Consent to Participate in Research

Title of Research Project: Telemedicine facilitated palliative care consultations in rural dialysis patients

Principal Investigator: Katharine Cheung, MD, PhD

Sponsor: National Palliative Care Research Center

Introduction

You are being invited to take part in this research study because you are receiving dialysis. We are looking into the potential benefits of palliative care for patients receiving dialysis. **Palliative care is an extra layer of support for anyone with a serious illness, like kidney disease or kidney failure. Palliative care helps relieve the stress and symptoms of having a serious illness and helps patients and families make decisions about what is most important in their health.**

This study is being conducted by the University of Vermont at the UVM Medical Center. We encourage you to ask questions and take the opportunity to discuss the study with anybody you think can help you make this decision.

Key Information to Help You Decide Whether or Not This Study Is Right for You

We know that getting to other doctor's appointments can be tough when you are on dialysis.
The purpose of this study is to figure out:

- Whether you think it's helpful to have a palliative care consult using telemedicine
- What you think of the quality of telemedicine communication
- To understand if the consult has any impact on your health care choices in the future

What will happen if you participate:

- You will be asked to complete a questionnaire before and after the consult.
- You will have a one-time palliative care consult that will be video-recorded.
- We will follow-up in 6 months by phone and/or review of your medical record, to see if the consult had any impact on your dialysis treatment or health care choices.

The information above is only a summary of the study. If you are interested in learning more, it is important to read the following pages for additional detailed information about the study. If you decide to take part in the research, you will be asked to provide written consent at the end of this document.

What Is Involved in The Study?

- We will contact you to schedule an appointment with the palliative care team via telemedicine. Your palliative care consult can happen *during* dialysis and we will bring an iPad to you during treatment. You will have headphones you can wear. You can also choose to have the palliative care consult *before* or *after* dialysis, or *at home*, *if you have an internet connection*.
- Before and after the consult, you will complete a 5-10- minute questionnaire.

- You will have a palliative care consult, that will be video-recorded to figure out the quality of telemedicine communication. This may last about one hour.
- We will follow-up 6 months after your consult by phone and/or by reviewing your medical record for any hospitalizations, or changes to dialysis treatment.
- Per usual care, the palliative care clinician will summarize the consult and send this to your nephrologist and/or primary care provider.

What Are The Risks and Discomforts Of The Study?
- The main risk of the study is the potential loss of privacy by having the palliative care consult video-recorded or other loss of confidentiality. We will protect your information by keeping it in locked filing cabinets in a locked office suite and under password protected folders for electronic files. There are no known risks of having a palliative care consult.
- It is possible that telemedicine consults may involve risks that are currently unforeseeable.
- If during the study we learn of your intent to harm yourself or others, we will give you information for additional support and Dr. Cheung or the palliative care clinician may be required to report to the appropriate authorities.

What Are The Benefits of Participating In The Study?
- The main benefit to you is in talking with a palliative care clinician.
- We anticipate the main benefits of the study will be to future dialysis patients, once we have learned from this study what works about telemedicine palliative care consults. If we can learn how to best use telemedicine palliative care consults, we will be able to help more dialysis patients get the care they need.

What Other Options Are There?
- You do not have to receive a palliative care consult.

Are There Any Costs?
There are no costs to you.

What Is the Compensation?
After completing the telemedicine consult and questionnaires, you will receive a token of appreciation for your time and participation of $25 in the form of a local grocery store gift card.

Can You Withdraw or Be Withdrawn From This Study?
You may discontinue your participation in this study at any time and the researcher may discontinue your participation in this study if we are unable to find a mutually agreed upon time for the consultation, or if you are unable to communicate.

What About Confidentiality of Your Health Information?

What health information will be used and disclosed for this study?
The health information we plan to collect for this study is listed below.
- Information that identifies you, such as your name, address, age, and sex
- Your health conditions, for example, diabetes
- Responses to health surveys and questionnaires

- Video recordings of the palliative care conversation
- How long you continue dialysis treatments
- If you are admitted to the hospital or hospice in the next 6 months.

Who is disclosing your health information for this research study?
- The University of Vermont Medical Center
- Other doctors' offices and hospitals where you may receive medical care while this study is active.

Who will use your health information in this study?
Our research team will use your health information. We may also share it with those who assist with the conduct of the research or oversight of the activities for this study. The representatives from the institutions, organizations, and agencies are listed below.
- The University of Vermont and its Committees on Human Research
- Officials from agencies and organizations that provide accreditation and oversight of research
- The University of Vermont Medical Center
- Your health insurer, for portions of the research and related care that are considered billable

Your health information is protected by a federal law called the Health Information Portability and Accountability Act (HIPAA). Once your health information is shared outside of the University of Vermont Medical Center, we cannot guarantee that these laws will continue to apply. As a result, your health information could be further disclosed for other purposes. In the absence of a Certificate of Confidentiality, it is also possible for a court or other government official to order the release of study data. The confidentiality of your health information cannot be guaranteed if you agree it may be used in this study.

How long will your health information be used for research?
Your permission to use your health information will not end until the study is completed. During this study, you will not have access to study data. You may ask for your data once study activities are complete. You have a right to receive a copy of the information in your medical record at any time.

What if you decide not to give permission for research use of your health information?
If you decide not to allow the use and disclosure of your health information, you may not take part in this study. Your decision will have no effect on your current or future medical care.

If you choose to stop taking part in this study in the future, you may cancel permission for the use of your health information. You should let the research team know that you are cancelling your permission. A member of the research team will assist you in making your decision effective. The study will continue to use the health information already collected for the study before you cancelled your permission, and you cannot get back information that was already shared with others.

Who can answer your questions about the use and disclosure of your health information?
If you have questions or concerns about the use and disclosure of your health information, you should ask a member of the study team at 802-656-8248 or the Privacy Officer at The University of Vermont Medical Center, Inc, at (802) 847-2667.

Safeguarding Your Health Information
A record of your progress will be kept in a confidential form at the University of Vermont College of Medicine. The security of your record will be maintained by the research team. The results of this study may eventually be published, and information may be exchanged between medical investigators, but patient confidentiality will be maintained.

This project includes digitally video-recording of the palliative care consult over telemedicine. This will be stored electronically securely in a locked research folder. The only persons who have access to the folder are approved research personnel.

Because we provide you with a token of appreciation (gift card), you will be asked to provide your name, social security number, and address. This information will be disclosed one time to either the University of Vermont's Procurement Services Department or UVM Medical Center Accounts Payable Department for purposes of reimbursing you for participation in this study. If you are not a US Citizen or Permanent Resident Alien, you will be required to complete additional paperwork for payment.

Clinical Trials Registration
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.

Contact Information
You may contact Dr. Katharine Cheung the Investigator in charge of this study, at 802-656-8248 for more information about this study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been injured as a result of your participation in this study you should contact the Director of the Research Protections Office at the University of Vermont at 802-656-5040.

Future Research
If you consent, the video recordings will be stored for future research use.

_____ The researchers may use my recording for future research.

_____ The researchers may not use my recording for future research.

Statement of Consent

You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

_____ _____

Signature of Subject Date

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Name of Subject Printed

_____ _____

Signature of Principal Investigator or Designee Date

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Name of Principal Investigator or Designee Printed

Name of Principal Investigator: Dr. Katharine Cheung, Address: 1 South Prospect Street, 2309 UHC Med-Nephrology, Burlington, VT 05401. Telephone Number: 802-656-8248

Committee on Human Research
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