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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Sleep treatment for teens

Principal Investigators: Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey; Catherine Glenn, Ph.D., Old Dominion University

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 test the effectiveness of a digital sleep treatment for teens with recent suicidal thoughts and behaviors, who also have insomnia. If you take part in the research, you will be asked to: Phase 1 (one time): answer questions in an interview and complete surveys on a computer; Phase 2 (6-10 weeks): complete a digital (smartphone-based) sleep treatment over the course of 6-10 weeks with weekly check-ins about the treatment (online survey and brief phone check in), complete short (1-3 minute) surveys on your phone, wear a special watch (like a Fitbit) to measure your sleep, and complete an interview and online survey at the end of treatment; and Phase 3 (one time): one month after you complete the treatment, complete a final follow-up interview and online survey.

Time in the study: Phase 1 (one time) will take 2 hours total; Phase 2 (6-10 weeks) will take 2 hours total for the sleep treatment, 30 minutes per week for the weekly check ins about the treatment session that week, less than 10 minutes per day for the daily surveys, and 1 hour for the assessment at the end of Phase 2; and Phase 3 (one time) will take 1 hour for the final assessment at the end of the study.

Possible harms or burdens of taking part in the study may involve feeling uncomfortable answering some questions (you can skip any question they are uncomfortable with); breaking confidentiality with you if we are concerned for your safety, breaking confidentiality if we learn a child under age 18 is being maltreated; and data breaches by unauthorized parties (we will take many steps to keep your data secure and confidential). Possible benefits include therapeutic benefits, such as improved sleep and reduced mental health symptoms.

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

This online 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 the study. It is your choice to take part or not. Ask questions if there is anything in the form that is not clear to you. If you decide to take part, instructions at the end of the document will tell you what to do next. Your alternative to taking part in the research is not to take part in it.

Who is conducting this study?
This is a study that has Principal Investigators at two different locations. A Principal Investigator has the overall responsibility for the conduct of the research. Evan Kleiman, Ph.D., is the Principal Investigator of this research study at Rutgers. He can be reached via email at evan.kleiman@rutgers.edu or 848-445-2345. Catherine Glenn, Ph.D., is Principal Investigator of the research study at Old Dominion University. However, there are often other individuals who are part of the research team.

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

SPONSOR OF THE STUDY: This study is funded by the National Institute of Mental Health (NIMH).

Why is this study being done?
The purpose of this research study is to test how effective a smartphone-based sleep treatment, digital cognitive-behavioral therapy for insomnia (dCBT-I), is for teens with suicidal thoughts and behaviors, who also have insomnia.

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

- Teens 14-18 years-old
- Recently (within past three months) in the hospital for suicidal thoughts or behaviors
- Clinically severe insomnia symptoms

Who may not be in this study?

- Prior experience with sleep treatment used in this study (CBT-I)
- High risk for obstructive sleep apnea
- Bipolar disorder or substance use disorder
- Factors that prevent teens from being able to consent to participate in research or to complete the study (ex. severe mental difficulties that prevent understanding the study, inability to read or speak English)

This study requires that you answer questions on your smartphone. If you do not have a smartphone, we will loan you a phone that can be used during the study.

Why have I been asked to take part in this study?
You are being asked to take part in this study because you are 14-18 years-old, were recently in the hospital for suicidal thoughts or behaviors, and have problems with insomnia.

How long will the study take and how many subjects will take part?
Approximately 30 teens and their parents/guardians will take part in this study across two sites: Rutgers, the State University of New Jersey, and Old Dominion University.

How long will the study last?
Your participation in the study will include three phases (described in the next section).

- Phase 1*:* Initial session (one time) will last approximately 2 hours total.
- Phase 2*:* Treatment phase (lasts 6-10 weeks, depending on how quickly you complete the treatment) includes sleep treatment of six 20-minute sessions, weekly check-ins about the treatment that will last 30 minutes, daily surveys that last no more than 10 minutes total each day, and wearing a special watch called an Actiwatch (Fitbit-like device) that doesn't take any time (just needs to be worn during the study). At the end of the treatment phase, there will be a 1-hour assessment including an interview and online survey.
- Phase 3*:* A follow-up assessment (one time), one month after treatment ends, will last approximately 1 hour total.
- Overall, your involvement in the study will last approximately 12 weeks (range 10-14 weeks, depending on how quickly you complete the sleep treatment sessions).

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What will I be asked to do if I take part in this study?
If you decide to take part in this study, you will be asked to do the following things:

Phase 1: Initial Session (one time). The first session will last about 2 hours total and will take place either: (1) during your hospitalization (on the unit); or (2) within three months after your discharge from the hospital (in our research lab or over the phone). This session can take place at one time (if in our lab or over the phone) or in a couple of separate sessions (on the hospital unit and/or over the phone). During this session, you will be asked a series of questions through interviews with the research team and in surveys you complete on your own. These questions will ask about your thoughts, feelings, behaviors (including your sleep, history of self-injury, suicidal thoughts and behaviors), and events that have happened to you. Separately, your parent/guardian will be asked similar questions about you and your family history. During this session, we also will provide you with an overview about the equipment needed for Phase 2 (sleep treatment available through your phone, smartphone-based app for surveys, and special watch to wear called an Actiwatch).

