University of Rochester Medical Center
300 Crittenden Blvd. – Box PSYCH
Rochester, NY 14642 USA

CONSENT FORM

Study title: The association between loneliness and substance use

Principal Investigator: Lisham Ashrafioun, PhD

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you identify feeling alone or lonely at times and report using substances
- The purpose of this study is to better understand how feeling alone or loneliness and drug use may be related to one another. We will be looking to see if two different approaches can have an impact on feeling alone or loneliness and drug use. This information will help us to better understand how to reduce feeling alone or loneliness and drug use.
- Your participation in this study will last approximately 4 months.
- Procedures will include (1) completing a set of questionnaires, (2) taking part in 6, ~45-minute intervention sessions, (3) completing a set of questionnaires and an exit intervention, (3) completing follow-up questionnaires 1- and 2-months after the intervention sessions. Some of these procedures may be optional.
- There are risks from participating. The most common risk is the possibility of experiencing emotional distress from filling out questionnaires and/or during your intervention sessions. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- You might not benefit from being in this research study. The potential benefit to you might be feeling less alone or using drugs less frequently.
- If you do not want to take part in this study, you might consider seeking care elsewhere. See this link for additional information: https://findtreatment.samhsa.gov/.

Purpose of Study

The purpose of this study is to better understand how feeling alone or loneliness and drug use may be related to one another. We will be looking to see if two different

approaches can have an impact on feeling alone or loneliness and drug use. This information will help us to better understand how to reduce feeling alone or loneliness and drug use.

Description of Study Procedures

If you decide to take part in this study, you will be asked to take part in completing a set of questionnaires at 4 time points, completing one of two 6-meeting interventions and completing a briefer set of questionnaires while completing the intervention. All study related interventions and assessments will be conducted by study staff with at least a master's degree in a counseling/health-related field. All parts of the study are conducted by phone or Zoom, but you can access calls through a toll-free number.

First, you will complete questionnaires about demographics, mental and physical health, and drug and alcohol use. This will take approximately one hour and will be completed by phone or Zoom.

Next, you will be assigned by chance (like a flipping a coin) to one of two groups. Group 1 will receive Cognitive-Behavioral Therapy focused on feeling alone or loneliness and Group 2 will receive an intervention focused on recommendations and benefits of healthy living on topics such as diet and exercise. There is an equal chance that you will be assigned to either group. Both involve 6, ~45 minute meetings that occur approximately once a week.

At the end of the 6 intervention sessions, you will complete questionnaires about mental and physical health, and drug and alcohol use and will conduct an exit interview to discuss your experience with the study. Two more sets of the questionnaires about mental and physical health and drug and alcohol use will be completed one-month and then two-months later. All assessments will be completed by phone or Zoom phone and will take approximately 30-60 minutes to complete.

Number of Subjects

Approximately 125 subjects will take part in this study. Subjects will be recruited from across the United States.

Risks of Participation

Due to the collection of mental health data and discussing substance use, which are considered sensitive information, this study has some potential risks. Study interventions and questionnaires ask about demographic information, your past and current physical and mental health and about aspects of your substance use. Some people may become distressed or embarrassed when completing study questionnaires.

You do not need to answer questions that you are uncomfortable with. If you (or we) become concerned about your stress level, level of substance use, mental health or safety, we will connect you with the study team's mental health care professionals and provide you with a referral for immediate or subsequent care as deemed appropriate at the time. There are instances that we are required to break confidentiality. These include cases in which you are at high risk of hurting yourself or others, or disclosures of unreported physical or sexual abuse of a child.

The self-report questionnaire includes screening instruments that may suggest a mental health problem that deserves further evaluation. In any such instances, we will provide you with referral information so you may seek further evaluation or care for a possible sleep or mental health disorder if you so choose.

- *Breach of confidentiality* is a common risk in social and behavioral research. In order to maintain confidentiality:
    - We will not keep your name or identifying information with any of the study data you provide.
    - Your data will be identified with a subject ID only.
    - We will keep all written ("hard copy") material in a locked file cabinet inside a locked suite at the URMC Department of Psychiatry.
    - We will keep all electronic data on secure, HIPAA-compliant URMC computer server space that is only accessible by study staff.
    - To minimize risk of disclosure of use of illegal drugs, we will obtain a Certificate of Confidentiality (described further below), which prevents disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence.

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

Benefits of Participation

You might not benefit from being in this research study. The potential benefit to you from being in this study might be that you feel less alone or lonely, or use substances less frequently.

Compensation for Injury

The University does not provide any payment for problems that could result from your participation in the study.

Costs
There will be no cost to you to participate in this study.

Payments
You will be paid up to $180 for taking part in this study. You will not be paid for study activities that you do not complete. You will be paid on a prorated amount as follows:

- Initial set of questionnaires [$40],
- Completing first 3 sessions within 4 weeks [$20]
- Completing mid-intervention questionnaires [$20]
- Completing questionnaires and exit interview after the intervention [$40],
- Completing the 1-month follow-up questionnaires [$30],
- Completing the 2-month follow-up questionnaires [$30].

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, your information on "hard copy" forms will be kept in locked filing cabinets and any electronic information will be stored on secured, password protected computers accessible only by the study staff.

Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen, we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

Information that may be used and given to others:
The study investigators will get your personal and medical information including:

- Information collected from questionnaires you fill out and the feedback you provide verbally during the exit interview
- Information gathered from the intervention to monitor your progress and track your homework completion

Who may use and give out information about you:

- The study investigators
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- National Institute on Drug Abuse
- Medical University of South Carolina and The Ohio State University

Why will this information be used and/or given to others?

- To do the research,
- to study the results, and
- to see if the research was done right.

If results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

How long will this be permission be valid?

This permission will last forever.

May I cancel my permission to use and disclose information?

You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the Principal Investigator. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?

If you withdraw your permission to be in the study, 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.

Circumstances for Dismissal

You may be withdrawn from the study if you cannot complete study activities.

New Study Information
If we discover any new information that might make you change your mind about continuing in the study, we will let you know.

Sponsor Support
The University of Rochester is receiving payment from the National Institute of Drug Abuse for conducting this research study.

Certificate of Confidentiality
To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Lisham Ashrafioun, PhD at 585-430-2026.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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Use of E-mail and Texting for Communication in Research

You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. Email communications between you and the study team may be filed in your research record.

Email and/or text communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email/text.

SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

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Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____ _____

Signature of Subject (Typed) Date

Person Obtaining Consent

I have read this form to the subject. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. The subject has provided oral consent to participate in this study.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent (typed) Date