically validated measures of suicide-related behaviors and associated risk factors were combined to create the CDEs. The CDEs assess the following factors: alcohol use (3 items), anxiety sensitivity (5 items), insomnia symptoms (5 items), thwarted belongingness (5 items), perceived burdensomeness (6 items), posttraumatic stress disorder symptoms (8 items), hopelessness (3 items), capability for suicide (7 items), suicidal ideation severity (4 items), likelihood of future suicidal behavior (4 items), suicidal intent during most recent attempt (if applicable, 4 items), and self-harm history (if applicable, 2 items). Item responses vary and generally rely on Likert-type scales or multiple choice options. The CDEs have demonstrated strong psychometric properties in samples of current servicemembers and veterans, including adequate reliability, construct validity, and predictive validity (Buchman-Schmitt et al., 2020; Ringer et al., 2018; Stanley et al., 2019). The CDEs will require approximately 25 minutes to complete.

Beck Depression Inventory, 2nd Ed.

The Beck Depression Inventory (BDI) is a 21-item, self-report rating inventory that measures characteristic attitudes and symptoms of depression (Beck, Steer, & Brown, 1996). Internal consistency for the BDI ranges from .73 to .92 with a mean of .86 (Beck, Steer, et al., 1988). The BDI demonstrates high internal consistency, with alpha coefficients of .86 and .81 for psychiatric and non-psychiatric populations respectively (Beck, Steer, et al., 1988).

Beck Anxiety Inventory

Beck Anxiety Inventory (BAI) is a brief, self report assessment for measuring anxiety severity and level. With the BAI, patients respond to 21 items rated on a scale from 0 to 3. Each item is descriptive of subjective, somatic, or panic-related symptoms of anxiety. The BAI has excellent overall internal consistency and a high test-retest correlation (r = 0.67)(Fydrich et al., 1992).

General Help Seeking Questionnaire (GHSQ)
The GHSQ (Wilson et al., 2005) is a 18-item measure of future help-seeking behavioral intentions and has 3 supplementary questions to assess prior actual help-seeking behaviors. The GHSQ includes a list of potential individuals who could provide support and participants rate the likelihood that they would reach out for support on a 7-point Likert scale ranging from 1 (extremely unlikely) to 7 (extremely likely) and whether they have reached out for help in the past 2 weeks (yes/no). The GHSQ has good reliability and validity (Wilson et al., 2005). The GHSQ requires approximately 5 minutes to complete.

Endorsed and Anticipated Stigma Inventory
The EASI (Vogt et al., 2014) is a 40-item measure of beliefs about mental illness and mental health treatment. The EASI includes three subscales evaluating beliefs about mental illness and two subscales evaluating beliefs about mental health treatment. Given that this study aims to understand help-seeking behaviors, only the following scales addressing mental health treatment beliefs will be administered: “Beliefs about mental health treatment” and “Beliefs about treatment.” Each subscale consists of 8 items evaluated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) with higher total scores indicating more stigmatizing beliefs. The EASI was developed and psychometrically validated in military and veteran samples (Vogt et al., 2014). The EASI subscales require less than 5 minutes to complete.

UPPS-P
The UPPS-P model of impulsivity proposes that impulsivity is a multi-faceted and multi-dimensional construct, comprising five impulsive personality traits. These traits include 1) Negative urgency, the tendency to act rashly under extreme negative emotions, 2) Lack of Premeditation, the tendency to act without thinking, 3) Lack of Perseverance, the inability to remain focused on a task, 4) Sensation Seeking, the tendency to seek out novel and thrilling experiences, and 5) Positive Urgency, the tendency to act rashly under extreme positive emotions (Whiteside & Lynam, 2001). We will administer the short version of the UPPS-P scale, which has 20 items, and has shown high reliability and validity (Cyders et al., 2014).

NIH Toolbox Functional and Quality of Life (NIHQOL) Assessment
The NIHQOL is a clinically-relevant and psychometrically-robust quality of life (QOL) assessment tool. The measures enable clinical researchers to compare the QOL impact of different interventions within and across various conditions within multiple domains including social, behavioral, emotional, and cognitive. Measures in this self-report QOL assessment have been found to be reliable and show concurrent validity as they can differentiate people based upon the number of reported health conditions and whether those reported conditions impede normal function [Cella et al., 2012]. Five sub-sections (general well-being, emotion regulation, cognitive functioning, social ability, and social satisfaction) were chosen from the overall NIH Toolbox Quality of Life battery to address challenges frequently encountered by suicide risk populations.

Keele Assessment of Participation
The Keele Assessment of Participation (KAP) is intended to measure an individual’s level of participation in various activities including work, education, social activities, and activities of daily living. The KAP has 15 items, including four conditional screening questions (e.g. “if yes, proceed to the next question”). The KAP has shown moderate to strong convergent validity correlations (>0.50) with the Reintegration to Normal Living Index (RNL)(Noonan et al., 2010).

Pittsburgh Sleep Quality Index
The Pittsburgh Sleep Quality Index (PSQI) is a self-rated questionnaire which assesses sleep quality and disturbances. Nineteen individual items generate seven "component" scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of scores for these seven components yields one global score. A global PSQI score greater than 5 yielded a diagnostic sensitivity of 89.6% and specificity of 86.5% (kappa = 0.75, p less than 0.001) in distinguishing good and poor sleepers (Buysse et al., 1989).

Difficulties in Emotion Regulation Scale

The Difficulties in Emotion Regulation Scale (DERS) is a widely-used, theoretically-driven, and psychometrically-sound self-report measure of emotion regulation difficulties. The validity of the brief 16 item version (DERS-16) was evaluated comparing the relative strength of the association of the brief and long versions of the DERS with measures of emotion regulation and related constructs, psychopathology, and clinically-relevant behaviors theorized to stem from emotion regulation deficits. Results demonstrated that the DERS-16 had excellent internal consistency, good test-retest reliability, and good convergent and discriminant validity (Bjureberg et al., 2016).

Groton Maze Learning Task

The Groton Maze Learning Task (GMLT) is a cognitive test of spatial working memory and error monitoring that has been shown to be sensitive to detecting longitudinal change in cognitive ability (Pietrzak et al., 2008). It consists of a 10 x 10 grid of grey tiles. To complete the maze, the participant has to click on the tiles to follow a hidden pathway through the grid from the top left corner to the bottom right corner. They must only click on adjacent tiles, and return to the previous tile if an error is made before moving on. The participant receives visual and auditory feedback for correct and incorrect moves. There are various types of errors (e.g. perseverative error, rule-break error) recorded depending on which type of rule has been broken, and the time to complete the maze is recorded. The trial ends once the participant reaches the bottom right corner of the grid of tiles.

Information Sampling Task

The Information Sampling Task (IST) is a test of reflection impulsivity (L. Clark et al., 2006). It presents a series of trials with an array of 25 grey boxes arranged in a 5x5 matrix. The grey boxes conceal yellow or blue squares on each trial. The subject decides which of the two underlying colors (yellow or blue) lay in the majority. The subject can open as many boxes as they wish to make a decision. Correct decisions are awarded a number of points. Trials are blocked into two conditions: (i) Fixed Win (FW) condition, a correct decision yields 100 points, irrespective of the number of boxes opened and (ii) Decreasing Win (DW) condition, the number of available points decreases with every box opened. The DW condition introduces a reinforcement- certainty conflict, so that this condition encourages impulsive responding and exaggerates individual differences.

Two Choice Impulsivity Paradigm (TCIP)

The Two Choice Impulsivity Paradigm (TCIP) is a delay discounting task. In the TCIP, participants choose between larger rewards accompanied by longer delays and smaller rewards accompanied by shorter delays. In the TCIP, participants experience the rewards and delays in real-time (Dougherty et al., 2009). The TCIP is designed to measure the consequence sensitivity aspect of impulsivity. In TCIP, participants experience discrete trials in which they select one of two shapes (circles and squares). These shapes appear on the computer monitor and responses to these shapes produce their respective consequence: clicking on a circle earns 5 points after waiting 5 seconds and clicking on a square earns 15 points after waiting 15 seconds. During the testing session, the circle and the square appear on the monitor together and participants make choices between the two rewards by clicking on either the circle or the square to add points to their counter. The left/right orientation of the shapes is randomly determined for each trial. After choosing one shape, the other shape disappears and the chosen shape fades to gray. When the scheduled delay elapses, the chosen shape resumes its black color, flashing for 500 msec once per second, at which time the participant clicks on the shape a second time to add its respective reward to the counter.

