Pharmacist-guided, Patient-driven Management of High Blood Pressure in CKD: A Novel Approach

NCT05546099

10/2/2025

Department of Veterans Affairs

RESEARCH CONSENT FORM

FOR IRB USE ONLY
APPROVED BY: IRB-03 VA Only
IRB ID #: 202205210
APPROVAL DATE: 10/02/25

Participant Name: _____ **Date:**_____

Title of Study: Management of high blood pressure in CKD

Principal Investigator: Diana Jalal, MD **VA Facility:** Iowa City, Iowa

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is about learning ways to improve blood pressure management in Veterans living with chronic kidney disease. It is being funded by the Department of Veterans Affairs. By doing this study, we hope to learn more about whether pharmacist-guided self-management of blood pressure is an effective strategy for treatment of high blood pressure.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

This study involves monitoring your blood pressure at home using an automated monitor provided by the study. You will also record your readings and provide them to a study pharmacist or doctor at regular intervals. You may also participate in adjusting your blood pressure medication at home under the guidance of a clinical pharmacist. Your participation in this research will last about one year. During this time, you will have six in-person visits to the Iowa City VAMC. The time you spend at each clinic visit will range from 30 minutes to two hours, depending on the visit. There will also be an optional phone interview that will occur after participants have been enrolled in the study for at least 3 months. The phone interview will last approximately 30 minutes to one hour.

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

We don't know if you will benefit from being in this study. However, we hope that others may benefit in the future because of what we learn by doing this study.

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

You might not want to volunteer if you find the study procedures to be too burdensome.

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 the study is Diana Jalal, M.D. of the Iowa City VAMC. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study the study contact information is: Katie Geasland (319) 353-6318 or (319) 356-1616 pager #9971.

Participant Name: _____ **Date:**_____

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RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you have chronic kidney disease and high blood pressure.

With this research we hope to learn if pharmacist-guided self-management of high blood pressure is an effective strategy to improve blood pressure control in Veterans with chronic kidney disease.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to last approximately three years. Your individual participation in the project will take approximately 12 months. We plan to enroll about 250 participants.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

<u>The first session</u>: (about one hour)
- The administration of informed consent
- Questionnaires involving demographics, medical history, allergies, and current medications. Kidney function lab results will be reviewed and collected for confirmation of kidney disease.
- Blood pressure measurements taken in both arms after a 5 minute seated rest and then again two more times 1-2 minutes later in the arm with the highest measurement.
- Orthostatic BP measurement
- Heart rate, weight, and height measurements
- 7-day physical activity recall (International Physical Activity Questionnaire)
- Family medical history questionnaire
- Pregnancy test if women in child-bearing age. Women who test positive for pregnancy will not be eligible to continue in the study.

- Education regarding the collection of 24-hour urine for sodium and creatinine. You will be provided a urinary collection container to bring back before the intervention visit (at your convenience).

Randomization: This will take place after the first session. This study will have 2 different groups of participants. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin. You will have a 50/50 chance of being in either group. One group will learn how to adjust medication dosages at home by following a titration plan developed by the study physician. One group will follow standard practice of provider-driven follow up for dosage changes.

We will also subscribe you to Annie Text Messaging prior to meeting with the pharmacist. Annie is a messaging service that allows the Veterans to take an active role in their care. You will receive a daily text message from Annie reminding you to check your blood pressure. You will need to respond to Annie with your blood pressure values so that they can be entered in your medical chart. During the study period, you may not modify your Annie settings.

The second session: (about one hour)
This will be with the clinical pharmacist approximately 2-4 weeks after the first session. Of note, office BP measurement will be done.

Intervention group:
- You will be provided a BP monitor. You need to use this monitor even if you have a BP monitor at home.
- The clinical pharmacist will provide instruction regarding the proper BP measurement technique.- Additional instruction will include: frequency and timing of BP measurements, BP goal, medication changes indicated for measurements above target.
- All the necessary labs will be ordered by the clinical pharmacist during this visit. You will receive written instruction regarding the follow-up plan including laboratory work if indicated
- Educational resources provided as well as instructions for interim monitoring

Control group:
- You will be provided a BP monitor. You will need to use this monitor even if you have a BP monitor at home.

- The clinical pharmacist will provide instruction regarding the proper BP measurement technique.
- Additional instruction will include frequency and timing of BP measurements, BP goal, and instructions for when to contact the primary care provider.
- Educational resources provided as well as instructions for interim monitoring

This session will be followed by safety assessments via telephone or in person if coinciding with an in-person visit at months 1 and 2 which will take about 5-10 minutes.

The third session: at 3 months (about 30 minutes)
- Blood pressure measurements taken in both arms after a 5 minute seated rest and then again two more times 1-2 minutes later in the arm with the highest measurement.
- Orthostatic BP measurement
- Heart rate, weight, and height measurements

- Review of adverse events
- Safety assessment completion
- You will be offered an optional phone interview regarding the acceptability and adherence to the treatment approach. This can be conducted at a different time by the study staff.

