

COMPENSATORY COGNITIVE TRAINING VIA TELEHEALTH FOR VETERANS WITH  
ALCOHOL USE DISORDERS: A PILOT FEASIBILITY TRIAL

By

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## LIST OF ABBREVIATIONS

AUD	Alcohol use disorder
CCT	Compensatory Cognitive Training
CDW	Corporate Data Warehouse
CIVIC	Center to Improve Veteran Involvement in Care
CONSORT	Consolidated Standards of Reporting Trials
DKEFS	Delis-Kaplan Executive Function System
EBT	Evidence-based treatment
HIPAA	Health Insurance Portability and Accountability Act
ME-CCT	Motivationally Enhanced Compensatory Cognitive Training
ME-CCT-A	Motivationally Enhanced Compensatory Cognitive Training for Addictions
PCSS	Portland Cognitive Strategies Scale 2.0
PRMQ	Prospective-Retrospective Memory Questionnaire
PROMIS	Patient Reported Outcomes Measurement Information System
RCT	Randomized Controlled Trial
SATP	Substance Abuse Treatment Program
SUD	Substance use disorder
VVC	VA Video Connect
VA	Department of Veterans Affairs
VHA	The Veterans Health Administration
WRAT5	Wide Range Achievement Test, Fifth Edition

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## ABSTRACT

**Background.** Veterans with alcohol use disorders (AUDs) often experience cognitive deficits during the initial and early stages of alcohol remission, which can increase recurrence of alcohol use, reduce treatment compliance, and impair overall treatment outcomes. This study piloted a telehealth version of Motivationally Enhanced Compensatory Cognitive Training for Addictions (ME-CCT-A), a group-based cognitive rehabilitation intervention developed as an adjunctive treatment to address cognitive concerns during recovery from addiction. The primary aim of the study was to assess the feasibility and acceptability of the research protocol and intervention delivered via telehealth to Veterans with AUD in initial and early remission. A secondary aim was to evaluate the preliminary efficacy of ME-CCT-A delivered via telehealth on objective cognitive performance and subjective functioning, including perceived cognitive complaints/functioning, engagement in compensatory strategies and lifestyle practices that support cognition and overall health, and involvement in risk and protective factors/activities associated with alcohol use.

**Methods.** In this feasibility study, Veterans with AUD in initial and early remission participated in an 8-week cognitive rehabilitation intervention (i.e., ME-CCT-A) via telehealth and completed performance-based tests of objective cognitive functioning and self-report measures at baseline (pre-treatment) and at the conclusion of the intervention (post-treatment). Qualitative data were also obtained at post-treatment through open-ended responses on a treatment satisfaction questionnaire. Primary outcomes focused on recruitment, retention, telehealth feasibility, and participant satisfaction. Secondary outcomes evaluated changes in objective cognitive performance, perceived cognitive functioning, compensatory strategy use, health-related quality of life, and substance use factors. The study adhered to the Consolidated



Standards of Reporting Trials (CONSORT) guidelines for the conduct and reporting of pilot and feasibility trials.

**Results.** The study demonstrated feasibility of delivering the study protocol and ME-CCT-A intervention via telehealth, as evidenced by successful recruitment and retention. A total of 19 Veterans enrolled in the study, with 15 completing both the intervention and post-treatment assessments. Technical feasibility was demonstrated through the successful implementation of the intervention with minimal disruptions, highlighting the practicality of delivering ME-CCT-A via telehealth. Participants reported high satisfaction, with over 90% rating the program as “excellent.” Preliminary efficacy results showed promising trends, with significant improvements on several neuropsychological measures of attention, memory, and executive function following the intervention. Although some objective measures showed slight declines at post-treatment, participants perceived cognitive improvements. Significant improvements were also observed on self-report measures of compensatory strategy use, substance use, and quality of life indicators such as anxiety, fatigue, sleep disturbances, and social participation. Additionally, participants showed reductions in risk factors related to recurrence of alcohol use, including substance craving, physical health concerns, and relationship problems.

**Conclusion.** Results from this pilot study support that the research protocol and ME-CCT-A intervention via telehealth are feasible and acceptable among Veterans with AUD in initial and early remission who have cognitive concerns, evidenced by strong adherence, successful implementation, and high satisfaction. Preliminary findings suggest the intervention may positively impact subjective cognitive functioning, compensatory strategies, quality of life, and substance use, though objective cognitive gains were modest and not statistically significant. These findings offer important direction for future research, including refining recruitment

strategies, expanding to more diverse populations, and enhancing telehealth delivery with the ultimate goal of rigorously evaluating the intervention's efficacy in a larger clinical trial.

## CHAPTER I

### INTRODUCTION AND BACKGROUND

#### **Alcohol Use Disorders**

Alcohol use disorders (AUDs) and their associated symptoms have significant health, social, and economic consequences that profoundly impact American society. AUDs are among the most common psychiatric conditions in the United States with 29% of the population experiencing an AUD in their lifetime (Grant et al., 2015). AUD is frequently accompanied by various psychiatric conditions including depression, anxiety, and post-traumatic stress disorder (PTSD); medical conditions such as liver disease and cancer; and psychosocial challenges like accidental injuries, violence, and housing insecurity (Odlaug et al., 2016; Rehm et al., 2014; Shield et al., 2020). In addition to comorbidities, a significant increase in alcohol related mortality has been observed in the U.S. following the COVID-19 pandemic with approximately 178,300 people dying from alcohol-related causes in 2021, an increase of approximately 29% from 2017 (Esser, 2024). Beyond morbidity and mortality, AUDs costs the United States \$249 billion annually (Sacks, 2015) with the largest contributors being losses to workplace productivity, healthcare expenses, criminal justice expenses, and motor vehicle crashes (Rehm et al., 2009; Rehm & Shield, 2019; Sacks, 2015).

Rates of AUDs are higher among Veterans compared to the general population with lifetime prevalence of 41% (Panza et al., 2022), indicating that Veterans are nearly 1.5 times more likely to develop AUDs over their lifetime compared to civilians. Veterans' elevated risk may be related to the unique stressors associated with military service, such as the high rates of trauma exposure, readjustment stressors, and heavy alcohol consumption normalized within military cultures (Meadows et al., 2022; Osborne et al., 2022; Straus et al., 2020). Veterans with

AUD disproportionately utilize healthcare services compared to Veterans without AUD, evidenced by the high rates of hospitalization for alcohol-related conditions (e.g., liver disease, withdrawal complications), increased need for co-occurring mental health and substance use disorder (SUD) services, and strain on VA emergency services for alcohol-related incidents (Boden & Hoggatt, 2018; Fuehrlein et al., 2016; Panza et al., 2022). The elevated prevalence of AUD among Veterans is of critical importance given its impact on Veteran health, healthcare costs, and Department of Veterans Affairs (VA) system strain.

### **Psychiatric Comorbidities**

Adults with AUDs suffer from high rates of comorbid psychiatric conditions, especially depressive disorders, anxiety disorders, trauma- and stressor-related disorders, sleep disorders, and other SUDs (Castillo-Carniglia et al., 2019; Koob & Colrain, 2020). This is particularly true for Veterans, as results from the National Health and Resilience in Veterans Study (NHRVS) showed that Veterans with history of AUD were approximately four times more likely to have history of major depressive disorder (MDD) and PTSD compared to Veterans without AUD (Campbell et al., 2018). Additionally, individuals with AUD who engage in polysubstance use exhibit greater psychopathology and more severe AUD compared to those with AUD alone (Saha et al., 2018). This includes higher rates of mood and anxiety disorders, as well as increased levels of excessive drinking, drug use, and drug cravings.

Among adults seeking treatment for AUD, rates of psychiatric comorbidities are high and are associated with greater alcohol use severity and poorer functional outcomes (Engelhardt et al., 2024; Yang et al., 2018). According to the National Epidemiologic Survey on Alcohol and Related Conditions (Grant et al., 2004), of adults who sought treatment for AUD, approximately 40% had a mood disorder and 33% had an anxiety disorder. These comorbid conditions can

exacerbate one another, contributing to greater overall symptom severity, poorer treatment outcomes, and greater likelihood of recurrence of use (Bradizza et al., 2006). Additionally, many clinical features of AUD overlap with those of other disorders, such as sleep disturbances, cognitive complaints and impairments, and negative emotional states like worry, irritability, and sadness, all of which are often heightened during alcohol withdrawal and craving (Yang et al., 2018).

### **Challenges to Initial and Early AUD Remission**

Initial remission from AUD can be a difficult and uncertain period, as the detoxification process from alcohol typically lasts 3 to 7 days, but the exact duration can vary depending on multiple biopsychosocial factors (Gottlieb et al., 2024; Substance Abuse and Mental Health Services Administration, 2015). Key determinants include the severity of AUD with heavier and more prolonged alcohol use associated with more severe and long-lasting withdrawal symptoms. History of prior detoxification can increase the risk for complications and lead to a longer, more intense detoxification process, as repeated withdrawals have been shown to contribute to more intense symptoms (Becker, 2008). Additionally, the presence of co-occurring mental and physical health conditions can also complicate the detoxification process by intensifying withdrawal symptoms, increasing health risks, and necessitating more intensive medical management. Genetic vulnerabilities and nutritional deficiencies can also influence the severity and course of the detoxification process. These interrelated factors make the initial phase of remission one of the most vulnerable and demanding periods of recovery from AUD.

Even after detoxification, early stages of recovery from AUD are often fraught with recurrence of alcohol use that are attributable to a combination of neurobiological, psychological, and social factors. More than half of individuals return to using alcohol within two weeks of

trying to stop their use (Manning, Staiger, et al., 2016). Chronic alcohol use alters brain signaling pathways, particularly within the reward system, leading to heightened cravings, impulsivity, and impaired self-regulation, which make sustained recovery challenging (Czapla et al., 2016; Huang et al., 2024; Oscar-Berman & Marinkovic, 2007). Many individuals with AUD experience co-occurring mental health disorders and SUDs, which complicate recovery and increase the likelihood of recurrence of use (Castillo-Carniglia et al., 2019). Additionally, individuals often rely on alcohol to cope with difficult emotional states and experiences, creating a deep psychological dependence that can be difficult to overcome if other coping strategies are underdeveloped (Hawn et al., 2020; Osborne et al., 2022). Furthermore, environmental triggers such as social situations involving alcohol or exposure to alcohol-related cues further exacerbate risk of alcohol use, especially during early stages of remission (Vafaie & Kober, 2022). The absence of strong social support and limited access to evidence-based treatments (EBTs) compounded by societal stigma and shame can prevent individuals from seeking help, reinforcing a cycle of isolation and hindering the recovery process (Kilian et al., 2021; Miller et al., 2017; Schomerus et al., 2022). Although many of these factors can influence recovery long-term, they are particularly critical during initial and early remission when individuals are most vulnerable to recurrence of alcohol use given the acute neurobiological disruptions, emotional instability, and lack of established coping skills or support systems. This combination of multiple biopsychosocial challenges positions initial and early remission as particularly high-risk periods, highlighting the need for comprehensive treatment strategies to reduce recurrence of use and improve long-term outcomes for individuals with AUD.

## **Evidence-based Treatments for AUDs**

While spontaneous remission from AUD does occur (Mellor et al., 2019), untreated remission is associated with increased risk of recurrence of use compared to treated remission (Moos & Moos, 2006). This increased vulnerability is likely due in part to the absence of key protective factors typically provided in treatment settings, such as medical supervision, skills training, motivational enhancement, and psychosocial support (Substance Abuse and Mental Health Services Administration, 2019). Additionally, individuals who do not pursue AUD treatment may not have the opportunity to address underlying biopsychosocial factors that contribute to heavy alcohol use, such as co-occurring mental and physical health conditions and psychosocial stressors. Thus, EBTs offer improved efficacy and more prolonged benefit for individuals reducing or stopping their alcohol use.

A variety of practice guidelines are available for AUD treatment, including those issued by the VA and Department of Defense (Veterans Administration/Department of Defense, 2021), the American Psychiatric Association (Reus et al., 2018), Substance Abuse and Mental Health Services Administration (Substance Abuse and Mental Health Services Administration, 2019), National Institute on Alcohol Abuse and Alcoholism (National Institute on Alcohol Abuse and Alcoholism, 2024), and American Society of Addiction Medicine (Alvanzo et al., 2020). These guidelines primarily focus on pharmacological approaches to treating AUDs, which largely target neurotransmitter systems implicated in alcohol cravings, withdrawal symptoms, and risk of recurrence of alcohol use. Guidelines also promote evidence-based behavioral treatments, offered either alone or alongside medications for AUD, and include cognitive behavioral therapy, motivational enhancement therapy, contingency management, 12-step facilitation, community

reinforcement approach, and behavioral couples therapy (Substance Abuse and Mental Health Services Administration, 2019; Veterans Administration/Department of Defense, 2021).

Although the evidence base for current pharmacological and behavioral treatments for AUD continues to expand, treatment rates remain low. According to the 2023 National Survey on Drug Use and Health, of the 28.1 million adults with AUD in the past year, only 7.8% received alcohol use treatment, indicating a treatment gap of 92.2% (Center for Behavioral Health Statistics and Quality, 2024). Treatment rates for AUD within the VA are higher, with approximately 25% of Veterans with AUD receiving specialty addictions treatment (Williams et al., 2021). This is likely related to the VA's routine screening for AUD in primary care and mental health visits and the VA's integrated care model, which facilitates referrals to specialized care for Veterans with AUD (Bradley et al., 2006; Veterans Administration/Department of Defense, 2021), whereas the general public may face more barriers to accessing treatment, such as lack of identification of AUD, costs, and limited resources. Other barriers for both Veterans and the general public include stigma and privacy concerns, lack of interest, and the perception that existing treatments are ineffective or aversive (Venegas et al., 2021). Those with co-occurring psychiatric conditions are even less likely to seek or receive treatment (Alsuhaibani et al., 2021), highlighting the need for interventions that integrate mental health support within AUD treatment. For those who enter treatment, rates of recurrence of alcohol use remain very high (~40-60%), with more than half of individuals experiencing recurrence of use within six months of completing treatment (Moos & Moos, 2006; National Institute on Drug Abuse, 2020).

### **Cognitive Deficits and AUDs**

The majority of individuals seeking treatment for AUDs exhibit cognitive impairments across a variety of domains, including attention, memory, executive functions, and visuospatial



capabilities (Bruijnen et al., 2019; Crowe et al., 2020; Glass et al., 2009; Le Berre et al., 2017; Stavro et al., 2013). Cognitive deficits are particularly evident in initial remission from AUD (0-30 days) as studies have shown 50-80% of adults recently detoxified from alcohol exhibit cognitive impairments (Bernardin et al., 2014; Oscar-Berman & Marinkovic, 2007). Different cognitive domains are more or less affected over the course of remission from alcohol. In a meta-analytic study investigating the impact of AUD on cognitive functioning and its relationship to remission duration, Crowe et al. (2020) observed that cognitive deficits during initial remission (defined as 0-31 days) were primarily associated with executive function, including working memory and processing speed. In contrast, cognitive deficits in early remission (32-365 days) were largely related to visuospatial abilities, verbal processing, and memory. However, the persistence of these deficits follows a variable course with recent data highlighting individual differences in cognitive recovery with some individuals fully recovering from cognitive impairments after alcohol detoxification, while others continue to experience cognitive deficits even after one year of abstinence (Stavro et al., 2013). Notably, memory impairments have been shown to frequently persist into sustained remission (beyond 365 days) (Crowe et al., 2020).

The high prevalence of psychiatric comorbidities among adults with AUDs may partly exacerbate or contribute to the elevated rates of cognitive impairments in this population, as conditions like depression, anxiety, and PTSD are associated with cognitive symptoms (Millan et al., 2012). Numerous studies have shown that, compared to individuals without psychiatric conditions, those with MDD, PTSD, obsessive-compulsive disorder, panic disorder, and generalized anxiety disorder (GAD) experience significant cognitive impairments, particularly in domains such as attention, memory, and executive function (Rock et al., 2014; Scott et al., 2015; Shin et al., 2014; Vöhringer et al., 2013). In addition to psychiatric comorbidities, the cognitive

effects of AUD and the course of cognitive recovery are influenced by a variety of factors including the age of initiation, quantity consumed, duration of use, demographic factors (e.g., age, education), genetic predisposition, substance use comorbidities, and general overall health (Loeber et al., 2010).

Cognitive abilities are essential for developing awareness and overcoming ambivalence about behavior change, both of which are crucial for fostering the desire to change problematic drinking habits (Blume et al., 2005; Miller & Rollnick, 2013). Cognitive impairments can affect motivation for behavior change and hinder decision-making skills essential for altering problematic alcohol use and maintaining abstinence (Le Berre et al., 2012). Thus, cognitive impairments during initial and early remission from alcohol use may hinder an individual's ability to fully benefit from AUD treatment. Consistent with these findings, cognitive deficits are associated with increased rates of recurrence of alcohol use, less treatment compliance, and poorer treatment outcomes in individuals seeking AUD treatment (Czapla et al., 2016; Mahoney, 2019; Schmidt et al., 2017). Despite the high rates of cognitive impairments among adults with AUDs and their negative impact on treatment outcomes, current evidence-based pharmacotherapies and behavioral treatments do not specifically treat or address cognitive symptoms. For AUD treatment to be more effective, comprehensive approaches that address the multiple symptoms and challenges that interfere with recovery, including treatment of cognitive impairments, will be necessary.

### **Treatment of Cognitive Impairment in SUDs**

Recent research supports the potential benefit of structured treatments for cognitive deficits in SUDs, referred to herein as “cognitive interventions.” Cognitive interventions are not intended to replace evidence-based SUD treatments; rather, cognitive interventions can

potentially increase the efficacy and engagement in established EBTs as adjunct to ongoing treatment (Manning et al., 2017). The optimal timing and setting for integrating cognitive interventions into SUD treatment remains an important consideration with a recent expert consensus study (Verdejo-Garcia et al., 2023) recommending implementation of cognitive interventions during early remission, specifically after detoxification and within the first three months of remission. Additionally, experts suggest incorporating cognitive interventions into both abstinence-only and harm reduction SUD programs, indicating its potential usefulness for individuals with no use, ongoing use, or occasional recurrences of use.

