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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: E-Manage: A brief mHealth intervention for university students
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 a brief psychological intervention for college students delivered through treatment sessions and a smartphone app. If you take part in the research, you will be asked to spend about 30 minutes taking a series of surveys that will include questions about your demographics, emotions, and mental health. You will then be provided with instruction on how to download and use MetricWire (smartphone app) on your device. Over the next 8 weeks, you will be asked to complete up to 4 surveys a day, on MetricWire, that will assess your emotional health. It is expected to take between 5-15 minutes a day to complete these surveys. You will be asked to learn emotion regulation skills through one of the following: up to three one-on-one therapy sessions (~30 minutes per session, which will likely occur weekly); a group session (~60-90 minutes a week for 3 weeks); or a workshop (a single ~60-90 minute session). You may also be invited to an optional booster workshop where you can review the skills you learned previously. Your total time in the study will be approximately 8 weeks, but may be longer if the time between therapy sessions is longer than one week.

Possible harms or burdens of taking part in the study may be experiencing some psychological distress while taking surveys about your emotional health or distressing topics such as self-injury. Other risks include a possible loss of confidentiality following a breach in data security or while completing momentary surveys. Possible benefits of taking part may be a reduction in distress and improved coping with the distress associated with negative emotion.

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?
Dr. Evan Kleiman 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. Kleiman may be reached at 848-445-2345. His office is located in Tillett Hall, 53 Avenue E, Piscataway NJ 08854.

You are being asked to electronically sign this consent form. You will be emailed a copy of the signed consent form to keep.

Why is this study being done?
This study is being done to evaluate the effectiveness of different ways of learning a psychological intervention aimed to help people respond to negative emotion and emotional distress in more adaptive ways. This study is also assessing how effective the intervention is when delivered via a smartphone app in conjunction with therapy or workshop sessions.

Who may take part in this study and who may not?
We are looking for current Rutgers students (both undergraduate and graduate) to take part in this study who are at least 18 years of age, currently reside in the US, are currently enrolled at Rutgers (on campus or remote), and have an iOS or Android smartphone that is compatible with the app, MetricWire (most phones released since 2014 are compatible). You may not be eligible for the study if you are unable to provide informed consent for any reason.

Why have I been asked to take part in this study?
You are being asked to take part in this study because you are a current Rutgers student over 18 years of age that has been referred to us by CAPS or responded to advertisements for the study.

How long will the study take and how many subjects will take part?
We will enroll up to 400 participants to take part in this study. Should you choose to take part in this study, your participation will last for 8 weeks or 4 weeks from your final therapy/workshop session, whichever comes last.

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

1. **Baseline Assessment:** We will ask you to complete a series of surveys at the beginning of the study. These surveys will ask questions about your contact information, demographic information, exposure to COVID-19, academic information, emotions, and mental health. This baseline assessment can be completed entirely online and will take you approximately 30 minutes to complete.

2. **Daily Smartphone Surveys:** After completing the baseline, you will be given instructions to download the MetricWire app. As soon as you install the app, you will begin to receive surveys on the app up to 4 times a day. You will be prompted to fill out these surveys by a discrete push notification at random or pre-specified times of the day. These surveys will include questions about your emotional health such as your current mood. It is expected to take a total of 5-15 minutes each day to complete all of the surveys.

3. **Treatment Sessions**: During this phase, you will be asked to attend sessions to designed to teach you emotion regulation skills. These sessions will be conducted virtually via telehealth on HIPAA-compliant platforms. You will complete one of the treatment options below. We will not be randomly assigning you to conditions- you will be asked to attend the treatment option you we referred to or volunteered for.
    a. **One-on-One Session**: You will attend up to three ~30 minute individual session with a study therapist, spaced about 1 week apart. The number and spacing of sessions may vary depending on your schedule.

b. **Group Session**: You will be asked to attend group sessions, facilitated by a trained study therapist. The group session will be ~60-90 minutes long. You will attend one group session a week for three weeks.
c. **Workshop:** You will be asked to attend a single workshop session facilitated by a study therapist. This workshop session will last ~60-90 minutes.

