Computerized Cognitive Behavioral Therapy in Adolescents and Young Adults with Substance Use Disorder

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COMPUTERIZED COGNITIVE BEHAVIORAL THERAPY IN ADOLESCENTS AND YOUNG ADULTS WITH SUBSTANCE USE DISORDER

A Thesis Presented to: Faculty of the School of Medicine Yale University

In Candidacy for the degree of Master of Medical Sciences

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Special credit: The late Dr. Kathleen Carroll
# Table of Contents

Abbreviations: iv  
List of Figures and Tables: iv  
Abstract v  

1. Chapter 1 Introduction 1  
   1.1 Overview 1  
      1.1.1 Adolescents and Young Adults with Substance Use Disorders 1  
      1.1.2 Potential for Technology-Based Treatments for adolescents and young adults with SUD 2  
      1.1.3 Utilizing CBT4CBT for adolescents and young adults with SUD 4  
   1.2 Statement of the Problem 6  
   1.3 Goals and Objectives 6  
   1.4 Hypothesis 8  
   1.5 References 8  

CHAPTER 2: REVIEW OF THE LITERATURE 11  
   2.1 Introduction: 11  
   2.2 Review of Empirical Studies 11  
      2.2.1 CBT4CBT as an Intervention for Substance Use Disorder 11  
      2.2.2 CBT for Adolescents and Young Adults with Substance Use Disorder 15  
   2.3 Identifying confounding variables 20  
   2.4 Review of relevant methodology 21  
      2.4.1 Study Setting and Design 21  
      2.4.2 Review of Recruitment Techniques 22  
      2.4.3 Inclusion and exclusion criteria 23  
      2.4.5 Review of successful CBT4CBT components- The Intervention 24  
      2.4.6 Review of the Primary Intervention: CBT4CBT 24  
      2.4.7 Content of Control Condition 25  
      2.4.8 Outcomes 26  
      2.4.9 Review of Sample Size and Calculation Power 27  
   2.5 Conclusion 28  
   2.6 References 29  

Chapter 3- Study Methods 32  
   3.1 Study Design 32
Abbreviations:

- ACRA - Adolescent community reinforcement approach
- ANOVA - Analysis of Variance
- CBT - Cognitive Behavioral Therapy
- CBT4CBT - Computer Based Therapy for Cognitive Behavioral Therapy
- FSN - Family support network
- MET - Manualized Embodiment of MI
- PROMIS - Patient Reported Outcomes Measurement Information System
- RCT - Randomized Control Trial
- SUD - substance use disorder
- TAU - Treatment as usual
- TLFB - Timeline Follow Back

List of Figures and Tables:

- Figure 1: The Seven Lessons of CBT4CBT……………………………………..15
- Table 1: Inclusion and Exclusion Criteria………………………………………33
- Table 2: Timeline for Study Completion…………………………………………41
Abstract

Substance use disorder is a condition that affects the brain and results in the inability of a person to manage their substance use. Approximately 9% of adolescents and young adults in the United States suffer from a substance use disorder, and the majority that receive treatment relapse within 6 months. Adolescents and young adults, especially those with low socioeconomic status, have access to fewer resources for treatment. In this study, we will assess an accessible computer-based cognitive behavioral therapy for treatment in adolescents and young adults with substance use disorders as an efficacious and durable treatment. We will use a prospective, randomized control trial to examine the percentage of drug-negative urine in young adults and adolescents with substance use disorder whose initial treatment includes Computer Based Training for Cognitive Behavioral Therapy (CBT4CBT). Our goal is to expand access to treatment for young adults and adolescents with substance use disorder.
1. Chapter 1 Introduction

1.1 Overview

1.1.1 Adolescents and Young Adults with Substance Use Disorders

One of the most prevalent healthcare-related issues in the twenty-first century has been the overwhelming increase in substance use. In the United States, over 4% of adolescents (age 12-17) and 4.8% of young adults (ages 18-25) suffer from a substance use disorder. In addition, on average less than 5.7% of these people decided to pursue treatment for their disorder. While there are numerous factors that play a role in the low percentage of people seeking treatment, a few stand out. These factors include the cost of the treatment, accessibility, and social stigma. The initial standard treatment that most are referred to is a combination of group therapy, rehabilitation centers and the use of pharmacology. Unfortunately, all of these methods fail to consistently address the main concerns of adolescent and young adult patients entering treatment. Rehabilitation centers are notoriously expensive, group therapy offers little protection from social stigma, and pharmacology can be expensive and hard to access. In addition to this, unfortunately, more than 85% of patients will relapse and return to substance use within one year after treatment. These statistics clearly show that treatment should be aiming to meet the needs of adolescents and young adults as an individual, and alternative empirically-validated treatment options should be considered.

Despite the prevalence of substance use disorder and high relapse rates among adolescents and young adults, there has been a lack of research on the effectiveness of adjunctive therapies for this population. Most patients in this age group are provided

1
similar treatment as adults, or to treatments that do not address the concerns listed above. Additionally, research shows that substance use disorders are more likely to be lifetime disorders than anxiety or depression in young adults.\(^6\) Considering this, it is imperative that there be more research to assist in preventing the likelihood of the substance use disorder from becoming a life-long issue for young adults.

As mentioned previously, there are many necessary considerations for adolescents and young adults seeking treatment for substance use disorder. The most prominent of these include stigma, cost, and accessibility.\(^2,\!^3\) While considering these factors, there are few standard treatments offered to these patients that address all of them. Many of these patients will experience stigma for seeking help, as well a lack financial means and transportation. Therefore, new treatment options should be considered that will address these concerns.\(^2\)

### 1.1.2 Potential for Technology-Based Treatments for adolescents and young adults with \textit{SUD}

There has been a prominent rise in the use of technology and computer-based activities in young adults and adolescents.\(^7\) A review by Marsch et al., found that not only are over 74\% of young adults using social media platforms daily, but almost 87\% of Americans are subscribed to a cell-phone plan with internet access.\(^7\) In addition, the rate of increase in the use of mobile devices to access the Internet among minority groups is twice the national average since 2007; for example, there was a 141\% increase in use among African Americans versus the 73\% average increase.\(^7\) These statistics show the relevancy
of utilizing technology to deliver treatment methods as being accessible for all people, including minorities. Therefore, utilizing technology for treatments is an effective solution to address the aforementioned barriers to care.

Not only would technology help eliminate the barrier of access to treatment, but also stigmatization and cost. A study by Olmos et al., compared technology-based treatment to TAU for participants looking to decrease their cannabis use. The study found that there was a lower incidence of cannabis use in patients utilizing technology rather than TAU. Reasons cited for this include a reduction in stigmatization by delivering therapy online, without an in-person therapist, and a lower cost for treatment and transportation. Additionally, while there is a clear increase in interest for this form of intervention, younger generations are more prepared to make this adaptation. A study by Antoine et al., sought to differentiate the interest in these technology-based treatments by age group and found a positive correlation between interest in technology-based treatment and younger ages.

