Pilot Testing of a Communication Intervention to Promote Shared Dialysis Decision-Making in Older Patients with Chronic Kidney Disease (DIAL-SDM Trial)

Informed Consent Form

NCT04392440

Date: 11/09/2023

CONSENT FORM (PATIENTS)

Pilot Testing of a Communication Intervention to Promote Shared Dialysis Decision Making in Older Patients with Chronic Kidney Disease (DIAL-SDM Trial)

Principal Investigator (**PI):** Fahad Saeed, MD
Research Coordinator: Brooke Daigneault

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- Your participation in the study could last up to approximately 12 months.
- If you choose not to take part, your routine medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you have chronic kidney disease and will need to make future medical decisions including dialysis. Your kidney doctor is also participating in this study. Making decisions about dialysis can be difficult at times.

Purpose of Study

The purpose of this study is to improve communication and decision-making between patients and nephrologists through the feasibility, acceptability, and fidelity outcomes of an intervention called DIAL-SDM. DIAL-SDM is an enhanced dialysis decision-making intervention aimed to teach doctors how to communicate better and engage patients in decision-making. Half of the enrolled

RSRB Approval Date: 11/9/2023
Expiration Date: 11/8/2024

patients will receive DIAL-SDM intervention and the other half will receive Usual Care.

Description of Study Procedures

We would like to inform you that this is a randomized study, and your own study assignment will depend on which assignment your nephrologist has received. The manner of assignment to DIAL-SDM intervention or Usual Care is random, like the flip of a coin. Your chance of being assigned to DIAL-SDM intervention instead of Usual Care is 50/50.

There are multiple phases of this study and your total involvement will include coaching sessions, survey sets, phone calls from a coach, and an interview about the feasibility/acceptability of the study.

All interviews and meetings with research team members will be conducted in a private area based on your comfort and preference (e.g. meeting room, office, your home, by phone or via Zoom).

If you decide to take part, you will be asked to:

- Provide the name of a partner, friend, relative or caregiver who you rely on for help and/or support. This could be a family member, friend or someone else. We will ask you to provide three people in the order of preference.

- Participate in a baseline survey and allow collection of demographic data.

- If in the intervention group:

    - Read an educational booklet about renal replacement therapy options and conservative management and also read another booklet containing a list of most commonly asked questions. The educational booklet will also be sent in a video format that you will be asked to view.

    - Meet with a coach for approximately 60-90 minutes where you will identify goals/preferences of kidney disease treatment two to four

weeks prior to your next visit with your nephrologist. The coach will not answer any questions regarding renal replacement therapy options but will rather help you formulate questions about different therapy options including conservative management. Subsequently, the coach will give you (and caregiver) a list of commonly asked questions ("question prompt list" or QPL), and use brief role-plays to identify and help prepare you to ask personally relevant questions during your upcoming nephrologist visit. This will be so you can participate more actively and assertively in discussions with your nephrologist.

- Review your list of questions and visit checklist with the nephrologist at the time of your visit and then speak to the coach during a follow-up telephone call (after the nephrology office visit) to address any concerns.

- Optionally attend additional coaching session if unable to make a decision about dialysis with your nephrologist in one session. You will be able to participate in these sessions via zoom or in-person.

- Give us permission to audio-record 1-2 visits with your nephrologist. The audio-recording will help us improve our intervention for future research. Anyone else in the room (friends, family members, etc.) will also be asked to provide verbal consent before the audio-recording begins.

- If in the control group:

  - Meet with the dialysis educator and your nephrologist, as per the standard clinic protocol.

- Allow us to look at your medical record to review the kind of care you are receiving, such as emergency room visits, intensive care and medical procedures, patient mortality, place of death, receipt of hospice services, receipt of aggressive procedures such as CPR, dialysis etc. and long-term healthcare utilization for both the control and intervention groups within 3 years of your study completion date.

- Complete an additional survey (that will mirror most of the baseline assessments) within 1 month of seeing your nephrologist.

- Participate in and end of study survey and one brief (15- 20 minutes - either in-person or via Zoom) interview about your overall experience with the DIAL-SDM study. This will occur within 4 months of your visit(s) with your nephrologist.

Information about your study participation and study results such as discussions that identify your goals and preferences of kidney disease treatment and choices made regarding renal replacement therapies may be included by the study coach and your nephrologist within your electronic health record in order to promote effective communication between you and your nephrologist. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

Number of Subjects: Patients from the nephrology group at Strong Memorial, Highland, FF Thompson and Rochester General Hospital are eligible to participate. Approximately 16 Nephrologists and 60 patients in Rochester and surrounding areas will take part in this study. Each patient can invite one (1) partner/friend/relative/caregiver to participate. Those without a caregiver will still be eligible to participate in the study.

Risks of Participation: You may experience some emotional discomfort while discussing your medical decisions, quality of life, and end-of life care. Some of the survey questions may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or to leave the study at any time.

There is a very small chance that your identity will be found out during the audio-recordings of your visit with your nephrologist. However, this risk is low. Only a case number will identify your individual research material.

If you consent to Email and/or text communications, these may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team.

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 website at any time.

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Benefits of Participation: You may not benefit from participating in this study but the potential benefit to you from being in this study might be a better understanding of your illness improved quality of life and dialysis-related decisions. Some patients benefit from knowing that their participation in studies like this can help other patients and families in the future.

Sponsor Support: The University of Rochester is receiving payment from the National Institutes of Health and the American Society of Nephrology for conducting this research study.

Costs: There will be no cost to you to participate in this study. There will be no co-pay for enhanced dialysis education visits for patients assigned to that arm.

Payments: You will be paid a total of $100 for taking part in the study. The payment process includes $50 for completion of first set of data collection and

$50 for completing the last set. If you decide to withdraw early from the study, you will receive $10 for completion of an exit interview.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will keep all data collected in password protected electronic records or locked in a locked cabinet in the Research Coordinator's office. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.
If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

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

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- American Society of Nephrology
- National Institutes of Health (NIH)
- University of Illinois Urbana-Champagne
- Mount St Joseph University

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

- To do the research
- To study the results
- To see if the research was done correctly

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 participate this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, 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?
No. There is a risk that your information will be given to others without your permission.

Return of Research Results

In general, we will not give you any individual results from your participation in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Some things you should know about results:

- Sometimes the meaning of the results will be uncertain. It is important to know that our understanding of health is changing quickly, and in many cases, we may not know for sure what the results mean for your future health.
- Sometimes, even if you learn of a clear diagnosis, there will be no clear treatment.

Certificate of Confidentiality

To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Contact Persons

For more information about this research, or if you feel that your participation has resulted in any emotional or physical discomfort, please contact: Brooke Daigneault or Dr. Fahad Saeed at 585-275-7033.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. If you decide to withdrawal from the study, you will be asked to voluntarily participate in an exit interview regarding your overall experience with the DIAL-SDM study. This interview will occur at the confirmation of withdrawal.

No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

Signature/Dates

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;

- How your personal information will be protected;
- What to do if you have problems or questions about this study.

In order to assess your understanding, please answer the following questions by circling the best choice for each question.

1. Why is this study taking place?
   a. To improve communication and shared decision making between patients and physicians to help lower decisional conflict regarding renal therapy
   b. To study a new drug
   c. To monitor how exercise affects kidney disease

2. What will happen during this study?
   a. Multiple blood draws
   b. Participation in multiple phases including coaching sessions, survey sets, phone calls from a coach, and an interview about the feasibility/acceptability of the study
   c. Experimentation with a new drug

3. What are possible risks from participating in this study?
   a. You may have an allergic reaction
   b. You could fall and become injured
   c. You may experience some emotional discomfort while discussing your medical decisions, quality of life, end-of life care and a very small chance that your identity will be found out during the audio-recordings.

4. What are the possible benefits from participating in this study?
   a. You will become famous after the study is published
   b. You may gain a better understanding of your illness, dialysis-related decisions and improve quality of life as well as help other patients and families in the future.
   c. You will make extra money by participating in this study

5. Is this study voluntary and can you withdrawal at any time?
   a. Yes

b. No

6. How will your personal information will be protected?
   a. All data collected is kept in password protected electronic records or locked in a locked cabinet in the Research Coordinator's office
   b. All data is burned after collected
   c. All data is sent to your primary physician's office for safe keeping

7. What do you do if you have problems or questions about this study?
   a. Contact your Nephrologist
   b. Call 911
   c. Contact the study's principle investigator, Dr. Fahad Saeed or the University of Rochester Research Subjects Review Board

If you prefer to receive a copy of your signed consent via email (only if signing a hard copy of this consent in person), please enter your email address below:

_____

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Subject Consent

Subjects that are able to provide consent must sign on the subject line below. Alternatively, for adult subjects unable to consent, the Legally Authorized Representative (LAR) must provide permissionand the subject shall provide assent.

I have read (or have had read to me) the content of this consent form and have been encouraged to ask questions. I have received answers to my questions. I voluntarily agree to participate in this study. 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. I have received (or will receive) a **signed** copy of this form for my records and future reference.

If not signing in the presence of the study's research coordinator, please call Brooke Daigneault at 585-275-5033 to review any questions regarding the study before signing. After the consent is received by the research coordinator and any questions you may have are discussed, you will be able to receive a printout of the paper copy, download a pdf, and/or receive an email with a PDF attachment of the consent form signed by both you and the research coordinator for your records. (Note: for mailed consents, the date of your signature and the researcher's may be different).

A confirmation email will be sent to all respondents that have completed the survey on-line, but because your email address is not on file, the confirmation email cannot be sent automatically.

You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. Email communications between you and the study team may be filed in your research record.

Messages will be limited to appointment reminders and consent confirmation.
Email and/or text communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this risk.

The University of Rochester is not responsible for any interception of messages sent through email/text.

For text messages:
You are responsible for any fees charged by your carrier's service plan for text messaging.
You may decide not to receive or send text messages with research study staff at any time, in person or by sending the research number a text message that says "Stop Research Text". Your consent, and any request to stop email or text messaging, applies to this research study only.

Mailing address to send signed consent is:

Nephrology Research Department
601 Elmwood Ave.
Rochester, NY 14642
Box 675
ATTN: Brooke Daigneault

_____
Subject's Name (print name)

_____
Subject's signature Date

Authorized Representative (if subject is unable to give consent)

I have read (or have had read to me) the content of this consent form and have been encouraged to ask questions. I have received answers to my questions. I authorize participation for _____ in this study. I have received (or will receive) a **signed** copy of this form for my records and future reference.

If not signing in the presence of the study's research coordinator, please call Brooke Daigneault at 585-275-5033 to review any questions regarding the study for before signing. After the consent is received by the research coordinator and any question you may have are discussed, you will be able to receive a print out of the paper copy, download a pdf, and/or receive an email with a PDF attachment of the consent form signed by both you and the research coordinator for your records. (Note: for mailed consents, the date of your signature and the researcher's may be different)

Mailing address to send signed consent is:

Nephrology Research Department
601 Elmwood Ave.
Rochester, NY 14642
Box 675
ATTN: Brooke Daigneault

_____
Authorized Representative's Name (print name)

_____
Authorized Representative's Signature Date

_____
Authority of Subject's Legally Authorized Representative or Relationship to Subject

Subject Assent

Assent is required for subjects able to provide assent who are unable to provide consent. If assent is required, the LAR must provide consent above.

The research study has been explained to me and I agree to be in this study.

_____
Subject's Name (print name)

_____
Subject's signature Date

For Study Communication Purposes:

___ I consent to the use of email in this study.

_____
Email Address

___ I consent to the use of text messaging in this study.

_____
Phone Number

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Person Obtaining Assent/Consent or Permission

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a **signed** copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject (or Legally Authorized Representative, if applicable) has demonstrated comprehension of the information.

- □ Subject demonstrated capacity to provide consent, and provided consent to participate.
- □ Subject lacked capacity to provide consent but did assent to participate.
- □ Subject was unable to assent to participate.
  Reason for inability to provide assent:
  _____

_____ _____
Print Name of Person Obtaining Assent/Consent Title

_____
Signature of Person Obtaining Consent Date