

**COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION
IN A RESEARCH STUDY****YALE UNIVERSITY****Study Title:** Piloting a novel social support intervention for addiction recovery**Principal Investigator (the person who is responsible for this research):** Li Yan McCurdy, PhD; 1 Church St, 7th floor, New Haven, CT 06510**Research Study Summary:**

- We are asking you to join a research study.
- The purpose of this research study is to test whether using a web-based intervention is feasible, acceptable and helpful for people who engage in hazardous drinking trying to cut down or quit drinking.
- Study activities will include: using the intervention for a few minutes each night for one month, and filling in questionnaires about who you are, your drinking habits, and your support network.
- Your involvement will require 5.5 hours in total over the course of approximately 1 month.
- There may be some risks from participating in this study. There may be breaches of your confidentiality, however this is unlikely. You may feel upset when answering questions about yourself, but you will be able to skip any questions you do not want to answer.
- The study may benefit you. As part of this study, you will receive encouragement and information that may help you cut down or quit drinking.
- 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 will not have any effect on your relationship with Yale University.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. 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 an adult in Connecticut who engaged in hazardous drinking in the past year and have some desire to cut down or quit drinking. We are looking for 30 participants to be part of this research study.

Who is paying for the study?

This study is paid for by the Society of Addiction Psychology, which is a part of the American Psychological Association.

What is the study about?

The purpose of this study is to test whether using a web-based intervention is feasible, acceptable and helpful for people who engage in hazardous drinking trying to cut down or quit drinking. The goal is to create a freely-available resource that provides daily motivation and information to help people in early recovery reach their recovery goals.

What are you asking me to do and how long will it take?

If you agree to take part, your participation in this study will involve 1) filling in questionnaires about who you are, your drinking habits, and your support network, 2) using the intervention for a few minutes each night for a month (which entails answering whether you reached your

recovery goal for the day, and receiving information and encouragement to support your recovery), and 3) filling in the same questionnaires at the end of the intervention, and again one month later. We think that the study will take a total of 5.5 hours of your time.

Are there any risks from participating in this research?

If you decide to take part in this study, there are some risks. This intervention is focused on alcohol use, which some may find upsetting to think about. While unlikely, you may feel distress when using the intervention or filling in questionnaires. To prevent this, the intervention is carefully designed and monitored to ensure nothing distressing will occur, and you can skip any questions for any reason. There may be breaches of your confidentiality. However, this is unlikely as all data you will provide will not have your personal information attached to it. We do not expect any physical risks from taking part in this study.

How can the study possibly benefit me or others?

You may benefit from taking part in this study. When using the intervention, you will receive supportive and motivating videos and/or information about recovery support services each night for a month, which may keep you motivated in your recovery as well as decrease barriers to these recovery services. Taking part in an intervention study that may improve treatment outcomes for others with alcohol use issues may be considered a benefit. This study will also provide important evidence as to whether this intervention may be helpful for individuals who engage in hazardous alcohol use.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only cost may be your time participating in this study.

Will I be paid for participation?

You will be paid for taking part in this study. You will receive a \$30 gift card for filling in questionnaires at the start of the intervention. You will receive \$2/night for clicking on the intervention link and completing the activities, or \$15/week if you do it on all nights on weeks 1 and 3 of the intervention, so you may receive a maximum of \$30 for using the intervention. (You will receive this as one lump sum at the end of the intervention.) You will receive a \$30 gift card for completing questionnaires at the end of the intervention, and another \$30 gift card for completing the same questionnaires one month later. In total, you may receive up to \$120 in gift cards for participating in this study. Taxes are not withheld from your payments. According to the rules of the Internal Revenue Service (IRS), payments for taking part in a study may be considered taxable income.

How will you keep my data safe and private?

All of your responses will be held in confidence. Only the researchers involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, the Yale University Institutional Review Boards, and others) will have access to any information that could identify you that you provide. 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 we learn that you are hurting a child or an older person.

Data will be stored on password-protected, Yale-managed computers. All questionnaire data and data about how often you used the intervention will be linked to your participant ID and not your identifying information like your name. Your identifying information will not be stored in the same file as your data.

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.

Identifiers might be removed from the identifiable private information, and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

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
- Information obtained during this research regarding
 - How often you use the intervention
 - Information on your alcohol and other drug use and other behaviors when using the intervention and from filling in questionnaires.

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 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.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

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.

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 Society of Addiction Psychology 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, for example child abuse and neglect, or harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, for example your answers on questionnaires.

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 Li Yan McCurdy at liyan.mccurdy@yale.edu or LDART@yale.edu

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.

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 will not have any effect on your relationship with Yale University.

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 email the Principal Investigator at liyan.mccurdy@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 Documentation of Consent

Your signature below indicates that you read and understand this consent form and the information presented and that you agree to be in this study.

We will email you a copy of this form.

Participant Printed Name _____ Participant Signature _____ Date _____

Person Obtaining Consent Printed Name _____ Person Obtaining Consent Signature _____ Date _____

Participant email address: _____

If you decide not to consent, would you be willing to tell us why?

- Time commitment: one month is too long
- Time commitment: every night is too frequent
- Don't like the idea of watching videos of people in my community
- Am concerned about confidentiality/privacy, that my data will be leaked
- Others: _____

I consent to being emailed by the study team about participating in a 30-minute interview about my experiences in this study, for which I would receive a \$20 gift card. YES/NO