Study Title: Cognitive Behavioral Suicide Prevention for Psychosis: Aim 2
NCT # NCT05345184
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HEALTH SCIENCES & BEHAVIORAL SCIENCES IRB
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CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Aim 2 of Cognitive Behavioral Suicide Prevention for psychosis (CBSPp) Bornheimer NIMH R34

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 contains information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start the study. Before you sign, be sure you understand what the research study is about.

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 and our study is hoping to determine if the treatment is more helpful than the standard (usual) services that clients at community mental health (CMH) receive.

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

If you are eligible and choose to participate, you will complete a 2-3 hour survey (called the baseline survey) and be randomly selected by a computer to either be placed in the treatment group or standard services group at Washtenaw County Community Mental Health.

If you are selected to the standard services group, you will continue to receive your current services at CMH and complete a survey in approximately 1-month, 3-months, and 5-months.

If you are selected to the treatment group, you will attend weekly one-on-one therapy sessions with a trained provider for up to 10 weeks, use a treatment website between sessions, complete a survey in approximately 1-month, 3-months, and 5-months, and possibly be invited to attend a 30-minute interview with research staff at the end of the study.

Any eligible participant will be invited to attend a 1-hour interview with research staff at the end of the study if interested and have a history of suicide attempt per the screening assessment. This interview will be recorded and include questions about your suicide attempt experience.

For all participants, we will collect service use data from your electronic medical record at Washtenaw County Community Mental Health. Data will include appointments, attendance, and services received at CMH, along with any documentation of emergency room visits and inpatient hospitalizations. The purpose of this is to see what services you receive while in the study.

There can be risks with any research study. For this study, some risks may include getting bored, tired, or upset with the treatment (if in the treatment group), survey, or interview questions. Another risk is possible breach of confidentiality. More detailed information will be provided later in this document.

If you receive the treatment, 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. If you choose to not participate, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. This means your current CMH services will not be impacted. If you do join the study, 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. This means your current CMH services will not be impacted.

2. PURPOSE OF THIS STUDY

In this study, we will test a Cognitive Behavioral Suicide Prevention for psychosis (CBSPp) treatment program to help adults in community mental health with psychosis who have had thoughts of suicide or attempted suicide. We are hoping to see how the treatment (CBSPp) compares to usual services at CMH.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study? Adults (over 18 years of age) who speak English and have at least a 6th grade reading level can take part in this study. In addition, adults must have a schizophrenia spectrum or other psychotic disorder and have experienced suicide thoughts or made a suicide attempt within 1 year of today. We will confirm you meet study eligibility using a brief screening survey.

3.2 How many people are expected to take part in this study? We will enroll 60 participants to be randomly chosen to either: 1) receive the new treatment, or 2) receive standard services in community mental health.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study? The first portion involves a 1.5 hour maximum screening survey. In this survey given by research staff, we will confirm your diagnosis, recent experiences with suicide thoughts and attempt, and reading level. The screener will be recorded to make sure data are accurately collected.

If you are not eligible, your study participation will be complete at this time. We will destroy your screening data along with all other study data within 5 years of the end of the study. As described below in section 8.1, you will be given a study ID number and that number will be listed on your data instead of your name.

If you are eligible and choose to participate, you will complete a 2-3 hour survey and be randomly selected by a computer to either be placed in the treatment group or standard services group at Washtenaw County Community Mental Health.

If you are selected to the standard services group, you will:

- Continue to receive your current treatment at Washtenaw County Community Mental health, with the option to receive this new treatment after the end of our study.

- Complete a 2-3 hour survey in approximately 1-month, 3-months, and 5-months. Surveys will be focused on your experiences with symptoms of psychosis, depression, suicide thoughts and suicide attempt. Survey assessments will also be recorded to make sure data are accurately collected.

If you are selected to the treatment group, you will:

- Attend weekly one-on-one therapy sessions with a trained provider for up to 10 weeks. Therapy sessions at Washtenaw County Community Mental health may seem similar, but this is a new therapy that we are testing that has not been offered before. Our research staff will set this up for you and therapy sessions will take place at Washtenaw County Community Mental health at your convenience. Therapy sessions will be focused on improving thoughts of suicide and preventing suicide attempt. All therapy sessions will be recorded so we can check that therapists are correctly giving you this treatment.

