Identifiers: NCT04689867
Unique Protocol ID: HUM00152247
Secondary IDs: R34MH123609

Title: Cognitive Behavioral Suicide Prevention for Psychosis: Aim 1

Contents: Consent form for client participants finalized and approved by IRB on 12/10/2021

HEALTH SCIENCES & BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

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CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Feasibility, acceptability, and preliminary effectiveness of a cognitive behavioral suicide prevention-focused intervention tailored to adults diagnosed with schizophrenia spectrum disorders

Principal Investigator: Lindsay A., Bornheimer, PhD, School of Social Work, University of Michigan

Co-Investigator(s): Joseph A. Himle, PhD, School of Social Work, University of Michigan; Cheryl King, PhD, Department of Psychiatry, University of Michigan; Stephan Taylor, MD, Department of Psychiatry, University of Michigan

Study Sponsor: National Institute of Mental Health

You may be eligible to take part in a research study. This form has information to help you decide if you want to join the study. Take time to read this information and ask us any questions you have. Make sure you understand what the study is about. If you decide to join the study, you will be asked to sign this form before you can start.

1.1 Key Information

This research tries to understand if a treatment program can be helpful. The treatment is for adults with psychosis who have thoughts of suicide.

To see if you can participate, you will answer questions in a 1 to 1 ½ -hour meeting with our research staff.

If you are eligible and want to participate, you will:

1. Be scheduled to answer questions in a 1-1.5 hour assessment; also in 1-month, 3-months, and 5-months. Assessment questions will ask about mental health symptoms including experiences with psychosis, depression, suicide thoughts and suicide attempt. These assessments will also include cognitive testing to learn about how you attend to and make meaning about suicide-related information.
2. Go to weekly one-on-one therapy sessions with a therapist for up to 10 weeks. Our research staff will set this up for you and therapy sessions will take place either in-person or virtually (using videoconferencing software like Zoom) with a therapist from Washtenaw County Community Mental health. All therapy sessions will be recorded. This is so we can check that therapists are doing a good job with treatment.
3. Use a treatment website between therapy sessions. The website has short videos to help you practice skills.

4. Receive text messages weekly (with your consent). Messages will include supportive statements and information about treatment.
5. Answer questions in a 30-minute interview with research staff when treatment is over. This will be recorded and questions will be about your treatment experience.

There can be risks with any research study. For this study, some risks may include getting bored, tired, or upset with the treatment, survey, or interview questions. More detailed information will be provided later in this document.

This study may not benefit you now but could help others who receive this new treatment in the future. However, it is possible that your symptoms of psychosis and depression may get better. Also, thoughts of suicide and attempt may get better. Other studies of this treatment found those improvements. You may also experience more support from Washtenaw County Community Mental Health and may find it enjoyable to share your experiences with the research team. This is very important because your participation will help us to provide better mental health services to you and community members to prevent suicide.

More information about this study continues in Section 2 of this document.

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

2. PURPOSE OF THIS STUDY

In this study, we will test a Cognitive Behavioral Suicide Prevention for psychosis (CBSPp) treatment program. This treatment is for adults in community mental health with psychosis who have thoughts of suicide or attempted suicide. At this time in our study, we are looking for adults to participate in testing the treatment.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

We will confirm you meet study eligibility using a short survey. The following are required:

- Must be an adult (over 18 years of age)
- Must be a client at Washtenaw County Community Mental Health
- Must have received services in Community Mental Health within 6 months
- Must speak and read English
- Must have a schizophrenia spectrum or other psychotic disorder
- Must have thoughts of suicide or have made a suicide attempt within 3 months of today.
- Must have access to a phone and device for internet use (computer or smart phone with internet access) for remote engagement (if in-person is not possible)

3.2 How many people are expected to take part in this study? We will enroll 8 participants to receive the treatment.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study? The first step involves completing a 1 to 1 ½ hour screening meeting with research staff either in-person or remotely (through a secure videoconferencing software like Zoom when in-person is not possible). This meeting will help us see if you are eligible to participate. This means, we need to see if you meet the requirements listed above in section 3.1. In this brief screening meeting with research staff, we will confirm your diagnosis, experiences with suicide thoughts and attempt, and reading level in English.

If you are eligible and choose to participate, you will:

1. Be scheduled to answer questions in a 1-1.5 hour assessment; also in 1-month, 3-months, and 5-months. Assessment questions will ask about mental health symptoms including experiences with psychosis, depression, suicide thoughts and suicide attempt. These assessments will also include cognitive testing to learn about how you attend to and make meaning about suicide-related information.

