RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Supplementing brief psychotherapy with a mobile app
Principal Investigator: Evan Kleiman, Ph.D.

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to: evaluate the effectiveness of a smartphone-based intervention that helps you use the skills you learn in therapy. If you take part in the research, you will be asked to complete surveys today and install some apps on your phone. Shortly after you are discharged you will be asked to complete short surveys on your smartphone each day for 4 weeks after you leave the hospital. The mobile apps will prompt you to complete these surveys. Your time in the study will last from now until 28 days after you leave the hospital. As you will see below, study activities in the first day of the study will require about 35 to 60 minutes and the remaining days should require about 15 to 25 minutes each day.

Possible harms or burdens of taking part in the study may be distress when responding to questions or completing smartphone surveys. We may need to break confidentiality if you indicate during the study that you are at imminent risk of harming yourself. There are no direct benefits to you from your participation in this research. We expect the knowledge gained from this research will help other people in the future.

An alternative to taking part in the research study Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Evan Kleiman, Ph.D. is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Evan Kleiman may be reached at:
Tillett Hall, 53 Avenue E
Piscataway, NJ 08854
848-445-2345 | kleimanlab@psych.rutgers.edu

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: This study is sponsored by the National Institute of Mental Health.

Why is this study being done?

During the time shortly after hospitalization, it may be difficult to access and use the skills you have learned in therapy, which may make what you learn less effective. The goal of this research is to evaluate the effectiveness of a smartphone-based intervention that helps you practice the skills you learn in therapy.

This intervention 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; however, 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 during the study.In addition to testing whether these exercises are effective, the goal of this study is to improve the exercises for future studies.

Who may take part in this study and who may not?

Inclusion Criteria: adult status (18+ years), admission to either the UBHC Adult Inpatient Unit (AIPU) or Early Intervention Service (EISS), the ability to speak and write English fluently, ownership of and consistent access to an internet-capable smartphone (e.g., an iPhone or Android phone).

Exclusion Criteria: the presence of any factor that impairs an individual's ability to provide informed consent and comprehend and effectively participate in the study including: an inability to speak or write English fluently, the presence of gross cognitive impairment due to florid psychosis, intellectual disability, dementia, acute intoxication, or the presence of extremely agitated or violent behavior**.**

Why have I been asked to take part in this study?

We invite you to take part in this research study because you are an adult patient who has been admitted to and received up to three sessions with a clinician that explained core Unified Protocol (UP) content at Rutgers University Behavioral Healthcare (UBHC).

How long will the study take and how many subjects will take part?

This study will last from now until 28 days after you leave the hospital. As you will see below, study activities in the first day will require about 35 to 60 minutes each day. The remaining days should require about 15 to 25 minutes each day. We expect that 200 people will take part in this study. The entire study will last until 200 participants have completed the study.

What will I be asked to do if I take part in this study?
The table below lists the main activities in the study, as well as how long each activity will take each day and over the course of the study. Below the table is more description of what we will ask you to do.

Timeline	Major activities (time to complete)	Time per day
During your inpatient stay		
Day 1 (today)	- Consenting (15 minutes) - Initial survey (20 minutes) - Download smartphone apps (10 minutes) - Training on apps (15 minutes)	60 min
Remainder of inpatient stay	- Complete 3 short exercises on your phone (10-15 minutes total) - Complete 1 short nightly survey (3-5 minutes)	15-20 min
Last day at UBHC	- Discharge meeting (20 minutes) - Daily tasks (15-25 minutes)	35-45 min
After you leave the hospital		
Daily for 28 days	- Daily tasks (15-25 minutes) - Complete one weekly smartphone survey (15 minutes)	15-25 min + 15 min weekly
End of 28 days	- Complete a final survey - End of study interview	50 min

<u>If you decide to take part in this study, we will ask you to complete the following:</u>

1. **Initial Survey**: We will ask you to complete a series of self-report surveys, which will ask you questions about your demographic background and mental-health related factors. This will occur today and take approximately 20-30 minutes to complete.

2. **Smartphone App Download**: We will then ask you to download a smartphone application (app) onto your smartphone. We will provide instructions on how to use these apps. This will occur today and take approximately 25 minutes to complete.

   The MetricWire app will send you brief, daily surveys throughout the day. The app requires minimal use of your cellular data and will use WiFi if you have a connection.

