UNIVERSITY OF WASHINGTON
CONSENT FORM
User-centered design of a single-module digital mental health intervention for college students at risk for psychosis

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Researchers' statement

You may print this out for your records if you wish, but there is no need to sign or turn this form in to the research staff. You will agree to the terms of this consent form on the website when you click the button "I consent."

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Before you decide if you want to take part in this study, please read this form carefully.

You are being asked to take part in this study because you:

- Are 18-30 years old,
- Speak English,
- Have reported specific mental health symptoms
- Are currently enrolled in a post-secondary college program in the United States.

PURPOSE OF THE STUDY

The purpose of this study is to develop and optimize a digital mental health intervention (DMHI) for college students by engaging young adults at risk in a needs assessment and co-design interview. During these interviews, participants will (1) describe their needs and preferences in a digital mental health resource and (2) will interact with (A) example features (i.e. illustrative examples from other areas of public health) and (B) example prompts (i.e. varied messaging strategies and frames) inviting users to download and use the intervention. The interview will be completed remotely over Zoom.

STUDY PROCEDURES

The list below provides an overview of all study procedures and when they occur during the study period.

1. Screening surveys
2. Outreach from the Study Team
    a) Pre-Interview Survey
3. Co-Design Interview
    a) Post-Interview Survey
4. Study payment and debriefing

(1) Screening surveys (10 minutes): If you volunteer to participate in this study, you will be asked first to provide your name, email, phone number, and demographics. Then, to determine your eligibility, you will complete a survey where you will answer questions about these topics:

a) Your current enrollment in a United States college program
b) Your experience of various symptoms (like hearing unusual sounds, feeling that other people are watching you)
c) Your diagnoses and mental health treatment history

(2) Outreach from the Study Team: Within three business days of completing the screening survey, you will be contacted by the study team with your eligibility status. If you are eligible to participate, you will be contacted by phone to confirm your eligibility and interest in participating. Once confirmed, you will schedule a time for the Co-Design Interview with the study team. If you are ineligible, you will be sent an email thanking you for your time.

a) Pre-Interview Survey: If you are eligible, you will also be emailed a link to a short (5 minute) survey. You will be asked to complete this survey prior to the Co-Design Interview, but the survey can be completed during the interview session if needed. The survey will ask you to share your preferences of various messaging prompts inviting you to complete an online mental health tool.

(3) Co-Design Interview (90 minutes): After scheduling, you will attend a 90-minute Co-Design interview session with a member of the study team via Zoom. The interview will be recorded for later analysis, and will be de-identified to protect your privacy. We will deidentify the recording by (1) having you turn off your screen during the interview, (2) removing your name from display during the session, and (3) never referring to you by name during the interview session. The recording will also only be labeled with an identification number, not with any identifying information. Once deidentified, your interview will be transcribed by a third party transcription service. During the session, you will answer open-ended questions about your experiences with your mental health and well-being, as well as factors impacting your likelihood of engaging with digital resources. You will be asked to react to some example screens from a potential digital tool to help college students with their mental health.

a) **Post-Interview Survey:** At the conclusion of the interview, you will be emailed a link to a set of brief questionnaires that will ask you for additional feedback on the digital tool prototype (5 minutes). These surveys can be completed on the call or privately after disconnecting.

(4) Study payment and debriefing. After the Co-Design interview and all surveys are completed, participants will receive compensation for their time in the form of a $50 Amazon Gift Card, sent to their email address.

NOTE: This study does not involve clinical services. Although mental health topics will be discussed, no suggestions, guidance or feedback will be provided on what may be shared. The study is not a substitute for mental health treatment. All participants will be provided with mental health resources at the end of the study.

If you are in need of emergency services, please call 911. If you are experiencing a mental health crisis, the 988 Suicide and Crisis lifeline is available 24/7 to support you. The lifeline provides free and confidential support (and if needed, information on resources) around the clock. You can access the lifeline by (1) dialing 988 by phone or (2) sending a text message SMS to 988.

