Consent to Act as a Participant in a Research Study

STUDY TITLE: ***Randomized Control Trial to Evaluate the Efficacy of a Digital Mental Health Intervention Embedded in Routine Care Compared to Treatment as Usual in Adolescents and Young Adults with Moderate Depressive Symptoms***

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Invitation to Participate in a Research Study

We are conducting research to determine whether a mobile-based self-management program is effective in improving behavioral health outcomes in patients seen at pediatric practices. This program, called RxWell, can fill a resource gap by providing preventive management services to promote wellness and enhance usual care.

We are asking you to participate in this research because you are between the ages of 16 and 22 and meet criteria based on the questionnaire you completed at your routine clinic visit. We will ask a total of 750 individuals who also have smartphone access to enroll in a study in which we examine a mobile app-based self-management program (RxWell).

We will first ask you a series of questions regarding your behavioral health to further screen for eligibility. If eligible, you will be asked to complete several brief questionnaires now, 6 weeks, and 12 weeks after today. These are questionnaires that will ask about your satisfaction with life and your behavioral health, including mental health symptoms, diagnoses, and treatment history. You will also be asked to complete a demographics form as part of the initial set of questionnaires. You may be contacted by a study research team member to complete these questionnaires over the phone if you are unable to complete them online. If you consent to participate, you will have a completely random chance at being assigned to either 1) receive RxWell in addition to medical care within your pediatric practice or 2) only the medical care within your pediatric practice, which includes routine monitoring of your behavioral health.

Research studies include only people who choose to take part. This form provides information to help you decide if you would like to participate in this research study. You should take your time to make your decision. Members of the research study team can answer any questions that you have about the

study.

Who is conducting this research study?
This research study is being led by Dr. Eva Szigethy and other researchers at UPMC, Boston Children's Hospital (Boston, Massachusetts), and Rady Children's Hospital and Health Center (San Diego, California).

What is the purpose of this research study?
We are conducting research to determine the effectiveness of a digital behavioral intervention in improving behavioral health outcomes for patients ages 16-22 seen in pediatric practices. We are interested in studying how utilization of a coach-enhanced digital behavioral app compares to care as usual.

How many people will participate in this research study?
We hope to enroll 750 individuals in total from UPMC, Boston Children's Hospital, and Rady Children's Hospital and Health Center. This site, UPMC, will enroll up to 250 participants over the duration of the study.

How long will my participation in this study last?
Your participation in this study will last for 12 weeks (3 months).

What will I be asked to do if I participate in this study?

- You will be asked to read, complete, and sign this consent form.

- By agreeing to participate in this research study you are giving the research team permission to access your medical records. We will have access to this information for the duration of the study.

- You will be randomly assigned to one of two different ways (approaches) behavioral health care can be provided to you. Being randomly assigned means that you will have the same chance of being assigned to each of the care approaches described below. It is important to know that neither you nor the study team can pick your care strategy.

- You will be asked to answer questions about your behavioral health and satisfaction with life at three time points during the study (after you sign this form, in 6 weeks, and then in 12 weeks). The questions will be related to your personal background (age, race/ethnicity, education), behavioral health symptoms and history, including treatment, and your quality of life. Your responses will be entered into a secure website, but the research team may ask you to complete the questionnaires over the phone with a member of the research study staff, or online.

    - **If you are in Care Approach 1**: You will receive the RxWell app as well as continue to have access to your medical and behavioral health team at your pediatric practice as needed.

      You will be asked to utilize a UPMC owned digital behavioral tool, which is a phone application that consists of brief, 5-15 minute, audio and visual techniques to help manage any level of symptoms of stress, anxiety and/or depression. Because the digital tool is an application on your phone, it can be used anytime and anywhere.

      You will be matched with a coach who will provide guidance and support throughout the course of the program. Coaches are not therapists, and they do not provide psychotherapy. Instead, they provide

motivational interviewing, guidance through the program, and encouragement in setting and working towards your goals. The coach will communicate with you through secure asynchronous text messaging in the program, in which the coach provides feedback and responds to your questions. The coaches exchange short written messages with users through the app, starting with a welcome message after initial sign-up. You can also communicate with your coach.

