# Acceptability and Feasibility of Cognitive Behavioral Therapy for Treatment-Seeking (CBT-TS) with Deaf Individuals

Study Protocol and Statistical Analysis Plan

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**Acceptability and Feasibility of Cognitive Behavioral Therapy for Treatment-Seeking (CBT-TS) with Deaf Individuals**

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## 1. PURPOSE OF STUDY

The purpose of the current study is to assess the acceptability and feasibility of a Zoom-based intervention, Cognitive Behavioral Therapy for Treatment Seeking (CBT-TS) to improve professional treatment-seeking among Deaf[1] adults with mental health and/or alcohol use problems. This study is a Stage 1A intervention refinement study (Onken et al., 2014) consisting of a single-arm open pilot trial that will recruit 45 Deaf subjects, aged 18 years or older, with significant symptoms of alcohol use disorder (AUD), post-traumatic stress disorder (PTSD), depression, anxiety, and/or insomnia, who are not currently engaged in treatment. Subjects will be recruited online from across the United States (U.S.) for this remote study. All subjects will complete a baseline assessment of their behavioral health symptoms, perceptions towards treatment, and intent to seek treatment prior to engaging in the CBT-TS intervention. The primary clinical outcome, assessed at one-month follow-up, will be whether subjects scheduled professional treatment. Secondary outcomes include changes in subjects' perceptions towards treatment and intentions to seek treatment. During the one-month follow-up assessment (i.e., at the completion of their participation in the study) subjects will also complete a client satisfaction survey and a semi-structured interview with open-ended questions to provide feedback about the CBT-TS intervention. All study activities will be conducted via Zoom. The specific aims include the following:

**Aim 1**: Assess the acceptability and feasibility of CBT-TS for Deaf Individuals using recruitment and retention data and qualitative and quantitative subject feedback.

**Aim 2**: Generate a preliminary estimate of the effect size for CBT-TS for Deaf Individuals using one-month follow-up assessments to assess changes in subjects' utilization of professional treatment services, perceptions of treatment, and intentions to seek treatment.

**Aim 3**: Refine CBT-TS for Deaf individuals intervention using qualitative and quantitative data from the study to enhance the acceptability and potential effectiveness of CBT-TS for Deaf individuals.

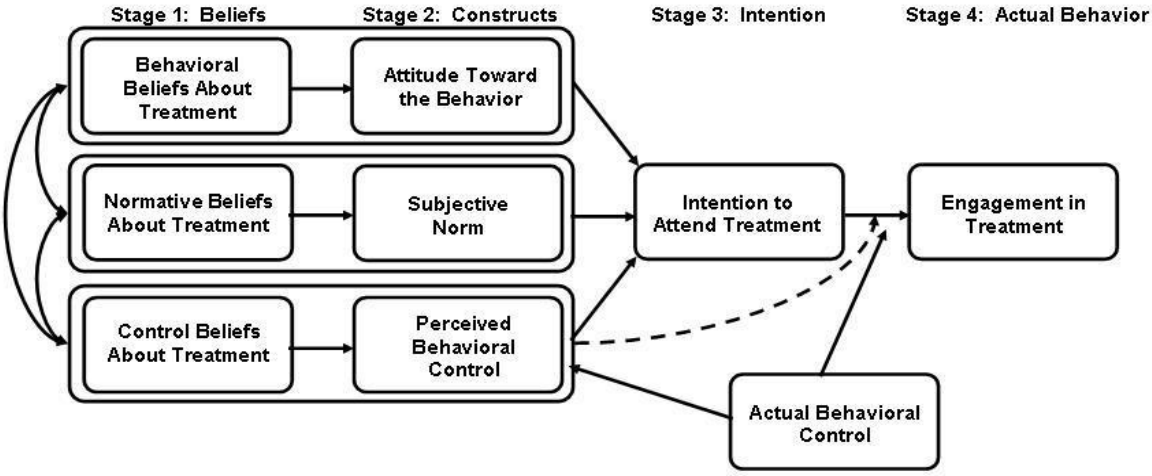
## 2. BACKGROUND AND RATIONALE

[1] The Deaf population consists of a diverse group of individuals with hearing loss that have varied language and communication preferences (i.e. English, American Sign Language (ASL), Cued Speech, etc.), community affiliations, (i.e. general community, Deaf culture, etc.), and sociocultural norms (Anderson et al., 2018). Many deaf individuals consider themselves a part of a unique and vibrant culture with its own language (ASL), belief systems, values, and standards (Best, 2016). This perspective on deafness is referred to as the culture-linguistic model and a capital "D" is often used to signify the cultural perspective. This project will focus on this subgroup of Deaf individuals; thus, a capital "D" is used throughout the text when referring to Deaf individuals and the Deaf community.

A major barrier to the effective treatment of behavioral health disorders is that individuals in need of care do not seek professional treatment services. Data from the Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health indicates that in 2019, only 10.3% of individuals with a substance use disorder and 44.8% of individuals with any mental health disorder received treatment (SAMHSA, 2020). Thus, more than half of individuals with behavioral health problems are not receiving treatment. This is a major public health concern considering the significant disease burden of untreated behavioral health disorders (Carvalho et al., 2019; Lépine & Briley, 2011; Nichter et al., 2019).

The Theory of Planned Behavior (TPB) provides an organizing framework for understanding why individuals may not seek professional treatment. The TPB purports that the decision to engage in any behavior can ultimately be traced to a person's beliefs about the behavior, including their beliefs about the likely consequences of a behavior (behavioral beliefs), beliefs about the normative expectations of others in one's community (normative beliefs), and beliefs about the factors that may facilitate or prevent performance of the behavior (control beliefs; Ajzen, 1991). These beliefs lead to the formation of an overall attitude towards engaging in a behavior, a subjective norm about the behavior in one's community, and a perceived behavioral control regarding enacting the behavior. The more favorable an individual's attitude and subjective norm regarding a behavior, and the more perceived behavioral control they feel, the stronger should be an individual's intention to perform the behavior (Ajzen, 1991). Dr. Tracy Stecker and colleagues used the TPB to examine treatment-seeking behavior and identified several cognitive and emotional factors that may prevent individuals from seeking treatment for a behavioral health disorder, including beliefs that they should be able to handle their problems on their own, that treatment would not be helpful, a fear of stigma or being labeled as crazy, experiencing negative consequences at work, feeling uncomfortable admitting one's own struggles, and a desire to avoid confronting their own pain, among others (Stecker et al., 2007; Stecker & Fortney, 2011).