In addition to a rise in technology use, there has also been a rise in interest and research about technology-based interventions for substance use disorders. Many researchers have sought to adapt treatment options for this new generation of technology users. Recent research reported that there is a place for treatment for SUD via smart technology. Additionally, it was found that participants even preferred using their smartphone for treatment (46.8%), rather than being in person (36.2%). This clearly supports that technology-based interventions have risen in popularity. These interventions have the potential to provide valuable assistance those who have substance use
disorders.\textsuperscript{12,13} For example, current technology based interventions have improved adherence management, reinforced evidence-based psychosocial interventions, improved communication between patient and physician, increased the retention in office-based treatment, and increased abstinence with minimal disruption to health care personnel and clinical workflow. \textsuperscript{2,9}

1.1.3 Utilizing CBT4CBT for adolescents and young adults with SUD

One of the new prominent forms of treatment for substance use disorders is CBT4CBT, or Computer Based Therapy for Cognitive Behavioral Therapy. This program introduces cognitive and behavioral skills to assist patients in gaining control of their substance use disorder and is relatively low-cost per patient compared to in-person interventions.\textsuperscript{27} This program is a web-based interactive guide that includes seven different core skills that can be completed at the user’s individual pace.\textsuperscript{1,14,15} These skills/lessons include on-screen narration, video-based vignettes, quizzes, interactive exercise, and graphic animation to teach effective use of skills.\textsuperscript{16} After completion of each lesson, there are take home practice exercises (i.e., homework) to further enhance the skills taught through cognitive behavioral therapy.\textsuperscript{16} It is also user-friendly, with little to no previous experience on computers required and includes minimal reading.\textsuperscript{17} The modules within the program are based on the Cognitive Behavioral Therapy manual published by NIDA, which is considered an evidence-based intervention for treating substance use disorders.\textsuperscript{17} With these aspects of the treatment in mind, CBT4CBT can address many of the needs for young adults initiating treatment for a substance use disorder as it is affordable, user friendly, and accessible for everyone that can access a computer.
The efficacy of computer-based cognitive behavioral therapy has been consistently demonstrated through several randomized clinical trials. These trials found that when CBT4CBT was provided in addition to treatment as usual (TAU, standardized treatment including weekly group and/or individual therapy, and pharmacotherapy), the self-reported days of abstinence from participants’ most commonly used drug was significantly increased, when compared to TAU as the primary treatment regimen. These same treatment conditions were compared in another trial with patients enrolled in methadone maintenance who were currently also cocaine dependent. The study found that individuals assigned to CBT4CBT with TAU were significantly more likely to attain at least 3 weeks of continuous abstinence from cocaine compared to those who only received TAU. Additionally, not only is CBT4CBT effective in increasing abstinence in the short-term, it is also durable in its effects. A study of follow-up data from the initial trial in 2008 showed that participants receiving CBT4CBT maintained the gains they had achieved in treatment up to 6-months after treatment termination, while those assigned to TAU tended to return to their patterns of drug use. Furthermore, participants assigned to CBT4CBT rather than TAU were significantly more likely to submit a drug-negative urine specimen during follow up.

This novel treatment represents advancements in the field of substance use disorders that should be used more widely in adolescents and young adults suffering from substance use disorder. CBT4CBT can provide young adults and adolescents with substance use disorders an evidence-based, high-quality form of treatment. Therefore, this study would generate comparative data between TAU and TAU plus CBT4CBT in hopes of providing this population of young adults and adolescents with another form of
low-cost treatment that is more effective, while also allowing for privacy and accessibility. 21

1.2 Statement of the Problem

Young adults and adolescents face high barriers to treatment for SUDs such as cost, accessibility and stigma. 4 Not only does this population face these difficulties in initiating treatment, they also face high relapse rates if they do go through with treatment. 4 One of the most well validated and effective treatments for SUD in young adults and adolescents is cognitive behavioral therapy. 22,23 However, this age group is unlikely to proceed with this treatment as it is expensive and often inaccessible. 8,9 There have been a number of studies using CBT4CBT as a low cost and accessible adjunctive intervention for people with SUD. 1,15,16,18,20,24 However, none of these studies have validated this treatment for young adults and adolescents. Therefore, we propose a randomized controlled trial (RCT) to evaluate the efficacy of CBT4CBT as an adjunctive treatment to TAU in adolescents and young adults with SUDs. The results gained by this novel study have the potential to provide a low-barrier option for effective treatment for young adults and adolescents with SUD.

1.3 Goals and Objectives

The overall objective of this study is to provide an efficacious and validated adjunctive treatment for adolescents and young adults with substance use disorders. This RCT will compare a TAU control group to TAU plus CBT4CBT intervention group to examine if there is a significant difference in the percentage of negative urine toxicology screens during an 8-week treatment, and up to 6 months after the completion of
treatment. Treatment as usual (TAU) will consist of the typical treatment recommended for this age group in an outpatient setting. This will include but is not limited to: psychotherapy, group therapy, medications. CBT4CBT is a seven-session online program that can be completed over a period of 8 weeks, on any smart device.

The primary outcome will be the percentage of drug-negative urine samples. Once participants initiate treatment, they will be asked to submit urine samples weekly for the eight weeks of treatment when they are at the clinic for their TAU. We will continue to collect urine at one, three, and six months after the conclusion of the eight-week study as a secondary outcome. Other secondary outcomes for our analysis will assess the percentage of days during treatment that participants self-report using drugs, or frequency of drug use. This outcome will be assessed through self-report, utilizing the Time Line Follow Back (TLFB) method. The TLFB assessment will be administered at the same time as every urine specimen is given, as the urine specimen will be used to validate the self-report. Additional secondary outcomes include mental health and severity of substance use measures from the Patient Reported Outcomes Measurement Information System (PROMIS). This is a set of validated measures, that will provide the ability to evaluate aspects of mental and social health as well as addictive behaviors in young adults and adolescents. The results of this study will determine the efficacy of CBT4CBT as a low barrier adjunctive treatment option for adolescents and young adults with SUDs. Finally, we will examine the engagement in treatment as measured by the number of SUD treatment sessions attended and/or CBT4CBT modules completed.
1.4 Hypothesis

Among adolescents and young adults (13-24) with a newly diagnosed substance use disorder, those receiving weekly Computer Based Therapy for Cognitive Behavioral Therapy (CBT4CBT) plus the standard treatment will have a statistically significant higher percentage of drug-negative urine toxicology screens collected during the eight week treatment intervention, as compared to those who received the standard treatment alone.

1.5 References


 CHAPTER 2: REVIEW OF THE LITERATURE

2.1 Introduction:

We conducted an extensive and thorough review of the literature between November 2020-June 2021 using Pubmed, Ovid (Medline), PSYCinfo, Web of Science and Cochrane Review. Only articles in English were read. An initial review of each article utilizing their title and abstract was used to determine the relevance of each study. Key terms used in every databased to find articles that relate to our study population and intervention were: substance use disorder, substance abuse, drug abuse, drug dependence as well as adolescents, young adults, and the age group of 13-24 and cognitive behavioral therapy. Terms used to identify overlap between the study setting and intervention were: cognitive behavioral therapy, behavioral treatment, CBT, computer based, computer delivered, technology delivered and computer assisted. Terms used to identify the model CBT4CBT intervention include: CBT4CBT, Computer Based Training for Cognitive Behavioral Therapy, and computer-assisted cognitive behavioral therapy.

2.2 Review of Empirical Studies

2.2.1 CBT4CBT as an Intervention for Substance Use Disorder

Computer-based interventions are an effective and feasible form of treatment for substance use disorder. In a meta-analysis by Riper et al., it was reported that of sixteen studies, internet interventions for treatment of alcohol use showed a statistically
significant effect (p = .056) in reducing alcohol consumption over standardized treatment such as in-person group therapy or psychotherapy. While there is not yet a review comparing all computerized behavioral interventions for SUD, this meta-analysis supports the efficacy of computer-based therapies that can be low cost compared to standard treatments. In a recent systematic review, the authors found that multiple forms of computer assisted behavioral therapy also had a statistically significant effect on decreased use of opioids, when compared to TAU (treatment as usual). In the context of treating SUD, cognitive behavioral therapy has also proven to be incredibly efficacious in both adult and adolescent populations. A relevant randomized controlled trial by Dennis et al., reported that in a population of 600 adolescent subjects with alcohol use problems randomized to 5 different intervention groups, the interventions that included CBT were the most efficacious in increasing total days of abstinence, as well as the highest percentage of subjects in recovery.

