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A Randomized Trial of CBT4CBT for Women in Residential Treatment for Substance Use Disorders

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University

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Abstract

A RANDOMIZED TRIAL OF CBT4CBT FOR WOMEN IN RESIDENTIAL TREATMENT FOR SUBSTANCE USE DISORDERS

by Sydney S. Kelpin, M.S.

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Women with substance use disorders (SUD) face unique barriers to substance use treatment, and as a result, are less likely than their male counterparts to seek treatment for the disorder. Cognitive behavioral therapy (CBT) is an evidence-based treatment known to reduce relapse rates by teaching clients to recognize and respond to their cues for substance use. Recent research suggests CBT may be particularly of benefit to women. Despite the effectiveness of CBT, its dissemination in clinical practice is limited due to a range of barriers (e.g., time, cost). Computer-based training for cognitive behavioral therapy (CBT4CBT) offers an opportunity to improve the quality and reach of SUD treatment services that is both feasible and cost-effective. Research to date has supported the effectiveness of CBT4CBT in outpatient settings; however, it has not yet been tested in residential treatment. The present study was a two-arm clinical trial comparing women randomized to either standard residential treatment plus access to the CBT4CBT program (N = 34) or residential treatment alone (TAU; N = 29). Assessments occurred at baseline, discharge from residential care, and at 4 and 12-weeks post-discharge. Although the present study was not powered for statistical significance, findings were in the predicted direction, with women in the CBT4CBT group reporting lower likelihood of relapse,

longer time to relapse, and fewer days of substance use in the follow-up period compared to TAU. This pattern was most evident for women not receiving pharmacological treatment for opioid use disorder. Exploratory analyses examined correlates of treatment outcomes, as well as the acceptability and feasibility of implementing CBT4CBT in a residential treatment program. Primary outcome variables were used for effect size estimations to determine the sample size needed for an adequately powered RCT of the intervention. The present study expanded on the current literature supporting the use of CBT4CBT in outpatient settings and provides benchmark data on the use of CBT4CBT in a residential treatment program for women with SUDs. This body of research has important implications for SUD treatment, with potential to expand the reach of evidence-based addiction treatment across different modalities and patient populations.

Introduction

Addiction constitutes a major public health problem; one that costs the United States over $740 billion annually through health care costs, lost work productivity, and crime (NIDA, 2017). In 2015, an estimated 21.7 million people age 12 and older (8.1%) were in need of substance use treatment, defined as meeting criteria for having a substance use disorder (SUD) or receiving treatment at a specialty facility (NSDUH, 2015). Women represent a subpopulation of particular concern, as research has demonstrated an increased vulnerability among women for adverse medical and social consequences associated with substance use (Greenfield et al., 2007). Women have been found to progress more rapidly from regular use to first treatment episode compared to their male counterparts, a phenomenon known as telescoping (Greenfield et al., 2007; Greenfield et al., 2010). Further, despite having used for fewer years at treatment entry, research has shown that women have more medical, psychiatric, and adverse social consequences on average compared to their male counterparts (Greenfield et al., 2007; Greenfield et al., 2010).

Women with SUDs also face unique barriers to seeking and receiving substance use treatment (Terplan, Longinaker, & Appel, 2015; Greenfield et al., 2007; Green, 2006; Ashley, Marsden, & Brady, 2003). As a result, women are less likely to seek treatment than men. Gender-specific treatment programs seek to address such barriers, providing interventions tailored to deliver information and services to women, such as childcare assistance and housing (Greenfield et al., 2010; Claus et al., 2007). Research has found that women in such programs have higher retention rates, less drug use, and report fewer barriers to care (Terplan, Longinaker, & Appel, 2015). However, even in such programs, relapse rates remain high, with 40-60% of women relapsing (NIDA, 2014).

Cognitive behavioral treatment (CBT) is an evidence-based intervention for relapse prevention (McHugh, Hearon, & Otto, 2010; Hendershot et al., 2011). The CBT approach emphasizes the role of contextual factors (e.g, environmental stimuli and cognitive processes) as proximal relapse antecedents (Hendershot et al., 2011). CBT focuses on the identification and prevention of high-risk situations and relationships that increase patient risk for substance use (McHugh, Hearon & Otto, 2010). CBT seeks to improve the individual's ability to cope with these high-risk situations that commonly lead to relapse (Sugarman, Nich, & Carroll, 2010). Through the use of CBT, patient cognitions around substance use are challenged (e.g., perceived benefits) and psychoeducation is provided to help the patient make a more informed choice when confronted with their cues for use. In addition, CBT focuses on specific skills training and behavioral techniques to prevent substance use. CBT has been well supported in the literature (Dutra et al., 2008; Magill & Ray, 2009) and there has also been evidence of gender differences, with a recent meta-analysis demonstrating that women appeared to benefit more from CBT compared to men (Magill & Ray, 2009).

The fact that CBT may particularly benefit women is consistent with other research showing that their reasons for relapse differ from men. Depression, interpersonal stress and relationship conflict are more likely to be associated with relapse in women (Tuchman, 2010). Further, research has shown that women are more likely to relapse when their romantic partners are substance users (Rubin, Stout, & Longabaugh, 1996); and women are more likely to report personal problems prior to relapse (McKay et al., 1996). Thus, the coping skills and stress management techniques in CBT may be central to relapse prevention among women.

Despite its effectiveness, CBT is rarely implemented in community-based treatment (IOM, 1998). This is due to a range of barriers, including limited availability of professional

training in CBT (Weissman et al., 2006), high rates of clinician turnover (McLellan, Carise, & Kleber, 2003), complexity and cost of training clinicians (Sholomskas et al., 2005; Morgenstern et al., 2001), high caseloads and limited resources (McLellan & Meyers, 2004). Evidence suggests that only a minority of individuals in need of addiction and other psychiatric services receive evidence-based treatment (IOM, 1998). Further, although many clinicians report using CBT techniques in their practice, they tend to overestimate their use of CBT and other empirically supported therapies (Carroll et al., 2008).

Computer-assisted delivery of CBT offers an opportunity to improve the quality and reach of treatment services that is both feasible and cost-effective (Carroll et al., 2014). Computer-assisted therapy provides a platform for teaching CBT skills to patients that enables clinicians to focus on acute concerns and problems (Carroll et al., 2008). Further, the computerized format standardizes treatment delivery, providing a more consistent, and potentially more effective, method of teaching and demonstrating CBT skills than is available in clinical settings. Computer-assisted delivery of CBT presents the information via a range of media (text, video, interactive exercises) and allows participants to select or tailor the content based on their specific needs. Studies to date have demonstrated the utility of CBT4CBT in outpatient settings, with individuals randomized to CBT4CBT exhibiting better outcomes, including more negative urine specimens, longer periods of abstinence, better durability of effects over time (Carroll et al., 2014; Carroll et al., 2009; Carroll et al., 2008; Kiluk et al., 2016) and improved coping skills compared to treatment as usual (TAU) (Kiluk et al., 2010; Sugarman et al., 2010). Coping strategies have been identified as a potential predictor of such outcomes. For example, studies have found participants in the CBT4CBT condition showed greater improvements in both the use (Sugarman et al., 2010) and quality of coping skills (Kiluk et al.,

2010) compared to TAU. Further, increases in coping strategy use were associated with decreases in drug use (Sugarman et al., 2010), and the quality of coping responses mediated the effect of treatment on participants' duration of abstinence following treatment (Kiluk et al., 2010).

Although CBT4CBT has demonstrated effectiveness in outpatient settings, it has not yet been evaluated as an adjunct to residential treatment for SUDs. The present study conducted a 2-arm randomized clinical trial (RCT) comparing post-discharge relapse rates for TAU with access to the CBT4CBT program (CBT4CBT; intervention) vs. treatment as usual (TAU; control) in a residential sample of women with SUDs. All women completed a baseline assessment, followed by random assignment to either CBT4CBT or TAU. Women in the CBT4CBT condition had access to the CBT4CBT program throughout their residential stay. Follow-up assessments occurred at discharge, with weekly smartphone assessments during weeks 1-3 post-discharge, and in-person assessments at 4 and 12 weeks following residential treatment (see Table 1 for assessment schedule). Primary outcome measures included: 1) relapse Y/N (any alcohol/drug use) in the 12 weeks post-discharge; 2) number of days of substance use in the 12-weeks post-residential care; and 3) coping strategies score, as measured by the Coping Strategies Scale (CSS; Litt et al., 2008; Sugarman et al., 2010). Other psychosocial variables (e.g., depression, stress) were also examined to identify correlates of observed treatment outcomes.

Specific Aim 1: Examine feasibility for use of CBT4CBT in a residential treatment program for women with SUDs, as well as follow-up rates, methods, effect size, and sample size estimates to power a larger RCT.

Specific Aim 2: Conduct a small RCT comparing TAU with access to the CBT4CBT program (CBT4CBT; intervention) vs. treatment as usual (TAU; control) using relapse rates and days of use as primary treatment outcomes.

Hypothesis 1: Women in the CBT4CBT group will be less likely to relapse (Y/N) during the 12-week follow-up period than women in TAU.

Hypothesis 2: Women in the CBT4CBT group will report fewer days of substance use compared to women in TAU during the 12-week follow-up period.

Sub-aim 2a: CBT4CBT and TAU will also be compared on time to first substance use (survival analysis) during the 12 weeks post-discharge.

Specific Aim 3: Longitudinally examine correlations between CBT4CBT and the use of coping strategies (baseline, discharge, and 12-week follow-up) and associations between coping strategies and substance use, as well as other treatment outcomes.

Hypothesis 3: Women in the CBT4CBT group will have higher coping scores over time compared to TAU; higher coping scores will be associated with lower risk of relapse.

Specific Aim 4: Conduct exploratory analyses to identify other correlates (e.g., depression, stress) of relapse at 4 and 12-weeks post-discharge.

Review of the Literature

Addiction is a chronic, relapsing disorder that is characterized by compulsive drug seeking and continued use, despite harmful outcomes. Negative consequences of substance use disorders (SUD) include medical conditions, such as cardiovascular disease, stroke, cancer, as well as psychosocial impairment (NIDA, 2014). Addiction constitutes a major public health problem; one that costs the United States over $740 billion annually through health care costs, lost work productivity, and crime (NIDA, 2017). In 2015, an estimated 21.7 million people age 12 and older (8.1%) were in need of substance use treatment, defined as meeting criteria for having a SUD or receiving treatment at a specialty facility (NSDUH, 2015). However, only 11% of those in need of services received substance use treatment at a specialty facility. Thus, the majority of persons with heavy/problem alcohol or drug use are not actively engaged in traditional substance abuse treatment.

Women and Substance Use Treatment

Women represent a subpopulation of particular concern, as research has demonstrated an increased vulnerability among women for adverse medical and social consequences associated with substance use (Greenfield et al., 2007). Women have been found to progress more rapidly from regular use to first treatment episode compared to their male counterparts, a phenomenon known as telescoping (Greenfield et al., 2007; Greenfield et al., 2010). Further, despite having used for fewer years at treatment entry, research has shown that women have more medical, psychiatric, and adverse social consequences on average compared to their male counterparts (Greenfield et al., 2007; Greenfield et al., 2010).

Women also face unique barriers to seeking and receiving substance use treatment (Terplan, Longinaker, & Appel, 2015; Polak et al., 2015; Greenfield et al., 2007; Green, 2006;

Ashley, Marsden, & Brady, 2003). Barriers include social stigma, pregnancy, domestic violence, lack of childcare, and fear of legal consequences (Terplan, Longinaker, & Appel, 2015; Andrews et al., 2011; Laudet, Stanick, & Sands, 2009; Greenfield et al., 2007). Further, these barriers are often more prevalent among women with SUDs. For example, the prevalence of intimate partner violence ranges from 10-30% in the general population, while estimates range from 25-60% among substance-using women (Andrews et al., 2011). There are also higher rates of certain co-occurring mental health conditions in women compared to men, such as mood, eating, anxiety, and post-traumatic stress disorder, which serve as additional barriers to receiving appropriate services (Greenfield et al., 2007). Lastly, a history of sexual or physical trauma may make certain treatment approaches or mixed-gender treatment facilities less desirable for women to seek care at such programs (Greenfield et al., 2007). As a result of these barriers, early research demonstrated that women were less likely to seek treatment for substance use compared to men with similar problem severity (Terplan, Longinaker, & Appel, 2015; Andrews et al., 2011; Laudet, Stanick, & Sands, 2009; Green, 2006).

In response to this research, efforts were made to address such barriers with gender-specific treatment programs, providing interventions tailored to deliver information and services to women (Greenfield et al., 2010; Claus et al., 2007). Many treatment programs provide either gender-specific services, such as gender-specific treatment groups and content, or integrate gender-sensitive approaches more broadly into their curriculum, such as gender-matching with counselors and mixed-gender treatment groups led by male and female co-leaders (Green, 2006). Many treatment programs also provide services to minimize barriers to care, such as childcare, transportation, and housing (Greenfield et al., 2010; Claus et al., 2007; Green, 2006). Following the introduction of gender-specific treatment programs, research has found that women in such

programs have higher retention rates, less substance use, and report fewer barriers to care (Grella, 2008; Campbell et al., 2005; Hser et al., 2011; Ashley et al., 2003).

Despite these advances, relapse rates remain a central concern of addiction, with approximately 40-60% of patients relapsing following treatment (NIDA, 2014). Relapse was traditionally conceptualized as any substance use following a period of abstinence; however, in recent years the definition of relapse has shifted to a more dimensional approach in an effort to account for the variability of the relapse process (Brandon et al., 2007). As a result, greater emphasis has been placed in differentiating between a lapse, often referred to as a 'slip', and a full relapse. A lapse refers to a brief episode of substance use in which the individual quickly stops afterward and returns to recovery. A relapse, however, refers to the resumption of extended, problematic use.

Cognitive Behavioral Therapy

Cognitive-behavioral therapy (CBT) is a goal-oriented short-term intervention that posits targeting maladaptive thoughts and beliefs can lead to changes in emotional distress and problem behaviors (Beck, 1970; Ellis, 1962; Hofman et al., 2012). It is based on the premise that maladaptive cognitions play a key role in the maintenance of emotional distress and behavioral problems. CBT takes a collaborative approach in which the patient plays an active role in testing and challenging their thoughts and behaviors. It represents one of the most studied forms of psychotherapy and has been applied to a range of disorders, including depression, anxiety, addiction and substance use disorders, bipolar disorder, schizophrenia and other psychotic disorders, somatoform disorders, eating disorders, insomnia, personality disorders, anger and aggression, criminal behaviors, general stress, distress due to medical conditions, chronic pain

and fatigue, pregnancy complications and hormonal conditions (Hofman et al., 2012; Butler et al., 2006).

CBT for treatment of SUDs focuses on the identification and prevention of high-risk situations and relationships that increase patient risk for substance use (McHugh, Hearon & Otto, 2010). CBT emphasizes the role of contextual factors (e.g, environmental stimuli and cognitive processes) as proximal relapse antecedents (Hendershot et al., 2011). A high-risk situation refers to any circumstance in which an individual's efforts to abstain from substance use are threatened, such as specific people (e.g., drug dealers), places (e.g., liquor store), and events (e.g., parties) (Witkiewitz & Marlatt, 2004). Through the use of CBT, patient cognitions around substance use are challenged (e.g., perceived benefits) and psychoeducation is provided to help the patient make a more informed choice when confronted with their cues for use. In addition, CBT focuses on specific skills training and behavioral techniques to prevent substance use. Refusal skills are taught through demonstrations and role-playing, as well as coping strategies (e.g., diaphragmatic breathing).

CBT for SUDs has been supported in meta-analytic reviews, with effect sizes in the small to moderate range using heterogeneous comparison conditions (Dutra et al., 2008; Magill & Ray, 2009), and larger effect sizes when compared to a no-treatment control (Magill & Ray, 2009). Treatment effects for CBT have been found to decrease over time, with diminishing effect sizes across the 6- 9- and 12-month follow-up visits (Magill & Ray, 2009). Further, there has been evidence of gender differences, with a recent meta-analysis demonstrating that women appeared to benefit more from CBT compared to men (Magill & Ray, 2009).

The fact that CBT may particularly benefit women is consistent with other research showing that female reasons for relapse differ from those for males. Depression, interpersonal

stress, relationship conflict (Tuchman, 2010), personal problems (McKay et al., 1996), and low mood (Messer et al., 2018) are more likely to be associated with relapse in women than in men. Further, research has shown that women are more likely to relapse when their romantic partners are substance users (Rubin, Stout, & Longabaugh, 1996). Taken together, the coping skills and stress management techniques in CBT may be central to relapse prevention among women.

CBT Dissemination

While recognized as an evidence-based practice (EBP), efforts to disseminate and implement CBT in community-based treatment have had only limited success. One promising opportunity for improvement came through the National Drug Abuse Treatment Clinical Trials Network (CTN), whose mission was to improve the translation of science-based addiction treatments into clinical practice (Tai et al., 2010). The CTN brought together academic researchers and SUD treatment providers to develop and implement provider-informed clinical trials in community-based treatment programs (Donovan et al., 2011). The partnership promoted reciprocal exchange of ideas, with researchers able to address practice-relevant questions, while also fulfilling the practical needs of those providing SUD treatment services. However, even this large-scale effort resulted in limited success in the dissemination of EBPs. In fact, a prominent CTN study examining audiotapes of what constituted standard practice across nine community-based treatment programs found that the only EBPs consistently present were those associated with basic MI skills (e.g., open-ended questions, reflective listening) (Santa Ana et al., 2008). While program directors and clinicians had indicated they frequently used evidence-based approaches, particularly CBT, these interventions were largely absent from the taped sessions.

One of the primary barriers to the dissemination of EBTs has been the time and cost of the clinical training required to deliver these interventions effectively. Clinical training programs

(e.g., psychiatric residencies, clinical psychology doctoral programs, PsyD programs, and social work) provide one opportunity to teach EBPs in advance of entry into clinical practice (Weissman et al., 2006). The combination of didactic training with clinical supervision is often considered the gold standard of learning a new treatment (Weissman et al., 2006). However, a national survey of training programs found that while a range of psychotherapy electives were offered across clinical training programs, they were mostly non-EBT's and often did not require supervision. While CBT was among the most frequently offered EBT across the surveyed disciplines, training in this treatment without supervision has been found to be largely ineffective, with Scholomskas and colleagues (2005) finding that only 15% of clinicians demonstrated adequate CBT skills following manual-based training compared to 54% of clinicians assigned to the seminar plus supervision training condition. As a result, even when clinicians have received training, the subsequent fidelity with which they are delivered can vary greatly across programs and therapists (Marsch, Carroll & Kiluk, 2014). Clinicians have also been found to overestimate their use of EBTs compared to what is actually delivered in practice (Carroll, Martino & Rounsaville, 2010). Moreover, while most mental health counseling practices require therapists trained at the masters-level, the field of SUD treatment has no such requirement (Sias, Lambie & Foster, 2006). Many counselors working in community-based substance abuse treatment programs have not completed their bachelor's or master's degree training and have varying levels of exposure to empirically supported treatments (Sholomskas et al., 2005).

Larger systemic barriers have also been identified as limiting the dissemination of EBTs. Training in CBT is relatively expensive and time intensive and may not be feasible for institutions to provide adequate training for their clinicians (Sholomskas et al., 2005). Further, a

national survey of substance abuse treatment programs found high staff turnover rates among clinicians and program directors, with over half of the program directors having been in their jobs for less than one year (53%) (McLellan, Carise & Kleber, 2003). One sixth of the programs had either closed or ceased providing addiction treatment, programs were understaffed, had limited resources to meet their needs (e.g., computers), and one sixth had either closed or ceased providing addiction treatment. Thus, many treatment programs do not have the sustainability and resources required to successfully integrate EBTs into their curriculum.

