UNIVERSITY OF WASHINGTON
CONSENT FORM
Implementing mHealth for Schizophrenia in Community Mental Health Settings

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Researchers' statement

We are asking you to be in a research study. Before you decide if you want to take part in this study, please read this form carefully. Feel free to ask questions if you don't understand something. Feel free to take the time to talk about it with a family member or friend.

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

- Have a diagnosis of schizophrenia, schizoaffective disorder schizotypal disorder, delusional disorder or other schizophreniform disorder.
- Own an Android smartphone with data plan (3G, 4G or 5G data allowance).
- Receive services from a participating mental health center.
- Are over 18 and can speak English.
- Are able to participate in the study for 6-months.
- Have NOT used the smartphone application, FOCUS, in the past.

ABOUT THE STUDY

The purpose of the study is to test the effectiveness of two different ways a treatment smartphone application (app) program is delivered. The University of Washington is partnering with mental health clinics around the State of Washington for this research study.

The intervention used in this study is called FOCUS. The intervention includes 1. The FOCUS smartphone application, 2. An mHealth Support Specialist who will call you once a week (10-15 minute calls) throughout the intervention, 3. A clinical dashboard that summarizes the data from using the app. The intervention involves installing the FOCUS app on your phone and using it as you would like and will have weekly calls with an mHealth Support Specialist. Your responses to the questions in the app will be used by the mHealth Support Specialist to better understand how you are doing, and may relay this information to your treatment team if they see you may need additional support.

The intervention lasts for 3 months, with research assessments conducted over your phone using a secure web-page, three times over a 6-month period (when you begin the study, right after the 3-month intervention, then again 6 months after you began the study).

STUDY PROCEDURES

Overview of the process:

1. **Screening visit: (over phone)**
    a. If found eligible: review study procedures over the phone with research staff and give consent. You will be given the choice on how to receive your $40 VISA card (either by mailing to your home address, or picking up at your clinic).
2. **First assessment:**
    a. A researcher will call you ahead of time to let you know the assessment will be texted or emailed to you (your choice). The assessment will be sent to you in the form of a web address that you can access in the privacy of your own home to answer questions about you and your mental health. You will receive a $40 VISA card based on your choice as a thank you for your time and to cover data expenses.
    b. After the assessment is completed, research staff will give you instructions on how to meet with your mHealth Support Specialist.
3. **Meet with your mHealth Support Specialist**
    a. Meet with your mHealth Support Specialist who will help you install FOCUS onto your phone.
    b. Use the FOCUS app.
    c. Connect with your mHealth Support Specialist once a week over a 10-15 minute phone call.
4. **3 Months after visit:**
    a. A researcher will call you ahead of time to let you know the assessment will be texted or emailed to you (your choice). The assessment will be sent to you in the form of a web address that you can access in the privacy of your own home to answer questions about you and your mental health. You will receive a $40 VISA card based on your choice as a thank you for your time and to cover data expenses. FOCUS will automatically disable on your phone.
5. **6 Months after visit:**

A researcher will call you ahead of time to let you know the assessment will be texted or emailed to you (your choice). The assessment will be sent to you in the form of a web address that you can access in the privacy of your own home to answer questions about you and your mental health. You will receive a $40 VISA card based on your choice as a thank you for your time and to cover data expenses.

Screening:

If you volunteer to participate in this study, you will be asked to answer a few screening questions to see if you are eligible, which should take between 5-10 minutes to complete. These could be asked in person or over the phone.

These questions will ask you about:

- Your age, race, gender and education.
- Whether or not you own a smartphone with a data plan or reliable WiFi at home.
- We will also need to verify that your operating system is compatible with the study smartphone application.

Not everyone who completes the screening questions will be invited to continue with the study.

If you are invited to continue with the study, participation will last for 6 months and will include the following:

Research visits:
Participants enrolling in person will be asked to complete the following 3 assessments over your smartphone through a web-page. Each assessment takes approximately 20-30 minutes to complete.

