Study Protocol with Statistical Analysis Plan and Informed Consent Form

Last Updated: 11/3/2025

OVERVIEW OF STUDY PROCEDURES

We will pilot test the acceptability and feasibility of peer support worker delivery of the combined CLF + THN intervention to adults involved in BCRI's pre-booking diversion program (*N* = 30). RAND staff will train and supervise BCRI peer support staff in the delivery of the intervention. BCRI staff will recruit participants from the Law Enforcement Assisted Diversion program. Peer support staff will deliver the intervention; they will coordinate with BCRI's 988 and harm reduction staff to ensure that study participants have the chance to practice utilizing crisis interventions (i.e., engaging in a practice 988 call and practicing naloxone administration steps). Participants will also have access to treatment as usual through the Law Enforcement Assisted Diversion program including trauma-informed intensive case management services.

We will use a mixed methods approach for evaluating the CLF + THN outcomes and processes. We will use pre- and post-intervention surveys to assess the acceptability of the combined intervention from the perspective of service recipients. Other outcome measures will include changes in self-reported knowledge about crisis resources, barriers to the utilization of crisis resources, and likelihood of using crisis resources. Surveys will be delivered on BCRI devices through REDCap. Participants will receive a $30 gift card upon completion of the post-intervention survey.

Quantitative process measures of feasibility will include the number of trained BCRI staff, the proportion of eligible participants who agreed to participate in the pilot intervention, and the proportion of eligible participants who completed the pilot intervention. We will use semi-structured interviews with BCRI staff who were trained in, delivered, or administered the combined intervention to evaluate its acceptability and feasibility from the diversion program perspective. We will also assess ways the diversion program could *leverage or create data resources to identify and follow pre-booking diversion participants* who may benefit from CLF and/or THN.

EMERGENCY & DISTRESS PROCEDURES

Interviews will occur by telephone, Zoom, or Teams, without any knowledge of where the interviewee is physically located.

1. DISTRESSED PARTICIPANT

Distress related to the interview is possible, and expected to be mild and temporary. Distress may be observed in the following ways:

- Interviewee becomes so emotional (angry, sad) that they are unable to continue the interview
- Interviewee becomes very withdrawn to the point they are not engaged in the interview
    - You may say: "*We appreciate your participation in this interview, as it will help us improve services at the clinic. However, I also would like to reiterate that your participation in this interview is voluntary and you can end at any time.*
- Interviewee ends participation abruptly
- You may say or text/leave a message if they hang up abruptly:

Thanks for doing the interview. It can be hard to talk about these kinds of things, but most people feel better pretty quickly. Remember, you can always call 988 or text 741 741 for support that is available 24 hours a day and 7 days a week.

2. IMMEDIATE INTENT TO ENGAGE IN SUICIDAL BEHAVIORS

If an interviewee indicates that they are currently considering killing themselves at that time, or thinking about taking their life, or have a current active death wish, research staff should immediately follow these procedures.

Example of statements that meet this criterion include:

"I'm thinking about suicide/killing myself/ending it."

"I feel like I want to kill myself."

"Nothing is going to get better, I hate this, I don't want to live anymore"

- Record on paper verbatim what the respondent reported, and call consulting Co-Investigator as soon as possible (Julie Cerel at [phone number]).
- You may say to the participant:

"You said (repeat what they said).

"Sometimes these thoughts and feelings are normal responses to what you experienced. However, sometimes these thoughts can lead someone to harm himself or herself. I want you to make sure you are safe. Let me ask you some questions so we can figure out a plan to keep you safe.

- Assess risk using Columbia-Suicide Severity Rating Scale (https://suicidepreventionlifeline.org/wp-content/uploads/2016/09/Suicide-Risk-Assessment-C-SSRS-Lifeline-Version-2014.pdf) or similar risk assessment questions.

- Depending on suicide risk assessment, discuss next steps:

"I want to make sure you are safe.

"Do you have a doctor / therapist you can call?"

"Is there anyone with you that I could talk to, to help keep you safe?"

[If none of these options seem to be working] *"Can you go to the ER?" "Do you want to call 911 for immediate help?"* [talk through steps]

"I'd also like you to write down these numbers you can call so that you can talk to someone if you think you might hurt yourself later.

[Provide participant with the contact number for crisis text line repeat if they don't have them handy from the interviewer, make sure they have a pen and are writing the numbers down,].

"Will you call someone?"

- If interviewee has said it is okay, notify their clinician.
- If there is imminent risk to the interviewee (e.g., lethal means and imminent intent), call 911 to initiate a wellness check on the study participant, and stay on the call until help arrives. Work with interviewee to restrict access to lethal means.
- File incident report and consult with HSPC (RAND IRB) to consider other steps.

3. REPORTED CHILD ABUSE OR ELDER ABUSE

No questions in the interviews ask directly about child abuse. If an interviewee spontaneously reports that a **child**, **elder**, or dependent adult is currently being abused or has been abused in the past (including physical injury caused by other than accidental means, sexual abuse, sexual exploitation, other emotional abuse, unjustified punishment, and neglect that causes harm or threatened harm to the child's health or welfare), interviewer should immediately follow these procedures:

Record on paper verbatim what the respondent reported.

You may say to the participant:

"That worries me. I want to make sure you/he/she is safe, so I'm going to talk about this with my supervisor so we can be sure everyone is safe."

Complete an incident report and call Child Protective Services if advised by HSPC to make a report.

DATA ANALYSIS PLAN

As described above, we aimed to take a mixed qualitative-quantitative approach to data analysis. We calculated descriptive statistics to assess participants' perceptions of the intervention's acceptability and appropriateness. We also calculated descriptive statistics to assess participants level of satisfaction with the intervention, knowledge about 988, and knowledge about naloxone. To assess changes in knowledge and comfort using 988 and naloxone, we conducted paired t-tests with pre- and post-intervention survey measures.

Our survey included several open-ended questions that solicited qualitative information about participants' perceptions of the intervention and ways it may be improved. Few study participants responded to these items and the responses that were provided were very brief (e.g., one to two words.) While we planned to conduct a Rapid Qualitative Analysis of these data, we ultimately decided not to analyze this very limited set of data and to rely, instead, on quantitative assessments.

CONSENT SCRIPT

Introduction: You are being asked to participate in a new Crisis Ready Training and to complete two surveys about the training.

Who are we? This research project is being conducted by RAND, an independent, nonprofit research organization. Researchers from the University of Michigan are also part of the research team.

Purpose: Suicide and overdose are a serious problem in our community. The National Center for Health and Justice Integration for Suicide Prevention funded RAND to explore ways to test a training about two crisis resources called Crisis Ready training. The Crisis Ready training is experimental. You and about 30 other people who receive services from Baltimore Crisis Response, Inc are invited to participate in an evaluation of this training. We invite you to participate in and to complete two surveys that will ask about your knowledge, experiences, and opinions about the training. You will complete the surveys before and after the Crisis Ready training.

Training Length: The Crisis Ready training will take about 45-60 minutes and the two surveys will take about 15 minutes each.

Voluntary Participation: Your participation is completely voluntary, and you may stop at any time. There are no consequences for deciding not to participate, for skipping questions, or for deciding to stop the surveys after you begin. If you need to break off before completing the surveys, you can take a break and come back to it. If you decide to quit the training or the survey, the questions you have already answered will be retained.

Incentive: You will receive a $30 Walmart gift card for completing the two surveys and participating in the Crisis Ready Training. You will receive the gift card after you finish the second survey.

Privacy: Some of the questions in the surveys will be personal. For your privacy, you may want to take the surveys where other people won't see your paper. To protect your privacy, we won't write down your name or any information that could be used to identify you. The information you share during the Crisis Ready Training or on the survey will be treated as confidential. However, if we learn that you are a danger to yourself or another person, or if we learn about abuse of a child or elderly person we may be required, by law, to notify someone who can help.

This research project is part of the National Center for Health and Justice Integration for Suicide Prevention (NCHATS). The de-identified information in a final de-identified database will be shared with the NCHATS methods core (Michigan State University, Brown University, and Henry Ford Health System). This database may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. Individuals with oversight of research responsibilities at RAND, our partnering institution Michigan State University (MSU) along with the funding agency the National Institute of Mental Health (NIMH) may have access to the research records.

We may present findings from the surveys in scientific journals or presentations but we will not share your name or any other information that could be used to identify you.

Risks of Participation: The primary risk associated with this research project is a loss of confidentiality. We have taken many steps to protect your confidentiality (see above).

The training and surveys talk about overdose and suicide prevention. Some people might find the training or the survey questions upsetting. These questions are included to make sure the survey will accurately measure the needs and experiences of people who participate in the training. If you become upset while completing the surveys, you can access support by calling 988 to get information about crisis services.

Who do you contact if you have questions or concerns about the training or surveys?

- **Questions about the overall project or RAND**: Contact the RAND research team by emailing the project leads, Dr. Alison Athey at aathey@rand.org or Dr. Sapna Mendon-Plasek at smendon@rand.org
- If you have questions about your **rights as a research participant** or need to report a research-related injury or concern, you can contact RAND's Human Subjects Protection Committee toll-free at (866) 697-5620 or by emailing hspcinfo@ rand.org . If possible, when you contact the committee, please reference research project 2024-N0187 .

Do you agree to participate in the Crisis Ready training and surveys?