COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE and
YALE-NEW HAVEN HOSPITAL and
CONNECTICUT MENTAL HEALTH CENTER
The Hispanic Clinic
The Substance Abuse Treatment Unit (SATU)
The Multi-Cultural Ambulatory Addiction Services (MAAS)
Midwestern Connecticut Council on Alcoholism (MCCA)
Cornell Scott - Hill Health Center.

Study Title: Computer Based Training in CBT for Spanish-Speaking Alcohol Users

Principal Investigator (the person who is responsible for this research):
Manuel Paris, PsyD
34 Park Street
New Haven, CT 06511
Phone Number: 203-974-5819

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to evaluate a computer learning program for people with alcohol use problems. You have been invited because you are seeking treatment at this clinic for a problem with alcohol use.
- Study procedures will be conducted virtually via Zoom or phone or in-person and will include: If you are willing and eligible to participate in the study and sign the consent form, you will be interviewed by a member of the research team, asked to fill out questionnaires (this should take about 1 hour), and agree to provide a breath and urine specimen for alcohol and drug testing to the clinic who will share results with the research team. These questions will include information on your current alcohol and drug use and alcohol and drug use history, as well as any alcohol-related problems you may be having. If you are found eligible for this study you will then be assigned to one of two treatments explained in detail below.
- 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 week (this will take about 15 minutes each time), and at the end of the 8 weeks (this will take about 1 hour). We will contact you for follow-up interviews at 1 month, 3 months, and 6 months after you finish the study, and these interviews will take about 1.5 hours each time.
- There will be 8 study “visits” or timepoints that are required plus 3 study “visits” or timepoints during follow up.
- You will be provided with a tablet including a data plan for the duration of the 8 weeks of the active study. You may choose to keep the tablet instead of weekly payments or return the tablet in good, working and damage-free condition as explained below.
- There are some risks to participating in this study. There is the possibility of the loss of confidentiality from participation in this study that are explained below. We will make every effort to minimize this risk.
- The study may have no direct benefits to you.

- There are other choices available to you outside of this research. Participating in this study is voluntary. If you choose not to participate you will be referred to the regular evaluation and intake procedures and will receive treatment as usual at this clinic.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?
We are asking you to take part in a research study because you are seeking treatment at this clinic for a problem with alcohol use. We are looking for 90 participants to be part of this research study.

Who is paying for the study?
National Institute on Alcohol Abuse and Alcoholism (NIAAA)

What is the study about?
The purpose of this study is to look at the effects of using a computerized program, which teaches coping skills in Spanish, versus usual treatment at this clinic.

What are you asking me to do and how long will it take?
If you agree to take part in this study, this is what will happen: The main part of this study will last for 8 weeks, with follow-up visits one month, three months, and six months after the end of the treatment part of the study. All study procedures will be conducted virtually via Zoom or phone or in-person. 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, asked to fill out questionnaires (this should take about 1 hour), and provide a breath and urine specimen for alcohol and drug testing according to the clinic schedule. By signing this form you give permission for the research team to access your urine and breath test results. These questions will include information on your current alcohol and drug use and alcohol and drug use history, as well as any alcohol-related problems you may be having.

If you are found eligible for this study you will then be assigned to one of two treatments. We will decide what treatment you will receive by random selection. This means that your treatment will be decided by luck of the draw and not selected deliberately because of any special characteristics or problems you have. Each participant will be assigned by random selection to one of the two following treatments:

1. Standard treatment as usual (TAU)

This is the same as the treatment you would normally receive at this clinic. This will be tailored to your needs, but generally includes individual and group therapy sessions and regular urine monitoring. Sessions will generally last for 1 hour one time per week for 8 weeks and include issues such as:

• Teaching about the treatment program

• Teaching you important ideas about recovery
• Increasing your knowledge about specific problems you may have about your addiction
• Demonstrating new ways of coping with skills designed to fit your lifestyle.

You will also be asked to complete a brief questionnaire about your alcohol use in the past week either virtually or in-person with the Research Assistant and to provide breath and urine specimens for alcohol and drug testing one time each week or per clinic schedule. The urine samples will be collected by the clinic and results will be shared with research staff.

