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

Study Protocol and Statistical Analysis

NCT04392440

Date: 8/28/2025

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
Co-investigators: Ronald Epstein, MD
Kevin Fiscella, MD
RGH Site PI: Pulkit Gandhi, MD
Research Coordinator: Brooke Daigneault

1. PURPOSE OF THE STUDY AND BACKGROUND

1.1. Objective:

The objectives of this study proposal are:

Aim 1 (primary): Assess the feasibility, acceptability, and fidelity of the DIAL-SDM intervention, as measured in both nephrologist and patient coaching sessions by the Feasibility of the Intervention Measure,[1] Acceptability of the Intervention Measures,[1] and fidelity checklists for both nephrologist and patients' coaching sessions. We will also gather qualitative data from nephrologists, patient coaches, research coordinators, patients, and caregivers to guide the modification of the study protocol.

Aim 2: Generate preliminary effect sizes and examine the effect of the intervention on the following patient outcomes:

(a) **Active patient participation in dialysis decision-making**, as measured by the Active Patient Participation Coding (APPC) scores from audio recordings of office visits.[2,3]

(b) **Shared dialysis decision-making**, as measured by the modified OPTION scale scores,[4] from audio recordings of office visits, and the patient-reported Shared Decision-Making Questionnaire and the Decisional Engagement Scale.[5]

(c) **Patients' initial choice of ESRD treatment options** (home vs. in-center dialysis vs. CM) at study entry and completion.

(d) Patient report of **prognostic discussions**, as measured by the prognosis questionnaire.[6]

(e) **Decisional conflict**, as measured by the decisional conflict scale.[7]

(f) **Patient report of goal concordant care**, as measured by the goal concordant questionnaire.[8]

Aim 3: Aim 2: Generate preliminary effect sizes and examine the effect of the intervention on the following caregiver outcomes:

(a) **Decisional conflict**, as measured by the decisional conflict scale. [6]

(b) **Shared dialysis decision-making** as measured by the Shared Decision-Making Questionnaire and the Decisional Engagement Scale.[4,5]

1.2. Background:

National guidelines recommend that nephrologists engage patients with chronic kidney disease (CKD) in shared decision-making (SDM) before initiating dialysis.[9,10] More than 200,000 older adults receive dialysis for end-stage renal disease (ESRD),[3] despite the high burden of treatment,[11-14] and guidelines encourage physicians to consider conservative management (CM), rather than dialysis, for older patients with poor prognosis.[9] In older adults with multiple co-morbidities, dialysis may have minimal impact on survival but worsens quality of life (QoL) and entails frequent hospitalizations.[17,18] They often prefer maintaining QoL over prolonging life.[17,18] They wish to know prognostic information but nephrologists infrequently engage these patients in meaningful discussions about their preferences and prognosis, including CM. [17,18] As a result, patients often overestimate prognosis and have unrealistic expectations for a cure.[18-23] Honest yet sensitive discussions about prognosis and treatment choices are associated with more realistic prognostic estimates and decisions better aligned with patients' preferences.[24,25] However, changing decision-making conversations is not straightforward.[26,27] There are currently no scientifically proven interventions to improve communication between nephrologists and older patients with CKD around shared decision-making (SDM) for dialysis initiation. Prior interventions with limited effectiveness that studied non-CKD patients generally addressed either clinicians' or patients' communication behaviors[28-33]or used a third party to facilitate communication.[34,35] Yet the **ecological framework** and prior studies of SDM suggest that attention to both clinician and patient communication behaviors is essential to facilitate difficult conversations in the emotionally-sensitive, value-driven, and highly personal context of serious illness such as CKD.[36-42] Therefore**, we need to improve the process of decision-making about the initiation of dialysis, enhancing patient-physician communications so that they can meaningfully share treatment decisions.** Patients' voices need to be heard when they are facing difficult choices that will determine the course and quality of their lives.

2. STUDY DESIGN

2.1. Overview

We propose a prospective, cluster-randomized clinical trial of **DIAL-SDM** vs Usual Care (UC) with nephrologists from the renal group at Strong Memorial Hospital, Highland Hospital, FF Thompson, and Rochester General Hospital as the unit of randomization and patients as the unit of analyses. Routine nephrology follow-up of patients in both arms will be at the discretion of nephrologists.