What do the research visits involve?

- **Online Assessment 1*** (at the beginning of the study): After expressing interest in the study and found eligible to participate, you will be texted or emailed a web-page that will ask you to answer questions about your health history, including questions about your mental health, if and what types of services you have accessed before, and information about yourself (such as marital status, technologies you have access to at home, etc). These questions should take 45-60 minutes to complete. After the assessment is completed, you will receive your payment of $40 (VISA giftcard), either by having it mailed directly to you, or for you to pick up at your clinic.

  FOCUS INTERVENTION BEGINS
  FOCUS Installation: After the first online assessment, you will be given instructions on how to meet with your mHealth Specialist who will help you install the FOCUS application onto your smartphone and show you how to use it. They will also talk with you about scheduling the weekly calls that will last roughly 10 minutes each. During the intervention they will review the data from using the FOCUS app and can discuss this data with the people in charge of your clinical care. The intervention lasts 3 months.

  Online Assessment 2* (3 months after visit 1): At the end of your 3 months using the FOCUS Intervention, you will work with your mHealth Support Specialist toward graduation and the app will expire. You will be texted or emailed a second online assessment to answer questions about your health history, including questions about your mental health and your experiences using FOCUS. These questions should take 45-60 minutes to complete. After the assessment is completed, you will receive your payment of $40 (VISA gift-card), either by having it mailed directly to you, or for you to pick up at your clinic.

  Online Assessment 3* (6 months after visit 1): 3 months after you complete the FOCUS intervention you will be sent another online assessment asking you questions about your health history, including questions about your mental health. These questions should take 45-60 minutes to complete. After the assessment is completed, you will receive a certificate of completion in addition to your payment of $40 (VISA giftcard), either by having it mailed directly to you, or for you to pick up at your clinic. You have

the option to decline the certificate of completion by letting your mHealth Support Specialist or research team know before the end of treatment.

***If you think you will have difficulty completing the online assessments, you can let the research team know and the same questions can be asked over the phone with a researcher.**

Data Collected by FOCUS

No identifiable information will be transmitted by FOCUS. Only responses to the questions asked in the program along with their timestamp will be recorded and sent to the research team. Your responses may also be shared with your clinical team to inform your care.

We try to protect your privacy as much as possible. NO written content, pictures, video, phone numbers, Internet browsing history, account information or other files you create on your phone will be captured by anyone related to this study or smartphone application.

***** FOCUS does not provide emergency care. In the case of an emergency, please use 911 services*****

RISKS, STRESS, OR DISCOMFORT

Sometimes answering questions may be boring or make you feel uncomfortable. If this occurs, you may take a break and continue later, skip a question, or stop the study. A list of services can be provided to you. Research staff can call your provider if you need someone to talk to.

There are also risks involved with using a mobile phone. You should only use the mobile phone only when it is completely safe to do so. Operating a mobile device while driving or crossing the street can be dangerous. During your participation there is a possibility that your phone could be lost or stolen. If you share your phone with others, they may have access to resources on the phone for study purposes or otherwise. Password protecting your device through a code (i.e. 2894), dot-design, or fingerprint is a good way to protect your personal information stored on your device.

CONFIDENTIALITY OF RESEARCH INFORMATION

How will your privacy be protected?

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.

The data in this study includes:

- Basic information such as age, gender, race, and education.
- Information about your mental health and health history.

- Information collected through the study smartphone (responses to questions along with their timestamp- no identifiable information will be collected by the FOCUS app or clinician dashboard).

We will make every effort to keep the data in this study private.

We will maintain your privacy by *coding your data* or in other words keeping your data labeled with only a number, not your name. For example, instead of Jane Smith, we would use 1001. The name-number code will be kept separate from your data in a password protected file. 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.

All data from the study smartphone application will be securely encrypted when transmitted. Physical data (paper-based documents) will be kept in locked storage.

Some study data will be kept on computers. These files will be password-protected, or stored on password-protected and encrypted computers or servers. If data is sent via email, documents will be password protected and passwords will be sent in a separate email. We will keep unidentifiable data from this study indefinitely.