During the period you are receiving treatment, some of your daily smartphone surveys will be replaced with exercises designed to help you practice the skills you are learning in treatment. Each exercise will take approximately 3-4 minutes long. You will still be completing a total of 4 momentary prompts a day (totaling ~15 minutes at most).

Optional Booster. You may also be invited to an optional booster workshop where you can review the skills you learned previously. This session will last 75-90 minutes and will take place during the post-treatment period described below.

4. **Post-Treatment Daily Smartphone Surveys:** After your final treatment session, you will continue to receive assessment prompts on your smartphone up to 4 times a day. These surveys will include questions about your emotional health such as your current mood. It is expected to take a total of 5-15 minutes each day to complete all of the surveys. These prompts are expected to continue for four weeks after your final treatment session.

5. **End-of-Study Assessment**: At the end of your participation in the study, you will be asked to complete a series of surveys similar to the surveys you completed as baseline. These surveys will ask questions about your emotions, mental health, and experiences with the smartphone app. This questionnaire can be completed entirely online and will take you approximately 30 minutes to complete.

Your participation in the study will end after 8 weeks or 4 weeks post-treatment, whichever comes last.

Additionally, by consenting to this study, you are agreeing to allow Counseling, Alcohol and Other Drug Assistance Programs, and Psychiatric Services (CAPS) at Rutgers to disclose your health information to the study team. Information will only be disclosed for the purpose of assisting with the research study. You will be asked to sign another consent form related to this disclosure at the end of this form.

What are the risks of harm or discomforts I might experience if I take part in this study?
The risks of harm or discomforts associated with this study involve the possibility of experiencing distress while answering some questions about your emotional state or other potentially distressing topics, such as self-injury. However, you can skip any question that you feel uncomfortable with or do not wish to answer. You will also be provided with a “risk resources” sheet you may use if needed. There is also a chance that someone may learn of your participation in this study or get access to the information that you provide other than the research staff. However, we take strong precautions to ensure your data stay confidential as described in detail below.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be a reduction in distress and improved coping with the distress associated with negative emotions. 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?
There are no alternative treatments available. Your alternative is not to take part in this study. If you would still like to receive help in coping with distress, there are several resources available at Rutgers university for students.

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?
In general, we will not give you any individual results from the study. However, if you are interested to read the results of the study, in general, you may contact the principal investigator who will send you the research article once published.

Will there be any cost to me to take Part in this study?
There will not be any cost to you to take part in this study. The app we will ask you to install on your phone takes very little data and can upload over Wi-Fi.

Will I be paid to take part in this study?
You can receive up to $205.00 for taking part in this study in the following ways:

- Baseline Measures: You will receive $15 for completing the first 30 minute survey.
- Daily EMA Surveys: Over the next 8 weeks, you will receive momentary surveys from the MetricWire app 4 times a day. You will be paid for your completion of each individual survey and the amount of surveys you complete in a given day according to the following scheme:
    - Weeks 1-4: $0.25 for each daily survey prompt. You will receive a $0.25 bonus for each day you complete over 3 surveys.
    - Weeks 5-6: $0.75 for each daily survey prompt. You will receive a $0.50 bonus for each day complete over 3 surveys.
    - Week 7-8: $1.00 for each daily survey prompt. You will receive a $0.50 bonus for each day complete over 3 surveys.

The following is a breakdown of the maximum amount that can be received:

Item	Compensation	Frequency	Total
Completing baseline measures	$15	Once	$15
Week 1- 4:			
Completing each daily survey prompt	$0.50	4x/day	$56.00
Completing 3 or more assessments/ day	$0.25	1x/day	$7.00
Week 5 and 6:			
Completing each daily survey prompt	$0.75	4x/day	$42.00
Completing 3 or more assessments/ day	$0.50	1x/day	$7.00
Week 7 and 8:			
Completing each daily survey prompt	$1.00	4x/day	$56.00
Completing 3 or more assessments/ day	$0.50	1x/day	$7.00
End of Study	$15	Once	$15
Total			$205.00

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. Should you choose to participate in this study, information from the baseline survey (e.g., name, email address, RUID, IP address in Qualtrics) may be kept and used to contact you about the study in the future. All data collected at the baseline will be recorded into secure electronic forms and linked with a randomized ID number on secure and password-protected computers.

Your name, email address, and RUID will not be stored alongside these data. In some cases (e.g., in Qualtrics), your IP address may be collected alongside your data. We will delete the IP address from any datasets we use for analysis. Electronic consent forms, contact forms, and screener information will be temporarily stored onto secure electronic forms and transferred onto a secure Rutgers database. Consent forms will not be linked to participant ID numbers.

All data collected in Qualtrics via MetricWire will also be coded by linking a unique identifying code. All coded baseline EMA data will be collected and encrypted before being stored on cloud-based databases. This data will then be downloaded directly and stored on a secure Rutgers site. Only Dr. Kleiman and key personnel involved in this study will have access to the research data collected.

Confidentiality may be broken if research staff determines that a child is being abused or neglected or if research staff determines that you are at imminent risk of harming yourself or someone else. If the scores on survey questions pertaining to suicidal thoughts and behaviors or self-harm are high, indicating that you may be at serious risk of harming yourself, we may have to break confidentiality to ensure your safety. In these cases, we may share info with the following groups:

- Provided Emergency Contact(s)
- Local Police or Emergency Services
- Rutgers University Police Department
- Rutgers Counseling, Alcohol and Other Drug Assistance Program & Psychiatric Services (CAPS)
- Rutgers University Behavioral Health Care Acute Psychiatric Services (APS)
- Dean of Students, Residence Life and RUPD (e.g., via a Community Concerns Report)

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
- The National Institute of Health (NIH): National Institute of Mental Health

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.

All of your medical records are protected under N.J. regulations applicable to physicians and other health care professionals and the Federal Protected Health Information regulations. Your health information may be subject to re-disclosure and not protected by Federal or State Statutes in the occurrence of a medical emergency, reporting of communicable disease as required under NJ Public Health statutes, disclosure in response to a subpoenas duces tenem or court order, or required disclosure to a government agency. Specific information to be disclosed in your medical record may include information regarding drug or alcohol use, counseling referrals, and information about diagnoses. You may revoke this authorization at any time by notifying Rutgers Health Services (RHS) in writing, except that revocation will not cancel any action taken by RHS upon the original Authorization for Release of PHI.

What will happen to my information collected for this research after the study is over?
After information that could identify you has been removed, de-identified information collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you.

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 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 your permission, your information will no longer be used or shared in the study. However, data that has already been used or shared with others cannot be withdrawn because there may not be any identifiers to link the data with you. If you agree to take part in this study now, but change your mind later for use of your information in research you must write to Dr. Evan Kleiman at Tillett Hall, 53 Avenue E, Piscataway NJ 08854 and inform him of your decision.

CAPS Consent Form for Disclosing Information to Study Staff

I hereby give permission to:

Counseling, Alcohol and Other Drug Assistance Programs, and Psychiatric Services (CAPS) Provider/Counselor:

2. To disclose the health information of:
Patient/Client Name:
Address:
City/State:
Zip Code:
Date of Birth:
Patient/Client Email:
Patient/Client Mobile Phone:

3. Release, obtain, or discuss health information:
Release information to: Kleiman Lab
Obtain information from: Kleiman Lab
Discuss information on an ongoing basis with Kleiman Lab

4. Person or organization that information/records are to be released to or obtained from:

Kleiman Lab
Tillett Hall, 53 Avenue E, Piscataway NJ 08854
848-445-2345
Kleiman-lab@psych.rutgers.edu