2.2. Rationale for Study Design

To examine the outcomes of the DIAL-SDM intervention for CKD patients ≥ 65 years (and their caregivers), a prospective, cluster-randomized design is preferred over a nonrandomized prospective design or retrospective design. If the results of this pilot study show feasibility and acceptability of the **DIAL-SDM** intervention (as hypothesized), we plan to design a larger-scale cluster randomized control trial.

3. CHARACTERISTICS OF THE RESEARCH POPULATION

3.1. Subject Characteristics

(a) **Number of Subjects:** The study subjects include nephrologists, research coordinators, patient coaches, patients, and caregivers from Strong, Highland, FF Thompson, and Rochester General Hospital. The study will be performed between August 2021 and September 2025. Nephrologists (n= up to 16), in the Strong, Highland, FF Thompson, and Rochester General Renal Group will be eligible to participate and will provide informed consent. For physicians who withdraw from the study prior to the enrollment of their own participating patients, they will be replaced with additional physicians, therefore keeping the number of participating physicians up to 16. Research Coordinators (n=up to 3) who have assisted in the study will be eligible to participate in a qualitative interview and will provide informed consent. Patient Coaches (n=up to 3) who have assisted in the study will be eligible to participate in a qualitative interview and will provide informed consent. With a total sample size of 60 patients (approximately 5 patients per nephrologist depending on the total number of enrolled nephrologists), we would have 80% power at an alpha of 0.05, assuming a coefficient of variation of cluster sizes as high as 0.5 and an intracluster correlation coefficient of 0.1 to detect mean differences of at least 15 points (standard deviation 11) on the OPTION scale scores reflecting shared decision making between two groups. The data generated in this pilot study will be useful to generate effect size estimates for a future trial. We expect to enroll 36 caregivers assuming a 60% participation rate of caregivers. The proposed recruitment plan aligns with the goals of the K-23 which is a small pilot.

(b) **Gender and Age of Subjects:** For patients, we will include men and women who are ≥65 years old. We expect the same distribution of men (48%) and women (52%) as of the general population. All adult caregivers (21-years or older) will be eligible to participate in the study. Based on prior research, we expect the following age distribution for caregivers: age 21-44 yrs. = 15%; 45-54 yrs. = 25%; age 55-64 yrs. = 30%; 65-74 yrs. = 20%; age 75 yrs. or older = 10%. For caregivers, we expect that we'll enroll 38% male caregivers and 62% female caregivers. [41] In the Strong, Highland, FF Thompson, and Rochester General Hospital Renal Group, we have 9 female nephrologists, 19 male nephrologists, and 1-3 fellows/yr. Faculty age ranges from 34-65 plus.

(c) **Racial and Ethnic Origin:** We do not restrict enrollment based on race or ethnic origin. The demographics of the population in the Greater Rochester area in 2010 was 77% White, 16.2% Black or African American, 8.5% Hispanic or Latino (either Black or White). We expect the racial and ethnic distribution of the enrolled subjects to be the following (Tables 1, 2 & 3): However, to encourage recruitment of minority participants, we will seek input on the study protocol from minority patients. Additionally, a coach will have the option to do home visits in order to prevent financial burden on the participants.

Table 1. Racial and Ethnic Category of Physicians
(Expected number of participants = 10)

Racial/Ethnic Category	
White (including Latinos or Hispanics)	8 (80%)
Asians	2 (20%)

Table 2. Racial and Ethnic Category of Patients
(Total participants = 60)

Racial/Ethnic Category	
White (including Latinos or Hispanics)	46 (77%)
Black or African American (including Latinos or Hispanics) 16%)	10 (16%)
Other	4 (7%)

Table 3. Racial and Ethnic Category of Caregivers
(Expected number of participants = 36)

Racial/Ethnic Category	
White (including Latinos or Hispanics)	27 (77%)
Black or African American (including Latinos or Hispanics) 16%)	7 (16%)
Other	2 (7%)

(d) Vulnerable Subjects: We do not plan to include vulnerable subjects such as children, pregnant women, fetuses, or prisoners. Employees (physicians/fellows) will be assured that taking part in research is not a part of their duties, and refusing to participate in the study will not affect their job. To ensure their autonomy, the research coordinator (rather than the PI) will consent them. We realize that some patients in the study may have a cognitive or decisional impairment. To protect the rights of these patients, we have specified all the details in section 4.2 (Process of Consent). Caregivers lacking capacity will be excluded from the study.

3.2. Inclusion and Exclusion Criteria

Participant inclusion and exclusion criteria are listed in Table 4.

Table 4. Inclusion and Exclusion Criteria

	Physicians	Patients	Caregivers	Research Coordinator	Patient Coach	Physician Coach
Inclusion Criteria	**1.** Member of Strong nephrology group working at Strong Memorial Hospital, Highland Hospital, FF Thompson or Rochester General Hospital **2.** Treat patients with CKD	**1.** Age ≥65 years old **2.** Presence of advanced CKD stage 4 or 5 (i.e. GFR, eGFR, or GFR by Cystatin ≤ 25 ml/min) **3.** Patient's nephrologist is enrolled in the study and has seen that nephrologist at least once **4.** Speaks English **5.** Have not attended a dialysis education class or met with the dialysis education coordinator within 2 years prior to the study start date. **6.** Have not made a dialysis decision	Consenting patients will be asked for permission to contact up to three caregivers, defined as a "family member, partner, friend or someone else who is involved with their health care issues, for example, someone whom they talk to about personal issues including medical decisions or who comes to doctor appointments with them. This person may also help with routine day-to-day activities, like transportation or paperwork." The term "caregiver" is used here for scientific purposes only; it is not essential that this individual self-identify as a caregiver. **1.** Self-identified caregiver (per the definition above) **2.** 21 years of age or older.	**1.** Assisted in the study by recruiting, consenting, and interviewing at least one subject.	**1.** Assisted in the study by completing at least one coaching session with a subject.	1. Assisted in the study by completing at least one coaching session with a nephrologist

Exclusion Criteria	**1.** Expecting to leave in six months.	**1.** Patient has already been seen by a palliative care clinician or is enrolled in hospice **2.** Is already on dialysis **3.** Hospitalized at the time of recruitment **4.** Cognitive impairment and no legally authorized representative is available	**4.** Support is offered primarily in a professional role (e.g., clergy). **5.** Cognitive impairment	**6.** Did not recruit, consent, or interview any patients.	**7.** Did not complete any coaching sessions with patients.	**8.** Did not complete any coaching sessions with nephrologists.

		5. Anyone needing a language interpreter (including sign language)	

4. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT

4.1. Method of Subject Identification and Recruitment

A Study personnel (PI or the RA) will provide an overview of the study to the nephrologists as a group, or meet with nephrologists in person or via Zoom to brief them on study procedures including physician measures (Table 5).

The PI will provide an overview of the study to the Research Coordinators as a group, or individually via Zoom or in person.

A study personnel (PI or the RA) will provide an overview of the study to the patient coaches and physician coaches as a group, or individually via Zoom or in person.

Based on the inclusion and exclusion criteria, the PI or RA will screen nephrology clinic patients at Strong, Highland, and FF Thompson for study eligibility using e-record and at Rochester General Hospital through RGH's PI screening. The study team will communicate with the participating nephrologist's in-person, via telephone, or by email if they have questions about the eligibility of a patient or need more information. This process is implemented to eliminate patients with favorable renal prognosis who are less likely to need dialysis in the future. The assumption is that participating nephrologists will permit all their patients to be approached, and this will be stated in the nephrologist consent form. However, nephrologists' can decline patient participation in the study if a patient is unlikely to progress to needing dialysis. Data on nephrologists' reasons for refusal and referral will be captured on a separate sheet.

After acquiring consent from the nephrologists, The RA will approach eligible patients (and caregivers, if present) either in person in the clinic, by calling them on the phone, emailing them, or sending them a message via MyChart. If through MyChart, eligible subjects will receive an email or text notifying them that they have a new research opportunity available in MyChart. It can only be viewed after they log in to MyChart and visit the Research Studies page. Subjects will see a description of the study, which is included on the attached MyChart for Recruitment Request form (uploaded as part of recruitment materials). Underneath the study description on the Research Studies page, subjects will indicate whether or not they are interested in participating by clicking on the corresponding button. This will trigger a notification that is sent to the study coordinator's Inbasket in eRecord.