OR

2. Standard treatment as usual (TAU) PLUS web-based CBT4CBT

This is the same as the treatment described above, but in addition you will be able to access the CBT4CBT website in Spanish as an add-on to treatment. In this treatment you will work with a computerized program that teaches skills for stopping alcohol use and increasing coping skills, such as how to understand patterns of alcohol use, how to cope with cravings for alcohol and, how to refuse offers of alcohol, and so on. You will be taught how to use the computer program by a staff member and will be asked to spend about 8 hours using the program (approximately one hour per week) at the clinic or at home. Staff will be available at all times while you are using the program at the clinic if you have any concerns or questions about the computer program. You will also be asked to complete a brief questionnaire about your alcohol use in the past week virtually or in-person with the Research Assistant and to provide breath and urine specimens for alcohol and drug testing per clinic schedule.

All eligible participants will receive a tablet including a data plan for the 8 weeks of the active part of the study. It is expected you will use the tablet for virtual meetings with the research assistant and viewing the web-based CBT4CBT if assigned to that treatment. You will receive the tablet either from your clinician at this clinic or by mail. You will be asked to decide when signing this consent form if you choose to keep the tablet as a form of payment for your weekly sessions valued at $200 **or** return the tablet in good, working and damage-free condition either to your clinician or by mail in a prepaid envelope provided to you by the study and then receive up to $200 ($25 per week for sessions completed) for your participation. At the end of the 8 weeks the data plan will be turned off.

If you choose to keep the tablet at the time of signing this consent form and the tablet then is lost, broken, stolen or otherwise damaged you cannot then decide to take the payment of up to $200.

It is expected you will take care of the tablet provided and use it responsibly. It is expected you will not use, retrieve, store, or send improper language, pictures, or other digital content including but not limited to illegal content. This tablet will be assigned to you and if you do not abide by this user agreement you will be held responsible.

Assessments and Follow-ups

At the end of the 8 weeks you will be asked to fill out more questionnaires, provide a breath and urine specimen for alcohol and drug testing as outlined above, and be interviewed again. This interview will be conducted virtually via Zoom or phone or in-person. This will take about 1 hour. Again, these questions will focus on your current alcohol use and any alcohol-related problems

you may be having. At the end of this part of the study, you may continue treatment at this clinic, or if you wish, be referred elsewhere or leave treatment.

We will contact you by telephone, mail or text one, three and six months after you leave the study and ask you to schedule a brief interview, to fill out questionnaires, and to provide a urine and breath specimen for drug and alcohol testing if you are still enrolled in the clinic. This will take about 1½ hours each time.

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 the follow-up 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 alcohol or drug use or other problems); and we will not tell these persons any information about this study or your participation in it. We would also ask you to provide your email and/or account username on websites such as Facebook as another way to keep in contact with you during the study. We will ask for other similar information that may be used in conjunction with public databases to locate you.

What are the risks and discomforts of participating?

We believe that there are very few risks to participating in this treatment. 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 substance use. Also, we know that stopping substance use can be quite difficult. In order to be helpful to you we simply need to know about your substance use. The urine drug tests and the breathalyzer tests for alcohol enables us to be certain of our results. The only way you might be dismissed from the study is if you repeatedly do not come to treatment or violate the rules of this clinical program. We would only ask that you do your best to stop using alcohol and drugs, be honest about yourself and your problems and to be available at your appointment times for both the research assistant and your counselor.

If you decide to be in this study, the researcher will get information that identifies you and your personal health 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 principal investigator, Manuel Paris, PsyD 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

A risk to this study is the possibility of the loss of confidentiality. We will make every effort to minimize this risk. The web-based intervention is highly secure, and ***does not collect any PHI identifiers nor specific information regarding illegal activities,*** and has passed stringent Yale Information Technology Security Design Review (September 2011). It is accessible only through a username/password system monitored by Yale staff. Moreover, the design of the CBT4CBT program has closely followed recommended ethical and safety guidelines for use of computer assisted behavioral therapies developed by Sampson and Pyle, including (1) assurance of confidentiality, (2) determination of appropriateness of the specific form of training, in this case, CBT, which has been shown to be effective for a wide number of substance use disorders and populations, (3) adequate introduction to the computer program by staff to reduce possible anxiety about use of the system, (4) provision of follow-up consultation with a clinician if needed, and (5) supervision of the treatment process by a clinician.