Following the identification of these beliefs, Dr. Stecker and colleagues developed a brief intervention, Cognitive Behavioral Therapy for Treatment-Seeking (CBT-TS), to address these beliefs, improve individuals' perceptions about behavioral health treatment (i.e., their attitudes, subjective norm, and perceived behavioral control), and ultimately increase treatment-seeking behaviors among individuals with behavioral health problems (Stecker, 2010). CBT-TS consists of a one-session, tailored, individual intervention delivered by telephone lasting 45-60 minutes (Stecker, 2010). The intervention targets a change in the beliefs of treatment that influence whether or not someone initiates behavioral health treatment. The premise of CBT-TS is that by modifying an individual's beliefs about treatment, an overall modification in a person's perceptions toward treatment would occur, thereby changing their intention to engage in treatment, and ultimately changing their treatment-seeking behaviors (Stecker et al., 2011). CBT-TS has shown efficacy in increasing treatment-seeking behaviors among adults with a breadth of behavioral health disorders including AUD, PTSD, and depression (Stecker et al., 2012; Stecker et al., 2013; Stecker et al., 2011). However, CBT-TS was not designed with consideration of the unique cultural and linguistic perspectives of the Deaf community that impact their treatment-seeking behaviors.




*Note.* Reprinted from "Engagement in Mental Health Treatment by Veternans", by Stecker, T., Fortney, J., Hamilton, F., Sherbourne, C., Ajzen, I., 2010, *Patient Preference and Adherence, 4,* p. 46

The U.S. Deaf community consists of a group of 500,000+ individuals who use American Sign Language (ASL) and have varied hearing statuses, community affiliations, and sociocultural norms (Anderson et al., 2018). Deaf individuals experience nearly triple the rate of lifetime problem drinking (Anderson et al., 2018; Berman et al., 2010; Titus et al., 2008), twice the rate of trauma exposure (Anderson & Leigh, 2011; Johnson et al., 2018; Schild & Dalenberg, 2012), higher rates of depression and anxiety (Kushalnagar et al., 2019), and increased suicidal ideation and lifetime suicide attempts (Fox et al., 2020) compared to the general population. Yet, Deaf individuals remain one of the most understudied and underserved populations in behavioral health (Anderson et al., 2018). Preliminary data from my postdoctoral work indicates that only 31% of Deaf individuals who screened positive for AUD, PTSD, depression, or anxiety were connected to treatment. The unmet treatment needs of Deaf individuals contribute to behavioral health disparities (Barnett et al., 2011), and there is an urgent need for solutions that may address the low rates of treatment engagement. CBT-TS could be an effective intervention to improve treatment-seeking behaviors among Deaf individuals, but the intervention needs to be designed to meet the unique cultural and linguistic needs of the Deaf community.

Clinicians working within the Deaf community have documented the need for alterations to existing evidence-based interventions to effectively treat Deaf individuals, including incorporating Deaf cultural formulations and characteristics into treatment, addressing specific barriers (e.g., language, literacy, communication), and addressing gaps in health literacy (Glickman, 2009; O'Hearn & Pollard, 2008). Thus, during my postdoctoral fellowship, I designed a multi-step project to adapt CBT-TS for Deaf individuals informed by the ADAPT-ITT model (Wingood & DiClemente, 2008). The goal of the adaptation process was to ensure that the adapted intervention-maintained fidelity to the core intervention tenants while incorporating critical cultural formulations and materials. I first conducted elicitation interviews using the TPB to identify the behavioral, normative, and control beliefs that predict treatment-seeking among Deaf individuals. Next, I conducted focus groups with Deaf individuals and treatment providers to gather feedback about possible adaptations to the original CBT-TS intervention to increase the relevancy, acceptability, and efficacy of the intervention for Deaf individuals. I then integrated the data from the elicitation interviews and

focus group sessions to produce CBT-TS for Deaf Individuals. CBT-TS for Deaf Individuals includes an updated measure with treatment-seeking beliefs specific to Deaf individuals (D-PASS), cultural formulations and examples incorporated into the intervention manual; visual intervention materials to aid in comprehension of session concepts (to accommodate the visual communication preferences of the Deaf community); a longer session time (60 – 90 minutes, to allow for the development of trust and rapport, exchange of information for a group who may have lower health literacy, and to allow for Deaf cultural styles of information sharing and storytelling); a pamphlet with information about different treatment options, expectations for the process of treatment (i.e., intake, assessment, therapy, medications, etc.) and goal outcomes for treatment (to increase knowledge of treatment among a group who has les access to healthcare information); a list of treatment-seeking resources for Deaf individuals; an optional follow-up session with the provider to offer practical assistance in problem-solving barriers and scheduling professional treatment services (to mitigate the numerous barriers to healthcare experienced by Deaf individuals); and ASL versions of all the materials.

CBT-TS for Deaf Individuals has not yet been tested within the Deaf community. The current study will pilot test CBT-TS for Deaf Individuals with a small sample of Deaf adults to assess the acceptability and feasibility of the intervention as well as generate a preliminary estimate of its efficacy. Finally, the information gathered during this study will be used to refine the intervention to enhance its acceptability and effectiveness to improve treatment-seeking among Deaf individuals.

This study will break new ground as one of the first clinical trials of a psychotherapy intervention developed to meet the cultural and linguistic needs of Deaf individuals. This study leads a significant paradigm shift in behavioral health interventions by incorporating Deaf cultural formulations into the manual and materials for intervention delivery. In addition, this study will lead to an intervention with the potential to address the significant unmet treatment needs of Deaf individuals, and by extension, reduce existing health disparities in the Deaf community.

