A Mobile Personal Health Record for Behavioral Health Homes

NCT01890226

Informed consent date: June 13, 2016

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: A Mobile Personal Health Record for Behavioral Health Homes

Short Title: Health Smart

Principal Investigator: Benjamin Druss MD, MPH, Department of Health Policy and Management

Sponsor: National Institutes of Mental Health (NIMH)

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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 may search this Web site at any time.

What is the purpose of this study?

The purpose of this research study is to see if using an electronic personal medical record on a cell phone can improve health and healthy habits in patients with a mental illness and a variety of medical conditions.

What will I be asked to do?

We are asking you to take part because you are getting mental health care and medical care at the Central Fulton Community Mental Health Center at Grady Hospital, have been diagnosed with a serious mental illness, and because you may have one or more long-lasting medical conditions including diabetes, high blood pressure, and high cholesterol. If you agree to take part, we will meet with you every six months for a one year period to ask you questions about your medical health, emotional health, and your health and diet habits.

If you agree to join the project, a member of the research team will first ask you some questions in an interview. You will meet for about an hour with a research interviewer to talk about the care you've been getting and how you've been feeling. We will also ask you about your health and diet habits at this time.

If you qualify, we will invite you to take part in the study. If you are enrolled, a random (like a flip of the coin) method will be used to decide whether you will be enrolled in the mobile personal health records group or whether you will continue to get your medical care as you have in the past.

Research Interviews:

Whether you end up in the group that gets a mobile personal health record or in the group that gets their usual medical care in the community, we will ask to meet with you soon after you register. You will talk with one of the study researchers in a private office at the Central Fulton Community Mental Health Center at Grady Hospital for about one hour about the care that you have been getting, your satisfaction with that care and how you have been feeling, both medically and emotionally. We will ask to meet with you every six months for one year to talk about the care that you have been getting. The total time you would be in the study is 1 year and you would have a total of 3 meetings: (1) Day of enrollment, (2) Six months after enrollment and (3) 12 months after enrollment. These meetings will last about one hour and you will be paid $20 for the first interview, $20 for the second interview and $20 for the third interview. During the meetings, we will ask about how you are feeling and any medical or emotional symptoms that you may have. We may also ask you if you would be willing to answer more questions in other, related studies in which case we would pay you for your time and effort. We will also check your medical records to see who has been treating you and the sorts of medical treatment you have gotten.

Personal Health Records Group:

If you are assigned to the mobile personal health records program, we will ask you to meet once a month with a personal health records (PHR) specialist for about 1 hour each time. We

will also ask you to have a phone call with the PHR specialist once a month. You will be asked to meet with the PHR specialist for a period of twelve months. You will learn how to use a smartphone (a phone that has internet access, data storage, and email). We will also show you how to use programs (apps) on the smartphone that help you keep track of your health, food, and diet. We will introduce you to the mobile personal health record, go over your medical history, and talk with you about what kind of goals you have for your health and medical care.

An electronic personal health record system stores your individual medical records and information with the aid of computers. You can access the record on a mobile phone, often over an internet network. It may be made up of electronic medical records from many locations and/or sources, including your medical records from both your mental health provider and your medical provider. A variety of types of healthcare-related information may be stored and accessed in this way. The PHR Specialist will provide on-going support and be available for any questions you may have. After the training, you will be provided with a study smartphone for 12 months. You will be asked to use the mobile personal health record app on the phone at least once a day for approximately 15-30 minutes per day to help you keep track of your health, diet, and food.

You can take part in this study even if you don't feel comfortable with computers and the internet. If you feel like you could use some help with the computer part, we will show you how you can find some classes in the community.

Data Security:

Your health information will be held in the strictest confidence. Your information will be protected by a password. In addition, your information will be housed in a secure storage space. The research staff will be available to respond to any concerns you might have about keeping your information safe.

If you are in the group that gets a personal health record, you will have access to your personal medical records on the study supplied smartphone. All of the information contained within the personal health record mobile application is stored securely on HIPAA compliant servers and is password protected. The information you enter into your personal health record is not stored locally on the phone, but is stored on HIPAA compliant, secure servers. Additionally, the smartphone we will provide you is password protected and encrypted.

Usage of the Smartphone and Monitoring of Browsing Activities:
You may also use the phone to make calls, text, and browse the internet during this time. The information you enter into your personal health record will be sent to the study database and will be securely stored on HIPAA compliant servers. Internet browsing activities on the phone will not be monitored. The phone service provider may block certain internet sites, such as those with adult content. Unless the phone is reported as being lost or stolen, the study researchers will not monitor the phone's location.

Costs Associated with the Smartphone and Loss of the Phone:
The phone will be provided free of charge to you and you will not be charged for any minutes or data used. There are only 450 minutes available for phone calls per month. Data usage is limited to 2 gigabytes per month. If you go over the allotted phone and data usage, the phone will be automatically shut off for the remainder of the month. The information you enter on the phone will be sent to the study database.

