

RMET15-955 Episodic Thinking (ET) as a Candidate Technique to Reduce  
Alcohol Consumption

Study Protocol

10/26/2017

## **Study Protocol**

### **Introduction**

Nearly 18% of United States adults meet criteria for alcohol dependence sometime in their lifetime, with only 24% of those individuals ever receiving any treatment for their disorder (Hasin et al., 2007). The pervasiveness of alcohol dependence indicates a need for continued development of high-impact treatments that are both effective and easily disseminated to a broad population. Recent evidence indicates that Episodic Future Thinking (EFT), the ability to self-project and pre-experience a future event, can help individuals to make changes to habitual behaviors, such as alcohol drinking (Snider et al., 2016). Here, we will evaluate the efficacy of EFT to help individuals reduce alcohol consumption. We anticipate that EFT will result in a reduction in alcohol consumption over a 2-week experimental period when compared to the control group.

### **Participants**

Up to 200 alcohol-dependent adults will enroll in this study. Participants must

- (1) provide written informed consent,
- (2) be 18-65 years old,
- (3) meet DSM-V criteria for moderate or severe alcohol use disorder, and
- (4) express a desire to quit or cut down on their drinking.

Individuals who are pregnant or lactating (through urine screen at time of consent), meet DSM-V criteria for any other moderate or severe substance use disorders (excluding caffeine, nicotine, and marijuana), score 23 or greater on the Alcohol Withdrawal Symptom Checklist (a score indicating that medication would be likely required to manage alcohol detoxification, see Pittman et al., 2007), use prescribed or over-the-counter medicines containing alcohol, participated in any previous studies that included EFT and conducted at the Addiction Recovery Research Center in the last 3 months, or have immediate plans to move out of the area will be excluded from participation. Participants may be compensated based on time and travel.

## **Recruitment**

This project will use recruitment strategies and procedures that are successful in the recruitment and retention of the targeted samples at the Addiction Recovery Research Center. Specifically, participants will be recruited from the Roanoke and Blacksburg, VA communities using IRB-approved study advertisements via posted flyers, and the Internet (e.g., Craigslist, Facebook, etc). Advertisements will include descriptions of the studies and contact information.

To the extent possible, we will attempt to minimize obstacles to participation. For example, travel barriers will be addressed by providing transportation or parking costs to participants, and scheduling barriers will be minimized by offering a flexible assessment schedule. All methods and measurement will be conducted using standard operating procedures, and all staff (including recruitment staff) will be provided with cultural

sensitivity training. We have a history of successful recruitment of alcohol-dependent adults into research programs. All participants will enroll on a voluntary basis and sign an IRB-approved consent form prior to study participation.

## **Consenting Process**

Potential participants will be given adequate time in a quiet room to read the written consent form. VTCRI research staff will review each element of the written consent form with the potential participant. The potential participant will be given the opportunity to ask questions and will have as much time as they need to decide whether they would like to participate in the study. Staff will reiterate that the potential participant can choose to decline participation in the study at that time or at any time thereafter without consequence. The potential participant and person obtaining consent will sign the consent form after the potential participant verbally states that s/he understands the conditions of the study, has no more questions, and chooses to participate.

## **Procedures**

Study design. After the initial consent and assessment sessions, participants will be asked to provide daily self-report assessments of previous-day drinking over cell phone (see below) for 7 days with no other study intervention taking place. The purpose for this baseline period is to quantify baseline drinking patterns and ensure that the participant reliably responds to and conveys study information via cell phone. At the end

of this baseline period, participants who indicated adequate patterns of drinking and successfully reported their level of drinking as requested on baseline days will be invited to continue in the study. Participants will return to the laboratory to be provided with a SOBERLINK breathalyzer and be given instruction in its use.

Participants will be counterbalanced to either the active or control group based on alcohol use (e.g., average drinks per day). Both groups will be exposed to the same treatment events. The intervention period will last for 14 consecutive days, with three breathalyzer screens per day. During this 14-day period as they did during the baseline period, participants will self-report their previous-day alcohol use daily with a text message and/or phone call. Assessment sessions will be conducted prior to the intervention, immediately following the intervention, and at a 1-month follow-up.

Participants will be provided with a prepaid cell phone (if necessary) at the beginning of the study and a SOBERLINK breathalyzer at the beginning of the 14-day period, and receive a \$50 study completion bonus at the end of the study provided these devices are returned.

Cellular phone communication. All participants will either be allowed to use their own personal cell phone for study communications or receive a prepaid cell phone with service through a nationwide cell phone service provider that specializes in providing powerful usage controls with their cell phones, allowing us to restrict phone communication to a study phone and 911 service. If a participant chooses to use his or her personal cell phone for study communications and pays for text messages and/or phone calls on a per unit basis, we may reimburse the participant for the cost of those

messages and calls made for this study. We have used study-provided cell phones to facilitate study communication previously (Koffarnus et al., 2011).

SOBERLINK breathalyzer monitoring. The SOBERLINK breathalyzer ([www.soberlink.net](http://www.soberlink.net)) contains a number of technological advances that make it ideally suited for remote breath samplings of alcohol use. To complete scheduled breathalyzer assessments, participants will simply blow into the device for 4 seconds. During the assessment, a picture is automatically taken of the user, which can be compared to a reference picture taken at study intake. The SOBERLINK device will automatically upload the breathalyzer results, the participant's location, and the picture of the user to a centralized, secure website where the data will be available to research staff. An on-screen display will notify participants of their blood alcohol content as indicated by expired Breath Alcohol Content (BrAC) as a percentage, and confirm submission if successful or instruct participants to redo the assessment if not successful for any reason (e.g., insufficient air flow to measure BrAC). Research staff will monitor these results and verify that the picture matches a reference picture for that participant.

All participants will be asked to complete breathalyzer screens 3 times per day for 14 days. A period of 14 days was chosen to determine if this procedure could result in alcoholic drink reduction using the EFT intervention. At the study onset, participants will be asked to designate the time at which each of the three breathalyzer screens will be scheduled each day. Participants will be asked to choose an assessment time shortly after they usually awaken, shortly before they go to bed at night, and one throughout the

day. They will be allowed to choose any times for the screens, excluding the hours between midnight and 5 am, provided that they are each separated by at least 6 hours. This will ensure that the first and last screens each day will be at least 12 hours apart and the screens will be distributed throughout the day, maximizing the likelihood of detecting alcohol use without placing an unreasonable burden on the participant. Throughout the intervention phase of the experiment, participants will be required to submit three daily breathalyzer assessments at the predetermined times. They will be reminded via text message when a sample is to be collected, and samples will be accepted up to 15 minutes before the scheduled time and 30-60 minutes after the scheduled time, giving the participant 45-75 minutes total to submit the sample. Both groups will receive a \$1 payment for each breathalyzer result submitted within the allowed submission period, regardless of the result of that test. This payment is to encourage participants to complete screens, even if they had consumed alcohol that day. Breathalyzer schedules will be similarly arranged for both groups.

**Intervention.** Participants will be assigned to either the active Episodic Future Thinking (EFT) condition or the control Episodic Recent Thinking (ERT) condition. EFT participants will generate positive future events they are looking forward to and that could happen at different future time points (e.g., in 2 weeks, 1 month, 6 months, 1 year) and participants in the ERT condition will list positive recent events (events that have already happened) that they enjoyed that occurred at different past time points (e.g., 12 hours ago, 24 hours ago, 1 week ago). Participants will be instructed to use and think about their episodic cues as they make decisions. All participants will be provided

with a copy of their episodic cues to take home with them and will receive periodic text messages from research staff to remind them of their cues. Research staff will be available throughout business hours and periodically during evening and weekend hours to deliver text messages and payments. Participants who choose breathalyzer assessment times late at night (e.g., after 8pm) will receive the corresponding payments the following day. Participants will have immediate access to these payments as soon as they are deposited by research staff (see below).

