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Study Fact Sheet

Study Title: Augmenting Hospital Care for SMI by Targeting Interpretation Bias

Principal Investigator: Courtney Beard, PhD

Study Overview:

This research study is being done to examine the helpfulness of smartphone apps designed to help people practice cognitive behavioral therapy skills. We are asking you to take part in this research study because you have endorsed symptoms of depression or anxiety on standard clinical assessments. We expect to enroll about 84 participants from the Behavioral Health Partial (BHP) Program at McLean Hospital in this phase of the testing of the app.

The study will last for three months following your discharge from the BHP, however the group you are randomized into will determine the number of sessions required.

After your first visit you will be randomized into one of two smartphone apps designed to augment treatment at the BHP. You have a 50% (one in two) chance of being randomized into either group: HabitWorks or Symptom Tracking.

Those randomized to receive HabitWorks will receive a smartphone apps designed to reduce psychiatric symptoms by improving mental habits. You will use the HabitWorks smartphone application for approximately 10 min each day while you attend the BHP and shorter sessions (5 min) at least 3 times per week during the month after you discharge. You will also complete weekly symptom surveys during the month following discharge.

Those randomized to receive Symptom Tracking will receive a smartphone app designed to reduce symptoms by helping participants practice self-monitoring. You will complete brief symptom monitoring surveys once a week (5-10 minutes) during the month following discharge.

For both the HabitWorks and Symptom Tracking groups, we will ask you to complete brief (1min) EMA surveys in the MetricWire app 4 times per day during the month following discharge. These surveys are designed to assess how you are feeling in the moment, and will help us see how the intervention impacts your mood.

In addition to app use, we will ask you to complete assessments for the study at pre-treatment, post-treatment (BHP discharge), 1-month follow-up, and 3-month follow-up. These assessments will take approximately 1-2 hours and will occur remotely via phone or Zoom video call.

Interview measures will be audio-recorded to make sure that the interviewers are conducting the interviews in a reliable manner. To assure the confidentiality and protection of participants with respect to audio-recording, the following steps will be taken: a) audio-recordings will be labeled with the date and participant id number only;

b) all recordings will be stored on a secure sever or in locked files in a secured office; c) access to the audio-recordings will be limited to individuals who will be rating the recordings for reliability and to the PI who will provide ongoing supervision; and d) all participants will have the right to revoke their consent for audio-recording or ask that any of the recordings be erased immediately or at any point during or after the study.

Further, as part of treatment at the BHP, you have already completed a packet of self-report assessments relating to your diagnosis, symptoms, coping skills, and overall functioning, and a diagnostic interview. By signing this form, you give us permission to link your responses from this study to the de-identified clinical data you provide. By signing this form, you also give us permission to extract data from your medical record, specifically whether you experience any psychiatric hospitalizations during the 3-month follow-up period.

As part of this study, staff will monitor your safety.

While attending the BHP:

As part of standard clinical care, the BHP Progress Monitoring Coordinator will monitor your depression symptoms, including suicidal ideation, via the brief questionnaires completed each day. Should your responses indicate a significant increase in symptoms or increase in suicidal ideation, the progress monitor will let your Clinical Team Manager know. If at any time, you feel that you need immediate attention, you should contact your Clinical Team Manager. If you feel that you need immediate attention outside of the BHP program hours, follow the BHP's guidelines of calling or paging your outpatient providers, going to your local Emergency Room, or calling 911.

Following Discharge from the BHP:

Study staff will **not** monitor your responses to the smartphone app for safety **AT ALL** during any phase of the study.

If at any time during the study you feel unsafe and need to reach out for help, call or page your outpatient clinician, go to your local Emergency Room, or call 911. You can also Text HOME to 741741 to connect with a Crisis Counselor, or call 1-877-382-1609 for 24/7 crisis support (enter zip code when prompted).

As part of this study, you will be asked to sign a release of information form so that we can contact your treatment team in the event of clinical deterioration or suicide risk following treatment at the BHP.