Phase 2: Sleep Treatment (6-10 weeks).

- You will be asked to complete a phone-based sleep treatment that includes six 20-minute weekly sessions that need to be completed over 6-10 weeks. For each week of treatment, you will be asked to complete a 30-minute weekly survey and phone check in about the treatment session (to make sure you don't have trouble completing the session, that you understand the material provided to you, and to get your feedback about the treatment session that week).
- During this phase, you will be asked to complete short surveys (1-3 minutes each) via smartphone several times during the day (you will answer questions on your own phone). You won't be asked to complete surveys during school hours. Surveys will ask about your thoughts, feelings, behaviors (such as your sleep, self-injury, and suicidal thoughts and behaviors), and events that may have happened to you.
- In addition to answering survey questions on your phone, you will be asked to wear a special watch called an Actiwatch, like a Fitbit, to monitor your sleep and activity. You will be asked to wear the watch on your non-dominant (non-writing) wrist all the time, except for when you are showering, bathing, or swimming. If removed, you should put the watch back on as soon as possible. We will ask you to return the watch to the research team when the study ends.
- At the end of treatment, you will be asked to complete a 1-hour assessment including an interview (over the phone or in person) and online survey. Questions will ask about your thoughts, feelings, behaviors (such as your sleep, self-injury, and suicidal thoughts and behaviors) and feedback on the treatment you completed.

Phase 3: Follow-up Phase (one time). One month after you finish the sleep treatment, you will be asked to complete an interview (over the phone or in person) and an online survey again, which will take 1 hour total for you to complete. During this session, you will be asked similar questions as other phases of the study – your thoughts, feelings, behaviors (including your sleep, self-injury, suicidal thoughts and behaviors), and events that may have happened to you. We may also ask you questions about what it was like to be in the study, which will help us conduct similar studies in the future.

(Optional) Phase 4: Medical Record Follow-Up. With your permission, the research team may obtain information from your medical record about any additional admissions to psychiatric units or hospitals for one year after you enroll in the study. This phase of the study does not require any interaction with you. This part of the study is optional and will not impact your ability to participate in the other parts of the study.

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What are the risks of harm or discomforts I might experience if I take part in this study?
Sometimes things happen to people in research studies that may hurt them or make them feel bad. These are called risks. The risks of this study are described in this section.

You might find some of the questions asked in interviews and surveys to be upsetting or uncomfortable. If you experience distressing thoughts or feelings during or after the study, we strongly encourage you to let us know when the study is in progress or after it has been completed (see contact information at the end of this form). You are encouraged to take breaks and can skip any questions or tasks that you find uncomfortable.

Your safety is the top priority. If your answers to questions indicate that you may be at imminent risk for hurting yourself, we will contact you to ask you questions and take appropriate steps to keep you safe (like suggesting you go to the hospital, or call emergency services on your behalf). However, it is important for you to know that your answers are not monitored 24 hours a day, so your survey should not be used as a way to get help in a crisis. We will provide resources to you that can be used in a crisis situation. For example, we can help you access and use the personalized safety plan you made with your clinical provider (or can help you make a safety plan if you do not have one).

If we learn during the study that a child under 18 is being abused or neglected, we are ethically and legally obligated to file a report with the Department of Children and Families (if you are in NJ) or Child Protective Services (if you are in VA). If you prefer not to disclose any information about child abuse, you can choose not to answer these kinds of questions during the study.

For the watch you are being asked to wear, there is a possibility after repeated use that you may experience mild redness or irritation on the wrist under the watch. This possible redness or irritation is temporary and not dangerous. If you experience redness or irritation, you should remove the watch and clean both your wrist and the watch with mild soap and water before putting it back on. If redness or irritation persists after cleaning, you should remove the device for the remainder of the study and inform the research team.

There is sometimes concern that sleep treatments, which include sleep restriction (where people reduce their available time to sleep in order to improve their sleep quality), may be risky for teens with emotion regulation difficulties. To address these concerns, your sleep will not be reduced to less than 7 hours a night, making it safe for teens.

Although we take several steps to keep your study information secure and confidential, you should be aware that there is an extremely small possibility that your data could be viewed by unauthorized parties (such as computer hackers). However, your identifying information (such as your name) will not be stored with your survey data, so even hackers will not be able to link your data to your identity. (See section *Will others know what I say and do in the study?* for additional details.)

Are there any benefits to me if I choose to take part in this study?
This is a treatment study and therefore you may receive therapeutic benefit by participating in the study. Other potential benefits include learning more about your mental health and about mental health resources available to you (e.g., a personalized safety plan). However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?