As a result of these barriers, there continues to be a disconnect between behavioral and pharmacological treatments supported in the literature and those delivered in practice (Padwa & Kaplan, 2018). Current estimates indicate that less than half of SUD treatment programs deliver EBT to their patients (Molfenter, 2014; Saunders & Kim, 2013). Instead, widely accepted treatments that lack empirical support continue to be implemented in practice. For example, many substance use programs include educational lectures and films in their curriculum, while research has demonstrated no effect of such approaches. Similarly, acupuncture, confrontational therapeutic styles, insight-oriented psychotherapy, or mandatory attendance of Alcohol Anonymous still enjoy widespread use despite controlled trials showing little to no benefit of such approaches. This may reflect a tendency of practitioners to continue doing what is familiar and comfortable in their clinical practice, as well as current research being published in outlets and forums that may be inaccessible to busy clinicians (Miller et al., 2006).

Technology-Based Interventions

Technology has been identified as one strategy to address barriers to care and improve the reach of EBTs. Early research has highlighted a number of advantages of technology-based interventions, including low cost, standardized treatment delivery, longer therapeutic contact,

greater confidentiality, increased flexibility and convenience, and increased opportunities for practicing skills (Moore et al., 2011; Marsch, Carroll & Kiluk, 2014). Technology offers a platform to disseminate EBTs that improves treatment fidelity without increasing demands or training needs of the health care professionals (Marsch, Carroll & Kiluk, 2014). Technology-based interventions have been conceptualized as "clinician extenders," offering access to therapeutic services when patients are not engaged in clinical interactions, and more broadly, technology may serve as a means of disseminating EBTs beyond what is possible in the current model of care.

Computer-based interventions have been shown to be effective across a number of disorders, including depression, anxiety, diabetes, poor nutrition, and sexual risk behaviors (Moore et al., 2011). A range of computer and Internet-based programs for SUDs has also been developed in recent years and demonstrated positive treatment outcomes. Computer-based interventions for alcohol use have been found to significantly improve alcohol use outcomes compared to no treatment and assessment only interventions (Carey et al., 2009; Elliott, Carey & Bolles, 2008). For tobacco, meta-analyses have demonstrated abstinence rates from computer-based interventions are approximately 1.5 times higher than control conditions (Myung et al., 2009). Similarly, a recent review found computer-based interventions for other drug use led to less substance use, higher motivation to change, better retention, and greater knowledge of the presented information, compared to treatment as usual (Moore et al., 2011). Further, recent research comparing computerized and in-person interventions found comparable outcomes across conditions (Schwartz et al., 2014), with treatment gains maintained through twelve months of follow-up (Gryczynski et al., 2015)

This exciting body of research also parallels the technology revolution, offering a medium of treatment delivery that will be widely accessible. As of 2018, an estimated 95% of Americans own a cellphone of some kind, with 77% owning smartphones (Pew Research Center, 2018). Internet and mobile access also continues to grow, providing a platform capable of providing service to traditionally underserved and vulnerable populations, such as individuals with SUDs (Marsch, Carroll & Kiluk, 2014). Thus, technology offers a means of providing treatment that will be readily accessible to those in need, limiting barriers to receiving substance use treatment.

Computer-Assisted Delivery of CBT

One of the most prominent computer-based interventions for substance use disorders provides computer-assisted delivery of CBT, known as CBT4CBT. CBT4CBT consists of seven modules based on the NIDA-published CBT manual (Carroll, 1998). CBT4CBT provides a platform for teaching CBT skills to patients that enables clinicians to focus on acute concerns and problems (Carroll et al., 2008). Further, the computerized format standardizes treatment delivery, providing a more consistent, and potentially more effective, method of teaching and demonstrating CBT skills than is available in clinical settings. CBT4CBT presents the information via a range of media (text, video, interactive exercises) and allows participants to select or tailor the content based on their specific needs.

Studies to date have demonstrated the utility of CBT4CBT as an adjunct to addiction treatment in outpatient settings. The first randomized clinical trial of CBT4CBT examined the program as an adjunct to standard addiction treatment compared to treatment as usual (TAU) among 77 individuals seeking treatment at an outpatient community program for a range of SUDs (Carroll et al., 2008). Primary substances included alcohol, cocaine, marijuana, and

opioids, with the majority of participants reporting polysubstance use (80%). The trial lasted eight weeks and women in the CBT4CBT condition accessed the program biweekly. Participants in the CBT4CBT submitted significantly more negative urine specimens and tended to have longer continuous periods of abstinence compared to the TAU condition. A follow-up study examined the durability of these effects at a 6-month follow-up visit, and with 82% of the sample contacted for follow-up, the CBT4CBT condition demonstrated significantly better treatment outcomes compared to TAU for both self-reported substance use, as well as urinalysis (Carroll et al., 2009).

Building upon these early findings, a second, larger RCT was conducted in 101 cocaine-dependent methadone-maintained individuals (Carroll et al., 2014). This patient population was chosen in an effort to examine the CBT4CBT program in a more homogeneous patient population. Participants were again randomized to either standard methadone maintenance (TAU) or standard care with weekly access to the CBT4CBT program. Participants in the CBT4CBT condition were significantly more likely to attain 3 or more consecutive weeks of abstinence within treatment compared to TAU. Further, data from the 6-month follow-up visit demonstrated continued improvements, with the CBT4CB condition showing a greater reduction in cocaine use compared to TAU, further supporting the durability of the program's effects.

Next, an RCT was conducted among 68 individuals seeking treatment for alcohol use disorder at a community outpatient facility (Kiluk et al., 2016). This study expanded upon existing research and randomized participants to one of three conditions: 1) standard TAU; 2) TAU plus on-site access to the CBT4CBT program (TAU+CBT4CBT); or 3) CBT4CBT plus brief weekly clinical monitoring (CBT4CBT+monitoring). There were higher rates of treatment retention in both of the CBT4CBT conditions. Significant reductions in alcohol use were found

across all treatment conditions, with participants in TAU+CBT4CBT showing greater increases in percent days abstinent compared to TAU, and comparable outcomes across TAU and CBT4CBT delivered with clinical monitoring only. Further, when examining costs across the treatment conditions, TAU was substantially higher (approximately 4 times) compared to either of the CBT4CBT conditions.

The most recent RCT of CBT4CBT examined the intervention as a stand-alone treatment in 137 treatment-seeking outpatients with SUDs (Kiluk et al., 2018). Participants were randomized to receive TAU, weekly individual CBT, or CBT4CBT with brief weekly monitoring. Participants in both the CBT and CBT4CBT conditions reduced the frequency of their substance use significantly more compared to TAU. Further, participants in the CBT4CBT condition demonstrated maintained treatment gains at the six-month follow-up visit compared to TAU. Clinician-delivered CBT was unexpectedly associated with higher dropout rate and lower effects at follow-up. This trial represented the first study to support CBT4CBT as a stand-alone intervention in an outpatient setting.

In addition to these early RCTs on CBT4CBT, there has been limited research examining characteristics associated with the observed treatment outcomes. Coping strategies have been identified as a potential predictor of treatment outcomes. For example, studies have found participants in the CBT4CBT condition showed greater improvements in both the use (Sugarman et al., 2010) and quality of coping skills (Kiluk et al., 2010) compared to TAU. Further, increases in coping strategy use were associated with decreases in drug use (Sugarman et al., 2010), and the quality of coping responses mediated the effect of treatment on participants' duration of abstinence following treatment (Kiluk et al., 2010). While the CBT literature more broadly has been mixed regarding the role of coping strategies in treatment outcomes (Morgenstern et al.,

2010; Litt et al., 2003; Litt et al., 2008), the level of standardization associated with CBT4CBT may offer an opportunity to gain a clearer understanding of this relationship (Sugarman et al., 2010). IQ has also been identified as influencing this relationship, with individuals with higher IQ at baseline improving the quality of their coping skills more than those with a lower IQ (Kiluk et al., 2011). Lastly, engagement with the CBT4CBT program has been identified as influencing treatment outcomes, with more completed modules and homework assignments associated with greater reductions in substance use (Carroll et al., 2008), affirming the importance of treatment dose (e.g., number of sessions).

Taken together, CBT4CBT has been well supported in outpatient treatment programs. However, to-date this innovative therapy has not been evaluated in an inpatient setting. Further, CBT4CBT has not been evaluated specifically in women, a population that may particularly benefit from the treatment program.

Statement of the Problem

Women represent a population of particular concern in the field of addiction, as research has demonstrated an increased vulnerability for adverse medical and social consequences associated with substance use (e.g., Polak et al., 2016). Further, women have been found to progress more rapidly from regular use to first treatment episode compared to their male counterparts (Greenfield et al., 2007; Greenfield et al., 2010). Women with substance use disorders (SUD) also face unique barriers (e.g., childcare) to seeking and receiving substance use treatment (Terplan, Longinaker, & Appel, 2015; Greenfield et al., 2007; Green, 2006; Ashley, Marsden, & Brady, 2003). Gender-specific treatment has sought to address such barriers, resulting in higher retention rates, less drug use, and improved access (Terplan, Longinaker, &

Appel, 2015). Despite these improvements, relapse rates remain high, 40-60% of women relapsing following treatment (NIDA, 2014).

Cognitive behavioral treatment (CBT) is an evidence-based intervention for relapse prevention that emphasizes the role of contextual factors (e.g., environmental stimuli and cognitive processes) as proximal relapse antecedents (McHugh, Hearon, & Otto, 2010; Hendershot et al., 2011). CBT seeks to improve the individual's ability to cope with these high-risk situations that commonly lead to relapse (Sugarman et al., 2010). CBT has been well supported in the literature and there has also been evidence of gender differences, with a recent meta-analysis demonstrating that women appeared to benefit more from CBT compared to men (Magill & Ray, 2009). This is consistent with other literature suggesting women's reasons for relapse differ from men, with depression, interpersonal stress, relationship conflict (Tuchman, 2010), personal problems (McKay et al., 1996), and low mood (Messner et al., 2018) more likely to be associated with relapse in women. Despite its effectiveness, CBT is rarely implemented in community-based treatment (IOM, 1998) due to a range of barriers, including limited availability of professional training in CBT (Weissman et al., 2006), high rates of clinician turnover (McLellan, Carise, & Kleber, 2003), complexity and cost of training clinicians (Sholomskas et al., 2005; Morgenstern et al., 2001), high caseloads and limited resources (McLellan & Meyers, 2004).

Computer-assisted delivery of CBT (CBT4CBT) offers an opportunity to improve the quality and reach of treatment services that is both feasible and cost-effective. CBT4CBT provides a platform for teaching CBT skills to patients that enables clinicians to focus on acute concerns and problems (Carroll et al., 2008). Further, the computerized format standardizes treatment delivery, providing a more consistent, and potentially more effective, method of

teaching and demonstrating CBT skills than is available in clinical settings. Studies to date have demonstrated the utility of CBT4CBT as an adjunct to addiction treatment in outpatient settings (Carroll et al., 2008; Carroll et al., 2014; Kiluk et al., 2016; Kiluk et al., 2018), with individuals randomized to CBT4CBT having better outcomes, including more negative urine specimens, longer periods of abstinence, better durability of effects over time (Carroll et al., 2014; Carroll et al., 2009; Carroll et al., 2008; Kiluk et al., 2016) and improved coping skills compared to treatment as usual (TAU) (Kiluk et al., 2010; Sugarman et al., 2010). Coping strategies have been identified as a potential predictor of such outcomes, with research demonstrating that participants in the CBT4CBT condition showed greater improvement in both the use and quality of their coping skills compared to TAU (Kiluk et al., 2010; Sugarman et al., 2010). Further, increases in coping strategy use were associated with decreases in drug use (Sugarman et al., 2010), and the quality of coping responses mediated the effect of treatment on participants' duration of abstinence following treatment (Kiluk et al., 2010).

While CBT4CBT has been supported in outpatient settings, it has not yet been evaluated as an adjunct to residential treatment. Specific aims for the study were to: 1) examine feasibility for use of CBT4CBT in a residential treatment program for women with SUDs, as well as follow-up rates, methods, effect size, and sample size estimates to power a larger RCT; 2) conduct a small RCT comparing TAU with access to the CBT4CBT program (CBT4CBT; intervention) vs. treatment as usual (TAU; control) using relapse rates and days of use as primary treatment outcomes; 3) longitudinally examine correlations between CBT4CBT and the use of coping strategies (baseline, discharge, and 12-week follow-up) and associations between coping strategies and substance use, as well as other treatment outcomes; and 4) conduct exploratory

analyses to identify other correlates (e.g., depression, stress) of relapse at 4 and 12 weeks post-discharge.

Statement of Hypotheses

Based on the literature and study aims, the following hypotheses were tested:

1) Women in the CBT4CBT group will be less likely to relapse (Y/N) during the 12-week follow-up period than women in TAU.

2) Women in the CBT4CBT group will report fewer days of substance use compared to women in TAU during the 12-week follow-up period.

3) Women in the CBT4CBT group will have higher coping scores over time compared to TAU; higher coping scores will be associated with lower risk of relapse.

In addition, qualitative data was collected to examine the feasibility and acceptability of the CBT4CBT program in a residential treatment setting, including perceptions of the program, as well as barriers and facilitators to implementation.

Method

Objectives of Study

The primary goal of this study was to test a computer-based cognitive behavioral therapy program (CBT4CBT) as an adjunct to residential treatment. This study was approved by Virginia Commonwealth University's Institutional Review Board under "A Randomized Trial of CBT4CBT for Women in Residential Treatment for Substance Use Disorders," protocol number HM20012674.

Study Site

RBHA North Campus (RBHA-NC), formerly known as Rubicon Inc., was reopened under new management in 2018 to reestablish addiction treatment services for women with substance use disorders and co-occurring mental health conditions in Richmond, Virginia and surrounding areas. The large non-profit organization provides substance abuse treatment services through a 57-bed residential program, including medication education and management, individual and group counseling, and case management for patient needs such as housing, transportation, and childcare. Counseling services cover a range of topics, including relapse prevention, re-entry skills, health and wellness, relationships, anger and conflict management, leadership skills, domestic violence, sexual abuse, and parenting.

Based on the patient SUD severity and the number and nature of comorbid conditions, RBHA-NC program offers two levels of care, the 3.5 level offers high intensity residential services for women with greater medical and psychosocial needs such as criminal activity, serious mental health conditions, and/or impaired functioning. This level of care provides a stable living environment where women can develop and implement sufficient recovery skills before reengaging in day-to-day activities outside of the treatment program. Treatment activities include: a range of evidence-based cognitive, behavioral, and other therapies in individual and group formats; medication education and management; educational skill building groups; and occupational or recreational activities. Women in the 3.5 level of care have highly structured treatment plans held exclusively at the RBHA-NC facility or facilitated within the community by the program (e.g., 12-step meeting) in order to practice and integrate their coping skills in a supportive and more controlled environment. Treatment plans are individualized, with treatment goals and overall length of stay determined by patient needs. The 3.5 level of care is viewed as

one part of the recovery process, with many resident treatment plans including a step down to a lower level of care (e.g., 3.1 level and/or intensive outpatient services) when clinically indicated.

The 3.1 level of care at RBHA-NC offers low intensity residential services designed for women who still need time and structure to practice their recovery and coping skills, while working to reintegrate and engage in day-to-day activities outside the program. Women in this level of care require a minimum of 5 hours per week of clinical and/or structured support services. They often receive vocational and housing services, as well as groups focused on personal health and wellness with the goal of establishing and maintaining independent living within the community. Random drug screenings are used to monitor and reinforce treatment gains. Women in this level of care often step down to outpatient services and/or 12-step meetings following their discharge from residential care.

Participants

Participants were recruited in-person by the principal investigator (PI) or RAs, who were unaffiliated with the RBHA-NC treatment program. Women were approached within the first few days of residential treatment and asked if they were interested in participating in a study examining a computer-based cognitive behavioral therapy program as an adjunct to treatment.

Recruitment. Recruitment occurred at RBHA-NC, a residential women's substance abuse treatment facility, from October 4, 2018 through August 30, 2019. Recruitment procedures were based on those used successfully in four previous RCTs at RBHA-NC (Svikis et al., 2007; Langhorst et al., 2012; Choi et al., 2011; Meshberg-Cohen et al., 2014; Islam & Svikis, 2015). The PI or RA worked closely with site staff to identify potential participants with minimal disruption to clinical care. Identified residents were asked to report to the Staff on Duty (SOD) office to meet with the PI or RA and screened for eligibility.

Inclusion criteria. Eligibility criteria for study participation included:1) ≥18 years of age; 2) female; 3) meet DSM-5 criteria for a SUD (current); 4) recommended residential stay ≥3.5 weeks; 5) own a smartphone; and 6) able to return to facility for the 4 and 12-week follow-up visits.

Exclusion criteria. Women were ineligible to participate if they were currently pregnant or presented with a serious cognitive or psychiatric impairment, or language barriers that prevented them from giving true informed consent. Pregnant women were excluded because their length of stay was likely to vary compared to non-pregnant women and they also may be discharged early for medical reasons associated with their pregnancy.

**Note: Inclusion criteria were broadened to include patients who did not have a phone at time of treatment admission but had plans of obtaining one during their residential stay. This expansion in inclusion criteria was prompted by low rates of patient eligibility, with many women obtaining a phone over the course of their treatment. Further, in the event women were unable to complete the 4 and 12-week follow-up visits in person (e.g., moved away, limited transportation), the assessments were completed over the phone. These changes were made to maximize study enrollment and follow-up data collection.*

Sample size. A statistical power analysis was performed for study sample size calculation. Previous CBT4CBT studies have demonstrated moderate to large effect sizes (.45-1.21) across outpatient settings when evaluated as an adjunct to standard care and compared to a treatment as usual control group (Carroll et al., 2014; Shi et al., 2019; Cohen et al., 2003), Accordingly, a sample size calculation (2-tailed test, $\alpha = .05$, power of 80%) assuming equal variance and equal n in the 2 groups to detect a large effect size (d = 0.8) determined that N=26 per group (N=52 total) was sufficient for the study (Cohen et al., 2003). However, to allow for

dropouts and to increase power, we planned to enroll 35 patients per group (N=70) and estimated we would enroll 6-7 women/month (N=70 over 10 months) with 85% (N=60) completing the 4 and 12-week follow-ups. The present study sought to collect pilot data to inform a future R01 grant application.

Study Procedures

Screening and consent. Women who met preliminary screening criteria (age, not pregnant, own a smartphone) were invited to participate in an RCT for relapse prevention. Women were given a VCU IRB-approved consent form, which was summarized aloud by the RA/PI. Potential participants were told that study participation would include a 90-minute baseline visit followed by randomization to either TAU with access to the CBT4CBT program (CBT4CBT; intervention) or TAU (TAU; control). Residents were told that if assigned to the CBT4CBT group, they would be given access to the program for a minimum of two 1-hour sessions per week to aid in their completion of the seven CBT4CBT modules. Potential participants were informed that regardless of group assignment, they would be asked to complete study assessments in person at discharge, followed by weekly smartphone assessments during weeks 1-3 post-discharge from residential care, and in-person at 4- and 12-weeks post-discharge. Potential participants were informed that they could receive up to $130 in gift cards if they completed all research assessments. All of the women were encouraged to ask questions and assured that a decision not to participate in the study would in no way affect their care at RBHA-NC. Potential participants were also assured that study data would not be shared with RBHA-NC staff. Women who chose to participate were asked to sign a VCU IRB-approved consent form and scheduled for a baseline visit. The participant was offered a copy of the consent document and the original was retained by the research team in a locked filing cabinet on-site.

Baseline assessment. Assessment measure administration schedule is summarized in Table 1. The baseline assessment battery consisted of twelve measures (summarized below) that were administered by the RA or PI in a private setting at RBHA-NC. The baseline assessment took approximately 90 minutes and was completed over one to two sessions. Study participants were reminded that study data would not be shared with RBHA-NC staff and they would receive a $20 gift card upon completing the assessment.

Demographics. Demographic variables included age, race/ethnicity, marital status, education, employment, income and insurance coverage.

Addiction Severity Index (ASI; McLellan et al., 1980; McLellan et al., 1992). The Addiction Severity Index was used to evaluate domains commonly affected by substance use, including medical, employment/self-support, alcohol, drug, legal status, family-social environment, and psychiatric status. The ASI requires 45 minutes to administer and has demonstrated excellent reliability and validity (Makela, 2004). The PI completed ASI training and completed all ASI baseline assessments with back up and supervision from Dr. Svikis. The full ASI was administered at baseline, with a subset of items re-administered at the 12-week follow-up to examine changes in psychosocial functioning from baseline to follow-up.

Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1997). The MINI is a brief structured diagnostic interview for the assessment of substance use disorders and other psychiatric disorders. The MINI was developed jointly by psychiatrists and clinicians in the United States and Europe in an effort to provide a tool that can provide brief and accurate assessment of psychiatric disorders that was compatible with international diagnostic criteria, including the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; APA, 2013) and International Classification of Diseases codes (ICD-10; World Health Organization, 1993). The

MINI has demonstrated good reliability and validity for SUD diagnoses (Sheehan et al., 1998; Lecrubier et al., 1997; Sheehan et al., 1997). The alcohol and drug use sections of the MINI required 20-30 minutes to administer and were done by either the PI or RA, as trained lay interviewers who do not have a clinical background are able to administer the MINI. Select modules, including alcohol use disorder and substance use disorder (non-alcohol), were administered only at baseline to confirm diagnosis of a substance use disorder.

Timeline Follow Back (TLFB; Sobell & Sobell, 1992). The TLFB is a semi-structured, calendar-based interview used to collect retrospective estimates of daily substance use over a specified time period. Memory aids are used to enhance participant recall. The TLFB has been shown to have high test-retest reliability (ICC values ranging from .70 to.94, with all $p<0.001$), as well as good convergent and discriminate validity (Robinson et al., 2014). The TLFB was administered at baseline, weekly during weeks 1-3 post-discharge, and at the 4 and 12-week follow-up visits.

Coping Strategies Scale (CSS; Litt et al., 2008; Sugarman et al., 2010). Coping strategies were assessed using a modified version of the CSS. The CSS was originally adapted from the Processes of Change questionnaire (Prochaska et al., 1988) to assess alcohol-related coping strategies. Subsequent research modified this measure for use among pathological gamblers (Petry et al., 2007) and marijuana users (Litt et al., 2008). Most recently, Sugarman and colleagues (2010) adapted this measure to include 17 items that assess coping strategies for both alcohol and other drugs. Cronbach's alpha for the 17 items was .82. Participants rated the frequency with which they employed specific coping strategies over the past week on a 5-point Likert scale (0 = *never*, 4 = *all the time*). Scores range from 0 to 68, with higher scores indicating

more coping strategies. The CSS was administered at baseline, discharge, weekly during weeks 1-3 post-discharge, and at the 4 and 12-week follow-up visits.

Brief Substance Craving Scale (BCBS; Somoza et al., 1995). Craving for primary drug of abuse was assessed using eight items from the BCBS. The BCBS measures the intensity, frequency, and length of cravings during the past 24 hours. Items are rated on a 0-4 Likert scale and summed to yield an overall measure of craving ranging from 0-12. The BSCS was administered at baseline, discharge, and the 4 and 12-week follow-up visits.

Fagerstrom Test for Nicotine Dependence (FTND, Heatherton et al., 1991). The FTND is a widely used 6-item measure of nicotine dependence. The scores range from 0 to 10, with higher scores indicating greater nicotine dependence. The FTND was administered at baseline, discharge, and the 4 and 12-week follow-up visits.

Center for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977). The CES-D is a 20-item measure of depressive symptomatology. Respondents rate how often they have experienced a range of depressive symptoms over the past week on a 5-point scale (0 = *rarely or none of the time* and 4 = *most or all of the time*). Scores range from 0-60, with higher scores representing greater severity of depressive symptoms and scores ≥16 indicating probable depression. A recent review of the CES-D demonstrated sensitivity was 0.87 and specificity of 0.70 (Vilagut et al., 2016). The CES-D was administered at baseline, discharge, weekly during weeks 1-3 post-discharge, and at the 4 and 12-week follow-up visits.

Generalized Anxiety Disorder (GAD-7; Spitzer et al., 2006). Anxiety symptoms were assessed using with the GAD-7. The GAD-7 is a 7-item anxiety measure, which scores the 7 core symptoms of generalized anxiety disorder over the past two weeks on a 4-point scale (0 = *not at all* and 3 = *nearly every day*). The diagnostic validity of the GAD-7 has been well established,

with a criterion-standard study performed in 15 primary clinics in the United States demonstrating good consistency between GAD-7 diagnosis and those of independent mental health professionals (sensitivity, 89%; specificity, 82%) (Spitzer et al, 2006). A score of ≥ 10 represents a probable diagnosis of Generalized Anxiety Disorder. The GAD-7 was administered at baseline, discharge, and the 4 and 12-week follow-up visits.

Perceived Stress Scale (PSS; Cohen et al., 1983). The PSS is a 10-item measure of the degree to which situations in one's life are appraised as stressful over the past month. Each item is rated on a 5-point scale (0 = *never*, 4 = *almost always*) and scores range from 0 to 40. Positively worded items are reverse scored and responses are summed, with higher scores indicating more perceived stress. Scores ranging from 0-13 are considered low stress, 14-26 are considered moderate stress, and 27-40 are considered high perceived stress. The PSS has demonstrated adequate internal reliability (Cohen & Williamson, 1988). The PSS was administered at baseline, discharge, and the 4 and 12-week follow-up visits.

Interpersonal Support and Evaluation List-12 (ISEL-12; Cohen et al., 1985). The ISEL-12 is a 12-item measure of the perceived availability of current social support (Cohen et al., 1985). Items are rated on a 4-point scale (0 = *definitely false*, 4 = *definitely true*) and summed to yield an overall measure of social support. Scores range from 0 to 36, with higher scores indicating more perceived availability of social support. The measure also consists of three subscales comprised of four items each, including *appraisal*, *belonging*, and *tangible* (scores range 0-12). The ISEL-12 has demonstrated good convergent and divergent validity, as well as adequate test-retest and internal reliability (Dinenberg et al., 2014, Cohen et al., 1985; Merz et al., 2014). The ISEL-12 was administered at baseline, discharge, and the 4 and 12-week follow-up visits.

Participant Tracking Form. Participants completed the Participant Tracking Form and provided their current address and phone number(s) (home, cell, work), as well as the names, addresses and phone number for at least 3 persons who generally know the participant's whereabouts and can get a message to her. This information was used to locate participants to schedule follow-up visits following treatment and was completed at baseline to ensure participants would be able to be contacted in the event they discharged from treatment early. This tracking form has been used successfully by Dr. Svikis and colleagues to achieve >75% follow-up rates with SUD populations (Langhorst et al., 2012).

Table 1

Assessment Measures and Schedule

	Assessment schedule			
Measure	**Baseline**	**Discharge**	**Week 1,2,3 Post-Discharge**	**4 and 12-wk Follow-up**
Method	In-person	In-person	Phone	In-person
Demographic Information	F			
Addiction Severity Index	F			P (12-wk only)
Mini-International Neuropsychiatric Interview	F			
Timeline Follow Back	F		P	F
Coping Strategies Scale	F	F	P	F
Brief Substance Craving Scale	F	F		F
Fagerstrom Test for Nicotine Dependence	F	F		F
Center for Epidemiological Studies Depression Scale	F	F	P	F
Generalized Anxiety Disorder-7	F	F		F
The Perceived Stress Scale	F	F		F
Interpersonal Support and Evaluation List-12	F	F		F
Participant Tracking Form	F	P		
Treatment Satisfaction Scale		F		
Treatment Services Review				F
Urine Drug Toxicology/Breathalyzer				F

F=Full assessment
P=Partial assessment

Randomization. Following baseline assessment, participants were randomly assigned to either the CBT4CBT (intervention) or TAU condition (control) using a computer-generated random numbers table.

CBT4CBT condition. The CBT4CBT program consists of seven modules based on a NIDA-published CBT manual (Carroll, 1998) used in several previous RCTs across a range of substance-using populations (Carroll et al., 1994; Carroll et al., 2005; Carroll et al., 2006). As described by Carroll et al., 2008, "the modules cover the following core concepts: 1) understanding and changing patterns of substance use, 2) coping with craving, 3) refusing offers of drugs and alcohol, 4) problem-solving skills, 5) identifying and changing thoughts about drugs and alcohol, and 6) improving decision-making skills." The first module provides instructions about the program's use. Following completion of this introductory module, participants could complete the modules in the order they wanted and could access the modules as many times as they wished.

As described by Carroll et al., 2008, the material in each module is presented by first introducing a key concept with a brief 'movie' to depict a particular situation associated with substance use, explaining the key skill covered in the module with graphics and voice-overs, and then replaying the movie to illustrate a different outcome when the characters apply the skills to the situation. Each module is followed by an interactive assessment and a short vignette to further explain the skills covered, how to apply them across settings, and demonstrations of practice assignments (e.g., 'homework'). This overall format is intended to mirror the CBT manual's therapist guidelines for structuring sessions (e.g., introduction of the concept, didactic instruction, practice via modeling and role-plays, assessment of the patient's understanding, and homework). Further, this format offers the unique advantages of multimedia computer-assisted

instruction, including presentation of information in a range of media formats. Each module takes approximately 45 minutes to complete. A demonstration of the CBT4CBT program can be found here: http://www.cbt4cbt.com

In addition to the standard care provided at RBHA-NC, women in the CBT4CBT condition had access the CBT4CBT program on a tablet in a private area on-site. They were scheduled for a minimum of two sessions/week over the 3.5 weeks post-randomization (see Figure 1 for example timeline). Sessions were scheduled at times that did not interfere with the treatment curriculum at RBHA-NC (e.g., groups). In session 1, the PI or RA guided participants through their initial use of the program and answered any questions. In sessions 2-7, staff were available to assist participants with program access and to answer any questions. Participants accessed the program through an ID/password system to protect confidentiality and allow monitoring of how often they access the modules. These seven sessions provided protected time to access the interventions, but the women were able to access the modules and complete homework as much as they wished.

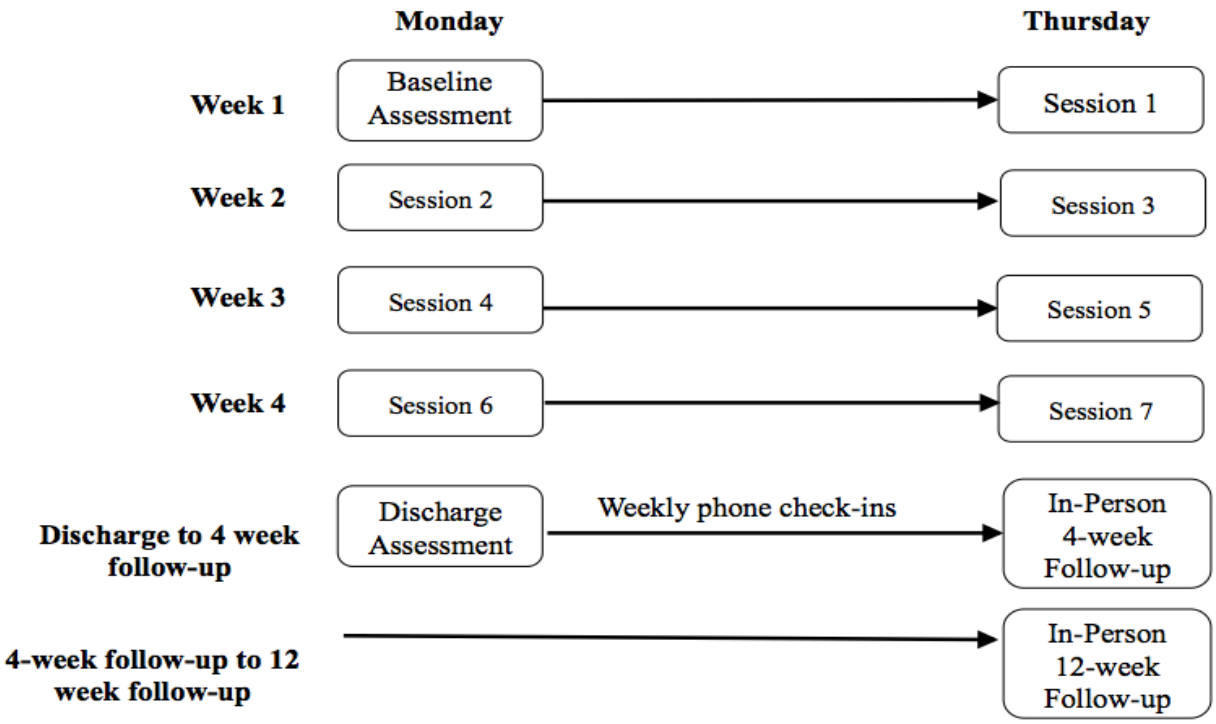

Figure 1. Intervention Timeline

Control condition. In the control condition, women participated in treatment as usual at RBHA-NC. Participants attended group and individual counseling sessions and engaged with the range of treatment services offered through the RBHA-NC treatment program. Participants in the control group completed all the same baseline and follow-up assessments as women in the CBT4CBT condition.

Discharge assessment. At discharge, participants completed an in-person assessment in which many of the assessments completed at baseline were administered again, including, the CES-D, GAD-7, PSS, CSS, ISEL-12, BSCS, and FTND (see Table 1). In addition, participants completed an evaluation of their treatment experience (described below) and the Participant Tracking Form was reviewed to ensure there were no changes/additions to their contact information. The smartphone assessments were also piloted on the participant's phone prior to discharge. RA/PI completed the discharge assessment and answered any questions about the

smartphone and study follow-up procedures. Participants received a $20 gift card following the assessment. In the event participants discharged from treatment early and were unable to complete their discharge assessment prior to leaving, the RA/PI called them and completed the assessment over the phone. If completed via phone, the participant was emailed their gift card, or it was provided in person at their 4-week follow-up visit.

Treatment Satisfaction Scale. Participants completed a 10-item measure of treatment satisfaction (Carroll et al., 2008). They were asked to rate their level of agreement with satisfaction statements (e.g., "Overall, how satisfied are you with the treatment you received?") on a 5-point scale. Participants in the CBT4CBT condition completed an additional 15 items specifically about their satisfaction with the CBT4CBT program. Participants rated their agreement with a range of statements about different aspects of the CBT4CBT program (e.g., "The computer program helped me think about my problems in a new way").

Post-Discharge Follow-Up Assessments

Weeks 1, 2, and 3 post-discharge. Participants completed brief weekly assessments via their smartphones on days 7, 14, and 21 following discharge. Survey Monkey was used to collect the weekly smartphone assessments. This method was chosen due to its detailed privacy policy it provides, as well as the fact that it is HIPAA compliant. Survey Monkey allowed the assessments to be sent via text message, limiting any barriers to completing the post-discharge assessments.

Only a subset of items from the baseline assessment battery were administered. In order to keep the assessment brief and encourage patient participation, each brief assessment (<10 minutes) included a subset of questions from the primary and other central outcome measures, including substance use, coping skills, and mood. Using TLFB framework, participants reported on days of use over the past week. Participants received text message reminders to complete each

assessment weekly. The survey was password protected to ensure only study participants accessed the survey. If the survey was not completed within the first two hours of the text message, a reminder was sent. The weekly phone assessments helped maintain contact with the women post-discharge and served as a reminder for their 4-week follow-up assessment. Participants received a $10 gift card for each phone assessment ($30 total). Gift cards were provided via email or at the 4-week follow up visit.

Note: Participants were also provided with the option to have the RA/PI call them to complete their phone assessments verbally. This option was offered due to many participants not having texting capabilities on their phone and/or feeling more comfortable being called than having to navigate the web-based survey. This procedure change was made in an effort to maximize data collection and maintain contact with participants in the follow-up period.*

4 and 12-Week post-discharge assessments. The 4 and 12-week follow-up visits were in person visits at the Institute for Women's Health. This location was chosen due to participants being unable to return to RBHA-NC following discharge from treatment. The visit took approximately 60 minutes to complete and were scheduled at discharge with smartphone reminder one week and one day prior to appointment. If participants did not show for their appointment they were called using the information provided on their Participant Tracking Form. Assessment included a subset of baseline measures (see Table 1), as well as the Treatment Services Review (described below). Urine drug screens and Breathalyzers were also administered at these visits in order to provide biological confirmation of self-report data. Participants received a $30 gift card for each assessment.

Treatment Services Review (TSR; McLellan et al., 1992). The TSR was used to ask about any treatment services received over the past 28 days. The TSR asks about services

received across seven domains, including medical status, employment and support, drug use, alcohol use, legal status, family/social status, and psychiatric status. The TSR has demonstrated test-retest reliability, concurrent validity, and correspondence with independent measures of treatment provided (McLellan et al., 1992). The TSR was administered at the 4 and 12-week follow-up visits in order to gain an understanding of any treatment services received since being discharged from residential treatment.

Urine Drug Screen. A 5-panel urine drug screen from a certified FDA approved supplier (drugstrips.com) was used to test for cocaine, amphetamines, marijuana (THC), opiates and phencyclidine at the 4 and 12-week follow-up visits.

Breathalyzer. A Breathalyzer was also used to confirm recent self-reported alcohol use at the 4 and 12-week follow-up visits.

Compensation. Participants received $20 each for baseline and discharge assessments, $10 for each phone check-in ($30 total) and $30 each for the 4 and 12-week follow-ups for a total of $130 in gift cards to local merchants (e.g., Target).

Note: In addition to physical gift cards, the study also started offering compensation via electronic gift cards in July 2019. This addition was made to facilitate payment for the phone assessments, as well as payment to participants who were unable to complete the 4 and 12-week follow-up visits in person.*

Outcome Measures

Any Relapse: Defined as any substance use (alcohol or other drugs) by self-report (smartphone or in person) and/or urine drug toxicology or Breathalyzer during 12-week follow-up period.

Relapse to Primary Drug of Choice: Any use by self-report and/or urine or Breathalyzer of relapse to the participant's primary drug of choice during the 12-week follow-up period.

Days of Use (Any): Number of days of any substance use in 12 weeks post-discharge.

Days of Use (Primary): Number of days of use of primary drug of choice during 12-week follow-up period.

Time to Relapse: Number of days post discharge to first use of any substance.

Coping Strategies: Mean score across 17 items on the Coping Strategies Scale, with higher scores representing greater coping.

Data Analysis Plan

Descriptive statistics were computed to examine participant characteristics. T-test and chi-square analyses were used to determine whether there were significant differences between the experimental and control conditions at baseline.

Hypotheses 1. The primary hypothesis predicted that women in the CBT4CBT group would be less likely to relapse (Y/N) during the 12-week follow-up period than women in TAU. To test this hypothesis, relapse rates (yes/no over the 12-week follow-up period) were compared for the two groups using chi-square analyses. Analyses examined both relapse to any substance (regardless of drug class) and relapse to primary drug.

Hypothesis 2. The second hypothesis predicted women in the CBT4CBT group would report fewer days of substance use compared to women in TAU during the 12-week follow-up period. To evaluate this hypothesis, days of substance use (both use of any substance and primary drug of choice) during the 12-week follow-up period were compared across the two groups using a two-sample t-test. In addition, analyses were repeated using a more conservative

Mann-Whitney U test to account for non-normality of the primary outcome variable. Standard effect sizes were also calculated to inform sample sizes needed for powering future studies.

Finally, a Kaplan-Meier analysis was performed to compare the two groups with regards to time to relapse. Women who did not relapse were treated as censored observations, while those who did relapse were considered non-censored observations (observed failures).

Missing data. Missing data were handled in several ways. First, intention to treat analyses were conducted to include all participants who enrolled in the study (N=61). Second, analyses were repeated on a subgroup of the intent-to-treat sample, excluding participants who dropped out of the study within one-week post-randomization (N = 55). Third, analyses were completed on "study completers", defined as women who completed the study through at least the 4-week follow-up visit (N = 44). Participants missing all follow-up data were considered relapsed on day one (for both primary and any substance use) following discharge from residential treatment; all other data was carried forward from the last point of contact with the participant (e.g., discharge carried forward to 12-week follow-up).

Hypothesis 3. The third hypothesis predicted that women in the CBT4CBT group would have higher coping scores over time compared to TAU and that higher coping scores would be associated with a lower risk of relapse. To test this hypothesis, we compared coping strategies (CSS) across the two groups at baseline, discharge, and 12-week follow-up using repeated measures analysis of variance (RMANOVA). These RMANOVA were performed using a mixed linear model. The model's fit included one between-subjects factor (group: TAU, CBT4CBT), one within-subjects factor (time: baseline, discharge, 12-week follow-up), and the interaction between group and time. A significant groupxtime interaction would indicate that both factors were significant and differences would be evaluated using post-hoc comparisons. These post-hoc

tests were adjusted for multiple comparisons using a standard Bonferroni correction. In addition, exploratory analyses examined relationships between coping strategies and substance use variables across conditions using Pearson correlations.

Exploratory analyses. Lastly, exploratory analyses were used to identify correlates of treatment outcomes. Baseline measures examined included: medication-based treatment for opioid use disorder (MOUD) (yes/no), stress management (PSS), social support (ISEL-12), psychiatric symptomatology (GAD-7, CES-D), craving (BSCS), as well as smoking status and nicotine dependence (FTND). Intervention variables included: number of CBT sessions completed, number of homework exercises completed, and time spent engaged in the intervention. Post-discharge variables included: engagement in outpatient treatment, and AA or NA attendance. Within and across group comparisons were made using chi-square analyses for categorical and t-tests for continuous measures. Pearson correlations were also conducted to analyze influence of variables on primary outcomes (e.g., days of substance use post-discharge).

Results

Flow of Participants through Study

A schematic diagram summarizing participant flow through the study from recruitment through the 12-week follow-up visit is shown in Figure 2. A total of n = 82 women were approached to participate in the study following their admission to residential treatment. Of those, 12 were ineligible and 7 women were not interested in participating. A total of n = 63 provided informed consent, completed the baseline assessment, and were randomized to either the intervention (CBT4CBT; n = 34) or control (TAU; n = 29) conditions.

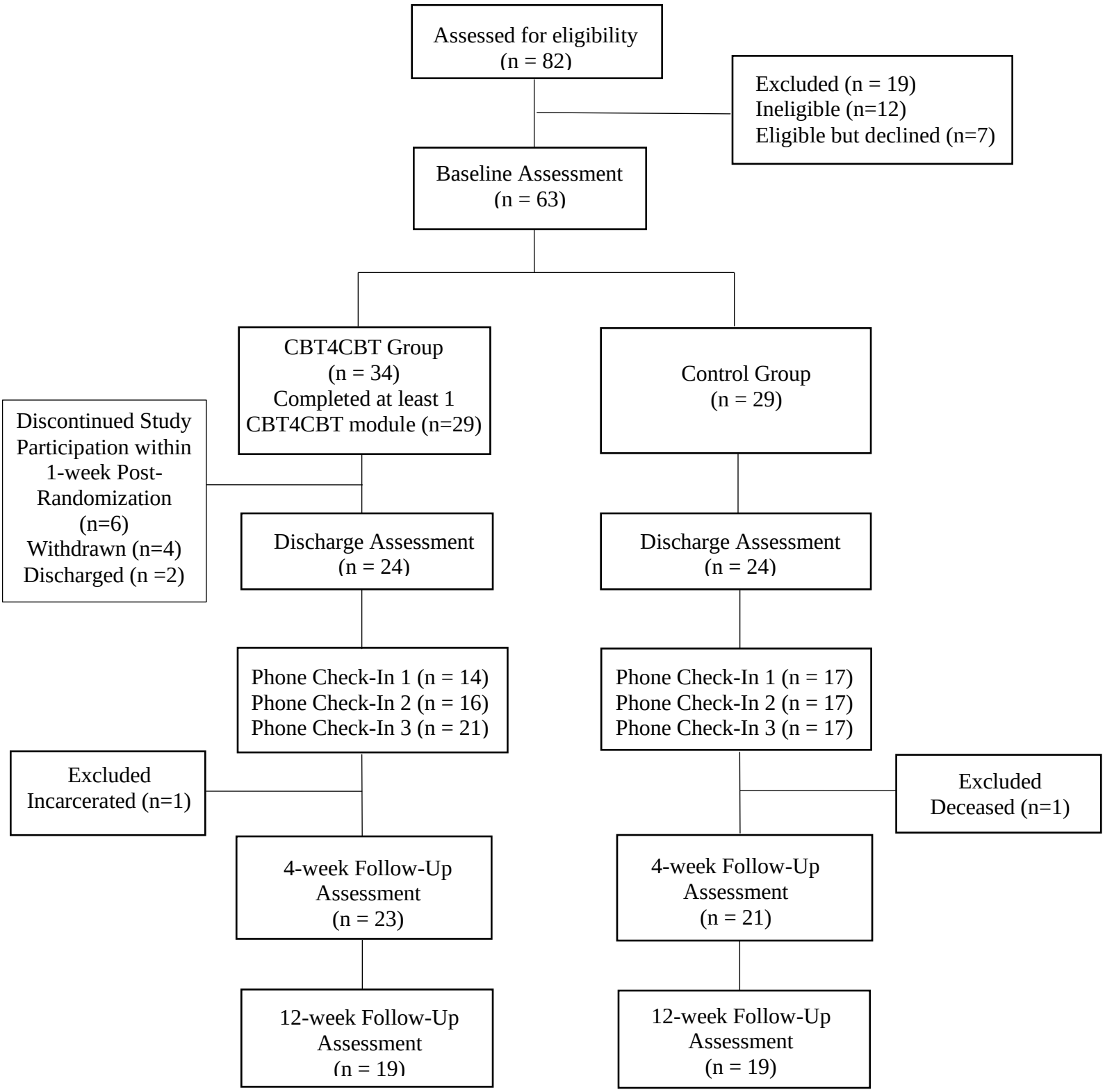

Figure 2. Flow chart of participants through study

Attrition from Study

As shown in Figure 2, *n* =6 women in the CBT4CBT condition discontinued study participation within one-week post-randomization. Of these women, *n* = 4 withdrew from study participation while in treatment. One had completed two CBT4CBT modules, two had completed one module, and one withdrew prior to starting the CBT4CBT intervention. Reasons for discontinuing study participation included lack of time and/or current stressors (*n* = 3) and dissatisfaction with lack of compensation for completing each CBT4CBT session (n =1). Further, a total of *n* = 2 women left treatment against medical advice (AMA), one was programmatically discharged for medical reasons and one elected to leave treatment early. The discharge assessment was completed by *n* = 24 women in each of the two treatment conditions (total N = 48). If women did not complete the discharge assessment prior to leaving treatment, they continued to be followed and invited to complete the follow-up assessments.

Rates of completion of weekly phone assessments at 1, 2, and 3 weeks post discharge ranged from n = 31 (week 1) to n = 33 (week 2) and finally n = 38 (week 3). Four participants were lost to follow-up for the entire 12-week follow-up period due to either incarceration (*n* = 3) or death (one participant passed away due to medical reasons unrelated to treatment participation). Research staff followed up with local jails regarding incarcerated participants, two participants were incarcerated for new drug-related charges and were considered relapsed in the follow-up dataset. One participant was incarcerated for reasons unrelated to substance use and was excluded from analyses, as was the participant who passed away shortly following discharge from residential treatment. Completion rates for study follow-up visits across treatment conditions are summarized in Table 2; there were no significant differences between study groups (all $p > 0.05$).

Table 2

Study Visit Completion Rates in CBT4CBT and TAU Conditions

	Baseline	Discharge	1 week	2 weeks	3 weeks	4 weeks	12-week
CBT4CBT (n = 34) % or *M* (SD)	100% (34)	**70.6% (24)**	41.2% (14)	47.1% (16)	50.0% (17)	**67.6% (23)**	**55.9% (19)**
TAU (n = 29) % or *M* (SD)	100% (29)	**82.8% (24)**	58.6% (17)	58.6% (17)	58.6% (17)	**72.4% (21)**	**65.5% (19)**

Demographics

Table 3 summarizes demographic characteristics for the entire sample and separately for participants randomized to the CBT4CBT and TAU groups. Overall, women were in their early 40's (M = 41.2, SD = 12.1, range 18-65 years) and the majority identified their race as Black/African American (79.4%). Nearly half reported at least a high school education or obtained their GED (49.2%), and the majority were single/never married (73%). While more than four-fifths of the sample reported having one or more children (87.3%), nearly two-thirds (64.5%) of those with at least one child had no children currently living with them. There were no significant group differences across participant characteristics (all $p > 0.05$).

Table 3

Participant Characteristics

	CBT4CBT (n = 34) % or *M* (SD)	TAU (n = 29) % or *M* (SD)	Total (n = 63) % or *M* (SD)	p value
Age (years)	39.8 (11.3)	42.8 (12.9)	41.2 (12.1)	0.31
Race				
Black/African American	76.5% (26)	82.8% (24)	79.4% (50)	0.71
Caucasian	17.6% (6)	10.3% (3)	14.3% (9)	

Other	5.9% (2)	6.9% (2)	6.3% (4)	
Education				
Less than high school	29.4% (10)	13.8% (4)	22.2% (14)	0.19
Grade 12 or GED	50.0% (17)	48.3% (14)	49.2% (31)	
Some college and beyond	20.6% (7)	37.9% (11)	28.6% (18)	
Marital Status				
Single/Never Married	79.4% (27)	65.5% (19)	73.0% (46)	0.06
Married/In a relationship	14.7% (5)	6.9% (2)	11.1% (7)	
Divorced/Separated/Widowed	5.9% (2)	27.6% (8)	15.9% (10)	
Employment				
Full Time	35.3% (12)	20.7% (6)	28.6% (18)	0.33
Part Time	2.9% (1)	17.2% (5)	9.5% (6)	
Unemployed	50.0% (17)	51.7% (15)	50.8% (32)	
On disability	2.9% (1)	3.4% (1)	3.2% (2)	
Homemaker/Mom	8.8% (3)	6.9% (2)	7.9% (5)	

Note. CBT4CBT = Intervention Condition; TAU = Treatment as usual; Total = Total Sample

Descriptive Analyses

Psychosocial History. Psychosocial variables from the Addiction Severity Index (ASI) for the CBT4CBT and TAU groups are summarized in Table 4. Over three-fourths (85.7%) of participants entered residential treatment from a controlled environment, with over two-thirds (71.4%) coming from another alcohol/drug treatment facility (e.g., detox, another residential treatment facility). Over half of the women (52.4%) endorsed having a chronic medical illness and an average of 3.2 (*SD* = 4.4, range 0-21) medical hospitalizations throughout their lifetime. Over half of women (58.7%) reported past history of treatment for drug use. In that group, the mean number of previous treatment episodes was 3.4 (*SD* = 2.5, range 2-16). Over one-fourth of participants (27%) indicated their admission to residential treatment was prompted or suggested by the criminal justice system, and two-thirds (66.7%) of women reported one or more convictions for a criminal offense. In the psychiatric domain, over half of women reported a history of inpatient or outpatient care (57.1% and 54.0%, respectively) and over three-fourths of women (81.0%) had been prescribed a medication for a mental health problem. Over half of

participants reported a history of physical and/or sexual abuse (55.6% and 50.8%, respectively). There were no significant group differences in psychosocial variables from the ASI at baseline (all $p > 0.05$).

Table 4

Psychosocial Variables from the Addiction Severity Index (ASI)

	CBT4CBT (n = 34) % or M (SD)	TAU (n = 29) % or M (SD)	Total (n = 63) % or M (SD)
Any controlled environment (30 days prior to tx)	94.1% (32)	75.9% (22)	85.7% (54)
Jail	14.7% (5)	6.9% (2)	11.1% (7)
Alcohol/drug treatment	73.5% (25)	69.0% (20)	71.4% (45)
Medical treatment	5.9% (2)	0.0% (0)	3.2% (2)
Medical			
Hospitalizations (lifetime)	3.0 (4.5)	3.4 (4.3)	3.2 (4.4)
Chronic medical illness	47.1% (16)	58.6% (17)	52.4% (33)
Medical disability	2.9% (1)	0.0% (0)	1.6% (1)
History of SUD treatment (lifetime)			
Any previous drug treatment (% yes)	55.9% (19)	62.1% (18)	58.7% (37)
No. of tx episodes (of individuals with ≥ 1)	3.2 (1.6)	3.6 (3.2)	3.4 (2.5)
Legal			
Admission suggested by criminal justice system	20.6% (7)	34.5% (10)	27.0% (17)
Criminal convictions (Y/N)	70.6% (24)	62.1% (18)	66.7% (42)
No. of convictions (of individuals with ≥ 1)	4.8 (5.5)	2.7 (1.5)	3.9 (4.4)
Psychiatric History			
Inpatient care	67.6% (23)	44.8% (13)	57.1% (36)
Outpatient care	50.0% (17)	58.6% (17)	54.0% (34)
Rx for psychological problem (lifetime)	85.3% (29)	75.9% (22)	81.0% (51)
Abuse History (Lifetime)			
Physical Abuse	58.8% (20)	51.7% (15)	55.6% (35)
Sexual Abuse	55.9% (19)	44.8% (13)	50.8% (32)

Alcohol and Drug Use (lifetime). Participants reported drinking regularly (three or more days/week) for an average of 10.4 years (SD = 11.7) (lifetime) and drinking three or more

drinks/occasion nearly all of those years (*M* = 10.1, *SD* = 11.4). Nearly two-thirds (60.3%) of the sample reported a history of regular heroin use, with 4.8 average years (*SD* = 6.4) of use. Over half (57.9%) of these women reported using heroin intravenously and over one-third (42.1%) reported nasal use. Nearly two-thirds of women (30.2%) reported use of other opiates, with 1.9 average years (*SD* = 4.5) of use. Nearly three-fourths (74.6%) of women reported a history of cocaine use; most women (88.2%) reported smoking cocaine, with some women reporting intravenous (7.8%) and nasal use (7.8%). Nearly two-thirds (65.1%) of women reported regular use of cannabis, with an average of 9.0 years (*SD* = 9.6) of use. Most participants (81.0%) reported concurrent regular use of two or more substances, with an average of 9.9 years (*SD* = 9.3) of regular use.

Substance Use (past 28 days) Prior to Treatment Admission. Because the majority of the sample entered treatment from a controlled environment (e.g., inpatient alcohol or drug treatment, medical hospitalization, jail), substance use was examined separately based on how many days participants had access to alcohol and other drugs. Over one-third (38.1%) of the sample was in a controlled environment for the entirety of the 28 days prior to treatment entry and reported no drug use within this timeframe. Nearly half (47.6%) of the sample spent approximately one week (*M* = 6.1 days, *SD* = 2.5) in a controlled environment prior to their admission to RBHA-NC, with most (80%) of these women coming to residential treatment after completing 5-7 days of detox. Among these women, they reported an average of 21.1 days of substance use, with use of their primary drug of choice nearly all of these days (*M* = 21.0, *SD* = 4.1). Only 9 women (14.2%) were not in any type of controlled environment prior to treatment entry. These women reported drug use an average of 14.1 days (*SD* = 12.5) in the 28 days prior to baseline, with 10.8 days (*SD* = 11.1) of primary drug use.

DSM-5 Substance Use Disorder Diagnoses (current). Current (past 12 months) SUD diagnoses are summarized in Table 5. Cocaine and opioids were the most frequent diagnoses, with nearly three-fourths (73.0%) of the sample meeting criteria for severe cocaine use disorder and 61.9% meeting criteria for severe opioid use disorder. Over one-third (38.1%) of the sample met criteria for severe alcohol use disorder. Sedatives and stimulants were less common, with only 1.6% of the sample meeting diagnostic criteria for these disorders. Polysubstance use was common among study participants, with two-thirds (66.7%) of the sample meeting DSM-5 criteria for more than one SUD. There were no significant differences in current SUD diagnoses at baseline for the two treatment conditions (all $p > 0.05$).

Table 5

DSM-5 Substance Use Disorders Diagnoses (current) for Study Participants

	CBT4CBT (n = 34) % or M (SD)	TAU (n = 29) % or M (SD)	Total (n = 63) % or M (SD)
Alcohol Use Disorder, mild	0.0% (0)	3.4% (1)	1.6% (1)
Alcohol Use Disorder, moderate	0.0% (0)	3.4% (1)	1.6% (1)
Alcohol Use Disorder, severe	35.3% (12)	41.4% (12)	38.1% (24)
Cocaine Use Disorder, severe	76.5% (26)	69.0% (20)	73.0% (46)
Opioid Use Disorder, severe	64.7% (22)	58.6% (17)	61.9% (39)
Sedative Use Disorder, severe	2.9% (1)	0.0% (0)	1.6% (1)
Stimulant Use Disorder, severe	2.9% (1)	0.0% (0)	1.6% (1)
Met criteria for 2 or more DSM-5 SUD (current)	70.6% (24)	62.1% (18)	66.7% (42)

Primary Problems at Baseline. Primary substance use problems, identified by participant self-report, are summarized in Table 6. Opioids and cocaine use were among the most frequently identified (61.9% and 73.0%, respectively), with nearly half (47.6%) of the sample reporting both of these substances as their primary problem. Opioid use was predominantly

heroin use, with only 3.2% of the sample identifying prescription opioids as their primary problem. Over one-third of the sample reported alcohol use as their primary problem. Stimulants and sedatives were endorsed at the lowest rates across groups (1.6% and 1.6%, respectively). There were no group differences in primary problems (all $p > 0.05$).

Table 6

Primary Problems at Baseline for Study Participants

	CBT4CBT (n = 34) % or *M* (SD)	TAU (n = 29) % or *M* (SD)	Total (n = 63) % or *M* (SD)
Opioids	64.7% (22)	58.6% (17)	61.9% (39)
Heroin	61.8% (21)	55.2% (16)	58.7% (37)
Prescription Opioids	3.4% (1)	2.9% (1)	3.2% (2)
Cocaine	76.5% (26)	69.0% (20)	73.0% (46)
Alcohol	35.3% (12)	44.8% (13)	39.7% (25)
Stimulants	2.9% (1)	0.0% (0)	1.6% (1)
Sedatives	2.9% (1)	0.0% (0)	1.6% (1)

Smoking and Nicotine Dependence. Smoking status at baseline and nicotine dependence, as measured by the Fagerstrom Test for Nicotine Dependence (FTND), is summarized in Table 7. Most study participants (88.9%) reported currently smoking, with a mean of 5.3 (SD = 2.3) on the FTND, indicating a moderate level of nicotine dependence. There were no significant differences in baseline smoking status or FTND scores across study conditions (all $p > 0.05$).

Table 7

Smoking Status and Nicotine Dependence

	CBT4CBT (n = 34) % or *M* (SD)	TAU (n = 29) % or *M* (SD)	Total (n = 63) % or *M* (SD)
Current Smoker (% Yes)	82.4% (28)	96.6% (28)	88.9% (56)

Nicotine Dependence (among smokers)	5.7 (2.4)	4.9 (2.1)	5.3(2.3)

Craving and Coping Strategies at Baseline. Craving for primary substance of use and coping strategies at baseline across the two groups are summarized in Table 8. Participants reported high baseline levels of craving, as measured by the Brief Substance Craving Scale, with a mean score of 10.7 out of 12. Participants reported low levels of baseline coping, as measured by the Coping Strategies Scale, with a mean score of 13.4 (*SD* = 16.9) out of 68. There were no differences between the two conditions in levels of coping or craving at baseline (all $p > 0.05$).

Table 8

Craving (primary substance) and Coping Strategies at Baseline

	CBT4CBT (*n* = 34) % or *M* (SD)	TAU (*n* = 29) % or *M* (SD)	Total (*n* = 63) % or *M* (SD)
Craving (BSCS; primary substance)	11.1 (1.2)	10.21 (2.1)	10.7 (1.7)
Coping Strategies (CSS score)	10.4 (16.5)	17.0 (17.0)	13.4 (16.9)

Psychosocial Variables at Baseline. Baseline psychosocial variables are summarized in Table 9. Nearly three-fourths (73%) of the women obtained clinically elevated scores on the CES-D at baseline, with a mean score of 28.1 (*SD* = 15.3). Over half (55.6%) of the participants reported clinically elevated levels of anxiety on the GAD-7 at baseline, with a mean score of 11.1 (*SD* = 7.0). The mean score on the Perceived Stress Scale at baseline was 23.8 (*SD* = 8.0), indicating moderate levels of perceived stress. Regarding social support, the women had a mean score of 23.8 (10.3) on the Interpersonal Support Evaluation List at baseline, with scores ranging from 2 to 36 and higher scores indicating greater levels of social support. There were no differences between the two conditions on psychosocial variables at baseline (all $p > 0.05$).

Table 9

Psychosocial Variables at Baseline

	CBT4CBT (n = 34) % or M (SD)	TAU (n = 29) % or M (SD)	Total (n = 63) % or M (SD)
Depression (CES-D score)	26.1 (16.0)	30.4 (14.3)	28.1 (15.3)
CES-D Cutoff ≥ 16	67.6% (23)	79.3% (23)	73.0% (46)
Anxiety (GAD-7 score)	10.9 (7.4)	11.2 (6.6)	11.1 (7.0)
GAD-7 Cutoff ≥ 10	58.8% (20)	51.7% (15)	55.6% (35)
Perceived Stress (PSS score)	23.4 (8.9)	24.3 (6.9)	23.8 (8.0)
Social Support (ISEL Score)	25.6 (9.6)	21.8 (10.9)	23.8 (10.3)

Treatment Adherence

Residential Treatment. Women in the TAU condition completed a mean of 50.9 days (*SD* = 21.8, range 20-111), with a median length of stay of 46 days. Women in the CBT4CBT group completed a mean of 42.8 days (*SD* = 20.25; range 3-81), with a median length of 43 days. There was no significant difference in length of treatment between the TAU and CBT4CBT groups ($p > 0.05$). None of the participants in the TAU condition left treatment AMA or withdrew from study participation. In the CBT4CBT group, two women left treatment AMA within one-week post randomization, one was programmatically discharged for medical reasons and one elected to leave treatment early. Four women in the CBT4CBT condition withdrew from study participation but continued in residential treatment. One participant in the CBT4CBT condition eloped from treatment against medical advice (AMA); the research team continued to contact her regarding study participation but was unable to reach her for follow-up.

CBT4CBT Program. CBT4CBT intervention dose (# sessions) information is summarized in Table 10. Of the 34 women randomized to the CBT4CBT condition, 29 completed at least 1 module of the CBT4CBT program. Of the women who did not complete any

modules, two left treatment AMA within a few days of their admission, one was transferred to another treatment facility within a few days of her admission, one withdrew from the study prior to completing her first module, and one elected to not complete any modules throughout her residential care. Of the participants who initiated the CBT4CBT program, they completed a mean of 5 modules (*SD* = 2) and spent an average of 31 minutes (*SD* = 13.2; range 10-67 minutes) completing each module. Participants tended to complete the modules in the recommended order, with everyone completing module 1 (e.g., Recognize the Triggers), approximately three-fourths completed each of the modules 2-6, and just over half (58.6%) completed module 7 (e.g., Stay Safe). Most of the women (75.9%) completed at least one of the weekly homework assignments, with a mean of 4 assignments completed (*SD* = 3). Notably, among the women who initiated the CBT4CBT program, over two-thirds (72.4%) completed six or more of the modules and over half (55.2%) of the women completed all seven modules. Further, over one-third (34.5%) of the women completed all seven of the weekly homework assignments. Monitoring of access to the CBT4CBT program indicated that only one woman accessed the program outside of the protected time provided by the research team while in residential treatment and that none of the participants accessed the program following discharge from residential treatment.

Table 10

Treatment Adherence to the CBT4CBT Program

	Participants who Initiated CBT4CBT Program (*n* = 29) % or *M* (SD)
Number of CBT4CBT Modules Completed (range 1-7)	5 (2)
One	10.3% (3)
Two	10.3% (3)

Three	6.9% (2)
Four	0.0% (0)
Five	0.0% (0)
Six	17.2% (5)
Seven	55.2% (16)
Mean Time per Module (minutes)	31 (13.2)
Modules Completed (in recommended order):	
Recognize the Triggers	100% (29)
Deal with Cravings	89.6% (26)
Stand Up for Yourself	72.4% (21)
Stop and Think	72.4% (21)
Plan Don't Panic	75.9% (22)
Go Against the Flow	72.4% (21)
Stay Safe	58.6% (17)
Homework Assignments Completed (range 0-7)	4 (3)
Zero	24.1% (7)
One	13.8% (4)
Two	6.9% (2)
Three	0.0% (0)
Four	3.4% (1)
Five	10.3% (3)
Six	6.9% (2)
Seven	34.5% (10)

Hypothesis One

The study hypothesized that women in the CBT4CBT group would be less likely to relapse (Y/N) during the 12-week follow-up period than women in TAU. As shown in Table 11, for any relapse (regardless of drug class), the two groups did not significantly differ, 43.5% in the CBT4CBT condition compared to 47.6% in TAU, $\chi_2(1, N=44) = .08$, $p = 0.78$. For relapse to primary substance, 30.4% of women in the CBT4CBT condition relapsed compared to 47.6% in TAU, $\chi_2(1, N=44) = 1.4$, $p = 0.24$. This same pattern of results was seen in the intention to treat samples.

Hypothesis Two

The study also hypothesized that women in the CBT4CBT group would report fewer days of substance use compared to women in TAU during the 12-week follow-up period. As shown in Table 12, women in the TAU condition reported nearly twice as many days of any substance use (M = 9.8, SD = 16.3) compared to women in the CBT4CBT condition (M = 5.7, SD = 14.2); however, this difference was not statistically significant, t (42) = 0.88, p = 0.39. Regarding days of use of primary substance, women in the TAU condition reported nearly three times more days of use (M = 9.2, SD = 16.5) compared to women in the CBT4CBT condition (M = 3.4, SD = 7.7); this difference also did not reach the level of significance t (27.8) = 1.46, p = 0.16. This same pattern of results was seen in the intention to treat analyses.

Table 11

Relapse Rates and Days of Substance Use 12 Weeks Post-Discharge

	CBT4CBT % or *M* (SD)	TAU % or *M* (SD)	*p* value
Study Completers (n=44)	*(n = 23)*	*(n = 21)*	
% Relapsed (Any substance)	43.5% (10)	47.6% (10)	0.78
% Relapsed (Primary substance)	30.4% (7)	47.6% (10)	0.24
Days of substance use (Any substance)	5.7 (14.2)	9.8 (16.3)	0.39
Days of substance use (primary)	3.4 (7.7)	9.2 (16.5)	0.16
Intention to Treat Sample (excluding dropouts within one-week post-randomization) (n=55)	*(n = 27)*	*(n = 28)*	
% Relapsed (Any substance)	51.9% (14)	60.7% (17)	0.51
% Relapsed (Primary substance)	40.7% (11)	60.7% (17)	0.14
Days of substance use (Any substance)	17.3 (31.2)	28.3 (35.6)	0.23
Days of substance use (primary)	15.4 (30.0)	27.9 (35.9)	0.17
Intention to Treat Sample (n=61)	*(n = 33)*	*(n = 28)*	
% Relapsed (Any substance)	60.6% (20)	60.7% (17)	0.99
% Relapsed (Primary substance)	51.5% (17)	60.7% (17)	0.47
Days of substance use (Any substance)	29.5 (38.4)	28.3 (35.6)	0.91
Days of substance use (primary)	27.8 (38.1)	27.9 (35.9)	0.99

Time to Relapse (Any Substance). A Kaplan-Meier analysis was performed to compare the two groups with regards to time to relapse. As shown in Figure 3, Panel A, the CBT4CBT condition had lower relapse rates to any substance over time; however, this difference did not reach statistical significance, Log Rank (Mantel-Cox) = 0.14; df 1; $p = 0.71$. The mean survival time for the CBT4CBT group was 57.4 days ($SD = 6.8$) compared to 51.8 days ($SD = 7.5$) for women in the TAU condition. Nearly all participants who relapsed to any substance did so in the first four weeks post-discharge from residential treatment. The mean time to relapse across the sample was 19.7 days ($SD = 15.7$) with women in the TAU condition reporting a shorter time to relapse ($M = 16.4$, $SD = 9.4$) compared to women in the CBT4CBT condition ($M = 22.9$, $SD = 20.2$). This pattern of results was consistent across the intention to treat analyses (Figure 3, Panel B).

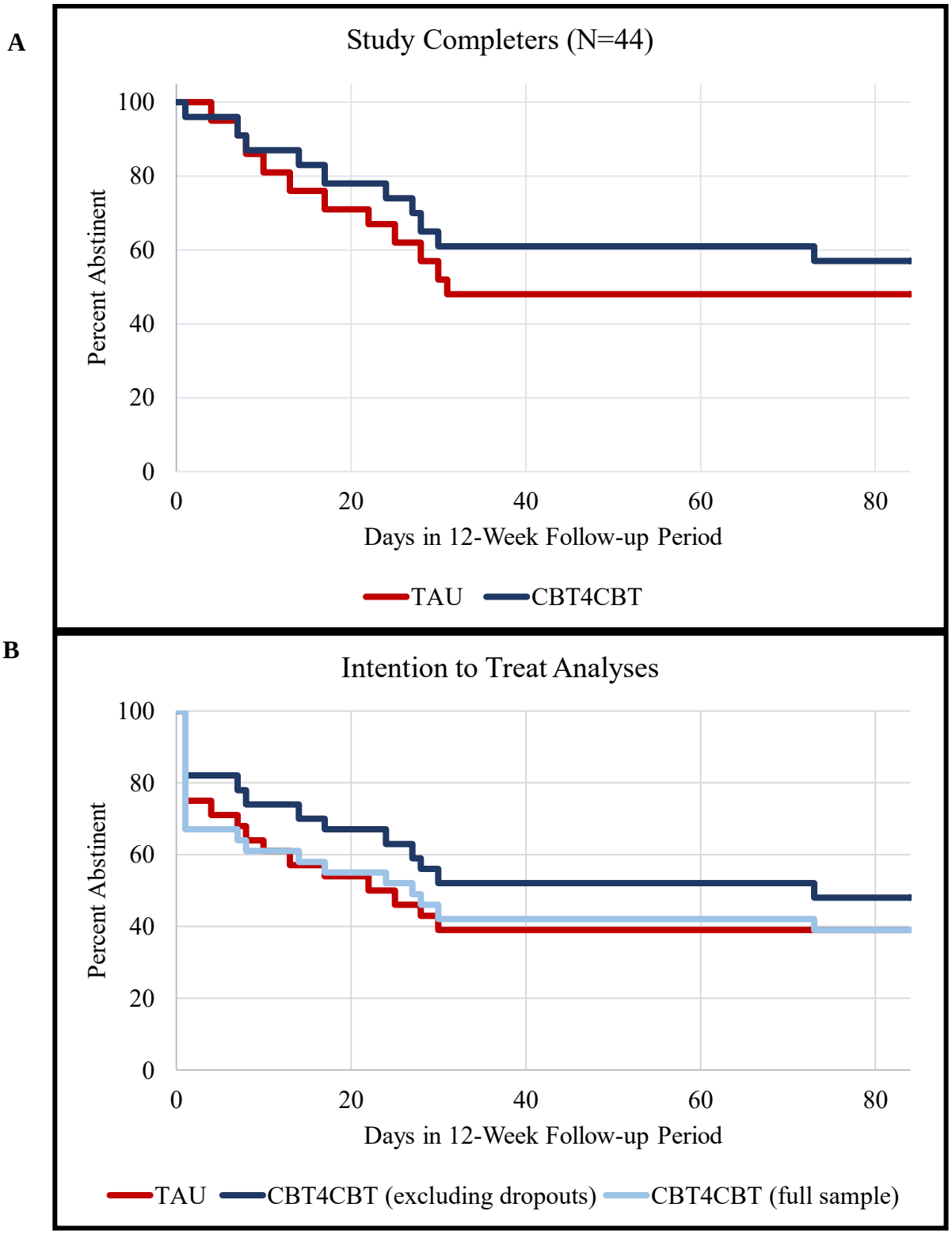

Figure 3. Survival analysis of relapse to any substance

Time to Relapse (Primary Substance). Survival curves for time to relapse to primary substance of use across the two treatment conditions are shown in Figure 4, Panel A. Consistent with relapse to any substance, the CBT4CBT condition had lower relapse rates over time. While this difference did not reach statistical significance, Log Rank (Mantel-Cox) = 1.46; df 1; p = 0.23), the mean survival time for the CBT4CBT group was 67.0 days (SD = 6.1) compared to 53.2 days (SD = 7.1) for women in the TAU condition. The pattern of results showed that all of the women who relapsed to their primary substance of use in the TAU condition, did so within the first four weeks post-discharge, while women in the CBT4CBT group showed a more gradual relapse rate over time. The mean time to relapse across the sample was 23.1 days (SD = 18.3) with women in the TAU condition reporting a shorter time to relapse (M = 19.4, SD = 8.9) compared to women in the CBT4CBT condition (M = 28.3, SD = 26.8). Further, among study completers, relapse rates to primary substance at the 4-week follow-up visit approached statistical significance, with 42.9% of women in the TAU condition compared to 17.4% of women in the CBT4CBT group, $\chi_2(1, N=44) = 3.42$, p = 0.06. This pattern of results was consistent across the intention to treat analyses (Figure 4, Panel B). All other substance use outcome data at the 4-week follow-up visit was consistent with the pattern of results seen at the 12-week follow-up.

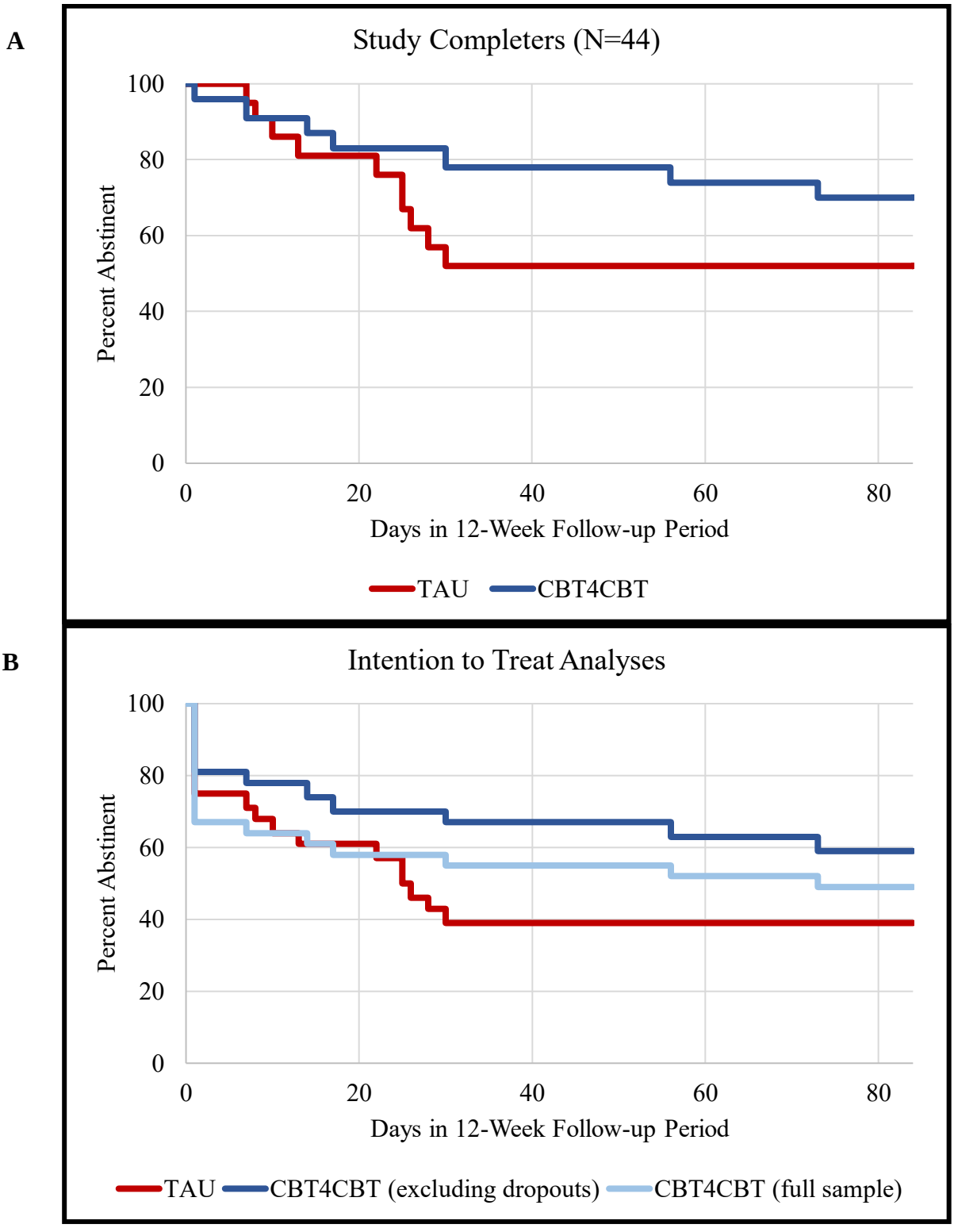

Figure 4. Survival analysis of relapse to primary substance

Medication-Based Treatment for OUD and Primary Outcomes

Given that over half (54.0%) of the sample was prescribed medications for OUD (MOUD), analyses were also completed to examine treatment outcomes separately within women receiving MOUD and those not receiving MOUD. While the groups did not significantly differ across these analyses, treatment outcomes in women not on MOUD demonstrated a larger difference across conditions than that seen in the full sample. As shown in Table 12, nearly twice (44.4%) as many women in the TAU condition relapsed to any substance compared to women in the CBT4CBT condition (25.0%), $\chi_2(1, N=21) = 0.88$, $p = 0.35$. For relapse to primary substance, nearly three times (44.4%) as many women in the TAU condition relapsed compared to women in the CBT4CBT group (16.7%), $\chi_2(1, N=21) = 1.94$, $p = 0.16$. Regarding days of substance use, women in the TAU condition reported over seven times more days of use of any substance, t (8.6) = 1.42, $p = 0.19$, and over eight times more days of use of their primary substance compared to women in the CBT4CBT condition t (8.6) = 1.39, $p = 0.20$. Figure 5 illustrates the differences in treatment outcomes among women receiving MOUD and those not receiving MOUD for both relapse to primary substance (Panel A) and days of primary substance use (Panel B). This same pattern of results was consistent across the intention to treat analyses.

Table 12

Treatment Outcomes in Women Not Receiving MOUD

	CBT4CBT % or *M* (SD)	TAU % or *M* (SD)	*p* value
Study Completers (n=21)	*(n = 12)*	*(n = 9)*	
% Relapsed (Any substance)	25.0% (3)	44.4% (4)	0.35
% Relapse (Primary substance)	16.7% (2)	44.4% (4)	0.16
Days of substance use (Any substance)	1.2 (3.4)	8.8 (15.8)	0.19
Days of substance use (primary)	1.1 (3.5)	8.6 (15.9)	0.20
Intention to Treat Sample (excluding dropouts within one-week post-randomization) (n=27)	*(n = 14)*	*(n = 13)*	
% Relapsed (Any substance)	35.7% (5)	61.5% (8)	0.18
% Relapse (Primary substance)	28.6% (4)	61.5% (8)	0.09
Days of substance use (Any substance)	13.0 (30.2)	31.9 (38.4)	0.17
Days of substance use (primary)	12.9 (30.3)	31.8 (38.4)	0.17
Intention to Treat Sample (n=28)	*(n = 15)*	*(n = 13)*	
% Relapsed (Any substance)	40.0% (6)	61.5% (8)	0.26
% Relapse (Primary substance)	33.3% (5)	61.5% (8)	0.13
Days of substance use (Any substance)	17.7 (34.4)	31.9 (38.4)	0.31
Days of substance use (primary)	17.7 (34.5)	31.8 (38.5)	0.32

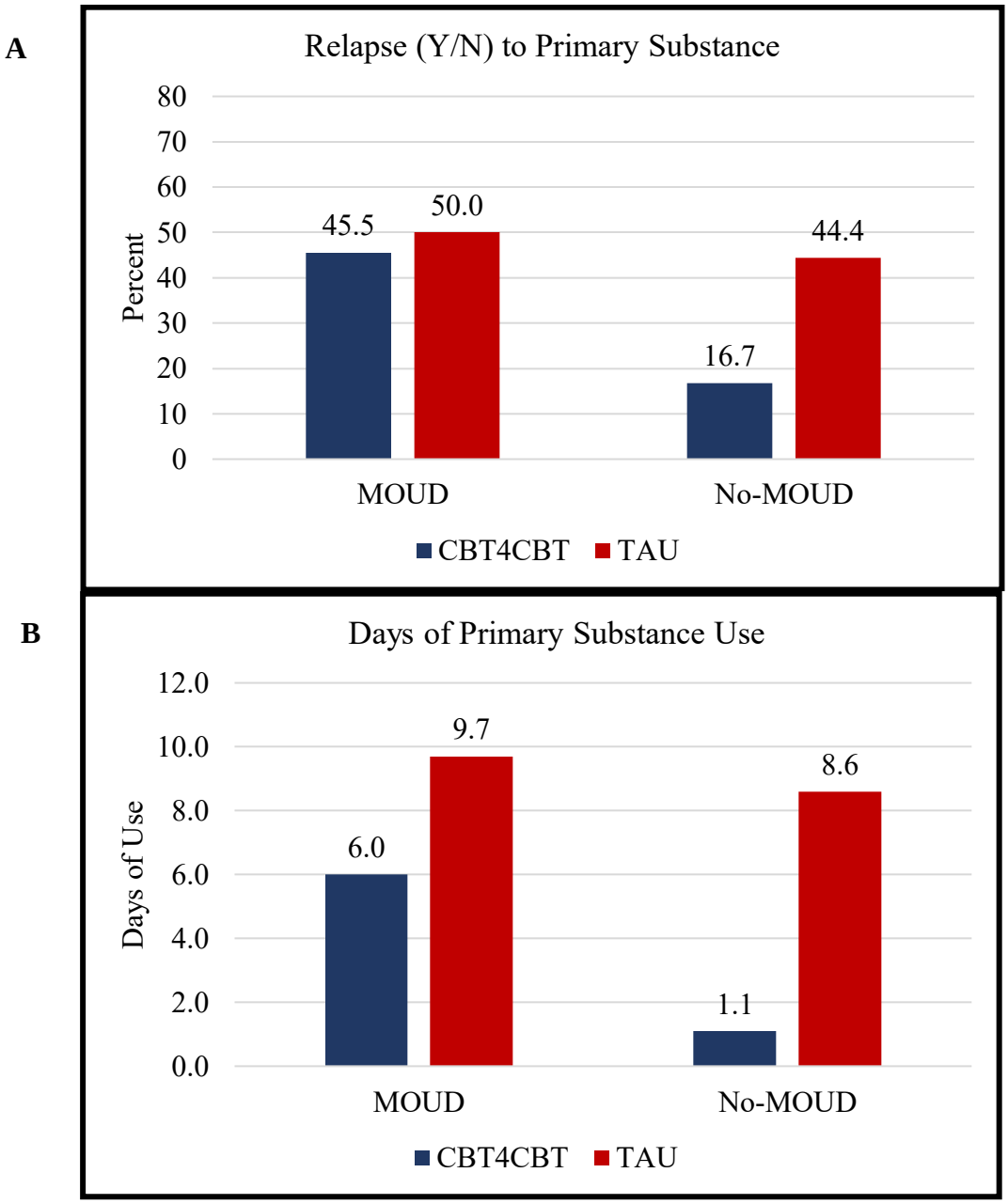

Figure 5. Primary outcomes in MOUD and no-MOUD groups among study completers (N=44)
Sample: N=23 MOUD (12 TAU, 11 CBT4CBT); N=21 No-MOUD (9 TAU, 12 CBT4CBT)

Effect Size Estimation

Primary Treatment Outcome (Days of Use). Effect size estimation was accomplished using days of substance use in the follow-up period, looking at both days of any substance use (regardless of drug class) and days of primary substance use in both the study completers (n =

44) and intention to treat sample (excluding dropouts <1 week post-randomization; n = 55). The means and standard deviations for the days of substance use in the follow-up period yielded small to moderate effect sizes for both any substance use (range 0.27–0.32) and days of primary substance use (range 0.38–0.48) in the 12-week follow-up period. A power analysis was performed using these estimated effect sizes to determine the sample size required for a larger clinical trial. It is estimated that a future RCT will need 70-110 participants per group for 80% power to detect an effect for days of primary substance use in the follow-up period. For any substance use (regardless of drug class), a future study would need 155-217 participants per group.

Primary Outcomes in Women Not Receiving MOUD. Effect size estimation was also completed looking at women not receiving MOUD. Within this sample, means and standard deviations for days of substance use in the follow-up period yielded moderate to large effect sizes for both any substance use (range 0.55–0.79) and days of primary substance use (range 0.55–0.77). A power analysis was performed using these estimated effect sizes to determine the sample size required for a larger clinical trial conducted in women not currently receiving MOUD. It is estimated that a future RCT will need 27-53 participants per group for 80% power to detect an effect for days of primary substance use in the follow-up period. For any substance use (regardless of drug class), a future study would need 28-53 participants per group.

Hypothesis Three

Lastly, the study hypothesized that women in the CBT4CBT group would have higher coping scores over time compared to women in the TAU condition. Figure 6 shows the mean coping strategy scores as measured by the CSS at baseline, discharge, and the 12-week follow-up visit for each condition. Mauchly's Test of Sphericity indicated that the sphericity had been

violated, $\chi_2(2) = 30.27$, $p < .001$; therefore, a Greenhouse-Geisser correction was used and indicated a significant effect of time on coping strategy scores, F (1.43, 84.1) = 121.1, $p < .001$. However, no significant condition x time interaction was observed, F (1.43, 84.1) = 1.18, $p = 0.30$. As shown in Figure 6, the trend of coping scores over time was quadratic in nature, with low scores at baseline ($M = 13.6$, $SD = 2.2$), high coping scores at the time of discharge ($M = 54.6$, $SD = 2.9$), and then slightly decreased at the 12-week follow-up visit ($M = 50.1$, $SD = 3.0$). This pattern of results was consistent across treatment conditions.

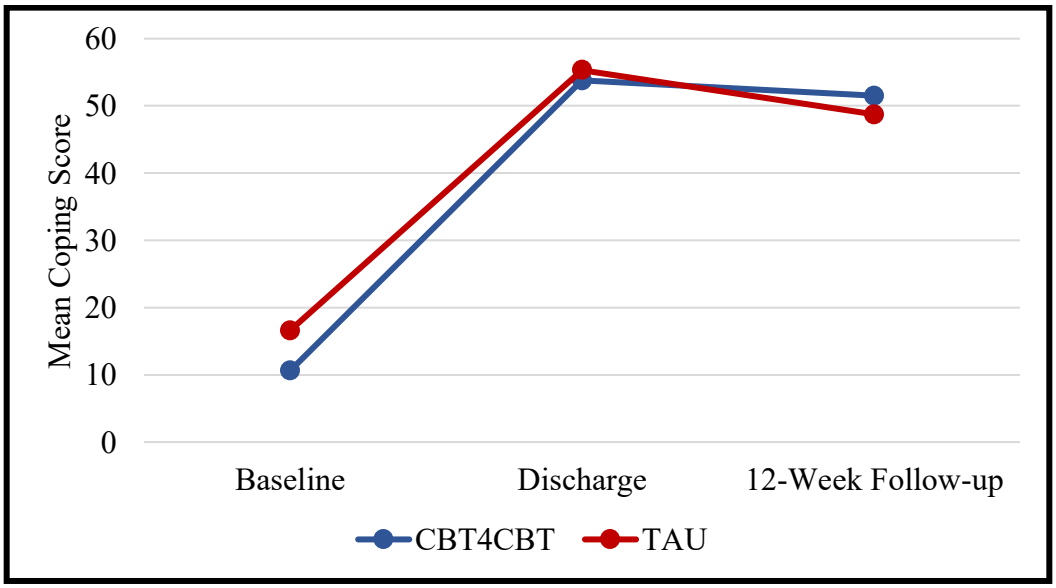

Figure 6. Coping strategies at baseline, discharge and 12-week follow-up *(n=61)*

We also hypothesized higher coping scores would be associated with a lower risk for relapse. Table 13 shows the correlation between substance use and coping scores across the treatment conditions. Using a one-way Pearson correlation test, a significant moderate negative correlation was found between coping scores and days of substance use in the 12-week follow-up period for both any ($r = -0.68$, $p < 0.001$) and primary ($r = -0.65$, $p < 0.001$) substance use. Further, when analyzed by condition, this relationship was found to be stronger for women in the CBT4CBT group for both any ($r = -0.86$, $p < 0.001$) and primary ($r = -0.84$, $p < 0.001$) substance

use compared to women in the TAU condition (r = -0.57, p < 0.01). This pattern of results was consistent across the intention to treat samples.

Table 13

Correlations of Substance Use Outcomes with Coping Strategies Scores

	CBT4CBT CSS Score	TAU CSS Score	Total Sample CSS Score
Study Completers (n=44)			
Days of substance use (Any substance)	-0.86**	-0.57*	-0.68**
Days of substance use (primary)	-0.84**	-0.57*	-0.65**
Intention to Treat Sample (excluding dropouts within one-week post-randomization) (n=55)			
Days of substance use (Any substance)	-0.67**	-0.50*	-0.58**
Days of substance use (primary)	-0.61**	-0.50*	-0.56**
Intention to Treat Sample (n=61)			
Days of substance use (Any substance)	-0.69**	-0.50*	-0.61**
Days of substance use (primary)	-0.66**	-0.50*	-0.60**

* p < 0.01, ** p < 0.001

Exploratory Analyses

Exploratory analyses examined correlates of treatment outcomes. Analyzed variables included smoking, craving, depression, anxiety, stress, and social support. Engagement in treatment services following discharge was also examined and how this may influence risk for relapse. To minimize missing data, all Repeated Measures ANOVA analyses were completed on the full intention to treat sample, with any missing data replaced by carrying forward each participant's previous score (e.g., baseline value or discharge value).

Engagement in CBT4CBT Program and Primary Treatment Outcomes. The influence of engagement in the CBT4CBT program on treatment outcomes was also examined. For participants randomized to the CBT4CBT condition, the number of CBT4CBT modules completed had a significant negative correlation with days of any substance use in the 12-week

follow-up period (r = -0.41, p = 0.03). This correlation was also seen in intent-to-treat analyses (*range* -0.30 – -0.59, $p < 0.05$). There was also a negative correlation between CBT4CBT modules completed and days of primary substance use. While this relationship did not reach statistical significance among study completers (r = -0.14, p = 0.27), it was significant in the intent-to-treat analyses (r = -0.53, p = 0.001).

Smoking. Smoking rates at the 12-week follow-up visit among women who reported smoking at baseline are summarized in Table 14. Nearly all of the women in the TAU condition resumed smoking by the 12-week follow-up visit (90.5%) compared to 80.0% of women in the CBTCBT condition. This pattern was consistent across the intention to treat analyses; however, the difference did not reach statistical significance (all $p > 0.05$).

Table 14

Smoking Rates Post-Discharge Among Baseline Smokers

	CBT4CBT % or *M* (SD)	TAU % or *M* (SD)	P value
Study Completers (n=40)	*(n = 20)*	*(n = 20)*	
Current Smoker (% Yes)	80.0% (16)	95.0% (19)	0.15
Intention to Treat Sample (excluding dropouts within one-week post-randomization) (n=50)	*(n = 23)*	*(n = 27)*	
Current Smoker (% Yes)	82.6% (19)	96.3% (26)	0.11
Intention to Treat Sample (n=54)	*(n = 27)*	*(n = 27)*	
Current Smoker (% Yes)	85.2% (23)	96.3% (26)	0.16

Nicotine Dependence. Levels of nicotine dependence were also examined over time. Figure 7 shows levels of nicotine dependence at baseline, discharge and the 12-week follow-up visit among women who reported smoking at treatment entry. Mauchly's Test of Sphericity indicated that the sphericity had been violated $\chi_2(2) = 7.0$, $p = 0.03$; therefore, a Greenhouse-Geisser correction was used and indicated a significant effect of time on nicotine levels, F (1.77,

92.2) = 35.7, $p < .001$. However, no significant condition x time interaction was observed, F (1.77, 92.2) = 0.02, $p = 0.98$. The trend in nicotine levels over time was also quadratic in nature, with moderate nicotine dependence at baseline ($M = 5.3$, $SD = .31$), low dependence at discharge ($M = 2.6$, $SD = 0.36$), and low to moderate dependence at the 12-week follow-up visit ($M = 3.3$, $SD = 0.33$). Pairwise comparisons demonstrated significant differences in nicotine dependence across all timepoints (all $p < 0.05$). Notably, nicotine levels were significantly lower at the time of follow-up than levels prior to treatment admission, suggesting many women maintained reduced nicotine use following discharge from residential treatment ($p < .001$).

The association between nicotine dependence and substance use outcomes was also examined across groups using Pearson correlations. While there was no significant relationship seen in the study completers sample ($p > 0.05$), there was a significant positive correlation between nicotine dependence and days of any ($r = 0.33$, $p = 0.02$) and primary substance use ($r = 0.31$, $p = 0.02$) in the intention to treat samples.

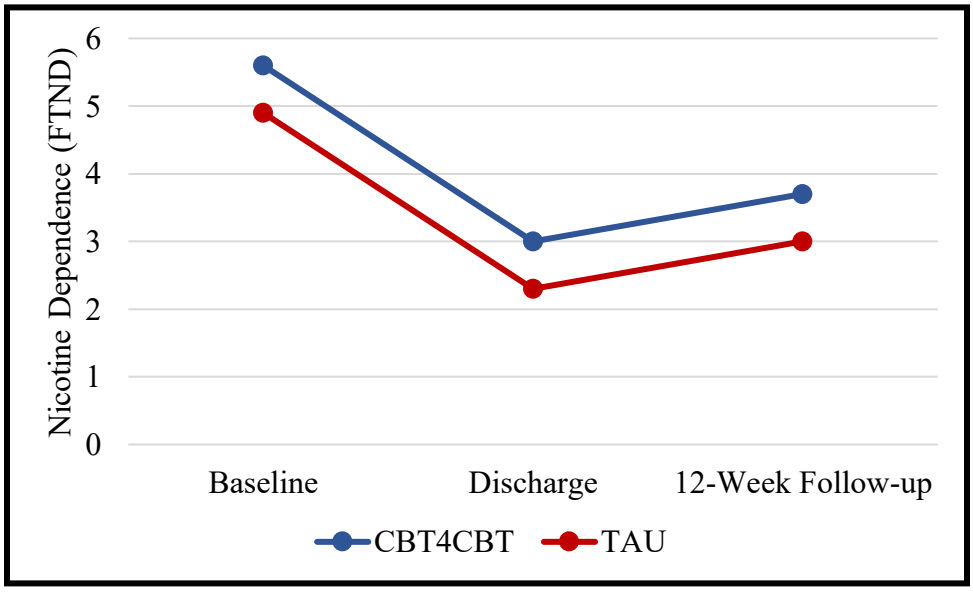

Figure 7. Nicotine dependence among baseline smokers at baseline, discharge and 12-week follow-up (n=54)

Craving. Figure 8 shows the mean craving scores (primary substance) at baseline, discharge, and the 12-week follow-up visit for each condition. The Greenhouse-Geisser correction was used, as Mauchly's Test of Sphericity indicated the assumption of sphericity had been violated, $\chi_2(2) = 8.4$, $p = .02$. As shown in Figure 8, there was a significant effect of time on craving, F (1.76, 103.9) = 116.3, $p < .001$; however, there was not a significant interaction of condition x time, F (1.76, 103.9) = 0.7, $p = 0.49$. The trend of craving scores over time was quadratic in nature, with high craving scores at baseline ($M = 10.6$, $SD = 0.2$), low scores at the time of discharge ($M = 2.8$, $SD = 0.5$), and slightly increased at the 12-week follow-up visit ($M = 4.0$, $SD = 4.6$), and this pattern was consistent across treatment conditions. Pairwise comparisons demonstrated significant differences between craving levels across all timepoints (all $p < 0.05$).

The association between craving (primary substance) and substance use outcomes was also examined across groups using Pearson correlations. There was a significant positive correlation between craving and days of substance use in the follow-up period for both days of any substance use ($r = 0.47$, $p < 0.001$), as well as primary substance use ($r = 0.48$, $p < 0.001$). This association was seen for women in both the CBT4CBT ($r = 0.54$, $p < 0.01$) and TAU conditions ($r = 0.38$, $p = 0.04$) and was consistent across the intention to treat samples ($r = 0.51 – 0.60$, all $p < 0.05$).

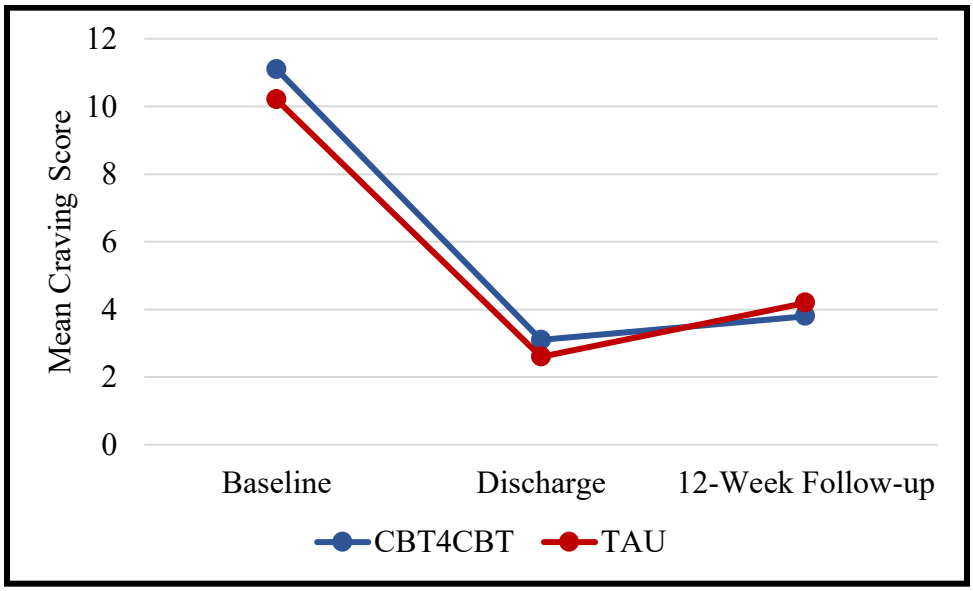

Figure 8. Craving scores at baseline, discharge and 12-week follow-up (n=61)

Psychosocial Correlates. Psychosocial correlates of treatment outcomes were also explored. Depression, anxiety, stress, and social support levels across treatment conditions at baseline, discharge, and the 12-week follow-up visit are summarized in Table 15. Repeated measures ANOVAs indicated no significant treatment condition by time effects for any of the psychosocial variables. However, there was a significant effect of time across all surveyed variables. For stress, depression, and anxiety, the scores were quadratic in nature, with high levels of distress at baseline, low levels at the time of discharge, and slightly increased at the time of the 12-week follow-up visit. The scores for social support were also quadratic in nature; however, it was in the inverse relationship, with low social support at baseline, high levels at the time of discharge, and slightly decreased at the 12-week follow-up visit. This pattern of results was consistent across treatment conditions. For depression, social support, and stress, pairwise comparisons revealed significant differences between the baseline and discharge assessments, as well as the baseline and 12-week follow-up assessment (all $p < 0.05$). For anxiety, there were only significant differences between baseline and discharge levels of anxiety ($p < 0.05$).

Table 15

Psychosocial Correlates of Substance Use Outcomes Across Time (n = 61)

	CBT4CBT *n* = 33	TAU *n* = 28	Group x Time	
Study Variable	Estimated Mean	Estimated Mean	*t*	*p*
Depression				
Baseline	26.8	29.7	0.93	0.52
Discharge	16.0	15.1		
12-week follow-up	18.1	20.3		
Anxiety				
Baseline	11.1	11.0	0.94	0.14
Discharge	9.0	6.5		
12-week follow-up	8.2	9.3		
Stress				
Baseline	23.8	24.3	1.0	0.66
Discharge	17.0	16.5		
12-week follow-up	16.3	18.3		
Social Support				
Baseline	25.2	21.3	1.0	0.97
Discharge	29.3	25.3		
12-week follow-up	28.6	24.1		

Treatment Services Post-Discharge. Treatment services received following discharge from residential treatment across conditions are summarized in Table 16. Most participants (70.5%) lived with others following discharge from residential treatment. Over one-fifth (21.7%) of women in the CBT4CBT condition lived in a structured living situation (recovery house) compared to only 4.8% (n = 1) of women in the TAU condition. One participant (4.3%) in the CBT4CBT condition was homeless for a portion of the 12-week follow-up period. Regarding treatment services received, over three-fourths (77%) of the sample engaged in outpatient services following discharge from residential treatment (*M* = 20.0 days, *SD* = 15.2 days, range 1-76) and 9.1% of the sample received inpatient substance use treatment post-discharge (*M* = 7.5

days, *SD* = 4.5 days). Further, over half (52.3%) of the sample was on medication-based treatment for OUD (MOUD) Most of the participants (81.8%) also attended 12-step/self-help meetings post-discharge, with 40.9% of the sample reporting use of a sponsor. There were no significant group differences in treatment services received during the 12-week-follow-up period (all $p > 0.05$).

Table 16

Treatment Services Post-Discharge in Treatment Completers (N=44)

	CBT4CBT % or *M* (SD) *n* = 23	TAU % or *M* (SD) *n* = 21	P value
Living Arrangement			
With others	65.2% (15)	76.2 (16)	0.43
Alone	13.0% (3)	19.0% (4)	0.59
Structured living situation (recovery house)	21.7% (5)	4.8% (1)	0.10
*Homeless**	4.3% (1)	0% (0)	0.33
Inpatient Treatment	8.7% (2)	9.5% (2)	0.92
Days of Inpatient Treatment (range 4-14)	9.5 (6.4)	5.5 (2.1)	0.49
Any Outpatient Treatment (% yes)	69.6% (16)	85.7% (18)	0.20
Days of Outpatient Treatment (range 1-48)	19.7 (14.5)	20.3 (16.3)	0.91
≥10 Days of Outpatient Treatment (% yes)	43.5% (10)	61.9% (13)	0.22
Medication-Based Treatment for OUD (% yes)	47.8% (11)	57.1% (12)	0.54
Engagement in 12-step Program (% yes)	82.6% (19)	81.0% (17)	0.89
12-step/Self-help Meetings (range 1-76)	20.2 (20.0)	22.9 (19.0)	0.68
Use of Sponsor (% yes)	52.2% (12)	28.6% (6)	0.11

**Note:* The participant who was homeless also lived with others for a portion of the follow-up period; she is counted in both of these categories.

Engagement in Treatment Services and Relapse. Analyses also examined the association between outpatient treatment engagement and days of substance use among study completers using Pearson correlations. A negative correlation was found between days of primary substance use and days of outpatient treatment in the follow up period. This relationship was statistically significant for days of primary substance use ($r = -0.35$, $p = 0.02$), and

approached statistical significance for days of any substance use in the follow-up period (r = -0.28, p = 0.054). No significant relationship was found between 12-step/self-help meetings and days of substance use in the follow-up period for days of any or primary substance use (p > 0.05).

Acceptability of the CBT4CBT Program

Quantitative Feedback. Lastly, secondary analyses examined the acceptability of the CBT4CBT program within residential treatment. Select treatment satisfaction ratings for the CBT4CBT program are summarized in Table 17. Participants were asked to rate their level of agreement with specific aspects of the CBT4CBT program using a Likert scale with 1 indicating low satisfaction and 5 indicating high satisfaction; 22 participants in the CBT4CBT condition completed the evaluation prior to leaving residential treatment. Quantitative data revealed high satisfaction across all items, with mean ratings ranging from 4.68 (*SD* = 0.5) to 4.86 (*SD* = 0.5).

During this evaluation, participants were also asked if they shared any information about the CBT4CBT program with other individuals in residential treatment or allowed anyone else to access the modules to assess for any issues of treatment contamination across groups. Four women indicated they shared information about the program but noted it was primarily with their counselors or other staff in the context of sharing information they had learned in the modules. Further, the participant who accessed the program independently while in residential treatment indicated she did so via her own tablet and headphones and noted she did not share program materials with anyone else in treatment.

Table 17

Quantitative Feedback on the CBT4CBT Program

	Participants in CBT4CBT Condition (n=22)

	M (SD)
General content of computer program	4.77 (0.5)
Ability to learn from the program	4.73 (0.6)
Computer program as a tool for learning	4.82 (0.4)
Computer program was a fun way to learn	4.86 (0.5)
Applicability of material to your life	4.82 (0.5)
Homework helped me understand material	4.68 (0.5)

Qualitative Feedback. Participants were given the opportunity to provide free response feedback on aspects of the program they liked, as well as suggestions for improvement. Select responses that highlight the primary themes of qualitative feedback are summarized in Table 18. Free responses from the women centered largely around the following themes: 1) the content of the CBT4CBT program, 2) the mode of treatment delivery, and 3) areas for improvement.

Regarding content of the CBT4CBT program, participants expressed overall satisfaction with the material and that they found the program helped them learn coping strategies for their substance use. Participants indicated that the program was easy to understand and the material was relatable, with many women noting they liked the use of real-life scenarios to illustrate concepts. Finally, participants indicated they liked the True/False questions at the end of each module as an opportunity to test their knowledge. In particular, participants indicated the questions promoted their self-efficacy by demonstrating that they were engaged and learned the content in the module.

Participants also indicated overall satisfaction with the use of technology to deliver the CBT4CBT program. The women noted that while some of the material overlapped with content covered in their groups, the video content provided the opportunity to view the application of CBT skills in real-life scenarios. Participants also indicated they enjoyed the individualized

nature of the program and working through the material independently. Many participants described completing the modules as protected time for them to work through material at their own pace and without distractions.

Participants offered a number of specific suggestions as areas of improvement in the CBT4CBT program. Many women noted that the narrator at times talked too much and felt that the pace of the program was occasionally slower than they would like. In addition, women expressed some frustrations with the program taking time to load or difficulties with the internet connection at the treatment program. Consistent with women indicating the videos were one of their favorite components of the CBT4CBT program, many noted they would have liked even more video examples throughout the program. Participants indicated they would like to have more characters from diverse backgrounds and a range of scenarios for skill demonstration. In particular, one participant expressed interest in more gender-specific examples and more testimonials from women.

Table 18

Qualitative Feedback on the CBT4CBT Program

Theme:	**Participant Comments:**
Content of the Program	*"All the different stuff I didn't know about my triggers and craving, [CBT4CBT] helped me understand them a little better. For as long as I've been doing drugs I didn't even know that stuff played a part."* *"The modules were understandable/relatable and they taught you great coping skills to use in certain situations."* *"I liked how it went into detail in different people's lives, and how it had the different scenarios, and how to rethink situations, and live life differently instead of using."* *"I liked the questions at the end to test the knowledge of what I learned…I am so proud of myself. You can see how much I paid attention in this module because I got them all right!"*

Mode of Treatment Delivery	*"It was my first time doing something on the computer. I liked seeing people in the same situation as me and learning how to cope with triggers."* *"I thought it was more helpful than group sessions because it allowed me to work through things on my own."* *"Some parts overlapped with group, but getting it [the information] from the modules made it easier for me to see it in action. In group there are no visuals to show what we're learning. Those helped me a lot."* *"The videos were very helpful because they are realistic and they include everyday scenarios when you are dealing with addiction."*
Areas for Improvement	*"The narrator talked too much before the modules actually started."* *"Sometimes it took a long time to load."* *"More videos of people that are struggling. More videos with other people in addition to Anna and Sam. You could do a new person and situation with each topic."* *"Maybe make it gender specific, more women examples and testimonials."*

Discussion

The present study provided benchmark data on the use of CBT4CBT in a residential treatment program for women with SUDs. The study expanded on current literature supporting the use of CBT4CBT in outpatient settings and conducted a 2-arm RCT with N = 63 women in residential treatment who were randomized to either TAU with access to the CBT4CBT program or TAU alone. The study compared relapse rates following discharge from residential treatment, examining both relapse Y/N and number of days of substance use. Analyses were completed separately for MOUD and no-MOUD groups. Study outcomes (e.g., days of use) were used to estimate effect size to determine the sample size needed for an adequately powered RCT of the intervention. The study also examined coping strategy scores over time across groups, as well as the association between coping and substance use outcomes. In addition, exploratory analyses looked at psychosocial correlates of treatment outcomes and their relationship with substance use in the follow-up period. Finally, the study assessed the acceptability and feasibility of implementing CBT4CBT program within a residential treatment program.

Effect of CBT4CBT on Substance Use

Primary Outcomes. The present study predicted women in the CBT4CBT group would be less likely to relapse and report fewer days of substance use compared to women in TAU during the 12-week follow-up period. Rates of relapse post-residential treatment were similar to estimates seen in the literature (e.g., 37%-56%; Andersson et al., 2019; Sannibale et al., 2003; Brunette et al., 2001; Ouimette et al., 1998); however, women in the CBT4CBT condition seemed to have more positive outcomes relative to TAU. Although the present study was not powered for statistical significance, findings were in the predicted direction, with women in the CBT4CBT group reporting lower likelihood of relapse, longer time to relapse, and fewer days of

substance use in the follow-up period compared to TAU. Further, the pattern of results supported CBT4CBT, as relapses in the TAU condition were almost exclusively to primary substance, while only a subset of relapses in the CBT4CBT condition were to primary drug of abuse. Taken together, present findings suggest the intervention may have been having an effect.

Relapse rates and treatment outcomes in the present study were comparable to previous research examining CBT4CBT as an adjunct to outpatient treatment (Carroll et al., 2008; Carroll et al., 2009; Carroll et al., 2014). Further, the pattern of results through the 12-week follow-up are consistent with research demonstrating durability of effects of the CBT4CBT program. Previous literature has shown comparable effects of CBT4CBT in both MOUD and abstinence-based treatments (Carroll et al., 2009; Carroll et al., 2014); however, there has yet to be any direct comparisons between these treatment modalities within the same program.

Medication-Based Treatment for OUD. While it was not an initial aim of the study, given that over half (54%) of the sample received MOUD as part of their treatment, additional analyses examined whether CBT4CBT may have had greater impact for the abstinence-based as compared to MOUD treatments. Although the groups did not significantly differ, treatment outcomes showed particular benefit from the CBT4CBT program among women receiving nonpharmacological treatment. This pattern of results is consistent with literature identifying MOUD as a predictor of treatment attendance and retention, as well as positive treatment outcomes (Svikis et al., 1997; Timko et al., 2016; Jancaitis et al., 2020). Further, present study findings are consistent with research suggesting behavioral interventions, such as CBT4CBT, may be particularly beneficial among women receiving nonpharmacological treatment who may be at higher risk of treatment dropout and relapse (Svikis et al., 1996). While this pattern of results could reflect differences by type of substance use problems (e.g., opioids vs. alcohol or

cocaine), previous research is mixed, with some studies finding no relationship between type of substance use problem and treatment outcomes (e.g., McCaul et al., 2001). Instead, patient demographics (gender, race, employment status) were the best predictors of treatment participation and retention.

Effect Size Estimation. Although the original proposed study expected n=70 participants with 85% (N=60) follow-up rates, the present study enrolled N=63 participants with 70% (N=44) through at least the 4-week follow-up visit due to many factors described in later sections. Thus, a primary goal of the present study was to obtain effect size estimates for future RCTs of CBT4CBT in residential treatment. Using days of substance use, the present study supported a small to medium effect size (range 0.27—0.48) and calculated the sample sizes required for future RCTs to detect an effect for both relapse to any (155-217 per group) and primary substance (70-110). Notably, analyses of treatment outcomes among women not prescribed MOUD yielded moderate to large effect sizes (range 0.55-0.79), further supporting the potential benefit of additional studies examining the use of CBT4CBT in patients receiving nonpharmacological treatment. Effect sizes in the present study are comparable to those seen in studies examining CBT4CBT in outpatient settings (range 0.19-0.59, Carroll et al., 2008; Kiluk et al., 2018).

Coping Strategies. Since a primary aim of the CBT4CBT program is to teach coping strategies for substance use, the present study predicted women in the CBT4CBT group would have higher coping scores across study visits (e.g., discharge and 12-week follow-up) compared to TAU, and higher coping would be associated with a lower risk of relapse in the 12-week follow-up period. While no significant group differences in coping scores were found, a moderate negative correlation was found between coping scores and days of substance use in the

12-week follow-up period. Further, this relationship was stronger among women in the CBT4CBT group. This pattern of results is consistent with previous CBT4CBT research (Sugarman et al., 2010) and suggests women used coping strategies at equal rates regardless of treatment group, but that women in the CBT4CBT group used them more effectively. Previous CBT4CBT research has gone beyond examining the quantity of coping strategies, assessing instead the quality of coping responses using behavioral role-play exercises (Kiluk et al., 2010). Such research has found improved quality of coping with CBT4CBT compared to TAU and that the quality of coping mediated the effect of treatment on substance use (Kiluk et al., 2010). The use of such a measure was out of the scope of the present pilot study but offers an exciting area for future research to examine this relationship within a residential treatment program.

Exploratory Analyses

Engagement in CBT4CBT Program. Present study findings supported a dose-response to the CBT4CBT program in which greater exposure to the material (e.g., number of modules completed) was negatively correlated with days of substance use in the follow-up period. The nature and strength of this relationship is consistent with that seen in studies examining CBT4CBT in outpatient settings (Carroll et al., 2009). The importance of patients receiving an adequate 'dose' of psychotherapy that results in clinically meaningful changes is well-documented in clinical research (Hansen et al., 2002). Such relationships have been found in the CBT literature (Dutra et al., 2008), as well as other behavioral interventions in the field of addiction (e.g., Ngjelina, 2019; Hien et al., 2012; McHugh et al., 2010; Tross et al., 2008).

Smoking and Nicotine Dependence. Baseline rates of smoking in the present study (88.9%) were consistent with national estimates (77.9%) of smoking in SUD treatment samples (Guydish et al., 2016). While national prevalence rates of smoking have steadily decreased over

the past decade, with approximately 13.7% of U.S. adults reporting smoking in 2018 (CDC, 2018), rates of smoking among individuals seeking SUD treatment remain high (Gubner et al., 2019). In an effort to address this disparity, approximately one-third of SUD treatment programs in the U.S. have implemented tobacco-free policies and increased availability of smoking cessation services, including nicotine-replacement therapy (NRT) and behavioral interventions (Gubner et al., 2019). With RBHA-NC being a smoke-free treatment facility, study participants were unable to smoke while on-site and were offered NRT and behavioral counseling as part of their treatment.

Despite such policies, the majority (87.5%) of women who smoked at baseline had resumed smoking by the 12-week follow-up visit regardless of RCT group assignment. These results are consistent with research showing low rates of continued smoking abstinence following discharge from smoke-free residential treatment facilities (Brose et al., 2018; Gariti et al., 2002; Ingram et al., 2017). While few participants maintained full abstinence following discharge, levels of nicotine dependence (FTND) among baseline smokers (M = 5.3, SD = .31) had significantly decreased by the 12-week follow-up visit (M = 3.3, SD = 0.33), suggesting maintained reductions in nicotine use following residential treatment. This is consistent with previous research suggesting that smoke-free policies in residential treatment may promote maintained reductions in cigarette use following discharge (Gariti et al., 2002; Joseph et al., 1990).

Many participants in the present study noted reinitiating smoking during residential treatment when they transitioned to a lower intensity of residential services (3.1 level of care) and had day passes for activities outside of the treatment facility. It may be that this pattern of use resulted in reduced cigarette use that was then maintained post-discharge from residential

treatment. However, the present study was limited by the FTND as its only measure of smoking behavior and incomplete data on the use of NRT in the follow-up period. Varied measures of smoking (e.g., cigarettes smoked, biological measures) and use of NRT products would be important to explore in future research to gain a better understanding of smoking behavior and quit attempts, as research has shown variability across assessment methods (e.g., Blank et al., 2016).

Previous research has demonstrated an increased risk of substance use relapse among smokers with SUDs who continue to smoke (Weinberger et al., 2017). While the present study found a significant positive correlation between FTND scores and days of substance use in the intent-to-treat analyses., this finding should be interpreted with caution due to the presumed relapses in the intent-to-treat samples and carrying forward of missing FTND data. The present study was limited in its ability to account for underlying reasons for this observed relationship; however, several factors have been explored in previous research. Smoking often cooccurs with other substance use, and cigarettes may become a cue for use of other drugs, increasing the risk for relapse (Weinberger et al., 2017). Further, combined use of nicotine and other drugs has been linked with greater psychiatric and personality disorders, which is associated with greater difficulty quitting (Ziedonis et al., 2008) and higher rates of SUD treatment dropout (Brorson et al., 2013).

Craving. The present study found no group differences in craving levels over time; however, interesting patterns in craving for the entire sample were observed. Consistent with previous research showing a positive effect of treatment on reducing craving (Serre et al., 2015; Oslin et al., 2009), the present study found craving significantly decreased over the course of residential treatment. At 12 weeks post-discharge, however, craving had significantly increased,

with a positive correlation between levels of craving (primary drug) and days of substance use. Research has long debated the role of craving in the relapse process (Wray et al., 2013), emphasizing the importance of examining this relationship in the context of other factors in the addictive process (e.g., environment, cues; Sayette, 2016). Particularly within the context of residential treatment, this pattern of results likely reflects participants being exposed to cues for use following their discharge from residential care, resulting in an increase in drug cravings and risk for relapse. Even in the context of day passes prior to discharge, these passes were typically to go to work or to pursue other services (e.g., housing, employment), still providing structured activity, as well as the known expectation that UDS/breathalyzer would be obtained upon return to the residential facility. Thus, the post-discharge period represents a time of reduced control and overall structure, as well as a concurrent increase in cues for substance use.

Psychosocial Correlates of Treatment Outcomes. No group differences were observed across psychosocial correlates of treatment outcomes, including depression, anxiety, stress, and social support. The pattern of results across all psychosocial variables were quadratic in nature, with high levels of distress at baseline, reduced levels at discharge, and slight increases in at the 12-week follow-up visit. Notably, distress levels at the 12-week follow-up did not return to those seen at baseline. Present study findings are consistent with previous research demonstrating significant reductions in psychosocial distress over the course of residential treatment (Ross et al., 2019). Further, the increase in distress post-discharge is likely a reflection of leaving the controlled setting offered by residential treatment and being confronted with environmental stressors. This level of distress is likely more representative of typical psychosocial functioning, as entry to residential treatment is often a time of heightened distress and such symptoms typically dissipate during the course of SUD treatment (e.g., Svikis et al., 1996). Previous

research has demonstrated the importance of exploring these factors in substance use treatment, with studies linking depression and anxiety to an increased risk for relapse following residential treatment (Bobo et al., 1998; Gil-Rivas et al., 2009; Suter et al., 2011; Moitra et al., 2013). Further, research has demonstrated a link between social support, the quality of social relationships, and risk for relapse post-discharge (Ellis et al., 2004).