- Use a treatment website that we will provide between therapy sessions and receive weekly text messages with video links to help you practice skills you will learn in treatment. Technology will be needed to access the website, videos, and receive text messages. We recommend participants always protect their privacy when using technology.

- Complete a 2-3 hour survey in approximately 1-month, 3-months, and 5-months. Surveys will be focused on your experiences with symptoms of psychosis, depression, suicide thoughts and suicide attempt. Survey assessments will also be recorded to make sure data are accurately collected.

- Attend a 30-minute interview with research staff at the end of the study if selected randomly by a computer. This interview will be recorded and include questions about your experiences in the study.

Any eligible participant regardless of study group who has attempted suicide may be asked to participate in a 1-hour interview with research staff at the end of the study. This interview will include questions about your suicide attempt experience, involving details surrounding the period before your attempt and your actions before, during, and after your attempt. The goal of this interview to better understand the experience of suicide thoughts and behaviors in addition to the survey questions. Resources and next steps will be given.

For all participants, we will collect service use data from your electronic medical record at Washtenaw County Community Mental Health. Data will include appointments, attendance, and services received at CMH, along with any documentation of emergency room visits and inpatient hospitalizations. The purpose of this is to see what services you receive while in the study.

As a participant, WCCMH and your current provider (e.g., case manager) will be aware that you are participating in this study. If you are selected for the standard services group and would like the treatment, you can receive it from a provider once you and our team finish the study.

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 vary based upon the study group you are randomly selected to join.

Treatment group: We anticipate approximately 20-21 hours total of time needed for clients to complete the following: signing consent, a screening interview (1.5 hours maximum), attending 10 sessions of therapy with a trained therapist at Washtenaw County Community Mental Health (10 hours maximum total), surveys with research staff at 4 points in time (2-3 hours each), a 1-hour interview if you have a history of suicide attempt, and possibly being randomly selected for a 30-minute interview with research staff including questions about thoughts and suggestions for this treatment.

Standard services group: We anticipate approximately 9.5-10.5 hours total of time needed for clients to complete the following: signing consent, a screening interview (1.5 hours maximum), surveys with research staff at 4 points in time (2-3 hours each), and a 1-hour interview if you have a history of suicide attempt,

4.2.1 When will my participation in the study be over? Once you complete the last survey at the end of the study. This will be up to 10 weeks after you start your first therapy session if in the treatment group, and 10 weeks from today if you are in the standard services group.

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 known or expected risks for all participants are as follows:

A potential risk is the possibility that clients may become upset, tired, or bored during the assessments and cognitive testing, given the inclusion of topics on psychosis and suicide.

The researchers will try to minimize these risks by: 1) you can take a break or stop answering questions at any time, 2) you can also stop participation at any time, 3) you do not have to answer any questions you do not want to answer, and 4) you don't have to be in this study if you don't want to. The research assistant collecting data from you will also be instructed to offer breaks and look out for when you might be bored, tired, or become upset.

Additionally, because this study collects information about you, there may be a risk of loss to confidentiality or privacy. See Section 8 of this document for more information on how the research team will protect your confidentiality and privacy.

If you are selected to the treatment group:

A potential risk is the possibility that clients may become upset, tired, or bored during the CBSPp treatment and engagement with treatment website, watching treatment reinforcing videos, and reading supportive text messages, given the inclusion of topics on psychosis and suicide.

The researchers will try to minimize these risks by: 1) you can take a break or stop answering questions at any time, 2) you can also stop participation at any time, 3) you do not have to answer any questions you do not want to answer, and 4) you don't have to be in this study if you don't want to. There will be no penalty if you leave the study or ask to stop treatment. The therapist who will deliver the treatment to you and research staff who collect data from you will be instructed to offer breaks and look out for when you might be bored, tired, or become upset.

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?

If you are selected to the standard services group:

Adult client participants may still benefit from case management and psychiatric care from WCCMH as standard services. Clients may also feel proud of their contribution to a study because your input will be used to shape future services at CMH to prevent suicide in your community.

If you are selected to the treatment group:

Adult client participants may experience reductions in psychiatric symptoms (e.g. symptoms of psychosis, symptoms of depression, and hopelessness) and SI/A (thoughts and attempts), as demonstrated in prior studies of CBSPp. Adult client participants may also experience increased sense of behavioral health support from treatment. Especially so, as their input will be utilized to shape future services aimed towards reducing premature suicidal death in their community.

