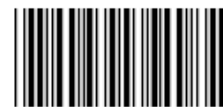


Study Title: Inpatient Cognitive-Behavioral Therapy to Reduce Suicide Risk Post-Discharge

NCT04168645

Document Date: 5.11.2022



Principal Investigator: David Tolin, Ph.D.
Anxiety Disorders Center
860-545-7685

You have been asked to participate in the research study, Inpatient Cognitive-Behavioral Therapy to Reduce Suicide Risk Post-Discharge. This research study is expected to last 3 years.

This research is funded by American Foundation for Suicide Prevention. American Foundation for Suicide Prevention is paying Hartford HealthCare and Dr. David Tolin to conduct this research.

A. The Purpose and procedures of this research

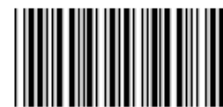
A.1. What is the purpose of this research?

You are being invited to participate in this study because you are receiving inpatient treatment following a suicide attempt. The goal of our research is to develop suicide prevention services that can be provided on the inpatient units at the Institute of Living (IOL). All participants in this study will receive the standard inpatient care provided at this hospital as well as monthly clinical monitoring for 6 months following discharge. In addition, half of the participants will receive a form of counseling called brief cognitive-behavioral therapy (BCBT) during their inpatient stay. The aim of our study is to find out whether adding BCBT is helpful in preventing future suicidal thoughts and behaviors. We intend to enroll approximately 200 people between the ages of 18 and 65, for this study.

A.2. What procedures are involved with participation in this research study?

1. You will meet with an assessment clinician who will ask you questions about your symptoms. This will be done using standard clinical interviews and on-line questionnaires. You will also complete a task on a computer where you will see and respond to different types of words. Some of these words will be words related to suicide, such as "death", while others are not. Your reaction times during the computer task will be stored on a server hosted by Millisecond. No personally identifiable information such as your name will be stored with these reaction time data. A study specific code will be stored with the data so that we can match up the reaction time data with your other study information. Only study staff at the Institute of living will know how to link your code with your other study data. These assessments will take about 2 hours.
2. Participants who meet all study eligibility requirements will then be randomly assigned (like flipping a coin) to receive either 1) clinical monitoring alone (CM) or 2) clinical monitoring plus BCBT (CM+BCBT). All study participants will receive CM, which includes monthly assessments for 6 months following discharge from the hospital. Participants in the CM+BCBT will also meet individually with a study therapist for up to 4 sessions of BCBT, depending upon how long you are on the unit. BCBT teaches new skills designed to improve coping without engaging in suicidal behaviors. In order to achieve this goal, the therapist will work one-on-one with you to solve problems, manage crises, and think about yourself and your life differently. To do this the therapist will ask you about stressors occurring in your life and how you typically cope with

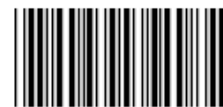
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these stressors. You will also be asked to describe your suicidal thoughts and behaviors, work with your therapist to develop a crisis response plan, identify alternatives to suicide, and practice new coping skills to handle life stressors differently in the future. The first session will be 1.5 hours and then each session thereafter will be about 1 hour. The first 3 sessions will occur daily (Monday-Friday) and the final session will occur within 2 days of your discharge from the hospital. The study therapist will be a postdoctoral fellow who is completing additional training at the Institute of Living. The study therapist completed training in BCBT, will be supervised by David Tolin, Ph.D. (the principal investigator of this study), and will receive additional consultation from M. David Rudd, Ph.D. (the developer of BCBT).

3. Before you leave the hospital, you will meet with the assessment clinician again to complete the interviews, on-line questionnaires, and computer task. These assessments are expected to last about 30 minutes. The assessment clinician will also call you once a month for 6 months after you leave the hospital for clinical monitoring. During these calls the assessment clinician will ask you about your symptoms, including any suicidal thoughts and behaviors. You will also complete the online questionnaires and computer task each month using remote access from a computer. These assessments are expected to last about 30 minutes. If you do not own a computer, public libraries typically provide computer access. If you are unable to complete the on-line portion of the assessments due to lack of computer access we can mail you the questionnaires and provide a self-addressed stamped envelope for you to return the questionnaires to us. Without computer access you will not be able to complete the computer task as part of the clinical monitoring assessments.
4. In order to complete the clinical monitoring we need to have a way to contact you after you leave the hospital. In addition, if the assessment clinician is unable to reach you within 24 hours of scheduled follow-up calls, we may attempt to reach you by calling a family member or friend that you have agreed for us to contact. If you are unwilling to provide us with your phone number and the names and phone numbers of at least two alternative contact persons, you will not be able to take part in this study. If we call your family member or friend, we will not disclose any details about the purpose of the call and will use the following language: "Hello, this is [caller's name] calling from the Institute of Living. I am trying to reach [your name]. She/he provided us with your number in the event that we could not reach him/her directly. Do you know how I might best reach him/her?" If we are still unable to reach you after contacting your family members or friends, we will send up to two follow-up letters to you. If we are unable to complete the clinical monitoring call after these attempts to reach you then we will not make any additional attempts to contact you during follow-up. We will continue to obtain follow-up information from your medical record unless we hear from you that you would like to withdraw from the study.
5. As long as COVID-19 safety regulations are being followed by Hartford Healthcare or research staff, you must wear a hospital-assigned mask during all in-person assessment and treatment sessions. If you are unwilling to wear a mask for the entire duration of all in-person sessions, you will not be able to take part in this study.
6. All assessment and treatment (CM+BCBT participants only) sessions will be audiotaped and may be reviewed by one of the study investigators so that we can be sure that the study procedures were done correctly. The content of the sessions may also be discussed with our study consultant, M. David Rudd,

