UMASS CHAN MEDICAL SCHOOL

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: [STUDY00001149] Evaluating *Signs of Safety*: A Deaf-Accessible Therapy Toolkit for AUD and Trauma

Protocol No.: 1R01AA031010

Sponsor: National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Investigator: Melissa L. Anderson, PhD

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Consent Version: 8/21/2023

We invite you to join a research study. A member of our team will explain this research to you. This form summarizes their explanation.

KEY INFORMATION

We invite you to join our research study. This is because you are Deaf, age 18+, and use ASL. You also reported problems with alcohol use and trauma.

If you have any questions, please ask. If you don't understand something, please ask.

Joining this study is voluntary. That means it is completely up to you. You can say "no" at any time. You can leave the study at any time.

If you decide not to participate, you will not be punished. The quality of your health care and benefits will not change.

We are trying to learn whether a new therapy can help Deaf people cope with alcohol use and trauma.

If you join this research and you live in a state served by National Deaf Therapy, you will be randomly assigned to:

- The new experimental therapy

  OR

- Therapy as usual.

Random assignment is like pulling a name out of a hat. In both conditions, we will offer you 12 one-hour, weekly individual therapy sessions. An ASL-fluent therapist will conduct these sessions on a secure virtual therapy platform. We will also ask you to complete online self-report surveys (in ASL) at five timepoints. The timepoints are baseline, mid-treatment/week 6, immediate post-treatment/week 12, three-month post-treatment follow-up/week 25, and six-month post-treatment follow-up/week 38.

If you join this research and you live in a state that is <u>not</u> served by National Deaf Therapy, you will automatically be assigned to a no-treatment control group. We will ask you to complete online self-report surveys (in ASL) at five timepoints. The timepoints are baseline, week 6, week 12, week 25, and week 38.

You may not want to be in this study if you are uncomfortable with:

- Random assignment. In other words, the fact that neither you nor the research team can pick which group you are in.

- Sharing your private information with researchers.
- Having your therapy sessions video recorded.

Risks: We do not think that this research will hurt you. However, all research studies have possible risks.

- **Loss of confidentiality.** One risk of is that your private information could be leaked. In other words, someone outside of the study could access the information we have saved about you. If that information suggests something serious about your health, it could be used against you. For example, it could make it harder for you to get or to keep a job or insurance. We believe the chance of this very small, but we cannot make guarantees. We will do everything we can to protect your information.

- **Discomfort or increased symptoms.** Therapy sessions or study surveys may cause discomfort, trauma triggers, and/or substance cravings. However, this new therapy does not require you to talk about your trauma in detail. We do everything we can to make sure you are safe and comfortable. If you experience severe distress, we will provide you with additional supports. These supports may include break-out sessions, contact with the lead researcher (Melissa Anderson), and/or referral to additional treatment. In very unlikely situations, this support may include hospital admission.

- **Alcohol withdrawal.** If you currently drink alcohol, there is a risk of alcohol withdrawal. Mild symptoms are anxiety, shaky hands, headache, throwing up, sweating, and trouble sleeping. If you are experiencing mild withdrawal symptoms, please inform your therapist or the research team. Severe symptoms include confusion, seeing or hearing things that aren't there, or seizures. Severe symptoms require immediate medical attention! If you are experiencing severe withdrawal symptoms, call 911.

There may also be risks that we do not know yet. If you experience a dangerous or unsafe situation, please seek immediate help or call 911. Then, contact your study therapist or the research team as soon as possible.

Benefits: We cannot promise any benefits. Potential benefits to you include:

- Access to an evidence-based therapy - *Seeking Safety*.
- Decrease in mental health and addiction symptoms.

- Increase in safe coping skills and ability to manage trauma symptoms.

Additionally, this study could result in the first-ever evidence-based therapy for the Deaf community.

Alternatives: You do not have to join this study to receive mental health care. Another choice is therapy through National Deaf Therapy (without enrolling in the study). We can also refer you to therapists outside of National Deaf Therapy.

If you are still interested in this study, please continue reading to learn more.

STUDY DETAILS

How many people will join this research?

Up to 144 people.

How long will I be in this research?

Between 9 months and 1 year.

If you join this research and you live in a state served by National Deaf Therapy, you will be randomly assigned to receive either:

- The new experimental therapy (Group 1)

  OR

- Therapy as usual (Group 2)

You will be put into a study group by chance. About 48 people will be in Group 1 and 48 people in Group 2. You cannot choose your study group. During the study, you and the lead researchers will not know which group you are in.

In both groups, we will offer you 12 one-hour, weekly individual therapy sessions. An ASL-fluent therapist will conduct these sessions on a secure virtual therapy platform. We will also ask you to complete online self-report surveys (in ASL) at five timepoints. The timepoints are baseline, mid-treatment/week 6, immediate post-treatment/week 12, three-month post-treatment follow-up/week 25, and six-month post-treatment follow-up/week 38.

If you join this research and you live in a state that is <u>not</u> served by National Deaf Therapy, you will automatically be assigned to the no-treatment control group. We will ask you to complete online self-report surveys (in ASL) at five timepoints. The timepoints are baseline, week 6, week 12, week 25, and week 38.

Will you be collecting any specimens from me?

No.

Will it cost me any money to take part in this research?

No.

Will I be compensated for being in this study?

You may be paid up to $500 total:

- $50 for baseline survey
- $75 for mid-treatment/week 6 survey
- $100 for end-of-treatment/week 12 survey
- $125 for three-month follow-up survey
- $150 for six-month follow-up survey

We will pay you with electronic Amazon gift cards. To receive gift cards, we need your name, address, email address, and phone number. We will share this information with the business offices and companies that need it for payment.

You will need to provide your social security number and complete a W-9 (tax form) if you receive:

- $300 or more from a single study within a single calendar year at UMass Chan, or
- $600 or more in a calendar year across multiple research studies at UMass Chan.

The Medical School may report payment to the IRS. If so, they will send you a 1099 form for your taxes. The business offices and companies will keep your information as part of their financial records. The research team will destroy this information three years after the study ends.

What happens if I am injured because I took part in this research?

If you are injured while in the study, get help immediately. Contact the research team as soon as possible.

UMass Chan Medical School does not provide money for research-related injury. If you are injured because of study participation, treatment will be provided. You or your insurance company must pay for treatment. No additional funds are available for injury or lost wages.

You do not give up any of your legal rights by signing this form.

What are my responsibilities if I join this study?

If you join this study, you are responsible to tell your study therapist or the lead researcher (Melissa Anderson) if:

- You engage in formal therapy outside of the study.
- You experience worsening distress or increase in mental health or substance use symptoms.
- You experience symptoms of alcohol withdrawal.
- You have thoughts, plans, or intent of suicide, hurting yourself, or hurting others.
- You arrive to a therapy session on drugs or alcohol.

What happens if I say yes, but I change my mind later?

We will tell you any new information that may affect your health, welfare, or decision to stay in this research study.

If you would like to leave this study, please contact the lead researcher (Melissa Anderson) to let her know.

If you want therapy outside of the study, Dr. Anderson will refer you to a signing therapist who specializes in substance use and trauma.

If you decide to leave the study, we may ask if we can contact you for safety reasons or to follow your health.

Data collected before you leave the study will remain in the study database. It will also be included in data analyses. You can prevent this by withdrawing your consent.

Can I be removed from the research without my approval?

The lead researcher (Melissa Anderson) can remove you from the study even if you want to continue. This does not happen often. This may happen if:

- You need a higher level of services than our study can provide.
- You pose immediate harm to yourself or others. Examples include physical aggression or verbal threats.

If we remove you from the study, we will provide referral to crisis or therapy services. Once you are stable, you may have the option to return to our study.