The fourth session: at 6 months (about 30 minutes)
- Blood pressure measurements taken in both arms after a 5 minute seated rest and then again two more times 1-2 minutes later in the arm with the highest measurement.
- Orthostatic BP measurement
- Heart rate, weight, and height measurements
- Collection of the 24-hour urine
- Review of adverse events
- Safety assessment completion

The fifth session: at 9 months (about 30 minutes)
- Blood pressure measurements taken in both arms after a 5 minute seated rest and then again two more times 1-2 minutes later in the arm with the highest measurement.
- Orthostatic BP measurement
- Heart rate, weight, and height measurements
- Review of adverse events
- Safety assessment completion

The sixth session: at 12 months (about 30 minutes)
- Blood pressure measurements taken in both arms after a 5 minute seated rest and then again two more times 1-2 minutes later in the arm with the highest measurement.
- Orthostatic BP measurement
- Heart rate, weight, and height measurements
- Collection of the 24-hour urine
- Review of adverse events
- Safety assessment completion

During the third, fourth, fifth or sixth session, you may be asked to bring your home blood pressure cuff to the visit for a validation procedure. This will consist of:
1. Device 1 (home device): Two measurements on your right arm.
2. Device 2 (office device): Immediately after, two measurements on your left arm.

Next, we will cross-over:
3. Device 2 (office device): Two measurements on your right arm.
4. Device 1 (home device): Two measurements on your left arm.

While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

Audio Recording

One aspect of this study involves making audio recordings of you. The recordings are being made to gather information on perceptions of past blood pressure treatment as well as the acceptability of the current intervention. We will also gather information on your needs, preferences, resources and perceived ability to be successful in blood pressure control. Only the study team will have access to the recordings. The recordings will be deleted per VA records administration guidelines.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

1. Risks associated with hypertension management: you may experience fatigue, shortness of breath, dizziness or fainting. You may also experience low blood pressure, acute kidney injury and potential emergency room visits or hospital admissions. These risks will be minimized by close follow-up with study pharmacists and primary care providers. In addition, safety assessments will be conducted by the study coordinator at months 1, 2, 3, 6, 9, and 12.

2. Risks associated with questionnaires and interviews: some people become uncomfortable at being asked questions about their health care; if, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

3. Risks if pregnant or become pregnant: women of childbearing potential enrolling in this study must (i) have been using a birth control measure (an intrauterine device (IUD), birth control pills, a condom, diaphragm, or abstinence) for the previous three months, (ii) must have a negative pregnancy test, and (iii) must agree to continue to use a birth control measure for the duration of the study. If, while participating in the study, you suspect you have become pregnant, please contact the study physician immediately. Women are considered to be of childbearing potential unless they have been surgically sterilized (for example tubal ligation or hysterectomy) or are post-menopausal, that is, no menstrual period for more than 6 months. Nursing mothers may not participate in this study.

4. Risk of loss of confidentiality of data: There is a risk that people outside the research team will see your research information. We have measures in place to protect your information but it cannot be guaranteed.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

Audiotaping:

The study team has explained that by signing this Informed Consent Document, I voluntarily authorize voice recording(s) to be made of me by the study interviewers while I am participating in this study. The said voice recording is intended to help the study determine the acceptability and adherence to the intervention. Please indicate your preference and sign below:

1. I agree to participate in the audiotaped interview:

Signature: _____ Date: _____

2. **I do not** agree to participate in the audiotaped interview:

Signature: _____ Date: _____

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include learning how to monitor and treat high blood pressure. In addition, the information that we gain by doing this study may help others in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, there may by other ways of treating your high blood pressure. These could include lifestyle changes such as limiting salt intake, smoking cessation, or exercising. You may discuss these options with your doctor. You may leave this study and still have these other choices available to you.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Paper records will be stored in the research coordinator's office in a locked cabinet. Electronic records are stored on computers which are password protected.

We will include information about your study participation in your medical record.

While this study is being conducted, you will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results, diagnoses, drug or alcohol treatment, genetic test results or mental health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the VA Cooperative Studies Program (CSPCC); CSP Clinical Research Pharmacy Coordinating Center (CSPCRPCC); CSP Site Monitoring; Auditing and Review Team (SMART); CSPCC's Human Research Committee (HRC); Institutional Review Board, Food and Drug Administration, Office of Human Research

Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Diana Jalal, M.D. and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid $25 per visit for study visits 1, 2, 3, 4, 5, and 6. If you choose to participate in the interview, you will be paid $35 for your time. If you live outside the Iowa City area, you will be paid $0.30 per mile for your travel expenses for in-person study visits 1, 2, 3, 4, 5 and 6. You will be paid by direct deposit or by Direct Express Debit Card approximately 2-4 weeks after each visit. The Department of the VA will disburse payments. Payments made to subjects

through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount. Depending on which payment method you choose, you may need to provide your SSN for payment processing. If you withdraw from the study early, you will be paid for the completed visits.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

No compensation is available in the event of an injury.
The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85).

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: Diana Jalal, M.D. at (319) 338-0581 x635214 during regular work hours. If you experience medical problems due to the study and it is outside regular working hours, please call 319-356-1616 and ask for pager 9971.

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in this 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.

If you choose to participate, you may discontinue taking part at any time without any penalty or loss of benefits. You may withdraw and still receive the same standard of care that you would otherwise have received.

Any data already collected prior to your withdrawal, will continue to be reviewed but the study cannot collect further information, except from public records, such as survival data. Specimens already used cannot be withdrawn.

Participant Name: _____ **Date:**_____

Title of Study: Management of high blood pressure in CKD

Principal Investigator: Diana Jalal, MD **VA Facility:** Iowa City, Iowa

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because, if in our judgment, it would not be safe for you to continue, because your condition has become worse, or because you are or became pregnant.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions about the research study itself, please contact:

Katie Geasland (319) 353-6318 or (319) 356-1616 pager #9971

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd. Iowa City, IA 52242, (319) 335-6564 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we will promptly provide you with that information. Clinically relevant research results can be made available to you after the study is over.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms._____ _____has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. A copy of this signed consent will also be put in my medical record.

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I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ Name	_____ Signature	_____ Date