## 3. ADMINISTRATIVE ORGANIZATION

This project will be conducted through the Department of Psychiatry at the University of Rochester Medical Center (URMC). All study procedures will be conducted remotely.

## 4. STUDY DESIGN

This is a Stage 1A intervention refinement study (Onken et al., 2014) to assess the acceptability, feasibility, and preliminary efficacy of CBT-TS for Deaf Individuals to improve professional treatment-seeking among Deaf adults with mental health and/or alcohol use problems. This study aims to identify clinical factors and formulate theories relevant to the intervention refinement (i.e., acceptability and feasibility data gathered through the trial) and further refine, modify, or adapt the intervention to boost its effects or ease of implementation for the given population. This goal will be accomplished through a single-arm, open pilot trial with a small sample of the new target population (i.e., Deaf individuals with behavioral health problems who are not currently engaged in treatment).

Interested subjects will be provided with an overview of the project goals and a detailed description of the screening procedures. Subjects will give verbal consent to participate in the screening assessments. Eligible subjects will then be invited to participate in the written

informed consent process for enrollment in the study. Upon enrollment in the study, all subjects will complete baseline assessments and then engage in the CBT-TS intervention via Zoom. One month after completing the intervention, all subjects will complete a follow-up assessment.

The main outcome data will include quantitative and qualitative feedback regarding the acceptability and feasibility of the intervention (i.e., recruitment and retention data, a client satisfaction survey, and qualitative subject feedback provided during the follow-up assessment), and clinical outcomes from the intervention (i.e., whether subjects scheduled professional treatment, and changes in subjects' perceptions towards treatment and intentions to seek treatment). Subjects' symptom severity at baseline and the follow-up assessment will also be examined to see how this data relates to treatment-seeking behaviors. The quantitative and qualitative subject feedback and the clinical outcome data will be used to refine the intervention content, materials, and procedures to enhance the intervention's efficacy for Deaf individuals.

## 5. SUBJECT POPULATION

Subjects will be Deaf adults in the United States with clinically significant symptoms of AUD, PTSD, depression, and/or anxiety, who are not currently engaged in treatment, and whose primary method of communication is ASL or Pidgin Signed English (PSE).

**Number:** Forty-five subjects will be enrolled in the study.

**Gender and Age:** Subjects will be 18 years of age and older. Subjects will include all genders.

**Race and Ethnic Origin:** Based on pilot data, we expect that approximately 73% of the population will be White, 10% will be Black or African American, 6% will be Asian or Pacific Islander, 1 % will be American Indian or Alaskan Native, 10% will be Multiracial, and 13% will be Hispanic or Latinx.

## 6. INCLUSION AND EXCLUSION CRITERIA

**Inclusion Criteria:** (1) age $\geq$ 18 years; (2) self-identify as Deaf or hard-of-hearing (any degree of hearing loss); (3) primary method of communication is ASL or PSE; (4) positive screen for one or more behavioral health disorders including: AUD (AUDIT $\geq$ 16 and alcohol use in the past 30 days exceeds the limit for low-risk drinking established by the NIAAA), PTSD (PCL-5 $\geq$ 31), depression (PHQ-9 $\geq$ 10), anxiety (GAD-7 $\geq$ 10), or insomnia (ISI $\geq$ 15); (5) no current behavioral health treatment per standardized self-report; and 6) access to video chat technology with internet and webcam.

**Exclusion Criteria:** (1) unable to communicate with the researcher in ASL or PSE; (2) current alcohol withdrawal necessitating medical evaluation; (3) current psychiatric impairment necessitating emergency services or inpatient admission (i.e., imminent danger of harm to self or others); (4) unable to comprehend the nature of the study; and (5) currently receiving behavioral health treatment for their symptoms.

## 7. RECRUITMENT METHODS

Subjects will be recruited nationally for this remote study. Subjects will primarily be recruited online using procedures that were successful during my postdoctoral pilot study. We will share IRB approved documents, including digital flyers and signed video announcements, on social media, Deaf listservs, and with Deaf community organizations. The digital flyers and signed videos will contain a brief description of the study, the general procedures, eligibility criteria, and information for interested subjects to contact study personnel.

This study will also identify potential subjects for recruitment using the University of Rochester's Clinical and Translational Science Institute's (UR CTSI) Research Participant Registry [STUDY00001978] and the Deaf Database at URMC [STUDY00004252]. Individuals included in these research lists have consented to be contacted regarding relevant research opportunities at the University of Rochester. Subjects on these lists who are 18 years of age or older, self-identified as Deaf or hard-of-hearing, and indicate that their primary language is ASL or PSE, will be contacted about the potential research opportunity. Study personnel will send a message including a brief description of the study goals, procedures, eligibility criteria, and information for interested subjects to contact the study personnel.

Finally, subjects will also be identified via the URMC's electronic health record system. We will identify subjects using information available in eRecord including age, hearing status, primary language, use of ASL interpreter, scores on available behavioral health measures, and connection to behavioral health services. Subjects will not be contacted if they have indicated that they do not want to be contacted for future research on a past consent form (for a different study) from this research team. Subjects that are eligible will receive an email notifying them that they have a new research opportunity available in MyChart. This can only be viewed after they log in to MyChart and visit the Research Studies page. The attached MyChart for Recruitment form (uploaded as part of recruitment materials) includes the study description that subjects will see. Subjects will indicate whether they are interested in participating or not by clicking on the corresponding button on the Research Studies page. Interested subjects will then be contacted for screening as described in this protocol. Subjects who are not interested will not be contacted and will be removed from the pool of potentially eligible subjects. If subjects do not indicate whether they are interested in participating or not, they will receive a second message one week later. When study accrual is completed, outstanding research opportunities in MyChart will be rescinded.

