UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 07.2010)

Project Title: Improving Medication Adherence in Hypertensive Individuals with Bipolar Disorder

Principal Investigator: Jennifer Levin, Ph.D.

Introduction/Purpose

You are being asked to participate in a research study about how to help people with hypertension and bipolar disorder remember to take their medication. You are being asked to participate in this study because you have hypertension (high blood pressure) and bipolar disorder and have recently missed taking some medication. Doctors at University Hospitals Cleveland Medical Center (UH) and Case Western Reserve University (CWRU) Department of Psychiatry want to find out if sending text messages, an intervention called Individualized Texting for Adherence Building - Cardiovascular (iTAB-CV) might help patients remember to take their medication.

This study will take place at UH. It is funded by the National Heart, Lung and Blood Institute (NHLBI) and Dr. Levin is the study principal investigator. A total of 38 people will participate in this study.

Before you decide whether or not to participate in this study, you must be told the purpose of the research study, how this study may help you, any risks to you, and what is expected of you. This process is called informed consent. You will be asked to sign this consent form before you can participate in the study. Please make sure you fully understand what this study is about and ask any questions you might have. If you decide to participate in this study a copy of this consent form will be given to you for your records.

You do not have to participate in this study. You may stop your participation in this study at any time, and your decision to be part of or not be part of this research study will in no way affect your clinical care.

The purpose of this study is to find out if certain text messages will help people to take their medications as they are prescribed.

Study Procedures

Your participation in this study will last approximately 3 months. During that time, you will be asked to come in for 4 study/research visits (screening, baseline/week 4, week 8, and week 12).

At the screening visit, you will sign the informed consent form and you will undergo a psychiatric diagnostic assessment. You will be asked basic demographic questions about facts such as your age and gender. Your height, weight, and blood pressure will also be taken. You will be asked questions about your attitudes, mental health symptoms, and how you are taking your medication. You will also receive an eCAP for your antihypertensive medication which will record time/date of bottle opening. The screening visit will last about 90-120 minutes. You will be asked to bring the eCAP to the next 3 visits.

At the baseline visit, you will be asked questions about your attitudes, mental health symptoms, and how you are taking your medication. Your blood pressure and weight will be measured again. A structured interview and educational presentation (about high blood pressure and bipolar disorder) with the study principal investigator or study staff will also be conducted, lasting 45-60 minutes. The structured interview will determine the following: preferred name, schedule of antihypertensive and bipolar disorder medications, and description of antihypertensive and bipolar disorder medications. This information will be used to create personalized text reminders. You will be given a cell phone at this visit that you will be able to keep after the completion of the study. During the duration of the study, you will be given unlimited texting and calling on that phone. You will begin receiving iTAB-CV texts about the role of medicine in treating hypertension and bipolar disorder starting a day after the baseline visit.

You will also be asked to rate your mood once a day through a text message. You will be taught how to use the phone and answer the text messages when you are given the phone. The baseline visit will last about 120 minutes.

At weeks 8 and 12, you will be asked questions about your attitudes, mental health symptoms, and how you are taking your medication. Your blood pressure and weight will be measured again. These visits will last approximately 45-60 minutes. After the week 8 visit, you will begin receiving text messages reminding you to take medication in addition to the mood rating text.

About one month after study completion, a member of the research team will call you and ask you questions about taking your bipolar and blood pressure medications.

Risks

Some of the questions you are asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question. You may feel tired after completing all the questionnaires.

Although your condition may improve during the study, it is also possible that your condition may worsen during the study. Your regular mental health care provider as well as your other regular primary care providers will continue to monitor your condition while you are in the study. Regardless of whether or not your condition improves or worsens while you are in the study, your regular care providers and you will continue to make decisions about your care such as medication changes and dose changes. These decisions may or may not include withdrawal from the study.

Should your condition unexpectedly worsen and you report to any of the study staff plans to harm yourself, for your own safety, you may be evaluated by the principal investigator or another mental health professional for possible hospitalization.

The study requires you to place a device on top of a standard pill bottle (eCAP) which may affect the use of pill organizers or other devices to manage your medications. It is possible that this may affect your medication adherence.

Even though every effort will be made to protect your confidentiality, there is a risk of loss of confidentiality. It is possible that you could put personal information on the device that could link you to the delivered text messages, but the risk of losing confidential information in this way is the same as the risk of owning and using any cellular phone. Reminders do not use medication names and mood questions are general. You will get to decide what words you would like to use to refer to bipolar disorder and hypertension. The text messages will be delivered from a phone number that will not be linked to the specific study goals.

