Official Title:	Pilot Randomized Controlled Trial of Integrated Palliative Care With Nephrology Care
NCT Number:	NCT04998110
Study Number:	21-00507
Document Type:	Informed Consent Form
Date of the Document:	• October 3, 2023

Research Subject Informed Consent Form

Title of Study:	Pilot Randomized Controlled Trial of Inegrated Palliative Care in Chronic Kidney Disease S21-00507
Principal Investigator:	Jennifer S. Scherer, MD NYU Langone Health Department of Medicine Bellevue CD Building, 665 347-899-0772 Jennifer.scherer@nyulangone.org
Emergency Contact:	Jennifer Scherer, MD 347-899-0772

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to test the impact of adding a form of care known as palliative, or supportive, care to your usual nephrology care. Palliative care, also known as supportive care, is specialized medical care for patients with serious illness. Adding palliative care to the treatment team of someone facing serious kidney disease has the potential to improve quality of life and to decrease symptoms such as pain, itch, or insomnia, although this has not been formally studied. We are asking you to take part in the study because you have chronic kidney disease.

This research study is randomized study that examines the effect of adding outpatient supportive care visits to your usual nephrology care. A randomized study means that similar to flipping a coin, you will be assigned to one of the study groups and receive either supportive care with your usual nephrology care, or your nephrology care alone. We will be evaluating how adding supportive care to your care impacts the symptoms you have that are associated with your diese, quality of life, and how you plan for your medical care in the future, a process known as advance care planning. Regardless of which group your assigned, your nephrology care will not change and you will be receiving standard of care.

3. How long will I be in the study? How many other people will be in the study?

We anticipate you will be in the study for a time period of six to twelve months. You will have at least three visits with the study team (or phone calls). If you are assigned the supportive care intervention group, you will have an additional six visits every one to two months (+/- 14 days) with the supportive care team. The study itself will be conducted for two years, but your involvement should be for the anticipated six to twelve months.We expect approximately 60 subjects to take part in the study. This study will be an outpatient study with study visits conducted either by telehealth or at Bellevue Hospital.

4. What will I be asked to do in the study?

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study. In this study, you will be asked information about your health, living situation, spiritual beliefs, quality of life, and to complete a certain number of surveys. All subjects will be asked to complete surveys three times: once upon enrollment, once at three months and once at six months to complete the study. We will schedule them at a time the is conveinient for you and these visits can occur in-person or over the phone. If you prefer to not answer any questions in the surveys, you can skip these. If you are assigned to the intervention group, you will be asked to attend visits with the supportive care team at Bellevue Hospital every one to two months (+/- 14 days). These visits can be done in-person or through telehealth.

Below is a list of each study visit that is part of the study. This list includes about how long each visit should take and a list of the research tests and procedures to be done at each visit and/or blood work to be taken. This section will help you understand what is expected of you at each visit.

Visit 1: Your Baseline Visit
This visit takes about 45 to 60 minutes. During this visit, we will ask you about your medical history, your living situation, your education level, your past nephrology care, any previous advance care planning documents and your relationship with a primary care doctor. You will then be asked to complete several surveys.

After this visit, you will be randomized to either the supportive care intervention group or usual care control group.

Group 1: Supportive Care Intervention Group

If you are assigned to this group by chance, you will be asked to do the following:

- **Visits 2-4, 6-8:** You will be scheduled for visitswith the supportive care team every one to two months (+/- 14 days) for six visits. If time and scheduling allows, then you can have your first appointment on the day you consent and fill out the initial surveys. These appointments will be routine supportive care appointments. You will be asked to fill out symptom surveys at these appointments (takes approximately 10 minutes to fill out). If you are unable to make your appointment, you will be contacted by phone and asked to reschedule. We will make every effort to make these visits at a time where you are already at Bellevue or at a time that is convenient for you. Additionally, you can choose to have your visit be a televisit. During this time, you will also receive your usual nephrology care.

- **Visit 5**: After three visits, you will be asked to complete the surveys you completed at baseline. This should take approximately 60 minutes and can be done in person or over the phone.

- **Visit 9**: You will be asked to participate in a final visit. This visit will take approximately 60 minutes. If scheduling allows, it can be done at the same time as your final supportive care appointment, During this visit, you will be asked to fill out the same surveys you took at the initial visit.

- If you are a Bellevue patient, we may collect some health information from your Bellevue medical record.

Group 2: Usual Care Control Group

If you are assigned to this group by chance, you will be asked to do the following:

- **Visit 2**: At three months, you will be asked to complete the surveys you completed at baseline. This should take approximately 60 minutes and can be done in person or over the phone.

- **Visit 3**: You will be asked to participate in a final visit. This visit will take approximately 60 minutes. If scheduling allows, it can be done at the same time as your final supportive care appointment, During this visit, you will be asked to fill out the same surveys you took at the initial visit.

- If you are a Bellevue patient, we may collect some health information from your Bellevue medical record.

DC 05/08/2020

- You will then be offered a supportive care appointment if you wish.

During this time, you will receive care from your nephrologist as usual and at his or her discretion.

OPTIONAL INTERVIEW:

Some of the participants will be offered to participate in an interview with a member of the study staff. The interview will last about 45 minutes and will be audio recorded. The recordings will be labeled only with a code number, which will be kept in the Investigator's files. The tapes will be used to further improve our clinic and research study. During the interview, you will be asked questions about your experience with the research study and kidney palliative care clinic. We will then transcribe the interviews. Only study staff will have accsesss to the interviews. The transcripts will not be shared for publications and presentations. Please mark your choice below:

YES ____ I agree to participate in the interview if I'm selected
No ___ I do not agree to participate in the interview

At any time in the study, you may decide to withdraw from the study. If you withdraw no more information will be collected from you. When you indicate you wish to withdraw the investigator will ask if the information already collected from you can be used.

Any information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

For both study groups, there is a risk of emotional distress and psychological discomfort from discussing difficult topics such as advance care planning or prognosis. The researchers involved in the study are experts in handling this and will provide expert management and support to minimize this risk. Additional risks include loss of time to participate in the study. Finally, there is a potential risk for loss of confidentiality. The study team will keep all records on a password protected software that only the team has access to. All data will be identified by a unique number and will not be linked to any of your personal information. This research may involve risks that are currently unforeseeable as well.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you.

This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

For the **Supportive Care Intervention Group**, we anticipate that you will benefit from the study by having added support to help you and your family cope with your kidney disease. We believe you may also have decreased symptoms, meaning possibly less pain or anxiety if you are currently experiencing this. We also anticipate that you may feel more informed about some of your treatment choices and your future medical care.

For the **Usual Care Control Group**, we anticipate you will benefit from the study by having access to supportive care at the end of your participation to assist with symptom control, to obtain emotional support and to have assistance with advance care planning for your future.

8. What other choices do I have if I do not participate?

Your current care will remain unchanged if you choose not to participate. You do not need to participate to receive appropriate standard of care for your condition. This study does not alter standard of care.

9. Will I be paid for being in this study?

You will be paid for being in this study and you will receive payment in ClinCard. If you choose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for each completed visit.

For the *Supportive Care Intervention Group*, you will receive:

- $25 for each of the study visits (baseline, 8th visit, and final)
- $10 for each of the six supportive care visits to help cover travel costs

For the *Usual Care Control Group*, you will receive:

- $25 for each of the study visits (baseline, 2nd visit, and final)

If you are randomly selected to complete the optional Qualitative Interview, you will receive:

- $25 for the qualitative interview

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (i.e. check, Clincard or bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research

payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise Dr. Jennifer Scherer at Jennifer.Scherer@nyulangone.org.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

10. Will I have to pay for anything?

You will not have to pay out of pocket for any procedures that occur as part of this study. You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. We anticipate you will be involved with the study for 6-12 months. This study may also be stopped or your participation ended at any time by your physician, the or study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health and/or Bellevue Hospital. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research

information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: NIDDK (NIH)
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- H+H personnel responsible for the support or oversight of the study at Bellevue Hospital
- GreenPhire - company that processes ClinCards

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?

Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

If you have never been a patient at NYU Langone Health, you may not have an EMR at NYU Langone Health. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at NYU Langone Health will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, research-related notes, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by NYU Langone Health.

This information will be accessible to other members of the NYU Langone workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record?

The 21st Century Cures Act allows patients increased access to their EMR. If you agree to participate in this study, this means that any research-related information placed in your EMR will be available to you immediately.

As a research participant, this means that you have immediate access to any research-related information that is placed in your EMR before the researchers have had an opportunity to review the information.

The research-related information that will be available to you immediately are as follows:

- ***Results that may be placed in the medical record:*** *Informaton and results from supportive care intervention*

Access to research-related information within your EMR can be found through NYU Langone Health's patient portal, MyChart.

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

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.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

DC 05/08/2020

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

DC 05/08/2020

Witness to Consent Process for Non-English Speaking Subjects (using a translated consent form OR "Short Form" in Subject's Spoken Language)

Statement of Witness
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness
I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date

DC 05/08/2020