COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE UNIVERSITY SCHOOL OF MEDICINE
DEPARTMENT OF PSYCHIATRY

Title: A pilot feasibility study of providing substance use treatment in the Black Church

Study Sponsor: Yale Center for Clinical Investigation and Learning for Early Careers in Addiction and Diversity (LEAD) funded by National Institute on Drug Abuse. R25 DA035163

Principal Investigator: Ayana Jordan, MD, PhD

Invitation to Participate and Description of Project

You are invited to participate in a research study evaluating a computer-learning program for people with alcohol or drug problems. You have been invited because you are open to seeking treatment for an alcohol or drug problem in a Black church setting.

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

Description of Procedures

This study will last for 8 weeks. If you are willing to participate in the study and sign the consent form, you will be interviewed by a member of the research team and asked to fill out questionnaires, which is a set of many questions. This should take about 1 hour. These questions will include information on your current drug use and drug use history, as well as drug-related problems you may be having. You will also be asked to provide a urine and breath specimen for drug and alcohol testing at this time. Only the research team will have access to the results of the drug and alcohol tests. Not even the church based health advisors will see this information.

You will then be asked to choose a particular day in which to go to the church for treatment. Every group will receive treatment. You will decide what day you will come to the church for treatment. Eight people can come on each day, if the day you select is already full, you will be asked to pick another day. Each participant will be asked to choose <u>one</u> of the following treatment days:

1). Tuesday, Wednesday, Thursday, Friday, or Saturday.

Each treatment day will consist of computer learning at the church. This is the same as the treatment you would normally receive at a clinic, except that we are doing it at the church and there will be praise and worship and scripture reading. You will work with a computerized program that teaches skills for stopping drug use and increasing coping skills, such as how to understand patterns of drug use, how to cope with cravings for drugs, how to refuse offers of drugs, and so on. You will be taught how to use the computer program by a church based health advisor (CHA) and will be asked to spend about 8 hours using the program (approximately one hour per week). Church health advisors (CHAs) will be available at all times while you are using the program at the church, if you have any concerns or questions about the computer program. You will also be given the option to participate in praise and worship and scripture reading before the start of each computer session. You do NOT have to participate in the spiritual or faith-based components added before each computer-learning session day. You will also be asked to complete a brief questionnaire (which is a set of questions) and to provide urine and breath specimens for drug and alcohol each time you come to the church. This will take about 15 minutes each time.

Assessments

At the end of the 8 weeks you will be asked to fill out more questionnaires (which is a set of questions), provide a urine and breath specimen for drug and alcohol testing, and be interviewed again: this will take about 1 hour. Again, these questions will focus on your current drug use and any drug-related problems you may be having. At the end of this part of the study, you may continue treatment at a clinic we refer you to, or if you wish, to be referred for more treatment somewhere you are interested in.

We will ask you to provide the names and telephone numbers of several persons in your life who are likely to know your whereabouts, to help us locate you for interviews. These persons will be contacted only if we cannot locate you directly first; we will ask them only about where we may contact you (we will not ask about drug use or other problems); and we will not tell these persons any information about this study or your participation in it.

Risks and Inconveniences

We believe that there are very few risks to participating in this treatment. Since the project is taking place in a church setting, there is the possible risk of loss of confidentiality, (in other words, someone in the project or at the church may find out you are using drugs and/or alcohol). Every effort will be made to keep information confidential; however, this cannot be guaranteed.

We would like you to tell us about any times you use alcohol or illegal drugs while you are in the study. It is not illegal to report past drug or alcohol use. Also, we know that stopping alcohol or drug use can be quite difficult. In order to be helpful to you, we simply need to know about your alcohol or drug use. The urine drug tests and the breathalyzer tests for alcohol enables us to be certain of our results. Only reThe only way you might be dismissed from the study is if you repeatedly do not come to treatment or violate the rules of this program. We would only ask that you do your best to stop using alcohol or drugs, be honest about yourself and your problems and to be available at your appointment times for both the research staff and your church based health advisor or CHA.

You should be aware that access to the computer learning program called CBT4CBT program, you will be using at the church, is free of charge via wifi, but if you choose to use a

device (phone, tablet, etc.) on a data plan outside of wifi you may accrue billable charges which you will be responsible for.

If you become uncomfortable for any reason or at any time in using the computer program, you should inform your church based health advisor (CHA), the Project Coordinator, or Dr. Jordan immediately.

Benefits
This program may help you control your drug use; however, there is no guarantee that you will benefit from participating in this program. If the computer program given in a different setting like the Black church is shown to be an effective treatment for alcohol or drug use, it may help other Black people with drug and alcohol problems stop taking drugs.

Economic Considerations

You will be paid $20 cash for completing screening, $20 cash for completing the questionnaires (set of questions) at pretreatment, $10 in cash for completing week 4 assessments, $10 in cash for completing each module during the 8 weeks of the study (thus a total of $80 for treatment part of the study), and $50 cash at the end of study (week 8). If you complete all of the computer modules you will also get a $50 bonus in cash. Therefore, if you complete every component as scheduled you would be paid a total of $230.

If you leave the study prior to completing it, you will be paid only for those assessments you have completed.

Subject Compensation Schedule

Activity	Compensation Available	Form of Payment
Screening	$20	Cash
Pretreatment	$20	Cash
Week 4 assessments	$10	Cash
Completing modules during 8 weeks	$80 Total (@ $10 a session)	Cash
Completing all modules	$50	Cash
Post (end of study, week 8)	$50	Cash
Total Available	$230	

Alternative Treatments

You are free to choose not to participate, and if you do become a participant, you are free to withdraw from the study at any time. If you withdraw it will not adversely affect your relationship with this university, future studies related to Dr. Jordan, or other research studies.

