Official Study Title:
Evaluating the Effect of an Evidence-Based One Page with Supplemental Visual Aids on the Knowledge and Perceptions of Blood Pressure Management Among Adults with Hypertension

Version Date: 06.12.20

The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for Participants in:
Evaluating the Effect of an Evidence-Based One Page with Supplemental Visual Aids on the Knowledge and Perceptions of Blood Pressure Management Among Adults with Hypertension, Version 061220

You are being invited to take part in a research study about high blood pressure and behavioral changes that may help improve blood pressure management.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn if a one-page education sheet on behavioral changes, education provided to you by PharmD students, and supplemental handouts will improve your knowledge of how to manage your blood pressure numbers and improve your confidence to make lifestyle changes. The one-page is from the latest evidence-based guidelines for adult hypertension. Your participation in this research will last about 8 weeks, with approximately 30-60 minutes of active participation.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may wish to participate in this study to learn about behavioral changes that can help you to manage your blood pressure. You will receive education from PharmD students about ways to help you improve your blood pressure.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may experience some discomfort when answering pre-test/survey or post-test/survey questions. You may experience a loss of privacy and/or confidentiality.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Alexandra Herman, PharmD, of the University of New Mexico Health Sciences Center, Department of Pharmacy Practice and Administrative Sciences. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is 505-272-7630 or asible@salud.unm.edu.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

DETAILED CONSENT

Version 061220

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

If you are pregnant, under the age of 18 or over the age of 75, do not speak English, cannot consent for yourself, or do not have a diagnosis of primary hypertension, you are not eligible to participate in this study. If you have sleep apnea and do not follow your prescribed treatment plan, you are not eligible to participate in this study.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at Walgreens Pharmacy, Store #6587 in Albuquerque, NM. This study is a collaboration with the University of New Mexico (UNM) College of Pharmacy, Walgreen's Pharmacy, and a Doctor of Nursing (DNP) student enrolled in the DNP program at Missouri State University (MSU). We will mail you materials to help you learn about managing your blood pressure, and a PharmD student will make three phone calls, of approximately 5 minutes each, at a phone number that you provide. The total amount of time you will be asked to volunteer for this study is approximately 30-60 minutes over the next 8 weeks.

WHAT WILL YOU BE ASKED TO DO?

In this project you will receive education from a PharmD student, and some additional material to review. You will be asked to use apps and web sites, if you choose to do so. You will be given a pre-survey and pre-test given to ask you questions about blood pressure management. There will be a post-test and post-survey.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You may experience some discomfort when answering pre-test/survey or post-test/survey questions. You may choose not to answer any questions on tests and surveys. You may experience a loss of confidentiality and/or privacy.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect. You will be asked to follow up with your primary care provider or other healthcare provider for continued management of your blood pressure.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. However, some people have experienced improved blood pressure when provided with evidence-based education about blood pressure management. However, if you take part in this study, information learned may help others with your condition.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is. Information will be stored in a locked filing cabinet inside the pharmacy, which is secured and accessible only with personal security codes and/or keys. Information will be entered into a web-based program called REDCap.

You should know there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with the following agencies and for the following reasons:

- The law requires us to share your information with authorities if you report information about a child being abused
- If you pose a danger to yourself or someone else.
- A court or agencies, if you have a reportable disease or condition.
- Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

REDCap is a secure, web-based program to capture and store data at the University of New Mexico. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the internet, we can never guarantee the confidentiality of the data while still in route to the server.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The study intervention will no longer be provided to you. This may occur for a number of reasons. You may be removed from the study if you are not able to follow the directions or they find that your participation in the study is more risk than benefit to you. Circumstances for withdraw from the study by the investigators include: becoming pregnant or being hospitalized for a major health event such as stroke, myocardial infarction (heart attack), or heart failure exacerbation resulting in significant medication changes. In addition, if we are unable to reach you for follow up phone calls after three attempts, you will be removed from the study.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEACH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator and your doctor know if you are in another research study. You should discuss this with the investigator and your doctor before you agree to participate in another research study while you are in this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not receive any payment for taking part in the study. You will receive a complimentary pill box, valued at approximately $5.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information information/diagnoses and cannot be used to make decisions about standard medical care.

You can be given feedback about the results from your tests, surveys, and blood pressure measurement done for purposes of this research.

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 50 people to do so.

FUTURE USE OF YOUR INFORMATION, PROTECTED HEALTH INFORMATION OR SPECIMEN(S).

Your information collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number, or date of birth.

INFORMED CONSENT VERBAL CONSENT

You are participating in this study. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after you give verbal consent.

_____

Name of Individual Obtaining Consent (Printed)

_____

Signature of Individual Obtaining Consent

_____

Date