BOSTON MEDICAL CENTER AND THE
BOSTON UNIVERSITY SCHOOLS OF MEDICINE,
PUBLIC HEALTH AND DENTAL MEDICINE

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Nov 12, 2020

RESEARCH CONSENT FORM

Basic Information

TITLE: Improving Medical Decision Making for Older Patients with End Stage Renal Disease

PROTOCOL NO.: H-39981
WIRB® Protocol #20193321

SPONSOR: National Institutes of Health, National Institute on Aging (NIH/NIA)

INVESTIGATOR: Name
Address
City, State Zip Code
Country

STUDY-RELATED PHONE NUMBER(S): Phone Number
Phone Number

Concise Summary

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. Your alternative is not to participate in the research.

How long will I be in this research?

We expect that your taking part in this research will last 12 months.

Why is this research being done?

The purpose of this research is to understand and help older adults with chronic kidney disease make decisions about the care they receive.

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What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include answering a series of survey questions every two months over the course of one year. At your first study visit you will be randomly assigned to one of two groups.

If you are assigned to the intervention group, we will show you two short videos about advance care planning decisions. We will then help you record a short personal video of your own. In this video, you will describe in your own words what you would want for yourself regarding your future. We will then ask you some questions about the experience of making this short personal video. We will audiotape this part of the visit. Afterwards, we will discuss how to get a copy of your personal video for yourself and how you can share it with your family member or caregiver. After this visit, we are going to send this to your nephrologist.

We will call you every 2 months for one year to ask you some questions about your health and ask if you would like to re-record your personal video also known as a "video-declaration". If you would like to re-record your declaration, we will audio-record you over the phone.

If you are assigned to the usual care group, you will not be shown the advance care planning video and you will not be asked to record a personal video about your preferences. You will be asked to complete a survey by phone every two months one year after the first survey is completed.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include being uncomfortable or upset with questions that we may ask. If this happens, you do not have to answer those questions. In addition, you may feel uncomfortable or upset by the video decision aid or the video declaration process, if that happens, you do not have to complete either activity. Another small risk is a loss of confidentiality, that your private health information will be seen by people who would not normally be able to see it.

Will being in this research benefit me?

The most important benefit that you may expect from taking part in this research include helping the investigators learn about the video decision aid and/or the video declaration process. It is not expected that you will personally benefit from this research.

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be

Eneanya ND, *et al. BMJ Open* 2022; 12:e059313. doi: 10.1136/bmjopen-2021-059313

in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are doing the research to help older adults with chronic kidney disease make decisions about the care they receive. If you agree, you will answer a series of survey questions every two months over the course of one year. You will be in the study for up to one year if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are that you might feel uncomfortable with the survey questions or with the information given to you in a decision making video, but if you feel uncomfortable with any part of the study, you can request to skip any question or activity. You will find more information about risks later in this form.

Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. You may want to get another opinion about being in the study. You can do so now or at any time during the study. A doctor who is not part of this study could give you their opinion about being in the study. You do not have to agree to be in this study even though it is offered by your doctor.

Purpose

We are trying to understand what participants with Chronic Kidney Disease think of a video decision aid and video declaration process compared to usual care.

What Will Happen in This Research Study

In order to complete this research, we are doing the same process at several locations. We will be asking adults over the age of 75 who have a diagnosis of chronic kidney disease (CKD) to participate in this randomized controlled trial. If you are eligible and agree to participate, we will ask you a series of questions about your healthcare knowledge and preferences. You will be actively enrolled in the study for one year. From the time you are enrolled until the study is complete, we will periodically review your medical chart and extract information relating to care that you receive.

At your first study visit you will be randomly (like the flip of a coin) assigned to one of two groups.

If you are assigned to the intervention group, we will show you two short videos about advance care planning decisions. We will then help you record a short personal video of your own. In this video, you will describe in your own words what you would want for yourself regarding your future. We will then ask you some questions about the experience of making this short personal video. We will audiotape this part of the visit. Afterwards, we will discuss how to get a copy of your personal video for yourself and how you can share it with your family member or caregiver. After this visit, we are going to send this to your nephrologist. Are there any other providers you would like us to send it to?