Experts in the field of cognition-based treatments for SUDs endorsed four adjunctive cognitive interventions for the treatment of cognitive impairments in SUDs: cognitive bias modification, contingency management, cognitive rehabilitation, and emotion regulation training (Verdejo-Garcia et al., 2023). The four interventions target different cognitive processes through distinct techniques and mechanisms (i.e., active ingredients of the interventions). Cognitive bias modification and contingency management seek to modify addiction-related changes in the incentive salience system by reducing sensitivity to drug-related rewards and increasing the value of alternative reinforcers. Specifically, cognitive bias modification involves modifying implicit biases to drug-related cues and addressing inhibitory control deficits (often through computerized cognitive training), whereas contingency management facilitates behavior change through motivational incentives (e.g., money) dependent upon progress on a goal or behavior (Davis et al., 2016; Wiers et al., 2013). Cognitive rehabilitation and emotion regulation interventions address addiction-related changes in executive and decision-making cognitive systems by utilizing cognitive resources in a purposeful and strategic manner to achieve goals. Cognitive rehabilitation teaches internal and external strategies designed to restore or

compensate for cognitive deficits with the goal of enhancing everyday functioning (Nardo et al., 2022). Emotion regulation training involves strengthening cognitive control ability to directly impact emotional responses through mechanisms such as cognitive reappraisal and selective attention (Cohen & Ochsner, 2018). While all four intervention approaches have shown efficacy in clinical trial literature, effectiveness varies across type of SUD and impacted cognitive domains (Verdejo-Garcia et al., 2023). Additionally, these studies have several limitations, including small sample sizes, lack of result replication, and low specificity of the interventions. As a result, there is no gold-standard cognitive intervention for SUDs, highlighting the need for further research to determine the optimal treatment of cognitive impairment in SUDs (Maurage et al., 2024).

### **Cognitive Rehabilitation Interventions for AUDs**

An increasing number of recent reviews and expert consensus guidelines have identified the theoretical support and empirical evidence for the development and testing of cognitive rehabilitation treatments for adults with AUD (Anderson et al., 2021; Caballeria et al., 2020; Nardo et al., 2022; Rezapour et al., 2016; Verdejo-Garcia et al., 2024; Verdejo-Garcia et al., 2023). Cognitive rehabilitation interventions can be general (e.g., targeting global cognitive function) or focused on specific cognitive functions (e.g., inhibition, executive function, memory). Cognitive rehabilitation typically follows two distinct treatment approaches: 1) computerized cognitive training utilizing software to target and retrain specific cognitive functions through repetitive exercises and 2) learning and practicing of internal (e.g., cognitive, motivational, metacognitive) and external (e.g., physical environment) strategies to compensate for cognitive problems (Verdejo-Garcia et al., 2019)

Table 1 provides an overview of the design and outcomes of the limited number of published trials over the past 15 years that have assessed the efficacy of specific cognitive rehabilitation interventions for AUD. Of the 11 efficacy studies, only 5 studies included cognitive rehabilitation as an adjunctive treatment for AUD; the remaining 6 studies used cognitive rehabilitation as a standalone treatment. Additionally, of the 11 studies, 9 were computerized cognitive training and two were cognitive rehabilitation. Most interventions, particularly those targeting working memory, response inhibition, attention, and executive function, demonstrated significant cognitive and/or behavioral improvements compared to control conditions. Most interventions, particularly those targeting working memory, response inhibition, attention, and executive function, demonstrated significant cognitive and/or behavioral improvements compared to control conditions. Notable outcomes included improvements in working memory, response inhibition, verbal learning, and executive functioning; reduced alcohol consumption; and enhanced psychological wellbeing. While some studies showed mixed or minimal transfer effects beyond the trained tasks, especially in long-term outcomes or broader cognitive domains, cognitive rehabilitation combined with treatment-as-usual (TAU) often yielded greater benefits. Overall, cognitive rehabilitation appears promising, though there is substantial variability among studies in the types of cognitive rehabilitation interventions, participant characteristics, targeted cognitive domains, and outcome measures, demonstrating the need for additional research in this area. Moreover, few interventions incorporated strategies to enhance motivation or facilitate the transfer of cognitive gains to real-world settings. These limitations highlight the need for a more comprehensive approach to cognitive rehabilitation, specifically, one that strategically combines motivational

enhancement with compensatory strategy training to support sustained engagement and improve individuals' ability to manage cognitive and functional challenges in daily life.

**Table 1. Published Efficacy Trials of Cognitive Rehabilitation Treatments for AUD**

<b>Treatment type, targeted cognitive domain (Reference)</b>	<b>Design, setting, and sample size</b>	<b>Findings</b>
Computerized cognitive training  Working memory (WM)  (Houben, Wiers, et al., 2011)	Adults with AUD recruited from the community ( $N = 48$ ), randomized to virtual cognitive remediation (Cogmed; 20-25 sessions over ~25 days, $n = 20$ ) or a control condition ( $n = 28$ ).	Significant interactions indicated the cognitive training group showed better performance in WM from pre- to post-test compared to the control group (using the same tasks they were trained on), and this improvement remained significant at 1-month follow-up. Reductions in alcohol use were significantly greater in the treatment group compared to the control group at post-test and follow-up. WM capacity at post-test mediated the effect of the intervention on alcohol use at post-test in individuals with strong automatic impulses to drink, but not in those with weak impulses to drink.
Computerized cognitive training  Response inhibition  (Houben, Nederkoorn, et al., 2011)	College students who heavily consumed alcohol recruited from the community ( $N = 52$ ), randomized to response inhibition training (1 session, $n = 25$ ) or a control condition ( $n = 27$ ).	Significant interaction effects revealed that, compared to the control group, individuals in the cognitive training group were more likely to associate alcohol images with negative emotions at post-treatment (Implicit Association Test) and reported lower alcohol consumption one week after treatment.
Computerized cognitive training with treatment as usual (TAU)  Attention, memory, executive function  (Rupp et al., 2012)	Adults with AUDs in initial remission in inpatient treatment ( $N = 41$ ) were randomized to computerized remediation (Cogpack; 12 sessions of 45-60 minutes over 4 weeks, $n = 20$ ) with TAU or TAU only; $n = 21$ ).	The remediation group showed significant improvements from pre- to post-treatment on measures of general cognition (Mini Mental Status Exam), attention/executive function (Test Battery of Attentional Performance, Digit Span, N-back task), memory (Word List Long Delay Recall, Complex Figure Test Long Delay Recall; psychological well-being (Symptom Checklist-90-Revised), and the compulsion aspect of craving (Obsessive Compulsive Drinking Scale-German version).
Computerized cognitive training with TAU  Attention, memory, executive function  (Gamito et al., 2014)	Adults in early remission from AUD in a SUD program ( $N = 54$ ), randomized to mobile-based cognitive remediation (mHealth; 10 60-minute sessions for 4-6 weeks, $n = 26$ ) or TAU ( $n = 28$ ).	The cognitive remediation group demonstrated significantly greater improvement on one executive function task (Frontal Assessment Battery) but no change on other measures (Mini Mental Status Exam, Wisconsin Card Sorting Test [WCST], Color Trail Test).

Computerized cognitive training and work therapy with TAU	Veterans with AUDs in initial or early remission in an outpatient program ( $N = 31$ ) randomized to computerized cognitive remediation (Posit Science; daily for 3 months) combined with work therapy and TAU ( $n = 16$ ) or work therapy and TAU only ( $n = 15$ ).	Significant improvements were observed in verbal learning and memory (Hopkins Verbal Learning Test) at 3- and 6-month follow-up in the computerized cognitive remediation/work therapy group but not in the work therapy only group.
Learning and memory (Bell et al., 2016)		
Computerized cognitive training	Adults recruited from the community ( $N = 145$ ) with current AUD ( $n = 69$ ) or no AUD ( $n = 76$ ) randomized to adaptive (complex-span) WM training program (15 sessions over 4-weeks) or a control condition.	Results indicated enhanced WM in adults with AUDs and controls with improved scores on multiple transfer measures (Rotation Span Task, Running Letter Span, Running Spatial Span) following adaptive WM training. Adults with AUD demonstrated lower program compliance and smaller performance gains on the training tasks compared to controls.
Working memory (Gunn et al., 2018)		
Computerized cognitive training	Adults with AUD recruited from the community ( $N = 50$ ) were randomized to active WM training (Cogmed; 20 sessions over 5-weeks, $n = 25$ ) or a control condition ( $n = 25$ ).	Active WM training improved performance on the near-transfer task (Cogmed's "Following Instructions" task) but did not find group-level differences in change on delayed discounting tasks (Delayed Discounting and Episodic Future Thinking).
Working memory (Snider et al., 2018)		
Computerized cognitive training	Adults with AUD recruited from the community ( $N = 205$ ), randomized to online inhibitory control training (14 sessions over 4-weeks, $n = 155$ ) or a control condition ( $n = 50$ ).	Across groups, there were no significant changes on overall inhibitory control (Stop-Signal Response Task) or the disinhibiting effects of alcohol cues (Alcohol Implicit Association Task).
Response inhibition (Jones et al., 2018)		
Computerized cognitive training	Adults with active AUD recruited from the community ( $N = 50$ ) randomized to active WM training (Cogmed; 20 sessions over 5-weeks, $n = 25$ ) or a control condition ( $n = 25$ ).	Significant improvements in verbal WM (Digit Span) were observed in the active WM training group compared to the control group. WM training did not produce a statistically significant effect on any other neuropsychological tasks or alcohol use outcomes.
Working memory (Khemiri et al., 2019)		
Cognitive rehabilitation with TAU	Adults with AUD ( $N = 50$ ) in inpatient treatment randomized to a	Significant improvements in executive function (Matrix Reasoning, Controlled Oral Word Association Test, Color Trails, Five-Point Test,

Executive function (Kumar et al., 2019)	cognitive rehabilitation program that included mind-body exercises with TAU (18 sessions, $n = 25$ ) or TAU ( $n = 25$ ).	Digit Span, Spatial Span, Stroop Color-Word Interference Test, and Game of Dice Task) and affect regulation (Affect Regulation Checklist) were observed in the cognitive rehabilitation group compared to the control group. The cognitive rehabilitation group had lower rates of recurrence of alcohol use at 6-months compared to the TAU group.
Cognitive rehabilitation with TAU  Executive function, attention (Gamito et al., 2021)	Adults with AUD in inpatient treatment ( $N = 36$ ) randomized to a therapist-guided virtual-reality cognitive rehabilitation program with TAU (10 sessions, $n = 22$ ) or TAU ( $n = 18$ ).	Significant improvements were observed in the cognitive rehabilitation group on two out of five measures of attention (Toulouse Pierón test) and in two out of six measures of cognitive flexibility (WCST).

Of note, existing literature often uses the terms “cognitive rehabilitation,” “cognitive remediation,” and “cognitive training” interchangeably and inconsistently with conflicting descriptions of the assumed targets, proposed mechanisms of action, and goals of the interventions (Keshavan et al., 2014). Whereas traditional cognitive training programs were generally intensive, designed based on theory, and delivered in individual and group formats by trained instructors (Lustig et al., 2009), computer-based interventions, often in the form of gamified neuropsychological tests, have overtaken the field of cognitive training due to the booming commercial “brain training” industry, projected to be worth more than \$29.5 billion by 2027 (Market Research Engine, 2021). It is widely accepted that these computerized cognitive exercises promote learning; however, there is conflicting evidence on whether gains extend beyond the specific trained tasks (Boot & Kramer, 2014; Hampshire et al., 2019). At present, as no standardized terminology exists for these different approaches, “cognitive rehabilitation” is utilized herein to represent a comprehensive and multifaceted cognition-based intervention that incorporates structured exercises with compensatory strategies, psychoeducation, and practical real-world application. The goal of cognitive rehabilitation should be not only to enhance the



targeted cognitive domains but also to extend these improvements to other cognitive abilities and real-world situations.

### **Development of Motivationally Enhanced Compensatory Cognitive Training for Addictions**

Dr. Marilyn Huckans initially developed Cognitive Strategy Training (CST), a manualized intervention for adults with traumatic brain injury (TBI) at the VA Portland Healthcare System (Huckans et al., 2010). Meanwhile, Dr. Elizabeth Twamley developed the cognitive rehabilitation program, CogSMART, for adults with severe mental illness at the VA San Diego Healthcare System (Twamley et al., 2014; Twamley et al., 2008). Drawing on their complementary expertise, Drs. Huckans and Twamley collaborated to refine their interventions, co-developing the Compensatory Cognitive Training (CCT) for TBI manual, whose effectiveness was later demonstrated in a multi-site RCT (Storzbach et al., 2017).

Building on this foundation, Dr. Huckans led a major revision of the CCT for TBI manual, resulting in Motivationally Enhanced Compensatory Cognitive Training (ME-CCT). This updated version incorporates brief motivational interviewing techniques and modules designed to support behaviors that enhance cognition, such as physical activity, mental exercise, mindfulness, and the use of day planners and calendars. The updated version also facilitates discussion of home practice exercises, introduces more frequent mindfulness practices, and includes new decision-making strategies designed to reduce impulsivity. ME-CCT was recently evaluated in a multi-site RCT for Veterans with mild cognitive impairment (MCI), with results forthcoming. Dr. Huckans subsequently adapted ME-CCT for adults with addictions, resulting in the development of the Motivationally Enhanced Compensatory Cognitive Training for Addictions (ME-CCT-A) manual, which has been piloted in Veterans with AUD in a clinical setting at the VAPORHCS (Shirley et al., 2023).

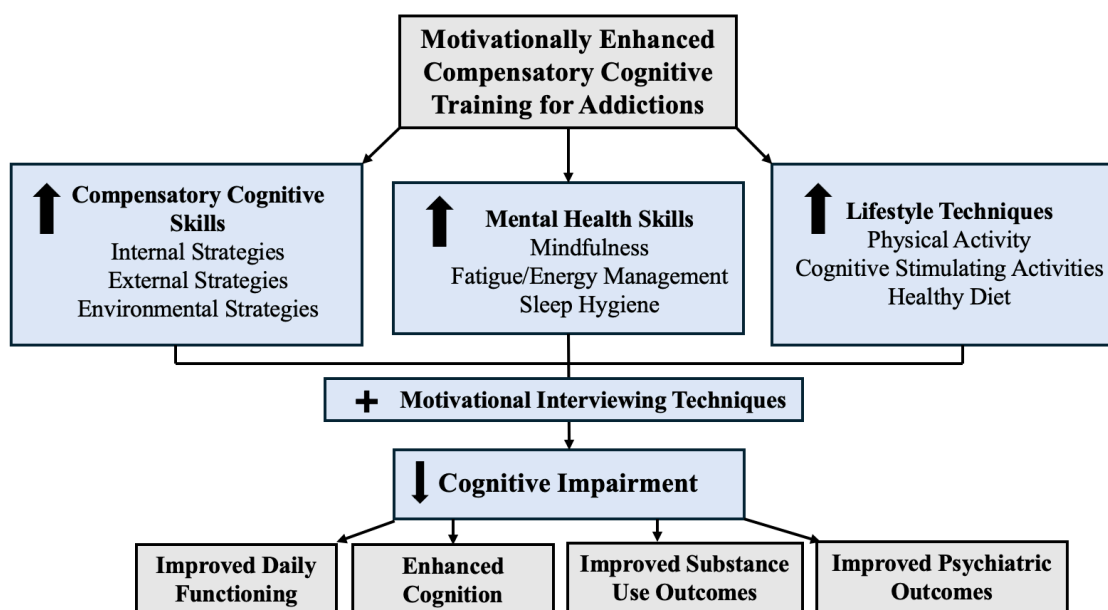
## **Motivationally Enhanced Compensatory Cognitive Training for Addictions**

Motivationally Enhanced Compensatory Cognitive Training for Addictions (ME-CCT-A) is a manualized group-based cognitive rehabilitation intervention designed to support cognitive functioning in Veterans with SUDs and cognitive complaints. The intervention is informed by two theoretical frameworks: Cognitive compensation and habit learning (Twamley et al., 2008). Cognitive compensation refers to the use of alternative strategies to circumvent cognitive weaknesses by drawing upon an individual's preserved cognitive strengths, often through engaging different brain regions to support the execution of complex cognitive tasks. Habit learning emphasizes the development of automatic, routine behaviors that are resistant to forgetting. This process relies on the dorsal striatum, a key structure in procedural memory. While the dorsal striatum is often more resilient than prefrontal regions in the face of chronic alcohol use and cognitive impairment, it may be vulnerable to dysfunction in more severe cases of AUD (Tochon et al., 2023). Guided by these two frameworks, CCT targets four cognitive domains – prospective memory, attention, learning/memory, and executive functioning – given their critical role in everyday functioning and evidence indicating they can be improved through compensatory strategies. As reflected in its name, CCT emphasizes the use of compensatory strategies (i.e., techniques to mitigate or manage cognitive difficulties) rather than restorative approaches (i.e., repeated exercises and practice to enhance cognitive function such as drill-and-practice activities), aiming to help individuals address cognitive impairments in ways that support their personal goals, social roles, and daily functioning.

Consistent with the expert recommendations for cognitive interventions in the context of SUDs (Verdejo-Garcia et al., 2023), ME-CCT-A utilizes compensatory approaches to support

cognition, improve functional outcomes, and promote AUD recovery. ME-CCT-A is a comprehensive treatment in that it addresses multiple types of symptoms and concerns that interfere with recovery from addictions: cognitive impairments, neuropsychiatric symptoms, and lifestyle patterns that increase risk of cognitive impairment, poor health, and recurrence of alcohol use. ME-CCT-A differentiates itself from other cognitive rehabilitation interventions for SUDs through its emphasis on the real-world application of cognitive strategies, aiming to enhance daily functioning and the management of cognitive difficulties. Additionally, ME-CCT-A incorporates motivational enhancement strategies, which facilitate sustained engagement and promote long-term behavior change. Figure 1 outlines the treatment components of the ME-CCT-A intervention.

**Figure 1. Treatment Components of ME-CCT-A**



**Compensatory Cognitive Skills.** Participants in ME-CCT-A are introduced to a variety of compensatory cognitive strategies aimed at enhancing memory, attention, and executive functioning. These strategies include internal techniques (e.g., visual imagery, categorization,

and acronyms to aid memory; assessment of immediate and long-term benefits and drawbacks to support decision-making), external tools (e.g., calendars and timers), and environmental modifications (e.g., establishing a quiet workspace). Strategies are designed to be particularly relevant for adults in remission from AUD; for example, explicit problem-solving and decision-making skills enhance participants' cognitive control when confronted with alcohol use triggers. Directly addressing triggers may help participants learn to manage or avoid situations that prompt cravings, supporting long-term recovery (Byrne et al., 2019; Kaplan et al., 2011). However, there is potential risk that focusing on alcohol use triggers could contribute to a resurgence of craving or increased distress if the trigger is repeatedly encountered without reinforcement, which could potentially reinforce the cycle of addiction. Alternatively, if the triggers are paired with nonreinforced exposure, the process may contribute to extinction, gradually reducing the trigger's influence over time. Thus, strengthening problem-solving and decision-making skills in ME-CCT-A is critical because it helps participants apply compensatory cognitive strategies and motivational techniques to manage triggers and real-world high-risk situations. Furthermore, to facilitate real-world application, participants engage in in-class activities and weekly home exercises designed to reinforce these cognitive strategies and tools. Home exercises are reviewed in subsequent sessions, allowing participants to receive feedback and troubleshoot challenges in applying new skills to daily tasks.

**Mental Health Skills.** ME-CCT-A incorporates mental health skills and strategies including mindfulness practices, fatigue and energy management, and sleep hygiene techniques to promote cognitive functioning and AUD recovery. Mindfulness has been shown to decrease impulsivity and enhance decision-making in individuals with SUDs (Anderson et al., 2021; Bowen et al., 2011), making it particularly valuable for those working to reduce or abstain from

alcohol use. Additionally, mindfulness may improve cognitive control over responses to substance-related cues, helping individuals recognize and regulate cravings while reducing automatic, habitual behaviors (Witkiewitz et al., 2013). Fatigue, a common symptom of alcohol withdrawal and associated medical conditions (e.g., nutritional deficiencies, liver dysfunction, disrupted circadian rhythms), can further compromise cognitive functioning (McCallum et al., 2019). Techniques such as pacing, taking structured breaks, and task modification can help manage energy levels and reduce cognitive strain. Finally, sleep hygiene techniques are crucial, given the high prevalence of sleep disturbances among individuals with AUD and the established link between poor sleep, cognitive dysfunction, and increased risk of relapse (Koob & Colrain, 2020; Laniece et al., 2021). Together, these strategies provide practical ways to compensate for cognitive impairments and enhance engagement in recovery-related tasks.

**Lifestyle Techniques.** Strategies to optimize brain health and cognitive recovery are incorporated throughout treatment to influence modifiable risk and protective factors associated with cognitive impairment in the context of AUD. Lifestyle strategies include direct participation in health-promoting activities (e.g., structured programs focused on exercise, diet, or tobacco cessation) and education on the cognitive benefits of healthy habits and the detrimental effects of unhealthy ones. Maintaining sufficient physical activity, participating in cognitively stimulating activities, optimizing one's diet, and reducing use of other substances (e.g., tobacco, cannabis) are key areas of focus, as studies indicate that these lifestyle habits enhance neural plasticity and brain resilience (Gomez-Pinilla & Kostenkova, 2008; Phillips, 2017).

**Motivational Interviewing Techniques.** Motivational interviewing exercises (MI; Miller, 2013) are incorporated throughout treatment to enhance participants' engagement, commitment, and adherence to regularly practicing the cognitive strategies, external aids, and

lifestyle techniques taught in ME-CCT-A. MI is an evidence-based intervention that has been shown to be effective in reducing unhealthy behaviors (e.g., excessive alcohol use) and promoting healthy behavior (e.g., physical activity), especially when combined with other treatments (Frost et al., 2018). Semi-structured MI activities guide participants in examining the costs and benefits of behavior change pertaining to mindfulness, routine use of a calendar or day planner, healthy diet, physical exercise, and mental exercise, while also strategically evoking participants' change talk and addressing ambivalence to change.

ME-CCT-A is designed to be easy to administer and an adjunct to standard AUD treatment programs. Groups run for eight weeks with each session lasting approximately two hours. ME-CCT-A can be facilitated by a diverse range of mental health or substance use providers including psychologists, substance use counselors, social workers, and nurses (Lindamer et al., 2022). While initially designed to be delivered in-person, ME-CCT-A can be delivered through virtual platforms with little to no modification of the content and structure of the intervention. The effectiveness of CCT in research and clinical settings has been established, with evidence of sustained effects and moderate to large effect sizes (Lindamer et al., 2022; Storzbach et al., 2017; Twamley et al., 2015). However, to our knowledge, no studies have investigated the use of ME-CCT-A in Veterans with AUD. This gap in the literature highlights the potential for a novel, targeted approach to address cognitive impairments in Veterans with AUD.

### **Use of Telehealth by Veterans**

The Veterans Health Administration (VHA) is a pioneer in the implementation of telehealth, defined as the use of technologies to deliver healthcare services remotely, typically involving both video and audio components (Roy et al., 2022). The VA rapidly expanded access

to telehealth visits through VA Video Connect (VVC) during the COVID-19 pandemic to reduce disruptions in care and mitigate risk of infection (Connolly, Stolzmann, et al., 2021). From February 2020 to November 2020, weekly telehealth visits increased by 1,653% with over 40,000 telehealth visits completed daily (US Department of Veteran Affairs, 2021). Rates of telehealth utilization within the VA have remained high with approximately 32,000 telehealth visits per day in 2023 (Veterans Health Administration, 2024). Furthermore, the VA has made significant efforts to enhance telehealth accessibility for Veterans of diverse racial and ethnic backgrounds, geographic locations, and age groups (Wray et al., 2022; Zulman et al., 2019). Initiatives such as the Digital Divide Consult implemented in September 2020 broadened eligibility for VA-loaned telehealth devices and provided financial assistance with internet connectivity, reaching Veterans from a number of high-need groups such as Veterans experiencing homelessness and rural-dwelling Veterans (Ferguson et al., 2024).

A national study of approximately 140,000 VHA patients who received AUD treatment from 2020-2021 found that about 90% of patients received at least part of their AUD treatment via telehealth (Perumalswami et al., 2024). Receiving care via telehealth was associated with higher rates of treatment initiation, amount, and retention compared to in-person care only. Additionally, patients with depressive disorders, PTSD, and anxiety were more likely to access AUD treatment via telehealth compared to in-person treatment, suggesting that telehealth may play a role in reaching and engaging AUD patients with co-occurring mental health disorders more effectively.

Telehealth can significantly enhance access to EBTs for Veterans with SUDs. Several randomized control trials (RCTs) and meta-analyses have investigated the efficacy of SUD EBTs delivered via telehealth versus in-person and found little to no difference between delivery

modalities (Fiacco et al., 2021; Lin et al., 2019; Shigekawa et al., 2018; Uhl et al., 2022; Young, 2012). Overall, studies indicate that SUD EBTs delivered via telehealth are equally effective as in-person delivery in improving SUD treatment outcomes. Moreover, these trials indicate similar rates of treatment completion between telehealth and in-person SUD EBTs.

In addition to improving access to EBTs, telehealth has many documented advantages for Veterans and providers. Telehealth can address concerns related to privacy and stigma in accessing SUD treatment by reducing public exposure and providing a degree of anonymity (Couch et al., 2024; Zinzow et al., 2012). This is particularly important given that prior studies have identified stigma as a primary barrier to SUD treatment for Veterans (Clement et al., 2015; Frost et al., 2022; Kulesza et al., 2015; Morris & Schomerus, 2023). With more than half of Veterans residing in rural areas, telehealth helps eliminate geographical and mobility barriers that can limit access to in-person SUD services (U.S. Department of Veterans Affairs, 2025). Telehealth also provides information into the Veteran's home environment and lifestyle that may not be easily accessible or disclosed during in-person appointments, allowing the provider to gain a more comprehensive understanding of the Veteran's daily life, including factors that may influence treatment and recovery (Slightam et al., 2023). Additional benefits include increased convenience, time saving effects, and increased flexibility for scheduling (Gajarawala & Pelkowski, 2021; Kintzle et al., 2022). Furthermore, studies have found a high degree of acceptability towards telehealth with data showing that many Veterans prefer telehealth to in-person visits (Slightam et al., 2020), strong support among VA providers for the ongoing use of telehealth (Connolly, Gifford, et al., 2021), and high patient and provider satisfaction with group-based SUD treatments delivered via telehealth (Gentry et al., 2019).



## **Purpose of the Current Study**

Veterans experience high rates of AUD and commonly present with cognitive impairments that can hinder treatment outcomes. As such, there is a critical need for an evidence-based cognitive rehabilitation intervention tailored to address their unique needs. Motivationally Enhanced Compensatory Cognitive Training for Addictions (ME-CCT-A) is a promising manualized cognitive rehabilitation intervention for addictions that was developed and piloted by the original developers of CCT. This study extends the research by evaluating ME-CCT-A delivered via telehealth in the context of AUD in initial and early remission. The specific aims of the study are 1) To assess whether the research protocol and intervention delivered via telehealth are feasible and acceptable for Veterans with AUD in initial and early remission and 2) To evaluate the preliminary efficacy of ME-CCT-A delivered via telehealth on objective cognitive performance and subjective functioning, including substance use, perceived cognitive functioning, compensatory strategy use, and health-related quality of life.

To our knowledge, no studies have been conducted to evaluate the feasibility of a telehealth-delivered, manualized, and comprehensive cognitive rehabilitation intervention for Veterans with AUDs and cognitive deficits. This study will allow us to optimize ME-CCT-A for the telehealth format and assess the feasibility, acceptability, and preliminary efficacy of the intervention in preparation for a larger-scale pilot trial.

## CHAPTER II

### METHOD

This study was informed by key elements of prior research (Huckans et al., 2010; Storzbach et al., 2017) and employed a pre-post research design to assess the feasibility and acceptability of the research protocol and ME-CCT-A intervention via telehealth for Veterans in initial and early remission from AUD. This single-arm pilot clinical trial was conducted at the VA Portland Health Care System (VAPORHCS) in Portland, Oregon. All procedures were reviewed and approved by VAPORHCS and Oregon Health & Science University (OHSU) joint IRB (Protocol #6208). The trial has also been registered at [clinicaltrials.gov](https://clinicaltrials.gov) under the ID NCT06134128. The study is presented in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting protocols of pilot and feasibility trials (Eldridge et al., 2016).

#### **Participants**

The target sample size was determined by the number of participants estimated to be feasible to recruit within the designated timeframe (i.e., October 2023-October 2024), not to exceed 30 Veterans. An upper limit was placed on the sample size to ensure the study remained feasible within the constraints of the project timeline, available resources, and staffing capacity, while still allowing for meaningful evaluation of key feasibility outcomes. Pilot data (Shirley et al., 2023) informed these feasibility estimates, as did the availability of personnel and funds for subject compensation.

Criteria for participation in this pilot trial included being a Veteran age 18 years of age or older and meeting *DSM-5* (American Psychiatric Association, 2013) criteria for AUD in initial or early remission. According to *DSM-5* criteria, remission from AUD requires that an individual no

longer meet any AUD criteria, with the exception of craving. “Initial remission” is specified if criteria have not been met for up to three months (1-90 days), while “early remission” is specified if criteria have not been met for three months to one year (90-365 days).

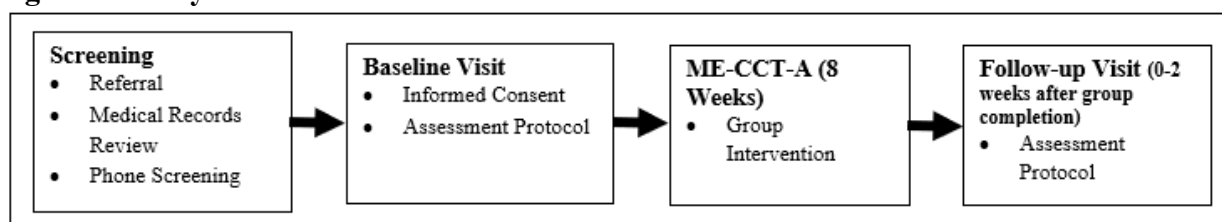
Additionally, eligibility for participation included concern about a mild cognitive decline identified by the Veteran or a knowledgeable informant (e.g., SUD treatment providers) with the Veteran wanting treatment for their cognitive concerns. Given that all study activities were delivered via telehealth, eligible Veterans were also required to have reliable access to internet and webcam.

Potential participants were excluded if they presented to study visits intoxicated or exhibiting impaired capacity to understand study risks and benefits; had diagnoses of Major Neurocognitive Disorder, dementia, neurodegenerative disorder (e.g., Parkinson’s disease); and/or experienced auditory or visual impairments that would prevent their ability to participate in the cognitive rehabilitation group or benefit from compensatory strategies. Eligibility was established by electronic medical record review and was confirmed by the Veteran during the initial screening phone call.

## Procedure

This study mirrored the procedures intended for a future pilot trial of ME-CCT-A delivered via telehealth to evaluate the feasibility of the proposed study design, intervention, and outcome measures. Figure 2 outlines the study procedures and timeline.

**Figure 2. Study Flow Chart**



To better understand, amplify, and accurately represent Veteran perspectives in this pilot trial, study staff engaged the Veteran Engagement Group (VEG) at the VHA Health Systems Research (HSR) Center to Improve Veteran Involvement in Care at VAPORHCS to solicit feedback on the implementation of the research protocol and intervention. VEG is comprised of Veterans from multiple service eras and branches of the military, including VA service users and non-users, VA employees, Veteran clinicians, and Veteran community members. Study staff gathered feedback on two focus areas: recruitment strategies to encourage Veteran participation and visual communication tools (e.g., study advertisements, PowerPoint slides used in the virtual group) to enhance Veteran engagement. VEG members reviewed materials in December 2022 and provided ongoing consultation during the research project.

During the December 2022 meeting, VEG members recommended that study advertisements refrain from identifying specific diagnoses (e.g., AUD) in the eligibility criteria and, instead, be more descriptive and person-first in the framing of problematic alcohol use. VEG members identified stigma as a major barrier to help-seeking by Veterans and recommended avoiding use of the term “AUD” to prevent implicit negative stereotypes that could deter participation in the study. This aligns with research demonstrating that AUDs are heavily stigmatized conditions (Kilian et al., 2021), and internalized stigma often undermines self-efficacy, stigma, treatment and research participation, and recovery outcomes (Hartwell et al., 2022; Morris & Schomerus, 2023; Schomerus et al., 2022). Thus, study advertisements opted to recruit Veterans who identified as having “reduced or stopped their alcohol use” to effectively reach Veterans with alcohol-related issues while minimizing stigma.

### ***Recruitment and Screening***

Veterans were recruited from the VAPORHCS through a variety of methods including provider referrals, study advertisements, virtual presentations to staff and Veterans, and outgoing letters to Veterans who met study criteria. All recruitment activities were documented to identify the most effective recruitment strategies for future trials.

Substance use treatment providers, mental health treatment providers, and research scientists were informed of the study through internal emails and presentations delivered at interprofessional meetings by the study staff. These healthcare professionals informed patients of the study and obtained their verbal consent to be contacted by the research team for a phone screening. Study announcements and advertisements were disseminated to VA treatment providers and posted in community locations frequented by Veterans with SUDs. Research staff attended Substance Use Treatment Program (SATP) treatment groups via VVC to advertise the study directly to Veterans engaged in SUD treatment. Social media was utilized for recruitment purposes, including posts on VAPORHCS-sponsored social media accounts and Craigslist. Potential participants contacted the study personnel after learning about the study (e.g., from providers, advertisements, or presentations).

To identify additional potentially eligible participants, the VA Corporate Data Warehouse (CDW; VA Informatics and Community Infrastructure), a national repository that contains comprehensive patient-level information such as clinical encounters and medical and mental health diagnoses, was utilized to compile a list of Veterans (Department of Veterans Affairs, 2013). Veterans with ICD-10 coded history of AUD who had accessed treatment at VAPORHCS within the past two years through the Residential Rehabilitation Treatment Program (RRTP) were identified with the assistance of data analysts at VAPORHCS' Center to Improve Veteran

Involvement in Care (CIVIC). Veterans identified through this data pull who appeared eligible following chart review were mailed a letter from the VAPORHCS Mental Health Clinical Director, a letter of introduction from the study team, the study flyer, and a form with the option to opt-in or opt-out of hearing more about the research either by calling study staff or returning the enclosed opt-in/opt-out form. A self-addressed, postage-paid return envelope was included for the Veteran's convenience. Study staff called all Veterans who indicated interest to provide more information about the study, answer any questions the Veteran had, and, if applicable, schedule an initial baseline visit.

Potential participants were screened by study personnel using a screening form. The method of participant recruitment (e.g., study advertisement, provider referral) was recorded for each potential participant. Following screening, eligible Veterans were sent an e-mail via DocuSign containing the Informed Consent Form and the Health Insurance Portability and Accountability Act (HIPAA) form. Informed consent was either obtained at the end of the screening call or conducted during the initial assessment study visit.

### ***Assessment Study Visits***

This pilot study involved two assessments visits: baseline (approximately 0-2 weeks prior to ME-CCT-A) and conclusion of the intervention (approximately 0-2 weeks following ME-CCT-A completion). Table 2 outlines the study timeline and participant activities. Study visits were held virtually through VVC and lasted approximately two hours. Visits involved a clinical interview and an assessment battery consisting of performance-based tests of objective cognitive functioning and self-report measures of subjective cognitive complaints/functioning, engagement in targeted lifestyle practices associated with improved cognition, and engagement in protective activities/factors associated with reduced recurrence of alcohol use. Participants were reimbursed

\$50 for the initial baseline assessment visit and an additional \$50 for their post-treatment visit.

Once at least 4 eligible Veterans completed baseline assessment visits, the 8-week ME-CCT-A group began via telehealth (i.e., VVC).

**Table 2. Study Timeline and Participant Activities**

<b>Study Phase</b>	<b>Timeframe</b>	<b>Activities</b>	<b>Compensation</b>
<b>Screening and enrollment</b>	Prior to baseline	Eligibility screening, informed consent	N/A
<b>Baseline assessment</b>	~0-2 weeks before ME-CCT-A start	Informed consent (if not completed during screening call), clinical interview, SCID-RV, cognitive battery, self-report measures	\$50
<b>Intervention period</b>	8 weeks	ME-CCT-A (group-based cognitive rehabilitation intervention, 1x/week)	N/A
<b>Post-treatment assessment</b>	~0-2 weeks after ME-CCT-A completion	Clinical interview, cognitive tests, self-report measures	\$50

Note: All study visits and groups were conducted virtually via VVC.

### ***Motivationally Enhanced Compensatory Cognitive Training Group***

Groups were facilitated by master's level mental health clinicians who underwent intensive training in CCT, which included observing a neuropsychologist facilitating the intervention, facilitating the intervention under supervision, and eventually co-leading sessions with a CCT expert. Group sessions lasted approximately 2 hours and consisted of interactive didactic information, discussions, and activities that introduced a variety of cognitive strategies and external aids. The ME-CCT-A treatment manual (Huckans et al., 2018), which is extensively used during group sessions, was mailed to participants prior to the start date of the group. Study staff completed reminder phone calls to participants the day prior to group to support attendance. The attendance of each Veteran at each session was recorded. Individual make-up sessions were

offered to Veterans who missed a session, and attendance at make-up sessions was recorded. Following each group session, facilitators completed a survey to assess interference presented by technology.

## **Materials**

Selection of materials was guided by previous research (Huckans et al., 2010; Storzbach et al., 2017) and a pilot study conducted by the investigators as part of usual care at the VAPORHCS (Shirley et al., 2023). Objective cognitive and subjective functioning measures were chosen to assess cognitive domains impacted by AUD and key topic areas covered in ME-CCT-A.

## ***Clinical Interview***

Participants were administered a clinical interview at baseline to collect demographic data and medical, psychiatric, and substance use history. Participants were asked questions regarding whether they have been diagnosed with specific medical and psychiatric conditions, the age at which they were diagnosed, and treatment for the condition. Information regarding hospitalizations, surgeries, and current medications was collected. Substance use history including duration and remission of alcohol, tobacco, cannabis, and other substances (e.g., sedatives, tranquilizers, opiates, methamphetamine), as well as treatment history, was also collected. Additionally, all participants underwent *the Structured Clinical Interview for DSM-5, Research Version (SCID-5-RV*; First et al., 2015) to comprehensively assess the presence of current and past psychiatric disorders.

At the post-treatment visit, participants underwent a brief interview to assess any changes in their medical or psychiatric conditions, as well as their substance use, during the course of the research study.



