UNIVERSITY OF WASHINGTON
CONSENT FORM
User-centered design of a mobile health intervention to promote help-seeking and reduce duration of untreated illness among young adults with early 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,
- Live in the United States,
- Speak English,
- Have reported specific mental health symptoms, for example:
    - Hearing voices or sounds others do not hear
    - Having suspicious or confusing distressing thoughts
- Are not currently receiving individual therapy or antipsychotic medications for these symptoms, and
- Use an iPhone.

PURPOSE OF THE STUDY

The purpose of this study is to test a mobile intervention called NORTH. NORTH is an app designed by researchers at the University of Washington to teach coping skills and provide support to young adults experiencing mental health symptoms that indicate an increased risk for psychosis. This study aims to determine (1) whether it is acceptable, useful, and feasible to provide, and (2) to determine what version of NORTH provides greater benefits in helping users cope with mental health symptoms. Participants will be asked to carry NORTH on their smartphone devices for three months, use it regularly, and complete a series of surveys/questionnaires about their mental health symptoms, attitudes, functioning, and their experience with NORTH.

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. Installation of NORTH
4. Use of NORTH
5. Short surveys
6. Qualitative surveys
7. Final study payment and provision of resources

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. Installation of NORTH	30 minutes (Zoom)		✓												
4. Use of NORTH	Ongoing, daily			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
5. Short surveys	2 minutes			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
6. Qualitative survey	15 minutes										✓				
7. Final study payment and provision of resources*	--														✓

**Participants are eligible for payment only if they are eligible for and complete the relevant study procedures. They are eligible for a $60 payment after each assessment survey completed.*

(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:

- Your experience of various symptoms (like hearing unusual sounds, feeling that other people are watching you)
- Your diagnoses
- Your mental health treatment history

(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, symptoms, well-being, attitudes, and beliefs. During the course of 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. Participants will be sent study payments in the form of $60 Amazon Gift Cards (within five business days) following each assessment survey completed. Example topics on these assessments include:

- Your beliefs about psychosis and other mental health symptoms
- Your use of particular strategies to cope with stress
- Your perception of mental health treatment

(3) Installation of NORTH (30 minutes via Zoom): Once you have completed all surveys, a member of the study team will call or text you to answer any questions and schedule an app install session over Zoom. During this session, a member of the study team will assist you in downloading the study application, and provide orientation to the app, and additional study surveys. In this study, participants will be randomized (have a 50%-50% chance) to receive one of two versions of NORTH:

- **NORTH "Lite Version"** – A version of NORTH that contains lessons, coping skill practices, and tracking
- **NORTH "Full Version"** – Another version that contains all those features, plus additional support focused on barriers to access in-person treatment

(4) Use of NORTH: During the 12-week trial period, participants are expected to use their version of NORTH 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 app engagement and might reach out to you to encourage engagement or troubleshoot any barriers to full participation.

- NORTH also will collect information about your interactions with the system, including **(1) your numeric "well-being ratings", (2) the amount of time you spend using the NORTH 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 NORTH 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) "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 of NORTH and to collect information about your symptoms and well-being. Example topics include:

- Your current levels of stress, anxiety, and sadness
- Your ability to cope with mental health symptoms
- Your beliefs about mental health treatment and your interest in seeking it

Every other week, you will receive one additional optional survey that asks additional questions about your motivation to use NORTH.

(6) Qualitative surveys: During the 8-week survey, you will also be sent an invitation to provide feedback on your experience of NORTH 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) Final study payment and provision of resources. At the conclusion of the study period, participants will receive their compensation for the final assessment visit in the form of an Amazon Gift Card ($60), and again be provided with a list of relevant mental health resources. Across the duration of the study, participants can receive up to $180 dollars ($60 for each assessment survey completed.) They will also be asked to delete the study application at the conclusion of the study period.

NOTE: (1) NORTH 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 may be receiving. No one will be monitoring your study data in real time, but the study team may reach out to you if they become worried about your well-being. All participants will be provided with mental health resources during the installation session and at the end of the study. If you are in need of emergency services, please call 911.

(2) You will be asked the following question: "Do you ever feel as if you do not want to live anymore?" If you provide a response that indicates a "yes," then you will be provided information related to accessing crisis resources (e.g. the Suicide and Crisis Lifeline at 988), a reminder that your responses are not followed in real-time, and contact information for the study team if you have questions about your study participation.

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. NORTH content might make you uncomfortable as well. You might be encouraged to use coping skills that involve thinking about stressful topics. You are encouraged to discontinue use of any content you find distressing, and return to it later, or not at all. Use of NORTH might also encourage users to seek mental health treatment. Participants are encouraged to follow reputable and evidence-based treatment recommendations (provided in links in the app), 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 NORTH when in a situation 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:

- Basic information such as age, gender, race, education, state of residence. We will collect your IP address once when you take the eligibility survey.
- Your responses to the questionnaires, including reporting on your symptoms
- Your attitudes and perspectives on mental health treatment and technology
- The time you spend in the NORTH 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.

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 member of the federal government who needs it in order to audit or evaluate the research;
- 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;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- 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;
- 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. 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.

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 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 ($60 for each assessment). This payment will be provided to you within 5 business days of completing each assessment.

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 NORTH useful. You might learn more about mental health conditions, especially psychosis, you might develop some helpful coping skills to respond to stress, anxiety, or depression – or to maintain your wellness, you might gain some insight into your own wellness through the Tracking feature, and you might be empowered to seek out mental health treatment from the Treatment Seeking Guide.

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