UNIVERSITY OF WASHINGTON
CONSENT FORM
Development and testing of a caregiver-facing mobile health intervention to reduce duration of untreated 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 years old or older,
- Live in the United States,
- Speak English,
- Are involved in the care of a young adult who may be at risk for or experiencing psychosis, and
- Own an iPhone.

PURPOSE OF THE STUDY

The purpose of this study is to test a mobile intervention called Bolster. The Bolster intervention involves a mobile app and an app coach called a mobile health support specialist (mHSS) which were designed by researchers at the University of Washington to support caregivers of young adults experiencing symptoms of early psychosis. This study aims to determine (1) whether it is acceptable, useful, and feasible to provide, and (2) to determine if Bolster helps caregivers communicate with people experiencing psychosis, manage their own stress, and facilitate their loved one's engagement in mental health services.

Participants in this study will download and use Bolster for one month (ideally for a short period each day or most days), have access to a mobile health support specialist, and check in with the mHSS in 10-15 minute weekly coaching calls. Participants will complete a set of online surveys about caregiving, stress, and knowledge of mental illness at the beginning of the one-month period and again at the end. These surveys should take 30-45 minutes to complete each time. Participants who complete all study procedures will receive $180 in Amazon Gift Cards delivered in two increments.

STUDY PROCEDURES

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

1. Screening Surveys
2. Pre- & Post-Test Assessment Surveys
3. Welcome Session with mHSS
4. Use of Bolster
5. Coaching Calls
6. Qualitative Feedback
7. Study payment and re-sending resources

Study	Time estimate	T	Pre-Intervention	Intervention Period	Post-Intervention
1. Screening surveys	10 minutes	✓			
2. Assessment surveys	30-45 minutes		✓		✓
3. Welcome Session with mHSS	30 minutes (Zoom or phone)		✓		
4. Use of Bolster	Ongoing, daily			✓	
5. mHSS Coaching Calls	10-15 minutes, weekly			✓	
6. Qualitative Feedback	15 minutes				✓
7. Study payment and resources*					✓

**Participants are eligible for payment only if they are eligible for and complete all study procedures.*

(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. Your IP address will be collected once during the screening process to help us ensure data quality. Then, to determine your eligibility, you will complete a survey where you will answer questions about these topics:

A. Your perceptions of your loved one's mental health symptoms,
B. Your loved one's recent mental health treatment history.

NOTE: We will not ask for the identity of your loved one.

(2) Assessment surveys (30 minutes): If you are eligible to participate, you will be sent a link to complete a series of surveys or questionnaires measuring stress level, well-being, and illness knowledge. During the study, you will also complete the survey assessment again at the end of the one-month period. You will receive reminders to complete these surveys by text message daily for three days until they are completed. It is estimated that it will take 30-45 minutes to complete these surveys. Example topics include:

A. Your beliefs and knowledge about psychosis and other mental health symptoms,
B. Your use of particular strategies to cope with stress,
C. Your perception of your loved one's mental health and interactions with them.

(3) Welcome Session with mHSS: Once the assessment surveys are completed, a member of the study team will call or text you to schedule an onboarding session with the mHSS. During this session, the mHSS will assist you in downloading the study application, provide orientation to the app, review study logistics, and begin goal setting for the month-long study period.

(4) Use of Bolster: During the one-month trial period, participants are expected to use Bolster (i.e., for at least a few minutes each day, or for longer periods every few days). The mHSS is available to facilitate engagement and might reach out to you to encourage engagement or troubleshoot any barriers to full participation.

A. Bolster also will collect information about your interactions with the system, including **(1) the**

amount of time you spend using the Bolster system each day, and (2) what lessons, practices, and resources you use and when, and (3) symptom severity scores saved in the Tracking feature of the app. This information is collected to help the research team better understand what parts of Bolster are most useful. The app does not collect any personally identifying information, and only the members of the research team will have access to the identity of the individual with each account.

(5) mHSS Coaching Calls (weekly, 10-15 minutes): Once per week, you will have a brief phone call with your mHSS to evaluate your experience in the study, troubleshoot any technology issues, help apply app content, and track goal progress. Example conversion topics may include:

A. Technical support in navigating the app or finding content,
B. Suggestions of app content to support a specific situation,
C. Reflecting on how app content was applied with your loved one.

(6) Qualitative Feedback (15 minutes): At the end of the one-month study period, in addition to the assessment surveys that will be completed for a second time, participants will also be invited to provide their feedback on the Bolster intervention. Included in the final survey assessment will be surveys and questionnaires asking participants to share their opinions, feedback and thoughts on the Bolster mobile app as well as the mHealth support specialist.

(7) Study payment and resending of resources. Participants will receive compensation for their participation in the form of Amazon Gift Cards. They can receive up to $180 dollars ($90 for each Assessment Survey completed) Payment will be delivered in two increments: the first upon the completion of the first Assessment Survey AND the Welcome Session, and the second upon the completion of the post-test Assessment Survey. Participants with Bolster will also be asked to delete the application at the conclusion of the study period, as well as provided with crisis resources and information about seeking mental health treatment for their loved ones and themselves.

NOTE: Bolster is a guided self-help resource that includes a support specialist to enhance your motivation and engagement with the digital tool. It is not a substitute for mental health treatment. None of the resources provided to you, including the mHSS, replace any services you or your loved one may be receiving. No one will be monitoring your study data in real time. If you or your loved one are in need of emergency services, please call 911.

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. Bolster content might make you uncomfortable as well. You are encouraged to discontinue use of any content you find distressing, and return to it later, or not at all. Use of Bolster or the provided resources might also encourage users to help their loved one seek mental health treatment. Participants are encouraged to follow reputable and evidence-based treatment recommendations (provided in links in the app, and in the resources provided), 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 use of the app could increase the risk of breach of privacy. Participants are encouraged to (1) not leave their phone unattended, and (2) password-protect access to their phones to protect privacy, and (3) schedule coaching calls when they are able to talk in a private and comfortable place. Participants are also encouraged to never use Bolster when in a situation where full attention is required for safety (e.g. crossing a street, driving, taking care of a child). You are encouraged to be mindful of where you export your responses from Bolster practices, and to use the app or resource pages with discretion and protect your privacy if you are in public.

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,
C. Your attitudes and knowledge about mental health treatment and technology,
D. The time you spend in the Bolster app, as well numeric scores you record. Nothing you write in free-response fields will be saved in the app, and thus **nothing you write will be accessible to the research team.**

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.

Are there any limits to confidentiality?

There are 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.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

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 $180. This payment will be provided to you in increments within 5 business days of your completion of the study procedures.

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

We hope that you will find Bolster and the mHSS useful. We hope that you will learn some new communication skills and/or coping skills, and more about mental health conditions and treatments. Your participation may help the research community learn more about psychosis and the use of technology in mental health treatment. This information could help advance the development of technologies to help young adults and caregivers cope with psychiatric symptoms, and facilitate better outcomes.

SOURCE OF FUNDING

Funding: Garvey Institute for Brain Health Solutions.

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