CBT has been one of the most researched and evaluated behavioral therapies for SUD with considerable empirical support demonstrating its efficacy at reducing alcohol and drug use. Computer/technology-delivered interventions have emerged in the past decade as promising platforms for delivering evidence-based treatments, including CBT. One such computer-delivered CBT program is CBT4CBT. A pilot study of the program CBT4CBT by Carroll et al., randomized 77 individuals seeking treatment for substance dependence to either TAU or TAU and CBT4CBT for an eight-week period. The CBT4CBT intervention uses module-based computer lessons to engage participants in a user-friendly and palatable way. The goal of this strategy is to provide a standardized and accessible form of cognitive behavioral therapy. This study found that
those randomized to CBT4CBT plus TAU submitted 19% fewer urine specimens positive for any drug (p=0.5), and had a 5 day longer period of abstinence than those receiving TAU only. Additionally, subjects were also followed for 6 months to examine the durability of their treatment. The results of this showed that those assigned to CBT4CBT submitted fewer positive drug urine specimens (48% vs 76% of control group) and had an average of 105 consecutive days abstinent, compared to 72.5 days abstinent in the control group (p=0.5). This outcome was statistically significant. Not only was CBT4CBT more effective during the eight-week treatment period, it was also successful in its durability over the control. It is important to note however, that 34% of subjects did not complete the study in both intervention and control groups. Therefore, this is the most likely reason that analysis of the one of the primary outcomes for this study (frequency of substance use) was not statistically significant. This study highlights the need for a larger sample size, of large subgroups of participants, as well as utilizing CBT4CBT as a promising treatment.

This pilot study, as well as a second study that extended the efficacy findings to a methadone-maintained sample, examined CBT4CBT as an add-on to standard outpatient treatment. Subsequent trials were conducted to evaluate CBT4CBT as a potential stand-alone treatment compared to in-person counseling. In a RCT by Kiluk et al., 137 individuals with substance use disorder were recruited to evaluate the efficacy of CBT4CBT provided with brief clinical management compared to treatment as usual (TAU). This trial also included a clinician-delivered CBT condition, although the computerized and clinician-delivered CBT conditions were not directly compared. Participants were randomized to TAU, CBT4CBT or clinician CBT. The primary
outcome of this study was the frequency of substance use over the 12-week treatment period.¹² Clinician CBT was delivered via a PhD with standardized training in CBT. Participants were assessed before treatment, weekly during treatment, at the 12-week treatment termination point, and 1, 3, and 6 months after the termination point.¹² The results of the study showed that participants assigned to either clinician CBT or CBT4CBT had greater reductions in drug and alcohol use during the treatment period as compared to TAU. Also, those assigned to either CBT condition were less likely to meet DSM5 criteria for a substance use disorder by the end of treatment as compared to TAU. Further, those assigned to CBT4CBT showed sustained reductions in substance use during the 6-month follow-up period compared to TAU.

There has been a total of 8 RCTs evaluating CBT4CBT in different settings and populations, all demonstrating the efficacy of CBT4CBT at reducing rates of substance use. Clearly, this is an evidence-based intervention with multiple benefits. As is true for nearly all computer or technology-delivered interventions, CBT4CBT removes traditional barriers to evidence-based and affordable care to all patients. All CBT4CBT studies have utilized patient populations that need accessible and affordable care.¹,¹⁰,¹² Also, by using the same standardized computer program for every patient utilizing CBT4CBT, treatment equity is ensured. This virtually eliminates concerns regarding variability in the quality of clinician-delivered care.¹ These components of CBT4CBT demonstrate the need for a program like this in all communities facing issues with substance use disorder, by addressing the needs of communities with the least access to treatment.
2.2.2 CBT for Adolescents and Young Adults with Substance Use Disorder

CBT4CBT has shown success in the majority of populations facing issues with SUD. However, one key group missing in these studies is young adults and adolescents. Using CBT4CBT as a primary intervention for our population would be a revolutionary form of treatment for people age 13-24 in need of affordable access to treatment. While there are no studies evaluating the use of CBT4CBT on young adults and adolescents, there are a number of studies assessing the use of CBT in this population for SUD, as well as internet-based therapies.

In a retrospective analysis, Davis et al., included 785 adolescents age (12-17) and young adults (ages 18-29) entering treatment for opioid use disorder from over 137 sites. Participants were either assigned to TAU, MET/CBT or adolescent community reinforcement approach (A-CRA). The primary outcome of this study was days to first relapse or use of an opioid, assessed by self-reported substance use. The results
concluded that female youth in the A-CRA intervention experienced an episode of substance use 12 days sooner than those in TAU and MET/CBT, and that in male youth, those receiving MET/CBT took one month longer to return to opioid use. The study also compared the ages at which CBT was most useful and determined that the older the participant, the less effective CBT was.\(^{13}\) While this study is important in demonstrating the feasibility of using CBT in our population for treatment of SUD, it did have limitations in that there was no evaluation of computer delivered CBT, which may have enhanced the efficacy. Additionally, there was no confirmation of self-reported opioid use with urinalysis.

Similarly, in a systematic review of 188 studies by Steel et al., adolescents between the ages of 12 and 20 with substance use disorders, not including tobacco were included. All forms of treatments including pharmacologic and behavioral were included in the review. In terms of behavioral therapies, the authors found that “adolescents who received CBT and education were about 3 times more likely to be abstinent at 1 year than those who received education alone (16% vs. 5%; RR 3.20, 95% CI 1.34 to 7.65).”\(^ {14}\) This analysis is yet another important study to justify the use of CBT in adolescents. It does not however address the potential use of computerized delivery of any form of behavioral intervention.

One study that exemplifies the effectiveness of CBT for adolescents in SUD is a RCT by Ogel et al., conducted in Turkey, 62 males were recruited from a hospital setting for either “volatile substance dependence” (deliberate inhalation of volatile substances in order to achieve intoxication) or “polysubstance dependence” according to DSM-IV-TR criteria.\(^ {15}\) The subjects in the study were placed either in a CBT based intervention or
educational program that educated them on the harmful effects of drug use. The subjects were followed for one year after treatment for self-reporting of substance use. The results of the study showed that despite a larger percentage of the experimental group dropping out (20% difference), the group assigned to CBT had a statistically significant lower rate of relapse compared to the control. There were however factors of this study that differ significantly from ours. First, there is no use of the computer assisted technology, ensuring standardized treatment. Second, the primary outcome relied on self-report rather than urinalysis. Finally, while this study did utilize a population of subjects with substance use disorder, they were also associated with volatile substance use rather than solely SUD. The study currently proposed will not be tested on subjects that have volatile substance dependence.

A specific study that highlights the superiority of CBT as treatment for adolescents with SUD over age specific treatments was performed by Dennis et al. This was a double randomized control trial that studied 600 adolescents and their families that were all recruited and randomized from sequential admissions to four treatment sites within CT. The subjects of this study were all diagnosed with a substance use disorder as well as a co-occurring psychiatric disorder. There were 2 different trials within the study. The first trial randomized participants to either five sessions of Motivational Enhancement Therapy plus Cognitive Behavioral Therapy (MET/CB5T) or twelve sessions of MET and CBT (MET/CBT12) or another group that included family education and therapy components (Family Support Network [FSN]). The second trial randomized the subjects to either a five-session MET/CBT or the Adolescent Community Reinforcement Approach (ACRA) or Multidimensional Family Therapy (MDFT). The primary
outcomes of the study were days of abstinence between the randomization date and the 12-month follow up interview as well as if the adolescent was in recovery at the end of the study. Overall, the study showed that in the first trial, the percent in recovery at the end of the study was 27% in the CBT group, 22% in the FSN group. The same primary outcome of the second trial was not statistically significant. Similar to other trials, this trial lacked in its use of computer-based CBT. Additionally, it did not use urinalysis to confirm self-reporting of abstinence.

While it is well established that CBT in youths is efficacious in treating SUD, there are much fewer trials regarding computer-based CBT. One study that did address this was performed by Braciszewskia et al. This RCT recruited 18–19-year-olds with substance use disorders that were leaving foster homes. The participants were randomized to Interactive Healthy Lifestyle Preparation (Ihelp), a technology-based substance use intervention that utilizes motivational interviewing. The primary outcome was percentage of days without substance use over a 6-month treatment period. The outcome of the study showed that participants preferred the ease of online treatment. Additionally, the intervention group also had a statistically significant higher percentage of days abstinent than the control which entailed a different computer program that focused on diet. This study showed the feasibility of online treatment for adolescents. It differs from ours however as the population is different with only 18-19 year-olds exiting foster care. Moreover, the primary treatment includes motivational interviewing which has been found to be inferior in adolescents compared to CBT.

Ebert et al., in 2015 conducted a meta-analysis of studies evaluating computer-based CBT interventions for adolescents with a diagnosis of anxiety and depression.
study included 796 participants that were treated for their anxiety or depression with an internet or computer based cognitive behavioral treatment. Results from the meta-analysis showed that there was a statistically significant improvement in the adolescents’ anxiety and/or depression. The authors concluded that computer-based CBT would be a useful treatment for adolescents, particularly in those where there may be limitations to face-to-face treatment. This study is a prime example of why computer based cognitive behavioral therapy should also be examined in adolescents with substance use disorder.

Of the few studies reported utilizing computer-based therapies or cognitive behavior therapy for adolescents and young adults with substance use disorder there is a general theme of providing accessible and quality care to patients. All of the studies aim to increase the accessibility by providing low barrier and evidence-based care. They help demonstrate the feasibility of implementing CBT4CBT for young adults and adolescents with substance use disorder as an effective and accessible treatment. While there are limited studies that directly focused on utilizing computer based cognitive behavioral treatment for adolescents and young adults with substance use disorders, the current data demonstrates that CBT4CBT is a well-studied accessible treatment that can be applicable to adolescents with substance use disorder. This literature review found statistically significant evidence that young adults and adolescents can respond well to computer-based therapies, and that CBT4CBT is an effective adjunctive therapy. The proposed project will extend the evaluation of CBT4CBT to young adults and adolescents with substance use disorders.
2.3 Identifying confounding variables

While reviewing the related literature, we identified several confounding variables that will be addressed in our study design. First, age group has been found to be a moderating variable in the effectiveness of CBT. Thus, we will use stratified random sampling to randomize participants by their age group, either young adults or adolescents. The age cut-offs being 13-17 for adolescents and 18-24 for young adults. By using stratification based on age group, we’ll ensure equal distribution of each age group among the treatment and control groups.

A previous study on treatment retention for substance use disorders sought to identify if there was a difference in treatment retention based on type of substance use (alcohol or drugs, or alcohol and drugs) as well as race and gender. It was found that all of these factors have the capability to impact the treatment retention. Given these findings, we will consider these demographic as confounders and measure them at baseline to ensure comparability across both groups.

Additionally, personal demographics and environmental factors have been found to correlate with success of treatment for youths with substance use disorder. Factors acknowledged in a study by Anderson et al., include age, sex, race, socioeconomic status, diagnosis of type of SUD, and substance use characteristics such as episodes per month of substance use. All of these factors have the potential to impact the patient’s likelihood of relapse. Therefore, we will assess these characteristics at baseline. If there are any imbalances between intervention and control groups then it will be adjusted for with statistical analyses via analysis of covariance (ANCOVA).
Other similar RCTS on CBT4CBT have assessed whether randomization was successful and to identify confounders. They compared the intervention and control arms of the study to identify confounders based on baseline characteristics of subjects in each arm.\textsuperscript{1,20} Examples of the characteristics in these studies include: severity of addiction, comorbid conditions, mental illness, age, education level and sex/gender. These will also be assessed in our study to ensure the treatment conditions are balanced with respect to these characteristics.

\textbf{2.4 Review of relevant methodology}

\textit{2.4.1 Study Setting and Design}

We will conduct a multi-site study which will include participants from primary care clinics within the New Haven County area. The proposed study has a multi-center design to expand our generalizability of aforesaid variables as well as to ensure adequate recruitment to reach statistical significance. According to the Department of Public Health surveillance data, New Haven county consistently has one of the highest monthly numbers for ED visits for suspected drug overdoses of adolescents and adults within Connecticut.\textsuperscript{21} This data is suggestive of the high levels of substance use disorder within New Haven county, ensuring that this area will have enough participants that meet the inclusion and exclusion criteria for our study. CBT4CBT is utilized as an accessible, affordable, and effective treatment platform.\textsuperscript{5} Therefore, this particular county, having one of the lowest socio-economic statuses in CT would benefit greatly from the program.
Our study will target adolescents and young adults age 13-24 with substance use disorder and randomly assign them to either CBT4CBT + TAU, or TAU alone. CBT4CBT contains 7 modules (i.e., core topics) that was modeled after the NIDA published manual for CBT. Each module covers one of the core concepts of CBT. They include: understanding and changing patterns of substance use, coping with craving, refusing offers of drugs and alcohol, problem-solving skills, identifying and changing thoughts about drugs and alcohol, and improving decision-making skills. The modules use engaging videos and questions to help the participant navigate through risky situations. The goal is to enable the user to navigate through tough situations without resorting to substance use. The program can be accessed from any device with internet access (e.g., smartphone, tablet, laptop, desktop), which will be a requirement to participate in this study.

2.4.2 Review of Recruitment Techniques

This study will recruit individuals from the primary care clinics within the New Haven County area. The recruitment technique we will be using in this study will be the referral approach. This approach involves having colleagues of the recruitment site giving information to potential participants about this study. More specifically, we will be using the chain referral method. This method is most effective for hard-to-reach, sensitive populations such as young adults and adolescents with SUD. Chain referral has a seven-step method of sampling:

1. Defining the population and subjects
2. Considering the sample size.
4. Gaining access.
5. Initiating chains and identifying locators.
6. Pacing and monitoring of the referral chains.
7. Discontinuing the referral chains.  

Utilizing these steps, we will be able to tap into the hard-to-reach population, and access a greater number of subjects than if we were to rely on physician referral. This effectively works by identifying a small set of subjects, who will then be asked to help identify and recruit more subjects.  

This will be monitored extensively to ensure diversity and proper inclusion/exclusion criteria. Strengths of this approach include gaining access to a diverse population, while maintaining privacy of the participants.