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Please note that the personal video you record as part of this study is not legally binding like a formal written advance directive would be. It is merely informational and will not be included in your medical record. The declaration is considered strictly a research activity and it will not guarantee that your medical team will follow your wishes expressed in the declaration. If you want to make sure your wishes are followed it is best to consult with your doctor and your caregiver and family members, and update or put in place a formal written advance directive.

After you are enrolled, we will call you every 2 months for one year to ask you some questions about your health, and ask if you would like to re-record your personal video also known as a "video-declaration". If you would like to re-record your declaration, we will audio-record you over the phone.

If you are assigned to the usual care group, you will not be shown the advance care planning video and you will not be asked to record a personal video about your preferences. You will be asked to complete a survey by phone every two months one year after the first survey is completed.

We are asking a small sample (around 20) of people from this study to be in an additional interview about barriers to care. This interview would last about 30 minutes and take place at your last study visit. The interview would be audiotaped. This interview is voluntary, you can still participate in the study even if you don't do the interview. People who complete the interview will receive an additional $30. Please initial your choice below:

I am interested in being contacted for the extra interview. _____Yes _____No

You will be one of approximately 600 subjects who will be asked to be in the study.

Risks and Discomforts

This study does not have many risks involved. You might feel uncomfortable or upset with questions that we may ask. If this happens, you do not have to answer those questions. In addition, you may feel uncomfortable or upset by the video decision aid or the video declaration process, if that happens, you do not have to complete either activity.

Another small risk is a loss of confidentiality, that your private health information will be seen by people who would not normally be able to see it. The way we will keep your information private is described in the "Confidentiality" section below.

Potential Benefits

You will receive no direct benefit from being in this study. Your being in this study may help the investigators learn about the video decision aid and/or the video declaration process.

It is possible that some of the research conducted using your information eventually will lead to the development of new commercial products. Should this occur, you will not receive any financial compensation generated from such profits.

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Costs
There are no costs to you for being in this research study.

Payment
You will receive $50 for completing the initial visit today. You will also receive $20 for each of the 6 telephone follow-ups that you complete (1 every 2 months for a year). You will receive an additional $30 if you are contacted to complete the extra interview. If you complete all study activities, you will receive $200. All payments will come on a pre-loaded debit card.

Confidentiality
We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

We have three options to share your video declaration with you. (1) We can post the declaration video on a website called Box, which is Boston Medical Center's secure file sharing site. We would then provide you with a web link to view the video online. (2) We can put the video on a password protected flashdrive and mail it to you; (3) We can post your declaration video on a YouTube unlisted video setting and provide the web link to you. An unlisted video can be seen and shared by a web link and is not secure. The unlisted video is not supposed to be available on YouTube's search results or for people who do not have access to the web link. Since we do not control the YouTube website, it's possible that they can change their settings without our knowledge and your video could be viewed by others.

Please note, we cannot guarantee the confidentiality of your information. For example:

a. If you lose the flashdrive it may be recovered and accessible by someone else; or

b. A link to Box or YouTube could be sent to the wrong person;

c. If the video is shared with another person, they may be able to reshare to anyone.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information, such as YouTube.

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We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

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

Use and Sharing of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this research includes:

- Information that is in your hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The reasons that your health information might be used or shared with others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information.

The people and groups that may use or share your health information are:

- Researchers involved in this research study from [Site], and/or other organizations
- Other people within [Site] who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study

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We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.

When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at [Site] at [Contact information].We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes ____No You may contact me again to ask for additional information related to this study

____Yes ____No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you.

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Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions, complaints or concerns at any time, contact [Name] at [Number]. Also call if you need to report an injury while being in this research.

You may also call (800) 562-4789 or email help@wirb.com. You will be talking to someone at the IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, complaints, or problems.

By agreeing to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described

_____ _____
Signature of subject Date

Researcher: _____
Printed name of person conducting consent discussion

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I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date

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****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?

The study doctor and the study staff. [They may also share the research information with [enter SMO company name], an agent for the study doctor. delete if the site does not have an SMO]

Who might get this information?

The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB).

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Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

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Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

Signature of Subject **Date**

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