Benefits

This study may or may not benefit you. Information obtained in this study may help improve care for other patients with bipolar disorder and hypertension.

Alternatives to Study Participation

While participating in this study you will continue to receive your usual treatment, including medication prescriptions from your regular mental healthcare provider. Therefore, the alternative to participating in this study is to not participate.

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Withdrawal

You may decide at any time to stop participating in this study. There are no consequences to you for withdrawing from the study. Your participation in this study may be discontinued by the study doctor if she feels it would be in your best interest.

Financial Information

Depending on completion of screening visit, you will receive up to $40 for the screening visit and $30 for the next three study visits. You will receive an additional $10 for bringing your eCAP to each of the last three visits. The total amount you may receive for the main part of the study is $160. You will be compensated after each study visit. You will either be paid by a check mailed to you or with cash. To receive payment, you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS. If necessary, transportation to and from your study visits will be provided in the form of a bus ticket or parking voucher. You will also be able to keep the cell phone given to you for this study, however, the data plan will end when you are finished with the study. There is no cost to you or your insurance for participation in this research study.

Student/Employee Rights

If you are an employee or student at UH or CWRU, you are not specifically being recruited for this study because of your UH or CWRU employee or student status. You will be allowed to participate in this study if you fit the study criteria and are not currently a direct report to the Psychiatry Department or Neurology Department. A direct report includes physicians, residents, general employees, and student workers within the aforementioned departments or divisions at UH or CWRU whether part-time or full-time. It also includes any employee not in those departments or divisions who is an employee of the principal investigator or co-investigators, with direct involvement in this study or other studies under the principal investigator or co-investigators. Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. Any information obtained during this study and identified with you will remain confidential and will be disclosed only with your permission. All information will be coded to protect

your confidentiality and then stored in cabinets in the locked offices of the investigators or on the UHCMC secure server. Information that is collected is subject to review by the National Heart, Lung, and Blood Institute (NHLBI), the Institutional Review Board, and the Office of Human Research Protection. These entities may also have access to your files.

We will do everything we can to keep others from learning about your participation in the research. The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.

You should understand that you or a member of your family are not prevented from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation and obtains your written consent to receive research information, then the investigator may not withhold this information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others including disclosure to local authorities of child abuse and neglect, or harm to self or others.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "Improving Medication Adherence in Hypertensive Individuals with Bipolar Disorder" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Jennifer Levin, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you:

- your name, initials, address, telephone number, date of birth and other demographic information;
- your medical history (including the history and diagnosis of your disease and your family medical history) and the name of your physician(s) and locations where you received any treatment;

- information about other medical conditions that may affect your participation, including information relating to mental health, behavioral health and psychiatric disorders; and alcohol and drug dependence or abuse;
- specific information about any treatment/therapy you receive while participating in the research study and treatment you received prior to the research study (including treatments and therapies, surgeries, hospitalizations and medications);
- information on side effects from the medicine you take or have taken and how these side effects were treated;
- information about how frequent you take your medications;
- information about your general health status and the status of your disease or medical condition; and
- numbers or codes that identify you such as your social security number, medical record number, and research study case number.

This PHI will be used to determine if an educational and behavioral intervention program is helpful in the treatment of patients with bipolar disorders and hypertension. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Case Western Reserve University, including the Department of Psychiatry, Department of Neurology, Department of Medicine, other staff from the Principal Investigator's medical practice group; University Hospitals, including the Department of Psychiatry, the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to:

Jennifer Levin, Ph.D., Department of Psychiatry,
University Hospitals Cleveland Medical Center, 10524 Euclid Ave., Cleveland, OH 44106

If you have a complaint or concerns about the privacy of your health information, you may also write to:

UH Privacy Officer, Management Service Center,
3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122

or to the Federal Department of Health and Human Services (DHHS) at:
DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services
Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203.

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Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

By signing this consent, you give us permission to get copies of your medical records.

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator, Dr. Jennifer Levin, can also be contacted at 216-844-5057. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about: concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

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Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

x	
Signature of Participant	Date
x	
Printed Name of Participant	
If participant does not have the capacity to consent and protocol is approved for inclusion	
x	
Signature of Legally Authorized Representative (LAR) or Next of Kin	Date
x	
Printed name of Legally Authorized Representative (LAR) or Next of Kin	
If Next of Kin, please mark ONE relationship from list below (in descending order of priority):	

	Spouse		Adult Child		Custodial Parent		Adult Sibling		Adult relative (related by blood or adoption)

Study personnel (only individuals designated on the checklist may obtain consent)

x	
Signature of person obtaining informed consent	Date
x	
Printed name of person obtaining informed consent	