If you become uncomfortable for any reason or at any time in using the computer program, you should inform your counselor, the Project Coordinator, or Dr. Silva or Dr. Paris immediately.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?
There is no direct benefit from participating. This program may help you control your alcohol use; however, there is no guarantee that you will benefit from participating in this program. The major potential benefit in this study is in reduction of alcohol use via the study treatments, which may, in turn, foster improvement in participants' legal, medical, interpersonal, psychological and occupational functioning.

How can the study possibly benefit other people?
The benefits to science and other people may include a better understanding of alcohol use disorders, may help other alcohol users stop drinking and may provide a general advancement of scientific knowledge.

Are there any costs to participation?
You will not have to pay for taking part in this study. The only costs include transportation and your time coming to the study visits.

Will I be paid for participation?
You will be paid for taking part in this study for each of the activities you complete as listed below.

Activity	***Compensation Available***	***Form of Payment***
Baseline Assessments	$40	Gift Card
Active Sessions (1x/wk for 8 weeks) **OR** Keep provided tablet	$200 Total (@ $25 a session) Valued at $200	Gift Card Tablet
Post (end of study, week8)	$50	Gift Card
Follow up 1 Month	$50	Gift Card
Follow up 3 Months	$75 ($50+ $25 bonus if completed on schedule)	Gift Card
Follow up 6 Months	$100 ($75+ $25 bonus if completed on schedule)	Gift Card
Total Available	$515	

You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What are my choices if I decide not to take part in this study?
Instead of participating in this study, you have some other choices. You could continue to get treatment at this clinic without being in a study.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person. Any of your identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission, with the following exceptions: We will disclose to appropriate authorities any reportable diseases, known or suspected abuse of a child or elderly person, or 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 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 researcher will get information that identifies you and your personal health 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 principal investigator, Manuel Paris, PsyD 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.

All Zoom conversations are conducted on secure and encrypted computers.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research but we will not use your name or other identifiers. All identifiers will be removed from your private information. Your information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. We will not ask you for any additional permission.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIAAA which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of such as child abuse and neglect, or harm to self or others.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Past and present medical records
- Medical and laboratory records of only those services provided in connection with this study.
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Laboratory, x-ray, and other test results
    - Diaries and questionnaires
    - The diagnosis and treatment of a mental health condition
    - Use of illegal drugs or the study of illegal behavior

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- National Institute of Health (NIH) who are the research sponsor
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Health care providers who provide services to you in connection with this study.
- Connecticut Mental Health Center (CMHC)
- The Hispanic Clinic
- The Substance Abuse Treatment Unit (SATU)
- The Multi-Cultural Ambulatory Addiction Services (MAAS)
- Midwestern Connecticut Council on Alcoholism (MCCA)

- Cornell Scott - Hill Health Center.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. 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.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Manuel Paris, PsyD; 34 Park Street; New Haven, Ct 06511.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

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.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary. Reasons for withdrawl may include your alcohol use getting continually worse so that you need more intensive care and non-compliance of research requirements as described above.

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.

What will happen with my data if I stop participating?

If you sign this authorization, you may change your mind at any time, but the researchers may continue to use information collected before you changed your mind to complete the research. To withdraw, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any appointments in the future.

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 or by writing to Manuel Paris, PsyD; 34 Park Street; New Haven, CT 06511.

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.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator, Manuel Paris at 203-974-5819

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Please check one of the following:
I choose to: Keep the tablet provided by the study as payment for weekly assessments _____

OR

I choose to return the tablet provided by the study in good working and damage-free condition as outlined above and receive up to a total of $200 for the weekly sessions I completed. _____

Participant Printed Name	Participant Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date