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Ph.D., a nationally recognized expert in suicide prevention treatments whose treatment program we will be using in this study. However, no identifying information about you will be shared with Dr. Rudd and Dr. Rudd will not have access to audio files. Audio files will be stored electronically with password-access login maintained on the Hartford HealthCare server. Access to the audiofiles will be limited to IRB-approved study staff. Files will be maintained for 6 years following study closure at which time they will be permanently deleted. The principal investigator (David Tolin, Ph.D.) and other staff associated with this project will have access to and will monitor the security of the recordings. If you are unwilling to be audiotaped, you will not be able to take part in this study. Audiofiles may be transcribed for research and publishing purposes. Transcriptions will not contain any identifying information.

Please indicate below if you give us permission to transcribe recordings of your study meetings:

☐

I agree

☐

I do not agree

Participant's signature: _____

A.3. Which of these procedures is experimental?

As part of this study you will be completing assessments, clinical monitoring, and counseling (CM+BCBT participants only) that are not currently part of routine care at this hospital.

A.4. Where will participation take place?

This study will take place on the adult inpatient units at the Institute of Living. You will also complete 6 clinical monitoring assessments via phone and computer after your discharge from the hospital.

A.5. How long will participation last?

Your participation in this study is expected to last about 6 months.

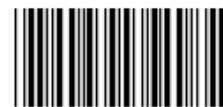
B. The possible risks, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection.

The most common risk is feeling upset when talking about stressful or painful situations, thoughts, and feelings. Treatment will involve discussions of emotionally difficult topics that can sometimes increase a person's distress in the short term. These periods of increased distress tend to be very brief, but they could increase your desire for suicide for short periods of time. Study staff will be consulting with your treatment team on the unit and sharing information with them that is discussed during any study meetings. It is therefore possible that information that is shared during the course of the study may be used by the inpatient treatment team to guide decisions about your discharge from the hospital.

Another common risk is suicide attempt. Approximately half of patients who have made a suicide attempt in past make another suicide attempt, and patients who have made multiple prior attempts are at the highest risk. The goal of this study is to develop interventions to prevent future suicide attempts. The risk of suicide attempt tends to decline over time, and when BCBT is provided in an outpatient setting for 12 sessions patients are about 60% less likely to make a suicide attempt compared to patients who do not receive this treatment. This

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improvement in risk lasts for up to 2 years after treatment. However, BCBT provided in an outpatient setting does not help everyone, and 15-30% of patients will continue to experience significant emotional distress and will make future suicide attempts during or shortly after treatment. How well this treatment works when provided for up to 4 sessions during an inpatient stay, as is done in this research study, is not yet known.

A much less common, but serious risk is death by suicide. Fewer than 2% of patients in outpatient treatment die by suicide. The risk of death by suicide is higher among patients with a history of suicide attempts, especially those who have made multiple suicide attempts. Patients who make a suicide attempt while participating in this study are at the greatest risk for dying by suicide.

As part of this study we will be in contact with you once per month for the first 6 months after you leave the hospital to monitor your symptoms. If we discover that you are having symptoms of suicidal thoughts and/or behaviors we will do an assessment to determine the best way to help you. Depending on our assessment we may provide you with referrals for follow-up care or emergency services. If we assess that you are in imminent danger of committing suicide we may contact your family, treatment providers, and/or the police to ensure your safety and wellness.

Please know that great care is taken to maintain your privacy and keep the information you provide as part of this research program confidential. There are a few situations where we are mandated to break confidentiality for the safety and protection of you and others including: 1) if we learn of abuse or neglect to a child, older person, or disabled person; 2) if we learn that there is an imminent risk of harm to yourself or someone else, and 3) if our research records are subpoenaed by a court of law. The use and disclosure of your protected health information is further described in the study authorization form.

C. There are possible benefits to you or others to be expected from your participation in this research.

You will receive either CM or CM+BCBT for suicide prevention at no cost. These study interventions may help reduce your symptoms although there is no guarantee that you will receive any therapeutic benefit.

D. There are alternatives to participation in this study that you should consider.

You may choose not to participate in this study. If you choose not to participate you will still receive the routine treatment programming provided at this hospital.

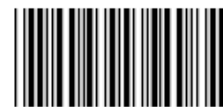
E. Who can you call if you have questions about this study?

You do not have to sign this consent form until all the questions you have at this time are answered. The investigator is willing to answer any questions you may have about the study procedures. Below is a list of contacts if you should have any questions about the study.

Questions about:	Contact	Phone #
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Informed Consent for Research



6816

the research, research-related treatments, or a research related injury	David Tolin, Ph.D.	(860) 545-7685
your rights as a research participant	An IRB Representative	(860) 972-2893
the research in general	Vice President, Research	(860) 972-2893
a confidential issue that you would like to discuss with someone not associated with research	Patient Advocates	(860) 972-1100

If you have any questions or need to contact us for an urgent or emergent situation, please contact our office at 860-545-7612.

After you have been discharged, if at any point you feel unable to stay safe, you can get help by calling the National Suicide Prevention Lifeline at 1-800-273-TALK (8255), 911, or by going to your nearest emergency room.

F. Your participation in the research is voluntary.

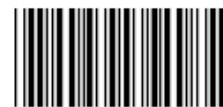
You may refuse to participate, withdraw your consent, and discontinue participation in the research at any time. You may do so without penalty, or loss of benefits to which you are otherwise entitled. Your decision whether to participate will not affect your future medical care at Hartford Hospital.

Your participation in this study may be stopped without your consent. Reasons you may be withdrawn from the study include not following the study instructions, if the study is stopped or other administrative reasons, or if new information is learned that you do not meet the eligibility requirements for the study. For example, participants undergoing electroconvulsive therapy (ECT) during their hospital stay are not eligible to participate in this study. If you undergo ECT at any point during the current hospital stay you will be withdrawn from the study.

G. You will receive financial compensation for your participation in this research.

You will receive up to \$50 for completing the post-treatment assessment (prior to discharge) and each of the 6 follow-up clinical monitoring assessments for a maximum total of \$350. Prorated payments will be provided for participants who complete only the clinical interview (\$25) or only the on-line measures (\$25). In cases where paper and pencil measures are administered due to lack of computer access the on-line computer task will not be required in order to receive payment. Assessments must be completed within one week before or after the originally scheduled date in order to qualify for payments. You will receive payment on a prepaid debit card at the completion of each study assessment. We will give you separate instructions on how to use the card. Payments will be loaded onto the card by the beginning of the next business day following a study assessment. Please be advised that once your participation in the study is over, you must spend the funds within 6 months or a monthly fee will be deducted from your card. If you lose the debit card, the lost card will be cancelled and a

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replacement will be mailed to you at the time of the next payment. Any unspent funds from the original card will be transferred onto your replacement card. We are not able to reimburse lost payment from funds that were already spent on the lost card

A note about the Internal Revenue Service (IRS): Hartford Hospital is required to report payments of \$600 or more to the IRS. This means that if you receive \$600 or more from Hartford Hospital during the calendar year, your compensation will be reported to the IRS and you will receive an IRS 1099 Form. Therefore, to receive this compensation you will need to sign a W-9 form, which includes your social security number. You may participate in this study without completing the W-9 form; however, if you choose not to complete the W-9 form we are not able to provide you with financial compensation.

H. Your confidentiality will be guarded to the greatest extent possible.

Hartford Hospital will protect all the information about you and your part in this study, just as is done for all patients at Hartford Hospital. Your records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project as described in the study's authorization form.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

Please indicate your contact preferences below.

Can we contact you by home phone? YES / NO

Is it okay to leave voice mail indicating where we are calling from and what it pertains to? YES/ NO

Can we contact you by cell phone? YES / NO

Is it okay to leave voice mail indicating where we are calling from and what it pertains to? YES/ NO

Can we contact you by text message? YES/ NO

Can we contact you by work phone? YES / NO

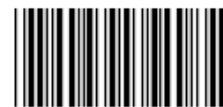
Is it okay to leave voice mail indicating where we are calling from and what it pertains to? YES/ NO

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of the emails may contain health information that identifies you.

- To contact you to schedule the clinical monitoring phone calls as part of your research participation.

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- Other information related to this research project.

Only the research team will have access to your email communications. We will only communicate by encrypted email to send you the information listed above.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your protected health information via email?

____ Yes
(Initials)

____ No
(Initials)

I. What happens if you are injured as a direct result of your participation in this research project?

In the event that you are injured as a direct result of taking part in this research, you will receive help in the following way:

If you have medical insurance, Hartford Hospital will collect fees for medical treatment at Hartford Hospital from your insurance company. If you are not fully covered by insurance or uninsured, the research sponsor of the study or Hartford Hospital will cover these expenses.

There is no plan for Hartford Hospital to pay for your medical expenses at other hospitals or for pain and suffering, travel, lost wages, or other indirect costs of taking part in this research. You do not waive any of your legal rights by signing this informed consent document.

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J. Signatures

You will be given a copy of this informed consent document to keep. By signing below, it means that you have read it, that you voluntarily agree to participate in this research, Inpatient Cognitive-Behavioral Therapy to Reduce Suicide Risk Post-Discharge, and that you consent to the performance of the procedures listed above.

--	--	--

Participant's Signature

Printed name

Date

--	--	--

Legally Authorized Healthcare Representative

Printed name

Date

--	--	--

Person Obtaining Participant's Signature

Printed name

Date

--	--	--

Witness signature

Printed name

Date

(A witness is the person observing the explanation of the above information to the participant. A witness to the informed consent process is optional unless presented orally.)

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