- **If you are in Care Approach 2:** You will continue to receive care from your medical and behavioral health team at your pediatric practice as necessary.

Will I be compensated (receive a payment) for participating in this research study?

- You will be compensated up to $75 for completing study questionnaires. You will get $20 for completing the first set of questionnaires, $20 for the second set of questionnaires, and $20 for the third (final) set of questionnaires. If you complete all 3 sets of questionnaires, you will be compensated an additional $15.

- Your study questionnaire payments will be loaded onto a debit card that you will receive after completing your first set of questionnaires. Additional study questionnaire payments will be loaded onto the same debit card within 2 business days of completing your second and third (final) set of questionnaires.

What are the possible risks, side effects, and discomforts of this research study?

***Infrequent (Rare) Risks*:**

- The risks associated with this study include the potential for a breach of confidentiality for both groups in the study. To reduce the risk of that happening, we will protect the confidentiality of this information by giving you a unique study ID that will be kept separate from any identifying information.

- You will be asked questions about private, personal matters and information related to your health. You may feel uncomfortable answering questionnaires/assessments or discussing your health with the research team. You may also feel tired from answering questionnaires or having discussions with the research team. There are no known psychological or physical risks associated with the questionnaires/assessments that will be used for this study.

- We would also like you to know that electronic or smartphone communications (e.g., text messages, emails) or internet communication that may happen as a result of contact with the research team cannot be guaranteed as confidential. It is possible that your confidential information may be collected and used by individuals who do not have permission to do so. UPMC takes precautions to prevent this from happening, but there is still a risk that your confidentiality may be breached.

Unknown Risks:

In addition to the risks listed above, there may be other risks to your health or well-being that are unknown at this time. We will monitor your safety during your participation in this research study.

What are the possible benefits from taking part in this study?

There is no guaranteed direct benefit to you from taking part in this research study. However, it is possible that you and other research study participants will benefit from the two care approaches that we are studying.

The potential benefits of using the digital app program include improvements in quality of life and behavioral health. This potential benefit is not guaranteed. In addition, the information we obtain from you and others may help us better understand how to implement a mobile-based program for adolescents and young adults

The results of this research study will be shared with other researchers and health care providers who may use this information to improve the way care is provided in other settings or health care facilities.

What treatments or procedures are available to me if I decide not to take part in this research study?
You can still receive care for your medical and behavioral health from this clinic or at other health care facilities where this care is provided. These treatments may or may not include similar types of treatment or technology that would be available to you if you choose to participate in this study. If you choose not to take part in or to stop participating in this study, you will still receive your regular care.

Your doctor may also be a member of the research study team. They are interested both in your medical care and in the conduct of this research. Before agreeing to participate in this research study or at any time during this research study, you may discuss your care with another doctor who is in no way associated with this research project. You are not obligated to participate in any research study offered by your doctor.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?
There is no cost to you for participating in this study. Neither you nor your insurance provider will be charged for the costs performed for this research study. You and your insurance company will continue to pay for your regular health care in the usual manner (care you would receive even if you were not participating in this research study).

CONFIDENTIALITY AND RELEASE OF YOUR PERSONAL HEALTH INFORMATION RECORDS

Who is requesting my personal health information and why is this information needed?
The research study team is requesting your authorization (permission) to access, review, and collect your medical records. We need this information to determine the impact, if any, of the care approaches being studied as part of this research study. We will access your medical records to collect demographic information; information related to your use of health care services (visits with your doctor and other health care professionals), the results of self-report assessments given to you as part of your normal care, and medications prescribed to you. This identifiable medical record information will be made available to members of the research team, and this authorization will be valid, for an indefinite period of time.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of 7 years after final publication and completion of this research study or for as long (indefinite) as it may take to complete this research study.