### ***Objective Cognitive Function Measures***

Participants were administered the Word Reading subtest from the Wide Range Achievement Test, Fifth Edition (WRAT5) at baseline to estimate premorbid intellectual functioning (Wilkinson & Robertson, 2017). WRAT5 utilizes age-based normative data to generate standard scores with a mean of 100 and standard deviation of 15, with higher scores indicating better word recognition abilities (Wilkinson et al., 2017).

Participants completed tests from the Neuropsychological Assessment Battery (NAB; Stern & White, 2003) at baseline and post-treatment visits. Measures were selected to assess the cognitive domains targeted in ME-CCT-A: attention/working memory (NAB Digit Span and Driving Scenes); memory (NAB List Learning and Shape Learning); and executive functions (NAB Judgment, Categories, and Daily Living Memory). Raw scores from NAB subtests are converted into T-scores using normative data based on age, education, and gender, where the mean is 50 and the standard deviation is 10, with higher T-scores indicating better function (Stern & White, 2003b).

The Verbal Fluency subtest of the Delis-Kaplan Executive Function System (D-KEFS; Delis et al., 2001) was administered at baseline and post-treatment. The Verbal Fluency subtest evaluates executive functioning, specifically cognitive flexibility, processing speed, and inhibitory control, by assessing semantic and phonemic fluency. Raw scores from the Verbal Fluency subtest are converted to T-scores using normative data based on age and education level, where the mean is 50 and the standard deviation is 10, with higher T-scores indicating stronger verbal fluency and executive functioning.

Table 3 lists the specific cognitive function measures and the corresponding cognitive domain(s) they assess.

**Table 3. Objective Cognitive Function Measures**

<b>Measure</b>	<b>Cognitive Domain(s) Assessed</b>
WRAT5 Word Reading	Premorbid intellectual functioning (baseline only)
NAB Digit Span Forward	Auditory attention capacity and working memory
NAB Digit Span Backward	Auditory attention capacity and working memory
NAB Driving Scenes	Visual attention and working memory
NAB List Learning Immediate Recall	Verbal learning and memory
NAB List Learning Delayed Recall	Verbal learning and memory
NAB Shape Learning Immediate Recognition	Visual learning and memory
NAB Shape Learning Delayed Recognition	Visual learning and memory
NAB Daily Living Memory Immediate Recall	Verbal learning and memory relevant to everyday function
NAB Daily Living Memory Delayed Recall	Verbal learning and memory relevant to everyday function
NAB Judgment	Everyday problem-solving/executive function
NAB Categories	Mental flexibility and categorization
D-KEFS Letter Fluency	Executive function
D-KEFS Category Fluency	Executive function

The cognitive domains were selected for assessment because previous research has demonstrated that SUDs can be associated with significant impairments in attention, memory, and executive functions, and because ME-CCT-A includes cognitive strategy training that specifically targets each of those domains (Huckans et al., 2021; Huckans, Fuller, Wheaton, et al., 2015; Huckans, Fuller, Chalker, et al., 2015; Huckans et al., 2010; Storzbach et al., 2017). Measures were selected because of their sound psychometric properties and their ability to be conducted virtually. Each neuropsychological measure has more than one form, minimizing test-retest confounds at the two assessment visits. Given that neuropsychological measures are considered intellectual property and one of the risks of administering them through telehealth is a possibility of unauthorized reuse or sharing of the measures, study staff informed Veterans at the beginning of each assessment session that they cannot record or otherwise preserve test stimuli

shown over the computer. Assessment measures were scored according to standardized test procedures. All assessments were administered by trained psychometrists and supervised by a licensed, credentialed, and privileged VA neuropsychologist.

### ***Subjective Functioning Measures***

Subjective self-report measures were hosted in the secure, web-based data capture software system, REDCap (Harris et al., 2019), which allowed participants to complete questionnaires independently on their virtual devices (e.g., computer, tablet) during or following study visits.

**Substance use.** The quantity and frequency of drug and alcohol use as well as risk and protective factors associated with substance use were measured via the Brief Addiction Monitor (BAM; Cacciola et al., 2013). The BAM includes three subscales that assess an individual's experiences over the past 30 days: "Use" (ranging from 0 to 12, with higher scores indicating more use), "Risk Factors" (ranging from 0 to 24, with higher scores indicating greater risk), and "Protective Factors" (ranging from 0 to 24, with higher scores reflecting more protection). The Timeline Followback (TLFB; Sobell et al., 1996) was administered to measure alcohol and other substance use (except nicotine and caffeine) over the last 30 days.

**Cognition.** The Prospective Retrospective Memory Questionnaire (PRMQ; Crawford et al., 2003) assessed the frequency of problems with aspects of everyday memory functioning. Total scores on the PRMQ range from 6 and 80 with higher scores indicating more frequent self-reported memory failures. Perceived cognitive functioning was assessed using the Patient Reported Outcomes Measurement Information System (PROMIS) Cognitive Function- Short Form 8a (Cella et al., 2019). This PROMIS scale is measured on a t-score metric with a mean of

50 corresponding to the mean score in the U.S. general population with higher scores indicating better cognitive function.

**Compensatory strategy use.** The Portland Cognitive Strategies Scale 2.0 (PCSS; Huckans et al., 2010, Shirley et al., 2024) was developed for use in CCT trials and is comprised of two subscales that ask individuals to rate the frequency with which they use specific cognitive strategies and external aids taught in CCT and the extent to which they find them useful. The total score of the frequency subscale ranges from 0 to 60 and the usefulness subscale ranges from 0 to 40. Higher scores represent greater frequency and/or perceived usefulness of cognitive strategies and external aids.

**Health-related quality of life domains.** The PROMIS-57 (Bevans et al., 2014) was administered to assess physical and emotional health, specifically: physical function, anxiety, depression, fatigue, sleep disturbance, satisfaction with social roles, pain interference, pain intensity. Raw scores were converted to a t-score, where a score of 50 represents the mean of the general U.S. population and 10 represents the standard deviation. Lower scores on the anxiety, depression, fatigue, sleep disturbance, pain interference, and pain intensity domains indicate better functioning, whereas higher scores on the physical function and satisfaction with participation in social roles domains reflect better functioning.

**Treatment satisfaction.** The Client Satisfaction Questionnaire (CSQ-8; Attkisson & Greenfield, 2004) and a series of structured, open-ended questions specific to ME-CCT-A via telehealth were included at the post-treatment visit to assess Veterans' satisfaction with the virtual CCT intervention. CSQ-8 scores range from 8–32, with higher scores indicating greater satisfaction with the intervention. The three open-ended questions probed participants'

perspectives on the benefits, disadvantages, and recommendations for the virtual ME-CCT-A group.

### ***ME-CCT-A Manual***

The structure of the intervention is determined by the ME-CCT-A treatment manual (Huckans et al., 2018). The manual was updated during this study to adopt non-stigmatizing, person-first, and clinically accurate terminology (Ashford et al., 2018; Morris & Schomerus, 2023). Changes to the text included updating “substance abuse” to “substance use,” “relapse” to “recurrence of use,” and “addicted person” to “person experiencing addiction.” Session materials correspond to compensatory cognitive training for cognitive domains commonly affected by SUDs, such as difficulties with learning, memory, processing speed, executive functioning (multitasking abilities), verbal functioning, concentration, and attention. Additionally, session content in the manual incorporates mindfulness exercises and MI techniques to better address symptoms related to SUDs that might influence cognitive functioning. Table 4 outlines the structure and content of the ME-CCT-A treatment manual and group sessions.

**Table 4. Structure and Content of ME-CCT-A**

Session	Major Concepts	Examples of Strategies	Session Activities	Home Exercise
1	Intro and SUD/cognitive functioning psychoeducation	Create a “home” for important items	Practice using a day planner/calendar	Find a home for a day planner/calendar
2	Organization and prospective memory, Part I	Time management	Scheduling and concrete goal setting	Practice using a calendar
3	Organization and prospective memory, Part II	Daily and weekly planning sessions	Enter activities into a day planner/calendar	Follow through with planning sessions
4	Attention and concentration	Paying attention during meetings and conversations	Practice paying attention during conversations	Practice active listening daily
5	Learning and memory	Internal and external memory strategies	Practice memory strategies	Use a memory strategy daily
6	Problem-solving and cognitive flexibility	Evaluating costs and benefits to identify better choices	Use 6-step problem-solving method	Practice problem-solving with 2 life goals
7	Planning and goal setting	Goal setting	Identify and re-evaluate priorities	Practice planning a goal
8	Skill integration and review	Review, practice, goals, and planning for the future	Discuss maintaining skills and applying them to goals	Review additional SUD-related resources

### ***Weekly Group Checklist***

The Weekly Group Checklist was designed for this study to record technical problems encountered during group sessions. Completed immediately after each group session, facilitators recorded the number and nature of technical problems encountered by facilitators and group participants. Categories of technical problems included: Audio, video, connection, or other problems. Facilitators assessed the level of disruption caused by the technical issue defined as: not disruptive at all; mildly disruptive (able to complete session, time disruption fewer than 10 minutes), moderately disruptive (able to complete session, time disruption of 10-15 minutes), or very disruptive (unable to complete session or time disruption of more than 15 minutes).

## **Human Subjects Protection**

All study data derived from subject procedures were obtained specifically for research purposes. Data were stored in a manner intended to preserve patient confidentiality. Raw data were stored on password protected computers in limited access folders behind the VA firewall. Each subject was assigned a unique identifier (study ID) based on study identifier and number (i.e., CCTA-xx). The file linking the unique identifier with the patient's name was stored in a separate password-protected file on a secure computer behind the VA firewall. Only coded or de-identified data were used for analysis. Coded data were also stored on OHSU's REDCap application, a highly secure and robust web-based research data collection and management system (Harris et al., 2019; Harris et al., 2009).

To further protect subjects' privacy and confidentiality, investigators obtained a Certificate of Confidentiality from the National Institute of Health. With this Certificate, the investigators could not be forced (e.g., by court subpoena) to disclose information that could identify subjects in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The informed consent document included a statement that this study had a Certificate of Confidentiality and described the type of information that was included in the subjects' VHA medical record.

## **Aims and Analytic Plan**

To characterize the sample, descriptive statistics for demographic, substance use, and mental health information were calculated as means and standard deviations for continuous variables and frequencies and percentages for categorical variables. Outliers were assessed by inspecting boxplots; outliers were rare and not extreme and were kept in the analysis. Shapiro–Wilk tests were used to examine normality of continuous data. Levene's tests were used to check

for homogeneity of variance. Patterns of missing data were assessed, and it was determined data were missing at random. Missing data were handled by pairwise deletion. A series of Welch's t-tests and Fisher's exact tests were conducted to examine differences in characteristics between successfully versus unsuccessfully recruited and retained Veterans to identify characteristics of Veterans who may require more intensive recruitment or retention efforts in a future trial.

Welch's t-tests and Fisher's exact tests were used to account for the small sample size. For all measures of association,  $p$  values  $< 0.05$  were considered statistically significant (all tests were two-tailed). All statistical analyses were performed using IBM SPSS Version 30.

**Primary Aim.** To assess whether the research protocol and cognitive rehabilitation intervention, ME-CCT-A, delivered via telehealth are feasible and acceptable for Veterans with AUD in initial and early remission.

**Hypothesis 1:** The research protocol and telehealth-delivered ME-CCT-A intervention will demonstrate feasibility and acceptability among Veterans with AUD in initial and early remission, as evidenced by adequate recruitment and retention; high treatment adherence; successful technical implementation with minimal disruptions; and positive participant feedback at post-treatment study visits.

Descriptive statistics were employed to examine feasibility of the planned design and intervention via telehealth. Recruitment feasibility was determined by calculating frequency rates and percentages to assess the effectiveness of recruitment mechanisms (e.g., advertisements, provider referrals) and participant screening, with the target of  $\geq 50\%$  of recruited Veterans enrolling in the study. Retention and adherence were assessed by calculating summary statistics for group attendance rates and the completion of follow-up assessments. Retention was deemed successful if at least 80% of participants completed post-treatment assessments, while adherence



was considered adequate if 75% or more of scheduled ME-CCT-A sessions were attended, including rescheduled sessions. Technical feasibility was evaluated by examining the frequency and nature of technical issues (e.g., connectivity problems) during sessions. Successful technical implementation was defined as fewer than 15% of sessions experiencing technical difficulties or significant disruptions.

Acceptability was assessed through descriptive statistics of participant feedback from the CSQ-8 and open-ended study-specific questions. ME-CCT-A was considered acceptable if  $\geq 70\%$  of Veterans scored  $\geq 24$  on the CSQ-8, indicating high satisfaction with the intervention. To facilitate qualitative analysis, a coding structure was developed based on the study-specific open-ended questions on the CSQ-8 and refined to incorporate emergent themes from the data. Responses were analyzed in two coding cycles: first descriptively, then conceptually. During the first cycle, two study staff members independently reviewed responses, noting potential codes and identifying illustrative quotes. They then met to reach consensus on meaningful content categories to organize the data. Content categories were retained if endorsed by at least two participants (representing over 10% of the sample), ensuring a meaningful level of agreement across participants. In the second coding cycle, principles of Applied Thematic Analysis were applied to organize descriptive codes into broader themes (Braun & Clarke, 2006). In addition to investigator triangulation through independent coding and collaborative consensus-building, the team maintained detailed records of the coding decisions, ensuring auditability. An independent research psychologist, unaffiliated with the study or VAPORHCS, reviewed the coding process, ensured consistency, and confirmed that the findings were accurately and objectively derived from the data, mitigating potential bias. Demographic and clinical characteristics (e.g., age,

gender, comorbid conditions) were considered to identify any subgroup patterns that might suggest a need for tailored recruitment or treatment adjustments in future trials.

**Secondary Aim.** To evaluate the preliminary efficacy of ME-CCT-A delivered via telehealth on objective cognitive performance and subjective functioning, including perceived cognitive functioning, compensatory strategy use, health-related quality of life, and substance use.

**Hypothesis 2:** Participation in ME-CCT-A delivered via telehealth will be associated with preliminary improvements in objective cognitive performance and subjective functioning, including perceived cognitive functioning, compensatory strategy use, health-related quality of life, and substance use, supporting the intervention's potential efficacy for Veterans with AUDs in initial and early remission.

Preliminary analyses using paired samples t-tests were conducted to examine pre-post changes on objective cognitive performance and subjective functioning measures. Significance and effect size were also examined. Effect sizes were calculated using Hedges' *g* correction to account for the small sample size, which is interpreted using the same criteria as Cohen's *d* (0.2 = small effect, 0.5 = medium effect, 0.8 = large effect).

Change scores were calculated to examine pre-post differences in objective cognitive performance at the individual task level. For each participant, task-level change scores were computed by subtracting the pre-test score from the post-test score on each task with a positive score indicating improvement, a negative score indicating decline, and a score of zero indicating no change. To summarize these patterns across participants, frequencies were calculated for each task, indicating the number of individuals who showed improvement, decline, or no change, providing a descriptive overview of the distribution of performance changes across tasks following the intervention.

## CHAPTER III

### RESULTS

#### **Hypothesis I: Feasibility and Acceptability**

##### ***Recruitment and Screening***

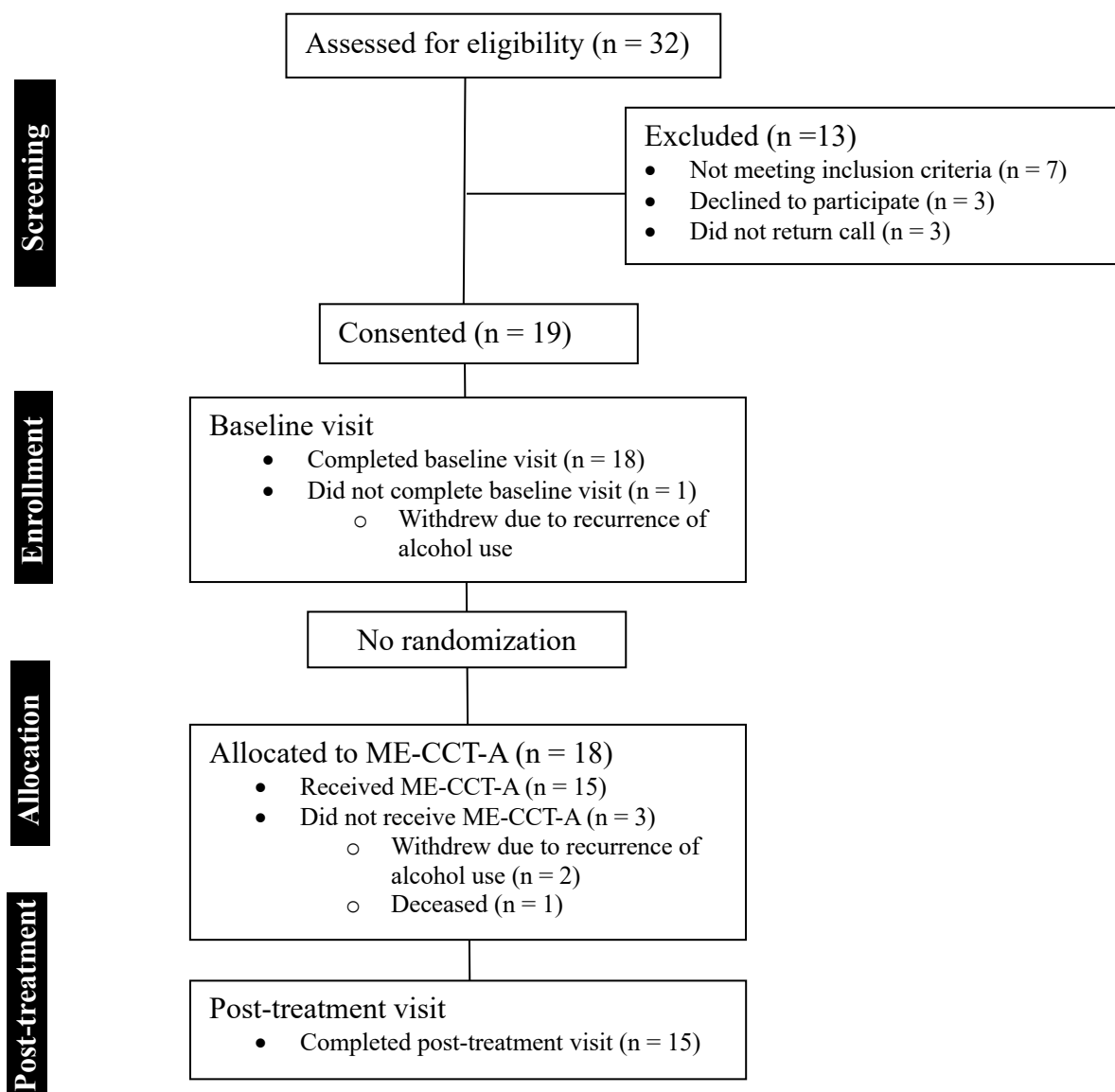
Recruitment and screening were conducted between October 2023 to October 2024. A total of 32 individuals were screened for participation after expressing interest through recruitment outreach ( $n = 27$ ; 84%) or being referred by their providers ( $n = 5$ ; 16%). Of the outreach efforts, study advertisements in elevators, lobby spaces, and clinics at VAPORHCS resulted in the highest number of contacts ( $n = 12$ ; 44%), followed by letters to Veterans who met study criteria ( $n = 11$ ; 41%) and presentations by study staff to Veterans in SATP groups ( $n = 4$ ; 15%). Study advertisements through social media and Craigslist did not result in any contacts. Referring providers included three SATP providers (social worker, psychologist, and psychiatrist), one Primary Care Mental Health Integration nurse, and one research psychologist.

Regarding recruitment through the CDW, 219 Veterans were identified, and 78 Veterans were screened for eligibility via chart review. The remaining 141 Veterans were not screened due to a shortage of personnel to conduct the chart reviews. Of the 78 screened, 61 met study criteria and were sent recruitment materials, with 11 contacting study staff for more information.

A total of 13 individuals were deemed ineligible for the study before completing the baseline study visit. Of these, 7 were excluded during the screening call due to not meeting AUD criteria (53.8%); 3 did not return calls to scheduling screening (23.1%), and 3 declined participation after screening (23.1%). The reasons for declining included time commitment ( $n = 2$ ) and discomfort with the use of the technology required to participate ( $n = 1$ ).

Recruitment was considered feasible if 50% of referred Veterans were screened, and 75% of those meeting eligibility criteria enrolled. Recruitment was successful, with 29 Veterans (90.6%) screened and 19 (76%) enrolled in the study. Telehealth delivery did not seem to significantly hinder interest or enrollment. Figure 3 outlines the CONSORT flowchart from eligibility assessment through post-treatment visits.

**Figure 3. ME-CCT-A via Telehealth CONSORT diagram**



### ***Participant Characteristics***

Demographic information and clinical sample characteristics are summarized in Table 5. A total of 19 Veterans enrolled in the study. Most participants were male (84.2%) and White non-Hispanic/Latino (78.9%), with an age range of 31-82 years ( $M = 49.9$ ,  $SD = 14$ ). Approximately 53% of participants did not have a college degree, while 47% had one or more degrees. The mean WRAT5 score was 103 ( $SD = 12$ ), indicating average premorbid intellectual functioning. Regarding employment, most participants were employed (31.6%), retired (26.3%), or unemployed (21.1%).

There were no significant demographic differences between study completers and dropouts, though premorbid intellectual functioning trended toward significance ( $p = 0.08$ ). Participants reported frequent memory failures (PRMQ,  $M = 55.7$ ;  $SD = 14.0$ ) and significant cognitive impairments (PROMIS Cognitive Function,  $M = 36.9$ ;  $SD = 6.8$ ), which were more than one standard deviation below the population average. No significant differences in cognitive functioning emerged between completers and dropouts.

**Table 5. Demographic Characteristics at Baseline by Completer Status**

	Completed ( <i>n</i> = 15)		Dropout ( <i>n</i> = 4)		Total ( <i>N</i> = 19)			
<i>Characteristic</i>	<i>n</i> (%)	<i>M</i> ( <i>SD</i> )	<i>n</i> (%)	<i>M</i> ( <i>SD</i> )	<i>n</i> (%)	<i>M</i> ( <i>SD</i> )	<i>g</i>	<i>p</i>
Gender								1.0
Male	12 (80)		4 (100)		16 (84.2)			
Female	1 (6.7)		0 (0)		1 (5.3)			
Other*	2 (13.3)		0 (0)		2 (10.5)			
Age (years)		50.8 (15.1)		46.5 (10.1)		49.9 (14.0)	0.16	0.88
Education (years)		14.2 (3.1)		13.0 (1.2)		13.9 (2.8)	1.21	0.25
Education								
< High school/GED	1 (6.7)		0 (0.0)		1 (5.3)			
High school	5 (33.3)		2 (50.0)		7 (36.8)			
Some college	2 (13.3)		0 (0.0)		2 (10.5)			
Associate's	2 (13.3)		2 (40.0)		4 (21.1)			
Bachelor's	1 (6.7)		0 (0.0)		1 (5.3)			
Master's	4 (26.7)		0 (0.0)		4 (21.1)			
Premorbid IQ estimate		105.1 (10.9)		90.0 (8.7)		102.6 (11.9)	2.62	0.08
Marital Status								
Single	2 (13.3)		1 (25.0)		3 (15.8)			
Married	4 (26.7)		0 (0.0)		4 (21.1)			
Widowed	2 (13.3)		0 (0.0)		2 (10.5)			
Divorced	5 (33.3)		3 (75.0)		8 (42.1)			
Separated	2 (13.3)		0 (0.0)		2 (10.5)			
Race/ethnicity								0.18
White, non-Hispanic	13 (86.7)		2 (50.0)		15 (78.9)			
White, Hispanic	2 (13.3)		2 (50.0)		4 (21.1)			
Employment								
Unemployed	2 (13.3)		2 (50.0)		4 (21.1)			
Employed	4 (26.7)		2 (50.0)		6 (31.6)			
Student	1 (6.7)		0 (0.0)		1 (5.3)			
Disability	3 (20.0)		0 (0.0)		3 (15.8)			
Retired	5 (33.3)		0 (0.0)		5 (26.3)			

Note: Data expressed as total (*n*) and percentage (%) or mean (*M*) and standard deviation (*SD*). Effect size (Hedge's *g*) and *p*-value (*p*) are reported. Other gender = Trans and gender diverse participants. Premorbid IQ estimate from the WRAT5 with dropout group of *n* = 3. No significant differences observed between completers and dropouts.

Tables 6 and 7 provide an overview of participants' substance use characteristics at enrollment and baseline. All participants were enrolled in outpatient or inpatient AUD treatment, with 89.5% receiving outpatient care. The majority of participants (52.6%) were in early remission (90-365 days), and 47.4% were in initial remission (0-90 days). The duration of abstinence ranged from 1 to 300 days ( $M = 123.9$ ,  $SD = 102.3$ ), and participants averaged 92.4 drinks per week prior to abstinence ( $SD = 67.5$ ). Participants averaged 15.6 years of problematic alcohol use ( $SD = 11.5$ ). Most participants had a history of tobacco use (47.4%) and 36.8% were current tobacco users. A quarter of participants (26%) were in sustained remission from another SUD (excluding cannabis and nicotine), most commonly opioids and stimulants. More than 20% of participants were current cannabis users, and one participant was in initial remission from another substance (i.e., tranquilizer). Substance use variables at enrollment and baseline did not significantly differ between study completers and dropouts.

**Table 6. Substance Use Characteristics at Enrollment by Completer Status**

	Completed ( $n = 15$ )	Dropout ( $n = 4$ )	Total ( $N = 19$ )	
<i>Characteristic</i>	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>	<i>p</i>
Current AUD Treatment				0.39
Outpatient	14 (93.3)	3 (75)	17 (89.5)	
Inpatient	1 (6.7)	1 (25)	2 (10.5)	
Remission Status				1.0
Initial Remission	7 (46.7)	2 (50.0)	9 (47.4)	
Early Remission	8 (53.3)	2 (50.0)	10 (52.6)	
Tobacco Use				1.0
Never User	2 (13.3)	1 (25.0)	3 (15.8)	
Current User	6 (40.0)	1 (25.0)	7 (36.8)	
Former User	7 (46.7)	2 (50.0)	9 (47.4)	
In Sustained Remission from Another SUD	4 (26.7)	1 (25.0)	5 (26.3)	1.0
Current Cannabis Use	4 (26.7)	0 (0.0)	4 (21.1)	0.54

Note: Data expressed as total ( $n$ ) and percentages (%) with  $p$ -values ( $p$ ) calculated with Fisher exact test statistic. No significant differences observed between completers and dropouts.

**Table 7. Substance Use Characteristics at Baseline by Completer Status**

	Completed ( <i>n</i> = 15)	Dropout ( <i>n</i> = 3)	Total ( <i>N</i> = 18)		
<i>Characteristic</i>	<i>M (SD)</i>	<i>M (SD)</i>	<i>M (SD)</i>	<i>g</i>	<i>p</i>
Duration of Abstinence from Alcohol (days)	128.5 (107.0)	100.7 (86.8)	123.9 (102.3)	0.49	0.66
Duration of Problematic Alcohol Use (years)	14.0 (14.4)	23.7 (15.5)	15.6 (11.5)	-1.04	0.41
Number of Alcoholic Beverages Per Week (prior to remission)	93.2 (73.6)	88.7 (55.4)	92.4 (67.5)	0.12	0.91
BAM Risk Factors	13.5 (3.8)	10.3 (7.0)	13.0 (4.4)	0.77	0.52
BAM Protective Factors	13.9 (4.1)	18.7 (3.8)	14.7 (4.4)	-1.97	0.14

Note: Data expressed as mean (*M*) and standard deviation (*SD*) with effect size (Hedge's *g* [*g*]) and p-value (*p*) calculated with Welch's t-tests. BAM = Brief Addiction Monitor. No significant differences on substance use characteristics were observed between completers and dropouts. The total sample size and the sample size for the dropout group were reduced by one participant, as the participant withdrew due to recurrence of heavy alcohol use.

Table 8 shows the frequencies and percentages of mental health diagnoses of participants. On average, participants met criteria for at least two non-SUD mental health diagnoses ( $M = 2.7$ ;  $SD = 1.1$ ), with the most common being depression (80%), PTSD (73.3%), and anxiety disorders (73.3%). The most common diagnoses were depression, PTSD, and anxiety-related disorders (e.g., GAD, panic disorder) at 80%, 73.3%, and 73.3%, respectively. No significant differences in mental health diagnoses emerged between study completers and dropouts.



**Table 8. Mental Health Diagnoses at Baseline by Completer Status**

	Completed ( <i>n</i> = 15)	Dropout ( <i>n</i> = 4)	Total ( <i>N</i> = 19)	
<i>Diagnosis</i>	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>p</i>
Depression (MDD)	12 (80.0)	2 (50.0)	15 (78.9)	0.27
Posttraumatic Stress Disorder	11 (73.3)	3 (75.0)	14 (73.7)	1.0
Anxiety (GAD, Panic Disorder, Social Anxiety, Agoraphobia)	11 (73.3)	3 (75.0)	14 (73.7)	1.0
Psychotic Disorder (Schizophrenia, Schizoaffective)	2 (13.3)	0 (0.0)	2 (10.5)	1.0
Bipolar Disorder (Bipolar I, Bipolar II)	1 (6.7)	1 (25.0)	2 (10.5)	1.0
Personality Disorders (Antisocial PD)	1 (6.7)	0 (0.0)	1 (5.3)	1.0
Obsessive Compulsive Disorder	1 (6.7)	0 (0.0)	1 (5.3)	1.0

Note: Data expressed as total (*n*) and percentages (%) with *p*-values (*p*) calculated with Fisher exact test statistic. Diagnoses determined by SCID-5-RV interview. Associations between mental health diagnosis and completer status were not statistically significant.

### ***Treatment Adherence and Retention***

Three groups (*n* = 15) were completed, with group sizes ranging from 3 to 8 participants. Informed by previous studies on CCT (Huckans et al., 2010; Twamley et al., 2014), adherence was defined as attending 75% of ME-CCT-A sessions, including rescheduled sessions. Participants attended a mode of 8 out of 8 sessions (range: 5-8 sessions; 95% adherence), with 73.3% of participants attending all 8 sessions. Thirteen make-up sessions (11.4%) were completed, primarily due to medical appointments (*n* = 7) and work conflicts (*n* = 4).

Retention was deemed successful if 80% of participants completed post-treatment assessments. Of the 18 baseline completers, 15 (83.3%) completed post-treatment assessments. Reasons for withdrawal included recurrence of heavy alcohol use (*n* = 1) and death prior to program start (*n* = 1). All 15 participants who started the intervention completed the program and

post-assessments. Post-treatment assessments were conducted between 1-28 days after completing the intervention ( $M = 8.9$ ,  $SD = 7.3$ ). Although post-treatment assessments were intended to occur within 0-2 weeks after group completion, two participants completed the assessment outside of this window due to extenuating circumstances. One Veteran was hospitalized, and the other was out of town; as a result, their follow-up assessments were completed on days 28 and 19, respectively.

### ***Technical Feasibility***

Technical feasibility was evaluated by documenting all technical problems encountered in the group sessions including the number and nature of the technical difficulties recorded on the Weekly Group Checklist. Of the 24 ME-CCT-A group sessions, technical difficulties were reported in three sessions (12.5%), including connectivity issues ( $n = 2$ ) and video problems ( $n = 2$ ). All technical difficulties were reported as “mildly disruptive” and able to be resolved in less than 10 minutes. Participants accounted for all technical issues; group facilitators did not report any technical problems. Additionally, self-report questionnaires hosted in REDCap had a 100% completion rate, supporting the feasibility of electronic data collection methods.

### ***Acceptability***

ME-CCT-A via telehealth was considered acceptable if  $\geq 70\%$  of Veterans scored  $\geq 24$  on the CSQ-8 at post-treatment. Scores on the CSQ-8 ranged from 24-32 ( $m = 29.5$ ,  $SD = 3.0$ ), suggesting high overall satisfaction with the intervention. Most participants (80%) were “very” satisfied, and the remaining (20%) were “mostly” satisfied. All participants (100%) reported that the intervention helped them manage their problems, and 93.3% rated the quality of services as “excellent.” All participants (100%) would recommend the intervention to a friend and reported they would participate again.

Qualitative analysis of participants' responses to a series of structured, open-ended questions further assessed Veterans' satisfaction with the telehealth group and recommendations for improvement. The most common positive themes were convenience of telehealth (e.g., "Easy to join the video call"); accessibility (e.g., "Video conferencing has made it easier for the VA to reach out and include more"); reduced stress (e.g., "Less stress of coming to the hospital"); and increased social incentives/support (e.g., "There could be more participation and consistency").

Perceived disadvantages included less social connection (e.g., "I prefer an in-person group because the connection between participants"); ineffective visual tools (e.g., "Maybe visuals would have been easier to see but we had handouts"); and technical difficulties (e.g., "Tech problems").

Suggestions for improvement included adjusting the intervention structure (e.g., "Mindfulness either shorten it or move it to the end"); improving technology use (e.g., "More training on how to use technology"); sharing an electronic version of the group manual (e.g., "Send an e-version of the book"); and increasing opportunities for social engagement (e.g., "Have online discussion forum platform to submit homework").

## **Hypothesis II: Preliminary Efficacy**

While the primary objectives of the current study were to assess feasibility and acceptability of the study protocol and ME-CCT-A intervention via telehealth, it was also important to examine whether pre-post changes on selected outcome measures were in the expected directions. This preliminary analysis aims to establish whether the intervention resulted in any changes in cognitive performance and subjective functioning, which could provide an early indication of its potential efficacy. Additionally, these analyses help determine whether the selected outcome measures should be retained, modified, or replaced in future trials.

The fifteen participants who completed the ME-CCT-A group were included in all analyses examining preliminary efficacy. Of note, the only missing data in this study were incomplete neuropsychological assessment data at post-treatment for one participant, which was addressed using pairwise deletion. Despite the small sample size, assumptions were checked, and the data followed a normal distribution. Pre-intervention and post-intervention scores on both objective cognitive performance and self-report measures were compared using paired t-tests, with effect sizes calculated using Hedges'  $g$  correction to provide a more accurate estimate due to the small sample size. For all analyses,  $p$ -values  $< 0.05$  were considered statistically significant, and effect sizes were interpreted according to standard thresholds (0.2 = small effect, 0.5 = medium effect, 0.8 = large effect).

### ***Objective Cognitive Performance***

As shown in Table 9, analyses yielded significant findings and encouraging effect sizes on several neuropsychological assessment measures. Participants who completed ME-CCT-A via telehealth exhibited statistically significant improvement on four out of the thirteen neuropsychological assessment measures. On a task requiring visual attention and working memory (i.e., NAB Driving Scenes), participants showed significantly higher scores post-treatment,  $t(14) = -4.65$ ,  $p = <0.01$ ,  $g = 1.17$ , indicating a large effect of the intervention. Statistically significant improvements were also observed on tests measuring visual learning and memory (i.e., NAB Shape Learning Immediate Recognition and Delayed Recognition), with moderately large effect sizes,  $t(14) = 2.61$ ,  $p = 0.02$ ,  $g = 0.66$  and  $t(14) = 2.48$ ,  $p = 0.03$ ,  $g = 0.62$ , respectively. Similarly, on a task requiring mental flexibility and categorization (i.e., NAB Categories), participants scored significantly higher post-intervention,  $t(14) = 2.48$ ,  $p = 0.03$ ,  $g = 0.63$ , also suggesting a moderately large effect.

When considering all measures, seven out of thirteen were in the expected direction, showing improvements in scores following the intervention. However, six measures revealed worse performance post-treatment, which warrants further investigation in future studies to understand potential contributing factors. The six measures were related to verbal learning and memory (i.e., NAB List Learning Immediate Recall, NAB List Learning Delayed Recall, NAB Daily Living Memory Immediate Recall, NAB Daily Living Memory Delayed Recall) and verbal fluency and executive function (i.e., D-KEFS Letter Fluency, and D-KEFS Category Fluency).

