

# **Study Protocol & Statistical Analysis Plan (SAP)**

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Project: Adapting and Piloting Behavioral Activation for Veterans With Alcohol Use Disorder and Posttraumatic Stress Disorder

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**This Study Protocol and SAP follows the 2013 *Standard Protocol Items: Recommendations for Interventional Trials* Guidelines**

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## **Brief Project Summary**

The goal of this clinical trial is to compare an adaptation of Behavioral Activation, a behavioral intervention, to Relapse Prevention treatment, another behavioral intervention, in a sample of U.S. military veterans with co-occurring alcohol use disorder (AUD) and posttraumatic stress disorder (PTSD).

The primary aims of this study are to:

1. Adapt Behavioral Activation to treat veterans with AUD/PTSD,
2. Evaluate the feasibility, acceptability, and preliminary effects of Behavioral Activation for AUD/PTSD, and
3. Explore geospatial analysis as a new method for measuring AUD/PTSD recovery.

Participants will complete self-report and interview measures immediately before and immediately after treatment. Participants will also be asked to participate in passive geospatial assessment for 14-day periods immediately before and immediately after treatment. Participants will be randomized to treatment condition, which involves 8 sessions of either Behavioral Activation or Relapse Prevention, delivered individually by a trained study therapist.

## Detailed Project Description

Alcohol use disorder (AUD) frequently co-occurs with posttraumatic stress disorder (PTSD) among U.S. military veterans. Compared to veterans with AUD only, veterans with AUD/PTSD have greater symptom severity, more psychosocial functioning difficulties, and higher risk of suicide. Many people with AUD/PTSD perform behaviors aimed at avoiding unpleasant emotions (e.g., drinking to avoid trauma-related nightmares, skipping social events to avoid anxiety-provoking crowds). These “avoidance behaviors” provide temporary relief from unpleasant emotions, but they maintain AUD/PTSD and interfere with long-term functioning. Although treatments for AUD/PTSD exist, they emphasize symptom reduction (not functional improvement) and have dropout rates as high as 50%.

Originally developed to treat depression, Behavioral Activation (BA) is an intervention that increases daily participation in rewarding, alcohol-free activities relevant to patients’ social, vocational, and health-related values. Randomized controlled trials (RCTs) adapting BA for other disorders have shown that BA is efficacious for adults with alcohol/drug use disorders and acceptable to veterans with PTSD, but BA has not been used to treat co-occurring AUD/PTSD.

Additionally, because RCTs of AUD/PTSD treatments typically emphasize significant mean group differences in AUD/PTSD outcomes, less is known about the degree to which these treatments yield clinically significant improvements at the individual level. Individual-level improvements in AUD/PTSD should be evident not only in subjective clinical assessments, but also in objective measures of geospatial activity. Specifically, patients’ daily geospatial activity is likely to change as they decrease their avoidance behaviors and increase their engagement in various social, vocational, and health-promoting activities. Advances in geospatial methods, coupled with discreet and portable global positioning system (GPS) trackers, have made it possible to objectively measure people’s spatial movement within their communities. Yet although geospatial methods have been used to identify social determinants of alcohol use, they have not been used to measure response to AUD or AUD/PTSD treatment.

As the long-term objectives of this work are to identify a more acceptable AUD/PTSD treatment option and improve the measurement of AUD/PTSD recovery, this R34 project will address the following specific aims:

1. Adapt BA for use with veterans with AUD/PTSD;

2. Evaluate the feasibility, acceptability, and preliminary effects of BA, relative to Relapse Prevention, for veterans with AUD/PTSD in a pilot RCT; and
3. Explore geospatial analysis of GPS-collected data as a new approach to measuring AUD/PTSD treatment response.

This study will advance research and practice by piloting a novel application of BA and a novel measure of AUD/PTSD recovery. This project aligns with the National Institute on Alcohol Abuse and Alcoholism's special interest in investigating treatments for patients with AUD and co-occurring disorders, dimensions of functioning and well-being associated with recovery, and innovative methods for evaluating AUD treatment and recovery.