5 Trial Delay Discounting Task

The 5 Trial Delay Discounting task is an adjusting delay discounting task where the delays are adjusted but the amounts are kept constant during the task (Koffarnus and Bickel, 2014). Participants select one of two options in each trial. One option is a bigger reward with a longer delay and one is a smaller reward with a shorter

delay. The two rewards are kept the same while the delays are adjusted based on the participant's choice. This task takes less than a minute to complete, which makes it suitable for use in the EMA surveys.

Grid Trails A and B Task

The Grid Trails A and B Task is a version of the classic Trail Making Test parts A and B used to measure executive functioning that has been adapted for presentation on a mobile device. This is a computerized version using a 4x4 grid shape within which the letter and number stimuli are presented. In Part A (TMT-A), the participant must click, in succession, consecutive numbers, from 1 to 16. In Part B (TMT-B), the participant clicks numbers and letters in an alternating progressive sequence, 1 to A, A to 2, 2 to B, and so on. In order to measure central executive functioning, the difference in time taken to complete TMT-B, which stresses central executive processes of task-set inhibition, cognitive flexibility, and the ability to maintain a response set and the time to complete TMT-A, which has little executive input, is calculated. The ratio of TMT-B to TMT-A can also be used (Arbuthnott & Frank, 2000; Kortte, Horner, & Windhan, 2002),

GoStop Impulsivity Task

The GoStop Impulsivity Paradigm is a stop signal task designed to measure response inhibition. The primary response of interest here is the failure to inhibit responding when a "go" cue is unexpectedly accompanied by a "stop" cue (Dougherty et al., 2009). In this task, 5-digit numbers are presented in rapid sequence. Half of these numbers are target trials (matching stimuli) and half are filler trials (novel stimuli). This task features "stop" trials for half of all target trials, where the matching number presented in black (the go cue) changes to red (the stop cue) at intervals ranging from 50 to 350 msec after the stimulus presentation. Participants are instructed to respond while the matching number is still on the monitor, but not to respond if that number turns red. The main impulsivity variable obtained from this task is the percentage of inhibition failures, which is calculated from the number of responses made to stop trials divided by the total number of stop trials.

Resting-state EEG

An electroencephalogram (EEG) measures the electrical activity in the brain (brain waves) using electrodes (small metal discs or sensors) placed on the scalp with gel. Resting-state EEG is a measure of ongoing brain activity. The oscillatory nature of resting-state EEG, as well as the functional connectivity between brain areas, is related to various cognitive functions (Rogala et al. 2020). Resting-state EEG will be collected while participants sit quietly, alternating between 3-minute periods of having their eyes closed and eyes open. EEG will be collected using a 64 channel Biosemi ActiveTwo system (https://www.biosemi.com/products.htm). The Biosemi system uses active electrodes to reduce input impedance at the scalp, allowing low-noise measurements free of interference without any skin preparation. Biosemi ActiView software will be used to acquire EEG data.

EMA Battery

The EMA Battery will assess the following fluctuating experiences and behaviors that influence suicide risk: help-seeking (intentions, behaviors), stress (severity, stressors), social connection (e.g., time spent alone, conflicts, connection), suicidal thinking and behavior, and related factors (e.g., sleep, impulsivity, current affect, fearlessness about death). Items have been used in previous and current EMA studies of suicidal behavior (Kleiman et al., 2017). Each daily assessment will be brief (approximately 5-10 min each, total 10-15 min per day) and questions will be evaluated using 11-point Likert scales, multiple-choice options, or fill-in-the-blank. There will also be four short cognitive tasks: a shortened version of the GoStop Impulsivity Task, a shortened version of the Information Sampling Task, a 5-trial Delay Discounting Task, and the Grid Trails A and B task. In addition to self-report data, information regarding app usage will also be obtained from the app's meta-data, including time the survey was completed, time spent on individual survey items, and time required to complete surveys.