2. Go to weekly one-on-one therapy sessions with a therapist for up to 10 weeks. Our research staff will set this up for you and therapy sessions will take place at Washtenaw County Community Mental health. All therapy sessions will be recorded. This is so we can check that therapists are doing a good job with treatment. If your trained provider leaves or cannot continue treatment as planned, a new trained provider will continue your treatment in the study.

3. Use a treatment website between therapy sessions. The website has treatment information and short videos to help you practice skills.

4. Receive text messages weekly (with your consent). Messages will include supportive statements and information about treatment.

5. Answer questions in a 30-minute interview with research staff when treatment is over. Questions will be about your treatment experience.

The screening meeting, all assessments, and 1-hour interview will be recorded via the videoconferencing software for research purposes. Video recording would be done if using a webcam is possible, otherwise we will audio record using the same software.

As part of the study, staff at Washtenaw County Community Mental Health will view your medical record to collect the following data:

- attendance and service use at Community Mental Health
- frequency and nature of emergency room visit documentation
- frequency and nature of inpatient hospitalization documentation

The purpose of collecting medical record data is to see what services you receive while in the study. Importantly, these staff will remove your name from data and replace it with your study ID number before to giving it to the research team (see section 8 below for more detail).

4.2 How much of my time will be needed to take part in this study? We expect the amount of time you will participate in the study to be approximately 19 hours total:

- Up to 1 ½ hour screening survey
- weekly one-on-one therapy sessions with a trained provider for up to 10 weeks (10 hours maximum)
- use of treatment website with short videos between treatment sessions during the 10 weeks of treatment (2 hours approximately)
- 1-1.5 hour assessments at 4 time-points (4 hours total)
- interview at the end of study (30-minute)

4.2.1 When will my participation in the study be over? Once you complete the interview with research staff at the end of the 5-month follow up (approximately 7 to 8 months from today).

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The possible risks are:

1. you may get upset with the survey, treatment sessions, treatment website and videos, and interview questions including topics on psychosis and suicide
2. possible loss to confidentiality or privacy
3. you may get tired with the survey, treatment sessions, treatment website and videos, weekly text messages, and interview questions
4. you may get bored with the survey, treatment sessions, treatment website and videos, weekly text messages, and interview questions

We will try to minimize these risks by:

1. You can take a break or stop treatment, answering questions, and use of the website, treatment reinforcing videos, or receiving treatment text messages at any time
2. You do not have to answer any questions you do not want to answer
3. You can stop participation at any time
4. You don't have to be in this study if you don't want to
5. The research staff who will give you the surveys, tell you about the treatment, and ask you questions in the interview will offer breaks and look out for when you might be bored, tired, or become upset
6. The therapists who are trained to deliver this treatment will offer breaks and look out for when you might be bored, tired, or become upset
7. Provide referrals to suicide prevention resources in the community and nation when in-person with research staff and on the treatment website
8. Research staff will follow-up with you if risk is of concern or if risk is experienced. We will provide resources and linkage to local care as needed to ensure your safety
9. Your provider will set up the recording and directly after your session will upload the file. The recording file will be uploaded without your name into a secure online storage system. Your provider will then delete the original recording off of their recording device.
10. We will use a study ID number to label all of your data instead of using your name. See section 8 below for more information

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 How could I benefit if I take part in this study? How could others benefit?
This study may not benefit you now but could help others who receive this new treatment in the future. However, it is possible that you may benefit from the treatment and your symptoms of psychosis and depression may get better. Also, any thoughts of suicide and attempt may get better from this treatment. Prior studies of this treatment found those improvements. You may also experience more support from Washtenaw County Community Mental Health and may find it enjoyable and/or rewarding to share your opinions and experiences with the research team. This is very important because your participation will help us to provide better mental health services to you and community members to prevent suicide. It is also possible that your symptoms of psychosis, depression, and suicide thoughts could improve if you continue your current treatment at CMH and don't participate in this study.

5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study? Yes, the researchers will tell you if they learn of important new information that may change your decision to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. Also, the care you already receive from Washtenaw County Community Mental Health will not be impacted.

Demographic information will be collected from participants who sign this consent and can participate but choose not to. This information will help us to compare to participants who do and do not participate in the study.

If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9, "Contact Information." If you choose to tell the research staff why you are leaving the study, your reasons may be kept as part of the study record. Research staff will keep the information collected about you in the study unless you ask us to delete it from our records. If the research team has already used your information in a research analysis, it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?