2.4.3 Inclusion and exclusion criteria

Inclusion and exclusion criteria will be similar to those from RCTs involving CBT4CBT and CBT for adolescents and young adults. Our inclusion criteria will be most closely modeled after a study by Tetrau et al., that evaluated CBT4CBT in adults with SUD diagnosed by primary care physicians as well as a trial by Sweeney et al., that studied adolescents with substance use disorder. Inclusion criteria will include: fluency in English, ability to read at 6th grade level, be willing to engage in treatment and meet the current DSM 5 criteria for substance use disorder, access to a smart device with internet access, and ages 13-24. The exclusion criteria will include: any untreated psychotic disorder, current legal case pending where incarceration is possible, any condition
requiring hospitalization, active drug withdrawal, current engagement in treatment for SUD, or any condition with significant cognitive impairment. 23,24

2.4.5 Review of successful CBT4CBT components- The Intervention

There have been multiple RCTs of CBT4CBT. CBT4CBT has been shown to be an effective and enduring treatment for substance use disorder. 3,25 According to multiple recent trials, not only was it effective, it also had the highest rate of adherence and participant satisfaction compared to standard treatment. 1,11,26 With this in mind, our proposed study will utilize CBT4CBT in a population that typically has low access to care, and high rates of relapse. 27

2.4.6 Review of the Primary Intervention: CBT4CBT

The core components of CBT4CBT includes 7 core modules that teach cognitive as well as behavioral skills. The skills teach the user tactics to help them gain control over their use of drugs or alcohol. 28 These skills include: recognizing and changing patterns of use, coping with craving and urges to use drugs or drink, challenging and changing negative thoughts, improving decision making skills, learning how to say no effectively, and improving problem-solving skills. 28

The modules take approximately thirty minutes to complete and can be completed at the person’s individual pace. They utilize video-based instruction and interactive games to engage the user. 28 The modules are structured to keep engagement throughout the thirty minutes as well. Initially, the user watches a short movie that uses actors in a
realistic setting that display a high-risk situation for substance use. There is then a narration over the movie, explaining what went wrong in the situation and how to change the outcome to avoid substance use. The movie then replays with this new outcome. 29 There are additional interactive vignettes to show how they use this skill in different ways. 29 After the videos, there is a short quiz and vignette to help solidify to the user the cognitive behavioral training skills that were taught in this module. There are also explanations of how this skill could be use in different settings. This also helps to address common areas of resistance in CBT. 29 The end of the module consists of a narrator reviewing the key skills they learned as well as example of how the user can complete their homework for the week, to practice the skills they learned within the module. 29

The average user will take about 8 weeks to complete the entire CBT4CBT program. In all prior studies of CBT4CBT a research assistant has been available to assist the user in accessing the program and guiding them through the initial login, as well as answer questions as needed. 30 Our study will also utilize this method in assisting participants, however research assistant may be available over the internet rather than in person for assistance.

2.4.7 Content of Control Condition

Our control condition, otherwise known as “treatment as usual” or TAU, will be the typical outpatient treatment a participant would receive for their substance use disorder. The standard treatment will depend on the site the patient is at. 31 However, it typically will consist of individual or group counseling for their substance use disorder. Participants assigned to TAU will engage in these sessions for 8 weeks. 31
With review of the aforementioned studies as well, in addition to other similar studies, TAU will involve individual or group therapy, as well as any other services by the participant needed (e.g., ancillary psychiatric services, case management), and very close monitoring of any other services requested or used by the participant.

2.4.8 Outcomes

The primary outcome for our study is the percentage of urine samples that are negative for substances during the 8-week treatment. This has been assessed in previous studies through periodic assessments during the study, as well as after the study treatment period. In all prior studies of CBT4CBT participants were screened via urinalysis prior to the initiation of treatment, as well as weekly during treatment period and at the conclusion of treatment. ¹

As a secondary outcome to evaluate enduring effects of CBT4CBT, participants have been screened via urinalysis at 1-, 3- and 6-month intervals post treatment. ¹⁰ We will adapt this model of urine screening up to 6 months post treatment to track the progress of the participants after treatment. Once participants initiate treatment, they will be asked to submit urine samples when they are at the clinic for their weekly TAU, as well as asked to come back to submit urine samples after treatment. The test will be administered and supervised by a clinician or research assistant. Additionally, we will examine the engagement in treatment as measured by the number of SUD treatment sessions attended and/or CBT4CBT modules completed.

Secondary outcomes for our analysis will assess the percentage of days during treatment that the participant uses drugs, or frequency of drug use. This outcome will be
assessed through self-report, utilizing the Timeline Follow Back (TLFB) method as recommended by Levy et al. The study performed by Levy et al., tested the reliability of adolescents (12-18 years old) self-reporting drug use with the CRAFFT screen vs TLFB. It was determined that the TLFB is a reliable method of self-reporting for adolescents when reporting their current usage of substances. The TLFB will be administered at the same time as every urine specimen is given, as the urine specimen will validate the self-report.

Additional secondary outcomes include instruments measuring mental health and severity of substance use from the Patient Reported Outcomes Measurement Information System (PROMIS). We will utilize three of these measures: Emotional and Behavioral Dyscontrol, Self-Efficacy, and Severity of Substance Use. The survey for Emotional and Behavioral Dyscontrol is a self-report of behavioral and emotional experiences over the past 7 days, and will be administered weekly along with the TLFB. Both the Self-Efficacy and Severity of Substance Use questionnaires measure items over the past 30 days and will be administered at the beginning of the study and the end of treatment. Results from all three surveys will be scored and evaluated by a research technician.

2.4.9 Review of Sample Size and Calculation Power

Our sample size calculation was determined primarily by the results of Carroll et al., with additionally considerations from Sweeney et al. In Carroll et al.’s original study on CBT4CBT, they found that participants being treated with CBT4CBT submitted 34% of their total urine specimens positive for substances within the time of treatment and the
subjects in the control group had a result of 53% of their total urine specimens positive for substances during the treatment time. This results in a cohen’s d effect size of 0.46, which we will use for our study as this effect size is of the same outcome.

A study by Sweeney et al., analyzed using working memory training (a computer based cognitive training) for adolescents with cannabis use disorders. One of the outcomes of this study was, urinalysis similar to our primary outcome. Subjects were asked to submit urine specimens weekly for the duration of their treatment. The study found that at the conclusion of treatment, the intervention arm had a 40% probability of submitting a positive urine sample, and the control arm had about a 60% probability of submitting a positive urine sample. With an effect size of approximately 20%, we determined that this adolescent population was comparable to the population we will be basing our sample size off in Carroll et al.’s study.

Ultimately, a prospective, randomized clinical trial study found that the association between relapse rates and CBT4CBT treatments to be significant, where participants being treated with CBT4CBT submitted 34% of their total urine specimens positive for substances within the time of treatment and the subjects in the control group had a result of 53% of their total urine specimens positive for substances during the treatment time. Using this cohen’s d effect size of 0.46, a 2-sided significance level of 0.05, and an 80% power, we calculated a minimum sample size of 150.

2.5 Conclusion

While CBT4CBT has been shown to be efficacious at reducing substance use and durable throughout this literature review across various populations, this form of
treatment has yet to been tested in the younger population. It is even more important knowing that young adults and adolescents having high rates of relapse, and having similar numbers of emergency department visits per month for substance use overdose compared to the adult population within New Haven county. The information suggests CBT4CBT may be a promising intervention for substance use disorder in the adolescent and young adult population. Our study design utilizes the original methods used to test CBT4CBT while incorporating aspects to ensure this study will be applicable to a new population. Through our literature review, we have described the aspects of our study design as well as the different aspects of the previous research that states the need for this intervention. Our study will add to the literature a new intervention for young adults and adolescents with substance use disorder.

2.6 References


Chapter 3- Study Methods

3.1 Study Design

This will be a multi-site randomized control trial. We will be evaluating the effect of CBT4CBT as an adjunctive therapy to standard outpatient care for SUD treatment among adolescents and young adults. Our multi-site study will be based out of primary care clinics in New Haven county. We will be using a 1:1 randomization to assign participants to the intervention or control group, stratifying based on site. Due to the nature of the intervention, it will not be possible to blind participants. Thus, the assignment given to each subject will be blinded to follow-up assessors.