Interested subjects will then be contacted for screening as described in this protocol. Subjects who are not interested will not be contacted and will be removed from the pool of eligible subjects. If subjects do not indicate whether or not they are interested in participating, they may be re-sent the email notification one additional time, no sooner than one week after the first email was sent. When study accrual has been completed, outstanding research opportunities in MyChart will be rescinded.

Also, patients from Rochester General will only be approached if their participating nephrologist has discussed the study with them first, they are aware of what the study is about and they are agreeable to speaking with the RA. This will be done either in person or by telephone depending on the patient's preference.

4.2. Process of Consent

Nephrologists from Strong, Highland, FF Thompson, and Rochester General Hospital will provide written informed consent, after receiving details of the study. They should be able to understand the study objectives, procedures, risks, and potential benefits. For mailed consents, the date of the physician's signature and the date of the research coordinator's signature may be different.

Informed consent will be obtained using the IRB-approved information sheet for Research Coordinators and Patient Coaches. This process will be completed by a member of the study team for patient coaches. For research coordinators this process will be completed by the principal investigator.

Similarly, study **patients** from all sites will provide informed consent after receiving a detailed description of the study's aims, procedures, and the risks and benefits of participation. Initial discussion for patients at RGH will take place with the patient's nephrologist or the RGH study-appointed PI. The scope of work conducted by the RGH study PI will consist of an initial discussion of the study with RGH nephrologists and RGH patients for recruitment and study participation purposes only. After initial discussion of the study with a member of the study team, either by telephone in person, or via Zoom, if the patient has expressed interest in participating, the consent form will either be handed to patients in person at either location and reviewed orally or mailed/emailed to the patient for review prior to the consent process. Patients will sign the consent document and enrolled into the study only if they have demonstrated an understanding of the study's aims, procedures and risks/benefits. This understanding will be determined by their answers to questions that were designed to assess the patient's understanding of the study. These questions can be found in their consent form. During and after the COVID-19 pandemic, patients will be consented in-person or via eConsent.

The consent document will be created using a REDCap-based electronic consent form. The IRB-approved consent form will be developed in REDCap, a secure, web-based, HIPAAcompliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g. read-only, de-identified-only data views) for other users. Potential subjects will participate in the consent process by:

eConsent Obtained in Person or Remotely with Required Remote Consent Process - Subject/Subject's legally authorized representative is approached in person at the study site, either Strong, Highland or Rochester General Hospital, when both the research coordinator and subject are at the same location, or it may take place remotely (e.g. at the subject's home or another convenient venue) and accesses the REDCap eConsent via a portable electronic device such as iPad, etc. If consent is being obtained at the subject's home, a room that ensures privacy and confidentiality will be requested for the process. All subjects will have the option to use paper-based or electronic informed consent methods completely or partially throughout the informed consent process and will be consented remotely or in-person following institutional safety protocols. When consent is being obtained remotely, not in person, the study team will request verbal permission to send the eConsent via email or text. The request will state:

"Because URMC can't control the security of email or text messages once we send them, we need your permission to text or email you. Do you want to receive the link to the eConsent via text or email?"

This permission will be documented and the email/text will not include PHI. Subject will be identified by the use of the "Survey Login" feature, the subject will be prompted to reply with the appropriate answers to two pre-designed questions. Correct responses to questions will

grant entry and non-matching responses will block the individual based on specified settings. This verification, known as the Passcode Based on Known Information is a method where the research coordinator will simply inform the subject/subject's legally authorized representative

that a combination of their demographic data will be used as their passcode. The study coordinator will use the combination of the subject's date of birth, and street name as variables to represent the verification passcode which the subject/subject's legally authorized representative will be prompted to answer when accessing the eConsent link. Subjects will have the capability to sign electronically with a stylus, mouse or finger. Once the consent form is signed and submitted, subjects 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 signed consent form. If a signed copy of the consent will be emailed to the subject using REDCap, the subjects will provide their email address on the completion page, the following statement will be included in the field where the email address will be provided:

Enter your email to receive confirmation message? A confirmation email will be sent to all respondents that have completed the survey, but because your email address is not on file, the confirmation email cannot be sent automatically. If you wish to receive it, please enter your email address below.

