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."

KEY INFORMATION

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 who is not in specialized mental health treatment,
- Use an iPhone.

The purpose of this study is to determine (1) whether a mobile health app intervention for caregivers of young adults with early psychosis (called "Bolster") is acceptable, useful, and feasible to provide, and (2) to determine whether that intervention 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 be randomly assigned to one of two groups. One group will download and use Bolster for twelve weeks, while another group will be given access to curated resources from advocacy and research organizations designed to provide support and information to caregivers. All participants will complete a set of online surveys about caregiving, stress, and knowledge of mental illness at the beginning of the 12-week period, at the midpoint, and at the end. These surveys should take 30-45 minutes to complete each time. Participants will also complete brief online surveys (about 2 minutes) once per week (12 times total) during the testing period. Participants who complete all study procedures will receive $180 in Amazon Gift Cards delivered in three increments.

We are careful to protect the identities of the people in this study, and we will not use your name in any reports written from this study. 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.
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 yourself, research staff, or the study sponsor.

If you have questions later about the study, or if you feel that you have been harmed by participating in this study, you can contact one of the researchers listed at the top of this form. If you have questions about your rights as a research subject, you can call the UW Human Subjects Division at (206) 543-0098

The following pages of this document provide more information about the study, and you can contact the study team with any questions.

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. Assessment surveys
3. Welcome Session
    A. Installation of Bolster, OR
    B. Presentation of resources
4. Use of Bolster or Resources
5. Short surveys
6. Qualitative surveys
7. Study payment and debriefing

Week	Time estimate	Now	0	1	2	3	4	5	6	7	8	9	10	11	12
1. Screening surveys	10 minutes	✓													
2. Assessment surveys	30-45 minutes		✓						✓						✓
3. Welcome Session	30 minutes		✓												
4. Use of Bolster OR Resources	Ongoing, daily			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
5. Short surveys	2 minutes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
6. Qualitative survey	15 minutes										✓				
7. Study payment and Debriefing*	--		✓						✓						✓

**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 six weeks later, and again six weeks after that. 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: In this study, participants will be randomized into one of two groups: One group will receive the Bolster mobile application, and the other will receive a website with a list of curated psychoeducational resources. These resources are designed to provide information and support to caregivers. Participants will have a 2:1 chance of being randomized into the Bolster group. Once the assessment surveys are completed, the study team will call or text you to schedule a session that will focus on one of the two below:

A. **Installation of Bolster (30 minutes via Zoom)**: During this session, a member of the study team will assist you

in downloading the study application, provide orientation to the app, introduce additional surveys, and review study logistics.

B. **Presentation of Resources (15 minutes via phone)**: During this session, a member of the study team will assist you in accessing the resource list, answer any questions, introduce additional surveys, and review study logistics.

(4) Use of Bolster or Resources: During the 12-week trial period, participants are encouraged to use Bolster or review resources frequently (i.e., for at least a few minutes each day, or for longer periods every few days). The study team is available to facilitate engagement and might reach out to you to encourage engagement or troubleshoot any barriers to full participation.

A. For the Bolster group: Bolster also will collect information about your interactions with the system, including **(1) the numeric "symptom severity" ratings provided about your loved one, (2) the amount of time you spend using the Bolster system each day, (3) what lessons, practices, and resources you use, and when.** 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.

B. For the Resources group: We will not be collecting any individual data about your usage of the website or linked resources.

(5) "Short" surveys (weekly, 2-3 minutes): Once per week, you will be sent a brief survey (about 2 minutes) by text to evaluate your experience in the study and to collect information about your well-being and communications. Example topics include:

A. Your knowledge and attitudes about psychosis and mental health symptoms,
B. Your current levels of stress,
C. Your communications with your loved one.

Every other week, participants in the Bolster group will receive one additional optional survey that asks additional questions about your motivation to use Bolster.

(6) Qualitative surveys (Bolster group only): During the 8-week short survey, you will also be sent an invitation to provide feedback on your experience of Bolster during the study period. This survey will feature screenshots and images from the study app, and you will be asked to report on the program's strengths, weaknesses, and suggestions for areas to change.

(7) Study payment and debriefing. Participants will receive compensation for their participation in the form of Amazon Gift Cards. They can receive up to $180 dollars ($60 for each Assessment Survey completed). Payment will be delivered in three increments: the first upon the completion of the first Assessment Survey AND the Welcome Session, the second upon the completion of the six-week Assessment Survey, and the third upon the completion of the 12-week Assessment Survey. Participants with Bolster will also be asked to delete the application at the conclusion of the study period.

NOTE: Bolster is a guided self-help resource. It is not a substitute for mental health treatment. None of the resources provided to you 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. 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 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 or 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 labeling makes it very unlikely people outside of the study will be able to connect your data with your name.

We have a Certificate of Confidentiality from the NIH. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, 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. We will voluntarily provide the information to:

A. a member of the federal government who needs it in order to audit or evaluate the research;
B. 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;
C. the federal Food and Drug Administration (FDA), if required by the FDA;
D. 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;
E. State authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this occurs in April 2025. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

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.

Will it cost money to participate?

Everything involved in this study will be free to access. However, participation in the study involves use of a mobile app and receiving surveys by SMS text messaging. You will not be reimbursed for additional data or text usage charges to your mobile phone plan this may cause..

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.

BENEFITS OF THE STUDY

We hope that you will find Bolster or the provided resources useful. We hope that you will learn some new communication skills and/or coping skills, and more about mental health conditions and treatments. Even if you are randomized to the group not given Bolster, you will receive a list of informational resources gathered by the study team. 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: National Institute of Mental Health.

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

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.

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