Recruitment for this study is feasible. Deaf subjects will be recruited nationally allowing for a large pool of eligible Deaf adults. The recruitment procedures used for the current study were successful in the PI's pilot study with the same population. Based on our previous recruitment experience with this population, we estimate that approximately 73% of subjects screened will meet the eligibility criteria for enrollment in this study and we will be able to recruit approximately 3 – 4 subjects per month. We expect to meet our recruitment goal of 45 subjects within 12 months.

## 8. CONSENT PROCESS

Prior to the screening assessment, interested subjects will be provided with an overview of the study goals and an in-depth explanation of the procedures for the screening assessment. Subjects will give verbal consent via Zoom to participate in the screening

assessment, and this consent will be documented by study personnel in REDCap (Research Electronic Data Capture), a HIPPA-compliant, secure, web-based application designed exclusively to support data capture for research studies. REDCap is hosted locally by URMC and employs user authentication and role-based security. The REDCap application resides in an isolated secure network segment designed for personal health information, personally identifiable information, and other types of regulated data. At the completion of the screening assessment, subjects who are eligible to participate in the study will be invited to participate in the written informed consent process for enrollment in the study.

Electronic, written informed consent will be obtained directly from eligible subjects via Zoom. An IRB-approved e-Consent form will be created using a REDCap-based electronic form. Potential subjects will participate in the consent process by accessing the e-Consent form via a link provided to them through e-mail. The study personnel will request verbal permission to send the e-Consent via email. The request will state “Because URMC can’t control the security of email once we send them, we need your permission to email you. Do you want to receive the link to the e-Consent via email?” The email will not include PHI. To authenticate the identity of the individual signing the e-Consent form, the study personnel and the subject will agree on a passcode for accessing the e-Consent form. This passcode will be saved as part of the subject’s record for verification use. Through the use of a “Survey Login” feature, an individual will be prompted to enter the passcode to grant entry to the e-Consent form. The entered passcode will be matched against the stored version entered by study staff for that subject. A matching response will grant entry to the e-Consent and non-matching responses will block the individual based on specified settings.

The informed consent form will contain a detailed description of the study procedures, along with statements regarding subjects’ rights to withdraw from the procedure at any time without consequences. It will be explained to subjects in easy-to-understand language. The limits of confidentiality will also be explained, including the potential to break confidentiality in the acute risk of suicidal behavior or violence, or disclosures of unreported physical or sexual abuse of a child. The consent form will include text regarding the retention and use of study data. This project is funded by the National Institute of Health (NIH) and includes a Certificate of Confidentiality which will be explained on the informed consent form.

Subjects will also be asked if they are interested in having their contact information stored in a Deaf database to allow researchers to contact them about future Deaf research opportunities. The subjects’ information will be stored in the URMC IRB-approved Deaf Database [STUDY00004252].

The subject will remain on Zoom while they access and read the e-Consent form. The study personnel will fully review the content of the consent form with the subjects in ASL. The study personnel will review the content section by section following the organization of the e-Consent form, clarifying points as needed, and checking for comprehension at the end of each section. If the subject indicates that they have comprehended the information they will click to proceed to the next section of the form. Subjects will have the opportunity to ask any questions they may have about the study as they review the content of each section.

Subjects with limited decision-making capacity will not be enrolled in the study. When obtaining informed consent, a “Determination of Capacity for Informed Consent” protocol will be utilized. At the conclusion of the consent process and prior to requesting that they sign the form, all subjects will be asked the following questions:

- Could you please tell me what this study is about?
- What are the potential risks to you of participating in this study?
- What are the benefits of participating in this study?
- Do you understand that your participation is voluntary and that you may stop at any time or not answer any questions that you feel uncomfortable answering?
- Do you have any questions about the assessments or intervention sessions?

If the subject is unable to demonstrate an understanding of the study or appreciation of the issues, study personnel and the subject will further review the consent form and repeat the pertinent questions. Subjects who achieve a demonstrated understanding of the study are determined to have the capacity to provide informed consent. Those who do not, will be thanked for their time and informed that they are not eligible for the study. Subjects' answers will be characterized on a checklist that is kept with the research record as documentation of the consent process.

Subject signatures will be obtained using a typed signature. Once the consent form is signed and submitted, subjects will be able to receive a printout of the paper copy, download a PDF version, and/or receive an email with a PDF attachment of the signed consent form. Informed consent will also be reviewed at the beginning of the baseline assessments, intervention sessions, and follow-up assessments.

## 9. STUDY PROCEDURES

**Screening Procedures:** Recruitment materials will direct individuals to contact the research team via email or video phone to schedule a screening assessment with study personnel on Zoom. We will use procedures for screening that were successful in the PI's postdoctoral pilot study conducted at URMC. During the screening assessment, study personnel will briefly review the overall study goals and then explain the screening procedures to interested subjects. Study personnel will obtain verbal consent from interested subjects prior to proceeding with the screening assessment. This verbal consent will be documented in REDCap.

Subjects will be screened for eligibility using a (1) brief demographic survey, (2) several behavioral health measures including: the 10-item Alcohol Use Disorders Identification Test (AUDIT) to screen for AUD, 4-items from the National Survey of Drug Use and Health (NSDUH; Center for Behavioral Health Statistics and Quality, 2015) to determine if alcohol use within the past 30 days exceeds the limits for low-risk drinking adopted by NIAAA, the Patient Health Questionnaire-9 (PHQ-9) to screen for symptoms of depression, the Generalized Anxiety Disorder 7-item Scale (GAD-7) to screen for symptoms of anxiety, the PTSD Checklist for DSM-5 (PCL-5) to screen for symptoms of PTSD, and the Insomnia Severity Index (ISI) to screen for symptoms of sleep disturbance, and (3) screening items on the Alcohol Use Disorders and Associated Disabilities Interview (AUDADIS) to determine if there is any history of or current engagement in professional alcohol or mental health treatment.