Who will have access to identifiable information related to my participation in this research study?
In addition to the individuals listed on the first page of this consent form and their research staff, the following individuals will or <u>might</u> have access to identifiable information (which may include your

identifiable medical record information) for the purposes of conducting and monitoring this research study:

- Authorized representatives, business associates, or affiliates of: the University of Pittsburgh Office of Research Protections; members of this research study's Data Safety and Monitoring Board, who will oversee and monitor some parts of this research study. Authorized representative of UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

- We may share identifiable information with your health care team if there is an immediate risk to your health. Your health care team will use this information to make decisions about your treatment.

- Under certain circumstances we may be required to release your identifiable information in response to an order by a court of law.

PRIVACY

We will protect your privacy and the confidentiality of your records as much as possible, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside of the research study team.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/, as required by United States 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 steps will be taken to protect my information provided for this research study?

Any information about yourself obtained from this research study will be kept confidential (private) to the greatest extent possible. Data collected during the study (e.g. medical records, other data forms and records) will be stored in a way that does not identify you by name. You will be identified by a unique Study ID and the information linking these subject codes with your identity will be kept separate from your research study records. Data stored on computers or web-based tools will be kept behind firewalls, encrypted, and password protected.

If your research data is shared with other researchers who are interested in this specific research study, your identity will not be revealed to those researchers. You will not be identified in any publication or presentation of the research results unless you sign a separate consent form giving your permission for us to do so.

Will the information I provide be used for anything other than the current study?

Our research study team may use information you provide for this research study, including your medical record information that we collect, to conduct research projects in the future that are different from what is described in this document. Your information will continue to be kept confidential.

We may also share information collected for this research study in the future with other researchers who are not involved with this research study. However, we will not share any information that

would directly identify you. All data provided to these individuals will be anonymous, and these researchers will be required to sign an agreement that states they will not attempt to determine your identity.

May I withdraw, at a future date, my consent for my participation in this research study?

- You have the right, at any time, to withdraw from participating in this study. You may also withdraw your permission to allow the research team to use and disclose health information from your medical records collected as part of this research study. If you withdraw authorization to collect medical record information, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

- You may withdraw your consent/authorization for your participation in this research study by providing a written and dated notice of this decision to the principal investigator of this research study at the address listed on page one of the consent form.

- The research team will continue to use any information already collected up to when you withdraw from the study.

- It is your decision to participate in this research study. If you chose not to participate in this research study or chose to withdraw at any point from this research study, your decision will not affect your current or future relationship with the University of Pittsburgh, UPMC, or any other health care providers.

If I agree to take part in this research study, can I be removed from the study without my consent?

The researchers may withdraw you from participation if the sponsor withdraws the study, or if necessary for other reasons. For example, you may be withdrawn because of changes in your health.

If you are withdrawn from the research study, the research study team's decision will not affect your current or future relationship with the University of Pittsburgh, UPMC, or any other health care providers.

Who else can answer my questions about my participation in this research study?

If you have any questions about your rights as a research study subject (participant) or wish to talk to someone other than the research team, you can call the University of Pittsburgh Human Subjects Protection Advocate toll free at 1-866-212-2668.

VOLUNTARY CONSENT:

All of the above information has been explained to me and all of my current questions have been answered. By providing my electronic signature below, I agree to participate in this research study and to allow the use and disclosure of my medical records and to collect data related to my care for the purposes described above, I consent to participate in the study and provide my authorization to share my medical records with the research team. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during this study, and that such future questions, concerns or complaints will be answered by a qualified individual of the research team or by calling the Principal Investigator of this study, Dr. Eva Szigethy (412-802-6696). I understand that I will be provided with a copy of my consent form for my records.

Participant's Full Name: _____

(first name, middle initial, last name)

Birthdate: _____/_____/_____(mm/dd/year)

Answer **one** of the following three questions:

- What is your mother's maiden name?_____
- In what city were you born? _____
- What high school did you attend? _____

Szigethy E, *et al. BMJ Open* 2023; 13:e067141. doi: 10.1136/bmjopen-2022-067141