Study Title: A Feasibility Open Trial of App-Enhanced Brief CBT for Suicidal Inpatients

NCT05486091

Document Date: 6.22.2022

Hartford HealthCare

Informed Consent for Research

6816

Principal Investigator: Gretchen Diefenbach, Ph.D., and David Tolin, Ph.D.
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KEY INFORMATION FOR
"A FEASIBILITY OPEN TRIAL OF APP-ENHANCED BRIEF CBT FOR SUICIDAL INPATIENTS"

We are asking you to choose whether or not to volunteer for a research study about reducing and preventing suicide. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

You have been asked to participate in the research study, A Feasibility Open Trial of App-Enhanced Brief CBT for Suicidal Inpatients. This research study is expected to last for about 6 months. The purpose of this study is to evaluate the feasibility of integrating Brief Cognitive-Behavioral Therapy (BCBT) counseling with a software application (app) to prevent future suicidal thoughts and behaviors.

You will meet with an assessment clinician to answer questions about your symptoms through standard clinical interviews and on-line questionnaires. Participants who meet all study eligibility requirements will then meet individually with a study therapist for up to 4 sessions of BCBT. The study therapist will also provide directions to download the app to your SmartPhone and review how the app works. Before you leave the hospital, you will meet with the assessment clinician again to complete the interviews and on-line questionnaires. You will have access to the app for up to 3 months after leaving the hospital, while you are participating in this study. The assessment clinician will also call you once a month for 3 months after you leave the hospital for clinical monitoring. During these calls, the clinician will ask you about your symptoms, including any suicidal thoughts and behaviors, and about your experiences using the app. You will also complete online-questionnaires each month during the 3 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you agree to take part in this study, you will receive BCBT counseling and use of an app for suicide prevention and clinical monitoring at no cost. Although these study interventions may help reduce your symptoms, there is no guarantee that you will receive any therapeutic benefit. We hope the information learned from this study will benefit other people experiencing suicidal thoughts in the future.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Most risks and side effects are part of regular medical care and exist even if you do not join the study. The most common risk is feeling upset when talking about stressful or painful situations, thoughts, and feelings. Treatment and app use will involve discussing or thinking about emotionally difficult topics that can sometimes

increase a person's distress in the short term. Although this study is designed to reduce suicidal behaviors, participants with a history of suicidal thoughts and behaviors are at risk for experiencing these symptoms in the future whether or not they participate in the study. Participants who attempt suicide are at risk for death by suicide whether or not they participate in the study. Although the study will protect confidentiality, loss of confidentiality is a potential risk of study participation. To participate in this study you will be required to provide your phone number and an alternative contact person's name and phone number, agree to be audiotaped, and wear a mask.

DO YOU HAVE TO TAKE PART IN THE STUDY?

You do not have to take part in the study if you do not wish to. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The people in charge of this study are Gretchen Diefenbach, Ph.D. and David Tolin, Ph.D. from the Hartford HealthCare Department of Psychiatry. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study their contact information is:

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If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact representatives from the Hartford HealthCare Human Research Protection Program (HHC HRPP) between the business hours of 8am and 5pm EST, Monday-Friday at 860-972-2893.

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INFORMED CONSENT FORM FOR
"A FEASIBILITY OPEN TRIAL OF APP-ENHANCED BRIEF CBT FOR SUICIDAL INPATIENTS"

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

This research is funded by Hartford Hospital Medical Staff. Hartford Hospital Medical Staff is paying Hartford HealthCare, and Dr. Gretchen Diefenbach and Dr. David Tolin to conduct this research. Oui, Therapeutics is not funding this study but is providing the app for use in this study at no cost.

The Hartford HealthCare Institutional Review Board (IRB) has reviewed the information in this consent document and has given approval for the study doctor to do the study. An IRB is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

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 reported experiencing recent thoughts about suicide and a previous suicide attempt. The goal of our research is to develop suicide prevention services. All participants in this study will receive a form of counseling called Brief Cognitive-Behavioral Therapy (BCBT) during their inpatient stay in addition to the standard inpatient care provided at this hospital. You will download and use a SmartPhone app during the counseling sessions. The app has been developed by Oui, Therapeutics and is experimental software, which means that it is being tested and is not approved by the United States Food and Drug Administration (FDA). All participants will also receive monthly clinical monitoring for 3 months following discharge and you will be able to use the app for up to 3 months after your discharge as well. The aim of our study is to get feedback from you about ways we can improve the app and to find out whether using an app along with BCBT counseling is helpful in preventing future suicidal thoughts and behaviors. We intend to enroll approximately 4 people between the ages of 18 and 24, 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. These assessments will take about 2 hours.