You might be contacted by the study team via email or text. In order to help protect your privacy no identifiable information will be used in the content of these messages. Email and text messaging are not secure forms of data transmission and will only be used to determine if you are experiencing technical issues, scheduling for future in person meetings, or if you've lost touch with the study team and want to know if you are still interested in participating.

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:

1. If you indicate that you plan to hurt yourself.
2. If you indicate that you plan to hurt someone else.
3. You provide information indicating abuse or neglect of vulnerable individuals such as a child, the elderly, or people with disabilities.

If you share with us that you plan to hurt yourself in person our research team will inform clinical staff and will try to work with you to get appropriate services to ensure your safety. If you share with us plans to hurt someone else, or share information about abuse or neglect of a vulnerable individual, we will report this to the appropriate authorities to protect their safety. If you indicate that you have thoughts about hurting yourself through the online survey, you will receive an email with a list of services you could access.

Will it cost money to participate?

You will be in charge of covering expenses for your smartphone data plan. There will be no additional cost to you or your insurance for any other research purposes.

Will you be paid to participate in this study?

Yes. All participants will be given $40 for each online assessment completed, for a total of $120. This includes $30 to thank you for your time, and an additional $10 to transmit data or to travel into the clinic if you are unable to complete the assessment remotely.

ALTERNATIVES TO TAKING PART IN THIS STUDY

What are the options if you do not want to take part in this study?

If you do not want to take part in this study, then you can let us know at any time. You will continue to receive services you are currently receiving. Your participation in this study may be stopped at anytime by research staff or the study sponsor.

BENEFITS OF THE STUDY

You might not personally benefit from being in this study. Your participation may help the research community learn more about ways mobile health programs can be delivered.

SOURCE OF FUNDING

Funding: The National Institute of Mental Health. The researcher for this study, Dror Ben-Zeev, is receiving funding from the study sponsor, the National Institute of Mental Health to conduct this research study.

Who may use or see your health information?

Some of the information we collect in this study is about your health- for example, we will collect information about your mental health. By agreeing to participate, you allow the research team to use your health information and give it to others involved in this research area. The research team includes the Principal Investigator and others working on this study at the University of Washington.

The information collected for this study may be used by researchers or officials of the following institutions:

- The University of Washington
- National Institute of Mental Health
- University of Pennsylvania

During this study, we could be asked to give information that identifies you to organizations that oversee research or ensure public safety and may not have a legal duty to protect it. These organizations may also use and disclose your information for these purposes.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over.

It is possible for a court or government official to order the release of study data including information about you. **To help us protect your privacy,** a Certificate of Confidentiality from the US Department of Health and Human Services (DHHS) is issued for this study. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about 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 University of Washington, 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;
- the proper authorities if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

What if you decide not to give permission to use and share your personal health information?
If you do not allow use of your health information for this study, you may not take part in this study.

If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes. An example of this would be using de-identified data (data that does **not** include your personal information) to answer questions that are not specified as core research questions in this study. There would be no way of linking this data to you personally as the data would not contain any of your identifiable information.

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 Rachel Brian at (phone number) for any of the following reasons:

- If you have any questions about your participation in this study,
- If you feel you have had a research-related injury,
- 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
Box 359470
Seattle, Washington 98195-9470
Telephone: 206-543-0098
(You may also call collect at 206-221-5940 if you do not otherwise have access to a telephone)
Email: hsdinfo@uw.edu

What happens if you get sick or hurt from participating in this study?

We do not expect that you will be harmed by participating in this study. This study is funded by the National Institute of Mental Health and compensation for a research-related injury or illness is limited by federal law.

If you are injured or become ill as a result of research procedures, you will be provided with medical treatment but the following organizations do not plan to pay for this treatment.

- The University of Washington
- The National Institute of Mental Health
- University of Pennsylvania

If you agree to take part in this study, you are not giving up any of your legal rights.