Potential risks:

There are no foreseeable physical, economic, legal or social risks or discomforts associated with this research. There may be other risks that are currently unknown.

It is possible, however, that you may have a negative emotional reaction to the app or questionnaires. Should this occur, research staff members will be available for

immediate consultation. You may of course skip questions you do not wish to answer and stop the study at any time.

Confidentiality poses another potential risk in this study. To maximize confidentiality, all results will be confidential, and will not be released in any individually identifiable form without prior consent, unless otherwise required by law. Data may be reported in scientific journals, but will not include any information that could identify your participation in this study. All data will be coded with a subject number, rather than your name.

The smartphone apps used in this study were designed to minimize any risks related to breach of privacy, confidentiality, or data security. Only research personnel will have access to study information. All data collected by the applications is de-identified, encrypted and uploaded to a secure server. The smartphone apps will not collect any identifying information. You may of course skip questions you do not wish to answer and stop the study at any time without any penalty of any kind.

You will be able to complete remote assessments via telephone call, encrypted email, and/or Partners licensed Zoom accounts. This version of Zoom is configured to be HIPAA compliant and Zoom implements a range of encryption technology to ensure all content remains between the intended recipients. Video, audio and screen sharing are protected across platforms with a combination of asymmetric and symmetric encryption using AES-256 and AES-128. Recordings through zoom are at the hosts discretion and there are preventative measures in place to ensure there will be no unauthorized access to these recordings. Additionally we will only be storing the audio-recordings from these assessments, and these will be stored within Partners approved Dropbox.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). The NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health and substance use to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send deidentified information about your health and behavior and in some cases, your genetic information, to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers find better

treatments. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

As part of your participation in the study, a unique subject number, GUID will be assigned to you that will allow researchers to see if you have been involved in more than one research study. If you have participated in more than one study or database, this unique subject number will help connect information across studies. This subject number will also allow your data to be combined with data from other research studies to increase the likelihood of meaningful analysis. This unique subject number can be shared with other investigators when your data is shared and may make it possible for a study doctor who used this unique subject number in another study that you took part in to identify you.

Potential benefits:

You may or may not experience any direct benefit from participating in this study. Your participation will be very valuable in helping us better understand and treat depression and anxiety. Thus, your participation may benefit other people experiencing depression and anxiety in the future.

Voluntary participation:

You do not have to take part in this study to be treated for your psychiatric symptoms. Other treatments or procedures that are available to treat psychiatric include medication and psychotherapy. You are encouraged to continue with the treatment recommended by your treatment team throughout your participation in this research study.

Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

If you take part in this research study, and 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 for you, if needed.

Compensation:

You will receive compensation for your time to complete study assessments. Participants will receive $20 for the eligibility and pretreatment assessment, $20 for the post-treatment assessments, $30 for the 1-month and 3-month follow-up assessments, and $20 for the post-treatment qualitative interview. You will also receive $10 for each week that you complete any EMA surveys, and a bonus of $30 for each week that you complete at least 70% of surveys (19/30). In total, you may receive $280 if you complete all study procedures. If you are unable or unwilling to accept checks from the study, we will compensate you with a one-time $50 giftcard.

Costs of Participation:

You will be responsible for costs associated with the use of your smartphone device for this study. Each time the app is used a small amount of data from participant responses needs to be sent back to the research team. If the device is not connected to a WiFi network but does have data services enabled, data will be transmitted and counted against the participant's data plan. The size of these encrypted data packages is extremely small—smaller than a single email containing only text, so even with daily transmissions there should be no discernible impact on data use. If the device is connected to a WiFi network, data will be transmitted and not counted against a data plan. If you do not have a data plan, data will be stored (encrypted) on the device until a WiFi connection is available, then sent at that time.

Contact information for questions:

PI of the study: Courtney Beard, cbeard@mclean.harvard.edu, 617-855-3557

Study coordinator: Erin Beckham, ebeckham@partners.org, 617-855-2036

IRB contact information:

If you'd like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at (857) 282-1900."

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask who receives it from us to protect your privacy.