Daily alcohol use self-reports. Each day, participants will be asked to report how many alcoholic drinks they consumed the previous day (from the time they awoke to the time they fell asleep). We will ask them about the previous day alcohol use instead of the current day to best capture all drinks consumed each day without inconsistent response times complicating the measurement. Participants will be allowed to report this information at any time throughout the day, but will be encouraged through prompts to do so in the morning to increase the likelihood of accurate recall of previous day use. Participants will be allowed to report this information via text message or phone call. Participants will receive a reminder to report their previous-day drinking with text messages, followed by a phone call if they haven't contacted us by early evening. For completing this daily self-report, participants will receive \$1 in compensation.

Assessment sessions. Assessment sessions will be completed before the 14-day intervention period, immediately after the 14-day intervention period, and at a 1-month follow-up. Participants will complete a battery of questionnaires and tasks grouped into

three general categories: measures of substance use (including a urine test for drug and alcohol metabolites and a breath sample to test for recent alcohol use), clinically relevant measures including treatment acceptability, and measures of alcohol value and sensitivity.

## **Risks and Benefits**

Participants risk loss of confidentiality. Participants might feel uncomfortable disclosing personal information, might become bored during the research sessions, or might become frustrated with the tasks. Alcohol-dependent adults that reduce alcohol drinking might experience mild alcohol withdrawal (e.g., anxiety, agitation, headache, hypertension, insomnia, irritability). There are no other foreseeable risks for participants.

The study will be conducted at the Virginia Tech Carilion Research Institute.

Participants will be screened, using medical history and structured interviews, for a history of medical contraindications (e.g., pregnancy), current unstable medical illness and psychiatric disorders. Participants will be free to withdraw from the study at any time, and their refusal to continue will not affect other medical care associated with Carilion Clinic. In addition, if participants develop medical problems during the course of the study, assessments to determine whether participants should continue will be conducted and necessary referrals will be provided. Using only ID numbers and keeping all data in limited-access areas in locked offices will protect confidentiality. Computer databases will have coded identifiers, and all study team members will be trained in the protection of human subjects. These screening, monitoring, and confidentiality

procedures have been in effect for more than 10 years and for more than 1,000 subjects across the various protocols employed by our group across various institutions.

Participants will also be educated about the risks of alcohol withdrawal and will be provided with contact information for emergency medical care in the event that they experience alcohol withdrawal symptoms that warrant medical care. No other foreseeable risks exist for participants.

Participants may benefit from possible reduction in alcohol use or cessation of alcohol use. The project involves minimal risk to confidentiality or other personal rights or to physical or emotional health. Thus, the expected benefits outweigh the very minimal risks to participants.

## **Data Protection**

All data, including any identifiable information, and participant binders will be stored in a safe place to protect confidential participant information. Safe places will include locked filing cabinets or locked rooms accessible only to study personnel. The full names of participants will not be listed on the outside of binders to protect confidentiality of study participants.

Electronic data will be saved in secure, limited access shared drives on password-protected computers accessible only to the research team. Breathalyzer data will also be stored on secure SOBERLINK servers located within the United States during the

period of active data collection for this study only, after which point it will be completely deleted.

## **Participant Compensation**

Participants will receive

- \$15 compensation for the consent session
- \$15 for completion of assessment measures
- up to \$7 compensation for completion of the daily self-reports during the baseline period
- \$15 for completion of the pre-intervention (second) session
- 15 for the third session
- \$30 for the last follow-up assessment session
- up to \$56 for submission of the breathalyzer assessments and reports of previous-day drinking for the 14-day intervention
- \$50 for returning your SOBERLINK device and prepaid cell phone (if applicable)

These payments will be up to \$203 per participant, but may be less (depending on what study procedures he/she has completed).

To allow for payments that are both convenient and rapidly available, we will pay participants with reloadable prepaid cards through Greenphire ClinCard ([www.greenphire.com](http://www.greenphire.com)), an FDIC-insured payment provider that specializes in clinical trial stipend payments that comply with IRB privacy regulations and considerations. At

intake, each participant will receive a prepaid MasterCard debit card that can be used anywhere that accepts MasterCard. As payments are earned in the course of the study, additional funds will be added to the account for that participant. Funds are immediately available when added and participants can check their balance as desired. This system will allow frequent, immediately available payments without the burden of frequent laboratory visits that would negate some of the advantages of remote alcohol monitoring.