TITLE: Short Message Service System for Patients With Uncontrolled Hypertension
NCT03596242
DATE: 11/20/20

SMS System for Patients with Uncontrolled Hypertension

Informed Consent Form to Participate in Research
Claudia L. Campos, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to find out how practical it is to use a text messaging system and monitor your blood pressure out of the clinic. You are invited to be in the study because your blood pressure is not well controlled and there is room for improvement. Your participation is completely voluntary.

This form contains information to help you decide whether to take part. All of this information is important, but here are some key points to keep in mind:

- Your participation in this study may involve:
  - Receiving and responding to text messages every week until your return visit with your doctor (in about 3 months).
  - Checking your blood pressure at home (with the home blood pressure cuff provided).
- We may ask about your blood pressure numbers and how you are taking your blood pressure medications.
  - We will communicate your answers with your doctor through your electronic medical record.
  - Your doctor may want to make suggestions or changes to your medications and will contact you if they think it is necessary.
- Risks: There is a slight risk that your doctor may be making changes to your medications without performing a complete physical exam. This means that there is a potential for physical exam findings that may suggest side effects that we may not know about through the text messaging system.
- Benefits: You may benefit from participation in this study by engaging more in your health care and by achieving better blood pressure control.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. If you decide to join the study you are free to leave at any time. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is **Dr. Claudia Campos**. If you have questions,

suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted]

If you have any questions, suggestions or concerns about your rights as a participant in this research, please contact the Institutional Review Board (IRB) at [redacted] or the Research Subject Advocate at Wake Forest at 3[redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have uncontrolled high blood pressure. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine if monitoring blood pressure via a text messaging system is an effective alternative to standard in-person office visits and blood pressure education with your doctor. There will be two phases in this study. The first five participants will be included in phase I of the study. Phase I of the study is to evaluate feasibility of the study, such as the amount of time involved in conducting the study, however all data collected is still being used to access the primary outcome of the study. The data collected from Phase I of the study will determine rather we continue to Phase II.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We will enroll 24 people here at Wake Forest Baptist Medical Center.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group.

- SMS Group: Will receive the text message intervention and will be provided with a blood pressure cuff in addition to standard blood pressure control education received at clinic visits
- Control Group: Will receive standard blood pressure l care and education, as well asa blood pressure cuff at their clinic visits

If you are placed in the SMS group you will receive and respond to text messages. You will need to have a cellular phone capable of sending and receiving text messages. They study team will send a test message to your cellular phone after the informed consent form is signed. The study team will also show you ways to protect your privacy while sending and receiving text messages for the study.

- Your participation in this study will involve:
  - Receiving and responding to text messages every week for 4 weeks and then every other week until your return visit with your doctor (in about 2 months).
  - Checking your blood pressure at home (either with a home blood pressure cuff or at your local pharmacy).
- We will be asking about your blood pressure numbers and how you are taking your blood pressure medications.
  - We will follow up with office (or phone if they no show for their visit) interviews at 2 weeks or 3 months to complete 2 validated scales: the MAQ, and SUS+ free comments

- We will communicate your answers with your doctor through your electronic medical record.

  - Your doctor may want to make suggestions or changes to your medications and will contact you if they think it is necessary.

We will send your blood pressure measurements numbers to your personal physician. If you do not wish to have any of your medical information sent to your physician, you will not be able participate in this research study.

If you are placed in the control group your healthcare provider will continue with blood pressure education. In addition, we will collect information from your medical record regarding your blood pressure.

How Long Will I Be in the Study?

You will be in the study for about three months until you have a follow-up visit for blood pressure with your doctor.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff.

Risks of being involved in this study are minimal. You may be contacted by a clinician to discuss changes to your blood pressure medications if necessary. We also may not make any intervention despite a persistently elevated blood pressure, which can be a risk factor of heart attack, stroke, heart failure, or kidney failure. Low blood pressure might seem desirable, and for some people, it causes no problems. However, for many people, abnormally low blood pressure (hypotension) can cause dizziness and fainting. In severe cases, low blood pressure can be life-threatening. We will not be able to perform a physical exam or blood work with only the blood pressure measurements that you send via text message. Text messages are not considered to be a secured method of communication and there is a possibility of someone accessing your study information who you did not give permission to access your study information.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: Improvement of your own blood pressure control and awareness of blood pressure. This may decrease your risk of heart attack or stroke.

WHAT ARE THE COSTS?

You will be responsible for the cost of your blood pressure medication and any text messages charges by your mobile phone carrier.

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WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid a total of $50, $25 per visit, in the form clincard if you complete all the scheduled study visits. The two scheduled visits where you will be paid will include the initial visit and the 2 week or the 3 month in clinic follow up visits. If you withdraw for any reason from the study before completion you will be paid for each complete study visit.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Wake Forest Clinical and Translational Science Institute. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

To help us protect your privacy, a Certificate of Confidentiality from the National Institutes of Health has been approved for this research study. With this Certificate, the researchers cannot be forced to disclose information in the research records that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for

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information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent for the researcher to disclose research information about you, then the researchers may not use the Certificate to withhold that information.

In addition to the Certificate of Confidentiality, we will also take other steps to keep your Protected Health Information private. We will store the research records containing your Protected Health Information in a cabinet in a locked office or on a password protected computer.

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information (PHI). The information we will collect for this research study includes**:** blood pressure measurements, information about blood pressure medications, and demographics including cell phone number.
If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your PHI and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy

regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate amount of time. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Claudia Campos, MD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Claudia L. Campos, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

A Wake Forest Baptist Hospital (WFBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the WFBH medical record, along with any routine medical test results that were obtained at WFBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because your condition worsened or you had an unexpected reaction to a blood pressure medication.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Claudia L. Campos, MD at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm