Home-based conservative care model for advanced kidney disease

NCT06411613

October 24, 2022

Consent and Authorization to participate as a Research Subject in:

Conservative Care for Kidney Disease

SUMMARY OF STUDY: The goal of this study is to learn about different approaches to caring for patients with kidney disease. If you join this study, you will be randomly chosen to be either continue with the kidney care you already receive or join a new home-based kidney care program for 1 year. Every 3 months for 1 year, we will ask you to complete surveys and interviews about your health and care experience. Each study visit takes about 45-75 minutes. We will also ask to observe your medical appointments to understand the care you receive during this year.

We are inviting you to be in a research study. The purpose of this Consent Form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully.

You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear.

Your participation in this study is entirely voluntary. Please take as much time as you need to discuss the study with your doctors, family, and friends. The decision to participate or not is yours. If you choose to participate, you have the right to withdraw from the study at any time.

Principal Investigator: [redacted]

Program Manager: [redacted]

Study Title: Home-based Conservative Care Model for Advanced Kidney Disease

1. Who can I contact with questions while I am in this study?

During business hours (9:00 a.m. – 5:00 p.m.), please call the Program Manager, [redacted], at [redacted]. After business hours (nights and weekends), please call [redacted] and ask the operator to page the on-call nephrologist.

The study researcher(s) listed above must be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research.
- You have any questions regarding your medical care issues specifically related to the study.

You may also contact the Institutional Review Board (IRB) at [redacted] if you:

- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

2. What is the purpose of this research study?

We are inviting you to join this study because you are a patient at VA Puget Sound Health Care System (VA Puget Sound), you have kidney disease, and your VA primary care provider and/or nephrologist (kidney specialist) thought this study would be a good fit for you.

The purpose of this study is to understand the care experiences of patients with kidney disease who are unsure about whether to undergo dialysis or who do not wish to undergo dialysis. We will also seek out feedback from the patients' caregivers and clinicians. The goal of this study is to learn how to better support these patients and the caregivers and clinicians who care for them.

This is a one-year study, which includes five study visits, each taking 45-75 minutes.

We will enroll up to 30 patients to be participants in this research study. If you wish to join, we will ask you to name a caregiver whom you would like to participate in the study with you. The caregiver should be a person who sees you regularly, such as your spouse, adult child, sibling, friend, or paid caregiver. We will ask your caregiver to answer questions about your health and your ability to do activities in daily life. If you do not have a caregiver, you can still participate in the study.

3. What will I be asked to do in this research study?

If you choose to take part in this study, we will randomly assign you to be in one of two groups. *Randomization* means that you will be put into a group by chance, like the flip of a coin. You will have an equal (50/50) chance of being in either group, which are described below:

- **Control Group (usual care)**
  If you are chosen to be in this group, nothing will change about the care you receive at VA Puget Sound as part of this study. You will continue to get primary and nephrology (kidney) care as you normally do from your clinicians.

- **Intervention Group (Kidney Care at Home Program)**
  If you are chosen to be in this group, you will start to receive primary and nephrology care from a special team of VA clinicians who will provide you care in your home.

  This team includes a lead doctor or nurse practitioner, nurse, pharmacist, nutritionist, social worker, psychologist, therapist, and chaplain. A nephrologist also helps this team with treating your kidney disease. The lead doctor or nurse practitioner will visit you at home every 3 months at a minimum and more often as needed. Other members of the team will also visit you at home depending on your needs.

  All the care that you receive from this team will be covered by your VA benefits and will be documented in your medical record.

  If you already have a VA primary care provider or nephrologist, then your primary and nephrology care will transfer to this team.

When you are done with the study, you can choose to continue your primary and nephrology care with this team or return to your prior primary care provider and nephrologist. If you withdraw from the study, your care will be returned to your prior primary care provider and nephrologist.

The following study procedures are for both groups to complete every 3 months during a one-year period:

Surveys

At each study visit, we will also you to complete several surveys. This should take about 15-30 minutes to complete. Completing the surveys is voluntary, and you can skip any question that you do not wish to answer. The surveys will include questions about the following:

- Your background, such as age and race;
- Your care preferences, such as whether you prefer care focused on maximizing longevity or maintaining independence;
- Your symptoms, such as shortness of breath;
- Your ability to function, such as whether you are able to care for yourself and do household chores;
- How satisfied you are with the care you receive for your kidney disease, such as how well your providers explain things and how much time they spend with you;
- The names of VA clinicians whom you view as important in your kidney care and whom you would allow us to interview about their experiences with caring for you; and
- Upcoming medical visits related to your kidney care that you would like a member of our research team to observe.

Interviews

At each study visit, we will also ask you to complete an interview with a member of our research team about your care experiences related to your kidney disease. Each interview will take 45-60 minutes. Completing the interviews is voluntary, and you can skip any question that you do not wish to answer. We will ask questions such as:

- *What works well about the care you receive for your kidney disease?*
- *What weaknesses do you see in the care approach?*

The interviews will be audio-recorded. We will later transcribe the recordings, which will be part of the collected study data. We will not transcribe personal identifiers if any are mentioned during the interviews. We will provide you a paper copy of your transcript to which you can choose to add or revise (but not delete) details.

Observation

We will ask you about any upcoming VA medical visits that are related to your kidney disease and if a member of our research team can observe the care that you receive during these visits for one year. These visits can be face-to-face, over the phone, or via video. These visits can also be from your home or in a VA outpatient or inpatient setting.

Before a visit, the researcher will contact the clinicians to let them know that the visit will be observed. During the visit, the researcher will not speak and will only observe.

You can choose whether you want the researcher to audio-record the visit, take written notes during the visit, or just listen and write notes after the visit is over. Audio-recorded visits will be transcribed without any personal identifiers. You will be given paper copies of the transcript to which you can choose to add or revise (but not delete) any detail. When writing notes, we will not record any personal identifying information. The researcher may ask you clarifying questions after the visit.

Medical record review

We will also ask you if we can review all progress notes entered in your VA medical record during the study to collect information related to your kidney disease (such as lab results, treatments, services that you received, and other medical problems).

4. What are some risks of joining this research study?

The study procedures may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk, even if you have completed the study. If any of the risks included in this Consent Form become significantly updated during this study, we may ask you to sign an updated Consent Form to document that this new information has been explained to you. You will have the right to decide either to continue with the research study or to withdraw.

Below are study-related risks that are known at this time:

Feeling unease: You may feel uncomfortable answering interview or survey questions or being observed during medical visits. We will make these interviews and visits as stress-free as possible. You will be able to take breaks during the interviews and survey questions if you want. You may choose to skip any questions and stop an interview at any time. You can also choose not to be observed.

Loss of confidentiality: All research staff are trained in methods to protect your privacy. Although we will make every effort to keep your information confidential, no system for protecting your information can be completely secure. We encourage you to be as honest and open as you can and to also know that there are limits to protecting privacy.

Audio-recording: Although we have procedures in place to protect your confidentiality, it is possible that your confidentiality could be at risk if someone outside the research team were to hear the recording. We will later transcribe the study recordings, which will be part of the collected study data.

We will not transcribe personal identifiers if any are mentioned during the interview. For details on the steps we will take to protect your confidentiality, please refer to Section 7.

New health care team: If you are chosen at random to be in the Kidney Care at Home Program, you will receive your primary and nephrology care from a care team who is new to you. It can take time to get to know your new care team and for them to get to know you and your health concerns. The lead doctor or nurse practitioner will contact your current primary care provider and nephrologist to learn about your health concerns and to make sure that you are safe to transfer your care to this team. If you withdraw from the study, we will make sure that your care is safely returned to your prior primary care provider and nephrologist.

5. What are some benefits of joining this research study?

If you are chosen at random to the Control Group, there will be no direct benefit to you by being in this study. If you are chosen at random to the Intervention Group, you might find benefit in the care that you receive from the Kidney Care at Home Program's team of clinicians. You might find it convenient to receive care in your own home.

All participants in this study will be making a meaningful contribution by helping researchers have a better understanding of ways to improve care for patients with kidney disease, as well as their caregivers and clinicians.

6. Are there other ways I could receive these benefits?

This study is voluntary and for research purposes only. The alternative to the study is not to take part in it.

7. Who will see my information and where will it be stored?

Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study.

If we learn you intend to harm yourself or others, we must report this information to appropriate authorities.