3.2 Study Population and Sampling

This study will recruit adolescents and young adults visiting their primary care office for any type of visit, who are identified to have SUD. These subjects must be between the ages of 13-24 and be diagnosed with a SUD based on DSM 5 criteria. Eligible candidates will be willing to initiate treatment and not currently engaged in SUD treatment. They would also have access to a smart device such as a computer or tablet.
3.3 Inclusion Criteria

Our inclusion criteria will be modeled after a study by Tetrault et al., that evaluated CBT4CBT in adults that were identified as having a SUD by their primary care clinicians as well as a trial by Sweeney et al., that studied adolescents with substance use disorder. Inclusion criteria will be as follows: fluency in English, ability to read at 6th grade level, meet the current DSM 5 criteria for substance use disorder, access to a smartphone/computer/tablet with internet access, and ages 13-24. 3,4

3.4 Exclusion Criteria

The exclusion criteria will be: current enrollment in SUD treatment, any untreated psychotic disorder, current legal case pending where incarceration is possible, any condition where hospitalization is required, active drug withdrawal, or any condition with significant cognitive impairment. 3,4

Table 1: Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
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<tbody>
<tr>
<td>Ages 13-24</td>
<td>Untreated psychotic disorder</td>
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<tr>
<td>Fluency in English</td>
<td>Current legal case pending where incarceration is possible</td>
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<tr>
<td>Ability to read at 6th grade level</td>
<td>Required hospitalization</td>
</tr>
<tr>
<td>Meet current DSM V criteria for SUD</td>
<td>Conditions with significant impairment</td>
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<tr>
<td>Access to smart device with internet access</td>
<td>Not in active withdrawal</td>
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<td>Guardian consent if under age 18</td>
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</table>
3.5 Subject protection and confidentiality

Before initiating recruitment, our team will obtain approval from the Yale Institutional Review Board. This will be done by applying for approval of the study as well as design. The application will be approved before initiating the study. To maintain compliance of the Yale IRB, there will be an Authorization and Consent for participation in Research Project 200 FR. 1 form. This form includes: invitation to participate, description of the project with risks and benefits, treatment alternatives, guidance on voluntary participation and withdrawal, confidentiality and privacy agreements, and economic considerations.

All participants will be required to review the form with a research staff member to ensure they understand all procedures, risks and benefits, and provide written consent prior to initiating treatment.

In addition, all research investigators involved must complete the Health and Insurance Portability Accountability Act (HIPPAA) training session. Evidence of completion via certificate must be provided to Yale IRB. This will ensure that all participants’ identifiable health information will remain protected. All information and records throughout this study will be kept on an encrypted computer system, that is only accessible by necessary personnel of the study. All personal participant data will be destroyed at the conclusion of the study.
3.6 Recruitment

This study will recruit individuals from the primary care clinics within the New Haven County area. The recruitment technique we will be using in this study will be the referral approach. This approach involves having colleagues of the recruitment site giving information to potential participants about this study. Chain referral has a seven-step method of sampling:

8. Defining the population and subjects
9. Considering the sample size.
10. Selecting and assessing settings.
11. Gaining access.
12. Initiating chains and identifying locators.
13. Pacing and monitoring of the referral chains.
14. Discontinuing the referral chains. ²

This will identify a small set of subjects, who will then be asked to identify and recruit more subjects. This will be monitored to insure proper inclusion and exclusion criteria.

3.7 Study Variable and Measures

The independent variable in our study will be access to the CBT4CBT program as an adjunctive therapy to TAU. The control variable will be TAU for all participants with no adjunctive therapy. The TAU will include typical interventions provided within a primary care facility, which may include brief intervention and referral to additional specialized services. Such specialized services can include: group therapy, individual psychotherapy, and/or medications. The dependent and primary outcome for our study is
the percentage of urine samples that are negative for substances during the two months of treatment. We will also include urine samples collected within the 6-month period after treatment as a secondary outcome. Participants will be screened via urinalysis prior to the initiation of treatment, as well as weekly during treatment and at the conclusion of treatment, as well as at 1-, 3- and 6-month intervals post treatment. Once participants initiate treatment, they will be asked to submit urine samples when they are at the clinic for their TAU, as well as asked to come back to submit urine samples after treatment. The test will be administered and supervised by a clinician or research assistant. Finally, we will examine the engagement in treatment as measured by the number of SUD treatment sessions attended and/or CBT4CBT modules completed.

3.8 Methodology Considerations

3.8.1 Blinding of Intervention

Due to the nature of this study (behavioral intervention), blinding of the intervention to each group will not be possible. The investigators will be blinded to the allocation of each subject when analyzing the results of the study. Additionally, subjects will be asked not to disclose their allocation to any staff.

3.8.2 Blinding of Outcome

The research staff that is collecting urine samples as well as TLFB results will be blinded to allocation of each study participant. The staff within the primary care clinics will not be assisting in assessing the study outcomes to ensure the validity and blinding of results.
3.8.3 Assignment of Intervention

All participants in the study will be assigned to either the intervention group (CBT4CBT+TAU), or control group (TAU) through stratified random sampling. The randomization will take place using a computer system that randomly assigns subjects to an intervention condition. Stratification will be by age group (13-17 or 18-24) and type of substance (cannabis, opioids, other) There will be a 1:1 allocation to the intervention or control group. After randomization takes place, each group will be notified of their respective intervention placement.

3.8.4 Adherence

Adherence for the group assigned to the CBT4CBT intervention will be monitored through the CBT4CBT program, which tracks for each participant the number of modules completed, and number of minutes engaged with the program. Additionally, adherence to TAU will be monitored via staff administering this treatment. Treatment completion will be defined as attending a minimum of 70% of the sessions for CBT4CBT as well as TAU. For CBT4CBT this will require completing 5/7 modules. If participants are prescribed medication to assist in treating their SUD, this will be assessed each time the participant gives a urine sample.

To encourage adherence, travel expenses for TAU will be reimbursed. Additionally, participants will receive $5 for each TAU session that is attended. Participants assigned to CBT4CBT will be given a $50 bonus for completing all 7 CBT4CBT modules, consistent with procedures from prior trials of CBT4CBT. Finally, to encourage participants to submit urine samples, participants will be given a ticket each
time they submit a urine sample that will be entered in a raffle at the end of the study worth $150.

3.9 Data Collection

Primary and secondary outcomes will be collected for a total of 8 months (2-month treatment period plus 6-month follow-up). Data will begin to be collected at the initiation of treatment and every week subsequently after during the treatment period. Urine screens will continue after treatment for 6 months at the 1-, 3- and 6-month intervals. Once participants initiate treatment, they will be asked to submit urine samples when they are at the clinic for their TAU, as well as asked to come back to submit urine samples after treatment. The test will be administered and supervised by a clinician or research assistant.

Secondary outcomes for our analysis will assess the percentage of days during treatment that the participant uses drugs, or frequency of drug use. This outcome will be assessed through self-reporting, utilizing the TLFB. The TLFB will be administered at the same time as every urine specimen is given, as the urine specimen will validate the self-report. We will also measure engagement in treatment, as measured by the number of SUD treatment sessions attended and/or CBT4CBT modules completed throughout the eight-week period. Additional secondary outcomes include instruments from the Patient Reported Outcomes Measurement Information System. We will utilize three of these measures: Emotional and Behavioral Dyscontrol, Self-Efficacy, and Severity of Substance Use. The survey for Emotional and Behavioral Dyscontrol will be given weekly along with the TLFB. Both the Self-Efficacy and Severity of Substance Use
questionnaires will be given at the beginning of the study and the end of treatment. Results from all three surveys will be scored and evaluated by a research technician.