Documentation of how consent was obtained will be kept in the subject files to ensure an accurate representation of the consent process used to obtain consent with each subject. Patients in both Intervention and Usual Care arm will receive nephrology visit documentation as per clinical standards. Visits with coach will not be documented in the patient's electronic medical record but on separate forms. Also, dialysis education for Usual Care arm is routinely not documented in patient's electronic medical record.

Once a **caregiver** is identified, a member of the study team will independently approach the caregiver in person at the study site location or by telephone and ask if they would be willing to participate and provide written or eConsent. A caregiver can be consented right after a patient has consented to participate in the study if both are present together in the room. If the caregiver has expressed interest in participating the consent form will either be handed to them in person (or via Zoom) and reviewed orally or mailed/emailed to the caregiver for review prior to the consent process. Caregivers will sign the consent document and enrolled into the study only if the agree to participate in the study and they have demonstrated an understanding of the study's aims, procedures and risks/benefits. The eConsent process for caregivers will be the same as the process as stated above for patients. During the COVID-19 pandemic, caregivers will be consented in-person following institutional safety protocols or via eConsent. Patients are eligible to participate in the study with or without a caregiver, but a caregiver will not be eligible to participate in the study without a patient. All participants should understand why this research is being done, what will happen during the study as well as possible risks and benefits. All consent documents will be stored in a locked drawer of the locked research coordinator's office located at Strong Memorial Hospital.

We will screen patients for cognitive impairment from their medical records. When obtaining informed consent for those with suspected cognitive impairment, we will formally assess capacity to consent using the University of California Brief Assessment of Capacity to Consent (UBACC) modified for our specific study design where needed. (Jeste DV, Palmer BW, Appelbaum PS, Golshan S, Glorioso D, Dunn LB, Kim K, Meeks T, Kraemer HC. A new brief instrument for assessing decisional capacity for clinical research. Arch Gen Psychiatry. 2007 Aug; 64(8):966-74 doi: 10.1001/archpsyc.64.8.966. PMID: 17679641.)

For patients who fail this screen or if the RA has additional concerns, we will require that their guardian participate in the consenting process and sign an informed consent. We will also require that patients still give consent, or at minimum assent if fully informed consent is not possible. For such patients, a legally authorized representative (LAR) will fill out the assessments and participate in coaching sessions, if assigned to the intervention group. In this study, the LAR will typically be, in order of priority: someone who is a healthcare agent by advance directive, or a healthcare surrogate decision maker by local law such as a spouse, adult child, or sibling. We are choosing to keep patients with limited capacity in our pilot as these patients may still be able to provide appropriate responses about their wishes etc. We will exclude the caregivers lacking capacity to consent for the study.

We will keep a record of the number of eligible physicians, patients and caregivers approached for potential enrollment as well as the number enrolled and declined. Reasons for refusal will be documented on a separate sheet. Patients deemed not to be eligible after approaching them will be informed about the lack of eligibility and their screening data will be maintained.

5. METHODS AND STUDY PROCEDURES

5.1. Overview of the Procedures

After a **nephrologist** has consented for the study, he/she will be asked to complete a study entry questionnaire. It should require no more than 15 minutes to complete the questionnaire **(Table 5).**

Randomization: After enrollment and baseline data are obtained, nephrologists will be randomized to either the intervention or control group of the study by study personnel who will be blinded to their identities. This is a cluster RCT. Thus, patients of nephrologists in the intervention group will be assigned to the intervention group; patients of nephrologists in the control group will be assigned to the control group.

After a **patient coach** has completed all coaching sessions and follow up calls with their assigned subjects they will be asked to participate in a qualitative interview.

After a **physician coach** has completed all coaching sessions and follow up correspondence with nephrologists enrolled in the intervention arm they will be asked to participate in a qualitative interview.