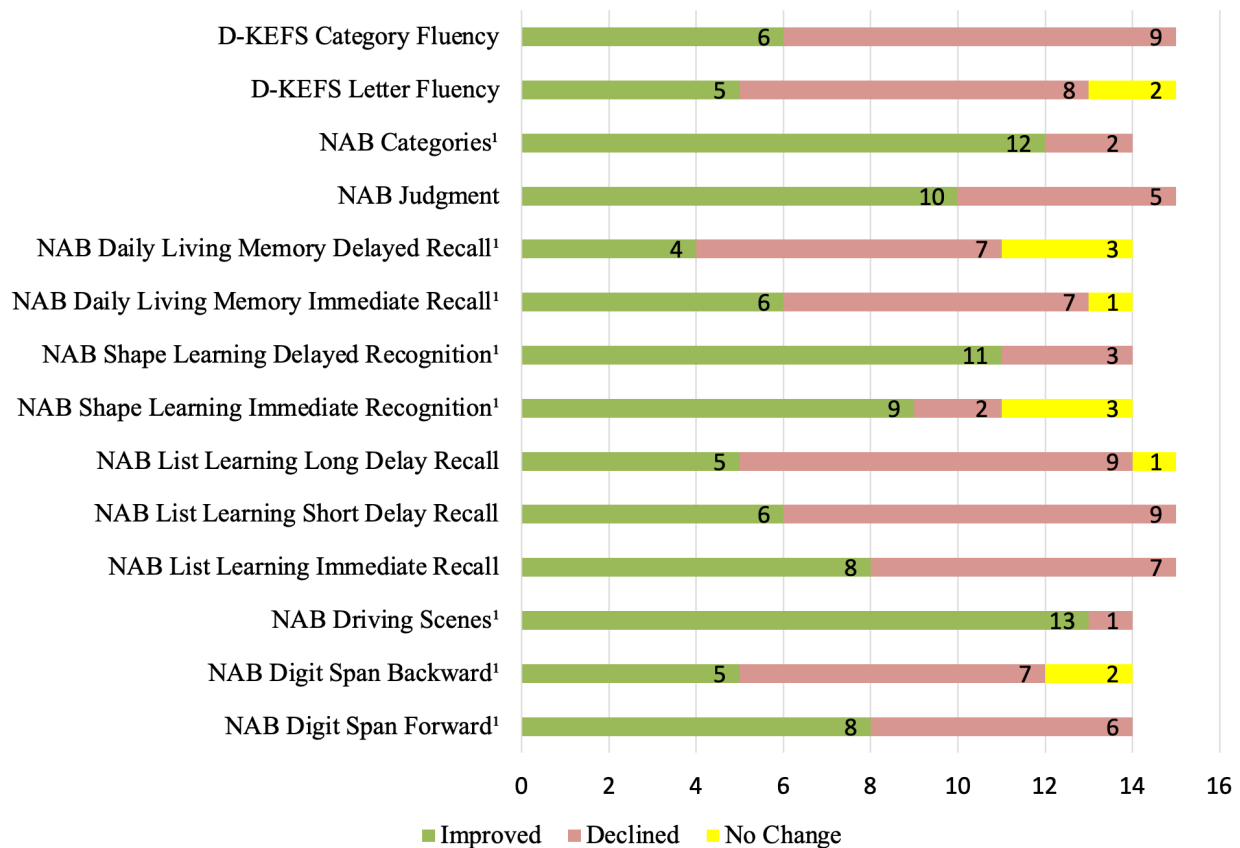
Individual-level change scores were analyzed to quantify the number of participants who improved, declined, or showed no change within each cognitive domain at post-treatment, offering a more nuanced and clinically relevant understanding of treatment effects. To facilitate interpretation, these results were visualized using a grouped bar chart (Figure 4). The analysis of change scores across the cognitive measures revealed a mix of improvement and decline among participants, with few instances of no change. On NAB Driving Scenes, 13 participants demonstrated improvement, 1 participant showed decline, and no participants exhibited no change, reflecting a clear trend toward improvement on this task of attention and working memory. In contrast, memory-related tasks, such as NAB List Learning Short Delay Recall and NAB List Learning Long Delay Recall, exhibited a greater number of participants experiencing decline (9 participants on each task) compared to those showing improvement (6 and 5, respectively), with no participants showing no change. Executive function measures, including NAB Categories and NAB Judgment, showed a higher number of participants improving (12 and 10) than declining (2 and 5). However, for the D-KEFS Letter Fluency and Category Fluency tasks, the number of participants who declined (8 and 9) exceeded those who improved (5 and 6).

Overall, the results indicated that while improvements were observed in several cognitive domains such as attention and working memory, memory measures were more likely to show decline, especially those involving delayed recall. The proportion of participants showing no change was generally low across all measures, suggesting task-specific variability in cognitive change over time within the sample.

**Table 9. Pre- and Post-Treatment (Tx) Data on Objective Cognitive Measures for Study Completers ( $n = 15$ )**

Measure	Pre-Tx score	Post-Tx score	Mean Change	T Score	P value	Hedges' <i>g</i>
NAB Digit Span Forward <sup>1</sup>	48.29 ± 8.1	47.29 ± 11.59	-1.00 ± 9.88	-0.38	0.71	0.10
NAB Digit Span Backward <sup>1</sup>	50.29 ± 14.24	51.71 ± 9.09	1.43 ± 11.76	0.46	0.66	0.11
NAB Driving Scenes <sup>1</sup>	38.57 ± 9.21	49.07 ± 9.09	10.5 ± 8.45	4.65	<b>&lt; 0.01</b>	1.17
NAB List Learning Immediate Recall	46.33 ± 7.39	45.20 ± 8.57	-1.13 ± 7.87	-0.56	0.59	-0.14
NAB List Learning Delayed Recall	47.53 ± 12.23	46.87 ± 7.03	-0.67 ± 8.86	-0.29	0.78	-0.07
NAB Shape Learning Immediate Recognition <sup>1</sup>	47.57 ± 10.38	56.29 ± 7.41	8.71 ± 12.49	2.61	<b>0.02</b>	0.66
NAB Shape Learning Delayed Recognition <sup>1</sup>	46.29 ± 9.59	53.21 ± 5.96	6.93 ± 10.46	2.48	<b>0.03</b>	0.62
NAB Daily Living Memory Immediate Recall <sup>1</sup>	46.43 ± 10.73	45.0 ± 10.24	-1.43 ± 8.53	-0.63	0.54	-0.16
NAB Daily Living Memory Delayed Recall <sup>1</sup>	45.14 ± 11.95	44.43 ± 9.37	-0.71 ± 7.02	-0.38	0.71	-0.10
NAB Judgment	50.80 ± 11.12	56.53 ± 7.79	5.73 ± 11.89	1.87	0.08	1.0
NAB Categories <sup>1</sup>	50.64 ± 6.25	53.43 ± 5.02	2.79 ± 4.19	2.48	<b>0.03</b>	0.63
D-KEFS Letter Fluency	11.20 ± 2.96	10.60 ± 2.9	-0.60 ± 1.81	-1.29	0.22	-0.31
D-KEFS Category Fluency	9.80 ± 3.26	9.27 ± 4.18	-0.53 ± 3.64	-0.57	0.58	-0.14

Note: Data expressed as mean total score ± standard deviation. NAB measures have a mean of 50 and a standard deviation of 10. D-KEFS measures have a mean of 10 and a standard deviation of 3. Higher scores indicate better performance. Effect sizes and p values reflect paired t-tests comparing pre-tx and post-tx scores on outcome measures. Bold font denotes  $p < 0.5$ . The full sample included 15 participants; however, <sup>1</sup> $n = 14$  for this task due to incomplete post-treatment data for one participant.

**Figure 4. Pre- and Post-Treatment Change Patterns Across Objective Cognitive Measures**

Note: Each bar represents the number of participants who showed improvement, decline, or no change on each cognitive measure from baseline to post-treatment. “Improved” indicates a higher score at post-treatment, “declined” indicates a lower score, and “no change” indicates identical scores at both time points. The full sample included 15 participants; however, <sup>1</sup>n = 14 for this task due to incomplete post-treatment data for one participant.

### ***Subjective Functioning***

Results from self-report measures are presented in Table 10. Regarding subjective cognitive functioning (i.e., PRMQ), participants reported significantly fewer memory problems post-treatment,  $t(15) = -4.77, p < 0.001$ , with a large effect size ( $g = -1.17$ ). Similarly, perceived cognitive functioning demonstrated significant improvement,  $t(15) = -4.77, p < 0.001$ , with a large effect size ( $g = -1.17$ ).

Concerning compensatory strategy use (i.e., PCSS), both the frequency of compensatory strategy use and the perceived usefulness of these strategies significantly increased after the intervention,  $t(15) = 5.44, p = <0.001, g = 1.33$  and  $t(15) = 4.66, p = <0.001, g = 2.0$ , respectively, both indicating large effects.

Significant improvements were observed in five out of eight PROMIS domains related to health-related quality of life. Specifically, significant large effects were observed in physical function ( $t(15) = 3.93, p = 0.002, g = 0.96$ ) and satisfaction with participation in social roles ( $t(15) = 4.24, p = <0.001, g = 1.04$ ), indicating improvement in these domains post-intervention. Significant large effects were also found in anxiety ( $t(15) = -4.38, p = <0.001, g = -1.07$ ) and fatigue ( $t(15) = -5.17, p = <0.001, g = -1.26$ ), indicating less anxiety and fatigue post-treatment.

Lower levels of sleep disturbance were observed post-treatment,  $t(15) = -3.02, p = <0.009, g = -0.74$ ), with a significant moderately-large effect. Depression, pain interference, and pain intensity did not differ significantly between pre- and post-treatment; however, while insignificant, outcomes appear to be in the expected direction across all PROMIS domains.

With respect to substance use (i.e., BAM), risk factors significantly decreased at post-treatment,  $t(15) = -4.85, p = <0.001, g = -1.18$ , indicating a large effect. However, substance use protective factors did not significantly change. On the TLFB, six participants (40%) experienced a recurrence of alcohol use during the intervention, with the average duration of use being 4 days (range = 2-7 days). One participant also increased their cannabis use during the study. No other participants initiated or escalated their use of secondary substances (e.g., cannabis, tranquilizers) during the study.



**Table 10. Pre- and Post-Treatment (Tx) Self-Report Data for Study Completers ( $n = 15$ )**

Self-Report Measures	Pre-Tx score	Post-Tx score	T-score	p value	Hedges' $g$	How is better function indicated?
<b>Subjective Cognitive Complaints</b>						
Prospective Retrospective Memory Questionnaire	57.3 $\pm$ 14.8	39.9 $\pm$ 10.6	-4.77	<b>&lt;0.001</b>	-1.17	Lower scores
PROMIS v2.0 Cognitive Function 8a	19.4 $\pm$ 7.1	26.9 $\pm$ 5.6	5.22	<b>&lt;0.001</b>	1.27	Higher scores
<b>Compensatory Cognitive Strategy Use</b>						
Portland Cognitive Strategy Scale (frequency)	27.2 $\pm$ 14.89	49.3 $\pm$ 4.8	5.44	<b>&lt;0.001</b>	1.33	Higher scores
Portland Cognitive Strategy Scale (usefulness)	24.2 $\pm$ 11.61	36.0 $\pm$ 5.6	4.66	<b>&lt;0.001</b>	1.14	Higher scores
<b>PROMIS-57 Domains</b>						
Physical Function	41.87 $\pm$ 7.85	48.69 $\pm$ 9.54	3.93	<b>0.002</b>	0.96	Higher scores
Anxiety	65.95 $\pm$ 7.66	58.57 $\pm$ 7.92	-4.38	<b>&lt;0.001</b>	-1.07	Lower scores
Depression	62.45 $\pm$ 9.44	58.42 $\pm$ 7.16	-1.98	0.068	-0.48	Lower scores
Fatigue	62.80 $\pm$ 10.85	54.86 $\pm$ 6.56	-5.17	<b>&lt;0.001</b>	-1.26	Lower scores
Sleep Disturbance	58.38 $\pm$ 9.47	53.22 $\pm$ 9.10	-3.02	<b>0.009</b>	-0.74	Lower scores
Satisfaction with Participation in Social Roles	42.61 $\pm$ 7.38	50.05 $\pm$ 9.40	4.24	<b>&lt;0.001</b>	1.04	Higher scores
Pain Interference	58.54 $\pm$ 10.75	55.31 $\pm$ 10.96	-1.98	0.068	-0.48	Lower scores
Pain Intensity	4.89 $\pm$ 2.42	3.73 $\pm$ 2.6	-2.0	0.066	-0.49	Lower scores
<b>Brief Addiction Monitor</b>						
Substance Use Risk Factors	13.5 $\pm$ 3.78	9.67 $\pm$ 2.97	-4.85	<b>&lt;0.001</b>	-1.18	Lower scores
Substance Use Protective Factors	13.87 $\pm$ 4.14	14.87 $\pm$ 3.70	1.01	0.33	0.25	Higher scores

Note: Data expressed as mean total score  $\pm$  standard deviation. Effect sizes and p values reflect paired t-tests comparing pre-tx and post-tx scores on outcome measures. Bold font denotes  $p < 0.5$ .

## ***CHAPTER IV***

### **DISCUSSION**

#### **Feasibility and Acceptability**

Regarding the primary question of feasibility, results support the feasibility of participant recruitment, retention, and telehealth delivery. Recruitment and eligibility rates indicated that the telehealth modality was not a substantial barrier to participation, with only one individual declining participation due to the telehealth format. However, several potential participants ceased communication during the screening process, suggesting that the telehealth format might have influenced their decision. Cognitive difficulties and the effects of AUD could have also contributed to these challenges. Recruitment was efficient, taking approximately one year to recruit 32 potential participants and consent 19 Veterans. Though the recruitment methods were effective in identifying participants with AUD in initial or early remission, provider referrals and online advertising were less successful than anticipated. The CDW provided a comprehensive list of eligible Veterans, but resource limitations prevented full review of these records. Future recruitment for larger trials may benefit from utilizing the CDW more efficiently, with adequate personnel to review records and deliver presentations directly to Veterans in SATP groups.

Regarding retention, this study did not find significant differences between completers and drop-outs in demographic, substance use, and mental health variables. This lack of significant differences may be attributed to the small sample size ( $N = 19$ ) and uneven group sizes (completers:  $n = 15$ , dropouts:  $n = 4$ ), which limited statistical power. For example, despite a noticeable difference in the duration of problematic alcohol use between completers and dropouts (14 years versus 24 years), results were not statistically significant ( $p = 0.41$ ), likely due to the high variability within both groups, particularly the dropout group with its small sample

size. The only variable nearing significance was estimated intellectual functioning, with dropouts showing slightly lower average scores at baseline. Significant differences in premorbid intelligence could introduce variability that might obscure the effects of ME-CCT-A in a future trial, as pre-existing cognitive abilities can influence pre- and post-treatment results. However, Twamley et al. (2011) found that premorbid intellectual functioning was not a predictor of cognitive improvement following CCT for adults with schizophrenia. Nevertheless, leveraging a larger, more diverse sample, particularly in terms of premorbid intelligence, will be important in future trials.

To improve future recruitment efforts, direct engagement through presentations in other VA clinics, such as the Liver Clinic or Mental Health Clinic, may be beneficial. Furthermore, collaboration with key stakeholders (e.g., VEG, SUD treatment providers) may help identify additional outlets for reaching Veterans with AUD from diverse backgrounds.

Of the 19 participants who completed baseline assessments, 83.3% completed the program, including post-treatment visits. Regarding the three participants who withdrew from the study after completing the baseline visit, none cited technological issues as the reason; instead, recurrence of alcohol use and death impeded participation. Treatment attendance was high, with participants attending an average of 7.6 out of 8 sessions. Treatment completion was very successful with all participants who started the intervention completing the intervention. The high treatment completion rate compares favorably with findings from a recent systemic review showing completion rates of web-based cognitive rehabilitation treatments ranging from 85-100% (Vuori et al., 2023). Overall, adherence and retention surpassed the target rate and was considerably higher than rates of adherence in earlier studies of CCT (Huckans et al., 2010; Twamley et al., 2014). Other markers of adherence are worth exploring in future studies, such as

tracking the completion of homework that is assigned each group session. Nevertheless, the planned design and group via telehealth did not appear to pose significant barriers to enrollment or completion of ME-CCT-A and, instead, appeared to support attendance and treatment completion.

Adherence was further supported by the inclusion of reminder phone calls and make-up sessions. Participants were reminded of group sessions the day before, and if they missed a session, they had the opportunity to complete make-up sessions. Forty-two percent of participants utilized at least one make-up session, which required substantial staff time. While these features were effective, they may not be feasible in larger trials without adequate resources.

Regarding acceptability, post-treatment quantitative and qualitative data on treatment satisfaction provided valuable insights into aspects of the telehealth program that participants valued, while also identifying areas for improvement in future trials. The treatment experience received high ratings of acceptability, as responses on the CSQ-8 suggested that participants benefited from and were satisfied with the intervention. These findings are consistent with those reported in previous CCT trials (Howe et al., 2019; Storzbach et al., 2017; Twamley et al., 2008), and suggest that telehealth is also perceived as an acceptable format for this intervention. However, it is important to consider the potential influence of the Hawthorne Effect, where participants may have reported higher satisfaction and perceived benefits simply due to the awareness of being observed in a research setting (McCambridge et al., 2014). This increased engagement and support may have enhanced participants' comfort with and perception of the telehealth delivery model, leading to more favorable evaluations than might be observed under typical clinical conditions. As such, high satisfaction with telehealth may, in part, reflect the structured, supportive research environment rather than the format alone.

Qualitative feedback highlighted the beneficial role of telehealth in increasing convenience, reducing stress, and boosting social support within the group. While 40% of participants denied disadvantages of the group being offered through telehealth, others mentioned challenges such as reduced social interaction, ineffective visual tools, and technical difficulties. Recommendations for improving the group via telehealth included possible changes to the intervention, such as improving interaction with other participants by creating a virtual message board or place to share completed homework. Participants also expressed interest in receiving an electronic copy of the ME-CCT-A manual rather than relying on a paper version. This recommendation is particularly pertinent given that all study contact is conducted electronically except for the physical mailing of the treatment manual. Participants may benefit from training in the use of VVC, either conducted by study staff or through a referral to the VA's Office of Connected Care Help Desk. Despite these suggestions, most participants viewed telehealth as an acceptable format, supporting the feasibility of ME-CCT-A via this platform.

### **Preliminary Efficacy**

Although the sample size was small ( $N = 15$  at post-treatment), significant improvements were observed in both objective and subjective outcome measures, indicating preliminary efficacy. However, the primary goal of this study was not to provide a definitive estimates of efficacy but to assess feasibility, acceptability, and the potential for a larger-scale study (Arain et al., 2010). While we anticipated that pre-post changes in means would be in the expected directions across all objective cognitive measures, this was not the case. Of the thirteen objective cognitive measures, six did not show the expected improvement. While statistically insignificant, the effect sizes for these measures ranged from small-negative to small-positive effects. On the other hand, seven measures showed the expected improvements, with four of them achieving

statistical significance and moderate to strong effects. Notably, significant improvements were observed on tasks related to attention, memory, and executive function, which are cognitive functions that play a critical role in decision-making and in supporting goal-directed behaviors such as engaging in treatment and maintaining abstinence and/or AUD recovery (Bates et al., 2013).

To supplement group-level analyses, individual-level change scores were calculated to capture variability more precisely in cognitive outcomes across participants. This approach highlights patterns of change that may be obscured in group means and allows for a more granular understanding of intervention effects. Delayed memory tasks were among the few domains where declines were more commonly observed, contrasting with the predominance of improvement in areas such as attention and executive functioning. This pattern may reflect known vulnerabilities in individuals with AUD, as memory, particularly delayed recall, often remains impaired even during sustained remission (Crowe et al., 2020). These findings highlight the importance of incorporating memory-supportive strategies within cognitive rehabilitation efforts, particularly for participants in initial and early remission who may face persistent difficulties with memory consolidation and retrieval.

Measures of reaction time, such as the digital adaptations of the Trail Making Test (Fellows et al., 2017), may be useful to include in future trials given that self-control for alcohol use is important in maintaining remission. Additionally, future testing with larger samples with a wide range of cognitive abilities will help to determine which measures are most appropriate for both virtual administration as well as measuring the effect of the intervention.