If the phone is lost or stolen, Emory University will provide one replacement phone at no cost to you. If the study researchers or PHR specialists have not heard from you or had contact with you for more than 60 days, the phone will be automatically shut off. If you withdraw early from the study, you will be expected to return the smartphone to the researchers. If you withdraw early, and do not return the phone to the study researchers, the phone will be automatically shut off.

After 12 months, you will keep the study smartphone, but the study will no longer pay for a phone or data plan. We will not collect any data from the smartphone after 12 months. Software is installed on the phone that allows the researchers to remotely track, wipe all data from the phone, and prevent the phone from being used if the phone is lost or stolen. Unless the phone is reported as being lost or stolen, the study researchers will not monitor your location. After 12 months, the phone will be restored to the factory default, all study-installed software will be removed, and all phone and data service suspended.

Who owns my study information and samples?
If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data and samples that were already collected may still be used for this study.

What are the possible risks and discomforts?
There may be potential risks from the study procedures that are not known at this time.

The training and the interviews will take some of your time. You may find that you get tired during the training or the interview. However, research staff will do his/her best to avoid tiring you, and will take any breaks that are needed. There is a minor risk of a breach of confidentiality should you decide to participate in this research project. However, all your personal information will be stored in a locked cabinet, in a locked office. In addition, all information collected during interviews will be stored electronically on a secure, password-protected, HIPAA compliant server.

You have the right to refuse to answer any question that is asked. All of the information that you give us is private.

The less common risks and discomforts expected in this study are:
If you are in the group that gets a personal health record, you may find errors in your personal health records. While we strive to keep all the information in the HealthSmart mobile app complete and accurate, we cannot guarantee that the information in your medical records will be error-free. Should you have cause to believe that your information within the HealthSmart app is not accurate, please contact your provider's office immediately. Please confirm all medication information, health history, and treatment information with your provider.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

Taking part in this research study may not benefit you personally, but the researchers may learn new things that will help others. Taking part in the project may help you improve your health. It may help you look after your illnesses. The results of this study will be used to decide whether this sort of program can improve the health of patients here at the Central Fulton Community Mental Health Center at Grady Hospital.

Will I be compensated for my time and effort?

It will not cost you anything to be part of this study. You will be paid $20 for each interview. If you do not finish the study, you will be paid for the visits you have completed. You will get $60 total, if you complete all study visits. If you are randomly assigned to the personal health records group, you will receive a smartphone for your use.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. You can continue to receive care at the Central Fulton Community Mental Health Center at Grady Hospital, as well as other providers in the community. You do not have to be in this study to be treated for your mental illness or cardio metabolic condition.

How will you protect my private information that you collect in this study?

Emory and Grady Health System will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Medical Record

Research Information Will Not Go Into the Medical Record:

If you are or have been an Emory or Grady Health System patient, you have an Emory or Grady Health System medical record. If you are not and have never been an Emory or Grady Health System patient, you do not have one. Please note that an Emory or Grady Health System medical record **will** be created if you have any services or procedures done by an Emory or Grady Health System provider or facility for this study.

If you agree to be in this study, a copy of the consent form and HIPAA patient form that you sign **will not** be placed in your Emory or Grady Health System medical record. Emory or Grady Health System may create study information about you that can help Emory Healthcare or Grady Health System take care of you. For example, the results of study tests or procedures. These useful study results **will not** be placed in your Emory or Grady Health System medical record. Anyone who has access to your medical record will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA Privacy Rule. On the other hand, some state and federal laws and rules may not protect the research information from disclosure.

Emory and Grady Health System do not control results from tests and procedures done at other places, so these results would not be placed in your Emory or Grady Health System medical record. They will not likely be available to Emory or Grady Health System to help take care of you. Emory and Grady Health System also do not have control over any other

medical records that you may have with other healthcare providers. Emory and Grady Health System will not send any test or procedure results from the study to these providers. If you decide to be in this study, it is up to you to let them know.

In Case of Injury

If you get ill or injured from being in the study, Emory or Grady Health System will help you to get medical treatment. Emory, Grady Health System and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Druss at telephone number 404-712-9989. You should also let any health care provider who treats you know that you are in a research study.

Costs

There are no costs, research or standard of care related, associated with the study.
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study in which you may choose to participate.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Emory and Grady Health System may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The National Institute of Mental Health is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections; Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: 404-712-9989

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your

safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr. Benjamin Druss at 404-712-9989:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Consent and Authorization

Please print your name and sign below if you agree to be in this study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed consent to keep.

_____
Name of Subject

_____ _____
Signature of Subject Date Time

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion Date Time