At study completion all assisting **research coordinators** will be asked to participate in a qualitative interview.

Intervention:

Nephrologist component: We will conduct a pre-research focus group or individual sessions for nephrologists to learn about the skills and barriers that will help them become better communicators for shared dialysis decision-making. Nephrologists in the intervention group may be provided with supplies such as a notebook, pen and highlighter. They will then participate in a brief value affirmation exercise and goals of communication training at the time of enrollment and completion of their baseline assessments. Nephrologists will receive links to watch 5 communication training videos and then partake in up to three Zoom educational sessions, each approximately 45-60 minutes in duration, approximately 1-3 weeks apart, with standardized patient instructors (SPI) who will be enacting roles of patients with advanced kidney disease. The SPI will provide immediate oral feedback to the nephrologist. The specific communication behaviors that will be targeted include: (1) engagement, by acknowledging and prioritizing patient concerns (2) empathy (3) ASK-TELL-ASK approach (4) decision-making skills:

(a) value/preference clarification (b) compare options including conservative management (c) choose an option that seems to best fit with patient preferences. An effort will be made to tailor these sessions to the individual needs of a nephrologist by reviewing the identified needs and discussion with the coach. The communication coaching session will be audio-recorded, and nephrologists will receive written feedback via email following the sessions to reinforce their

learning. A manual and fidelity checklist will be developed to deliver this component of the intervention.

Patient recruitment at Strong, Highland and Rochester General Hospital will start once a nephrologist in the intervention group has completed at least two communication coaching sessions. At the end of each patient visit, nephrologists will be asked if (a) a preliminary RRT decision has been made? If not, is there a plan to discuss it in the next visit? Once a patient has made an RRT decision or has seen the nephrologist twice, either in-person or via Zoom, a final set of assessments will be completed. At the end of the study, to check for contamination, nephrologists in the intervention group will be asked if they were able to share newly learned communication skills with the nephrologists in the control group.

Upon completion of the decision-making process with the nephrologist, depending on patient's choice, patients will be given a summary of the 'next steps,' prepared in conjunction with the treating nephrologist. A copy will be given to the patient by the research coordinator in-person or via mail: (1) When does the patient need to finalize the decision (only if the decision has not been made after two visits)? (2) At what GFR level, access will be placed? (3) Symptoms suggestive of need for dialysis (4) when will dialysis need to be initiated?

Patient component (and caregivers, if available):

Approximately, 2-4 weeks prior to the visit with a coach, patients will receive an educational booklet about renal replacement therapy options and conservative management and another booklet containing a list of most commonly asked questions. Educational booklet will also be sent in a video format. Participants in the intervention group will then meet with a coach for approximately 60-90 minutes within two weeks prior to an office visit with their nephrologist. This intervention can take place at the Strong Hospital site or an alternate location of the patient's choice. If intervention takes place at the subject's home, a room that ensures privacy and confidentiality will be requested for the process to take place. Also, if at subject's home, study activities that are being conducted will use the same methods as if on site at URMC. During the first half of the coaching session, the coach will administer the value affirmation exercise, identify goals/preferences of kidney disease treatment so that they can articulate to the nephrologist and review renal replacement therapy options including conservative management with the patient. The coach will not answer any questions regarding RRT options but would rather help patients formulate questions about different RRT options including conservative management. Subsequently, the coach will give each patient (and caregiver) a list of commonly asked questions ("question prompt list" or QPL), and use brief role-plays to identify and help prepare patients to ask personally relevant questions during their upcoming nephrologist visit, so they can participate more actively and assertively in discussions with their nephrologist. If a patient has not read the education material or QPL, they will be given an opportunity to read the material or watch the video. Patient's questions along with renal and overall prognosis, using standardized tools (Schmidt RJ, Landry DL, Cohen L, et al. Derivation and validation of a prognostic model to predict mortality in patients with advanced chronic kidney disease. Nephrology Dialysis Transplantation. 2019;34(9):1517-1525. doi:10.1093/ndt/gfy305) (Tangri N, Stevens LA, Griffith J, et al. A predictive model for progression of chronic kidney disease to kidney failure. JAMA - Journal of the American Medical Association. 2011;305(15):1553-1559. doi:10.1001/jama.2011.451) will be forwarded to the nephrologist a day before the visit, either in-person or via e-mail. Patients (as well as the research coordinator) will also bring a list of their questions and visit checklist to the nephrologist. The nephrology visit will be audio recorded and the recordings will be destroyed after transcription and analyzation is complete. The coach will make a follow-up telephone call

