Study Title: Real-time intervention for suicide risk reduction (pilot phase)

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Version Date: 4/23/19

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because we are doing a study to test different types of treatments to help people who are having thoughts of suicide. We are inviting patients who come in to the Inpatient Psychiatric Service (IPS or "Blake 11") Massachusetts General Hospital (MGH) to take part in this study. We expect that 25 people will take part in this study.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- Your participation is completely voluntary.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.

Why is this research being done?

The time leading up to and during the experience of suicidal thoughts can be distressing. During this time, it may be difficult to access and use the skills you have learned in therapy. Because it can be hard to access the skill you've learned in therapy when you're feeling distressed, it might make what you learn in therapy less effective. The goal of this study is to test a way of using your smartphone to help you use the skills you learned in therapy.

How long will the research last and what will I need to do?

This study will last from today until four weeks after you leave the hospital. It will have three parts:

1. The first part happens today, where we'll be giving you information about the study, asking you to complete some surveys, installing some apps on your phone, and showing you how to use the app and this wristband.

2. The second part happens during your time here at Blake 11. You'll be meeting with a study therapist three times (we'll be scheduling the first time today). The therapist will teach you

the skills that you'll be using in the study. The study therapists and three in-person sessions are separate from the standard clinical care you will receive during your inpatient stay.

3. The third part begins as soon as you've finished with the study therapist and lasts for 4 weeks after you leave Blake 11. During this time, we'll send you six surveys per day to your phone. Three of the surveys will give you a chance to practice the skills we'll be teaching you. We'll also ask you to wear a biosensor wristband during this time.

Is there any way being in this study could be bad for me?
You may feel upset when responding to questions or completing the exercises. You can stop participating in this study at any time. If we learn during the course of the study that you are at immediate risk of harm, we will take appropriate measures. This may involve doing things such as informing your treatment team (if you are still on the inpatient unit) or calling you to see if you're okay (if you have already been discharged).

More detailed information about the study procedures can be found under ***"What can I expect if I take part in this research"***

Will being in this study help me in any way?
There are no direct benefits to you from your participation in this research. We cannot promise any benefits to others from your participation in this research. However, the knowledge gained from this research will hopefully help other people in the future. Your participation will result in greater knowledge about the factors that contribute to, or protect against, suicidal feelings, thoughts, and behaviors. This understanding will be important in helping individuals who think about suicide or act in a manner to end their own lives.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

What is the purpose of this research?
The time leading up to and during the experience of suicidal thoughts can be distressing. During this time, it may be difficult to access and use the skills you have learned in therapy. Because it can be hard to access the skills you've learned in therapy when you're feeling distressed, it might make what you learn in therapy less effective. The goal of this study is to test a way of using your smartphone to help you use the skills you learned in therapy.

We think this may be helpful for two reasons: First, it is helpful to practice the skills you learn in therapy in the real world, even when you are not feeling distressed. It can be difficult to do this if you do not have access to the instructions for using the skill. Having this information on your smartphone might make it easier to practice the skills. Second, if you are in distress, you will be able to easily access the skills on your smartphone.

Along with seeing whether or not these exercises are effective, the goal of this study is to improve the exercises for future studies. This is why we'll also be asking you to wear a wearable sensor that can tell us things about how much you move around and how much distress you may be experiencing. This will give us information that we can use to make the exercise more effective.

How long will I take part in this research?

This study will last from now until 28 days after you leave the hospital. As you will see below, the first four days of the study will take between 45 and 60 minutes per day. After this, the remaining days will usually take between 15 and 25 minutes per day, with one day a week taking between 30 and 40 minutes.

What can I expect if I take part in this research?

The table below lists the main activities in the study, as well as how long each activity will take and the total time it will take each day. Below the table is more description of what we'll be asking you to do.