Wearable Activity Tracker

Each participant will be given a Garmin Vivosmart 4 wearable activity tracker to be worn on the non-dominant

wrist for the duration of the study. The activity tracker will be used to monitor participants' total estimated sleep time, sleep latency, and movement each night, as well as their overall activity and stress levels. The Garmin Vivosmart 4 has an application (Garmin Connect) that allows users to share their data. Each participant will be shown how to enable this feature to share with the study team. This will allow the study team to look at the data daily to ensure that the activity tracker is actually being worn and functioning properly.

Data Analysis & Methodological Considerations

Analyses will be descriptive in nature, although variability and precision estimates (95% confidence intervals) will be provided for acceptability, feasibility, performance, and symptom summary statistics. Slope estimates of trajectories of daily sleep, mood, social functioning, and stressors (as reported via EMA) will be calculated. Results will be presented across participants and individually for each group. As this trial serves as a precursor to a larger scale efficacy study, and one of our goals is to determine the fit of candidate outcome measures, we will enroll 19 participants per condition (38 participants total) with the goal of getting 30 complete datasets.

Potential Risks and Protections

Protected Health Information

Study staff will review private medical records during the study. The use of protected health information may be associated with negative feelings about sharing medical information. There is potential for unintended disclosure of sensitive personal information, although every effort will be made to lessen the risk. Review of medical records will be conducted by trained research staff who will be instructed to keep the content of the records confidential.

Only research staff will have access to participant information and collected data. Records containing identifying information will be stored in a locked file cabinet in a private research office and be accessible only by research staff who need access to identifying information to conduct their research duties. Paper and electronic records will be kept according to MVAHCS policies. Any identifying information on optical or digital media will be stored in a password-protected database behind the MVAHCS firewall. The password for accessing this information will be available to only research staff that need access to identifying information to conduct their research duties.

Assessments

The assessments (questionnaires and surveys) used in the study will involve questions about health symptoms, feelings, past experiences, and family history. Discussion of these topics could cause mild stress and/or discomfort. Participants who experience distress will be given the option of stopping the assessment for a rest break and resuming at another time, if needed. Additionally, participants will be reminded that they may decline to answer any questions they do not wish to answer at any time; however, this may lead to their discontinuation from the study protocol. Assessor training will include how to recognize and report distress, should it occur. See "In-person" safety procedures below for distress/risk safety assessment and follow-up procedures.

The cognitive functioning assessments used in the study could cause temporary feelings of stress, mental fatigue, or frustration. Research staff will provide participants with reassurance and offer breaks, if needed.

Transcranial Direct Current Stimulation

Transcranial direct current stimulation (tDCS) is considered to be a safe brain stimulation technique that rarely results in adverse events. There is currently no evidence of serious side-effects. Mild side-effects that typically resolve upon discontinuation of tDCS include light itching under the electrode at the beginning of administration (68%), headache (13%), fatigue (20%), and nausea (2%). Participants may choose to discontinue stimulation at any time during the session if they are experiencing excessive discomfort or side effects. No other risks are anticipated. Nonetheless, in order to minimize risks, research staff will use standards of administration that have been shown as safe in numerous other studies using tDCS. The length of administration of the current,

size of electrode sponges used, and method of applying stimulation are the same as methods of administration that have been demonstrated as safe.

Suicide Risk Safety Procedures

To ensure the safety of our study participants, several suicide risk safety procedures will be put into place and clearly outlined to all participants. Our approach to monitoring suicide risk during the study draws from the University of Washington Risk Assessment Protocol (UWRAP; (Linehan et al., 2012; Reynolds et al., 2006), a research-supported approach to managing/assessing risk in research with suicidal populations. We will assess and address risk using the VA's comprehensive suicide risk assessment forms and protocols, which are based on the Rocky Mountain MIRECC Risk Stratification Guidelines (see Appendix 1).