### 3.10 Sample Size Collection

After evaluating the literature, utilizing similar previous studies of CBT4CBT that matches our study design, outcomes and intervention, we estimated a cohen’s d effect size of 0.46 utilizing the SocStatistics calculator, which translates to a moderate effect size.

Ultimately, a prospective, randomized clinical trial study found that the association between relapse rates and CBT4CBT treatments was significant, where participants being treated with CBT4CBT submitted 34% of their total urine specimens positive for substances within the time of treatment and the subjects in the control group had a result of 53% of their total urine specimens positive for substances during the treatment time. Using this effect size of 0.46, a 2-sided significance level of 0.05, and an 80% power, we calculated a minimum sample size of 150 utilizing the Power and Precision software.

Our sample size calculation was determined primarily by the results of Carroll et al., with additional considerations from Sweeney et al. In Carroll et al.’s original study on CBT4CBT, they found that participants being treated with CBT4CBT submitted 34% of their total urine specimens positive for substances within the 8-week treatment and the subjects in the control group had a result of 53% of their total urine specimens positive for substances during the treatment time. Considering the standard deviations and sample sizes, and a moderate effect size (cohen’s d effect size of 0.46), 75 participants will be required per study arm in our study for a total sample size of 150.
3.11 Analysis

All statistical analyses will be performed by the research personnel that are completely blinded to the groups each participant was allocated to. Data will be analyzed with intention to treat, based on each participant’s original group allocation, regardless of their attendance in treatment. For this study, statistical significance will be defined as p<0.05 for all measurements. The primary outcome will be the mean percentage of negative urine samples over the 8-week treatment period reported as a continuous variable. This will be calculated with two sets of data. One data set will not include missed urine samples, and the second will include all urine samples that were intended to be collected (i.e., any missing will be deemed positive). Results with be compared with ANCOVA test for two unpaired variables. Primary outcome will be evaluated at the aforenoted intervals, whether participants adhered to their treatment. Analyses of secondary outcomes will also be compared via ANCOVA using continuous variables (e.g., number of treatment sessions attended, percentage of self-reported days of abstinence, scores on PROMIS measures).

There are multiple baseline characteristics of each subject that will be compared to ensure that there is limited variation between the intervention and control groups. Continuous variables such as age will be reported as a mean and standard deviation and compared via ANCOVA. Categorical variables such as gender, race and socioeconomic status will be compared using chi square test. If there is a difference between the control and intervention groups, we will then use ANCOVA (Analysis of CoVariance) to control for these covariates.
3.12 Timeline and Resources

The proposed study will be completed within the allotted 36-month time frame. The initial step in this process will be obtaining IRB approval. We will allocate 3 months for this process. Additionally, all research staff will attend a mandatory multi-day training to prepare for the study and ensure a standardized experience for each participant. Training will begin immediately after IRB approval. We will allocate one month for this, assuming we will be able to recruit 8-9 participants per month as we have multiple recruitment sites. Participant enrollment will then occur from months 4-22. After 18 months, enrollment will stop and data collection will continue for 8 months after each participant begins treatment. This ensures that participants enrolled on the last day of enrollment will be able to submit urine samples for the required 6 months after the 2 months of treatment. After 30 months when all data is collected, 6 months will be used to analyze the data by research staff.

Resources required will include: a research coordinator to recruit, consent, screen, and enroll participants, a research coordinator familiar with CBT4CBT to inform participants about this intervention and assist if questions arise, a research assistant to collect data (including urine samples) during the treatment period and follow-up and finally a research analyst to gather and organize data. At the conclusion of this study, all blinded research analysts will assist in data entry and calculations. Additionally, concerning the monetary prizes we will need a minimum of $6,000.
Table 2: Timeline for Study Completion

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<th>Month</th>
<th>IRB Approval</th>
<th>Staff Training</th>
<th>Enrollment</th>
<th>Data Collection</th>
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3.13 References:


Chapter 4: Conclusion

4.1 Advantages and Disadvantages:

Our proposed study will be the first of its kind to offer CBT4CBT, a validated adjunctive therapy for SUD, to adolescents and young adults. Aside from its novelty, the strength of our study aligns with those of previous studies utilizing CBT4CBT. Its effectiveness, along with compensation for attendance will ensure adequate intervention and control adherence utilizing monetary awards. Additionally, our study design and methodology will promote internal validity. The researchers will be blinded, and stratified randomization and allocation concealment will limit the amount of selection bias and ensure baseline characteristics are similar in potential confounding variables. Additionally, a multi-site approach using chain referral sampling and provider recommendations will allow us to draw from a large population. Previous similar studies have often been limited by their low sample size. Additionally, the given location of New Haven County will offer a diverse participant population as over 60% of the population is black or Hispanic. 48

To address the limitations of our study, we know that the path for many to treatment is difficult. As participation in our study will be on a volunteer basis, we will face bias among participants who are more willing to continue with treatment than others. Additionally, previous studies have had high loss of follow up to treatment. While we do account for loss to follow up in our sample size calculation and try to reduce this with a compensation plan, it is difficult to predict and mitigate this problem. Lastly, our study’s location sites are in an urban area where access to providers and treatment for SUD is
relatively high. Due to this, our findings may not generalize adequately to a more rural population where these services are less accessible.

4.2 Clinical and/or Public Health Significance:

Research is urgently needed to understand how to provide adequate and accessible treatment for young adults and adolescents with SUDs. The proposed study will address this critical gap in the literature by demonstrating how to provide empirically-validated care that addresses current barriers for this population. Beyond access to care, treatment of SUDs can result in lower rates of comorbidities related to SUD as well as incidence of death from overdose. If this intervention is successful, it can provide insight on how CBT4CBT can be incorporated into treating this population for SUD in the future. Additionally, this study can be a basis for future studies to provide evidence based adjunctive treatment for adolescents and young adults with SUDs.

4.3 References:

APPENDICES
Appendix A: Recruitment Flyer

Yale University
School of Medicine

Volunteers Needed for Research Study!

Are you a young adults or adolescent who uses drugs or alcohol, looking for treatment?

We are conducting a research study to investigate whether utilizing a computer based cognitive behavioral therapy in addition to typical treatment can help reduce the use of drugs or alcohol in young adults and adolescents with substance use disorders.

Who can join the study?

- People ages 13-23
- People with a substance use disorder seeking treatment
- Must have access to a device with internet access

What do you have to do?

- Access a computer-based program to participate in short weekly modules for 2 months
- Provide information about your experience with the program
- Be willing to submit urine samples each week during treatment, and multiple times after treatment for 6 months

Do you get anything in return?

- Participants will be given $5 for each CBT4CBT module they complete.
- $50 reward for attending the typical treatments required
- Entry to a $150 raffle for each urine sample submitted

To learn more or to determine if you are eligible please email us at: kidsCBT4CBT@yale.edu or call us at: 800-859-2000.
Appendix B: Compound Consent and Privacy Rule Authorization Form

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 1 (2016-2)

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN

Study Title: Computerized Cognitive Behavioral Therapy in Adolescents and Young Adults With Substance Use Disorder
Principal Investigator: Brian Kiluk, PHD

Invitation to Participate and Description of Project

You are invited to participate in a research study designed to look at the effects of using CBT4CBT as an adjunctive therapy to standard treatment for young adults and adolescents with substance use disorder. You have been asked to participate because you have met the inclusion criteria as an adolescent or young adult with a DSM-V diagnosed Substance Use Disorder, seeking initial treatment.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participate in this study, our research coordinator will ask you questions regarding your risk behaviors, and demographics. We will be collecting information such as age, sex, gender identity, sexual orientation, history of substance use, psychiatric and medical history, race, education, income, employment status, insurance and transportation needs.