	Day	**Major activities (time to complete)**	**Total time**
During your inpatient stay	Day 1 / today	- Consenting (15 minutes) - Completing surveys on iPad (20 minutes) - Installing apps on your phone (10 minutes) - Showing you how to use apps and wristband (15 minutes)	60 min
	Days 2, 3, 4	- Meet with study therapist to learn new skill (30 minutes) - Complete 3 short smartphone surveys (5-10 minutes total) - Complete up to 3 short exercises (10-15 minutes total)	45-55 min
	Any remaining days on Blake 11	- Complete 3 short smartphone surveys (5-10 minutes total) - Complete 3 short exercises on your phone (10-15 minutes total)	15-25 min
	Last day on Blake 11	- Complete 3 short smartphone surveys (5-10 minutes total) - Complete 3 short exercises on your phone (10-15 minutes total) - Complete surveys on iPad (20 minutes)	35-45 min
After you leave Blake 11	28 days after you leave Blake 11	- Complete 3 short smartphone surveys (5-10 minutes total) - Complete 3 short exercises on your phone (10-15 minutes total) - Complete one weekly smartphone survey (15 minutes)	15-25 min + 15 min weekly
	End of 28 days	- Complete a final survey - Send back wristband	15 min

During your inpatient stay

Day 1: We will ask you to complete some surveys on an iPad assessing things like your history of self-injurious thoughts and behaviors. After you complete the initial survey, we will loan you a biosensor watch called the Empatica Embrace and show you how to use it. This device gathers information about your physiological arousal throughout the day and the quality of your sleep at night by measuring things like skin conductance (how much you sweat), temperature, and movement. The Embrace watch should be worn as much as possible (including while sleeping), except when charging or during times when it would be immersed in water (e.g. showering or swimming).

We will also have you download two smartphone applications (apps) called LifeData and Empatica Alert onto your smartphone and we will provide instructions on how to use these apps. LifeData will allow us to send you brief, daily surveys throughout the day and the app will collect the GPS location of your

phone each time you complete a survey. Your actual GPS coordinates will be stored on the secure and encrypted LifeData server and will never be shared with anyone outside of the research team. The Empatica Alert app will monitor the data from the Empatica Embrace watch. LifeData runs primarily through Wi-Fi and requires a minimal use of data. If you do not want LifeData to use your data plan at all you may choose to have it run exclusively through Wi-Fi in the app settings. The Empatica Alert app uses Bluetooth to connect you Embrace and can only down the data via Wi-Fi.

Days 2, 3, and 4: We will ask you to meet with a study therapist to learn the exercises in the study and to practice the exercises. You will learn one each day, unless it is more convenient to do multiple exercises in one day over a longer session (or multiple sessions). During the day, we will ask you to practice the exercise three times (although we will not ask you to practice exercises you haven't yet learned, so the first day will only have one exercise and the second day will only have two exercises. We will also ask you to complete three short surveys every day.

Any remaining days on Blake 11: We will ask you to complete three short surveys and practice each exercise once. This will all happen on your smartphone.

Your last day on Blake 11: We will ask you to complete three short surveys and practice each exercise once. This will all happen on your smartphone. We will also ask you to complete a brief survey on the iPad asking about your experiences in the study so far.

After you leave the hospital

For the 28 days after you leave Blake 11: We will ask you to complete three short surveys and practice each exercise once. Once a week (on Friday afternoons) we will ask you to complete a longer survey about the past week. This will all happen on your smartphone through the LifeData app.

End of 28 days: On (or near) your last day in the study, we will ask you to complete a survey about your entire time in the study. We will also ask you to mail back your wristband using a pre-paid envelope we will mail you before the study ends.

After you finish the 28 day post-hospital period:

Other information: We would also like to use information from your electronic medical record to test whether the information that you provide in your surveys can help us to predict how you do after leaving the hospital better than the information that the hospital has already collected from you. We will collect information from the first time you came to Massachusetts General Hospital until 6 months after you finished the 28 day post-hospital period.

Contacting you: We may also contact you in the future to see if you are interested in participating in studies that you may be eligible for. You may choose to opt out of this option at the bottom of this consent form.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you do decide to leave (withdraw from) the study, you do not have to leave the entire study. If you decide to withdraw, we will ask you some questions about why you want to withdraw (which will help us in the future) and will give you some options to stop parts of the study, but not the entire study. For example, you may be able to stop wearing the wristband but continue doing the assessments and exercises.

Is there any way being in this study could be bad for me? (Detailed Risks)

There are some risks you might experience from being in this study. If you choose to participate, there is a risk that you might feel upset when responding to personal questions (such as those asking about suicide and related behaviors). You do not need to answer all survey questions and may skip ones that you find distressing. If we believe that you or someone else is at serious risk of harm, we will take appropriate measures in an attempt to decrease the likelihood of harm. For instance, we may provide you with a list of emergency resources through the LifeData app, contact you for a follow-up assessment, instruct you to call your clinician, or advise you to go to the emergency room or call 911. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research study.

There is also a risk of loss of privacy. Other people may be able to learn that you are in this study because you are wearing a biosensor watch or completing surveys. However, the watch looks like a regular smartwatch (like a FitBit or Apple Watch), and we encourage you to complete the surveys in a private manner. These steps can minimize the likelihood that other people will know you're in this study if you don't want them to know. Loss of privacy may also occur due to a data breach. We protect your privacy by referring to you by a number (rather than your name) throughout our study materials, and by keeping all collected data on secure and encrypted computer servers. Although we have taken numerous steps to ensure the security of your data, as with all data, we cannot guarantee that a breach will not occur (for instance, by someone hacking into the study servers).

Other risks include any physical discomfort associated with wearing the biosensor watch as some people have experienced skin irritation from wearing the biosensor. Please notify us at 857-242-6831 if skin irritation inhibits your ability to be a part of the study. You do not have to wear the sensors if you do not want to.

IMPORTANT!

Although we will be asking you questions about suicide on your smartphone it is important to note that we are not able to view your data in real-time and we are not able to ensure your safety over the course of the study. If your survey responses indicate that you are thinking about suicide, you may see a pop-up message encouraging you to seek help – these messages are automated and not monitored in real-time by our study staff. If you experience significant distress during the study period and have strong urges to hurt or kill yourself, you should contact your clinician (if you have one), call 911, or bring yourself to the nearest emergency room.

A member of our research team will check participants' study data each night. In some cases, we may contact you by phone, text, or email to ensure that you are safe, which may involve doing a brief risk assessment check-in with you. In case we have trouble reaching you, we would like you to provide contact information for two people who can help us reach you if needed, such as a family member and/or your psychiatrist or psychologist. We will only contact them by phone if we are unable to reach you after repeated attempts or if we have serious concerns about your safety.

Because we are not able to monitor your responses in real-time, you should not rely on the monitoring app or research team to send or provide help to you throughout the study. It is your responsibility to contact your clinician, 911, or the nearest emergency room to keep yourself safe and to receive emergency treatment in cases of elevated risk of suicidal thoughts or behaviors.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

We will take a number of steps to protect your privacy. First, we will keep your name and other identifying information stored separately from your research data so that no one outside of the research team will be able to link survey responses to specific participants. Second, the software apps that we are using store all data in a secure and encrypted form. The data will travel from your personal device over Wi-Fi to a secure cloud storage space and then to our secure study server space. Third, data from your medical record will be linked to your other data via a code number and not attached to your name. Fourth, none of your identifying information will be shared with anyone except:

- Members of the research team
- Members of the ethics board that oversees the research
- Public health and safety authorities (for example, if we learn that you or someone you know may be at risk of harm)
- Any people that you identify that we can contact to help us find you if we are unable to reach you directly. We will ask you to give us the contact information (e.g., phone number, email address) for at least one emergency contact that we can reach out to if we need to get ahold of you but cannot. If we do reach out to your emergency contact, we will only tell them that we are trying to get ahold of you. We will not tell them about the study you are in.

If you provide someone else's personal information (for example, an emergency contact) you should make them aware that you have provided the information to us. We will only use such Personal Information in accordance with this informed consent form and applicable law.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate of Confidentiality will not be used to prevent disclosure of child abuse or neglect, or harm to self or others as required by federal, state, or local law.