5. Purpose of disclosure: Verification of attendance, assist with research study

6. Type of Service/Record CAPS Facility/ Unit:
Counseling & Psychological Services; Psychiatric Services; and ADAP (Alcohol Drug Assistance Program for Students) 17 Senior St. & 61 Nichol Ave 17 Senior St. New Brunswick, NJ 08901 (848) 932-7884

INFORMATION TO BE DISCLOSED

Attendance Confirmation at CAPS
Intake Assessment
Evaluation/ Treatment/ Treatment Planning
Psychological Counseling Evaluation/ Therapy

Termination Summary
Alcohol/ Drug Information
Written Summary

7. Special Instructions about Information Released:

I understand that my medical records are protected under N.J. regulations applicable to physicians and other health care professionals. I also understand that my records are protected under the Federal Protected Health Information regulations. I have the right to review my medical records except in specific limited circumstances, and to request amendments where appropriate. My health information may be subject to re-disclosure and not protected by Federal or State Statutes in the occurrence of a medical emergency, reporting of communicable disease as required under NJ Public Health statutes, disclosure in response to a subpoenas duces tenem or court order, or required disclosure to a government agency. Specific information to be disclosed in my medical record may include information regarding drug or alcohol use, counseling referrals, and/or a history of testing or treatment of acquired immune deficiency syndrome (AIDS) or related conditions. There may be a fee as permitted under NJAC for copying medical records. I understand that I may revoke this authorization at any time by notifying Rutgers Health Services (RHS) in writing, except that revocation will not cancel any action taken by RHS upon the original Authorization for Release of PHI.

I understand that this information, regarding the ADAPS treatment record, has been disclosed to you from records whose confidentiality is protected by Federal Law. Federal Regulation [42 CFR, Part 2] prohibits you from making any further disclosure of it without the specific written consent of the person to whom it pertains, or as otherwise permitted by such regulations. A general authorization for the release of medical or other information is not sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute the patient.

8. Patient Electronic Signature
Date

9. Authorization will expire 6 years.

Who can I contact if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Dr. Evan Kleiman (Department of Psychology) at 848-445-2345 or evan.kleiman@rutgers.edu.

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at: 335 George St., Liberty Plaza Ste. 3100, New Brunswick, NJ 08901, (732)235-9806 or the Rutgers Human Subjects Protection Program at (973) 972-1149, email us at humansubjects@ored.rutgers.edu, or write us at 65 Bergen St., Suite 507, Newark, NJ 07107.

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 with CAPS

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
- Non-Rutgers Investigators On the Study Team: Dr. Kate Bentley, at Massachusetts General Hospital

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 him or her of your decision: Dr. Evan Kleiman at evan.kleiman@rutgers.edu

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.

Before you complete the consent process, please complete these four questions:

Question 1: Your participation in this study is entirely voluntary. What will happen if you agree to be in the study and later change your mind?

A. You must pay back all compensation you have received so far.
B. You must agree to a future study with our team.
C. You will be allowed to withdraw with no consequences and will be compensated for any study participation you have done up until that point.

Question 2: What will you be asked to do on your smartphone?

A. Complete 8 surveys per day.
B. Complete 4 surveys per day, up to 3 of which may include opportunities for you to practice the skills you've learned in the therapy sessions or workshops.
C. Share all passive data like your GPS and call log, as well as answer 4 surveys per day and complete 3 practice exercises per day.

Question 3: Which part is NOT involved in the study.

A. Either brief one-on-one therapy sessions, a workshop, or a group therapy session.
B. 30 minutes of surveys at the beginning and ends of the study
C. A one-hour in person session on campus.
D. Complete 4 surveys per day on your smartphone, up to 3 of which may include opportunities for you to practice the skills you've learned in the therapy sessions or workshops.

Question 4: Please briefly summarize, in your own words, what the goal of the study is and what you will be asked to do in the study.

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

Name: _____

Digital Signature:_____ Date:_____