Subjective measures showed consistent improvement, with significant increases in cognitive functioning, compensatory strategy use, and health-related quality of life. Participants

reported fewer memory problems, enhanced cognitive functioning, and frequency and perceived usefulness of cognitive strategies and external aids taught during the intervention. Improvements were observed in five out of eight PROMIS domains, including physical function, anxiety, fatigue, sleep disturbance, and satisfaction with participation in social roles. While no significant changes were observed in depression, pain interference, or pain intensity, these domains showed improvements in the expected direction with all scores nearing statistical significance. Given the high prevalence of MDD in this sample (80% of completers), these results are promising but may be influenced by the baseline rates of mental health conditions. Additionally, given the high rates of AUD and pain co-occurrence and the analgesic effects of alcohol on pain perception (Maleki et al., 2019; Thompson et al., 2017), it is not surprising that participants with AUD in initial or early remission reported minimal changes in ratings of pain interference or intensity. Prior research found that adults in acute alcohol withdrawal exhibited increased pain sensitivity for up to two weeks of no alcohol use (Jochum et al., 2010); this is particularly relevant given that approximately half of our sample had AUD in initial remission (0-30 days).

In terms of alcohol use, participants reported reduced risk factors post-treatment, including decreased substance cravings, physical health problems, sleep concerns, exposure to risky situations, and relational problems. However, it is important to highlight that ME-CCT-A is an adjunctive treatment, with all participants also engaged in outpatient or inpatient AUD treatment. Therefore, the observed reduction in risk factors is likely influenced by their participation in broader AUD treatment services as well.

Protective factors did not significantly change, though they improved in the expected direction. Protective factors captured within the BAM focus on social support structures (e.g., spirituality/religion, work/school participation, sober support), which often take time to build and

develop over the course of remission; thus, it is encouraging to see improvements but not unexpected that the change is insignificant given these structures often take more than 8 weeks to develop or improve (Islam et al., 2023). Additionally, a commonly observed pattern in recovery from a SUD involves achieving abstinence from the primary substance (e.g., alcohol) while initiating or escalating the use of a secondary or tertiary substance (e.g., cannabis) (White & Kurtz, 2006). In this study, captured by the TLFB and clinical interview during the post-treatment assessments, one participant who was already using cannabis at baseline increased their use, whereas all other participants maintained or reduced their use of secondary or tertiary substances over the course of the study. This pattern of substance use behavior highlights the need for continued investigation into substance use trajectories during recovery.

Findings from our outcome measures offer support for the inclusion of many of these measures in the next phase of intervention testing. Subjective functioning and substance use measures consistently demonstrated improvements in the expected direction and provided holistic coverage of domains targeted in ME-CCT-A. Objective cognitive measures did not reliably show changes in the expected direction from pre- to post-treatment, but effect sizes were small and likely of limited practical significance. At the individual task level, some measures, particularly those assessing attention and executive functioning, showed more frequent improvement, while tasks involving delayed memory were more likely to show decline. Although modest, these task-level changes suggest a clinically relevant signal that some individuals may experience cognitive benefit from ME-CCT-A. Interestingly, participants perceived themselves as having improved cognition functioning despite objective testing performance often demonstrating a slight decline. Discrepancies between objective and subjective cognitive functioning has been observed in other studies of adults with AUD in initial



and early remission. Manning, Teo, et al. (2016) compared adults with AUD at detox and 3-months later following inpatient AUD treatment and found that while there were improvements in self-reported cognitive functioning for adults who remained in remission, there were no observable differences in scores on neurocognitive tests. Discrepancies between perceived and actual cognitive performance highlight the importance of incorporating both subjective and objective measures of cognition into future studies of ME-CCT-A to obtain a comprehensive understanding of participants' cognitive functioning and effects of the intervention. Future studies should include larger sample sizes, long-term follow-up assessments, and further exploration of both objective and subjective cognitive outcomes.

### **Limitations and Future Directions**

Considering the early stage of this single-arm trial, certain inherent limitations must be taken into account when interpreting the findings. The most significant limitation is the absence of a comparison group, which limits causal inference. While improvements in cognitive and subjective functioning were observed, without a control condition it is not possible to determine whether these changes were attributable to ME-CCT-A or to other factors, such as concurrent AUD treatment, spontaneous recovery, or the effect of time. Although this pilot was not designed to establish efficacy, future RCTs are necessary to determine the true effects of ME-CCT-A.

Another important limitation is the small sample size, which restricted statistical power and precluded more complex analyses. While changes in means and effect sizes were examined to explore trends, the small sample, particularly the small dropout group, limits generalizability and confidence in findings. Still, small samples are typical and appropriate for feasibility studies, which are primarily intended to refine procedures, identify barriers, and guide future trials (Arain et al., 2010).

Additionally, the lack of diversity in the sample limits the generalizability of findings. Although the sample represented a wide range in age (31 to 82 years), educational attainment, and employment status, the sample was entirely White (100%) with the majority identifying as non-Hispanic (79%) and male (84%). This homogeneity restricts our ability to understand whether ME-CCT-A is feasible or acceptable for Veterans of other racial, ethnic, and gender identities. Diversity is particularly important in AUD research given evidence that treatment outcomes and recovery trajectories may differ across demographic groups due to factors such as cultural norms, historical and structural inequities, stigma, and social support networks, and access to care (Kranzler & Vickers-Smith, 2024; Vaeth et al., 2017). Future recruitment efforts should focus on recruiting a sample that has broader diversity of demographic characteristics, such as utilizing the CDW more effectively and engaging Veterans directly through outreach in relevant VA clinics to ensure a more diverse sample.

The recruitment and screening process for this pilot trial was intentionally designed to prioritize broad inclusion and efficiency; however, it is possible that this approach may have been overly inclusive. Enrolled participants remained eligible for the study if they experienced recurrence of alcohol use while participating in the group, which is consistent with harm reduction principles and supported by recent expert recommendations (Verdejo-Garcia et al., 2023).. This approach promoted retention and aligned with the realities of initial and early remission, when recurrence of use is common (Moos & Moos, 2006) but may have introduced greater variability into treatment response. In contrast to other studies on CCT (Huckans et al., 2010; Storzbach et al., 2017; Twamley et al., 2014) participants were not required to have documented cognitive concerns noted in their medical records (e.g., prior neuropsychological testing) to participate in this study. While the approach used in prior studies might produce larger

effect sizes on objective and subjective outcome measures, it would have limited our ability to recruit Veterans, as neuropsychological testing is often not conducted in adults with SUDs due to the challenges of accounting for substance effects, withdrawal symptoms, and motivation/engagement. Additionally, screening participants based on prior testing would have excluded individuals without clinically significant cognitive impairments who could still benefit from learning compensatory cognitive strategies. Thus, this inclusive approach allowed for broader participation and reflects a real-world clinical population that may benefit from cognitive rehabilitation, even without formally identified impairments.

Another notable limitation is the lack of blinding and the overlapping roles of the lead investigator, who was involved in nearly all aspects of the study. Despite efforts to remain neutral, the investigator's multiple roles as group co-facilitator, assessor, and data analyst may have influenced results or interpretations (Mahtani et al., 2018). Several steps were taken to address potential bias. Outcome measures were either objective (i.e., neuropsychological test performance) or self-report questionnaires completed by participants independently from the assessor. Additionally, an independent research psychologist, unaffiliated with the study or VAPORHCS, reviewed the qualitative coding process to ensure consistency and confirm that the findings were accurately and objectively derived from the data. This external review helped mitigate the risk of bias in the interpretation of qualitative data. Future studies of ME-CCT-A via telehealth should be conducted on a larger scale with different clinicians and researchers to reduce bias, assess replicability, and determine whether the research protocol and intervention are ready for a larger RCT.

Additionally, the group facilitators' extensive training and experience in CCT does not allow for the assessment of whether the intervention is easy to deliver and whether facilitators

without similar expertise will be able to implement it as intended. Given the structured nature of the intervention and treatment manual, we anticipate similarly skilled delivery and treatment fidelity in a larger-scale trial. Future trials should develop a Standard Operating Procedure (SOP) to ensure treatment fidelity and facilitate training of future facilitators.

Finally, while findings support the feasibility and acceptability of ME-CCT-A via telehealth, further optimization to the telehealth format is warranted. High levels of participant satisfaction and engagement with the telehealth format suggest that the telehealth format is a promising delivery method for ME-CCT-A. However, participants noted some drawbacks, such as limited peer interaction and occasional technical difficulties. Incorporating features like virtual message boards and multimedia (e.g., audio clips, videos) to supplement didactic material could further boost participant satisfaction and engagement. Adjusting the session structure, such as offering shorter sessions to minimize screen fatigue and maintain participant engagement, could also improve telehealth delivery. Additionally, participants recommended sharing an electronic version of the treatment manual in addition to the traditional paper version, as the study and intervention are fully virtual, making an electronic manual a more fitting option for some individuals. With refinement, telehealth delivery may further increase accessibility, particularly for Veterans in rural or underserved areas.

## **Conclusions**

This pilot study examined the feasibility, acceptability, and preliminary efficacy of ME-CCT-A via telehealth in Veterans with AUD in initial and early remission. Overall, the findings align with our first hypothesis, supporting the feasibility and acceptability of ME-CCT-A via telehealth, as demonstrated by successful recruitment and retention, strong treatment adherence, successful technical implementation, and high treatment satisfaction. The study successfully

established proof of concept of ME-CCT-A via telehealth, showing that the research protocol, intervention, and delivery method can be effectively implemented within this population.

While the study's sample size was small, preliminary efficacy results provide promising evidence of the intervention's impact on multiple outcome measures. These findings partially support our second hypothesis, which predicted the intervention's potential efficacy for Veterans with AUDs in initial and early remission. The subjective functioning measures consistently showed improvements in the expected direction, indicating that participants perceived positive changes in their cognitive functioning, compensatory strategies, overall quality of life, and substance use. Although we predicted significant improvements in objective cognitive performance across cognitive domains, the objective measures did not consistently reflect the anticipated gains. While some improvements were observed, they were generally small and did not reach statistical significance. This discrepancy may be due to factors such as the small sample size or the challenges inherent in measuring cognitive improvements in individuals with AUD in initial and early remission. Despite this, the observed trends suggest that the intervention may have a modest impact on cognitive functioning, warranting further investigation in larger, more diverse samples.

In conclusion, ME-CCT-A via telehealth has proven to be a promising intervention for Veterans with AUD in initial and early remission, offering a scalable, acceptable, and potentially effective approach to improving cognitive functioning and AUD remission. These findings provide valuable insights that can guide the next phase of research, including the refinement of recruitment strategies, inclusion of more diverse populations, and optimization to the telehealth format, ultimately aiming to evaluate the full efficacy of the intervention in a larger clinical trial.



## CHAPTER VI

### References

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## APPENDICES

## APPENDIX A: Institutional Review Board Approval Letter



DEPARTMENT OF VETERANS AFFAIRS  
VA Portland R&DC  
VA Portland Health Care System

**Date:** September 25, 2023

**From:** ACOS/R&D and R&D Committee

**TO:** Maya O'Neil, PhD

**Protocol Title:** [1771076-1] VAPORHCS/OHSU J: Compensatory Cognitive Training Via Telehealth for Veterans with Alcohol Use Disorders

**Submission Type:** New Project

**Review Type:** Full Committee Review

**Action:** Approved

**Effective Date:** September 25, 2023

**Subject:** Combined Associate Chief of Staff for Research and Development (ACOS/ R&D) and R&D Committee Study Approval Notice

- 
1. This research project was reviewed and found to be aligned with the mission of the VHA, scientifically valid, and reviewed by all appropriate subcommittees to ensure the safety of the study subjects and VHA staff. Approval was granted by **CONVENED BOARD REVIEW** of the VA Portland Health Care System Research and Development Committee on September 25, 2023.
  2. This research project has obtained the following additional approvals:
    - a. Affiliate (OHSU) Institutional Review Board Approval: **08/25/2023**
  3. If applicable, the Privacy Officer reviewed this research project on **08/18/2023** and found that the proposed research complies with VA Privacy Requirements.
  4. The Information Safety and Security Officer reviewed this research project on **06/22/2023** and found that the research project complies with information safety and security requirements for VA.
  5. You are responsible to your overseeing committee for any requests for information, continuing review (if required), or other project status updates. No changes may be made to your project without the permission of the reviewing subcommittee unless there is a circumstance where harm could come to a research subject. Immediate reporting to the responsible committee is then required.
    - a. The period of approval for this project is from the date of this letter until the date of expiration set by the applicable R&D subcommittee or oversight committee(s). Please refer to the subcommittee/oversight committee letter(s) for continuing review requirements and the date(s) of expiration. Please be reminded that Continuing Review (if applicable) is required by the appropriate oversight committee(s) prior to the expiration of approval.

6. If any of your personal or financial situations change that may reasonably put you in conflict with this study, you must submit a revised OGE 450 Alt to your local conflict of interest administrator.
7. Acknowledgment of the VA's contribution is required in any publications and presentations that may result from this research.
8. If at some point in the study the PI needs to expand the study population to include non-Veterans, the PI must inform the R&D Committee.
9. As all applicable approvals have been obtained, you may now begin your research project.



DAVID M COHEN  
386526

Digitally signed by DAVID M  
COHEN 386526  
Date: 2023.09.26 16:22:52 -0700

Associate Chief of Staff for Research and Development (ACOS/R&D)

This electronically generated document serves as official notice to sponsors and others of approval, disapproval or other VA Portland R&DC decisions. Only those individuals who have been granted authority by the institution to create letters on behalf of the VA Portland R&DC are able to do so. A copy of this document has been retained within VA Portland Health Care System IRBNet records. The IRBNet System is fully compliant with the technology requirements for Electronic Records per CFR 21, Part 11, Section 11.10 - Controls for Closed Systems, and the technology requirements for Electronic Signatures per CFR 21, Part 11 Subpart C - Electronic Signatures

## APPENDIX B: Recruitment Flyer

<b>VA</b>		<b>U.S. Department of Veterans Affairs</b> Veterans Health Administration Office of Research & Development	<div>IRB Approved: 8/14/2024</div> Compensatory Cognitive Training Via Telehealth for Veterans with Alcohol Use Disorders eIRB# 25693 / MIRB# 6208
<h1>RESEARCH STUDY</h1> <h2>Participants Needed</h2>			
<b>We are looking for Veterans who:</b>			
<ul style="list-style-type: none"> <li>▪ Are at least 18 years old</li> <li>▪ Have recently reduced or stopped their alcohol use</li> <li>▪ Have noticed concerns about a mild decline in attention, memory, concentration, or organization</li> <li>▪ Have access to internet and webcam</li> </ul>			
<p>If you fit these criteria and would like to participate, please call Kate at <b>(503) 220-8262, ext. 52470</b>.</p>			
<p>Our study will optimize Motivationally Enhanced Compensatory Cognitive Training (ME-CCT-A) to the telehealth context and evaluate the feasibility, acceptability, and preliminary efficacy of ME-CCT-A delivered via telehealth in Veterans in early remission from alcohol use disorders. This study does not involve medications or drugs. This is a research project and is not a clinical treatment offering.</p>			
<ul style="list-style-type: none"> <li>▪ If you decide to participate, you will be asked to attend 2 study visits (2 hours each) via telehealth (Veteran Video Connect [VVC]), which includes completion of questionnaires, interviews, and neuropsychological assessments that evaluate current cognitive and psychiatric symptoms.</li> <li>▪ Participants will be offered an 8-week cognitive skills training group.</li> <li>▪ Participation is strictly voluntary and confidential.</li> </ul>			
<p>You may or may not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.</p>			
<p>Participants will receive \$50 for the baseline visit and \$50 at the follow-up visit. If you attend both visits, you will be paid a total of \$100.</p>			
Principal Investigators: Maya O'Neil, Ph.D. and Kate Shirley, M.A. VA Portland Health Care System, 3710 SW US Veterans Hospital Rd., Portland, OR 97239			Version date: 02/11/2024



## APPENDIX C: Consent and Authorization Forms

<b>VA Portland Health Care System (VAPORHCS) Informed Consent Form</b>	
Page 1 of 8	
Subject Name: _____ Date: _____	
Title of Study: <u>Compensatory Cognitive Training Via Telehealth for Veterans with Alcohol Use Disorders</u>	
IRB Number: <u>6208</u>	
Principal Investigators: <u>Kate Shirley, Ph.D. Candidate and Maya O'Neil, Ph.D.</u>	
ICF Version Date: <u>10/16/2023</u>	

 IRB Approved: 8/14/2024  
 Approval Expires: 8/13/2025

### **WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?**

About the research, call Ms. Kate Shirley at 503-220-8262, ext. 52470 or Dr. Maya O'Neil at 503-220-8262, ext. 54522.

If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), call Kate Shirley at 503-220-8262, ext. 52470.

Other research team members include Co-Investigator, Dr. Jennifer Loftis. She can be reached at 503-220-8262 ext. 52461.

To speak with someone not connected with this research study about your rights, discuss problems, concerns, and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at (503) 273-5125, or the VAPORHCS Privacy Officer at (503) 273-5037.

### **SUMMARY OF KEY INFORMATION ABOUT THIS STUDY**

#### **WHAT AM I BEING ASKED TO DO?**

We are asking you to take part in a research study that is being funded by the American Psychological Association's Society for Military Psychology (Division 19). We conduct research studies to try and answer questions about how to prevent, diagnose, and treat diseases.

We are asking you to take part in this research study because you have been diagnosed with an alcohol use disorder.

#### **TAKING PART IN THIS STUDY IS YOUR CHOICE**

You can choose to take part or not to take part in this study. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

The VA Authorization for Use and Release of Individually Identifiable Health Information (Collected) for VHA Research to use your protected health information is also your choice. You may refuse to sign this consent form and the authorization. However, to participate in this study, you must sign this consent form and the authorization.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered.

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**Do NOT Change Anything below this line, including bottom margin.**

---

Subject's Identification (I.D. Plate or complete below)

\_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_  
 LAST FIRST SSN (last 4 digits)

VAPORHCS Research Service Template Date: 03/17/2022



<b>VA Portland Health Care System (VAPORHCS) Informed Consent Form</b>	
Page 2 of 8	IRB Approved: 8/14/2024 Approval Expires: 8/13/2025
Subject Name: _____ Date: _____  Title of Study: <u>Compensatory Cognitive Training Via Telehealth for Veterans with Alcohol Use Disorders</u>  IRB Number: <u>6208</u>  Principal Investigators: <u>Kate Shirley, Ph.D. Candidate and Maya O'Neil, Ph.D.</u> ICF Version Date: <u>10/16/2023</u>	

**WHY IS THIS STUDY BEING DONE?**

Ms. Kate Shirley and Dr. Maya O'Neil are conducting a research study to learn about cognitive rehabilitation treatments via telehealth for Veterans with alcohol use disorders. People in early remission from an alcohol use disorder often describe difficulties with memory, attention, concentration, and overall cognitive functioning, which can persist for six months or longer and affect treatment and health outcomes.

**WHAT IS THE USUAL APPROACH TO MY ALCOHOL USE DISORDER?**

The usual approach for patients not in a study involves evidenced-based pharmacological and/or behavioral substance use treatment. These treatments typically focus on recovery from the substance and do not address cognitive complaints.

**WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?**

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study if one is available.

**WHAT WILL HAPPEN IF I DECIDE TO TAKE PART IN THIS STUDY?**

If you decide to participate, you will be asked to attend two assessment visits and eight cognitive rehabilitation group sessions, all conducted virtually through VA Video Connect (VVC).

The two assessment visits will include a clinical interview, neuropsychological assessments, and questionnaires/surveys, which should take 2 hours to complete. The eight cognitive rehabilitation group sessions are 2-hours per week and include training in strategies to improve cognition and manage stress.

A detailed description of all activities that will be done as part of this study is located below in the "What will happen during this study?" section.

**WHAT ARE THE RISKS AND BENEFITS OF TAKING PART IN THIS STUDY?**

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

**RISKS**

We want to make sure you know about a few key risks right now, however, we provide more below information in the "What are the risks and possible discomforts from participation?" section. This study involves collecting sensitive information from you about your health and alcohol use history and you may be asked sensitive or private questions about things you normally do not discuss. The research team will make every effort to protect your information. However, a loss of privacy could occur. If there is information you do not want shared, you should consider this risk before agreeing to take part in this study.

**BENEFITS**

You may or may not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit others with alcohol use disorders in the future. You may experience an improvement in your cognitive ability, use of cognitive strategies, or daily functioning.

**Do not change anything below this line, including bottom margin.**

**VAPORHCS Research Service Template Date: 03/17/2022**

<b>VA Portland Health Care System (VAPORHCS) Informed Consent Form</b>	
Page 3 of 8	
<div style="border: 1px solid black; padding: 2px; display: inline-block;">             IRB Approved: 8/14/2024              Approval Expires: 8/13/2025           </div>	
<p>Subject Name: _____ Date: _____</p> <p>Title of Study: <u>Compensatory Cognitive Training Via Telehealth for Veterans with Alcohol Use Disorders</u></p> <p>IRB Number: <u>6208</u></p> <p>Principal Investigators: <u>Kate Shirley, Ph.D. Candidate and Maya O'Neil, Ph.D.</u>      ICF Version Date: <u>10/16/2023</u></p>	

**IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?**

Yes, you can decide to stop taking part in the study at any time.

**ARE THERE OTHER REASONS WHY I MIGHT STOP BEING IN THE STUDY?**

The investigators or research team members can terminate your participation in this study at any time at their discretion. If your participation in this study is terminated by the investigator or a research team member, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration. You will still receive all the medical care and benefits for which you are otherwise eligible. This will not affect your rights as a VHA patient.

**It is important that you understand the information in the informed consent before making your decision.** Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask study staff for clarification.

**WHAT IS THE PURPOSE OF THIS STUDY?**

The purpose of this study is to determine whether the cognitive rehabilitation treatment designed to improve cognition for Veterans in remission from alcohol use disorders is feasible and acceptable when delivered through telehealth. You have been asked to participate because you have been diagnosed with alcohol use disorder in early remission (>1 month, <12months).

**DO THE RESEARCHERS HAVE A PERSONAL, FINANCIAL OR OTHER INTEREST IN THIS STUDY?**

The investigators declare no conflicts of interest in the research study.

**HOW MANY PEOPLE WILL PARTICIPATE?**

Approximately 30 people will participate in this research study at the VA Portland Health Care System.

**WHAT WILL HAPPEN DURING THIS STUDY?**

If you agree to be in the study, the following will happen to you:

- 1) During your first scheduled virtual visit, you will have an opportunity to go over this informed consent form with a member of the research staff and to ask any questions about your participation in the research. If you would still like to participate, you will sign this informed consent form as well as other authorization forms, then take part in an assessment of your cognition, symptoms, and functioning, which will take approximately two hours. This first assessment battery assesses your current functioning and includes questionnaires about your symptoms and daily functioning; a clinical interview about your medical, psychiatric, and cognitive history; and neuropsychological tests, which may seem like games or activities that you did in school. These tests evaluate aspects of your cognition, such as memory, attention, and problem-solving skills. Regarding the questionnaires, we will ask you to complete the questionnaires through an online database, REDCap, and you will receive a link to the questionnaires within your first appointment confirmation letter. If you would rather complete the questionnaires on paper by mail, the questionnaires will be mailed to you along with your first appointment confirmation letter and a self-addressed stamped envelope so you can send them back to research staff after they are completed.

**Do not change anything below this line, including bottom margin.**

**VAPORHCS Research Service Template Date: 03/17/2022**

## VA Portland Health Care System (VAPORHCS) Informed Consent Form

IRB Approved: 8/14/2024  
Approval Expires: 8/13/2025

Page 4 of 8

Subject Name: \_\_\_\_\_ Date: \_\_\_\_\_

Title of Study: Compensatory Cognitive Training Via Telehealth for Veterans with Alcohol Use Disorders

IRB Number: 6208

Principal Investigators: Kate Shirley, Ph.D. Candidate and Maya O'Neil, Ph.D. ICF Version Date: 10/16/2023

- 2) You will then be enrolled in a virtual Compensatory Cognitive Training group, which will involve weekly groups with a qualified member of the study team for two hours per week for 8 weeks. Compensatory Cognitive Training includes training in strategies to improve cognition and manage stress.
- 3) Within two weeks after completing the group, you will take part in a repeat assessment of your cognition, symptoms, and functioning. This assessment is virtual and will take approximately two hours.

The neuropsychological tests, questionnaires, and interviews will be done for research purposes and will not be completed if you decide not to take part in the study. The groups provided in this study include approaches to address cognitive and functioning problems, and the hospital and other care facilities currently provide similar groups to individuals with mild cognitive impairments. However, the treatment is still experimental because we need more data before we can be certain that it is effective for individuals with alcohol use disorders.

### **WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?**

In addition to the risks described above in the Summary of Key Information About This Study, "What are the risks and benefits of taking part in this study?" section, the following risks could occur if you choose to take part in this study:

- Information that identifies you will be used in this study and shared with the approved research team and auditing entities. The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It also could carry other risks, such as embarrassment or affecting your ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history, or status in the community. Again, every effort will be made to protect against these types of outcomes. To protect your confidentiality, all of your paper research records will be kept in a locked filing cabinet under a code number rather than your name and social security number. Likewise, all electronic research records will be kept in password protected electronic files on the VA network.
- As a result of participation in this study, you may learn information about your cognition that could be upsetting to you. If you are upset about the results learned during the course of the research study, Ms. Shirley or Dr. O'Neil may refer you to a counselor.
- You may experience some fatigue, boredom, or stress while completing the neuropsychological tests.
- If you should ever express thoughts of wishing to harm yourself or considering suicide, we may call the National Suicide Prevention Hotline and/or the Veterans Crisis Line and transfer you to that call.
- During the study assessments, we will conduct an interview and have you complete questionnaires and tests to evaluate your symptoms and cognitive abilities. Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions. If the questions make you very upset, we will help you to find a counselor.

### **HOW WILL MY CONFIDENTIALITY BE PROTECTED?**

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate

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**VAPORHCS Research Service Template Date: 03/17/2022**



<b>VA Portland Health Care System (VAPORHCS) Informed Consent Form</b>	
Page 5 of 8	
<div style="border: 1px solid black; padding: 2px;">             IRB Approved: 8/14/2024              Approval Expires: 8/13/2025           </div>	
Subject Name: _____ Date: _____	
Title of Study: <u>Compensatory Cognitive Training Via Telehealth for Veterans with Alcohol Use Disorders</u>	
IRB Number: <u>6208</u>	
Principal Investigators: <u>Kate Shirley, Ph.D. Candidate and Maya O'Neil, Ph.D.</u> ICF Version Date: <u>10/16/2023</u>	

consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

We will take multiple steps to protect your privacy and confidentiality. A code number (participant ID) will be assigned to you and your information. We will retain a password-protected electronic database that allows us to match your code with your personal information; only approved research personnel will have authorization to access this database and link the code number to you. We will keep your coded information in a separate electronic database that is also password protected. Paper informed consent forms will be stored in a double-locked cabinet apart from your collected research information and electronic consent forms will be stored in a secure folder on the VA network; only approved research staff will have access to these forms. The code number which connects you with your private health information will no longer be used to identify you when the study is complete and closed out with the research office.

Identifiers related to you (i.e., information that can identify you) will be used in this research study and will include: name, street address, city, county, zip code, birth date, clinic and research visit dates, telephone number, e-mail address, social security number, and medical record number. These identifiers may be used to obtain information about you and your health from VA records.

By signing this informed consent, you give us permission to use your participant study ID in REDCap at Oregon Health and Science University (OHSU) to collect and/or store your questionnaire data. OHSU, Ms. Shirley, and Dr. O'Neil will be responsible for maintaining the security and confidentiality of the transferred data. VAPORHCS will continue to have ownership of your research data for this research study. All original research records, both hard copy and electronic, will be maintained at the VAPORHCS in accordance with current records retention requirements. Any information shared outside the VA may no longer be protected under federal law. Research records may be reviewed and/or copied by the sponsor.

The questionnaires that you will complete during the assessment sessions are completed in a database called REDCap. The REDCap database is password protected and maintained by the Oregon Clinical & Translational Research Institute (OCTRI) at OHSU. Information about you will be coded with your participant study ID and no personally identifiable information will be used or collected. By signing this informed consent, you give permission for this data to be maintained by OCTRI, which will be responsible for maintaining the security and confidentiality of the transferred data.

All other parties, including employers, insurance companies, personal physicians, and relatives, will be refused access to the data and specimens, unless you provide written permission or unless otherwise required by law.

To help us further protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

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**VAPORHCS Research Service Template Date: 03/17/2022**

## VA Portland Health Care System (VAPORHCS) Informed Consent Form

IRB Approved: 8/14/2024  
Approval Expires: 8/13/2025

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Subject Name: \_\_\_\_\_ Date: \_\_\_\_\_

Title of Study: Compensatory Cognitive Training Via Telehealth for Veterans with Alcohol Use Disorders

IRB Number: 6208

Principal Investigators: Kate Shirley, Ph.D. Candidate and Maya O'Neil, Ph.D. ICF Version Date: 10/16/2023

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child or elder abuse, communicable diseases, or harm to self or others.

**Mandatory reporting of suspected child, elder, or vulnerable adult abuse.** Under Oregon Law, suspected child, elder, or vulnerable adult abuse must be reported to appropriate authorities.

### **Possibility of Disclosure and Notice of Privacy Practices.**

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. If you do not have a copy of the notice, the research team will provide one to you. (Notice of Privacy Practices available online at [https://www.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=10127](https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=10127)).

### **WILL I BE TOLD ABOUT ANY STUDY RESULTS?**

The results of the research procedures will not be made available to you because the results will be general and not relate directly to you and/or your medical care. If you are interested, you may contact the Principal Investigators for a copy of the related publications once the study results are published.

### **WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**

**Participants.** A VA participant will not be required to pay for care and services received as a subject in a VA research project.

None of the participants will pay for any of the following because they are only for research study purposes: neuropsychological testing, cognitive rehabilitation groups.

Some Veterans are also required to pay co-payments for medical care and services provided by VA that are not part of this study (e.g., normal hospital and prescription expenses that are not part of the research study, any treatment that is standard clinical treatment for your condition).

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**VAPORHCS Research Service Template Date: 03/17/2022**

<b>VA Portland Health Care System (VAPORHCS) Informed Consent Form</b>	
Page 7 of 8	IRB Approved: 8/14/2024 Approval Expires: 8/13/2025
Subject Name: _____ Date: _____  Title of Study: <u>Compensatory Cognitive Training Via Telehealth for Veterans with Alcohol Use Disorders</u>  IRB Number: <u>6208</u>  Principal Investigators: <u>Kate Shirley, Ph.D. Candidate and Maya O'Neil, Ph.D.</u> ICF Version Date: <u>10/16/2023</u>	

### **WILL I BE PAID FOR PARTICIPATING?**

You will be paid \$50 for the initial baseline visit and an additional \$50 for the follow-up visit. Payment will be in the form of Amazon.com gift cards. If you drop out of the study before completing all study visits, you will only be paid for the study visits that you completed. If you complete both visits, you will receive \$100 total. Payment will help compensate you for your time.

An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

### **WHAT WILL HAPPEN IF I AM HURT?**

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to your non-compliance with study procedures. Additional compensation, beyond paying for treatment, has not been set aside.

The VA will also provide all necessary assistance in the event of any violation of confidentiality or privacy (for example, identity theft resulting from the loss of a social security number by anyone associated with this study). For eligible Veterans, compensation damages may be payable under 38 United States Code 1151. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with the provisions of the Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA General Counsel at (202) 461-4900. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

### **WHAT DO I NEED TO DO TO DROP OUT (WITHDRAW) AFTER I SIGN THIS CONSENT FORM?**

To withdraw, you must write to Kate Shirley at VA Portland Health Care System, 3710 SW US Veterans Hospital Road, R&D38, Portland OR 97239, or ask a member of the research team to give you a form to withdraw your consent and authorization. If you withdraw your consent and authorization, you may not be able to continue to participate in the study.

### **Signature**

Kate Shirley or another authorized member of the research team has explained the study to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I have been told I do not have to take part in this study and refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are medical problems or questions, I have been told I can call Dr. Maya O'Neil at 503-220-8262 ext. 54522 from 08:00-16:30, Monday through Friday. If any medical problems occur in connection with this study, the VA will provide emergency care.

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<b>VA Portland Health Care System (VAPORHCS) Informed Consent Form</b>	
Page 8 of 8	IRB Approved: 8/14/2024 Approval Expires: 8/13/2025
Subject Name: _____ Date: _____  Title of Study: <u>Compensatory Cognitive Training Via Telehealth for Veterans with Alcohol Use Disorders</u>  IRB Number: <u>6208</u>  Principal Investigators: <u>Kate Shirley, Ph.D. Candidate and Maya O'Neil, Ph.D.</u> ICF Version Date: <u>10/16/2023</u>	

My signature below indicates that I have read, or had read to me, all of the above information about the study, and that my rights as a research subject have been explained to me. I authorize the use of my information as described in this form. In the future, if I decide that I no longer wish to participate in this research study, and I do not withdraw my consent, I agree that my neuropsychological assessment data, demographics, and other information, which were already collected, may continue to be used only for this research by removing all identifying information. However, identifiers may be stored separately and held in accordance with the VA records control schedule.

I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

\_\_\_\_\_  
Printed Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

\_\_\_\_\_  
Signature of Person Obtaining Consent


\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

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**VAPORHCS Research Service Template Date: 03/17/2022**



 <b>Department of Veterans Affairs</b>		<b>Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research</b>	
<b>Subject Name (Last, First, Middle Initial):</b>		<b>Subject SSN (last 4 only):</b>	<b>Date of Birth:</b>
<b>VA Facility (Name and Address):</b> VA Portland Health Care System 3710 SW US Veterans Hospital Rd. Portland, OR 97239			
<b>VA Principal Investigator (PI):</b> Maya O'Neil, Ph.D., Kate Shirley, Ph.D. Candidate		<b>PI Contact Information:</b> 503-220-8262 ext. 54522; 503-220-8262 ext. 52470	
<b>Study Title:</b> Compensatory Cognitive Training Via Telehealth for Veterans with Alcohol Use Disorders (MIRB #6208)			
<b>Purpose of Study:</b> Maya O'Neil, PhD and Kate Shirley, PhD Candidate are conducting a research study to learn about cognitive rehabilitation treatments for Veterans in remission from alcohol use disorder. You have been asked to participate because you have been diagnosed with an alcohol use disorder.			
<b>USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):</b> <p>Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.</p> <p>Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.</p> <p>Your individually identifiable health information used for this VA study includes the information marked below:</p> <p> <input checked="" type="checkbox"/> Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings  <input checked="" type="checkbox"/> Specific information concerning:              <input checked="" type="checkbox"/> alcohol abuse      <input checked="" type="checkbox"/> drug abuse      <input type="checkbox"/> sickle cell anemia      <input checked="" type="checkbox"/> HIV  <input checked="" type="checkbox"/> Demographic Information such as name, age, race  <input type="checkbox"/> Billing or Financial Records  <input type="checkbox"/> Photographs, Digital Images, Video, or Audio Recordings  <input checked="" type="checkbox"/> Questionnaire, Survey, and/or Subject Diary  <input checked="" type="checkbox"/> Other as described: Neuropsychological assessment data         </p>			



<b>Authorization for Use &amp; Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research</b>		
<b>Subject Name</b> (Last, First, Middle Initial):	<b>Subject SSN</b> (last 4 only):	<b>Date of Birth:</b>
<b>USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH:</b> (Instruction: When banking or further analysis is an <b>optional</b> research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)		
<input checked="" type="checkbox"/> <b>Not Applicable - No Data or Specimen Banking for Other Research</b>		
An important part of this research is to save your <div style="margin-left: 20px;"> <input type="checkbox"/> Data  <input type="checkbox"/> Specimen           </div>		
in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.		
<b>DISCLOSURE:</b> The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VAVHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you. Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.		
<input checked="" type="checkbox"/> <b>Non-VA Institutional Review Board (IRB) at</b> <u>Oregon Health &amp; Science University</u> who will monitor the study		
<input type="checkbox"/> <b>Study Sponsor/Funding Source:</b> _____ VA or non-VA person or entity who takes responsibility for; initiates, or funds this study		
<input checked="" type="checkbox"/> <b>Academic Affiliate (institution/name/employee/department):</b> <u>Oregon Health &amp; Science University</u> A relationship with VA in the performance of this study		
<input type="checkbox"/> <b>Compliance and Safety Monitors:</b> _____ Advises the Sponsor or PI regarding the continuing safety of this study		
<input checked="" type="checkbox"/> <b>Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):</b> <u>FDA, DHHS, OHRP, GAO, IRS</u>		
<input type="checkbox"/> <b>A Non-Profit Corporation (name and specific purpose):</b>		
<input type="checkbox"/> <b>Other (e.g. name of contractor and specific purpose):</b>		

<b>Authorization for Use &amp; Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research</b>		
<b>Subject Name</b> (Last, First, Middle Initial):	<b>Subject SSN</b> (last 4 only):	<b>Date of Birth:</b>
<p><b>Note:</b> <i>Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.</i></p>		
<p><b>Access to your Individually Identifiable Health Information created or obtained in the course of this research:</b> While this study is being conducted, you</p> <p><input type="checkbox"/> will have access to your research related health records</p> <p><input checked="" type="checkbox"/> will not have access to your research related health records</p> <p>This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.</p>		
<p><b>REVOCATION:</b> If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:</p> <p>Attn: Kate Shirley, R&amp;D 38 VA Portland Health Care System 3710 SW US Veterans Hospital Rd. Portland, OR 97239</p> <p>If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.</p>		
<p><b>EXPIRATION:</b> Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:</p> <p><input checked="" type="checkbox"/> Expire at the end of this research study</p> <p><input type="checkbox"/> Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.</p> <p><input type="checkbox"/> Expire on the following date or event:</p> <p><input type="checkbox"/> Not expire</p>		

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research		
Subject Name (Last, First, Middle Initial):	Subject SSN (last 4 only):	Date of Birth:
<b>TO BE FILLED OUT BY THE SUBJECT</b>		
<p><b>Research Subject Signature.</b> This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.</p> <p>I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.</p>		
Signature of Research Subject		Date
Signature of Legal Representative (if applicable)		Date
To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)		
Name of Legal Representative (please print)		