Investigator Conflict of Interest

The Principal Investigator of this study, Ayana Jordan, MD, PhD, has not been involved in the development, creation and testing of the CBT4CBT program. Therefore, she has no financial interest in the CBT4CBT program. However, Kathleen Carroll, PhD, who is a Co-Investigator on this protocol, has been involved in the development, creation and testing of the CBT4CBT program. Therefore, she has a financial interest in the CBT4CBT program. This will not affect your treatment here or use of this program. If you have any questions or

concerns regarding Dr. Carroll's financial interest you are encouraged to contact Dr. Carroll at (203) 737-1544 or the Human Research Protection Program (HRPP) office of Yale University at (203) 785-4688.

In case of injury

If you develop any mental or physical problems as a direct result of being in this study, we will refer you for treatment. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. Your legal rights are not waived by signing this consent form.

Confidentiality and Privacy

If you decide to take part in this research study, you will be required to give us information about your drug use. Any of your identifiable information that is obtained in connection with this study will remain confidential and will not be disclosed or told to someone else, only with your permission, with the following exceptions: We will disclose to appropriate authorities, if you become a danger to yourself or others. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity, unless your specific consent (or permission) for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the research staff and church based health advisor or CHA will get information that identifies you and your personal health information, however 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.
This may include information that might directly identify you, such as your name and address. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The church based health advisors that you will meet with every week will also go through specialized training about how to protect your confidentiality and how to keep all information private during the entire research process.

The principal investigator, Ayana Jordan, MD, PhD. will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. All personal information will be coded and stored in a locked cabinet and any data stored on a computer will be password protected to further protect your confidentiality. The research team will only give this coded information to others to carry out this research study. The link to your 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.

The information about your health that will be collected in this study includes:

- Past and present medical records

- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Information obtained during this research about:
- Laboratory test results
- The diagnosis and treatment of a mental health condition

Information about you and your health, which might identify you, may be given to
- Yale New Haven Hospital
- Yale University School of Medicine
- National Institute of Health (NIH), Yale Center for Clinical Investigation (YCCI), Learning for Early Careers in Addiction and Diversity (LEAD), The research sponsors
- Members of the Human Investigations Committee or ethics Committee(s)
- Key Investigators
- Key Study Personnel
- Data and Safety Monitoring Board and others authorized to monitor the conduct of the study

By verbally saying yes or signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing or giving permission is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at Yale School of Medicine and Yale New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. The church based health advisors or CHAs are not subject to HIPAA, but by agreeing to be apart of the study, they agree to keep all information confidential. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

The research team can only give information about you to others for research with your permission. We will make every effort to insure your confidentiality. In all records of the study you will only be identified by a number. Your name will not appear in any publication or be released to anyone without your written consent. However, you should understand that there is a risk that you will be recognized by other participants or staff involved in the study. If you find this risk unacceptable you should not say yes or sign this consent form.

If you decide to take part in this research study, you will be required to give us information about your drug use and we will test you for drug use. We have a Certificate of Confidentiality (CoC) issued by the NIH. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena, meaning a document that states one has to show up for court. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a participant's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities.
Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for anyone to receive information about your participation in the research, then we may not use the CoC to withhold this information.

Voluntary Participation

You are free to choose not to participate, and if you do become a participant, you are free to withdraw from the study at any time. If you withdraw, it will not adversely affect your relationship with the university, the church or future studies. If you decide to withdraw, at your request, we can refer you to a clinic or doctor who can offer treatment.

Withdrawing From the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team, or tell your church based health advisor or CHA at any time that you no longer want to take part. This will cancel any future appointments

The research team may withdraw you from participating in the research if necessary only for not coming in for treatment or if you show signs of clinical deterioration, like you're not looking good and your health status worsens and need more intensive or more serious care. Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Yale-New Haven Hospital or with the church.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff, the church based health advisors or CHAs or by writing to Dr. Ayana Jordan, MD, PhD at Connecticut Mental Health Center, 34 Park Street, Room W203, New Haven, CT 06519. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight (make sure we are honest about everything that happened during the study).

Questions

Please feel free to ask about anything you do not understand and please consider this research and the consent form carefully before you decide whether or not to participate. You may take as much time as necessary to think it over.

SUMMARY

This is a study looking to see if the Black church is a good way to increase access to treatment we know that works for drug and alcohol problems among Black adults with drug and alcohol problems, by providing treatment in non-traditional settings of care, like the Black church. We want to see if using a computerized system, which teaches coping skills, and adding spiritual practices like prayer, praise and worship and scripture reading is an acceptable way to receive care for Black adults. Individuals who participate will select a different day of the week Tuesday-Saturday, and will receive treatment at the church on that day, each week with the same church based health advisor. Every participant will use a computer system in the church and will work with the computer system about one hour each week at the church.

The study will last eight weeks. You will be asked to complete some forms and answer some questions before beginning treatment (this will take about 1 hour), each time you come to the church (this will take about 15 minutes each time), and at the end of the 8 weeks (this will take about 1 hour).

Authorization and permission:

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

Name of Subject: _____

Signature:_____

Date:_____

Witness (when applicable): _____

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the principal investigator, Ayana Jordan, MD, PhD at 203-974-7238 or email Jordan.wellness@yale.edu. If you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688.

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203/432-5919.