



Rationale, design, and methodology of a randomized pilot trial of an integrated intervention combining computerized behavioral therapy and recovery coaching for people with opioid use disorder: The OVERCOME study

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ABSTRACT

Background: Opioid use disorder (OUD) has led to a staggering death toll in terms of drug-related overdoses. Despite the demonstrated benefits and effectiveness of buprenorphine, retention is suboptimal, and patients typically present with high rates of ongoing polysubstance use during treatment. A pilot trial provided preliminary support for the efficacy of computer-based cognitive-behavioral therapy (CBT4CBT) as an add-on to buprenorphine in reducing substance use. Recovery coaching services provided by individuals with substance use experience and successful recovery have also shown to positively influence recovery outcomes for people with OUD by increasing buprenorphine initiation and reducing opioid use.

Methods: The OVERCOME study is a randomized clinical trial (RCT) aimed to test an integrated intervention combining CBT4CBT and Recovery Coaching relative to treatment-as-usual (TAU) among individuals with OUD on buprenorphine. The primary outcome measure is the percentage of samples with any drug tested as positive at each research visit conducted during treatment (visits 1 to 8). Secondary outcomes include the percentage of samples with any drug tested as positive at 1- and 3- month follow-up and retention to buprenorphine at 3-month follow-up.

Results: We describe the rationale, design, and methodology of the OVERCOME Study.

Conclusion: This trial will provide evidence of the efficacy of an integrated intervention combining CBT4CBT and Recovery Coaching for reducing substance use and increasing buprenorphine adherence which has the potential to reduce mortality among people with OUD.

1. Introduction

Opioid misuse has led to an unprecedented public health crisis in the US. In 2019, an estimated 1.6 million Americans aged 12 or older had opioid use disorder (OUD) [1]. The opioid epidemic has caused a staggering death toll in the US that rose 29.4% in 2020 to an estimated 93,331 deaths in 2020, including 69,710 involving opioids [2]. Opioid misuse has also led to an increase of infectious diseases associated with drug-use behaviors, including HIV and hepatitis C virus [3–5]. The overall societal costs associated with opioid misuse and OUD, which

includes costs related to health care, criminal justice, and substance use treatment, have been estimated to be over 78 billion dollars annually [6].

Buprenorphine is a widely-used, effective approach for treating OUD [7] and producing substantial reductions in opioid use and other illicit drugs, risk of overdose, criminal activity, and other risky drug-related behaviors [8–11]. Unfortunately, retention to buprenorphine is generally low; at 56.8% after 6 months [12]. Another major issue in this population is related to the high prevalence of polydrug use [13], which has been associated with a lower likelihood of receiving maintenance

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treatment, increased criminal activity, poor mental and physical health, and increased medical and psychiatric care utilization [14–16].

Traditional cognitive-behavioral therapy (CBT), a proven efficacious intervention for the treatment of a wide variety of behavioral health disorders [17], has limited or no additive benefit to buprenorphine treatment [18–20]. However, a recent small pilot study (N = 20) of web-based CBT (i.e. CBT4CBT-Buprenorphine) provided favorable results regarding the preliminary efficacy of CBT as an add-on to buprenorphine relative to treatment-as-usual (TAU) [21]. Specifically, participants randomized to CBT4CBT-Buprenorphine submitted more drug samples that were negative for opioids (64% versus 91%) and other illicit substances (30% versus 82%) during the course of 12-week treatment than those assigned to TAU. Nonetheless, adherence to the CBT4CBT intervention was suboptimal (52.5%) warranting for investigation of enhancement in adherence as well as other treatment outcomes to test the long-term effects of the intervention.

Recovery coaching, which has been growing in interest, involves a form of nonclinical, peer support aimed at helping individuals with substance use disorders to achieve and maintain recovery [22,23]. Recovery coaches are individuals with lived experience of addiction and recovery who undergo training to assist and support others through the recovery process [24,25]. A recent systematic review has demonstrated that recovery coaching positively influences recovery outcomes for people with OUD by increasing maintenance treatment initiation, including buprenorphine, and reducing opioid use [26]. However,

coach-led clinical activities provided to participants or the formal training that the recovery coaches received were rarely described in these studies. Finally, a few studies explored the effect of recovery coaching on opioid use using an objective measure (i.e., toxicology screen) [27–29].

This paper describes the rationale, design, and methodology of the OVERCOME Study, **O**UD Intervention **R**ecovery Coach **C**BT and **O**UD Medications, an ongoing randomized controlled trial aimed at testing an integrated intervention combining CBT4CBT-Buprenorphine and recovery coaching in reducing substance use and increasing retention to buprenorphine among people with OUD receiving buprenorphine.

2. Materials and methods

2.1. Research design

The OVERCOME study is a prospective, 20-week randomized controlled trial (RCT) to evaluate the effectiveness of combining Recovery Coaching and CBT4CBT-Buprenorphine compared to TAU in reducing illicit drug use biochemically verified through saliva toxicology screens; and increasing buprenorphine retention (ClinicalTrials.gov; NCT04824404). The study is expected to last for approximately 2 years. Fig. 1 shows the flow diagram of the OVERCOME Study.

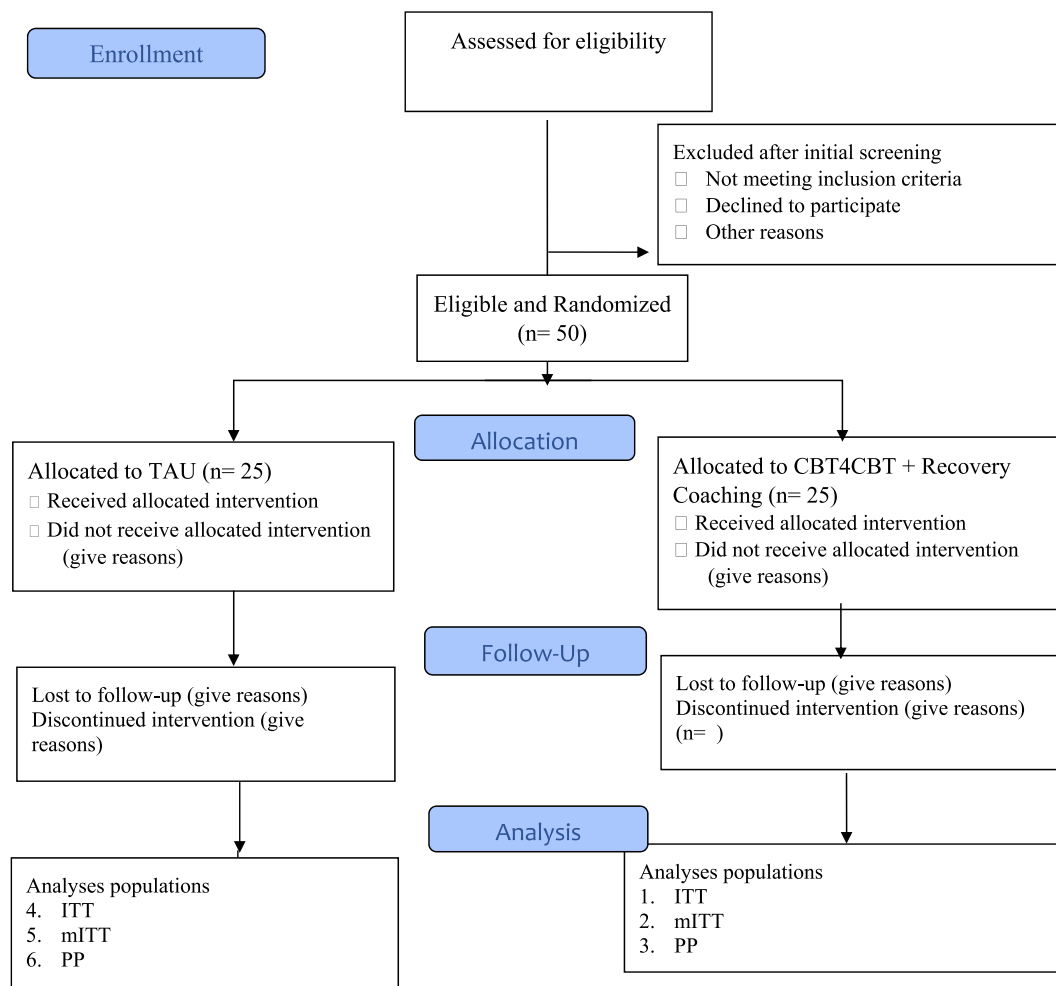


Fig. 1. Flow Diagram

Intention-to-treat (ITT) sample includes all randomly assigned participants. **Modified Intention-to-treat (Mitt) sample** includes participants who were randomly assigned, opened at least one CBT4CBT module and meet at least once with the recovery coach at initiated treatment. **Per-Protocol (PP) sample** includes participants who were randomly assigned who opened at least one CBT4CBT module and completed 50%, and meet at least once with the recovery coach.

2.2. Participants

Participants will be individuals receiving buprenorphine. Inclusion for participating in this trial include: (1) being 18 years of age or older; (2) having a diagnosis of OUD based on the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) [30]; (3) currently receiving sublingual buprenorphine/naloxone and/or buprenorphine; (4) having initiated maintenance treatment for OUD for at least 30 days before the screening; (5) self-report or toxicology screening positive for any substance within 30 days of screening; (6) willing to accept a random assignment to either TAU or CBT4CBT + Recovery Coaching; and (7) having adequate computer skills (verified using computer literacy survey) [31]. Exclusion criteria are: (1) having a severe medical or psychiatric disability that could impair ability to perform study-related activities (determined by the clinician); (2) being pregnant or breastfeeding (women); (3) being unable to independently read and/or comprehend the consent form or other study materials; (4) being unable to read/speak English (inability to independently read and comprehend the consent form or other study materials); (5) having current suicidal ideation based on the Patient Health Questionnaire-9 [32]. All participants are asked to provide written informed consent prior to enrolling in the study.

2.3. Procedures

This study was reviewed and approved by the Institutional Review Board (IRB) of the Prisma Health. Potential participants are recruited through advertisements, brochures, active referrals from clinicians, and research coordinators approaching patients in three outpatient clinics providing buprenorphine treatment in the greater Greenville area of SC. Interested and potentially eligible participants are screened for eligibility in person at their routine visits with their providers or via telephone. Individuals who appear eligible are scheduled for a comprehensive virtual research visit to verify eligibility and complete baseline assessments. After participants complete all the assessments and eligibility is confirmed participants are randomized in a 1:1 manner to receive either CBT4CBT-Buprenorphine + Recovery Coaching or TAU. Research visits are conducted at baseline, every week during the 8 weeks of treatment (weeks 1–8), and 1 and 3 months after the end of treatment. All research visits and encounters with the recovery coach are conducted virtually.

2.4. Study assessments

Data will be collected from 5 sources: (1) surveys and questionnaires; (2) saliva toxicology screen tests; (3) CBT4CBT-website; (4) recovery coach and participant encounters; and (5) chart review. The self-reported surveys and questionnaires are completed using REDcap. Saliva toxicology screens are completed virtually at each research visit using remote video observation. The CBT4CBT website has the ability to record information on both module and homework completion, time spent with each module, and participants' responses to quizzes. Information related to the encounters between recovery coach and participants is collected in a REDCap survey completed by the coach.

2.5. Research visits

Research visits are completed remotely using Zoom, at baseline, every week during treatment (weeks 1–7), at the end of treatment (week 8), and 1- and 3- month post-treatment follow-ups. These research visits are identical for all participants independently of the treatment arm. Participants complete a series of questionnaires (Supplemental Table) and a saliva toxicology test at baseline, end of treatment, and follow-ups. During the baseline, end of treatment assessment, and two follow-ups, participants complete a comprehensive battery of assessments and a saliva toxicology test. Twenty-four hours prior to the visit, participants

are emailed a REDCap survey link and are asked to respond to the questionnaires before the research visit. During these visits, the research assistant reviews the responses to the questionnaires and asks participants to complete a saliva toxicology test. During the weekly research visits (weeks 1–7) participants are asked to report various questions related to the prior 7 days including; any drug and alcohol use using the Time Line Follow-Back (TLFB) [33], adherence to buprenorphine using two visual analogue scales (VAS) asking how many of their prescribed doses were taken and how many of these doses were taken within 2 h of the correct time from 0% to 100% [34], readiness and confidence to change using two visual analog scales from 0 to 100 [35], any counseling or coaching received and its length, level of craving experienced using the Opioid Craving Scale [36], and the severity of withdrawal symptoms experienced using the Subjective Opiate Withdrawal [37] (week 4). The research assistant inputs participants' responses to self-reported questionnaires as well as saliva toxicology test results into REDcap. Participants are compensated for completing research visits using ClinCards, a personal, reloadable prepaid card. Participants' ClinCard is immediately loaded with the incentives after completing the research visits. Participants are paid \$40 for the baseline session, \$10 for visits weeks 1–7, and \$20 for week 8 and the two follow-ups for a maximum compensation of \$170.

2.6. Study arms

2.6.1. CBT4CBT-buprenorphine + recovery coaching

This condition will integrate CBT4CBT-Buprenorphine intervention and recovery coaching services (see Table 1). The CBT4CBT-Buprenorphine [21] is an 8-session (module) system for teaching with one module on the basics of buprenorphine and 7 CBT core skills tailored around issues related to buprenorphine, OUD and other SUDs: (1) introduction to functional analysis of substance use; (2) strategies for recognizing and coping with craving; (3) refusal skills and assertiveness; (4) training in problem solving skills; (5) strategies for recognizing and changing thoughts; (6) decision making skills; (7) how to use CBT skills to reduce HIV/HCV risk. Each module takes 20–30 min to complete and has a similar format, which includes on-screen narration, graphic animation, quizzes, and other interactive exercises to teach and model effective use of skills. All modules conclude with a practice exercise (homework). One recovery coach from FAVOR–Greenville, a recovery community organization, with training in the use of CBT4CBT and ongoing supervision in their adherence to the study protocol will be assigned to the participant. Recovery coaches are trained as both Certified Peer Support Specialists (CPSS) and Certified Assertive Community Engagement Specialists under the National Association of

Table 1
Intervention components- CBT4CBT-Buprenorphine + Recovery Coaching.

| CBT4CBT Module | Content of Module |
|----------------------------|--|
| 1. Basics of buprenorphine | Information about buprenorphine |
| 2. Recognize the triggers | Functional analyses; Changing patterns by recognizing them. |
| 3. Deal with craving | Recognizing and tolerating craving and strong affect |
| 4. Stand up for yourself | Refusal and assertiveness skills |
| 5. Plan don't panic | Problem solving skills |
| 6. Stop and think | Recognizing and changing thoughts |
| 7. Go against the flow | Decision-making skills |
| 8. Stay safe | HIV/HCV safe sex |
| RC Domain | Explanation of Domain |
| Recovery capital | Identify patients' needs, create a personalized plan to address these, support and motivate to achieve goals |
| CBT4CBT Adherence | Completing CBT4CBT modules and homework. RC provides personal insights and modeling |

CBT4CBT = web-based training in cognitive-behavioral therapy; RC = recovery coach; HIV = human immunodeficiency virus; HCV = hepatitis C virus.

Alcohol and Drug Abuse Counselors. In addition to the formal training, they are required to have ≥ 1 year in recovery and adhere to FAVOR code of conduct. Recovery coaches use an assertive engagement approach to provide comprehensive, client-centered, and strength-based support in four areas: emotional (i.e., demonstrate empathy, caring and concern to improve patients' self-esteem and confidence), instrumental (i.e., provide concrete assistance with an individual's needs including social determinants of health), informational (i.e., share knowledge and information), and affiliational (i.e., facilitate connection with other people, create community) [23]. Additional information about the activities and responsibilities of recovery coaches can be found elsewhere [38]. In this study, the first encounter with the recovery coach is at the baseline visit after participants are deemed eligible and complete the baseline visit. During this first encounter the recovery coach performs a needs assessment (recovery capital matrix) [39]. Based on the recovery capital matrix, the recovery coach and participant discuss a customized recovery plan for the 8 weeks of treatment, which always starts with the capital domain that requires more immediate attention. Examples of deficits with recovery capital may include unstable housing, legal issues, financial difficulties, familial problems or lack of health care. In addition, the recovery coach explains the CBT4BT-buprenorphine program and instructs the participant to start completing the modules. Recovery coaches and participants will meet once a week, either in-person or virtually, where they discuss the CBT4CBT module completed, resolve questions and doubts, complete practice exercises, and help with the homework. In addition, they assess the status of participants' recovery capital and move towards the next capital needing attention. The recovery coach is supervised by a licensed social worker and senior recovery coach on a weekly basis throughout the course of the treatment. Recovery coaching services are delivered for 8 weeks via in-person meetings, video calls, phone calls, and text messages. Recovery coaches are required to initiate at least one meaningful contact (video call or in-person visit) and 3 check-ins (i.e., text message, email, quick call) per week. The recovery coach assumes responsibility for the ongoing therapeutic relationship. The services provided by the recovery coach in our study are the same that recovery coaches do outside this study. The only difference is the incorporation of the CBT4CBT content.

2.6.1.1. TAU. Participants in the TAU condition will receive the standard treatment at their outpatient buprenorphine clinic, which consists of maintenance medication prescription, weekly, bi-weekly or monthly visits with a physician or nurse practitioner (at the discretion of the provider) in-person or virtually. Other behavioral or psychosocial support is accessible to participants as the standard of care in the clinic, including a FAVOR Recovery Coach. When a patient needs additional support, the provider makes an appointment with a counselor, introduces the on-site recovery coach to the participant, or provides patients' contact information to FAVOR Greenville. Additional details about services provided by FAVOR coaches are available above (i.e., 2.6.1.1).

2.7. Study outcomes

2.7.1. Primary and secondary outcomes

The primary outcome is defined as the percentage of drug-positive saliva toxicology samples for any of the drugs tested at each research visit during the 8 weeks of treatment (i.e., visits 1 to 8). Saliva samples were tested for oxycodone, THC/cannabinoids, cocaine, opiates, methamphetamines, amphetamines, barbiturates, benzodiazepine, methadone, buprenorphine, phencyclidine, and alcohol (American Bio Medica Corp, Kinderhook, NY). Secondary outcomes include retention to buprenorphine at 3-month follow-up and the percentage of saliva toxicology positive for any drugs at 1- and 3- months follow-up. First, retention to buprenorphine, a dichotomous outcome (i.e., yes vs no), is defined as receiving buprenorphine and/or other effective medication

treatment for OUD (methadone maintenance, or extended-release naltrexone) at 3- month follow-up, which will be verified by either report from the treatment clinic or electronic medical record. Second, the percentage of saliva toxicology positive screens for any of the drugs will be determined based on test results at 1- and 3- months post-treatment follow-ups.

2.7.2. Exploratory outcomes

Exploratory outcomes related to substance use are measured by using the addition severity index (ASI) [40], the Time Line Follow-Back (TLFB) [33], the Alcohol Use Disorders Identification Test (AUDIT) [41], and a modified version of the Behavior Risk Assessment [42]. Additional OUD outcomes included the Opioid Craving Scale [36] and the Subjective Opiate Withdrawal Scale [37]. Outcomes related to adherence to buprenorphine are assessed using two VAS; one asking how many of their prescribed doses were taken and another asking how many of these doses were taken within 2 h of the correct time from 0% to 100% [34]. These VAS will be administered at baseline, every treatment week, and post-treatment 1- and 3-month follow-ups.

2.7.3. Other clinical outcomes

Both history and current use of substance use treatment (e.g., maintenance treatment, psychiatric treatment and detox treatment) as well as use of recovery services (e.g., recovery coaching, 12-Step, and narcotics anonymous), is assessed with a survey developed ad hoc for this study. The Readiness Ruler, a 3-item questionnaire in a VAS format, is used to determine participants' willingness to change [35]. The Patient Satisfaction Questionnaire [21] used in prior CBT4CBT trials is completed in this study by participants to measure satisfaction with the research staff conducting the visits, the CBT4CBT program, and recovery coach. An adapted version of the Working Alliance Inventory-Short Revised [43] is used to measure the alliance between recovery coach and participant (only in the CBT4CBT-Buprenorphine + Recovery Coaching). Symptoms of depression and anxiety are measured using the Patient Health Questionnaire-9 [32] and the General Anxiety Disorder-7 [44]. Impulsive decision making was used with a delay discounting task [45]. The Recovery Capital Matrix is used to evaluate participants' deficits in employment, income, food, childcare, education, health coverage, life skills, and family/social relationships [39]. Health related quality of life is measured with the EQ-5D-3L, a 5-item questionnaire that uses responses for 5 health domains (mobility, selfcare, usual activities, pain/discomfort, and anxiety/depression) to measure participant's health [46].

2.8. Hypotheses

We hypothesize that participants assigned to the CBT4CBT-Buprenorphine + Recovery Coaching arm will submit fewer positive saliva toxicology screens for all drugs tested, including opioids, during the first 8 weeks of the study than those assigned to the TAU arm. We also expect that the effects of the integrated intervention would endure relative to TAU. Thus, we hypothesize fewer positive saliva toxicology screens for all drugs and opioids at 1- and 3-month follow-up as well as greater retention rates to buprenorphine at 3- month follow-up among those randomized to CBT4CBT-Buprenorphine + Recovery Coaching arm compared to those in the TAU arm.

2.9. Sample size determination

We plan to recruit $N = 25$ for each group. Each participant will be assessed for illicit drug use every week over the 8-week treatment period. Considering: 1) $<20\%$ attrition rates, 2) <0.2 intraclass correlation coefficient (ICC) of the longitudinal binary outcomes, and 3) 30% positive test in the control group, our study is powered to detect $>55\%$ positive test in the intervention arm (i.e., 30% vs. $>55\%$) with $>80\%$ power at a two-sided significance level of 0.05. This minimally

detectable effect size is much smaller than that estimated from a prior pilot study ($N = 20$) [21] which demonstrated the preliminary efficacy of CBT4CBT as an add-on to office-based buprenorphine for people with OUD in reducing substance; participants assigned to CB4CBT provided fewer urine samples that were positive for all drugs tested compared to TAU (30% vs. 82% $p = .004$, respectively).

2.10. Data analytic plan

The primary analytic sample will include all randomized participants, called intention-to-treat (ITT) sample. For the analysis of data from this ITT sample, the group membership will remain unchanged as randomized (as opposed to as treated) even if participants may cross over to the other group during the course of study period. We will also conduct modified ITT (mITT) including only participants in the intervention arm who opened at least one CBT4CBT module and met at least once with the recovery coach (i.e., participants who were randomly assigned and initiated treatment); and, per-protocol (PP) sample which will include participants in the intervention arm who opened at least one CBT4CBT module, completed $\geq 50\%$ of modules, and met at least once with the recovery coach (i.e., participants who were randomly assigned, initiated treatment, complied with the assigned intervention without crossover).

Descriptive statistics will be computed to summarize baseline characteristics in terms of mean, median, standard deviation, and percentages. In the presence of skewed distributions of data, we will use medians and interquartile ranges (IQR) to describe our data. Also, any continuous data that have a skewed distribution will be log transformed. The percentage of any illicit drug use will be ascertained by saliva toxicology test and will serve as the primary outcome and will be measured 8 times from study week 1–8. To compare the longitudinal binary outcomes of any illicit drug use between TAU and CBT4CBT-Buprenorphine + Recovery Coaching, we will apply the generalized mixed-effects models to the ITT sample. As this is an RCT with ITT sample, no adjusting variables will be included in the model. The analysis of the secondary outcomes will be similarly conducted, although choice of statistical models will depend on outcome scales and types, longitudinal or single outcome. For instance, 3-month retention rate will be a single outcome for each participant.

3. Discussion

The present paper presents the rationale, design, and methodology of an ongoing RCT examining the efficacy of combining web-based CBT (CBT4CBT-buprenorphine) and Recovery Coaching services to enhance treatment outcomes among people with OUD on buprenorphine. OUD is a chronic and debilitating condition that results in increased morbidity and mortality [1]. Despite the availability of effective medications to treat OUD, including buprenorphine [7], a substantial proportion of patients present polysubstance use or do not complete treatment [12, 13], evidencing that there is substantial room to improve treatment outcomes.

To our knowledge, the OVERCOME trial will be the largest RCT to examine the efficacy of web-based CBT4CBT-Buprenorphine for patients on buprenorphine with ongoing drug use. One recent pilot study provided evidence of the efficacy of CBT4CBT as an add-on to buprenorphine on reducing substance use in a sample of patients with OUD [21]. However, this study only enrolled 20 patients. Another limitation of this pilot study is that it excluded individuals with current cocaine, benzodiazepine, and alcohol use disorder. It is well known that the majority of patients with OUD (65%) on maintenance treatment (i.e., methadone or buprenorphine) have polysubstance use concurrent with their opioid use [13], which can compromise maintenance treatment in addition to increasing the risk of overdose. Thus, it is crucial to develop and test interventions that address concurrent substance use.

The OVERCOME trial will be the first RCT to examine the efficacy of

recovery coaching for both reducing substance use and improving retention to buprenorphine among people with OUD. Recovery coaching services involve a holistic, person-centered, and strength-based support tailored to the patient's specific needs and recovery stage, with the overall goal of promoting abstinence and improving quality of life [47]. This support focuses on four big areas: emotional (i.e., demonstrate empathy, caring and concern), informational (i.e., share knowledge and information), instrumental (i.e., provide concrete assistance with individual basic needs), and affiliational (i.e., facilitate connections with other people); and is provided by individuals with experience with substance use and successful recovery [22,23]. Existing literature has demonstrated that the use of recovery coaching is an effective approach for increasing maintenance treatment initiation and reducing opioid use among people with OUD [26]. These studies typically presented three major limitations. First, the nature of the peer recovery support services are rarely described; without information related to the specific peer-related activities carried out or its timeline, it is impossible for studies involving recovery coaches to be replicated, and thus prove its effectiveness. Second, these earlier studies did not monitor the frequency and intensity of the services provided by the recovery coach. Third, earlier studies explored the impact of incorporating recovery coaching on buprenorphine initiation rates. A recent review [26] stated no prior study has explored the impact of recovery coaching services on treatment outcomes among patients already enrolled on buprenorphine. To address these limitations, we designed a protocol with well-defined activities and timelines for the recovery coaching activities, and the encounters between the recovery coach and the patient are monitored closely by the study team members. In addition, we measure participants' satisfaction with the assigned coach which another critical factor in treatment success. In sum, this study represents an advancement in the research focused on testing recovery coaching services for treating people with OUD.

It is also important to highlight that this study is highly innovative as it will be the first RCT to test the efficacy of combining recovery coaching and CBT. Earlier studies assessing the effectiveness of recovery coaching for treating SUDs have combined recovery coaching with a variety of therapeutic strategies including intensive referral interventions, skills training, and multicomponent interventions (involving case management, individual/group treatment, and other services) [48–50]. The present study will be the first to use evidence-based CBT in addition to recovery coaching. In our study, the recovery coaches will conduct a needs assessment and provide assistance with any area of capital that requires attention (e.g. employment, income, food, childcare, education, health coverage, life skills, and family/social relationships). In addition, the recovery coach will encourage the participant to practice skills learned in the CBT4CBT program, and ensure that participants complete modules and homework. This multifaceted approach addresses the exacerbating factors that make recovery difficult (i.e. recovery capital), teaches behavioral skills (i.e., CBT4CBT) that are fundamental for individuals' behavior change and facilitates overlearning by practice and modeling with the recovery coach), and motivates and challenges participants' to change maladaptive behaviors through personal support (in four areas emotional, informational, instrumental, and affiliational) which are all essential to facilitate long-term adherence to buprenorphine and reduce substance use.

It is also worth mentioning that this integrated intervention combining CBT4CBT and recovery coaching has the potential to facilitate access to additional care for patients with OUD receiving buprenorphine in MOUD clinics. MOUD treatment is typically delivered in specialist settings which means that it is separated from other services that people with OUD may need, including counseling, psychotherapy, or social determinants of health care. Therefore, receiving additional care requires referral to another specialist clinic, resulting in delays of care. Additional structural barriers, such as transportation, co-payments, or health insurance, can considerably diminish the ability to

obtain care. Further, MOUD clinics traditionally require patients to have regular appointments to obtain their medication, complete drug tests, etc., which may prevent patients from seeking additional care. Thus, incorporating additional care into MOUD clinics, in which patients have regular visits to receive treatment for their opioid addiction, may be the most effective approach to deliver the additional care that people with OUD on MOUD need. Given the characteristics of our intervention, integrating this intervention into MOUD clinical settings can make adjunctive care for people with OUD accessible and eliminate some structural barriers to access to treatment.

This is the first study to use both CBT4CBT and recovery coaching entirely remotely. COVID-19 has challenged researchers and clinicians globally trying to conduct research studies and provide health care as many visits have transitioned from in-person to virtual [51,52]. The use of virtual platforms such as CBT4CBT or virtual coaching provides a new opportunity to provide care and conduct research using fewer resources and reducing the amount of in-person contact [53]. As the use of technological tools advance and become easier to implement in care and research, it is important to utilize these new tools in vulnerable populations so that we do not exacerbate health disparities in a population who already have suffered diminished health care. Although Shi et al. [21] study represents an initial step, we are not aware of any OUD-related studies that have provided treatment and conducted research-related activities remotely.

In summary, the OVERCOME Study employs an innovative approach for both the type of intervention (i.e., combining CBT and recovery coaching) and the form of delivery (via video calls) to treat patients with OUD on buprenorphine. The findings from this RCT will inform a rapidly evolving approach of treating patients with substance use disorders remotely, including people with OUD. In addition, our study will provide evidence of the efficacy of combining an evidence-based intervention of CBT and recovery coaching. Finally, the results of this study can inform the development of future research studies using recovery coaching, which is both timely and urgent given the lack of a well-controlled RCT testing recovery coaching services. Taken together, our proposed integrated intervention can serve as a viable option to be routinely incorporated in office-based buprenorphine programs.

Ethics approval

The study described in this manuscript was approved by the Institutional Review Board at Prisma Health, approval #87691.

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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work presented in this manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2022.100918>.

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