Academic-Community EPINET (AC-EPINET)

Comparison of Coordinated Specialty Care Delivered through Telehealth and Clinic-Based Models: A Pilot Study

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INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

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ABOUT THIS RESEARCH
You are being asked to participate in a research study. You were selected as a possible participant because you are receiving care at a mental health treatment clinic that uses a coordinated specialty care (CSC) model to treat early psychosis. We ask that you read this form and ask questions you may have before agreeing to be in the research study.

This study is being conducted by Alan Breier, MD at Indiana University. It is funded by the National Institutes of Health (NIH).

TAKING PART IN THIS STUDY IS VOLUNTARY
You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Eskenazi Health, Sandra Eskenazi Mental Health Center, or Indiana University.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to examine the effectiveness of mental health treatment delivered through telehealth versus the clinic-based delivery of treatment. Telehealth services are provided by your mental health treatment team through the phone or on a web-based video app. Clinic-based delivery services are provided at the physical building where you meet your mental health treatment team.

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of 160 subjects nationally and one of 30 subjects locally taking part in this research.

WHAT WILL HAPPEN DURING THE STUDY?
This study involves collection of information about you or from you. If you agree to be in the study, you will do the following things:

This study involves randomization to two study groups, telehealth treatment delivery or clinic-based treatment delivery. After you have completed the informed consent process you will be randomized to either the telehealth group or the clinic-based group. Randomized means that the type of treatment you receive will be determined purely by chance, like flipping a coin. You have a 50/50 chance of being entered into the telehealth or clinic-based treatment options.

You will complete a brief questionnaire that assesses how you engage with your mental health treatment team. You will then meet with your mental health treatment team, as clinically indicated, over one year. During the year you will complete quarterly assessments with your treatment team and your medical record will be accessed by the treatment team and study staff to answer questions related to your physical and mental health, basic demographic information, engagement with services,

legal involvement, and substance use. Some of these assessments will be self-report, meaning you fill out the answers yourself, while the other assessments will be completed by a staff person.

If you are assigned to the telehealth group you will receive your mental health treatment through telehealth-based services, like the phone or through a web-based app that is approved by your local mental health clinic. You may be asked to attend some appointments in-clinic, for example for injections, vitals, or the semi-annual assessments. Your treatment team will help you download an app to your phone called MOBI. MOBI is an app developed by Safari Health Inc. that will help you track any symptoms you might be experiencing so that your treatment team can monitor your progress between visits. Every day, for 52 weeks, MOBI will send you a notification, prompting you to complete a brief, app-based survey that will ask you about your mood, symptoms, and any medications that you might be taking. You will also be sent a weekly survey each week for 52 weeks. You may skip any items you prefer not to answer and will be paid for each survey you complete. Your responses to completed surveys in the MOBI app will be shared with your treatment team to help support your clinical care. The study team will provide your name, email address, and year of birth to Safari Health, as well as the psychiatrist and therapist to whom you are assigned. Safari's use of the data collected via the app is governed by the app's end user license agreement and privacy policy, which you will accept when installing the app on your phone.

In total, you will be participating in this research study for about one year or 52 weeks.

WHAT ARE THE RISKS OF TAKING PART AND HOW WILL MY INFORMATION BE PROTECTED?

This study includes collection of information about you. The risks involved in this study include: the possible loss of confidentiality, the possibility that some of the questions may be embarrassing or upsetting to you, and the possibility that you might experience frustration while using the MOBI app. We will not make you answer anything that you do not want to talk about; however, failure to answer questions could limit our ability to thoroughly assess your symptoms and impact your ability to participate in the study. We will teach you how to use the MOBI app and will provide support to you if you experience frustrations while using it. Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study and databases in which results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the Office for Human Research Protections (OHRP), the National Institutes of Health (NIH), research teams at other institutions or sites, and any state or federal agencies who may need to access your medical and/or research records (as allowed by law).

A description of this clinical trial will be available on 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.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal

proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
There are no direct benefits to you for participating. Information obtained from this study may improve the understanding and treatment of psychosis in the future.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?
Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

EPINET National Data Coordinating Center (ENDCC)
Data from this study may be submitted to the EPINET National Data Coordinating Center (ENDCC). The ENDCC is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send deidentified health information gathered during your research participation to the ENDCC. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

The information provided to the ENDCC may help researchers around the world treat future children and adults with mental illnesses so that they have better health outcomes. NIMH will also report to Congress and on its website about different studies that researchers are conducting using ENDCC study data. However, you will not be contacted directly about the health information gathered during your research participation.

WILL I BE PAID FOR PARTICIPATION?

You will receive payment for taking part in this study. You will receive $60 on the day of initial consent and earn $20 for each month you are active in the study. If you complete the entire study, you will receive a total of $300 for participation. You will receive your payments in cash and you must present in-clinic to receive this payment. You will be paid semi-annually (or about every 6 months) at your scheduled in-person clinical visit, or you may choose to present in-person to the clinic more frequently to receive your payments due.

If you are a part of the telehealth treatment delivery arm you also can earn fifteen dollars ($15) per week for completing the weekly MOBI app survey and two dollars ($2) per day for completing the daily MOBI app surveys. If you complete all of the daily and weekly surveys during your participation you will receive $1,510. If you do not complete all surveys, you will be paid for the number of surveys you do complete. You will receive payment in cash semi-annually (or about every 6 months) at your scheduled in-person clinical visit, or you may choose to present in-person to the clinic more frequently to receive your payments due. You must present in-clinic to receive this payment.

If you receive $600 or more in one calendar year from Indiana University, you will need to complete a form giving us your Social Security number (SSN) or tax identification number (TIN). You will receive a 1099 tax form the following January from Indiana University and will need to report this payment as income on your federal and state tax returns. You are responsible for paying any local, state, or federal taxes. If you have questions about how this impacts your tax return, please contact a tax professional. If you do not have an SSN or TIN, the Internal Revenue Service (IRS) requires Indiana University to deduct 30% from your research payment to pay required taxes on your behalf.

WILL IT COST ME ANYTHING TO PARTICIPATE?
There is no cost to you for taking part in this study.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about the study, contact the researcher, Dr. Alan Breier, at 317-880-8495.

If you are in need of medical/clinical attention please call the Prevention and Recovery Center for Early Psychosis (PARC) clinical line at 317-880-8494. If you are experiencing a mental health crisis and are in need of immediate attention you can contact the Eskenazi Health Crisis Intervention Unit at 317-880-8485 or call 911.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?
If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. If you decide to withdraw, the principal investigator might ask you to complete discontinuation assessments. Your participation may be terminated by the investigator without regard to your consent in the following circumstances: if we determine it is in your best medical interest, if you do not follow study procedures, if the study is stopped, or for other administrative reasons.

You will be told about new information that may affect your health, welfare, or willingness to stay in the study. This study may be terminated by the NIH, for any reason.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____ **Date**:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____

Printed Name of Parent/Legal Guardian:_____

Signature of Parent/Legal Guardian:_____ **Date**:_____

Participant's Printed Name:_____

Printed Name of Legally Authorized Representative (LAR): _____

Signature of LAR:_____ **Date:**_____