3. **Daily Smartphone Surveys**: We will ask you to complete 5 brief daily surveys through the MetricWire app on your phone each day that you are in the hospital and for 28 days after you leave the hospital.

   At least one of the surveys will be assessments that ask you about self-injurious thoughts and behaviors as well as related factors such as mood and sleep. The other three surveys will be exercises to practice the skills you learned with the study therapist. The last survey will be a nightly survey that asks questions about your whole day.

In the MetricWire app, you also have the option of practicing the learned skills at any time through the skills practice survey. We ask that you use this survey if you feel distressed and want to practice a skill.

(Note: For the first couple days we will not ask you to practice exercises you haven't learned yet, so the first day will only have 1 exercise, the second day will only have 2 exercises, and so on.)

4. **Weekly Smartphone Surveys**: Each week that you are in the study you will receive 1 weekly smartphone survey. This survey will also ask you questions about what you experienced in the prior week. It will take about 10 minutes to complete.

5. **Discharge Meeting and Survey**: On your last day in the hospital, you will be asked to meet with the study research assistant to review what will be asked of you after you leave the hospital. We will also ask you to complete a discharge survey that asks questions about your experiences in the study so far. This is expected to take approximately 30 minutes to complete.

6. **Exit Survey**: On or near your last day in the study (28 days after you leave the hospital), we will ask you to complete a follow-up survey about your entire time in the study. This will take about 20 minutes to complete.

7. **End of Study Interview**: At the end of study we will invite you to talk with us for a final interview to talk about how the study went for you. This phone-based interview will last about 30 minutes. Following the interview, you will be provided with instructions to remove the application from your phone as well as additional resources that can be accessed after the study.

Other information:

Electronic Medical Record: As a part of this study, we will collect 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 **UBHC** until 6 months after you finish the 28-day post-hospital period.

Contacting you: We may call, email, or text you throughout the study to check-in regarding study technology, engagement, and compliance. We may also contact you in the future to see if you are interested in participating in other studies that you may be eligible for. You may choose to opt out of this option at the bottom of this consent form.

Remote procedures (when applicable)

For any non-therapy meetings we have with you, it is possible that we will not meet with you in person while you are at UBHC, and some study procedures may be different in these cases. There are three different meeting types when this might happen.

Day 1: The meeting today when we describe and set you up in the study.

Your last day at UBHC: This is the final meeting just before your discharge. Again, we will meet using the study iPad, and a clinician will bring you to a private room where we will ask you to answer some questions on the study iPad.

Finally, all procedures after you leave the hospital will be the same as previously described.

In all remote cases, there is a chance that poor connectivity or some other technology issue interrupts or prevents us from meeting. In these cases, we may need to communicate directly with the on-unit clinician who will come get the study iPad and schedule our meeting later that day or sometime the following day once the technology issue is resolved.

What are the risks of harm or discomforts I might experience if I take part in this study? There are some risks you might experience from being in this study.

Psychological distress – 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). In rare cases, repeatedly responding to questions about suicidal thoughts may increase thoughts of suicide or self-injury. You do not need to answer all survey questions and may skip ones that you find distressing.

Loss of confidentiality – 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 MetricWire 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. If we know that you are in hospitalized care and believe that you or someone else is at serious risk of harm, we may contact the clinical staff at that site to communicate the risk. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research study.

Loss of privacy – 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 completing surveys. However, 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).

Loss of application access – At the end of the study, you will be able to remove the app from your phone and there will no longer be prompted skills practice. Following study participation, you will be provided with a document containing information about additional resources available if you need them.

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 day. 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. If you are feeling distressed, it is your responsibility to contact your clinician, the suicide hotline, 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. The app will also contain information to help you contact the suicide hotline.

Are there any benefits to me if I choose to take part in this study?
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, we expect the knowledge gained from this research will help other people in the future. Your participation will result in greater knowledge about the factors that contribute to effective use of therapy skills post discharge from hospitalization. This understanding will be important in helping individuals who have been recently hospitalized.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take Part in this study?
Taking part in this study may lead to added costs to you. If we text or call you, standard text messaging and call fees apply. You may inform us that you would like to opt out of text messages at any time throughout the study.

Will I be paid to take part in this study?
- If you agree to take part in this research study, we will pay you up to $120.00 for your time and effort. A summary of the payment schedule is in the table below.