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 willingness 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. An example would be if it was learned that the treatment needs to last longer in time (this is not anticipated to happen).

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 or impact in the care you already receive from Washtenaw County Community Mental Health. 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 researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have 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? You will receive payment for your time in the form of a gift card or check (you decide what you prefer) upon completion of each step in the study. Below describes payment for each of the 5 steps:

1. Screening assessment to determine eligibility: $30

If eligible:

2. Baseline survey assessment: $65
3. 1-month survey assessment: $50
4. 3-month survey assessment: $50
5. 5-months survey assessment: $55

If all 5 steps above are completed, the total amount you will receive is $250.

If you are selected and agree to the 30-minute interview with research staff at the end of the study (for those in the treatment group), you will get an additional $30 gift card or check ($280 total).

If you have a history of suicide attempt and agree to an additional 1-hour interview about your experience with research staff at the end of the study, you will get an additional $30 gift card or check ($310 total)

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information? To keep your information confidential, we will use a study ID number to label all of your data instead of using your name. We will transcribe your interview (if in the treatment group) at the end of the study on your experience with the treatment, and afterwards destroy the recording within 5 years of the study's ending. Your transcript from the interview will be labeled with your study ID number and not your name. A list linking your study ID number with your name will be kept in a locked cabinet within a locked office. All files with identifying information (name, contact information) will be destroyed as well within 5 years of the end of the study.

Recordings of therapy sessions and survey assessments may be transcribed and, if so, will be de-identified as described above. All identifying information of the transcripts will be destroyed within 5 years of the end of the study. Therapy sessions not transcribed will not be used as data and will be destroyed within 5 years of the end of the study.

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 will 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.
- 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 that can directly identify you will be stored securely and separately from the research information we collected from you. Therefore, the research information will have a study ID number and will not be identifiable. The separate file of your name and contact information will be destroyed within 5 years of the study's ending.

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, which means that it will not contain your name or other information that can directly identify you. 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 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: 734-615-2915

Study Coordinator: Nick Brdar, BS
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 document, you are agreeing to be in this study, have your screening and survey assessments, end of study interview (if selected), and therapy sessions (if given treatment) recorded. Make sure you understand what the study is about before you sign. We will give you a

copy of this document for your records (will be sent via email after you complete the form) and we will keep a copy with the study records. If you have any questions about the study after you sign this document, 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.

Print Legal Name: _____

Signature: _____

Phone Number (for correspondence with research staff):
_____

Email Address (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

If your email is not private, can we call you using the number you provided above to share participant 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 may opt out at any time).
[ ] Yes
[ ] No
[ ] N/A or no phone number

We would like to have emergency contact information in case of the following:

1) We cannot get in contact with you (e.g., your phone number is not working, or you haven't responded to our calls or voicemails)
2) An emergency occurs while you are interacting with research staff (e.g., medical emergency during an assessment)

If we contact the individual you list, they may learn that you are a participant in a research study.

Do you consent to us contacting your emergency contact individual for the above reasons?
[ ] Yes
[ ] No

If yes, please complete the following:

Emergency Contact Name (i.e. family member, spouse, roommate, friend):
_____

Emergency Contact Relationship (i.e. parent, sibling, spouse, friend):
_____

Emergency Contact Phone Number: _____

Emergency Contact E-Mail Address:
_____

HIPAA Authorization

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to WCCMH to use or disclose (release) your health information that identifies you for this research study.

The health information to be used for this research includes: service use information (types and frequency of CMH services used, such as case management services or medication management) and diagnostic information (diagnoses within the past year).

The health information listed above may be used by and/or disclosed (released) to: this suicide prevention study at the University of Michigan (PI: Bornheimer). All data will be de-identified, meaning WCCMH will share your information with use of the Study ID number and not your name.

WCCMH is required by law to protect your health information. By signing this document, you authorize WCCMH to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You may change your mind and revoke (take back) this Authorization at any time, except to the extent that the University of Michigan has already acted based on this Authorization. To revoke this Authorization, you must write to or call the study coordinator:

Study Coordinator: Nick Brdar, BS
Email: suicidepreventionproject@umich.edu
Phone: **774-813-0015**

This Authorization does not have an expiration date.

Print Legal Name: _____

Signature: _____