The access to your records, including your medical records, could be either for study-related purposes or to make sure your study record meets all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

If you are a VA patient, you already have a VA medical record. If you are not a VA patient, we will create a VA medical record for you. The creation of a VA medical record for you for the purposes of this study does not entitle you to any services at the VA beyond those services to which you are otherwise entitled.

We will put information about you from this study into your medical record. All approved users of the national VA medical records system can have access to your medical record. This may include health

insurance companies who are being billed for medical costs. This record will be kept according to the VA records retention policy.

By signing this form, the study team will access your medical records, which includes Protected Health Information (PHI). PHI consists of any health information that is collected about you including your medical history, such as lab (blood test) results, medical diagnoses, radiology reports, and scanned records.

Study Code & Data Storage: If you agree to join the study, we will assign you a study code. Your name, medical record number, or other identifying information will not appear with any study data we collect from you. Only your study code will be used with your study data. A master list that links your name to your study code will be kept in a secure, password-protected computer file that is separate from your study data. Access to this file will be restricted to study staff only.

All your study data will be kept confidential. Data will be kept in offices at VA Puget Sound in locked filing cabinets and on password-protected computers. The investigators, research coordinators, and study team members will be the only staff to have access to confidential records. Any paper study documents we have, receive, or create will be secured in locked file cabinets accessible only to study staff. Any electronic study records will be kept in folders on the secure VA network which has a two-factor authentication to ensure its security and restricted to designated study staff.

If you agree, the interviews and observed medical visits will be recorded using digital recorders. Audio-recordings will be listened to by research staff and then transcribed. The transcribed files will be stored securely with other study data on the secure VA network and locked cabinets. Transcriptions will be labeled with your study code and will not contain your name, social security number, or other identifying information. The audio-recorder will be stored in a locked security bag or cabinet when not in use and accessible only to authorized study staff. All audio-recordings will be kept in their entirety in accordance with VHA policy on quality assurance of records. Requests for amendment to the recordings will be documented in a transcribed version of the recording.

Study Completion: Once this study is completed, we will not use the study code linking you to your data, including any recordings and transcriptions, for any additional research. We will store the code linking you to your data in a secure database or in a locked filing cabinet in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed). We will keep your coded data indefinitely.

In the future, researchers may write about the information collected from this research study. Any future publications or articles will not include any identifying information about you without your approval in writing. Neither you nor your family will gain financially from discoveries made in the future using the information you provide.

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.

8. What are some other things to think about before I decide to join this research study?

The VA requires some Veterans to pay co-payments for medical care and services. You will still have to pay these co-payments as long as they are not related to this research study.

To show our appreciation of your time and willingness to participate in this study, we will provide you a $40 grocery gift card after each study visit for a maximum total of $200 if you complete all study visits.

9. What will happen if I decide I don't want to be in this research study later?

You do not have to take part in this study. If you are in this study, you can withdraw at any time. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits.

If you decide to withdraw from the study, no new information will be collected from you. Information already collected up to that point will continue to be used for the study. The study Principal Investigator has the power to terminate your participation at any time without your consent if they feel the safety of you or a member of the study team may be compromised.

If you miss any of your study appointments (either phone calls or home visits), study staff will make up to five attempts to contact you by phone to reschedule your appointment and/or confirm whether you wish to continue your participation in the study.

10. What will happen if I am hurt in this research study?

If you are injured as a result of participation in a VA-approved research study, the VA will provide you with the necessary medical treatment. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

The VA is obligated to reimburse medical expenses due to your non-compliance with study procedures as described in this Consent Form or otherwise communicated to you by study personnel.

You do not waive any legal rights by signing this Consent Form.

11. Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal laws, state laws, and the federal medical law known as the HIPAA Privacy Rule also protect your privacy. By signing this Consent 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 record such as laboratory tests, medical diagnoses, scanned records, and treatments received.

The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Research team members
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with VA Puget Sound to conduct research)
- Other federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research

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, [redacted] 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 your signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

12. What am I agreeing to by signing this form?

I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts I may encounter in the study, of the possible benefits of the study, and of the other choices of treatment that are available to me.

My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a copy of this Consent Form. I agree to participate in this research study as described in this document.

_____ _____

Subject's Signature Date

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Print Name of Subject