You will then be randomly assigned to receive (1) CBT4CBT access with standard treatment or (2) standard treatment. All participants will receive standard treatment regardless of allocation. Randomization occurs through a computer-based system in which you have equal chances of being allocated to either group. Once you have been assigned to the group, you will have a unique study code to identify you without bias throughout the study.

If you are assigned to the CBT4CBT intervention group, you will be asked to speak with a CBT4CBT moderator to answer any questions and learn about the program. After, you will be asked to complete as many of the CBT4CBT modules as you can, one per week for 8
Each module will take 30-60 minutes. Both groups will be asked to attend standardized treatment recommended by a physician (group therapy, medication assisted treatment.)

Research staff will contact you by phone to submit urine samples weekly at standardized treatment for the initial 8 weeks, and then again at the 1, 3 and 6 months intervals after finishing the intervention. You will also be asked to self report substance use, utilizing the TLFB screen prior to each submission of urine.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. You will be told of any significant new findings that are developed during the course of your participation in this study that may affect your willingness to continue to participate. If research results are published, your name and personal information will remain confidential.

**Risks and Inconveniences**

*Guidelines:*
There are no physical risks associated with this study. However, some questions may make you uncomfortable and there is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. We will also ask to collect urine via urinating in a sterile cup. There are no risks with this technique.

**Benefits**
The potential benefits of this study are connection to treatment for SUD and the initiation of CBT4CBT, which can significantly reduce the use of substances.

**Economic Considerations**
There are no costs associated with participation in the study. However, you may be responsible for costs associated with standard treatment or transportation. According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income. To encourage adherence, travel expenses for TAU will be reimbursed. Additionally, all patients will be given $5 for each CBT4CBT module they complete. To encourage participants to attend TAU, they will receive $50 at the end of the study if they complete at least 70% of the sessions recommended. Finally, to encourage patient to submit urine samples, participants will be given a ticket each time they submit a urine sample to submit for a raffle at the end of the study worth $150.

**Treatment Alternatives/Alternatives**
If you choose not to participate in this study, there are alternative treatments available. You may contact your primary care provider to learn about other options.
Confidentiality
Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained. Information will be kept confidential by using no patient identifiers on forms, and keeping all information locked. When the results of this study are published, no information will be included to reveal your identity.

Voluntary Participation and Withdrawal
Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments. Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors. We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment.

When you withdraw from the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions
We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization
I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.
Name of Subject: ________________________________

Signature: ____________________________________

Relationship: ________________________________

Date: ____________________________

______________________________  ________________________
Signature of Principal Investigator  Date

or

______________________________  ________________________
Signature of Person Obtaining Consent  Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator. If, after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.
Appendix C: Timeline Follow Back (TLFB) Screen

Name/ID#: ________________________________________  Date:___________________

TIMELINE FOLLOWBACK CALENDAR: 2022

<table>
<thead>
<tr>
<th>SUN</th>
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Complete the Following

**Start Date** (Day 1): __________________

**End Date** (yesterday): __________________
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- **JUNE 2022**
- **Father's Day**: June 19
- **Independence Day**: July 4
- **Labor Day**: September 5
### Instructions for filling out TLFB calendar:

To help us evaluate your drug use, we need to get an idea of what your use was like in the past ____ days. To do this, we would like you to fill out the attached calendar.

Filling out the calendar is not hard!

Try to be as accurate as possible.

We recognize you won’t have perfect recall. That’s OKAY.

**WHAT TO FILL IN**
• The idea is that for each day on the calendar we want you to indicate whether you “used” or “did not use” drugs.

• On days when you did not use drugs, you should write a “0” in the box.

• On days when you did use drugs, you should put a “\[” in the box. It’s important that something is written for every day, even if it is a “0”. YOUR BEST ESTIMATE • We realize it isn’t easy to recall things with 100% accuracy.

• If you are not sure whether you used a certain drug on a Thursday or a Friday of a certain week, give it your best guess! The goal is to get a picture of how many days you were using drugs and your patterns of use.

HELPFUL HINTS

• Holidays such as Thanksgiving and Christmas are marked on the calendar to help you better recall your use. Also, think about whether you used drugs on personal holidays and events such as birthdays, vacations, or parties.

• If you have regular drug use patterns you can use these to help you recall your use. For example, you may have weekend/weekday changes in your drug use or your drug use may be different depending where you are or whom you are with.

COMPLETING THE CALENDAR

• A blank calendar is attached. Each day should contain a "0" for no drug use or a "\[" for drug use.

• The time period we are talking about on the calendar is from __________________________ to _______________________.

• In estimating your drug use, be as accurate as possible.

• DOUBLE CHECK THAT ALL DAYS ARE FILLED IN BEFORE RETURNING THE CALENDAR.
Appendix D: Emotional and Behavioral Dyscontrol - Short Form

Emotional and Behavioral Dyscontrol – Short Form

Please respond to each question or statement by marking one box per row.

<table>
<thead>
<tr>
<th>In the past 7 days…</th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDOM1042</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<td>NSPER105</td>
<td>☐</td>
<td>☐</td>
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<td>NSPER106</td>
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<td>NSPER107</td>
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Appendix E: General Self-Efficacy - Short Form 4a

PROMIS® Item Bank v1.0 – General Self Efficacy – Short Form 4a

General Self-Efficacy – Short Form 4a

Please respond to each item by marking one box per row.

For the next set of questions, please read each sentence and rate your level of confidence in managing various situations, problems, and events.

<table>
<thead>
<tr>
<th>Rate your level of confidence.</th>
<th>I am not at all confident</th>
<th>I am a little confident</th>
<th>I am somewhat confident</th>
<th>I am quite confident</th>
<th>I am very confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSE11_G</td>
<td>I can manage to solve difficult problems if I try hard enough. .................................................</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>GSE14_G</td>
<td>I am confident that I could deal efficiently with unexpected events. ........................................</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>GSE19_G</td>
<td>If I am in trouble, I can think of a solution. .................................................................</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>GSE20_G</td>
<td>I can handle whatever comes my way....... .............................................................................</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
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Appendix F: Severity of Substance Use (Past 30 days) v1.0- Short Form 7a

### Severity of Substance Use (Past 30 days) v1.0 – Short Form 7a

Please respond to each question or statement by marking one box per row.

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
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<tr>
<td>In the past 30 days, have you used drugs, other than alcohol or your prescribed medications?</td>
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<td>I felt that my drug use was out of control.</td>
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<tr>
<td>My desire to use drugs seemed overpowering</td>
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<td>Drugs were the only thing I could think about</td>
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<td>My drug use caused problems with people close to me</td>
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<td>I have a drug problem</td>
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<tr>
<td>I craved drugs</td>
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<td>I spent a lot of time using drugs</td>
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Appendix G: Sample Size Calculation
The following calculation was made using the Power and Precision Version 4 tool:

Two-tailed test: Alpha (level of significance) = 0.05, B (type II error) = 0.20, corresponding to a power of 80%

For a given cohen’s d effect size of 46% (population proportions of 53 vs. 34 and standard deviation of 41), sample sizes (75 and 75), and alpha (0.05, 2-tailed), power is 0.80. This means that 80% of studies would be expected to yield a significant effect, rejecting the null hypothesis that the two population proportions are equal.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (M):</td>
<td>53</td>
</tr>
<tr>
<td>Standard deviation (s):</td>
<td>41</td>
</tr>
<tr>
<td>Sample size (n):</td>
<td>22</td>
</tr>
</tbody>
</table>

Cohen’s d = (34 - 53) / 40.950031 = 0.46398.

Glass’s delta = (34 - 53) / 41 = 0.463415.

Hedges’ g = (34 - 53) / 40.945682 = 0.464029.
Bibliography:


