HIC# 2000022733

YALE UNIVERSITY
HUMAN INVESTIGATION COMMITTEE

Application to Involve Human Subjects in Biomedical Research
100 FR1 (2011-2)

SECTION I: ADMINISTRATIVE INFORMATION

Title of Research Project: **A pilot feasibility study of providing substance use treatment in the Black Church**			
Principal Investigator: Ayana Jordan, MD, PhD		**Yale Academic Appointment:** Assistant Professor	
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Protocol Correspondent Name & Address (*if different than PI*)**:** Joanne Corvino; 40 Temple Street, Suite 6C			
Campus Phone: 203-785-2012	**Fax:** 203-737-1371	**E-mail:** Joanne.corvino@yale.edu	
Yale Cancer Center CTO Protocol Correspondent Name & Address (*if applicable*)**:** N/A			
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Faculty Advisor:(required if PI is a student, resident, fellow or other trainee) ☒ **NA**		**Yale Academic Appointment** **Professor**	
Campus Address:			
Campus Phone:	**Fax:**	**Pager:**	**E-mail:**

Investigator Interests:
Does the principal investigator, co-investigator, or any other responsible research team member, or any of their family members (spouse, child, domestic partner) have an incentive or interest, financial or otherwise, that may be viewed as affecting the protection of the human subjects involved in this project, the scientific objectivity of the research or its integrity? See Disclosures and Management of Personal Interests in Human Research http://www.yale.edu/hrpp/policies/index.html#COI

√ Yes ☐ No
If yes, list names of the investigator or responsible person:

Kathleen Carroll, PhD.

Version 2, Nov 21, 2016

APPROVED BY THE YALE UNIVERSITY IRB 4/8/2019

A COI agreement in in place for Dr. Carroll's similar projects.

All Yale University and Yale New Haven Hospital individuals listed as co-investigators must have a current financial disclosure form on file with the University's Conflict of Interest Office. If this has not been done, the individual(s) should follow this link to the COI Office Website to complete the form: http://www.yale.edu/coi/

NOTE: The requirement for maintaining a current disclosure form on file with the University's Conflict of Interest Office extends primarily to Yale University and Yale-New Haven Hospital personnel. **Whether or not they are required to maintain a disclosure form with the University's Conflict of Interest Office, all investigators and individuals deemed otherwise responsible by the PI who are listed on the protocol are required to disclose to the PI any interests that are specific to this protocol.**

SECTION II: GENERAL INFORMATION

1. **Probable Duration of Project:** State the expected duration of the project, including all follow-up and data analysis activities.
   The duration of the pilot in its entirety will be 1 year; March 2018-March 2019

2. **Targeted Enrollment:** Give the number of subjects: 40

a. targeted for enrollment at Yale for this protocol 40 If this is a multi-site study, give the total number of subjects targeted across all sites N/A
b expected to sign the consent form 60
c. expected to complete some or all interventions for this protocol? 40

SECTION III: FUNDING, RESEARCH TEAM AND TRAINING

1. **Funding Source:** In IRES

2. **Research Team:** In IRES

SECTION V: RESEARCH PLAN

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested.

We will conduct a pilot study evaluating the feasibility and acceptability of providing a computer-based program (CBT4CBT), used for the treatment of substance use disorders, in a church setting. Forty Black adults with a current DSM-5 alcohol or substance use disorder will utilize the 'CBT for CBT' program over a period of 8 weeks. Primary outcomes will be acceptability and feasibility of providing the treatment in a church setting. If found to be acceptable and feasible, with preliminary promise for reductions in substance use, the next step would be to adapt the computer intervention for this population and conduct a randomized controlled trial.

Specific aims are as follows:

(1) To determine the feasibility of recruiting Black adults with substance use disorders (BSUD) from within the Black church and immediate surrounding community and retaining BSUD in treatment, within a church setting.
(2) To evaluate the acceptability of CBT4CBT with BSUD in a church setting and to identify if religious behaviors led by trained church based health advisors (CHA), may increase the likely suitability of this intervention within the Black church.
(3) To obtain qualitative data from both CHAs and BSUD about providing substance abuse treatment in a church setting.
(4) To collect pilot data about the effects of CBT4CBT on substance use, recovery goals and level of functioning among BSUD.

2. **Background:** Describe the background information that led to the plan for this project. Provide references to support the expectation of obtaining useful scientific data.

A. SIGNIFICANCE

A.1. Overview of Research Activities

The overall aim of this proposal is to provide Black adults with substance use disorders (BSUD) access to an evidence-based, web-based, cognitive behavioral therapy intervention (CBT4CBT) and to pilot test it in a church setting. Given low rates of substance abuse treatment initiation and engagement as well as the importance of spirituality and the Black church amongst Black adults, this study will assess the feasibility and acceptability of conducting CBT4CBT in a Black church setting, and measure the effect of CBT4CBT on participant's substance use, recovery goals and level of functioning.

A.2. BSUD suffer more negative drug-related consequences, but less likely to initiate treatment

Substance Use Disorders (SUD) are one of the most devastating health and social issues confronting this country, causing a tremendous amount of suffering for individuals, families, entire communities, and disproportionately affect minority communities. Black adults use alcohol at lower rates compared with their white counterparts (43.6% vs 57.7%), with nicotine and illicit drug use at the same rate, however Blacks are more likely to suffer negative drug-related consequences, including physical ailments and higher rates of involvement in the criminal justice system. Despite this disparity, Blacks are less likely to initiate substance use treatment when compared with other racial groups, but the reasons accounting for this difference are not well understood. Several theories have been cited for low treatment engagement among Blacks, including societal and cultural stigma associated with accessing substance use treatment,

mistrust of the medical system due to historic maltreatment, lack of health care coverage, circuitous pathways to care, lower socioeconomic status, and the absence of culturally informed treatment options. However, limited research has been done to delineate which of these factors, if any, specifically impacts or deters BSUD from initiating treatment. Data from a preliminary needs assessment study indicates many Black adults with problematic illicit drug and alcohol use see the church as an acceptable place for help, that is comfortable, with access to programs, with emphasis on God, spirituality and religion (Figure 1 within the text to the Left).

A.3. The Role of the Black Church in promoting healthy lifestyles

The "Black Church," defined as the collection of seven predominately African American denominations of the Christian faith, including the African Methodist Episcopal Church, the African Methodist Episcopal Zion Church, the Christian Methodist Episcopal Church, the Church of God in Christ, Baptist, United Methodist Church, and Presbyterian Church, plays a key role in promoting healthy lifestyles. Religion and spirituality are foci for the Black community and a source of help for coping with psychological and emotional distress. For many Black adults, God and prayer are crucial in daily life, along with church and church attendance.[20] In urban Black communities, 65% to 80% of adults attend church regularly, and 55% are involved in church-related activities.

The Black church holds great cultural significance in the community, as a highly relevant institution dedicated to health promotion. Black churches have been successfully involved in research studies targeting stigmatized issues such as depression among Black men, and HIV care. Several reports also highlight the potential role of the Black church in addressing SUD, where members often seek informal help from clergy. Further, a number of investigators have shown improvement in functioning and decreased substance use among BSUD when standard treatment was coupled with religious behaviors and/or structured support from Black churches and the faith community.

A.4. Rationale for CBT4CBT for use the Black Church

Cognitive Behavioral Therapy (CBT) is an evidence-based psychotherapy shown to be effective in reducing substance use. Carroll and colleagues have developed a web-based intervention called CBT4CBT, which has demonstrated efficacy as an intervention for SUD, both as an adjunct to standard care, as well as a stand-alone intervention with clinical monitoring. Secondary analyses indicated no significant differences in outcomes between Blacks and whites in these studies (46% of the samples), which were delivered in traditional mental health/substance use treatment clinics. There are few data, however, evaluating the feasibility and acceptability of CBT4CBT in alternate settings, such as churches, where Blacks are likely to congregate. We hypothesize that despite stigma or biases that exist related to substance use, partnering with the Black church will increase BSUD participation with evidence-based treatments, such as CBT4CBT, by increasing access to treatment in a comfortable environment, among a population in need, who might otherwise not engage in care. Data from a needs assessment study (manuscript in progress) supports this hypothesis, demonstrating that 56% of Black adults with problematic illicit drug and alcohol use reported they would be willing to engage in treatment within a place of worship, such as the Black church.

A.5. Preliminary Data

Methods. Two phases of work were conducted in the needs assessment study assessing the Role of the Black church in increasing access to treatment for BSUD. The first phase involved qualitative methods and was comprised of 2 steps. (1) Three focus groups were

conducted in different Black churches with key stakeholders in the Black community, to (a) identify community and cultural factors related to BSUD that might increase or decrease perceptions of stigma and (b) identify community/church attitudes/biases that might impact a BSUD likelihood of engaging with treatment. (2) We also conducted in-depth interviews (recently completed) with BSUD to (a) identify perceived barriers to help seeking and treatment engagement among BSUD, (b) explore attitudes and experiences associated with spirituality, religion, and the Black church that might indicate a willingness to access treatment connected with the Black church; and (c) assess the acceptability of using a web-based intervention. The second phase of the study involved a quantitative approach, through the development of an online survey (N=205) to (a) quantify what percentage of Black adults would be willing to use a web-based intervention to decrease substance use, and (b) identify what population of Black adults are willing to engage in substance use help in the church setting. Selected data from the quantitative phase of this project (mobile, optimized qualtrics survey) is presented below.

Blacks who use drugs and alcohol identify with the Christian Faith and will access help in the church

Demographic data obtained from survey participants, who identified as Black (N=205), demonstrates a predominately heteronormative (77%), Christian cohort (76%); who are likely to access treatment in the church setting (56%).

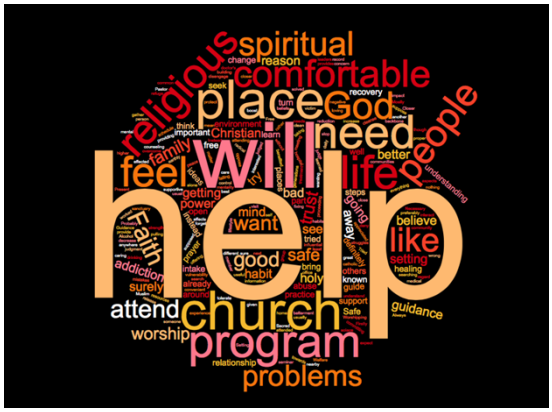


Figure 1. Word Cloud from free text portion of the quantitative survey outline, affirmative reasons to access care in the Black church setting.

Black church viewed as a major place for help

Analysis of free text, from the quantitative survey among Black adults with problematic illicit drug and alcohol use who would access the church for treatment, identified the Black church as a source of help, which is comfortable, has access to programs, with emphasis on God, spirituality and religion (Figure 1 within text to Left).

Black adults with drug and alcohol use are willing to engage with an online treatment

Among Black adults who use illicit drugs and have a problem with alcohol, the majority of this cohort indicates willingness to access online treatment (70%), making CBT4CBT a viable option. These findings underscore the important and dynamic role the Black church serves in the lives of many Black adults, including those with drug and alcohol problems. Based on preliminary data collected from the mixed methods needs assessment, the Black church, a central, trusted institution has been identified as a viable portal to improve access to and utilization of evidence-based treatments for substance use.

A.6. Collaboration with Community Partners

A main priority at the start of this project is to learn from and collaborate with community stakeholders who are invested in improving access to and initiation of SUD treatment amongst BSUD in New Haven. The PI has an established relationship with community leader and senior pastor, Reverend Frederick Streets, of Dixwell Avenue Congregational United Church of Christ (UCC), who has agreed to partner with the research team and allow use of the church, founded in 1820, the oldest African American Congregational UCC church in the world,

as the site for the pilot project. Reverend Streets was involved in the initial needs assessment project and is committed to execution of the research design for the pilot project proposed in this application. Specifically, Reverend Streets will identify church based health advisors (CHA) within the Black church and community that will be trained in CBT4CBT modules, who will meet together to identify religious practices, which can be coupled with each CBT4CBT module, to reinforce lessons taught, in each respective module. Reverend Streets will also assist with recruitment of research subjects from the Black church community and the immediate surrounding areas of Dixwell and Newhallville, two predominately Black neighborhoods within New Haven. Blacks comprise approximately 35% of the population in New Haven, and the Dixwell location where the pilot church Dixwell Avenue Congregational UCC is located, has the highest Black composition in New Haven (55.4%), making this an ideal location for the project site.

The PI is also a YCCI Community Based Participatory Research (CBPR) scholar, a program that teaches the tenants and methodology of CBPR research and allows investigators to establish and foster relationships with partners in New Haven for meaningful research collaboration, relevant to the needs of New Haven residents. As a YCCI CBPR scholar, Dr. Jordan has presented to and formed relationships with pastors in the Cultural Ambassadors Program (CAP), a partnership established in 2011 between YCCI and New Haven's Black and Hispanic communities, who meet once a month to discuss research and other initiatives that are relevant to their communities. CAP was developed to ensure Yale's clinical research reflects the diversity of New Haven's population, and directly offers benefits to the local community. These existing contacts and infrastructure have been utilized in the research approach by obtaining guidance related to participant recruitment, protection of BSUD confidentiality, and eliciting ideas on how the computer-based intervention can best be integrated within the Black church. We will continue to partner with CAP throughout all aspects of the project, including data collection, analysis and dissemination of findings. The integration of community ties is not limited to academic research but extends to social and community development.

3. **Research Plan:** Summarize the study design and research procedures using non-technical language that can be readily understood by someone outside the discipline. Be sure to distinguish between standard of care vs. research procedures when applicable, and include any flowcharts of visits specifying their individual times and lengths.

B. METHODOLOGY

B.1.a. Recruitment of BSUD:

Forty Black adults, 20 male and 20 female participants, who self-identify as Black and want help with drug and/or alcohol problems in the church setting, will be recruited from within the church itself, Dixwell Avenue Congregational UCC and the two predominately Black neighborhoods in New Haven, CT, Dixwell and Newhallville, immediately surrounding the church. Given past successes with the needs assessment study, using targeted recruitment strategies, including culturally normative flyers disseminated by Black church clergy, online and print ads in Black church bulletins, and culturally sensitive ads on urban radio stations, these same tools will be utilized to recruit the research participants for the pilot project. Participants will be screened by research staff using the DSM-5 Substance Use Criterion to ensure all potential participants meet criteria for a SUD as defined by DSM 5. Inclusion criteria: (1) at least 18 years of age (2) has at least one SUD diagnosis as defined by the DSM 5 (3) self-identified with having a SUD and confirmed after DSM 5 criterion checklist; Exclusion criteria: (1) inability to provide informed

consent or participate in the study procedures as proposed in the consent (2) active suicidal or homicidal ideation and (3) current engagement in substance abuse treatment.

B.1.b. Recruitment of Church Based Health Advisors (CHAs):
Community partner, Reverend Streets--pastor of Dixwell Avenue Congregational United Church of Christ, will advertise the role of the CHA (CHA description in attached documents) in the church bulletin, through church meetings, and by peer nomination, in order to identify church leaders interested in this role. All CHAs must be a member of a Black church in the targeted Newhallvile/Dixwell neighborhoods, be at least 18 yo, and have the ability to read and write. It would be preferable, but not necessary, if a CHA had lived experience with drug and/or alcohol use. 12 CHAs will be recruited in total, 10 consistent leaders, and 2 alternates for emergency/unplanned absences.

B.2. Procedure:
A total of 5 cohorts, each with 8 participants, will meet at Dixwell church on pre-determined days to take the intervention (CBT4CBT) online, simultaneously. Participants in each cohort will complete each online module at their own speed, but meet together on a weekly basis for a total of 8 sessions (8 weeks). Tablets, Wi-Fi hot spots and internet service, will be purchased for the church and made available to participants during the 8 weekly sessions, in addition to allocated times, for review of immediate session topics after each week of a CBT module.

The ten church staff members, known as CHAs, will undergo the informed consent process to participate in the research program, along with two extensive, 8-hour training days, including, but not limited to, topics such as the modules of CBT4CBT, basic research principles, and foundational knowledge related to addiction and drug and alcohol treatment. The CHAs, will then meet together to identify religious practices that can be coupled with each CBT4CBT module, to reinforce lessons taught in each respective module. Two CHAs will be assigned to each cohort, and will meet the 8 participants on a weekly basis, with a back-up CHA also assigned, for emergency/unplanned absences, to ensure each cohort has at least 2 CHA present. All religious practices will be led by the CHA, with any spiritual insights from participants reframed by the CHA, to reinforce lessons from a CBT4CBT module.

A member of the research team will also be present during all CBT4CBT sessions to collaborate with research participants and CHAs. **Table 1**, included below provides a detailed outline of the CBT4CBT modules and approximated spiritual practices to accompany each module. Final practices to accompany each CBT module will be pre-determined by the CHAs.

Table 1. CBT4CBT Intervention Topics

Every Session (led by CHA)	*Check-in, Opening Prayer, Scripture Reading, Praise & Worship (2 song selections) Testimony (optional), Ending Prayer *The proposed agenda above will be modified based on input from CHA.
Session 1	**Recognize the Triggers**-items that trigger substance use
Session 2	**Coping with Craving**-skills & tools to deal with cravings
Session 3	**Plan Don't Panic**-identifying problems in advance & coming up with solutions
Session 4	**Go Against the Flow**-learning how to make safer decisions
Session 5	**Stand up for Yourself**-learning how to be assertive & stand up for yourself
Session 6	**Stop and Think**-challenging negative thoughts
Session 7	**Stay Safe**-conscious plan to think about & enact decisions that lead to safety

Session 8	**Closing Potluck and Graduation**-fellowship affirmation of completing program, participants will receive a completion certificate

Description of computer-based training program.

The program has the following features:

- *Password protection*. Each participant will access the program through an ID/password system that will protect confidentiality and will be linked to an imbedded database that will track, for each participant, time logged onto the program, modules accessed, progress through the program from session to session, completion of homework assignments, progress in treatment, and learning of CBT principles through multiple choice tests after each module.
- *User-friendliness*. Given that many participants have minimal background in the use of personal computers, the program will be user-friendly, with extensive use of point-and-click features (as opposed to typed-in responses) so that no prior experience with computers or software is necessary. Whenever possible, presentation of didactic material will be done through graphics and cartoons, videotaped examples, and audio voice-overs, thus requiring very little reading of text. When text is used in presentation of material, audio voice-overs will accompany the text, as many participants may not be literate or become impatient or uncomfortable with reading large amounts of material. CBT concepts will be presented in a simple, straightforward style without jargon and in a visual style that is engaging and enjoyable (e.g., modeled on computer learning games).
- *Topics covered*: The 'CBT for CBT' program is modeled closely on our NIDA-published CBT manual. Seven core skill modules will cover the following topics, which correspond to the major session topics in the manual:
    - Understanding and changing patterns of drug use,
    - Coping with craving,
    - Substance refusal skills,
    - Seemingly irrelevant decisions,
    - Planning for emergencies, and
    - Problem-solving skills.
    - Staying Safe
- *Module format*. Each of the 7 modules follows a similar format:
    1. Once the participant accesses the program and enters his/her ID and password, the program greets the participant, inquires about the helpfulness of the last session and the last session's assignment. This is preceded by an offer to repeat or review earlier session topics
    2. Each new skills module is introduced through presentation of a videotaped vignette to heighten its relevance and applicability to the participant. For example, the 'coping with craving' module would start with a brief videotaped vignette showing an individual experiencing craving in response to a cue (e.g., seeing others use at a party), followed by audio/graphics asking, "What would you do?"
    3. Skills training are done through 5 strategies: didactic presentation, videotaped examples of effective coping, self-assessments of understanding, virtual role plays, and extra-session practice assignments. *This sequence of activities is very similar to the therapist guidelines for each session in the CBT manual (introduction of the skill topic, didactic instruction, practice via modeling and role-plays, assessment of the participant's understanding of the material, and assignment of homework), but*

additionally takes advantage of the unique advantages of computer-assisted instruction:

4. Finally, prior to log-off, participants are reminded to immediately report any concerns or uncomfortable feelings associated with use of the program to Dr. Jordan, the Project Coordinator, or the Research Assistants.

(1) Initial Screening:

At the first interview, the research staff will provide a brief overview of the protocol and obtain written or verbal informed consent for both the BSUD and CHAs. We routinely use a multiple-choice test to assess participants' comprehension of the protocol with ample time to review questions to assure understanding of the protocol, consent, and treatments offered. After determination of eligibility, pretreatment assessments will be completed (see Assessment Battery in **Table 2**).

(2) Intervention Phase:

The intervention will last 8 weeks. During the intervention, all participants will meet with a research assistant for completion of self-report, urine and breath samples when they come to the church. These results will not be shared with the church or CHAs and are for research purposes only.

- Clinical deterioration. We will closely monitor participant treatment response and safety in all conditions through assessment sessions. These will include breath and urine screens with assessment of psychiatric status. Although in our experience this is a very rare event in behavioral trials, participants who show significant deterioration (e.g., increased substance use or psychiatric symptoms that cannot be managed within the protocol) will be regarded as symptomatic failures, withdrawn from the study, and referred appropriately.

- Strategies to minimize attrition. In order to hold participant dropout to a minimum, we use multiple procedures to enhance adherence with alcohol and substance abuse treatment. These include rapid assignment treatment days, thorough explanation of study treatments and requirements, close monitoring of participants' clinical status, integration of the research with community and church, accessibility of study staff for questions and problems, and adequate compensation to participants for the time spent on completing assessment instruments.

(3) Post treatment assessment

At the end of the 8-week treatment period, all participants (BSUD) will be re-interviewed by the research assistant, who will complete post-treatment ratings (see Assessments, below) and by the PI, who will complete qualitative exit interviews with both the BSUD and CHAs about their experience in the research project. Access to the CBT4CBT program will be terminated for participants after the exit interviews. Participants will be strongly encouraged to continue substance abuse treatment at the end of the study, and resources/information about local substance abuse and mental health clinics will be made available.

(4) Study Termination

Participants will be withdrawn from the study if they show severe psychological or symptomatic deterioration, unacceptable levels of adverse events as determined by the PI Dr. Jordan or other research staff. Participants withdrawn from the study will be offered treatment as usual at a local clinic or be referred to a higher level of care when appropriate. Private referral and/or hospitalization may also be offered according to the participants' needs and wishes.

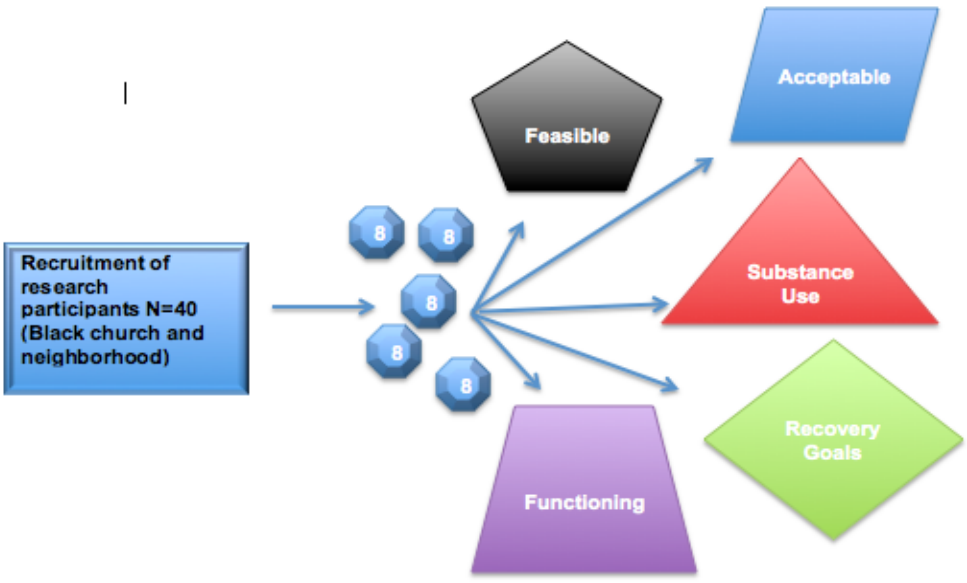
(5) Assessments

Assessments include measures used to: 1) Describe the sample, 2) Measure primary and secondary outcomes during treatment. We will rely on widely used, well-validated instruments. Please see a complete list of the Assessment Battery Below in **Table 2**.

Table 2 Assessment Battery

Instrument name	Interview or self-report	Rater	Screen	Pre Tx	Weekly	Monthly	Post Tx (8 wks)
Informed Consent Quiz	Self-report	P	X				
*Baseline Demographics	Interview	RA	X				
Inclusion/Exclusion criteria	Interview	RA	X				
Follow-up contact & tracking sheet		RA	X				X
DSM-5 Criterion Checklist	Interview	RA	X				X
Urine toxicology screen, breathalyzer		RA	X	X	X		X
Timeline Follow-back/ Substance Use Calendar (SUC)	Interview	RA	X		X		X
Brief Symptom Inventory (BSI)	Interview	RA		X	X		X
Quality of Life Scale	Interview	RA		X			X
Treatment Utilization	Interview	RA		X		X	X
Evaluation of treatment, endpoint	Self-report	P					X
Daily Spiritual Scale	Self-report	P		X			X
Multi Group Ethnic Identity Measure	Self-report	P		X			X
Racial Pride Scale	Self-report	P		X			X
Recovery Markers Questionnaire	Self-report	P		X			X
Religiosity Scale	Self-report	P		X			X
Religious Methods of Coping to Gain Control	Self-report	P		X			X
Sense of Community Index	Self-report	P		X			X
*Qualitative Exit Interview Guide	Interview	PI					X

*CHAs will complete Baseline Demographics and Qualitative Exit Interviews only



A pictorial overview of the pilot study is outlined below in **Figure 2.**

Figure 2: Overview of Pilot Study:
40 participants, divided into 5 cohorts of N=8, (1) Feasibility (2/3 Retention

N=27); (2) Acceptability (Evaluation of Treatment Survey, Qualitative Exit Interview); (3) Substance Use (Urine Tox, Breathalyzer); (4) Recovery Goals (Recovery Markers Questionnaire); (5) Functioning (Social Functioning Scale)

4. Genetic Testing N/A ☒

5. **Statistical Considerations:** Describe the statistical analyses that support the study design.

As this is a pilot evaluation of the acceptability and feasibility of providing CBT4CBT in a Black church setting, data analyses will focus on determining whether the results warrant further adaptation of the existing CBT4CBT program. Criteria for this will include (1) measuring acceptability of treatment by giving each participant a post-intervention satisfaction survey as well as a qualitative exit interview, to fully assesses satisfaction with the intervention, perception of outcome, attitudes about spiritual practices accompanying CBT modules, and whether the participant would recommend this program to a friend. (2) Feasibility will be measured by at least 2/3 of participants (N=27) completing the CBT4CBT intervention. Secondary analyses will include significant reductions in drug use, as measured by mean change scores in the severity and quantity of substance use, and functioning over the course of treatment intervention. The proposed sample size (n=40) is adequate to detect this effect.

SECTION VI: RESEARCH INVOLVING DRUGS, BIOLOGICS, PLACEBOS AND DEVICES

N/A

SECTION VII: HUMAN SUBJECTS

1. **Subject Population:** Provide a detailed description of the types of human subjects who will be recruited into this study.

Participants:
BSUD (20 male and 20 female) who self- identify as Black and want help with drug and/or alcohol problems in the church setting will be recruited from within the church itself, Dixwell Avenue Congregational UCC and the two predominately Black neighborhoods in New Haven, CT, Dixwell and Newhallville, immediately surrounding the church.
CHAs—12 Black church members and leaders who are well versed in the practices of the Black church will be recruited by Rev Streets to serve in this role.

2. **Subject classification:** Check off all classifications of subjects that will be targeted for enrollment in the research project. Will subjects who may require additional safeguards or other considerations be enrolled in the study? If so, identify the population of subjects requiring special safeguards and provide a justification for their involvement.

☐ Children	☐ Healthy	☐ Fetal material, placenta, or dead fetus
☐ Non-English Speaking	☐ Prisoners	☐ Economically disadvantaged persons
☐ Decisionally Impaired	☐ Employees	☐ Pregnant women and/or fetuses
☐ Yale Students	☐ Females of childbearing potential	

NOTE: Is this research proposal designed to enroll children who are wards of the state as potential subjects? ☐ Yes ☒ No (If yes, see Instructions section VII #4 for further requirements)

3. Inclusion/Exclusion Criteria for BSUD: What are the criteria used to determine subject inclusion or exclusion?

Inclusion criteria:

1. At least 18 years of age
2. Has at least one SUD diagnosis as defined by the DSM 5

Individuals will be excluded who:

1. Are unable provide informed consent or participate in the study procedures as proposed in the consent
2. Active suicidal or homicidal ideation
3. Current engagement in substance abuse treatment
4. Have a current legal case pending, such that incarceration during the 8 week protocol is likely
5. Are in need of detoxification from alcohol, opioids or benzodiazepines

Inclusion/Exclusion for CHAs:

1. At least 18 years of age
2. Membership in church in Newhallville/Dixwell neighborhoods
3. Are able to read and write

4. How will **eligibility** be determined, and by whom?

Individuals (both BSUD and CHAs) who indicate they are interested in hearing more about the study will be offered a meeting with research staff who will provide a brief overview of the protocol and continue the informed consent process. After written or verbal informed consent has been obtained* and a quiz successfully completed, screening assessments will be completed to determine eligibility. *CHAs will need to complete the informed consent process only, and will not need to complete a quiz, nor complete screening assessments.

5. Indicate recruitment methods below. Attach copies of any recruitment materials that will be used.

☒ Flyers	☒ Internet/Web Postings	X☐ Radio
☐ Posters	☐ Mass E-mail Solicitation	☐ Telephone
☐ Letter	☒ Departmental/Center Website	☐ Television
☐ Medical Record Review	☐ Departmental/Center Research Boards	☐ Newspaper
☐ Departmental/Center Newsletters	☐ Web-Based Clinical Trial Registries	
☒ Other (describe):	☒ Clinicaltrials.gov Registry (do not send materials to HIC)	

Direct referral from clinicians, church clergy, YCCI database

6. Recruitment Procedures:

a. Describe how potential subjects will be identified.

Participants who self- identify as Black and want help with drug and/or alcohol problems in the church setting will be recruited from within the church itself, Dixwell Avenue Congregational UCC and the two predominately Black neighborhoods in New Haven, CT, Dixwell and

Newhallville, immediately surrounding the church. Given past successes with previous studies, using targeted recruitment strategies, including culturally normative flyers disseminated by Black church clergy, online and print ads in Black church bulletins, and culturally sensitive ads on urban radio stations, these same tools will be utilized to recruit the participants for this pilot study.
CHAs will be recruited directly by Rev Streets, by advertisement in church bulletins and through peer nomination.

Individuals (BSUD and CHAs) who indicate they are interested in hearing more about the study will be offered a meeting with the research staff. An one page summary sheet providing a brief description of the study will be available for potential subjects to indicate their interest in learning more about the study, and how to contact a member of the research team.

b. Describe how potential subjects are contacted.

Potential subjects will be contacted via phone or email by research staff. Eligibility screening may occur at this time or scheduled at a more convenient time. Subjects in the study will be reminded via text weekly to complete modules

c. Who is recruiting potential subjects?

Reverend Streets, Project Coordinator and RAs

7. a. Will email or telephone correspondence be used to screen potential subjects for eligibility prior to the potential subject coming to the research office? ☒ **Yes** ☐ No

b. If yes, identify any health information and check off any of the following HIPAA identifiers to be collected and retained by the research team during this screening process.

HEALTH INFORMATION:
Name, email address (when applicable), phone number (when applicable), any positive responses to DSM-5 Substance Use Criterion

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HIPAA identifiers:

☒ **Names**
☐ All geographic subdivisions smaller than a State, including: street address, city, county, precinct, zip codes and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly-available data from the Bureau of the Census: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
☒ **Telephone numbers**
☐ Fax numbers
☒ **E-mail addresses**
☐ Social Security numbers
☐ Medical record numbers
☐ Health plan beneficiary numbers
☐ Account numbers
☐ All elements of dates (except year) for dates related to an individual, including: birth date, admission date, discharge date, date of death, all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
☐ Certificate/license numbers
☐ Vehicle identifiers and serial numbers, including license plate numbers
☐ Device identifiers and serial numbers
☐ Web Universal Resource Locators (URLs)

☐ Internet Protocol (IP) address numbers
☐ Biometric identifiers, including finger and voice prints
☐ Full face photographic images and any comparable images
☐ Any other unique identifying numbers, characteristics, or codes

8. Assessment of Current Health Provider Relationship for HIPAA Consideration:

Does the Investigator or any member of the research team have a direct existing clinical relationship with any potential subject?

☐ Yes, all subjects
☐ Yes, some of the subjects
☒ No

If yes, describe the nature of this relationship.

9. Request for waiver of HIPAA authorization: (When requesting a waiver of HIPAA Authorization for either the entire study, or for recruitment purposes only. Note: if you are collecting PHI as part of a phone or email screen, you must request a HIPAA waiver for recruitment purposes.)

Choose one: For entire study: _____ For recruitment purposes only: __X____

i. Describe why it would be impracticable to obtain the subject's authorization for use/disclosure of this data;
ii. If requesting a waiver of **signed** authorization, describe why it would be impracticable to obtain the subject's signed authorization for use/disclosure of this data;

The PHI needs to be obtained over the phone to streamline the screening process. All potential participants must meet DSM 5 Substance Use Criterion, so if they do not, there is no need to initiate the informed consent process, as they are not eligible for the study. **By signing this protocol application, the investigator assures that the protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.**

Researchers are reminded that unauthorized disclosures of PHI to individuals outside of the Yale HIPAA-Covered entity must be accounted for in the "accounting for disclosures log", by subject name, purpose, date, recipients, and a description of information provided. Logs are to be forwarded to the Deputy HIPAA Privacy Officer.

SECTION VIII: CONSENT/ ASSENT PROCEDURES

1. **Consent Personnel:** List the names of all members of the research team who will be obtaining consent/assent.
   Listed in IRES

2. **Process of Consent/Assent:** Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure subjects' independent decision-making.

The Project Coordinator and/or Research Assistant will obtain written or verbal informed consent prior to any study related procedures. The informed consent process will be conducted in a private, quiet setting. The Project Coordinator/RA and the participant will discuss the basic components described in the HIC-approved consent form. These include: participation is voluntary and participants may withdraw without consequences, purpose, procedures, visit schedule, risks and benefits, potential compensation, alternatives to study participation, and confidentiality. Potential participants will be provided an opportunity to ask questions and time to consider his/her decision to participate. A comprehension quiz will be given to BSUD to ensure the participant has an adequate understanding of study. A copy of the consent form will be given to the participant (both BSUD and CHA).

3. **Evaluation of Subject(s) Capacity to Provide Informed Consent/Assent:** Indicate how the personnel obtaining consent will assess the potential subject's ability and capacity to consent to the research being proposed.

   Study personnel will use a multiple-choice consent quiz to assess participants' comprehension of the protocol.

4. **Documentation of Consent/Assent:** Specify the documents that will be used during the consent/assent process. Copies of all documents should be appended to the protocol, in the same format that they will be given to subjects.

   (1) One Page Summary Sheet
   (2) Consent Form
   (3) *Consent Quiz

*BSUD only

5. **Non-English Speaking Subjects:** Explain provisions in place to ensure comprehension for research involving non-English speaking subjects. Translated copies of all consent materials must be submitted for approval prior to use.

   N/A

6. **Waiver of Consent:** Will you request either a waiver of consent, or a waiver of signed consent, for this study? If so, please address the following:

   ☒ **This section is not applicable to this research project**

   Waiver of consent: (No consent form from subjects will be obtained.)

   a. Does the research pose greater than minimal risk to subjects? ☐ Yes ☐ No
   b. Will the waiver adversely affect subjects' rights and welfare? ☐ Yes ☐ No
   c. Why would the research be impracticable to conduct without the waiver?
   d. Where appropriate, how will pertinent information be returned to, or shared with subjects at a later date?

   Waiver of **signed** consent: (Verbal consent from subjects will be obtained.)

   For recruitment/screening purposes, verbal consent will b necessary for initial screening to determine eligibility. In addition, in cases were potential participants may not be literate or can not write, verbal consent—instead of written consent will be obtained.

   ☐ **This section is not applicable to this research project**

a. Would the signed consent form be the only record linking the subject and the research? ☐ Yes ☐ No

b. Does a breach of confidentiality constitute the principal risk to subjects? ☐ Yes ☐ No

OR

c. Does the research pose greater than minimal risk? ☐ Yes ☒ No **AND**

d. Does the research include any activities that would require signed consent in a non-research context? ☐ Yes ☒ No

7. **Required HIPAA Authorization:** If the research involves the creation, use or disclosure of protected health information (PHI), separate subject authorization is required under the HIPAA Privacy Rule. Indicate which of the following forms are being provided:

☒ Compound Consent and Authorization form

☐ HIPAA Research Authorization Form

SECTION IX: PROTECTION OF RESEARCH SUBJECTS

1. **Risks:** Describe the reasonably foreseeable risks, including risks to subject privacy, discomforts, or inconveniences associated with subjects participating in the research.

Psychological risks are minimal and not different from those of equivalent non-study psychotherapeutic interventions.

Computer-based interventions have been used safely in multiple investigations with a range of populations, and we are unaware of any reported risks associated with these interventions.

The data collected from interviews and self-report forms, as well as urine and breath collection, carry minimal risk. Since the project is taking place in a church setting, there is the possible risk of loss of confidentiality. Every effort will be made to keep information confidential; however, this cannot be guaranteed. Further, only the research team will have access to the results of the drug and alcohol tests. The church based health advisors will not see this information.

2. **Minimizing Risks:** Describe the manner in which the above-mentioned risks will be minimized.

The Project Coordinator will supervise the participants' use and understanding of the program closely, and research staff will be available to monitor participants' reactions to the program and to answer any clinical issues.

The web-based intervention is highly secure (annual Security Design Review by Yale Information Technology Services is required). The program does not collect any PHI or specific information regarding recent drug use or illegal activities.

3. **Data and Safety Monitoring Plan:** Include an appropriate Data and Safety Monitoring Plan (DSMP) based on the investigator's risk assessment stated below. (Note: the HIC will make the final determination of the risk to subjects.) For more information, see the Instructions, page 24.

a. What is the investigator's assessment of the overall risk level for subjects participating in this study? Minimal

b. If children are involved, what is the investigator's assessment of the overall risk level for the children participating in this study? N/A

c. Copy, paste, and then tailor an appropriate Data and Safety Monitoring Plan from http://www.yale.edu/hrpp/forms-templates/biomedical.html for
   i. Minimal risk
   ii. Greater than minimal/moderate risk
   iii. High risk

d. For multi-site studies for which the Yale PI serves as the lead investigator:
   i. How will adverse events and unanticipated problems involving risks to subjects or others be reported, reviewed and managed?
   ii. What provisions are in place for management of interim results?
   iii. What will the multi-site process be for protocol modifications?

Overall level of risk for participants is minimal given the nature of this project and procedures in place for careful identification of potential subjects, informed consent process, and protection of confidentiality. We have used the CBT4CBT program successfully and safely in multiple previous trials {Carroll, 2008 #10267; Carroll, 2009 #10266;Carroll, 2014 #11309}.

A Data and Safety Monitoring Board (DSMB) will monitor this project because this population might be considered vulnerable due to their substance use. This board is already in place for the Yale Psychotherapy Development Center (Carroll, Faculty Advisor). The DSMB is composed of Yale investigators who are independent of the proposed trial and experienced in various aspects of the conduct of clinical trials for the treatment of addictive disorders. We have developed a standard DSMB report form that is used in all Center related trials that summarizes, *on a quarterly basis*:

1. Recruitment, retention, and follow-up rates for the study and compares them to target rates.
2. Rates of data completeness and availability of primary outcome data.
3. Occurrence of AEs and SAEs.
4. Report of study progress since the last report.
5. Rates of recruitment of women, minorities, and children with respect to targets.

These reports are generated by the Data Manager each quarter and signed by each study PI prior to their submission to the DSMB. DSMB comments are documented and forwarded to the Yale IRB at the time of the annual review and re-approval.

Because the projected effect sizes may not be large enough for detection during interim analyses, we are not proposing a preliminary analysis of accumulating efficacy and safety data by treatment. Instead, we propose to submit a quarterly report of aggregate data to the DSMB members that contains screening data, baseline demographics, retention data, serious adverse events data, as well as accrual status including projections, times to milestones, and any other data that will help in the assessment of the clinical trial. Based on this report, each DSMB member will complete a form making one of two recommendations: 1) continue recruitment as planned; or 2) schedule formal DSMB meeting immediately. If any DSMB member recommends a meeting, this will be scheduled within one week, minutes will be kept, the report will be reviewed with the PI, and the committee will vote on whether the study should: 1) continue recruitment unchanged; 2) continue with a protocol amendment; 3) stop recruiting pending further investigation. If, after this meeting, any DSMB member votes to stop recruitment or requests a protocol modification, the Yale IRB will be informed.

Participants who experience a significant psychiatric or medical problem requiring an overnight hospitalization at an acute care facility will be considered to have experienced an SAE. In general, most SAEs will result in inpatient care and thus in transfer to the inpatient division of CMHC or YNHH. All SAEs will result in the completion of an SAE Form and a verbal report within one hour to the Principal Investigator (Dr. Jordan). Within 24 hours, the following additional individuals will be informed: 1) All co-investigators; and 2) the DSMB. Adverse events that are serious and unanticipated and probably, possibly, or definitely related or adverse events occurring with greater frequency than anticipated will be reported to the Yale Human Investigation Committee within 5 days of discovery. The procedures for SAE reporting include written documentation using the clinical notes related to the adverse event and specific forms detailing the event with a sign-off by all appropriate supervisory personnel. Communication of recommendations and decisions from all parties (DSMB, Yale Human Investigations Committee, and CMHC Administration) are made back to the investigator in a timely manner. We will report all protocol amendments or changes in the informed consent form to NIDA as well as any temporary or permanent suspension of patient accrual.

4. **Confidentiality & Security of Data:**

a. What protected health information (medical information along with the HIPAA identifiers) about subjects will be collected and used for the research?

PHI that will be collected includes names, addresses, phone numbers, and email addresses for locator purposes.

Our study assessments/forms have been designed to avoid collecting identifiable information (e.g., no PHI identifiers are collected on CRFs). The only dates collected are protocol session dates. These are changed to 'number of sessions completed' when data sets are anonymized and released to other investigators.

b. How will the research data be collected, recorded and stored?

Research data are collected on CRFs and in Qualtrics, and sent to data managers in our research offices on a closed secure network. All computers used by research staff are password protected. No identifying information is on CRFs. Only authorized individuals will have access to CRFs.

c. How will the digital data be stored? ☐ CD ☐ DVD ☐ Flash Drive ☐ Portable Hard Drive ☒ Secured Server ☒ Laptop Computer ☒ Desktop Computer ☐ Other

d. What methods and procedures will be used to safeguard the confidentiality and security of the identifiable study data and the storage media indicated above during and after the subject's participation in the study?

Do all portable devices contain encryption software? ☒ Yes ☐ No

If no, see http://hipaa.yale.edu/guidance/policy.html

Confidentiality in regards to collected materials will be maintained via a numbered reference system maintained by the Project Coordinator. Participants' names will appear only on the consent form, and "key" form kept by the Project Coordinator. The key form linking subject names to ID codes will be stored in a separate, locked file cabinet. Data are stored at our secure data management center; data sets do not include identifying information.

In addition, we have designed all of our CBT4CBT websites such that no sensitive information (i.e., information on illegal behavior) or PHI is collected or stored by the website (including IP address). Moreover, to avoid participants inadvertently revealing sensitive

information, the website does not use any 'blank fills', and the program shuts down after 10 minutes of inactivity.

e. What will be done with the data when the research is completed? Are there plans to destroy the identifiable data? If yes, describe how, by whom and when identifiers will be destroyed. If no, describe how the data and/or identifiers will be secured.

Paper copies of participant records containing ID numbers will be moved to Iron Mountain Archives. Source files with subject names will be stored in the regulatory coordinator's office separately under triple lock (building entry, office entry, separate locked file cabinet designated for name files only). The paper log linking subject names to ID codes will be stored in a separate, locked file in the regulatory coordinator's office. The link to the subjects personal information will be kept for the 1 year follow up period after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form for a minimum of 3 years after the study has ended and then will be destroyed. At the end of the required record retention period, data will be destroyed in accordance with Yale ITS policies 1609 and 1609PR.01. Source data are generally destroyed 3 years after completion of the study at a secure location (Iron Mountain) or by Shred-It.

f. Who will have access to the protected health information (such as the research sponsor, the investigator, the research staff, all research monitors, FDA, QUACS, SSC, etc.)? (please distinguish between PHI and de-identified data)

The Yale PI and the research staff will have access to PHI and coded data. The funding agency, NIDA, may access the data for routine audits.

g. If appropriate, has a Certificate of Confidentiality been obtained?

Obtained

h. Are any of the study procedures likely to yield information subject to mandatory reporting requirements? (e.g. HIV testing – reporting of communicable diseases; parent interview -incidents of child abuse, elderly abuse, etc.). Please verify to whom such instances will need to be reported.

Limits to confidentiality include only disclosure of acute suicidality, homicidality, or abuse of a minor/elder, as is standard in clinical practice and indicated in the consent form. When there is reasonable cause to suspect or believe there is a case of child abuse or elder abuse, a report will be made to the CT Department of Children and Families (DCF) or CT Department of Social Services (DSS), Protective Services for the Elderly (PSE). Designated clinic personnel will be notified as per clinic policies.

6/29/2011SECTION X: POTENTIAL BENEFITS

Potential Benefits: Identify any benefits that may be reasonably expected to result from the research, either to the subject(s) or to society at large. (Payment of subjects is not considered a benefit in this context of the risk benefit assessment.)

The major potential benefit in this study is in reduction of substance use via the study treatments and affirmation of self-identity and spirituality, which may, in turn, foster improvement in participants' legal, medical, interpersonal, psychological and occupational functioning.

SECTION XI: RESEARCH ALTERNATIVES AND ECONOMIC CONSIDERATIONS

1. **Alternatives:** What other alternatives are available to the study subjects outside of the research?

   Individuals who do not wish to participate or who are ineligible for the trial will be given information about substance abuse clinics and mental health centers in the area.

2. **Payments for Participation (Economic Considerations):** Describe any payments that will be made to subjects, the amount and schedule of payments, and the conditions for receiving this compensation.

   BSUD subjects will be compensated for time required to complete screening assessments at $20, baseline assessment at $20, week 4 assessments at $10, study assessments at $10 for each weekly module time point; $50 for completing all modules, and $50 at post-treatment for a possible total of $230.
   CHA subjects will be paid $14.25 per hour by check for the time participated in the project, including time spent in the confidentiality and addiction trainings led by Dr. Jordan, as well as the qualitative interviews. The research team anticipates approximately 86 hours of time in the project, over an 8-12 week time period, for a total of $1,225.50 paid by check.

3. **Costs for Participation (Economic Considerations):** Clearly describe the subject's costs associated with participation in the research, and the interventions or procedures of the study that will be provided at no cost to subjects.

   There will be no costs to subjects associated with participation in this study. Subjects will not be charged for study treatments or evaluations they receive at the clinic.

4. **In Case of Injury:** This section is required for any research involving more than minimal risk.
   a. Will medical treatment be available if research-related injury occurs?
   b. Where and from whom may treatment be obtained?
   c. Are there any limits to the treatment being provided?
   d. Who will pay for this treatment?
   e. How will the medical treatment be accessed by subjects?

   Because we are evaluating standard behavioral approaches with strong empirical support and no known adverse consequences, study related injuries are expected to be extremely rare. There will be no compensation and/or medical treatment available if injury occurs. Participants or their insurance carrier will be expected to cover costs of any medical treatment.

APPROVED BY THE YALE UNIVERSITY IRB 4/8/2019

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