1. If you complete the screening survey today, you will get a $5 gift card.
2. If you are eligible, choose to participate, and complete the 1-hour survey today, you will get an additional $20 gift card.
3. If you attend the 10 therapy sessions, you will get a $10 gift card each week ($100 total if all attended)
4. If you complete the surveys at approximately 1-month, 3-months, and 5-months, you will get a $30 gift card each time.
5. If you agree to the 1-hour interview with research staff at the end of the study (approximately 7-8 months from today), you will get an additional $35 gift card.

Because this study pays more than $100, the University of Michigan will collect and safely store your name, address, social security number, and payment amount for tax reporting purposes. If you receive more than $600 in payments in a calendar year, this information will be sent to the Internal Revenue Service (IRS) for tax reporting purposes and an extra tax form (Form 1099) will be sent to your home. If you are a University of Michigan employee, your research payments are tracked separately and are not included as part of your payroll.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information? To keep your information confidential, we will

1. Use a study ID number to label all of your data instead of using your name. This means your name will not be on any files of your collected data (will be de-identified).
2. Only designated staff at Washtenaw County Community Mental Health will enter medical records and de-identify all information prior to giving it to the research team.
3. Transcribe your interview about the treatment. This means your name will not be on any interview data files and your answers to questions will be read by the research team on paper instead of listening to the tape (your voice will not be heard during analyses).
    a. All recordings will be destroyed 5 years after the study ends (8 years from this year).
4. Have a list linking your study ID number with your name will be kept in a separate locked office from the survey and interview data. Any contact information you provide to us will be used to schedule the 2-hour in-person meeting.
    b. All files with your identifying information (name, contact information) will also be destroyed 5 years after the study ends (8 years from this year).

8.1.1 Special Protections. This research holds a Certificate of Confidentiality (CoC) from the National Institutes of Health. This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. In general, we will use the Certificate to resist any demands for information that would identify you, except as described below.

We may disclose your information for any purpose to which you have consented, as described in this consent document including sharing your de-identified data (not including your name or any identifiable information) with others for future research. As required by law, we may report and disclose your information to the appropriate authorities if we suspect or learn about cases of child or elder abuse or neglect, or that you may harm yourself or others.

Please note that a CoC 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 written consent to receive research information, then we will not use the Certificate to withhold that information.

More detailed information about Certificates can be found at the NIH CoC webpage**:** https://humansubjects.nih.gov/coc/index

8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- If you receive any payments for taking part in this study, the University of Michigan accounting department will need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

8.3 What will happen to the information collected in this study?
We will keep the information we collect from you during the study for future research projects. During the study, your name and contact information will be stored safely and securely. this means it will be separate from your collected data. A study ID number will be used to label all of your collected data instead of using your name. The recording and list linking your study ID number with your name will be destroyed 5 years after the study ends (8 years from this year).

The results of this study could be published in an article or presentation but will not include any information that would let others know who you are.

8.4 Will my information be used for future research or shared with others?
We may use or share your research information for future research studies. If we share your information with other researchers, it will be de-identified. This means that it will not contain your name or other information that can directly identify you (for example: phone number or address). This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

We will also put the information we collect from you into a repository. The repository contains information about many people. Your information will be de-identified and labeled with a code, instead of your name or other information that could be used to directly identify you.

8.4.1 Special Requirements This study will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this Web site at any time.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Lindsay A. Bornheimer, PhD
Email: bornheim@umich.edu
Phone: 734-763-3372

Study Coordinator: Juliann Li Verdugo, MSW
Email: suicidepreventionproject@umich.edu
Phone: (774) 813-0015

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

10. YOUR CONSENT

Consent to Participate in the Research Study

By signing this form, you are agreeing to be in this study and have your screening, assessment, interview, and therapy sessions recorded for research purposes. Make sure you understand the study before you sign. We will give you a copy of this form for your records. We will also keep a copy with our study records. If you have any questions about the study after you sign this form, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about, and my questions so far have been answered. I agree to take part in this study.

I consent to participate in this study ☐
I do not consent to participate in this study ☐

Electronic Signature:
Email Address (for correspondence with research staff):
Phone number (for correspondence with research staff):

Please confirm that your email is private (not accessed/shared by anyone else):
My email is private ☐
My email is not private ☐
No email ☐

If your email is not private or if you don't have email, can we call you using the number you provided above to share participation information?
Yes ☐
No ☐

For text-messaging purposes:

Please confirm that your phone number is private (not accessed/shared by anyone else):
My phone number is private ☐
My phone number is not private ☐
No phone number ☐

If you have a phone number that is private, do you agree to receive our treatment text messages? (you can opt out at any time)
Yes ☐
No ☐
N/A or no phone number ☐