Treatment Services Post-Discharge. No group differences were found in the level of engagement in outpatient services post-discharge, with both groups demonstrating high rates of continuity of care. Over three-fourths (77%) of the sample reported at least one day of outpatient substance use care in the follow-up period, which is higher than those seen in previous research examining continuity of care following discharge from residential treatment (rates ranging from 15%-60%; Costello et al., 2019; Bergman et al., 2015; Garnick et al., 2009; Schaefer et al., 2005). Further, many participants appeared to be engaging in regular outpatient visits (e.g., weekly), with over half (52.3%) of the sample reporting ≥ 10 days of outpatient treatment in the follow-up period. The present findings are consistent with research supporting the value of continuity of care, with a negative correlation found between days of primary substance use and days of outpatient treatment in the follow-up period (r = -0.35, p = 0.02). Continuity of care following residential treatment has been linked with improved substance use outcomes (Blodgett et al., 2014; DeMarce et al., 2008), as well as lower risk of death two years following discharge (Harris et al., 2015).

The high rates of treatment engagement post-discharge from residential care is likely a reflection of the treatment network provided by RBHA in Richmond, Virginia and program efforts to facilitate connection to outpatient services prior to discharge. Further, rates of MOUD in the present sample also likely contributed to this pattern of results, as all women on MOUD

engaged in outpatient services post-discharge from residential care, and rates of women reporting ≥ 10 days of treatment were higher among women receiving MOUD (65.2%) as compared to the no-MOUD group (34.8%). Taken together, the high rates of continued care may have served to buffer treatment effects of the CBT4CBT intervention that may be seen in other residential treatment facilities with fewer opportunities for and engagement in continued care following discharge.

Consistent with outpatient treatment, the present study also showed high rates (81.8%) of engagement in 12-step/self-help meetings post-discharge; engagement rates were consistent with those seen in recent research (83.6%; Costello et al., 2019). While previous research has demonstrated associations between engagement in 12-step/self-help activities and positive treatment outcomes (Donovan et al., 2013; Costello et al., 2019), the present study did not find such a relationship. Despite present study findings, the value of such programs cannot be underestimated, offering a free, easily accessible, flexible, and supportive network to individuals in recovery. Previous research has found engagement in 12-step meetings is associated with reduced substance use, psychosocial improvements, and promotion of continued recovery (Costello et al., 2019).

Acceptability and Feasibility of CBT4CBT in Residential Treatment

Another primary aim of the present study was to examine the acceptability and feasibility of implementing the CBT4CBT program within a women's residential treatment facility. Quantitative satisfaction ratings with the CBT4CBT program were high and consistent with those seen in outpatient settings (Carroll et al., 2008; Kiluk et al., 2016). Similarly, qualitative feedback revealed largely positive perceptions of the CBT4CBT program consistent with many of the hypothesized benefits of technology-based interventions, such as providing varied

examples, the ability to tailor content to patient needs, and learning the material via media rich content (Moore et al., 2011; Marsch, Carroll & Kiluk, 2014). Interestingly, some of the women noted that while some of the CBT4CBT material overlapped with content covered in group, they also enjoyed learning it via modules because it enabled them to work through the content without outside distractions and the opportunity to see the skills applied in real-life scenarios. These comments highlight the potential benefits of CBT4CBT specifically within residential treatment. First, the CBT4CBT modules may offer the opportunity to see relapse prevention and other skills applied outside the controlled environment offered by the residential facility. Second, residential treatment includes many groups and structured activities, and the CBT4CBT program may provide a varied treatment modality to provide patients with the option of practicing skill development independently and tailoring content to their needs.

Regarding feasibility of implementing the CBT4CBT program in a residential treatment setting, the CBT4CBT modules were able to be completed during breaks from residential treatment activities with minimal disruption to clinical care. Women often completed modules during snack breaks or downtime between groups. Research staff were on-site to help navigate the program, but women largely completed the modules independently. Further, rates of treatment engagement were consistent with those seen in outpatient settings, with women completing a mean of 5 modules (SD = 2) and over two-thirds (72.4%) completing six or more modules. Taken together, the present study supported the feasibility and acceptability of CBT4CBT in residential treatment.

Participants also identified areas for improvement of the CBT4CBT program with many advocating for an increase in the number of vignettes to choose from when illustrating different CBT concepts. This feedback speaks to participants valuing this aspect of the CBT4CBT

program and the importance of including examples that can be flexibly applied to diverse situations and patient populations. Recent CBT4CBT research has focused on developing such content, with a recent study of CBT4CBT-Spanish, a culturally adapted version of the intervention (Paris et al., 2018). CBT4CBT-Spanish uses a telenovela format to promote patient engagement and provide culturally relevant examples to learn CBT concepts. Treatment outcomes showed significantly greater reductions in days of primary substance use in those assigned to CBT4CBT-Spanish compared to those who received standard treatment alone.

In addition to general feedback for more case vignettes, one participant in the present study suggested a need for more gender-specific examples and content tailored to women. This has empirical support, as gender-specific treatments have demonstrated higher retention rates, less substance use, and fewer barriers to care (Polak et al. 2015; Grella, 2008; Campbell et al., 2005; Hser et al., 2011; Ashley et al., 2003). This feedback suggests that such approaches in the development of technology-based interventions may also be warranted. Specifically, gender-specific content in interventions focused on relapse prevention may be beneficial, as research has demonstrated gender differences in reasons for relapse (Tuchman, 2010; Rubin Stout, & Longabaugh, 1996; McKay et al., 1996).

Study Implications and Applications

This study has a number of important implications. First, it provides benchmark data on the use of CBT4CBT in residential treatment and demonstrates acceptability and feasibility of the program comparable to that seen in outpatient settings (Carroll et al., 2008; 2014; Kiluk et al., 2018). The CBT4CBT program offers the potential to disseminate CBT more broadly, across a range of patient populations and treatment settings where it is not currently accessible to patients. The program offers a feasible, cost-effective intervention to reduce barriers to evidence-

based care for individuals with SUDs, as well as offering an intervention with standardized treatment delivery, media-rich content, and the ability to tailor content to patient needs.

This study is also the first study to examine the CBT4CBT program specifically in a sample of drug-dependent women. Research has shown women have unique risk factors for substance use (Greenfield et al., 2007; Greenfield et al., 2010), and additional barriers to accessing care (e.g., housing, childcare; Terplan, Longinaker, & Appel, 2015; Polak et al., 2015; Greenfield et al., 2007; Green, 2006; Ashley, Marsden, & Brady, 2003). CBT4CBT may prove particularly useful in providing access to evidence-based treatment in this population. Further, research has shown gender difference in reasons for relapse (Tuchman, 2010; McKay et al., 1996; Messer et al., 2018) and that women may particularly benefit from CBT (Magill & Ray, 2009), suggesting the CBT4CBT program may represent a particularly promising intervention for women with SUDs. Additional research examining CBT4CBT in women, as well as studies of gender differences in treatment outcomes is warranted.

Study Strengths, Limitations, and Future Directions

Strengths. The present study had a number of strengths. First, inclusion criteria were broad, promoting heterogeneity and sample representativeness of women in residential treatment for SUD. Also, women with comorbidities, polysubstance use, and varying ethnic backgrounds were all eligible for study participation, allowing the data to reflect the complexities often seen in residential SUD programs.

Second, the use of a technology-based intervention offered high levels of control and standardization over intervention delivery, ensuring fidelity across study participants. Further, the CBT4CBT program offers opportunities to track clinical contact (e.g., access to the program,

time taken in each module), allowing investigators to assess dose of the intervention that was received. Such data is often unavailable in studies of behavioral and psychosocial interventions.

Third, phone-based assessments were included at weeks 1, 2, and 3 post-discharge from residential treatment as a means of maintaining contact with study participants and increasing follow-up rates at 4 and 12-weeks post-discharge from residential care, supporting the utility of such procedures. Present study findings demonstrated success with this approach, with completion rates of the phone-based assessments increasing each week post-discharge.

Fourth, the study included biological measures of substance use (e.g., urine drug screen, breathalyzer), offering confirmatory measures of self-report data. Further, the study emphasized that the research study was independent of the women's treatment, that all data was anonymous, and would not be shared with RBHA-NC staff. Such procedures promoted participant confidentiality and overall comfort with study participation.

Lastly, the study used a conservative approach to handle missing data by assuming all missing substance use data in the follow-up period as 'presumed relapsed' on day one post-discharge from residential treatment. This approach is commonly used in substance use research to provide a conservative estimate of treatment effects. Further, the study included intent-to-treat analyses of outcomes to include all randomized participants in study analyses.

Limitations. Despite these strengths, the study also had a number of limitations. First, the study was limited by a small sample size. This was due in part to delays in study startup due to renovations at the RBHA-NC facility, which were scheduled to be completed in March 2018 but were not finished until summer of 2018. During this time, patient census at the program was lower than projected and there was considerable staff (and client) stress during the transition and subsequent opening of a new floor in the residential facility.

Second, follow up rates (60.3%) were lower than anticipated based on those achieved in earlier research at the target facility (e.g., 75% by Langhorst et al., 2012) and more broadly in the community (e.g., 80% by Svikis et al., 2012). The lower rate of follow-up in the present study was due in part to funding limitations, resulting in reduced staffing that was central to our ability to successfully track and assess study participants who were at high risk for relapse.

Another limitation was the reliance primarily on self-report measures of substance use. While biological measures were available when 4 and 12-week follow up assessments were completed in-person, many women were unable to complete face-to-face visits due to moving from the area or having limited transportation, which necessitated that the follow up visit be completed over the phone. Funding limitations and minimal staffing also contributed to an increase in phone-based follow-ups toward the end of the study.

Finally, the present study was limited to scheduling CBT4CBT sessions at times that did not conflict with residential treatment activities. This was due in part to practical issues of implementing CBT4CBT as an adjunct to intensive residential treatment and limited participant availability. Further, limited staffing and RA/PI availability on-site likely impeded participant access to the program. However, despite this limitation, the present study achieved engagement rates consistent with those seen in outpatient settings, suggesting present data may be an underestimate of what CBT4CBT engagement may look like in residential treatment with unrestricted access to the program.

Future Directions. The present study expanded on the current research supporting the use of CBT4CBT in outpatient care and serves as the first RCT of CBT4CBT for women in residential treatment for substance use disorders. Present study outcomes can inform sample size estimates for a larger RCT of CBT4CBT in residential treatment. Further, such research could

begin to include less tightly controlled effectiveness trials to examine clinical outcomes when delivered in clinical practice.

Second, women in the CBT4CBT arm of the RCT were offered the online sessions in addition to TAU. While TAU was substantive, there was nonetheless a difference in time and attention for the CBT4CBT group. Future research should compare CBT4CBT to an attention control group or an alternative intervention (e.g., guided imagery or mindfulness). This is important as contact alone may have a measurable effect on the outcome variables of interest.

Finally, future research should build on present study findings and continue to evaluate potential gender differences in CBT4CBT with attention given to potential tailoring of content. For example, given demonstrated gender differences in reasons for relapse (Tuchman, 2010; Rubin Stout, & Longabaugh, 1996; McKay et al., 1996), certain content and examples may be particularly salient to specific patient populations. More research is needed focused on tailoring to meet the needs of patient subgroups (e.g., CBT4CB-Spanish; Paris et al., 2018) and type(s) of substance use problems (e.g., alcohol dependence, Choi et al., 2011), as well as MOUD versus abstinence-based treatment, smoking cessation and relapse prevention. Such efforts should explore ways of tailoring content specifically to patients in residential treatment programs, such as exercises or videos related to their experiences (e.g., smoke-free treatment facilities) and relapse prevention post-discharge.

Conclusion

The present study provided benchmark data on the use of CBT4CBT in a residential treatment program for women with SUDs. Although the present study was not powered for statistical significance, findings were in the predicted direction, with women in the CBT4CBT condition reporting fewer relapses, longer time to relapse, and fewer days of substance use in the

follow-up period compared to TAU. Further, treatment effects were stronger in women receiving nonpharmacological treatment, suggesting behavioral interventions may be particularly beneficial in this patient population. The present study extends the current body of literature supporting CBT4CBT in outpatient settings and provides pilot data to inform the design of a larger RCT in residential treatment. This body of research has important implications for SUD treatment, offering the potential to expand the reach of evidence-based addiction treatment across diverse treatment settings and patient populations.

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Appendix A

General Information

1) How old are you? _____ yrs.

2) Of what race do you consider yourself?

_____ Black/African American
_____ White/Caucasian
_____ American Indian or Alaskan Native
_____ Native Hawaiian or Other Pacific Islander
_____ Asian
_____ Other (Specify: _____)

3) What is your marital status?

____ Single/Never Married
____ Married/Living as Married (5+ yrs together)
____ Divorced/Separated
____ Widowed
____Other

4) How much education have you completed?

____ Grades 1 through 8
____ Grades 9 through 11
____ Grade 12 or GED
____ Some college
____ Associates degree
____ Bachelor's degree
____ Technical training

5) What was your usual employment pattern (before entering RBHA)?

____ Employed Full Time (40 hrs/week)
____ Employed Part Time
____ Student
____ Homemaker/Mom
____ Unemployed
____ Disabled

6) How many children do you have? _____ kids
How many currently live with you? _____ kids

7) Describe your current living situation (past year)

____ With partner/spouse alone
____ With partner/spouse and kids
____ With kids alone (single parent)
____ Alone
____ With family/friends
____ Other

Brief Substance Craving Scale

Please answer the following questions with regard to your primary drug of abuse.

1. The INTENSITY of my craving, that is, how much I desired this drug in the past 24 hours:
   0 None at all
   1 Slight
   2 Moderate
   3 Considerable
   4 Extreme

2. The FREQUENCY of my craving, that is, how often I desired this drug in the past 24 hours:
   0 Never
   1 Almost never
   2 Several times
   3 Regularly
   4 Almost constantly

3. The LENGTH of time I spent in craving this drug during the past 24 hours was:
   0 None at all
   1 Very Short
   2 Short
   3 Somewhat long
   4 Very long

4. Write the NUMBER of times you think you had craving for this drug during the past 24 hours: _____

5. Write in the total TIME spent craving this drug during the past 24 hours:_____

6. WORST day: During the past week my most intense craving occurred on the following day:
   Options: Sunday-Saturday; All days of the same (skip to Q#8)

7. The date for that day was:_____

8. The INTENSITY of my craving, that is, how much I desired cocaine on that worst day was:
   0 None at all
   1 Slight
   2 Moderate
   3 Considerable
   4 Extreme

Fagerstrom Test for Nicotine Dependence

1. How soon after you wake up do you smoke your first cigarette?
    - Within 5 minutes
    - 6 to 30 minutes
    - 31 to 60 minutes
    - After 60 minutes
2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema)?
    - Yes
    - No
3. Which cigarette would you hate most to give up?
    - The first one in the morning
    - Any other
4. How many cigarettes per day do you smoke?
    - 10 or less
    - 11 to 20
    - 21 to 30
    - 31 or more
5. Do you smoke more frequently during the first hours after waking than during the rest of the day?
    - Yes
    - No
6. Do you smoke when you are so ill that you are in bed most of the day?
    - Yes
    - No

Center for Epidemiological Studies Depression Scale (CES-D)

During the past week	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.				
2. I did not feel like eating; my appetite was poor.				
3. I felt that I could not shake off the blues even with help from my family or friends.				
4. I felt I was just as good as other people.				
5. I had trouble keeping my mind on what I was doing.				
6. I felt depressed.				
7. I felt that everything I did was an effort.				
8. I felt hopeful about the future.				
9. I thought my life had been a failure.				
10. I felt fearful.				
11. My sleep was restless.				
12. I was happy.				
13. I talked less than usual.				
14. I felt lonely.				
15. People were unfriendly.				
16. I enjoyed life.				
17. I had crying spells.				
18. I felt sad.				
19. I felt that people dislike me.				
20. I could not get "going."				

Generalized Anxiety Disorder 7-item

Over the last 2 weeks, how often have you been bothered by the following problems?	**Not at all**	**Several Days**	**More than half the days**	**Nearly every day**
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritated	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
	Add columns Total Score			
8. If you checked off any problems, how difficulty have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	Somewhat difficult	Very Difficult	Extremely difficult

Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling how often you felt or thought a certain way.

0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often

1. In the last month, how often have you been upset because of something that happened unexpectedly?	0 1 2 3 4
2. In the last month, how often have you felt that you were unable to control the important things in your life?	0 1 2 3 4
3. In the last month, how often have you felt nervous and "stressed"?	0 1 2 3 4
4. In the last month, how often have you felt confident about your ability to handle your personal problems?	0 1 2 3 4
5. In the last month, how often have you felt that things were going your way?	0 1 2 3 4
6. In the last month, how often have you found that you could not cope with all the things that you had to do?	0 1 2 3 4
7. In the last month, how often have you been able to control irritations in your life?	0 1 2 3 4
8. In the last month, how often have you felt that you were on top of things?	0 1 2 3 4
9. In the last month, how often have you been angered because of things that were outside of your control?	0 1 2 3 4
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	0 1 2 3 4

Interpersonal Support and Evaluation List-12

This scale is made up of a list of statements each of which may or may not be true about you. For each statement check "definitely true" if you are sure it is true about you and "probably true" if you think it is true but are not absolutely certain. Similarly, you should check "definitely false" if you are sure the statement is false and "probably false" is you think it is false but are not absolutely certain.

1. If I wanted to go on a trip for a day (e.g., to the mountains, beach, or country), I would have a hard time finding someone to go with me.

   ____definitely true ____probably true ____probably false ____definitely false

2. I feel that there is no one I can share my most private worries and fears with.

   ____definitely true ____probably true ____probably false ____definitely false

3. If I were sick, I could easily find someone to help me with my daily chores.

   ____definitely true ____probably true ____probably false ____definitely false

4. There is someone I can turn to for advice about handling problems with my family.

   ____definitely true ____probably true ____probably false ____definitely false

5. If I decide one afternoon that I would like to go to a movie that evening, I could easily find someone to go with me.

   ____definitely true ____probably true ____probably false ____definitely false

6. When I need suggestions on how to deal with a personal problem, I know someone I can turn to.

   ____definitely true ____probably true ____probably false ____definitely false

7. I don't often get invited to do things with others.

   ____definitely true ____probably true ____probably false ____definitely false

8. If I had to go out of town for a few weeks, it would be difficult to find someone who would look after my house or apartment (the plants, pets, garden, etc.).

   ____definitely true ____probably true ____probably false ____definitely false

9. If I wanted to have lunch with someone, I could easily find someone to join me.

____definitely true ____probably true ____probably false ____definitely false

10. If I was stranded 10 miles from home, there is someone I could call who would come and get me.
    ____definitely true ____probably true ____probably false ____definitely false

11. If a family crisis arose, it would be difficult to find someone who could give me good advice about how to handle it.
    ____definitely true ____probably true ____probably false ____definitely false

12. If I needed some help in moving to a new house or apartment, I would have a hard time finding someone to help me.
    ____definitely true ____probably true ____probably false ____definitely false

Participant Tracking Form

Please provide the names, addresses, and phone numbers of three (3) people who are likely to know where you will be following treatment. This information will be used only to contact you to schedule the post-discharge follow-up visit. You will only say that you are participating in a research study. No information about your drug abuse treatment will be disclosed without written informed consent from you.

1) Name: _____

Address: _____

_____

Phone Number: _____

2) Name: _____

Address: _____

_____

Phone Number: _____

3) Name: _____

Address: _____

_____

Phone Number: _____