(after the nephrology office visit) to address patients' concerns. Patients (and caregivers) will be eligible to attend an additional coaching session if unable to make a decision about dialysis with their nephrologist in one session. A manual and fidelity checklist will be developed to deliver this component of the intervention. Patients will be able to participate in these sessions via zoom or in-person at Strong Hospital or an alternate location chosen by the patient (ex. patient's home).

*If the research coordinator or coach will be traveling to a subject's home, in order to ensure their safety, travel to homes will only take place during daylight hours. They will also ensure that there is another team member who knows where and when they are traveling. The research coordinator or coach will also know to cut the study visit short if or when necessary and that they will have means of communication with the PI by cell phone or 911 in the case of an emergency.

In addition, no mandated reporters will be entering the subjects home at any time but if there are any problematic behaviors observed in the home, the study team member witnessing the incident will report/discuss with the PI and, if necessary, the IRB.

Control Group patients (and caregivers, if available): will meet with the dialysis educator and their nephrologist, as per the standard clinic protocol, and complete three sets of assessments. Their first set of assessments will be done at study entry, the second set will be completed within 0-3 months of seeing their nephrologist and a decision has been finalized (spanning up to two visits), and their third set will be completed at study completion which will take place within 3-6 months after their nephrology visit.

Control Group Nephrologists: will receive no educational intervention and will deliver care to control patients using routine communication processes during the study period. After appointments with patients enrolled in the study, physicians in the control group will also be asked if (a) a preliminary RRT decision has been made? Once a patient has made an RRT decision or has seen the nephrologist twice, either in-person or via Zoom, a final set of assessments will be completed. Upon completion of their final qualitative interview, they will have access to communication videos and an opportunity to participate in a workshop to improve communication skills where nephrologists may be provided with supplies such as a notebook, pen and highlighter. However, up to two visits with their patients will be audio-recorded. Audio recordings will be destroyed after transcription and analyzation is complete. At the end of the study, to check for contamination, nephrologists in the control group, will be asked if they were able to learn new communication skills from the nephrologists in the intervention group.

Patients (and caregivers, if available): During recruitment periods, a research assistant will identify eligible patients by reviewing the clinic schedule at Strong, Highland Hospital, and FF Thompson (patients who meet the eligibility requirements at RGH will be identified by the RGH PI) to include all current patients who meet eligibility criteria. Patients will be introduced to the study in-person at the study site location or over the phone and asked by the research assistant if they are willing to speak in a private setting to learn more about the study. All patients will be told that the purpose of the study is to improve communication and decision-making between patients and nephrologists. Patients will be given time to think about participation, and if desired will be told how to contact the research assistant at a later time. The screening and consent process will continue as long as needed until the person obtaining consent is

comfortable that the prospective participant fully understands all aspects of study involvement. The research assistant will obtain written consent or eConsent from those who voluntarily choose to enroll, using approved consent forms. All patients (and caregivers, if available) will be asked to allow audio-recording of 1-2 future visits with their nephrologist depending on the status of dialysis decision-making, and for permission to participate in three sets of surveys, collection of demographic data, and the end-of-study interview, and exit interview for those who withdraw early from the study. We expect that most of the patients will need one in-person visit with a coach and one in-person visit with the nephrologist. We will keep a record of this data. For patients not able to make a decision after one visit (as assessed during the coach's phone call after the nephrologist's visit), an additional in-person coaching visit will be offered. For such patients, the follow-up nephrology visits will also be audio-recorded. Patients will be able to participate in these sessions via zoom or in-person.

