UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Evaluation of a Crowd-Powered Platform for Mental Health

Lead Researcher
Dr. Stephen Schueller
Department of Psychological Science
s.schueller@uci.edu
949-824-3850

Project Coordinator
Zoë Dodge-Rice
Department of Psychological Science
zdodgeri@uci.edu

STUDY LOCATION(S):
University of California
Social and Behavioral Sciences Gateway
234 Pereira Dr, Irvine, CA 92697

STUDY SPONSOR(S):
National Institutes of Health (NIH)

SUMMARY OF KEY INFORMATION:

The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.

Participation is Voluntary
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.

Study Purpose
The purpose of this research study is to evaluate a newly developed mental health platform and assess its impact on symptoms of depression and anxiety.

Study Procedures
You will be asked to engage with a newly developed platform for depression and anxiety for 8 weeks, at least 3 times a week. Each platform interaction is estimated to take between 5-10 minutes, but you may choose to engage on the platform for as long as you would like. You will be randomized into one of two conditions, where you may either interact with a version of this platform that includes content intended to teach you about mental health and skills, or a similar version that also includes peer support. You will be asked to complete an initial, one-time mental health assessment via Zoom call that will take approximately one hour. You will also complete a series of online surveys that will ask questions about your mental health, which will begin at the time of enrollment, and will be administered at 4 weeks, 8 weeks, and 16 weeks. Each of these surveys will take approximately one hour. At 16 weeks, you may also be asked to complete one additional remote interview to give feedback on user

experience, which will take one hour. All remote Zoom interviews will be audio recorded for analysis and quality assurance. Researchers will gather usage data directly through the platform, such as number of log-ins and length of use per session.

Expected Duration
Participation will last approximately 16 weeks and will include engaging with the assigned platform for the first 8 weeks, at least 3 times per week. Online assessments will be conducted at baseline, 4 weeks, 8 weeks and 16 weeks, and should take 1 hour each. You may be asked to complete one additional interview at 16 weeks to provide feedback on your experience using the platform, which will take one hour.

Risks of Participation
- One risk of this study is use of the online platform while driving. Driving while participating in remote study activities can lead to physical, financial, and legal risks. Please engage in remote participation in a dedicated space of your choice, with necessary study materials, as sent via web link, available for their review and discussion. Do not drive while using the platform.
- Some participants will engage in interactions with peers. Although the platform will be moderated, interactions with peers may change the experience while engaging online. This is a similar risk that people experience when entering other online spaces such as forums or social media.
- Research assessments include questions about depression, anxiety, family and personal functioning, and other mental and emotional problems. Answering these questions could make you think about such ideas and potentially lead to worsening in mental health. You are asked to provide voluntary responses to interview questions and you can decline to answer any questions that you choose.
- There is a slight risk of loss of confidentiality. While communications on the platform are secure and encrypted, there is some possibility that others may see your open webpage or mobile application. Confidentiality may be broken by research staff to ensure your safety if there is an imminent threat to self or others. There is also the remote possibility that research records will be subpoenaed by a court of law.

Benefits to Participants
A potential benefit of participation is that you will receive an intervention for anxiety and Depression. You may experience improvement in anxiety or depressive symptoms as a result.

Benefits to Others or Society
The potential benefit to future individuals is that the study may provide a novel treatment for anxiety and depression that is scalable. Furthermore, the intervention platform might improve knowledge about different implementations of evidence-based strategies that might be more beneficial for various individuals. Given that the risks associated with participating are minor, and the potential benefits of the platform are both to yourself and for thousands of other individuals with depression and anxiety are considerable, it is believed that the risks are justified.

Alternative Procedures or Treatments
There are no alternative treatments or procedures available. The only alternative is not to participate in this study. If you choose not to participate, but want mental health services, resources will be provided that might help find those services.

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to evaluate a newly developed mental health platform and assess its impact on symptoms of depression and anxiety.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 100 participants will take part in the research at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You must meet the following requirements to be in the study: Display significant mood and anxiety symptoms as defined by mental health screeners on Mental Health America's Screening to Support tool; 2) be able to speak and read English; 3) be at least 18 years of age; 4) currently reside in the United States

Exclusion Requirements
You cannot participate in this study if you 1) experience severe suicidality (has ideation, plan, and intent)

HOW LONG WILL THE STUDY GO ON?
Participation in this study will last 16 weeks. You will interact with the assigned mental health platform for 8 weeks, at least 3 times a week. You will receive online mood assessments at baseline, 4 weeks and 8 weeks. After you are finished using the platform, researchers will ask you to complete a follow-up assessment at 16 weeks and may ask you to complete an additional remote interview regarding your experience using the platform, which will take one hour. This additional remote interview will be hosted via Zoom.us.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
Before you can participate in the main part of the study...
You will need to have a "screening" assessment. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include completing an online, self-report mood assessment for depression and anxiety as well as a one hour remote call assessment

During the main part of the study...
If the screening survey shows that you can continue to be in the study, and you choose to take part, then you will be asked to do the following:
1. You will be randomized to receive one of two versions of the mental health platform for depression and anxiety. One version you may receive will include content intended to teach you about mental health and skills, and the other will include an additional feature that allows peer support and interaction. The platform that allows peer interaction is a publicly available platform, which means you may see content from users who are not enrolled in the study. You will receive a link with log-in information to access your assigned platform. This link will include a unique IP hashtag, which will ensure that no personal identifiers are collected during log-in.
1. You will use the assigned platform for a treatment period of 8 weeks, and will be instructed to use the platform at least 3 times per week.
2. At baseline, 4 weeks and 8 weeks you will be asked to complete a series of assessments via online link. Though the time it takes to complete these assessments varies by individual, it is expected that each session will take you no longer than 45 minutes- 1 hour.
3. At baseline, researchers will send you a link via email to subscribe to weekly newsletters through Mailchimp. These newsletters will include didactic information about the platform and platform content, reminders to engage with the platform, and reminders about upcoming study measures.

4. Researchers may send you text message reminders to complete online surveys (at baseline, 4 weeks, 8 weeks, 16 weeks)
5. Additionally, you may be contacted by researchers at the end of the study to complete an additional interview. You will be asked to provide feedback regarding your experience using the platform, as well as rate specific components of the platform itself.

***After you complete the main part of the study*,** you will be sent a follow up assessment at 16 weeks to assess the maintenance of any mood changes that may have occurred during the study.

RETURN OF RESULTS
You will not be provided any clinically relevant information that may pertain to your health.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?
There are no known harms or discomforts associated with this study beyond those encountered in normal daily life. The possible risks and/or discomforts associated with the procedures described in this study include:

Likely:
(a) **Randomization:** You will be assigned to a study group by chance (like a coin flip) rather than by a medical decision made by the researchers. The treatment you receive may prove to be less effective than the other study group(s), or than standard treatments available for your condition.
(b) **Risks of the platform**. Driving while participating in remote study activities can lead to physical, financial, and legal risks. Please engage in remote participation in a dedicated space of your choice with necessary study materials, as sent via web link, available for review and discussion. Do not drive while participating in this study. Web and mobile-based mental health interventions have not been shown to cause any harm. Additionally, all information shared with crowdusers on the platform will be anonymous and any inappropriate entries within the system will be flagged by automated processes and crowdworkers. Some participants will engage in interactions with peers. Although the platform will be moderated, interactions with peers may change the experience while engaging online. This is a similar risk that people experience when entering other online spaces such as forums or social media.
Less Likely:
(c) **Psychological discomforts:** Research assessments include questions about depression, anxiety, family and personal functioning, and other mental and emotional problems. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop.
(d) **Research Assessments:** The instruments and methodologies are well tested and are not known to cause problems or distress. All research interview-based assessments are audio- recorded, for the purpose of review by senior research staff (Ph.D. level clinicians) who make quality assurance ratings of staff performance, including ensuring that you are comfortable with the interview procedures. Audiotapes will be maintained on a secure server with no identifying information in the labels for the duration of the funded study, unless other arrangements are made. On occasion participants request that we delete audio files before the end of the study, in which case we will comply.
(e) **Risks associated with potential loss of confidentiality**. There is a slight risk of loss of confidentiality for participants. While communications on the platform are protected and encrypted, there is some possibility that others may see your open webpage or mobile application. Confidentiality may be broken by research staff to ensure your safety if there is an imminent threat to yourself or others. There is also the remote possibility that research records will be subpoenaed by a court of law.

Rarely Likely:
(f**) Risks of worsening mental or emotional state and or self-harm thoughts/events**. Some participants may show a worsening of symptoms of depression or anxiety, suicidality or problems during the study period. The development of suicidal ideation during the study remains the most serious risk.

However, these are risks inherent in the population and would remain whether or not you were enrolled in the study. We do not believe that the risk of these symptoms, suicidal, or other adverse outcomes are increased as a function of being enrolled in this study or receiving the platform.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

- You will receive $20 for each assessment you complete, which you can choose to receive in the form of either Amazon electronic gift cards or personal checks. There are 5 standard assessments, and one additional assessment possible. Total compensation possible for participation in this study is $120. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the assessments that you have completed. If you choose to receive payment via personal check, you will be sent a link to onboard in the UCI PaymentWorks system. You will directly input identification and tax information into the secure system. This sensitive information will be stored in the PaymentWorks system and will not be accessed by researchers. UCI will disburse University Checks to individuals who select this method of payment.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you for participation in this study.

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?

Subject Identifiable Data

Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. Contact information including names, email addresses and phone numbers will be collected to conduct remote screens, schedule study sessions, and send web screeners and login information for the platform.

Data Identifiers will be stored separately from all study data, in encrypted online files. Only the PI and study personnel will have access to these files. Email addresses will be used to send participants newsletters through Mailchimp.com. No additional identifying information will be shared with Mailchimp.com. Subjects may unsubscribe from Mailchimp newsletters at any time. Subjects may also access, correct, update, port, delete, restrict or object to Mailchimp's processing of their information at any time. When the study is complete, the contact list of subject emails will be deleted from Mailchimp. Identifiable data will be destroyed 5 years after the end of the study, while de-identified data will be recorded in the NIH data repository and may be accessible by future researchers. Audiotapes will be collected via Zoom.us and maintained on a secure cloud server with no identifying information in the labels for the duration of the funded study, unless other arrangements are made. The [audio/video recordings] will also be stored in a secure location and transcribed after each assessment. The recordings will be retained with the other research data. On occasion participants request that we delete audio files before the end of the study, in which case we will comply. All electronic data will be stored on secure servers behind firewalls meeting all security requirements of UC Irvine. Participants will be assigned a numerical code for identification in the files. Names and other identifiers will be kept in separate password protected files.

Mobile interventions will be provided through a secure development platform. All data collected via this intervention (e.g. online platform) is hosted on a Cloud VPS server using up to date security measures that are HIPAA compliant (Liquid Web). Any data collected and stored is automatically encrypted using SHA-256 RSA Encryption. Online assessments will be completed on REDCap which is provided by UC Irvine and data similarly conforms to security measures that are consistent with those used by Electronic Medical Records and are HIPPA compliant. Data presentation will be of aggregate-level data; participants are never individually named.

Data Retention
The researchers intend to keep identifiable research data for approximately 10 years after the completion of the study. The researchers intend to store your de-identified research data in a repository indefinitely. The researchers may continue to use and share your de-identified information indefinitely.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The research team, authorized UCI personnel, the National Institutes of Health (NIH), and regulatory entities such as the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Future Research Use
Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Certificate of Confidentiality
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Researchers will voluntarily disclose information to prevent serious harm to you or to someone else, including disclosed suicidal ideation.

Future Contact
The study team would like your permission to contact you for future research. Please initial your level of permission below:

_____ Yes, UCI researchers may contact me in the future to ask me to take part in other research studies.

_____ No, UCI researchers may **not** contact me in the future to ask me to take part in other research studies.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

Please contact UCI Institutional Review Board by phone, (949) 824-6662, by e-mail at IRB@research.uci.edu or at 160 Aldrich Hall, Irvine, CA 92697-7600, if you are unable to reach the researchers listed at the top of the form and have general questions; have concerns or complaints about the research; have questions about your rights as a research subject; or have general comments or suggestions.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep.
Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

_____ _____
Subject Signature **Date**

_____
Printed Name of Subject

_____ _____
Signature of Person Obtaining Informed Consent **Date**
(For research that is greater than minimal risk, this individual must be listed on Page 1 of this consent)

_____
Printed Name of Person Obtaining Informed Consent

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.