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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This form is here to help you decide whether to be in the study or not. Please read this form carefully.

What is the purpose of this study?

This study aims to test a digital mental health intervention (DMHI) called SPARK – a tool designed for college students at risk for certain mental health conditions. We are recruiting students who experience symptoms that could indicate risk for future psychosis and other conditions, including things like hearing voices or sounds others do not hear, confused, disorganized or paranoid thoughts, and difficulties with emotional experience and motivation. The SPARK program has been developed with the goal of supporting young adults in a short, single session intervention.

What will you be asked to do?

During this trial, participants will complete questionnaires and surveys about their mental health and interact with digital support in a two-week study period. This study is completed entirely remotely, and all study materials can be accessed via a computer or mobile device.

Participants will be randomly assigned to one of two groups: (1) **a group that will immediately have access to the SPARK program**, and (2) **a second group that will initially receive online mental health resources and receive access to the SPARK program at the end of the study period**. SPARK will feature video, text and reflective prompts that aim to deliver psychoeducation related to stigma and strategies for coping with mental health difficulties. Both groups will receive additional resources and information related to mental health conditions and treatment options during the study.

> **NOTE: To protect your privacy, you will not be asked to write in responses to the SPARK program. However, you will be asked to provide feedback and describe what you've learned to improve SPARK and to share encouraging messages with future users. None of these quotes will identify you personally (i.e. the quotes will be anonymous). At the end of the SPARK program, participants will have the option to download a copy of SPARK as a PDF.**

The graphic and table below outline the study procedures and when they will occur during the study period.

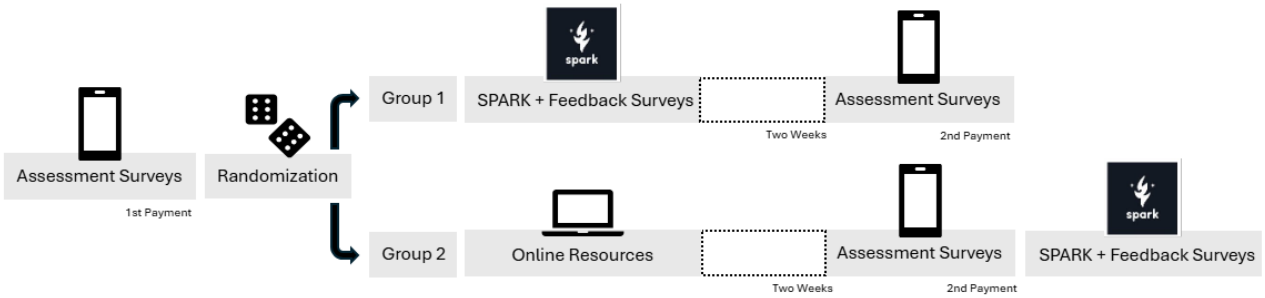

Figure 1: A visual depiction of study procedures

Procedures	Time	Group 1	Group 2
Screening Surveys – We'll ask for your name, email, phone number, and demographics. Your IP address will be collected once. You'll also answer some questions about your experience of various mental health symptoms as well as your diagnoses and mental health history	10 minutes	Step 1	
Outreach from the Study Team - After 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 interest in participating and offered next steps. If you are ineligible, you will be sent an email thanking you for your time.	0-5 minutes	Step 2	
Baseline Assessment Surveys - You will be sent a link to complete a series of online surveys and questionnaires measuring various topics including symptoms, well-being, attitudes, and beliefs.	30 minutes	Step 3	
Randomization - Participants will be randomly assigned to either Group 1 or Group 2. Participants will have a 1:1 chance of being assigned to either group.	-	Step 4	
SPARK Access and Feedback Surveys – Participants are encouraged to complete the SPARK program in one sitting. Afterwards, you will receive a survey containing brief feedback questionnaires. The surveys will ask how easy, helpful, and enjoyable the SPARK program was to use.	45 minutes	Step 5	Step 6
Post-Test Survey Assessments – You will take the assessment surveys from Step 3 for a second time after the two-week study period has passed.	30 minutes	Step 6	Step 5

Why might you want, or not want, to participate?

You may want to take part in the study because you might learn more about mental health conditions, especially psychosis risk, and you might develop helpful coping skills to respond to stress, anxiety, or depression. You might gain insight into your own wellness or feel supported and less alone. Or you might not personally benefit from being in this study, but your responses and feedback will be used to optimize the digital mental health intervention aimed to support college students being developed in this study.

You may not want to take part in the study because study surveys or content in SPARK might be boring or make you uncomfortable. We encourage you to take breaks when answering questions if needed. Participation involves the discussion of mental health topics and seeking treatment services, and participants may feel encouraged to seek mental health treatment. Participants are encouraged to follow reputable and evidence-based treatment recommendations (provided in resources), 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, but there are also ways your participation could increase the risk of breach of privacy. Participants are encouraged to access study surveys and materials when they have the privacy to view potentially sensitive mental health topics on their phone or computer. Participants are also encouraged to avoid accessing study materials when in situations where full attention is required for safety (e.g. crossing a street, driving, taking care of a child).

You will not have to pay anything directly to be in the study, but you will need access to a mobile device or computer with an internet connection. The study includes the use of SMS messaging for study survey invitations. Any data or service charges that may be billed to your phone plan will not be reimbursed.

We will pay you $25 for each of the Assessment Surveys you complete, for a total of $50. Payments will be made in the form of Amazon gift cards, which will be emailed to you no more than five business days after each set of assessments are completed.

NOTE: This study does not involve clinical services. It is testing the benefits of a self-guided informational tool, and no study procedures are a substitute for mental health treatment. We encourage you to talk to your doctor or other health providers about any mental health conditions. Responses to study questionnaires are not monitored in real-time.

If you need 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 . You can access the lifeline by (1) dialing 988 by phone or (2) sending a text message SMS to 988.

How will we protect the information you provide?

We are careful to protect participants' identities and 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 during screening.
b) Your responses to the survey questionnaires, including reporting on your symptoms and your attitudes on mental health conditions and treatments.
c) Your use of SPARK (i.e. what pages you viewed) and feedback for the program.

We will make every effort to keep the data in this study private. We will store your name and other identifiable information separate from the rest of your study data. 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. The research team includes the Principal Investigator and others working on this study at the University of Washington (UW). 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.

Other information

Your participation in this study may be stopped at any time by you, research staff, or the study sponsor.

Leaving the study: You may choose to stop taking part in this study at any time for any reason. If you decide to stop, it will have no effect on the quality of your health care. Please alert the study team if you choose to stop your participation. You will not be penalized in any way.

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 we need to get additional permission from you.

Funding: The University of Washington ALACRITY Center and the National Institute of Mental Health.

A description of this clinical trial will be available on https://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.

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

Whom should you call about this study?

For general questions about the study: contact the Primary Point of Contact, listed at the top of this form. Feel free to ask us any questions, even about things not in this document.

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