The screening will begin with the demographics survey and then proceed to the behavioral health measures if the subject is eligible. The behavioral health measures will be administered to subjects in the order listed (see Sources of Research Materials below) until the subject screens positive on one of the measures. If the subject screens positive on one of the behavioral health measures, they will skip to the treatment engagement screening questions. If the subject does not screen positive on any of the behavioral health measures,

they will be informed that they are not eligible for the study. Study personnel will share their screen with the measure items presented in written English and record the subjects' responses on paper forms. At the completion of the screening assessment, data from these paper forms will be manually transferred to REDCap, and the paper forms will be stored in a locked cabinet in the PI's locked office in the Department of Psychiatry at URMC. Study personnel will be present to clarify any items or translate the items to ASL if requested by the subject. The screening appointment should last approximately 25 – 40 minutes depending on the number of measures administered (e.g., if the subject screens positive early in the screening process or not), the subject's experience with research, and their fluency in English. Eligible and interested subjects will proceed to complete the written informed consent process for enrollment in the study.

**Baseline Assessment:** After completing the informed consent process, subjects will schedule a baseline assessment appointment with study personnel on Zoom. The baseline assessment will follow the same general procedures as the screening assessment. The baseline assessments will consist of a full demographics survey, administration of any remaining behavioral health measures, and the Deaf Perceptions About Services Scale (D-PASS). The baseline assessment appointment should last approximately 35 minutes – 1 hour. After completing the baseline assessment, subjects will schedule their intervention session with the interventionist.

**Intervention:** All subjects will receive CBT-TS for Deaf Individuals. The intervention will consist of 1 – 2 sessions with the interventionist, a Deaf clinical psychology doctoral intern supervised by the PI. All subjects will complete the first intervention session. The session will last approximately 60 – 90 minutes and will be structured in 4 phases beginning with an assessment of the subject's (1) history of symptoms and current functioning, and their (2) coping methods. Next, the interventionist will review the subject's responses to the D-PASS and collaboratively work with the subject to identify up to three problematic beliefs about treatment to evaluate. The interventionist will guide the subject in using CBT techniques to (3) evaluate and modify their beliefs about treatment. Finally, the interventionist and the subject will (4) collaboratively develop an action plan and the interventionist will provide the subject with a list of resources for seeking treatment. During the intervention sessions, the interventionist will record notes of the treatment beliefs discussed in the session, the alternative beliefs developed by the subject, and the subject's short-term action plan. This data will be manually entered into REDCap after the session and the paper copies will be stored in a locked cabinet in the PI's locked office in the Department of Psychiatry at URMC.

All subjects will be offered an optional second session with the interventionist. The second session will consist of a 60-minute appointment focused on providing practical assistance to identify available treatment options in the subject's area, scheduling treatment sessions, and problem-solving barriers to treatment (e.g., accommodations). Subjects will be informed that the second session must be scheduled within three weeks of completing the first session. The interventionist will immediately offer to schedule a second session at the end of the first intervention session. If subjects do not immediately schedule a second session, study personnel will check in with subjects 10 days after their first intervention session to see if they would like to schedule a second session. If three weeks pass without completing the second session, subjects will proceed with the follow-up assessment at the one-month mark after their first intervention session. If a second session is scheduled, subjects will be contacted for the follow-up assessment one month after completing their second intervention session. The intervention sessions will be video recorded on Zoom and stored on Box.com, a password-protected secure server hosted at URMC.

**Follow-up Assessment:** One month after their last intervention session, study personnel will contact the subjects to schedule a follow-up assessment session on Zoom. The follow-up assessment will follow the same general procedures as the screening and baseline assessments. During the follow-up assessment, study personnel will re-administer the behavioral health measures and the D-PASS from the baseline assessment, along with a validated treatment utilization survey which will assess subjects' use of 12 treatment services, their reasons for seeking or not seeking treatment, and any barriers they experienced through a series of structured questions.

Lastly, to obtain quantitative and qualitative feedback about CBT-TS for Deaf Individuals, subjects will complete the Client Satisfaction Questionnaire (CSQ-8) and a semi-structured interview including several open-ended questions about the intervention measure, content, materials, and delivery, including its appropriateness for use with the Deaf community, the acceptability of the techniques, and the usefulness of the content and materials. As these questions will be asked one month after the subjects complete their intervention session, study personnel will provide descriptions of each of the intervention procedures and show subjects the intervention materials again to refresh their memory of their experience as they provide feedback on the intervention. The interviewer will take notes of the subjects' responses to the structured questions and enter this data into REDCap after the session. The paper copies of the subjects' responses will be stored in a locked cabinet in the PI's locked office in the Department of Psychiatry at URMC.

The follow-up assessment will be video recorded on Zoom. The recordings will be stored on Box.com.

**Sharing Results:** Subjects will be given the opportunity to receive a summary of the results from the trial. If interested, subjects will be asked to check a box at the end of the written consent form to give the research team permission to contact them after the completion of the study. The research team will prepare a brief written and signed summary of the main findings from the trial and email this information to the interested subjects.

## 10. AUDIO/VIDEO RECORDINGS

The CBT-TS intervention sessions and the study assessments will be video recorded on Zoom. The recordings will be converted from Zoom and directly transferred to a folder on Box.com, a secure server hosted at URMC, for storage. The recordings will be used for supervision and monitoring of the intervention delivery, data storage, verification, and data analysis. Only IRB-approved study personnel will have access to the video recordings stored on Box.com.