In-Person: To monitor participants' suicide risk during assessment sessions, we will obtain ratings of stress and suicide risk before and after each assessment session (UWRAP (Linehan et al., 2012); see Appendix 2). This is a brief screening assessment that evaluates participants' (1) current level of stress, (2) urge to harm themselves, and (3) suicidal intent on a Likert scale ranging from 1 to 7. Elevations are defined as scoring 5 or more out of 7. If a participant reports elevated risk or if the assessor is concerned about the individual's level of risk for any other reason, further steps will be taken to reduce the suicide risk prior to ending the assessment. Should further assessment be warranted, research staff will reach out to Co-I Dr. Chu, a licensed clinical psychologist, or another licensed research staff member. Licensed research staff will conduct the VA's comprehensive suicide risk assessment and risk management actions (see Appendices 3 & 4). Following the procedures outlined by this suicide risk assessment, the comprehensive risk assessment will evaluate Veteran's suicide risk factors, suicidal intent, suicide plans, and access to lethal means. Veteran's acute and chronic suicide risk levels will be classified using the Rocky Mountain MIRECC Risk Stratification Guidelines. Finally, licensed research staff will take actions to reduce or address risk based on risk factors and risk level. For example, participants classified at low risk will be educated about emergency numbers, participants who endorse passive SI and stressors may be asked to create a safety plan, and participants classified at moderate risk with access to lethal means may require counseling around means safety. In all cases, all research staff who will be conducting risk assessments and risk screenings will receive training and supervision from study investigators. Additionally, all research staff will contact study investigators for consultation and follow-up within 24h of conducting the risk assessment. The PI and/or Co-I will be available to discuss difficulties or questions on weekdays and on the weekend.

EMA: For the EMA portion of the study, suicide risk will be assessed using two items (using a 0-10 Likert scale) modified from the UWRAP that are included in both the morning and afternoon EMA surveys. Elevations are defined as scoring 8 or higher out of 10 on suicidal intent. Data will be collected using either mPRO or Qualtrics. Study staff will not receive push notifications about participants who endorsed elevated suicide intent. Instead, study staff will be informed of all participants with elevated suicidal intent via the mPRO or Qualtrics web-based dashboard. Both programs have web-based dashboards that allow study staff to track participant survey completion and responses. During the study period (weekends included), study staff will check the dashboard three times daily, and for participants with elevated suicidal intent, licensed research staff will reach out by phone. Staff will check either the mPRO or Qualtrics dashboard for high-risk respondents once in the late morning (~10:00am) and once in the afternoon to catch respondents from the morning survey and afternoon survey (of that same day; if needed, calls made between 1:00pm - 4:30pm), and once after 8:00pm (after the survey closes) to catch high-risk respondents from the late afternoon/evening survey (of the same day; If risk assessment is needed, research staff will notify the Veterans Crisis Line for third-party contact). The UWRAP questions in the daily EMA surveys act as the risk screens. The next step will be for a licensed staff person to reach out to the Veteran for risk assessment. Also, in the event that the licensed staff is unavailable, we reserve the option to do a third party contact to the VCL, just as we would for the need to follow-up after hours or on a weekend or holiday.

Risk assessment will be conducted during the EMA portion of the study using the same research-supported assessments (see "In-Person"); however, they will be conducted over the phone. Study staff will confirm that they have the best contact number for the Veteran and the Veteran's location (in the event that the phone call is disconnected). Two attempts will be made to contact high-risk respondents by phone; the first attempt will be made within 24 hours of survey response, consistent with VA suicide risk and mental health assessment protocols and research recommendation (Michaels et al., 2015), and the second will be made within 48 hours of survey completion. The first call will not be made immediately after survey completion to allow time for respondents to practice using coping skills to manage their distress (e.g., calling a friend, calling the Veterans Crisis Line (VCL), breathing exercises, going for a walk) without interruption from study staff. These suggested coping skills, resources, and emergency numbers (along with the number for VCL) will be populated on the screen after completion of the survey. For participants who do not respond to the two phone calls, study staff will review their available health records and contact the Veteran's treatment team within 12 hours of the second phone call (this time frame allows time for Veterans to call back in the event that the reason for missing the second call was not risk-related). Study staff will provide the treatment team with information obtained in our study regarding suicide risk (see "Follow-up After Risk Assessment") and next steps, which may include additional attempts to make contact and welfare checks, will be determined by the Veteran's treatment team. Although Veterans recently discharged from inpatient hospitalization are at elevated suicide risk, it should be emphasized that existing evidence shows that daily EMA of suicidal intent will not contribute to increases in suicide risk (Glenn et al., 2020).