## Study Protocol and SAP

### Trial Design and Setting

This two-arm, 1:1, parallel RCT is being conducted by RTI International (a nonprofit research institute) and Duke University School of Medicine (an academic medical center), both based in the United States. Data will be collected by Duke and maintained at both Duke and RTI; RTI will conduct all outcomes analyses.

### Participants

**Sample size and recruitment.** This pilot study is not meant to be sufficiently powered to detect statistically significant group differences in clinical or functioning outcomes; rather, it is intended to examine BA's feasibility (i.e., participant recruitment and retention) and acceptability (i.e., treatment satisfaction). Results will inform the design of a future, fully powered efficacy trial. Forty-six veterans will be recruited via six established recruitment pipelines: (1) the Duke study team's research registry of military veterans who consented to be contacted about future research; (2) Duke University Health System clinics; (3) North Carolina institutions of higher learning; (4) North Carolina veteran and military family associations; (5) the Duke team's social media pages (e.g., Instagram, Facebook); and (6) flyers posted in the community.

**Eligibility criteria.** To be included, participants must: (1) be a U.S. veteran, (2) be 18 to 65 years old, (3) meet *Diagnostic and Statistical Manual of Mental Disorders, Fifth edition* (DSM-5)<sup>40</sup> criteria for current AUD, (4) report 3+ heavy drinking days (5+ drinks for men/4+ drinks for women) and 1+ heavy drinking week (15+ drinks men/8+ drinks women) in the past 30 days; (5) meet DSM-5 criteria for current PTSD; (6) endorse at least moderate difficulties with psychosocial functioning, defined as a score of 31+ on the Brief Inventory of Psychosocial Functioning (BIPF);<sup>32</sup> (7) be fluent and literate in English; and (8) be able to provide voluntary, informed consent to participate. Veterans will be excluded if they have/endorse: (1) lifetime mania/hypomania or current psychosis; (2) lifetime history of seizures; (3) lifetime alcohol withdrawal-related delirium or hallucinations; (4) prior inpatient alcohol withdrawal management; (5) a score of 10+ on the Clinical Institute Withdrawal Assessment of Alcohol Scale, Revised;<sup>41</sup> (6) current DSM-5 severe DUD (except for severe tobacco use disorder, which is not exclusionary) or past-30-day heroin or non-prescription opioid use; (7) psychotropic (including alcohol abstinence) medication changes within 90 days of study enrollment or plans to change medications

during the study; (8) current/planned non-study BA for any disorder during the study; or (9) current/planned evidence-based psychotherapy for AUD, PTSD, or DUD during the study. Eligibility criteria balance feasibility with participant safety (e.g., referring veterans at high risk for complicated withdrawal or with severe DUD for a higher level of care).

## **Interventions**

Participants will be randomized to receive eight weekly, individual, hour-long sessions of either BA or Relapse Prevention (RP) provided by a licensed psychological associate with a master's in clinical health psychology. This therapist is experienced providing manualized cognitive-behavioral treatments to veterans with PTSD and AUD/PTSD in the context of federally funded trials. Training for the current study included guided readings of relevant literature on BA and RP; didactic training from the PI in the theory, principles, and practices of BA and RP; multiple detailed reviews of the BA and RP manuals; and role play practices of intervention content with the PI. Sessions will be delivered virtually using Health Insurance Portability and Accountability Act (HIPAA)-compliant videoconferencing technology. The first session of both BA and RP includes identifying the veteran's alcohol use treatment goal (e.g., abstinence, low-risk drinking, or harm reduction), setting ground rules and treatment expectations, and reviewing alcohol withdrawal symptoms. Both conditions involve between-session practice tasks (i.e., homework) and address treatment termination in the final session.