HIPAA-Covered Data

Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

ClinicalTrials.gov

A description of this research study 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.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to respond to survey questions several days in a row (we will contact you before removing you from the study) or if you are not well enough to continue participating in the study. If new information becomes available that might change your mind about whether you want to stay in the study the research team will share this information with you as soon as possible.

What are my responsibilities?

As a participant, you are responsible for:

- Completing sessions with the study therapist.
- Completing surveys according to the planned schedule.
- Wearing the wristband as much as possible over the study.
- Returning the wristband at the end of the study.

What else do I need to know?

This research is funded by the National Institute of Health.

Compensation - If you agree to take part in this research study, we will pay you up to $275.50 for your time and effort. A summary of the payment schedule is in the table below.

Item	Compensation	Frequency	Weekly $	Total $
Completing each survey/exercise	$ 0.50	6x/day	$ 21.00	$ 105.00
Wearing wearable monitor	$ 1.00	1x/day	$ 7.00	$ 35.00
Completing weekly survey	$ 5.00	1x/week	$ 5.00	$ 25.00
Completing end-of-study survey	$ 15.00	1x/study	N/A	$ 15.00
			SUBTOTAL	**$ 180.00**
Bonuses				
Completing 4+ assessments and exercises/day	$ 2.00	1x/day	$ 14.00	$ 70.00
Wearing monitor for 4 days/wk	$ 5.00	1x/week	$ 5.00	$ 25.00
			SUBTOTAL	**$ 95.00**
			GRAND TOTAL	**$ 275.50**

Completing each survey or exercise ($35 per week maximum): Every time you complete a survey or do the exercise, you will earn $0.50 (6 x .50 = $3.00 max per day). If you complete 4 or more surveys/exercises each day, you will earn an additional $2 every day.

Wearing the wristband monitor ($12 per week maximum): If you wear the wristband for any time during the day, you will earn $1 per day. If you wear the wristband at some point for at least four days per week, you will earn an additional $5 every week.

Completing weekly survey ($5 per week): If you complete the weekly survey, you will earn $5 each time.

Completing end of study survey ($15): If you complete the end of study survey, you will earn $15.

You will be compensated in an Amazon.com giftcard at three points: (1) When you leave the hospital, (2) two weeks after you leave the hospital, and (3) after we receive confirmation that the wristband has been mailed back to us.

Participation in the study (even if you decide you no longer want to participate in the study) will have no effect on any clinical care that they you may receive at MGH.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by emailing Evan Kleiman, Ph.D. at ekleiman@fas.harvard.edu. If you have questions about the technology (troubleshooting) or payment, please contact research assistants Sarah and Erin at 857-242-6831 or nocklab@gmail.com.

Telephone calls will be monitored and responded to during business hours 9am – 5pm Monday through Friday and email correspondences will be replied to within 24 business hours. If we miss your call, please leave a message with your contact information and we will call you back. If you have an emergency, please call 911 or go to the nearest emergency room.

This research has been reviewed and approved by the Harvard University Area Institutional Review Board ("IRB"). You may talk to them at (617) 496-2847 or cuhs@harvard.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

To confirm that you understand the information that has been provided in this form, please respond to the following three items by selecting True or False.

1. We will reach out to (one of) your backup contact(s) if we can't get ahold of you, but will only ask the backup contact to give you a message and will not tell them about the study — True / False

2. In this research study, we are going to ask you to complete surveys sent through your smartphone during the time you are in the hospital and for 28 days after. — True / False

3. We will not be monitoring your survey responses in real time. If you are in distressed or feeling unsafe, it is your responsibility to contact your clinician, call 911, or visit the nearest emergency department. True / False

Signature Block for Adult Participant

Your signature documents your permission to take part in this research.

Signature of Participant

Name of Participant

Date

May we save your information in a secure database and contact you to participate in future studies?

☐ Yes

☐ No