Follow-up After Risk Assessment

Information obtained by study staff during suicide risk assessments and actions taken (during phone and/or in-person assessments) will be documented in Veterans' records within 24h of contact (on both weekdays and weekends); the Veteran's treatment team will be alerted to information obtained by study staff as co-signers on all chart documentation. Additionally, if necessary, we will provide a warm handoff to the Veteran's treatment team by Microsoft Teams chat, Microsoft Teams call, or phone call. The Veteran's VA treatment team members are listed in their medical record and may include one or more of the following: outpatient psychiatrist, outpatient psychiatric nurse, outpatient psychologist, outpatient social worker, MH treatment coordinator, Primary Care MH provider, and/or 1K inpatient treatment team (e.g., psychiatrist, nurse). If Veterans have a high-risk flag, their MH treatment team may also include their coordinator from the Suicide Prevention Team. We will prioritize reaching out to treatment team members who have had recent contact with the Veteran based on clinical notes and are able to conduct a follow-up comprehensive suicide risk assessment (e.g., licensed physician, psychologist, or social worker). Once a member of the Veteran's treatment team has responded to our warm handoff, any subsequent suicide risk monitoring and intervention will be determined and conducted by the Veteran's treatment team members.

Rapport between the Veteran and their MH team improves our ability to accurately diagnose and address risk; however, it is not necessary for suicide risk assessment and intervention. These procedures are designed to ensure a consistent response to increased suicide risk regardless of the availability of the MH team. If the Veteran's mental health team are unavailable (e.g. on the weekend or a holiday) and study staff/investigators view the Veteran to be at imminent risk for suicide based on available information, we will follow VA comprehensive suicide risk assessment protocol for managing high-risk Veterans that we have assessed via phone. This includes obtaining/confirming the Veteran's contact/location information, remaining on the phone with the Veteran, and a warm-handoff to the Veterans Crisis Line. We may also encourage going to the emergency room or calling 911. If we lose contact with the Veteran, we may place a third-party call to the VCL. Licensed research staff/PIs/Co-I will also reach out to the 24/7 Provider on Duty at the Minneapolis VA's emergency department for consultation as needed. This approach is identical to what would be done on a weekday if the treatment team were not immediately available.

Data

Breach of confidentiality is a potential risk due to the use of sensitive private information. The results of this study may be published or presented but participants' identities and records will not be revealed unless

required by Federal Law. A Federal Law allows the U.S. Food and Drug Administration, Office for Human Research Protections, Government Accountability Office and other Federal agencies, Department of Defense, the Research and Development Committee, and/or the Institutional Review Board (IRB)/Human Studies Subcommittee of the Minneapolis VA Medical Center to review records. Because of the need for these inspections, absolute confidentiality cannot be guaranteed. However, every effort will be made to minimize these risks by providing participants with unique numerical identifiers at the beginning of the study in order to protect their actual identification and maintain complete confidentiality.