**BA.** We will adapt empirically supported BA protocols<sup>14,23</sup> for this study. BA delivered to veterans with AUD/PTSD in this RCT will: provide psychoeducation and a treatment rationale; incorporate self-monitoring of activities and alcohol use; help veterans identify personal values in important life areas; specify and schedule alcohol-free activities that can move them closer to their values; and periodically revisit their values and brainstormed activities. Participants are encouraged to assume greater leadership of material review and in-session exercises over the course of treatment, and the frequency and/or perceived difficulty of scheduled activities are also increased across sessions.

**RP.** RP is a cognitive-behavioral psychotherapy that focuses on modifying thoughts and behaviors leading to alcohol use through self-monitoring and new coping skills.<sup>42,43</sup> Although RP is not trauma focused, it can reduce PTSD-related alcohol use because RP addresses each person's specific alcohol use "triggers." We therefore chose RP as our control condition because it can be used to treat AUD and PTSD simultaneously, is efficacious for veterans and civilians with AUD/PTSD, and is often used

as a comparator condition in AUD/PTSD trials.<sup>6,8 6,8</sup>In this study, we will adapt an RP protocol used in a prior AUD/PTSD trial<sup>87</sup> to match the BA condition for treatment frequency and therapist contact. RP sessions address coping with cravings and urges to drink, managing thoughts about drinking, drink refusal skills, planning for and coping with slips, seemingly irrelevant decisions, problem-solving, and coping with persistent problems.<sup>88</sup>

**Fidelity.** Therapist adherence to treatment protocols will be monitored using condition-specific fidelity scales (see Supplements 1 and 2). Fidelity scales will address three domains: general skill, adherence to manual guidelines, and condition-specific content delivery. Items assessing general skill will be drawn from an existing measure.<sup>44</sup> Items assessing guideline adherence and condition-specific delivery will be tailored to match session-specific manualized content. Therapy sessions will be recorded with participant consent; the RTI Principal Investigator (PI) will review 100% of recorded sessions until the therapist demonstrates manual proficiency and fidelity, after which a random 25% of recorded sessions will be rated for fidelity. The RTI PI and study therapist will meet weekly during the RCT to discuss cases and adherence. If therapist drift from either protocol is detected, the RTI PI will provide direct feedback and increase the frequency of recording review and consultation until fidelity returns to acceptable levels.

### **Intervention Assignment and Blinding**

Participants will be assigned to BA or RP via block randomization, which is preferred in pilot studies because it yields balanced arm sizes.<sup>45</sup> To ensure mastery of and fidelity to intervention protocols, the study therapist will first deliver one case each of BA and RP. The remaining 44 participants will be block randomized to intervention, yielding a final allocation of  $n = 23$  to each arm.

Sequence generation will be computerized by a programmer outside the study team. Only the study therapist and Duke PI will have access to password-protected allocation assignments for participants who completed or are actively in treatment. The RTI PI will not be blinded to assignment due to study therapist consultation calls and fidelity monitoring. Because BA and RP are behavioral treatments, participants will not be blinded to intervention. Outcomes assessors will remain blinded to participant condition throughout the RCT. To maintain blinding, allocations will be referred to via color code, not intervention name, and only the study therapist and PIs will know the code meaning.

Participants will be assigned to BA or RP after confirming eligibility during the pre-treatment assessment. At the end of the visit, a study coordinator will provide the participant with a sealed, opaque envelope containing intervention-specific handouts. The sealed envelopes will be color-coded and distributed in sequential order according to the allocation sequence. Participants will be instructed not to break the envelope seal until they leave the study office.

### **Participant Timeline**

Prospective participants will complete an initial telephone screening. Potentially eligible veterans will be invited to an in-person baseline visit to provide informed consent and complete the pre-treatment eligibility and outcomes assessment. Eligible veterans will then be randomized to either BA or RP. They will also be loaned a GPS logger to complete 14-day passive geospatial assessment prior to their first therapy session. Select measures will be administered mid-treatment. Outcomes and geospatial assessment will be administered post-treatment. See Figure 1 for this study schedule.

**Figure 1. Study schedule**

	Phone screen	Lab visit (baseline)	GPS return	Remote treatment sessions			Lab visit (post-treatment)	GPS return
				Sessions 1–4	Session 5	Sessions 6–8		
	Varies	Week -2	Week 0	Weeks 1–4	Week 5	Weeks 6–8	Week 8	Week 10
Participant compensation		X					X	X
Enrollment								
Eligibility pre-screen	X							
Informed consent		X						
Eligibility assessment		X						
Allocation		X						
Intervention (BA or RP)				X	X	X		
Assessments								
Sociodemographic and military background		X						
MINI		X						
TLFB		X		X	X	X	X	
LEC-5		X						
CAPS-5		X					X	
Geospatial metrics		X	→				X	→
BIPF		X					X	
PCL-5		X			X		X	
PHQ-9		X					X	
GAD-7		X					X	
ISI		X					X	
BADs		X			X		X	
DMQ-R		X			X		X	
RPI		X			X		X	
CSQ-8							X	
<p><i>Note.</i> Session 1 is scheduled for as soon after the 14-day GPS assessment period as possible, and the post-treatment assessment is scheduled for as soon after Session 8 as possible, based on participant and study team availability. MINI = Miniature International Psychiatric Interview for DSM-5; TLFB = Timeline Follow-back; LEC-5 = Life Events Checklist for DSM-5; CAPS-5 = Clinician-Administered PTSD Scale for DSM-5; BIPF = Brief Inventory of Psychosocial Functioning; PCL-5 = PTSD Checklist for DSM-5; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disorder-7; ISI = Insomnia Severity Index; BADs = Behavioral Activation for Depression Scale; DMQ-R = Drinking Motives Questionnaire-Revised; RPI = Reward Probability Index; CSQ-8 = Client Satisfaction Questionnaire-8.</p>								

## Data Collection

Outcome constructs, measures, assessment time frames, and descriptions are summarized in Table 1 and described further in Supplement 3. Assessments were selected based on construct relevance and psychometric properties. The pre-treatment assessment also measures sociodemographic and military background information and certain psychiatric diagnoses (using the Miniature International Psychiatric Interview).<sup>46</sup> Exploratory measures include the Drinking Motives Questionnaire–Revised,<sup>47</sup> Behavioral Activation for Depression Scale,<sup>48</sup> and Reward Probability Index.<sup>49</sup> Outcomes assessors will complete diagnostic and risk assessment training, which involves over 25 hours of didactic readings, in-person and web-based trainings, and role-play observations, followed by over 10 hours of supervised mock administrations. Assessors will also participate in monthly group consultation meetings during the RCT to discuss various interviewing topics and prevent assessment drift.

Geospatial data will be passively collected using a GPS logger, a small unit of equipment that self-locates via satellite triangulation. Geospatial data recorded by the logger (e.g., date, time, latitude, and longitude at each logged record) will provide estimates of participant movement patterns during the 14-day geospatial assessment periods. A 14-day period was chosen to be consistent with related research incorporating geospatial methods,<sup>33</sup> include weekday and weekend data (to capture work/school days and non-work/school days), and accommodate days with missing data.

To promote participant retention, study staff will send reminders before study visits, quickly reschedule missed visits, and send reminders to complete geospatial assessment and return the GPS logger after the 14-day period. We will compensate participants \$75 after both the pre- and post-treatment assessments and offer a \$25 bonus for returning the GPS logger after the post-treatment geospatial assessment period. Participants who withdraw early from treatment will be invited to complete the post-treatment assessment and receive compensation.

**Table 1.** Trial outcomes

Outcome Construct	Assessment Instrument	Brief Description	Additional Details
<b>Feasibility and Acceptability</b>			
Participant recruitment	N/A	Percentage of eligible veterans who enroll in the study	Participant recruitment will be deemed successful if we enroll 22 participants by RCT month 10 or else enroll 23 participants in the 10 months following mid-RCT recruitment strategy adjustments.
Treatment retention	N/A	Number of sessions attended; treatment dropout rate	Treatment completion will be defined as attending at least six out of eight ( $\geq 75\%$ ) BA sessions. Treatment retention will be deemed successful if at least two-thirds of enrolled BA participants ( $n = 15$ ) complete treatment.
Treatment satisfaction	Client Satisfaction Questionnaire–8 (CSQ-8)	Percentage of participants who report being “satisfied” or “very satisfied” with treatment	BA treatment will be deemed acceptable if BA participants’ mean item score on the CSQ-8 is $\geq 3$ .
<b>Primary Clinical Outcomes (Interviewer-Rated)</b>			
Alcohol use	Timeline Followback (TLFB)	Changes in past-30-day alcohol consumption from baseline to immediately post-treatment	Key indicators of alcohol use severity will include percentage of heavy drinking days, mean number of standard drinks per drinking day, and percentage of days with any alcohol use. Although drug use is not a primary outcome, the TLFB will also measure percentage of past 30 days with any drug use at pre- and post-treatment.
PTSD symptom severity	Clinician-Administered PTSD Scale for DSM-5	Changes in past-month PTSD severity from baseline to immediately post-treatment	In addition to calculating conventional total symptom severity scores, we will estimate latent PTSD symptom severity using moderated nonlinear factor analysis techniques.

(continued)

<b>Secondary Functioning Outcomes (Objective and Self-Reported)</b>			
Geospatial activity	GPS logger	Changes in past-14-day geospatial activity metrics from baseline to immediately post-treatment	Derived geospatial metrics will include mean distance of daily travel, mean number of locations visited each day, and activity space (e.g., km <sup>2</sup> ).
Psychosocial functioning	Brief Inventory of Psychosocial Functioning	Changes in past-30-day psychosocial functioning from baseline to immediately post-treatment	Instructions and scoring rules account for functioning domains that may not apply (e.g., if a respondent does not have children).
<b>Secondary Clinical Outcomes (Self-Reported)</b>			
PTSD symptom severity	PTSD Checklist for DSM-5	Changes in past-month PTSD severity from baseline to immediately post-treatment	N/A
Anxiety symptoms	Generalized Anxiety Disorder–7	Changes in past-2-week anxiety severity from baseline to immediately post-treatment	N/A
Depressive symptoms	Patient Health Questionnaire–9	Changes in past-2-week depressive symptom severity from baseline to immediately posttreatment	N/A
Sleep disturbance	Insomnia Severity Index	Changes in past-2-week sleep disturbance from baseline to immediately post-treatment	N/A

*Note.* The time frame for all clinical and functioning outcomes is from baseline through study completion (approximately 3 months). Treatment satisfaction is measured only at study completion (i.e., immediately post-treatment). Participant recruitment and retention metrics will be calculated from administrative study data. Additional information about these measures is provided in Supplement 3. RCT = Randomized controlled trial.

## Data Management and Analysis

Study data will be collected and stored via Duke-secured Qualtrics survey software, either entered directly by participants (for self-report measures) or by the study coordinator or therapist (for interview measures). Surveys will incorporate data quality promotion strategies (e.g., setting response validations). Analyses will focus on trial feasibility and acceptability. Preliminary effect sizes for clinical and functioning outcomes will be computed to inform the design of an anticipated fully powered efficacy trial. We will also explore whether geospatial data can be used to objectively measure AUD/PTSD recovery.

**Feasibility and acceptability benchmarks.** After accounting for treatment duration, we aim to finish enrollment by RCT month 20. If we have not enrolled at least 22 participants by RCT month 10, we will adopt additional recruitment methods. The *participant recruitment* benchmark will be met if we either enroll 22 participants by RCT month 10 or else enroll 23 participants in the 10 months following mid-RCT adjustments. *Treatment completion* will be defined as attending at least six out of eight ( $\geq 75\%$ ) sessions. We will conclude that the *treatment retention* benchmark was met if, at the end of the RCT, at least two-thirds of enrolled BA participants completed treatment. We will conclude that the *treatment acceptability* benchmark was met if BA participants' mean item score on the Client Satisfaction Questionnaire–8<sup>50</sup> is  $\geq 3$ , indicating they were “satisfied” or “very satisfied” with BA.

**Preliminary AUD/PTSD clinical outcomes.** We will follow recommendations for estimating participant-level clinically significant change (CSC) under measurement-error corrected multilevel modeling (MLM).<sup>51–53</sup> This involves a two-step process. Step 1 entails specification of a formal measurement model, with factor loadings and item intercepts estimated for the items (symptoms) underlying the outcome of interest from which scale scores and person-specific standard errors of measurement are extracted. In Step 2, AUD and PTSD severity outcomes will be analyzed separately using MLM accounting for two sources of error: measurement error and trajectory prediction error (i.e., typical Level-1 residual in MLM). Because this study will have only two time points, the level-1 residual variance will be constrained to zero, as an intercept and slope will fit “perfectly” through two time points. A “random-effects-only” two-level MLM will be specified by constraining the fixed effects for the intercept and slope to zero to ensure that each participant's slope is estimated in “raw” form instead of as the deviation of each participant's trajectory from the sample mean. Accordingly, statistical tests will

capture whether each individual participant's change over time (slope) differed significantly from zero.<sup>54</sup> Based on the direction of each participant's change, and whether their change is statistically significant,<sup>55</sup> each participant will be classified into one of four categories (significantly improved, nonsignificantly improved, nonsignificantly deteriorated, or significantly deteriorated), with differences in the proportion of participants in each category across BA and RP evaluated via multinomial logistic regression and 2x4 chi-square contingency tables.<sup>51,56</sup>

**Self-reported psychosocial functioning.** We will use MLM to examine within- and between-group changes in BIPF<sup>32</sup> scores.

**Geospatial analyses.** Consistent with related work,<sup>33,36,57</sup> geospatial metrics will include mean distance of daily travel, mean number of locations visited each day, and *activity space*. Activity space area (e.g., in km<sup>2</sup>) is typically estimated as a 1-standard deviational ellipse (1SDE) or convex hull polygon.<sup>58</sup> A 1SDE is constructed from 68% of a person's recorded locations and represents where a person generally spends time. A convex hull is constructed from the outermost coordinates and represents the perimeter boundary of where a person spends time. After conducting descriptives analyses, MLM will test within- and between-group changes in geospatial metrics for BA and RP participants. Finally, we will use parallel process latent growth curve analyses to explore longitudinal associations between geospatial metrics and pre- to post-treatment changes in alcohol use severity (TLFB), PTSD symptom severity (CAPS-5), and self-reported psychosocial functioning (BIPF), in addition to self-reported activation (BADs). These analyses will help us understand whether an apparent increase in activation, measured using geospatial methods, is associated with improvements on other outcomes.

**Missingness.** Outcomes analyses will be modeled under full information maximum likelihood (FIML) and supplemented by multiple imputation (MI) for missing data on key predictors. FIML and MI yield accurate estimates and standard errors under the assumption that missingness is at random. In assessing sensitivity to the missing-at-random assumption, we may explore latent pattern mixture models<sup>59–61</sup> or non-ignorable missingness.

## Monitoring

Duke, which is serving as the reviewing Institutional Review Board (IRB), has approved this study (Pro00113641). Any important protocol modifications, if approved by the sponsor, will be communicated to the IRB, updated within the trial registration record, and reported in dissemination

products. An independent Data and Safety Monitoring Board (DSMB) will serve as the RCT's monitoring entity. The DSMB will meet semi-annually during the RCT to review progress, interim results, and safety, and it will provide recommendations concerning study continuation, modification, or termination. Duke will additionally conduct periodic (at least semi-annual) auditing and reviews of trial conduct. Conducted independent from the research team, reviews will address compliance and quality.

### **Adverse Events**

Throughout treatment, the therapist will monitor for symptoms of alcohol withdrawal. Withdrawal symptoms, as well as any other adverse events spontaneously reported during study interactions, will be documented, rated for severity and study relatedness, and reported as required. Study staff engaged with participants will follow structured suicide and violence risk assessment and management protocols, which may involve contacting authorities and warning potential victims.

## **Ethics and Dissemination**

### **Consent**

Prospective participants will be provided with a consent form copy to review prior to attending their in-person baseline visit. Informed consent will be obtained on-site by study coordinators at Duke during the baseline visit and documented electronically. Study staff will meet participants in a private, distraction-free office and review each section of the informed consent form. To ensure understanding of study procedures before being enrolled, veterans must correctly answer six comprehension questions. Consent to geospatial data collection, as well as having their de-identified data submitted to the sponsor-designated data repository, will be obtained separately from consent to other RCT procedures. Participants will be informed they can still participate in the RCT even if they do not consent to GPS procedures or data repository submission. Participants will be informed they can withdraw from the study at any time without penalty, that the sponsor or regulatory agencies may terminate the study, and that the Duke PI might withdraw them from the study if indicated.

Immediately after providing written informed consent, participants will complete a breathalyzer test. In case of a positive result (over 0.00 g/dl), study staff will follow a structured protocol to ensure participant safety, reschedule the baseline visit (to also involve collecting new informed consent), and emphasize the need for a negative breathalyzer test to meet requirements for informed consent.

## Confidentiality

Prospective participant names, contact information, and basic eligibility information will be collected via certain recruitment pipelines (e.g., Duke clinics) and during the study telephone screen. Pre-enrollment data will be stored in a password-protected spreadsheet within in a firewall-protected, access-restricted Duke network location. This information is transferred to a different secure tracking database for enrolled participants and deleted for individuals who are ineligible or decline to participate. Recruitment and enrollment summary data will be reported to the sponsor and DSMB as required, but pre-enrollment identifying information will not be shared beyond Duke.

Outcome data will be collected, encrypted, and securely stored at Duke using Qualtrics. All surveys will be password-restricted and set up by study staff at each administration. Data will be transferred from Duke to RTI according to IRB-approved procedures and an inter-organizational Data Use Agreement. Once received by RTI, encrypted participant data will be stored on the study's secure, firewall-protected, access-restricted, and HIPAA-compliant network storage location ("RTI HIPAA share"). Geospatial data will be passively collected by study participants, who will carry a study-provided GPS logger continuously during 14-day periods at pre- and post-treatment. The loggers write geospatial data directly onto an inserted memory card. After the 14-day period, participants will use pre-paid shipping materials to return the logger to RTI, where study staff will download data from the memory card into the RTI HIPAA share. Data will then be permanently deleted from the memory card.

Virtual therapy sessions conducted using HIPAA-compliant videoconferencing technology will be recorded with participant consent to facilitate therapist fidelity assessment and case consultation. Session recordings will be transferred from Duke to RTI via approved protocols and saved on the RTI HIPAA share. Session recordings will be deleted after review.

Participants will be informed during the consenting process that study data will be maintained at Duke and RTI for at least six years after study completion. In accordance with sponsor policy, de-identified data from consenting participants will be uploaded to the National Institute on Alcohol Abuse and Alcoholism (NIAAA) Data Archive (NIAAA<sub>DA</sub>).<sup>62</sup> NIAAA sets semi-annual data submission deadlines and maintains the data indefinitely.

## Dissemination

De-identified data from consenting participants will be accessible via the NIAAA<sub>DA</sub> (collection ID C4785). Certain criteria related to protection of human subjects data must be met to be granted access to NIAAA<sub>DA</sub> data (see <https://nda.nih.gov/nda/standard-operating-procedures>).<sup>63</sup> Additional resources (e.g., statistical code) will be available from the RTI PI by request. We will register and report results on ClinicalTrials.gov, submit manuscripts for publication in refereed journals, present findings at conferences, and share findings with the public via digital and social media. Authorship will be determined according to the American Psychological Association's contributorship model<sup>64</sup> and code of ethics.<sup>65</sup>

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