## 11. RISKS TO SUBJECTS

The proposed study procedures pose minimal risks to subjects. The information below that describes the risks associated with the study interventions was taken from the IRB approved protocol and consent form.

a. **Assessment sessions (i.e., screening, baseline, and follow-up):** For the assessment sessions, the risks are as follow: mild reactions of distress or fatigue, identification of suicide ideation, invasion of privacy, or breach to confidentiality (if safety issues are detected). Subjects are not required to answer any questions posed during the study

and they may withdrawal from the study at any time without consequences. Subjects may request breaks if needed during the study or may request to stop at any time. Study personnel have specialized training in working with Deaf individuals who have behavioral health problems and are capable of providing support as needed. All of the assessment measures and the assessment procedures were safely used in my URMC IRB approved pilot study with Deaf individuals. No sustained negative effects from the assessments are expected, but negative outcomes cannot be ruled out. There is a slight risk that research data files might be compromised and obtained or viewed by unauthorized persons. Our procedures for protecting against such risks are described below.

b. **Intervention Sessions:** For the intervention sessions, the risks are as follow: subjects may experience mild reactions of distress or fatigue during the sessions if they recall past negative experiences attempting to seek treatment. Subjects will receive support from the interventionist for such experiences. In addition, due to the real barriers encountered by Deaf individuals when trying to access mental health or substance abuse treatment, it is possible that subjects who decide to seek treatment may not be able to access services or may have negative experiences in treatment. The intervention has features to address this possibility, including an optional second session with the interventionist to identify appropriate treatment options, problem-solve barriers to accessing treatment, and scheduling a treatment session. In addition, subjects will be provided with a list of multiple Deaf treatment resources, services for identifying treatment resources in their area, and accessible crisis counseling services (i.e., video phone and texting). No sustained negative effects are expected from the intervention sessions, but negative outcomes from behavioral interventions cannot be ruled out.

**Adequacy of Protection Against Risks:**

*Protections Against Risk:*

*a.* Confidentiality: In order to protect the confidentiality of subject information, we will take a number of precautions. These include training study personnel in confidentiality procedures; entry and storage of data using coded identification labels; separate storage of identifying information; use of URMC, encrypted, project laptops with restricted access by enforced password protection; and use of HIPAA compliant data management software (REDCap and Box.com). All data, including assessment measures, will be obtained with the written consent of the patient. Information pertaining to individual subjects will be released with the subject's informed and written consent only, except in unusual cases where withholding the information might pose a serious risk or danger to the subject or others. All data collection involving human subjects will be HIPAA compliant. Assessment data collected for this study will be entered into REDCap, a software toolset and workflow methodology for electronic collection and management of research data. REDCap was created specifically around HIPAA-Security guidelines including a full audit trail, user-based privileges, and integration with institutional servers. A unique study number will be assigned to each subject and all records pertaining to a given individual will be linked via this identification number. The databases will be password protected and access will be limited to relevant research personnel. All subject identification data (e.g., names, identification number, email address, video phone numbers, etc.) will be separated from the research data and stored securely in a separate folder on Box.com. Subject identification data will be used to contact enrolled subjects for scheduling, appointment reminders, or follow-up. Only IRB-approved

investigators with a need for access will have access to subject data. All paper copies of the assessment forms and notes from the intervention and follow-up interview sessions will be stored in a locked file cabinet in the PI's locked office in the Department of Psychiatry at URMC.

The assessment and intervention sessions will be video recorded on Zoom. Research personnel will use a licensed URMC Zoom account which protects and encrypts all audio, video, and screen sharing data and supports HIPPA compliance. Subjects participating in the assessment and intervention sessions will be sent unique Zoom links for entering the Zoom meetings. Research personnel will use the waiting room feature to control subject access to the sessions and will lock the meetings after the subject joins the session. Following the sessions, the recordings will be directly uploaded to password protected drives on Box.com for secure storage. The recordings will be accessible only by IRB approved study personnel at URMC.
Publications or presentations resulting from this study will report only cumulative data or descriptions certain to maintain subjects' anonymity. Lastly, to minimize social and legal risks, this study contains a Certificate of Confidentiality to protect subjects' information. An explanation of the Certificate of Confidentiality is included in the informed consent form

*b.* Identification of suicide ideation: Subjects will be screened for suicidal ideation using the PHQ-9, item 9. Subjects who endorse suicidal ideation will be administered a structured, validated follow-up assessment (P-4 Screener). Subjects who score as "high risk" on the P-4 Screener will be excluded from the study. Upon identification of a high risk for suicide, study personnel will provide support to the individual and contact the PI, Dr. Aileen Aldalur, a licensed clinical psychologist with specialized training in working with Deaf individuals, including those at high risk for suicide, and Dr. Kimberley Van Orden, a licensed clinical psychologist and expert in the prevention and treatment of suicide. Together, the team will take appropriate actions to reduce the individual's risk for suicide, including developing a safety plan, contacting treatment professionals, friends, family members, and/or emergency services if needed, and referring the individual to mental health services.

*c.* Subject distress: Risks associated with subject burden or distress will be minimized by employment of research personnel with appropriate background and experience with psychological factors and Deaf subjects. Study personnel have specialized training in working with Deaf individuals who have behavioral health problems and are capable of providing support as needed throughout the study to manage mild to moderate reactions of distress that may arise. In the rare situation that a subject experiences a more severe reaction of distress during the course of the study, study personnel will evaluate the subject's emotional state and safety. Study personnel will briefly attempt to de-escalate the patient's distress. If these measures do not effectively reduce the patient's distress within 10-15 minutes and depending on the severity of the patient's distress, study personnel will contact the PI and the PI's mentor, Dr. Kimberly Van Orden. Together, the team will take appropriate actions to reduce the individual's risk for suicide, including developing a safety plan, contacting treatment professionals, friends, family members, and/or emergency services if needed, and referring the individual to mental health services.

## 12. POTENTIAL BENEFITS TO SUBJECTS

Subjects may not receive any direct benefits from participating in this study. Potential benefits to subjects include the opportunity to reflect on their mental health and alcohol use, their beliefs about treatment, and any perceived barriers to treatment in a structured intervention session with a Deaf counselor. In addition, subjects will be provided a list of resources for seeking mental health and/or substance use treatment, as well as practical support in identifying available treatment options, scheduling treatment sessions, and problem-solving barriers to treatment (e.g., accommodations). This support may directly connect subjects with professional treatment for their symptoms. Finally, Deaf individuals are often not consulted for their opinions about services rendered within their own community. Therefore, by being asked for input on future interventions and services for Deaf people, Subjects may experience increased feelings of empowerment and self-efficacy. Given the minimal risks associated with the proposed research and the potential gains both to the individual and Deaf individuals more broadly, the benefits appear to outweigh the risks.