RISKS, STRESS, OR DISCOMFORT

Study surveys might be boring or make you uncomfortable. We encourage you to take breaks when answering questions if you need to. Interview questions might make you uncomfortable as well. You may decide to not provide a response to questions asked in the screener survey or during the co-design interview. Participation involves the discussion of mental health topics and seeking treatment services, and participants may be encouraged to seek mental health treatment. Participants are encouraged to follow reputable and evidence-based treatment recommendations (provided in de-briefing materials), but the study team does not take responsibility for the actions of providers unaffiliated with the program.

Another risk involves breach of confidentiality or privacy. We are careful to protect your privacy (read section below), but there are also ways your participation could increase the risk of breach of privacy. Participants are encouraged to schedule the co-design interview when they can have privacy to discuss potentially sensitive topics. Participants are also encouraged to avoid scheduling the interview when in situations where full attention is required for safety (e.g. crossing a street, driving, taking care of a child).

CONFIDENTIALITY OF RESEARCH INFORMATION

We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential. Data in this study includes:

a) Basic information such as age, gender, race, education, state of residence. We will collect your IP address once when you take the eligibility survey.
b) Your responses to the questionnaires, including reporting on your symptoms.
c) Your attitudes and perspectives on mental health treatment and technology shared in the interview.

We will make every effort to keep the data in this study private. We will keep your eligibility data, including any identifying information, separate from data from the rest of the study. Separating identifying information from study data helps to keep your data private. This process is called *coding your data*. *Coding your data* involves keeping your data labeled with only numbers, not your name. This way no one outside the research team can connect your data with your name. We will not use your name in any reports written from this study.

There are few cases wherein we may share data with organizations tasked with overseeing our research. For example, we will voluntarily provide information to:

d) a member of the federal government who needs it in order to audit or evaluate the research;
e) individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
f) the federal Food and Drug Administration (FDA), if required by the FDA;
g) individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;

There are also exceptions to the confidentiality of what you share with the research team. To protect you and others, confidentiality may be breached, when we can reasonably confirm specific identifiable cases of the following:

1. You plan to hurt yourself.
2. You plan to hurt someone else.
3. Abuse or neglect of vulnerable individuals (e.g. child, the elderly, or people with disabilities).

If you share with us plans to hurt someone else, or share information about abuse or neglect of a child or a vulnerable adult, we will report this to the appropriate authorities.

We have a Certificate of Confidentiality from the U.S. National Institutes of Health which allows us to protect identifiable research information that is stored in the U.S. from legal proceedings or in response to a legal request unless you give us permission to release it. You or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection, including reporting things like child or elder abuse, monitoring by the agencies conducting the research, and others as listed elsewhere in this consent form.

The Certificate expires when the funding for this study ends. Currently this is March 31st, 2028. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

Will it cost money to participate?

Everything involved in this study will be paid for by the study. You will not be reimbursed for travel to the study site.

Will you be paid to participate in this study?

Yes. All participants who are eligible and complete all study procedures will receive a $50 Amazon Gift Card. This payment will be provided to you within 5 business days of your completion of the study.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you do not want to take part in this study, then you can let us know at any time. Your participation in this study may be stopped at any time by research staff or the study sponsor.

BENEFITS OF THE STUDY

You might not personally benefit from being in this study. Your responses and feedback will be used to optimize the digital mental health intervention aimed to support college students being developed in this study. Your participation may also help the research community learn more about mental health and the use of technology in mental health treatment for college students at risk.

SOURCE OF FUNDING

Funding: The University of Washington ALACRITY Center

Who may use or see your research information?: The research team includes the Principal Investigator and others working on this study at the University of Washington (UW).

Future use of information: The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

OTHER INFORMATION

Leaving the study: You may choose to stop taking part in this study at any time for any reason. If you decide to stop taking part, it will have no effect on the quality of your health care.
Whether or not you decide to take part in this study, or if you decide to stop the study, you will not lose any benefits to which you are entitled. You will not be penalized in any way.

Product Development: You will not receive any compensation if the results of this research are used towards the development of a product that is sold for a profit.

RESEARCH-RELATED INJURY

Whom should you call about this study?: Contact **Benjamin Buck** at **206-221-8518** for any of the following reasons:

- If you have any questions about your participation in this study,
- If you feel you have been harmed from being in this research,
- If you have questions, concerns or complaints about the research.

If you have questions about research in general or about your rights as a research participant, you may contact:

Human Subjects Division University of
Washington
206-543-0098
hsdinfo@uw.edu