How will my information be stored and when will it be destroyed?

Paper research files will be stored in locked file cabinets in locked offices. We will remove your name and any other information that could identify you. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data.

We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

If you receive study therapy, some of your therapy sessions will be recorded. Video recordings are for quality control only. They will not be used for participant data collection. The recordings will not be transcribed into written English. Your therapist will inform you which sessions will be recorded. After these sessions, your therapist will upload the recording to UMass Chan's secure MoveIt file transfer system. The recording will be transferred to a password-protected file on a secure password-protected, encrypted internal server hosted by UMass Chan.

All paper records, video recordings, and electronic data records will be destroyed three years after the study ends. We will also destroy the master list linking participant code numbers to their identifying data (e.g., name, birthdate). This timeline follows NIH policy.

It is possible that we might use study data in other future research. We may also share data with NIAAA and researchers that are not part of UMass Chan. We will not share your name or other information that identifies you. We will not come back to you to ask you for your consent. Individual data will not be available for release.

Who has access to my information?

Signing this document means you allow our research team and others working with us to use some of your protected health information:

- Your name, date of birth, address, phone number, and email address.
- Self-reported medical information, like current and past therapies.
- Self-reported alcohol and drug use.
- Self-reported mental health symptoms.

Your research records will be shared with the research team. They will also be shared with individuals and organizations that watch over this research to make sure the study is conducted as planned. Information and records may be shared with:

- The research sponsor (NIAAA).
- People and companies who work with NIAAA.
- Federal and state government agencies, such as state auditors.

- UMass Chan Medical School, including the Institutional Review Board (IRB) and research and compliance offices.
- Therapists who provide services in connection with this study.

We will protect your identifiable information to the extent required by law. We cannot promise complete secrecy.

We are legally required to disclose information about child abuse, abuse of the elderly or disabled, or serious plans to harm yourself or others.

Any disclosure carries potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

You do not have sign this consent form. If you choose not to sign, you will not be punished. The quality of your health care and benefits will not change.

If you do sign, your consent does not expire. If you change your mind, you can revoke your consent. You can revoke consent in writing or by using the contact information at the beginning of this form. If you revoke consent, you cannot continue in the study. We will not collect any new information about you. We may only use the information already collected. Your information may still be used and disclosed if you experience an adverse event.

Because the National Institutes of Health (NIH) funds this research, this study has a Certificate of Confidentiality. The Certificate keeps us from sharing your identifiable sensitive information unless you allow us to. It also prevents us from being forced to release your information as part of a court, legislative, administrative, or other proceeding.

There are times when the Certificate cannot be used. We cannot refuse to give information to government agencies that oversee or fund research (e.g., NIH). We must also provide information to local government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger or if we are required to do so by law.

The Certificate does not stop *you* from giving out information about yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so.

We may publish study results. We plan to share results through ASL videos, conference presentations, and professional journal articles. We will keep your name and other identifying information confidential.

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

Will you share any results with me?

Research results can take years to become ready. Let us know if you would like us to reach out to you at that time. We will ask for your contact information. Individual data will not be available for release.

Who can I talk to?

If you have questions, concerns, or complaints about this study, please contact the research team. Their contact information listed on the first page of this form. Please also tell them if you think this research has hurt you or made you sick.

This research is supervised by an Institutional Review Board (IRB). An IRB is a group of people who independently review research studies. You can contact the IRB at (508) 856-4261 or irb@umassmed.edu. Please talk to them if:

- The research team is not answering tour questions, concerns, or complaints.
- You cannot reach the research team.
- You want to talk to someone outside of the research team.
- You have questions about your rights as a research participant.
- You want to get more information about this research.
- You want to provide input about this research.

Your signature documents your consent to take part in this research.

Signature of adult research participant	Date
Printed name of adult research participant	

Signature of person obtaining consent	Date

Printed name of person obtaining consent