2. Participants who meet all study eligibility requirements will then meet individually with a study therapist for up to 4 sessions of BCBT, depending upon how long you stay in the hospital. BCBT teaches new skills designed to improve coping without engaging in suicidal behaviors. In order to achieve this goal, the

IRB Use Only.

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 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.

Your study therapist will also provide directions for you to download the SmartPhone app to your phone and will review how the SmartPhone app works. No personal information is required to download the app, although you will have the option to share this information (e.g., e-mail address) with Oui, Therapeutics if you choose to do so. If you use your email address with the app it will allow you to change your own passwords. If you choose not to use your e-mail address you can contact study staff for assistance to change your password. Please discuss these options with a study staff member if you have questions so that you can make an informed decision about whether or not to share your e-mail address.

The first session will be 1.5 hours and then each session thereafter will be about 1 hour. Sessions will typically happen daily Monday through Friday, but the schedule may differ. The study therapist will be either a licensed psychologist or a postdoctoral fellow at the Institute of Living. The study therapist completed training in BCBT, and will receive supervision/consultation from the study investigators (Gretchen Diefenbach, Ph.D. and David Tolin, Ph.D.) and consultant M. David Rudd, Ph.D. (a developer of BCBT).

3. Before you leave the hospital, you will meet with the assessment clinician again to complete the interviews and on-line questionnaires. These interviews are expected to last about 30 minutes. The assessment clinician will also call you once a month for 3 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, and ask you about your experiences using the app. You will also complete the online questionnaires each month which are expected to take about 30 minutes.

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 for follow-up calls at your phone number, we will attempt to reach you by calling a family member or friend that you have agreed for us to contact. <u>If you are unwilling to provide us with your phone number and an alternative contact person's name and number, you will not be able to take part in this study.</u> 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]. They provided us with your number in the event that we could not reach them directly. Do you know how I might best reach them?" If we are still unable to reach you after contacting your family member or friend, we will send up to two follow-up letters to you. If we are unable to complete the clinical monitoring call after these attempts we will not contact you again to reschedule. We will continue to obtain follow-up information from your medical record for the 3 months following your discharge unless we hear from you that you would like to withdraw from the study.

5. Be aware that the app used in this study is not an emergency phone service. You must use the routine phone functionality on your SmartPhone in order to call 911 or other crises support services. The information you put into the app is not monitored, so the only way we will know if you are experiencing suicidal thoughts is if you tell the study clinician.

6. All assessment and treatment sessions will be audiotaped and may be reviewed by approved study staff 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, 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 (for example your name) 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 investigators (Gretchen Diefenbach, Ph.D. and 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: _____

7. As long as COVID-19 safety procedures are in place, you will be asked to wear a 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.

A.3. Which of these procedures is experimental?

As part of this study you will be completing assessments, clinical monitoring, and counseling that are not currently part of routine care at this hospital. The app used in this study is experimental.

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 3 clinical monitoring assessments via phone and\or computer after your discharge from the hospital.

A.5. How long will participation last?

Your participation in this study is expected to last about 3 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 the 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 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 along with an app 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 3 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 suicide we will contact 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 BCBT counseling and use of an app for suicide prevention and clinical monitoring 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 #
the research, research-related treatments, or a research related injury	David Tolin, Ph.D. or Gretchen Diefenbach, 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

After you have been discharged, if at any point you feel unsafe you can get help by calling the National Suicide Prevention Lifeline at 1-800-273-TALK (8255), texting HOME to 741741 to reach the Crisis Text Line, calling 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. You will continue to have access to the app while you are participating in this study. Once you are no longer participating in the study the app will be deactivated.

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 assessment prior to discharge and each of the 3 clinical monitoring assessments for a maximum total of $200. Prorated payments will be provided for participants who complete only the clinical interview ($25) or only the on-line measures ($25). Assessments must be completed within two weeks of 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 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.

Coded data (that is data that is only known by a study code number) may be shared with Oui, Therapeutics. Oui, Therapeutics will also obtain information directly from the app about app use including the number of log ins and number of sessions completed. 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 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.
- 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.

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, A Feasibility Open Trial of App-Enhanced Brief CBT for Suicidal Inpatients, 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.)