Compensation Schedule					
ITEM	**Compensation** *(per item)*	**Frequency**	**Inpatient (1 week)**	**Outpatient (4 weeks)**	**Total over study** *(5 weeks)*
Completing each daily assessment/ exercise	*$0.50*	*4x/day*	*$14*	*$56*	$70
Completing baseline survey	*$10*	*1x/study*	*$10*	-	$10
Completing discharge survey	*$5*	*1x/study*	*$5*	-	$5
Completing optional weekly surveys	*$5*	*4x/study*	-	*$20*	$20
Complete end-of-study interview*	*$15*	*1x/study*	-	*$15*	$15
		SUBTOTAL	*$29*	*$91*	*$120*
*** If a participant is initially unresponsive to requests to schedule the end of study interview, they will be offered an additional $20 bonus incentive**					

1. **Completing each daily assessment or exercise** ($14 per week max): Every time you complete an assessment or exercise survey (excluding the nightly survey), you will earn $0.50 (4 x .50 = $2.00 max per day).
2. **Completing baseline survey** ($10): If you complete the baseline survey, you will earn $10.
3. **Completing discharge survey** ($5): If you complete the discharge survey, you will earn $5.
4. **End of study interview** ($15): If you complete the end-of-study interview, you will earn $15.

You can choose to be compensated through an e-gift card to Amazon.com which we will distribute via email or text. You will be compensated at three points: (1) When you leave the hospital and (2) two weeks after you leave the hospital, (3) after the conclusion of the study.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. 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.

We will share your **coded** data (coded with a study identification number and without personal identifiers) with other universities and researchers conducting similar research outside of Harvard.

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. The results of this research study may be published in a medical book or journal or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

The research team may use or share your information collected or created for this study with the following people and institutions:
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Massachusetts Genral Hospital (MGH), where collaborating members of our team are located
- The National Institute of Mental Health (NIMH)

A description of this research study will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What will happen to my information—data, recordings and/or images—collected for this research after the study is over?
After information that could identify you has been removed (i.e., it has been "de-identified"), the de-identified information collected for this research will be stored on our secure servers for future use by our research team and our collaborators to answer additional questions about mental health in teens that are not the focus of this specific study. Additionally, you have the option to be a part of a larger data upload of de-identified data to the NIMH's data repository ("NDA") so that other researchers can use it. The NDA requires we create a non-identifiable ID called the GUID to link to your data. We will use your date of birth and place of birth on a secure computer program to generate this GUID, but your date of birth and place of birth will not be linked to your data. You can still participate in this research study even if you do not want their data to be added to NDA, and you can decide to change that decision at any time. However, once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed their mind. If you would like more information about NDA, it is available at http://nda.nih.gov.

We will take all efforts to make sure that no one will be able to identify you from these data. Specifically, your information will be given a code number and only certain information collected in the study will be linked with this code number. Researchers using these data will not have access to any personal identifying information. While the databases developed for future use and for the NDA will be coded to protect your personal information, people may develop ways in the future that would allow someone to link your child's information back to them. It is also possible that there could be violations to the security of the computer systems. There also may be other privacy risks that we have not foreseen.

DIGITAL AGREEMENT FOR NDA DATA SUBMISSION

Subject Consent:

I agree to submit de-identified data to the NIMH data repository (NDA).

Subject Name:

Subject Signature: Date:

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Evan Kleiman at Tillett Hall, 53 Avenue E, Piscataway, NJ 08854.

You can leave the research at any time, and 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 the assessments, but continue doing surveys and exercises.

Who can I contact if I have questions?
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Dr. Evan Kleiman at kleimanlab@rutgers.edu

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?
All information in your medical record (relevant to your psychiatric treatment)

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved in the Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Hospital Personnel as Necessary For Clinical Care
    - Rutgers University Behavioral Healthcare (UBHC)
- Non-Rutgers Investigators On the Study Team: Kate Bentley, MGH
    - Our funding sponsor, the National Institute of Mental Health (NIMH)

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision: Dr. Evan Kleiman at Tillett Hall, 53 Avenue E, Piscataway, NJ 08854.

How Long Will My Permission Last?
Your permission for the use and sharing of your health information will last until the end of the research study, about one month from your discharge date.

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AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____