**Importance of the Knowledge to be Gained:** There is an urgent need to identify interventions that may increase treatment-seeking among Deaf individuals with behavioral health disorders in order to begin addressing current health disparities. If shown effective, CBT-TS may be a promising intervention that could be disseminated within the Deaf community. Results will provide the necessary preliminary data to refine CBT-TS for Deaf individuals and proceed to a randomized controlled trial (RCT) by collecting evidence of the acceptability of the intervention, feasibility of the protocol, and preliminary evidence of the intervention's efficacy.

The proposed study will also provide a reproducible method for adapting evidence-based treatments and provide guidance on how to successfully conduct RCTs within the Deaf community. As such, this work will inform investigators across disciplines and, therefore, has the potential to improve multiple facets of Deaf people's health and wellness across the nation.

## 13. COSTS FOR PARTICIPATION

There are no costs to subjects.

## 14. PAYMENT FOR PARTICIPATION

**Baseline Assessment:** Subjects will be paid $75 after completing the baseline assessment.

**Follow-up Assessment:** Subjects will be paid $75 after completing the follow-up assessment.

Subjects will be paid via check.

## 15. SUBJECT WITHDRAWALS

Subjects will be advised during the consent process that they have the right to withdraw from the study at any time without penalty. If a subject chooses to withdraw from the study the data collected up until their withdrawal will be used for data analyses. Subjects may be removed from the study if they experience significant distress during the screening and baseline assessments or the intervention session. Withdrawn and removed subjects will be replaced.

## 16. PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA

Assessment data collected for this study will be entered into REDCap. A unique study number will be assigned to each subject and all records pertaining to a given individual will be linked via this identification number. The databases will be password protected and access will be limited to relevant research personnel. All subject identification data (e.g., names, identification numbers, email addresses, telephone numbers, etc.) will be separated from the research data and stored securely on a URMC password-protected server, Box.com. Subject identification data will be used to contact enrolled subjects for their follow-up assessment appointment. All paper files (i.e., assessment forms, intervention notes, interview notes, etc.) will be stored in a locked file cabinet in the primary investigators' locked office in the Department of Psychiatry at URMC. Only IRB-approved investigators with a need for access will have access to subject data. As an added protection, NIH-funded studies are covered by a Federal Certificate of Confidentiality.

The assessment and intervention sessions will be video recorded on Zoom. Research personnel will use a licensed URMC Zoom account which protects and encrypts all audio, video, and screen-sharing data and supports HIPPA compliance. Subjects participating in the assessment and intervention sessions will be sent unique Zoom links for entering the Zoom meetings. Research personnel will use the waiting room feature to control subject access to the sessions and will lock the meetings after the subject joins the session. Following the sessions, the recordings will be directly uploaded to password-protected drives on Box.com for secure storage. The recordings will be accessible only by IRB-approved study personnel at URMC.

Publications or presentations resulting from this study will report only cumulative data or descriptions certain to maintain subjects' anonymity. Lastly, to minimize social and legal risks, this study contains a Certificate of Confidentiality to protect subjects' information. An explanation of the Certificate of Confidentiality is included in the informed consent form

All data collected as part of this study will be stored for a minimum of 3 years after the completion of the study.

## 17. DATA AND SAFETY MONITORING PLAN

**Safety Monitoring:** Given that this study presents no more than minimal risk, data and safety monitoring will be the responsibility of the study PI, in consultation with the PIs mentoring team. Individual subject data will be monitored by the PI and study personnel over the course of the study to identify any subjects who may need additional support. Alcohol use, and symptoms of post-traumatic stress disorder (PTSD), depression, suicidal risk, anxiety, and insomnia will be assessed at screening, baseline, and one-month follow-up assessments. If at any time a subject is identified by study personnel or the PI as having a serious psychiatric or alcohol use problem that requires immediate and intensive treatment (i.e., danger to self or others), this concern will immediately be reported to the PI and the PI's primary mentor, who will provide support, referral, and bridging to appropriate treatment options for stabilization. Should a subject present at a study session under the influence of drugs or alcohol, study personnel will be trained to discontinue the session, reschedule the session for a later date, and work with the subject to ensure they are in a safe place (i.e., at home, with family or friends, etc.). Should a subject communicate distress and intent to withdraw from the study, the PI will provide the subject with a list of

Deaf treatment resources to help the individual locate possible treatment options in their area.

Study personnel will be trained contact 911 in the event of a dangerous situation. The PI will also be available for on-call phone consultation for less urgent clinical crises. The PI will intervene if at any time a subject's distress cannot be contained or in cases where anyone appears truly unsafe (e.g., suicidal intent, threatening harm, or other unsafe behavior). Although it is anticipated that this reaction is highly unlikely, if concerns of subject safety arise (i.e., intent to harm oneself or others) then, to promote safety, confidentiality will not be maintained, and appropriate professionals will be informed. During crisis situations, clinical information may be provided to other clinicians (or family members) in order to facilitate appropriate treatment and minimize the risks of self-harm or harm to others. The PI and her primary mentor are licensed psychologists; thus, in the event that a subject is found to pose imminent harm to themselves or others, the PI in collaboration with her mentoring team will implement any actions required by the law with regard to individuals who are determined to pose imminent harm to themselves or others.

**Evaluation of Adverse Events:** An adverse event (AE) is any negative reaction or untoward event which does not necessarily have a causal relationship with the study procedures. An AE can be any unfavorable or unintended experience (i.e., distress, worsening of symptoms, suicidal ideation, etc.) occurring during the study period, whether or not it is related to the study procedures. This includes any newly occurring event or previous condition that has increased in severity or frequency since the start of the study period.