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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 I receive the results of the research?
You will not receive results from your individual participation in the research study. It could take many years before we know the results of this research. However, when findings from the study become available, we will let you know by making research available on our lab website: kleimanlab.org.

Will there be any cost to me to take part in this study?
There is no cost to participate in this study.

Will I be paid to take part in this study?
You will receive free access to the sleep treatment and can earn up to $170.00 for participating in all phases of the study. How much you will earn in each part of the study is provided below:

Activity	Rate	Frequency	Total
Phase 1: Initial Session	$15/hour	Once (2 hours)	$30
Phase 2: Sleep Treatment			
Daily surveys during treatment	$10/weekly	6 weeks	$60
Weekly check-ins during treatment	$5/weekly	6 weeks	$30
Post-treatment assessment	$20	Once	$20
Phase 3: Follow-Up			
1-month follow-up assessment	$20	Once	$20
Returning Actiwatch	$10	Once	$10
		TOTAL	**$170**

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in the research record confidential, but total confidentiality cannot be guaranteed. We will take many steps to protect your identity, so no one knows you participated in this study. For example, the information that may identify you (names, dates of birth, phone numbers) will be kept separate from other information you provide in this study. Your study information will be identified by a confidential ID number (e.g., #9999) that is only known to the research team. Your information will be kept in locked cabinets and password protected electronic files on secure networks. Only approved members of the research team will have access to your study information.

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
- Our funding sponsor, the National Institute of Mental Health (NIMH)
- Non-Rutgers Investigators on the Study Team:
    - Catherine Glenn, PhD, Old Dominion University
- Our Data Safety Monitoring Board (DSMB)

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To help us further protect your privacy, 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. The Certificate does not stop you or a member of your family from giving out information about yourself or your involvement in this research. If we write an article about what we learn from the study, we will not use your name

A description of this clinical trial 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.

What will happen to my information—data, recordings and/or images—and biospecimens 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 collaborators to answer additional questions about mental health in teens that are not the focus of this specific study.

Additionally, as part of the requirements of funding for this study, we need to upload the 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. 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 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.

What will happen if I am injured during this study?
Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which are detailed in “What are the risks of harm or discomforts I might

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experience if I take part in this study?". In addition, it is possible that during this study, new adverse effects of CBT-I that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid, or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

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 you 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 want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed. Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care, if needed.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Evan Kleiman, Ph.D. at Rutgers (evan.kleiman@rutgers.edu). Any data that have already been sent to NIMH cannot be withdrawn because there will not be any identifiers with the data that indicate which data are yours.

Who can I contact if I have questions?
If you have questions, concerns, problems, information, or input about the research, you can contact the Principal Investigator at your site. If you are at the Rutgers Site, you should contact Evan Kleiman, Ph.D. at evan.kleiman@rutgers.edu or 848-445-2345.

If you have questions, concerns, problems, information or input about the research or would like to know about 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 at irboffice@research.rutgers.edu, Or, you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

If you experience a mental health crisis or emergency during your participation in this study, please call 988 or contact Rutgers' University Behavioral Health Center's Crisis Service Line by calling (800) 969-5300.

Follow-Up Contact:
If we have a study in the future that may be of interest to you, can we contact you to tell you about the new study in our lab? Your choice will not affect your ability to participate in the study or affect your treatment. (Please check one.) Yes No

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DIGITAL AGREEMENT TO PARTICIPATE

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 my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name:_____

Subject Signature:_____Date:_____

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

The next few paragraphs tell you about how investigators may 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. This is not required in order for you to participate in this study.

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?
We will collect only what is needed to satisfy study aims and is consistent with what is outlined in the protocol to be collected.

- 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
- Our funding sponsor, the National Institute of Mental Health (NIMH)
- Non-Rutgers Investigators on the Study Team:

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- Catherine Glenn, Ph.D., Old Dominion University
- Our Data Safety Monitoring Board (DSMB)

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, you will not be able to review your research record while the research is ongoing. It is important to note that the information gathered is for research purposes only and therefore cannot be used for clinical reasons. If you are need of an assessment for clinical purposes, you should consult with your doctor, or we can make a recommendation for a provider in your area.

Do I have to give my permission?
No. You do not have to permit use of your information. This part of the study is optional. (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 cancel your permission to use and disclose your health information at any time. You do this by sending written notice to us (see contact information below). Upon receiving the written notice, the study team will no longer use or disclose your health information. Information that has already been gathered may need to be used and given to others for the validity of the study.

How long will my permission last?
There is no set date when your permission will end. Your health information may be studied for many years. Therefore, this permission will last indefinitely or until you request that you no longer want your data to be used.

(OPTIONAL) CONSENT FOR USE OF HEALTH INFORMATION

Subject Consent:

I agree to let the investigators use my identifiable health information in the research.

Subject Name:_____

Subject Signature:_____Date:_____