DIGITAL INTERVENTIONS TO TREAT HAZARDOUS DRINKING

NCT04890652

INFORMED CONSENT FORM

VERSION DATE 3/17/2023

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: **Effects of Stress on Emotion and Risky Drinking**

Principal Investigator (the person who is responsible for this research):
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Phone Number: 475-441-3457

Funding: National Institute on Alcohol Abuse and Alcoholism; Yale Psychiatry Research Initiative Account

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to examine the effects of an intervention focused on building coping strategies, stress management, and breathing modulation on regulating symptoms of mood and addiction.
- Study procedures will include: 4-5 intake assessments, 4-week (2 sessions per week; a total of 8 sessions) intervention, 1 post-assessment, and daily smartphone app surveys during the study period (4-week intervention and 30 day follow-period).
- Approximately fourteen to fifteen (14-15) appointments are required, and each of the appointments will last about 2 hours.
- These appointments will take twenty-eight to thirty (28-30) hours total.
- There are minimal risks from participating in this study. Online assessments, telehealth intervention and smartphone app surveys are generally benign.
- The study may have no benefits to you. There are benefits to society, which would result from increased knowledge about how stress intervention affects mental health problems including alcohol use.
- There are other choices available to you outside of this research. You may be able to enroll in a similar stress regulation or exercise information session outside of this study. If you wish to enroll in one of these alternative programs, research staff will help you locate one.
- 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.
- You might be in an intervention group or a control group, and you will not know which group you are in until the end of the study.
- 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.
- Upon the completion of all study procedures, we will share all the information about how you did in the study.

Why is this study being offered to me?

We are asking you to take part in a research study because you have reported some health problems including drinking problems, stress, or emotional difficulties, or because you are healthy individuals seeking to learn self-regulation and coping strategies. We are looking for 110 participants to be part of this research study.

Who is paying for the study?
National Institute on Alcohol Abuse and Alcoholism; Yale Psychiatry Research Initiative Account

Who is providing other support for the study?
There is no other support for the study.

What is the study about?
The purpose of this study is to examine the effects of an intervention focused on building coping strategies and stress management on voluntarily regulating mood and addiction related symptoms. Participants are encouraged to develop emotion regulation strategies and build healthy coping styles through the intervention sessions.

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: You will participate in baseline assessments (2-3 weeks), 4-week intervention, and a 30-day smartphone follow up. Study procedure will be conducted remotely through REDCap, a secure HIPAA (Health Insurance Portability and Accountability Act)- compliant web application, and Yale ITS approved secure video communications technology (e.g., Zoom).

Study Timeline:
1. Intake (4-5 appointments)
2. 4-week intervention (2 appointments each week; 8 sessions total) with daily monitoring smartphone app survey
3. Post-assessment (1 appointment)
4. 30-day smartphone app follow-up (daily survey; no appointments)
5. Post evaluation (1 appointment)

You will be asked to keep information from other participants in this study private until the end of the treatment to assure objective response from other participants.

Detailed Description of Procedures:

Intake
If you agree to participate in this study, you will be asked to complete 4-5 intake appointments. Each appointment takes approximately 2 hours to complete. Depending on the individual speed completing the assessments, intake appointments will take either four or five sessions. During these appointments, we will ask you questions and ask you to complete assessments about your mood and stress levels, substance use, demographics and health history.

4-week intervention
During the 4-week intervention, you will be asked to participate in an 8-session intervention (two sessions per week) involving building coping strategies, stress management and breathing modulation. This session can be also be done remotely via video communications. Each session will take 2 hours. You will also be asked to use a smartphone app daily to assess intervention progress and learn coping skills. During your sessions, you will work with the study

team to increase your knowledge on stress, emotion, and addiction, to learn stress modulation skills, and to apply coping strategies to various challenges in life.

Post-Assessment
After completing the 4-week intervention, you will participate in a post-assessment appointment (approximately 2 hours) where you will be asked to fill out some questionnaires about mood, stress, and substance use related behaviors.

Smartphone app survey
We will assist you in installing an app on your smartphone device which you will use to report your daily experiences. You will be asked to use this app over the study period (intervention and 30-day follow-up). The app will prompt you to respond once daily in the evening. You will be answering each question related to mood, stress, and substance use by responding to interactive questions on the app, and the process takes around 10-15 minutes depending on individual speed.

Post-Evaluation
At the end of the 30-day survey period, you will have a remote session with a staff for post-study assessments and be remotely instructed on how to uninstall the app from your smartphone.

What are the risks and discomforts of participating?

Online Assessments
Online questionnaires are all noninvasive and should add no risk. The major disadvantages are the time taken to complete them and possible breach of confidentiality. For this procedure, we ask you to complete the online assessments when you are alone in a private space. To protect your confidentiality, your name will not be recorded in the online assessments. Instead, you will be identified by a study ID number.

Intervention
Participation in the study intervention is completely voluntary. If you feel uncomfortable at any time during the intervention, supportive counseling can be provided with a clinician and/or knowledgeable support staff, and you are free to choose not to take part in the intervention. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (i.e., healthcare benefits).

Use of the Smartphone App to Complete Assessments
You will be provided with a smartphone app on which you will report on your experiences, feelings, and behaviors. You may feel self-conscious while completing surveys about yourself on the phone. Your responses will be linked to a numbered ID so that they can be paired in our analyses, but do not ask for information that would identify who the responses belong to. These responses will be wirelessly transferred to a secure server that is password-protected. All participants are encouraged to use their smartphones. However, if it is lost or broken, please contact our research staff for the possibility of providing a smartphone.

Subject Obligation
We ask that you stay abstinent from any drugs or medicines, including over the counter medicines, street drugs, or alcohol, for 24 hours prior to your online assessment and telehealth intervention appointments during the study. If you do use any drugs or other medicines during this time, you must inform us of any information regarding your substance or drug use. Your honest response is highly important in this study. The only way you might be withdrawn from the

study is if you repeatedly do not show up for appointments and/or are not honest with us about your substance or drug use. For women participants, you will not be allowed to take part in the study if you are pregnant.

Most study procedures will be conducted remotely, but in-person appointments will also be available if participant resides locally and does not have a PC or internet access. In this case, we strictly adhere to the safety guidelines approved by the Yale Human Subject Research Committee in response to the COVID-19 epidemic.

Safety guidelines in response to the COVID-19 epidemic

To limit exposure to COVID-19, in-person meetings will be avoided as much as possible. If one-on-one meetings must be held in person, the following guidelines will be carried out.

Before any study visits, you will be screened for COVID-19 symptoms by filling out the COVID-19 questionnaires prior to the study visit and at the time of the on-site study visit.

You will be asked to fill out YSC safety questionnaire for YSC visits. If you say “yes” to any of the COVID-19 related symptom questions, your appointment will be moved to a later date, and you will be encouraged to contact the YNHH COVID-19 Support Call Center (203-688-1700 option1).

For your safety, the study site will be disinfected before and after each study visit based on CDC guideline. The measurements of temperature and oxygen saturation levels will be taken for both you and research personnel with a non-contact forehead thermometer and a pulse oximeter. If temperature is greater than 99.5 degrees Fahrenheit, you will be asked to leave and seek medical attention. If oxygen saturation is below 95%, you will not be allowed to participate in research appointment.

During in-person visits, both you and research staff will be asked to maintain the required distancing (6 feet) and wear a face mask. You are also required to properly wash your hands with alcohol-based hand sanitizer (containing at least 60% alcohol) or soap and water in protecting against the spread of germs and viruses. In case you do not have proper masks to wear, a mask and glove will be provided on-site study visits.

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?
This study is not designed to be of direct benefit to you. However, learning stress reduction, monitoring substance use, and participating in the breathing exercises may be helpful to some participants.

How can the study possibly benefit other people?
The benefits to science and other people may include a better understanding of how stress and emotion regulation affect and address mental health issues.

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 up to **$778**.

Baseline assessment
You will receive up to **$100**for completing baseline intakes study procedure. You will receive $20 for completion of each 2-hour remote intake appointment (4-5 intakes; total up to $100).

4-week Intervention
You will receive up to **$488** for completing the study procedure related to 4-week intervention for treatment sessions, smartphone app surveys and post-treatment evaluation.

Treatment sessions: You will receive up to $200 including $20 for per session (two sessions weekly; 8 sessions in total (8 x $20 = $160) and bonus. An additional $20 bonus will be rewarded for the completion of all treatment sessions every 2 weeks of treatment during the 4-week treatment period.

Smartphone surveys: You will also receive up to $248 for the completion of a 28-day daily smartphone app surveys including $3 for each daily intervention exercise (28 x $3 = $84), smartphone monitoring survey (28 x $3 = $84), and weekly bonus. You will receive an **additional weekly bonus** of **$20 for completing 100%** (**14/14 surveys;** per week), **$18 for completing at least 92.5% (13/14 surveys**; per week) or **$16 for completing at least 86% (12/14 surveys** per week) of the surveys in each week. Both the daily evening survey and daily intervention exercise must be completed for a day to count towards the weekly bonus.

Post-assessment: At the end of treatment, you will also receive $40 for a post assessment at the end of 4-week intervention.

Follow-up evaluations
You will be compensated for your time up **to $190** for 30-days follow-up after treatment. For daily monitoring follow-up assessments, you will be paid $3 for daily survey over 30 days (30 x $3 = $84). You will also receive additional $20 biweekly bonus for completing at least 100% (14 out of 14 surveys), $15 for 90% (13 out of 14 surveys), and $10 for 80% (12 out of 14 surveys) of every 14-day survey. Additionally, you will also receive $60 for a video session and completing online evaluation assessments at the end of the 30-day follow-up period.

Therefore, the total that you may be reimbursed for your time if you complete the study, attend all 8 treatment sessions and a 100% completion rate for the smartphone surveys, is **$778**

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. According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income.

For your participation in this study, you will receive payment(s) via a Bank of America pre-paid debit card. Please note that your name, address, and telephone number will be shared with Bank of America for ePayments. After your first payment milestone you will receive a card in the mail which you will need to activate over the phone, any subsequent milestones payments will automatically add additional funds to your card.

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:

- Get treatment without being in a study. You may be able to enroll in a similar stress regulation information session outside of this study. If you wish to enroll in one of these alternative programs, research staff will help you locate one.
- Take part in another study.
- Receive comfort care only, without any treatment for your health problems.

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 identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. All information collected on you will be kept in a locked cabinet or password protected on a computer. 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 date of birth. 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 will keep a link that identifies you to your coded information, and this link will be kept secure and available only to selected members of the research team. Any information that can identify you will remain confidential. 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 five years, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely until it is destroyed.

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. We will not ask you for any additional permission.

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
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Laboratory test results
    - 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
- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Principal investigator, Co-Investigators and other investigators
- Study Coordinator and members of the Research Team
- The Data and Safety Monitor 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.

If you decide to take part in this research study, you will be required to give us information about your substance use. We obtained a Certificate of Confidentiality (CoC) issued by the NIH. This means that 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. 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. When the CoC is obtained, we will inform all active study participants.

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.

NIAAA Data Archive (NIAAA$_{DA}$)

Data from this study will be submitted to the National Institute on Alcohol Abuse and Alcoholism Database (NIAAA$_{DA}$) at the National Institutes of Health (NIH). NIAAA$_{DA}$ is a large database

where deidentified study data from many NIAAA studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about alcohol problems more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the $NIAAA_{DA}$. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your deidentified data does have some risks, although these risks are very rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with $NIAAA_{DA}$. The study data provided to $NIAAA_{DA}$ may help researchers around the world learn more about alcohol problems and how to help others who have problems with alcohol. NIAAA will also report to Congress and on its website about the different studies using $NIAAA_{DA}$ data. You will not be contacted directly about the study data you contributed to $NIAAA_{DA}$.

You may decide now or later that you do not want your study data to be added to the $NIAAA_{DA}$. You can still participate in this research study even if you decide that you do not want your data to be added to the $NIAAA_{DA}$. If you know now that you do not want your data in the $NIAAA_{DA}$, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to the $NIAAA_{DA}$, call or email the study staff who conducted this study, and they will tell $NIAAA_{DA}$ to stop sharing your study data. Once your data is part of the $NIAAA_{DA}$, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about $NIAAA_{DA}$, this is available on-line at https://nda.nih.gov/niaaa.

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 Dongju Seo PhD at the Yale Stress Center, 2 Church Street South, Suite 209, New Haven CT 06519.

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 ensure 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 are injured while on study, seek treatment and contact the study doctor as soon as you are able.

The Yale School of Medicine do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. 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.

You do not give up any of your legal rights by signing this 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. This will cancel any future appointments.

The researchers may withdraw you from participating in the research if necessary, such as if you repeatedly do not show up for appointments or are found ineligible for the study.

What will happen with my data if I stop participating?

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 ensure 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 at 475-441-3457 or email at dongju.seo@yale.edu.

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.

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.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date