Data and Safety Monitoring Board

A Data and Safety Monitoring Board (DSMB) has been assembled for this study. The DSMB consists of 1) Eric Wittenberg, MSW, LICSW, Suicide Prevention Program Coordinator, 2) Tasha Nienow, PhD, Staff Psychologist and PI on multiple VA funded studies using tDCS and cognitive training as an intervention to improve cognition in disorders including schizophrenia and traumatic brain injury (TBI), and 3) Nicholas Davenport, PhD, VA Research Investigator, PI on the LIMBIC-CENC and CONNECT-TBI studies, with expertise in running clinical trials in a range of conditions, including schizophrenia, ADHD, PTSD, and TBI. DSMB members are not investigators on this study, and have no declared conflicts of interest. They will meet annually to 1) monitor the safety, quality and conduct of this study and 2) decide whether adequate subject safeguards are in place. The DSMB will review: 1) the progress of the study, including assessments of data quality and participant recruitment, accrual, and retention; 2) outcome and adverse event data to determine whether there is any change to the anticipated benefit-to-risk ratio of study participation and whether the study should continue, be changed, or terminated; 3) external factors or relevant information (e.g., pertinent scientific literature reports or therapeutic developments, results of related studies) that may have an impact on the safety of study participants or the ethics of the research study; and 4) study procedures designed to protect the privacy of the research subjects and the confidentiality of their research data. The study biostatistician, Paul Thuras, will be responsible for generating a de-identified annual report of key events that will be reviewed as part of the safety monitoring of the protocol. The tentative list of key events for monitoring will include: 1) side effects to the study treatment, 2) suicide attempts, 3) hospitalization, 4) worsening in non-suicidal self-injurious behaviors (e.g. acute worsening in frequency or severity of injuries), 5) premature drop-out from treatment, and 7) study protocol adherence. The key events will be reviewed at the first meeting of the DSMB to obtain the DSMB members' input into the list and to add any other events or measures that they feel would be relevant to include for evaluating the safety and conduct of the clinical trial.

Benefits

Although it is possible for participants to benefit from tDCS and cognitive training, this study is investigational and no benefit (direct or societal) is guaranteed to participants. The knowledge derived from this research will facilitate our understanding of whether tDCS can increase the effectiveness of cognitive training to enhance cognition in those at increased risk of suicidal behavior and improve treatment outcome.

Discontinuation

Discontinuation Criteria

Participants may be withdrawn from the study if there are concerns about their safety, eligibility, and data quality. Participants will be withdrawn from the study, if the following adverse effects occur:

- Sores at the tDCS administration site
- Headaches that impair global functioning
- They make a suicide attempt while enrolled in the study
- Other unanticipated problem where the principal investigator feels it would be unsafe for the participant to continue

Participants may be withdrawn from the study if they decline to complete tDCS, cognitive training, or other study assessments. In the case of a suicide attempt, study staff will notify their mental health team and the

Suicide Prevention Program following the same procedures laid out above in the “Follow-up After Risk Assessment” section.

Withdrawal/Termination Procedures

If a participant withdraws from the study, the research team will not contact them about the research in the future. If it is unclear why the participant withdrew, research staff will attempt to ask for clarification. If a participant is withdrawn from the study, they will be promptly informed of the reason and will not be contacted about the research in the future.

If a participant withdraws or is withdrawn from the study, data collection will be discontinued for that participant. Data collected prior to the withdrawal may be used in data analyses.

Sharing of Results with Participants

Information regarding individual research results will not be shared with participants unless an incidental finding indicates a significant or potentially life-threatening abnormality.

Privacy, Confidentiality, and Information Security

The purpose of the data collection activities is to conduct scientific research and no personnel involved may identify, directly or indirectly, any individual participant in any report of such research or otherwise disclose participant identities in any manner. In order to address the objectives of this study, PHI will be obtained directly from participants as well as from VA/DoD medical records.

Personal identifiers will be stored on the Informed Consent and HIPAA Authorization Forms and in a master participant list within the research database. All other documents will contain the unique participant ID number. All paper documents related to this study will be stored in a locked file cabinet within locked research study offices at the MVAMC. Only the principal investigator, co-investigators, and IRB-approved study personnel will have access to PHI/PII for participants and these data are stored on VA premises or VA computer servers behind the VA firewall. Access to the MVAHCS computer server requires individual authentication and password log-in. Individuals from the MVAHCS IRB may look at study records as part of their duties.

All data will be maintained at the MVAMC per MVAHCS policies. Study records will be maintained in a secure location, and destroyed according to VA Federal Records requirements in VHA Record Control Schedule (RCS 10-1).

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