Cognitive Behavioral Therapy for Treatment Seeking (CBT-TS) is a low-risk intervention focused on connecting individuals in need of treatment to professional services. Therefore, AEs related to the intervention are not expected. However, this study will include a clinical population with moderate to severe symptoms of anxiety, depression, trauma, sleep disturbance, and alcohol use. It is possible that subjects will experiencing a worsening of symptoms, suicidal thoughts or behaviors, acute intoxication, withdrawal, and/or hospitalization during the study period. We will monitor, collect, and report AEs through our screening and baseline assessments, intervention sessions, and follow-up assessments. All AEs will be reported to the study PI and her mentoring team.
Unexpected adverse events, or any negative experiences, the specificity or severity of which are not consistent with the risk information provided in the protocol, will also be monitored and reported to the study PI and her mentoring team.

The PI, in collaboration with her mentoring team, will distinguish a serious adverse event (SAE) from a non-serious adverse event (AE) and provide attributions (causality and severity). If needed, we will consult with the University of Rochester Medical Center (URMC) IRB for assistance and clarification in this process. A serious adverse event is defined as any event that is serious (i.e., death, hospitalization, and life-threatening events), unanticipated, and study related.

**Adverse Event Reporting:** SAEs that are associated with the study and occur while a subject is on the study until 14 days after the date the subject goes off study must be reported in writing to the URMC IRB within 2 working days. SAEs that are both **unexpected fatal or life-threatening events** must be reported immediately to the IRB. SAEs will also be reported to and University of Rochester Clinical and Translational Science Institute (UR CTSI) KL2 program directors. The PI and her mentoring team, will develop follow-up plans for any SAEs and unresolved unexpected adverse events in collaboration with the URMC IRB.

**Data Handling Considerations:**

*Data Collection, Entry, and Storage:*

Subjects will provide data to their best knowledge by responding to items on self-report questionnaires at screening, baseline and post-intervention. Subjects' responses will be recorded on paper forms and manually entered in REDCap. Study personnel will administer the screening, baseline, and follow-up assessments to the subjects on Zoom via ASL and record their responses on paper forms. This data will be manually transferred to REDCap after the assessment sessions. The intervention sessions will be video recorded on Zoom and stored on Box.com. During the intervention sessions, the interventionist will record notes of the treatment beliefs discussed in session, the alternative beliefs developed by the subject, and the subject's short-term action plan. This data will be manually entered into REDCap after the session. The semi-structured interviews during the follow-up assessment will be video recorded on Zoom and stored on Box.com. Study personnel will manually record subjects' responses to the structured questions and enter this data into REDCap after the session. All paper copies of forms, intervention notes, or interview responses, will be stored in a locked cabinet in the PI's locked office in the Department of Psychiatry at URMC.

Data entered into REDCap will be cross-checked by visual audit of forms, then checked through programmatic error checks prior to data analysis. Once data collection is complete, REDCap provides an automated export procedure for data download. Every effort will be made to reduce attrition and obtain follow-up data including flexible scheduling options, immediate scheduling of follow-up sessions, frequent appointment reminders, and follow-up contacts after missed sessions.

*Missing Data*

Every effort will be made to facilitate the subjects' completion of questionnaires and comprehensive collection of data. If there are missing data, reasons for missing data will be recorded, tabulated, and reported. We will use the information about missing data when assessing feasibility.

The assumptions underlying all statistical analyses will be thoroughly checked using appropriate graphical and numerical methods. If there are serious violations of distribution assumptions such as normality, appropriate nonparametric methods will be attempted. If outliers or influential data are detected, the accuracy of the data will be investigated. If no errors are found, analyses may be repeated after removing these cases to evaluate their impact on the results. However, the final analyses will include these data points. SPSS and Stata will be used for the statistical analyses.

*Data Security*

Every effort will be made to protect subjects' confidentiality. Only IRB approved study personnel with a need will have access to identifying information (i.e., subject names, contact information), which will be kept separate from subject data on a URMC password protected server (Box.com). Paper data will be stored in a locked file cabinet in the PI's locked office in the Department of Psychiatry at URMC. All intervention sessions and the follow-up assessment session will be video recorded on Zoom. The Zoom recording will be directly uploaded to a password protected server (Box.com) for secure storage.

All other study data will be entered into REDCap, a HIPPA compliant, secure, web-based application designed exclusively to support data capture for research studies.

REDCap is hosted locally by URMC and employs user authentication and role-based security. The REDCap application resides in an isolated secure network segment designed for personal health information, personal identifiable information, and other types of regulated data.

Data will be exported to SPSS and Stata for analyses. All analytic files will be stripped of personal identifiers. Only CITI-trained personnel with appropriate authorization and relevant project need will be allowed data access. Individual data will not be available for release.

## 18. DATA ANALYSIS PLAN

**Aim 1:** For the quantitative measures, we will calculate descriptive statistics including the mean number of subjects screened and enrolled per week, percentage of eligible subjects, percentage of eligible subjects enrolled, percentage of subjects completing the intervention and follow-up assessments, and mean ratings on the CSQ-8 items. We will use the Framework Method to analyze the qualitative data from the semi-structured interviews conducted during the follow-up assessment.

**Aim 2:** In order to obtain a preliminary estimate of the efficacy of the intervention, we will calculate the proportion of subjects who schedule professional treatment within one-month after receiving CBT-TS for Deaf Individuals. We will also use the standardized response mean (SRM) effect size to assess clinically significant change in our treatment-seeking indices: perceptions of treatment (i.e., attitudes toward treatment, subjective norms, and perceived behavioral control), and intention to seek treatment. The SRM represents the ratio of the mean change to the standard deviation of that change and is a form of Cohen's effect size index useful for indicating responsivity to an intervention. The SRM takes into account variability in change over time and is thus more conservative than scores using the standard deviation of the baseline score.

**Aim 3:** We will use the data from the semi-structured interviews conducted during the follow-up assessment, the quantitative ratings from the CSQ-8, data from the treatment utilization survey about reasons for seeking or not seeking treatment and barriers encountered when attempting to seek treatment, descriptive statistics from the clinical outcome data (e.g., perceptions about treatment, intention to seek treatment, and symptom severity), and recruitment and retention data to inform the refinement of the CBT-TS intervention to enhance its usefulness for Deaf individuals.

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