Patients will be informed that this is a randomized study, and their own study assignment will depend on which assignment their nephrologist has received. They will be informed about the multiple phases of the study and that their total involvement will take about 60-90 minutes for each coaching session, approximately 30 minutes to complete each survey set, approximately 15 minutes for each phone call from a coach, and approximately 30 minutes for an interview about the feasibility/acceptability of the study, approximately 5 minutes for an exit interview for those who withdraw early, till the end of the study. Patients will be asked for written permission to (a) Audio-record visits with their nephrologist and coaches (b) Complete surveys at study entry, within 0-3 months after visit(s) with their nephrologist, and within 3-6 months at study completion (c) Allow research staff to access their medical records (d) Participate in the end-of-study interview(d) participate in an exit interview upon study withdraw.

5.2. Assessments and Measurements

The Tables show the assessment batteries that will be administered to nephrologists **(Table 5),** patients **(Table 6),** and caregivers **(Table 7).** With the exception of questions administered in the qualitative interview, all of the proposed items have been used extensively in prior research. The questionnaire batteries are attached in the Appendix. Assessments will occur at the following time points for all the participants.

Physicians: (1) Study entry of physician (2) study entry of the patient (3) qualitative assessment of the physicians in the intervention and control groups (4) communication workshop offered to control group.

Patient and caregiver assessments will occur at three time points: (1) at Study entry, (2) 0-3 months from the nephrology visit once a decision has been finalized, spanning up to two visits, (3) within 3-6 months at study completion.

Additionally, with the patient's verbal permission, caregivers who are not interested in participating in this study are still welcome to be present to listen to the assessments and intervention via phone/any electronic media such as Skype, Zoom, etc. or in-person.

Patient Coaches: After all Intervention subjects have completed the coaching session the PI will conduct a Qualitative Interview to obtain perceptions of the coaching process, challenges faced, and successful strategies.

Physician Coaches: After all intervention nephrologists have completed their coaching session the PI will conduct a Qualitative Interview to obtain perceptions of the coaching process, challenges faced, and successful strategies.

Research Coordinators: At study completion the PI will conduct a Qualitative Interview to obtain perspectives on program implementation, logistical challenges, and suggestions for improvement.

1. **Audio-Recorded Data, Intervention and Control Arm:** Patient's visit with their nephrologists will be audio-recorded and recordings will be destroyed after transcription and analyzation have been completed. Providers that are precepting a Fellow who is enrolled in the study will be asked to give verbal consent to be audio recorded. If a preceptor does not consent the audio recorder will be paused during the preceptor's time with the enrolled patient. Intervention arm

patients, caregivers and nephrologists will be interviewed by the RA after the last meeting with the nephrologist to assess the feasibility and acceptability of the DIAL-SDM intervention. For patients in the intervention arm, the interviewer will ask open-ended questions on (1) benefits of the intervention (2) barriers to accessing DIAL-SDM (3) usefulness of the dialysis options knowledge materials (4) dialysis decision making. Interviews will be audio recorded. Similarly, patients in the control group will be asked about (1) the process of dialysis decision-making (2) experience of communicating goals and preferences with their nephrologist and if their goals were discussed during the visits with their nephrologist. Patients who decide to withdraw from the study will be interviewed when the individual confirms their withdrawal and will be asked (1) main reason for withdraw (2) suggestions for improving the study. These interviews will either take place at Strong Hospital or a location of patient's choice (ex: patient's home).

Medical Records Abstraction: We plan to record patients' labs, co-morbid conditions, advanced care planning, hospitalizations and ER visits for a total of 6 months before and 6 months after study entry on an abstraction form. This retrospective abstraction will be performed only for participants who have already enrolled and completed the study; no new patients will be recruited or consented for this purpose.

Because this is a retrospective study that involves retrospective chart review, we will also look at 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 the subjects study completion date without patient consent.

Because this study involves only participants who are already enrolled and poses minimal risk, we are requesting approval to obtain HIPAA authorization verbally using a short script. This approach reduces burden for participants who have already completed study activities, while ensuring they are informed about the additional retrospective chart review.

5.3. Data Banking for Future Research Use

Data will be stored in a password protected file on a password protected computer in the research coordinator's office. They may be used in future studies. Data will be de-identified to protect participants' privacy and then coded accordingly. Only the research investigators in this protocol will have access to the data. Each file will also be saved with password protection. The data will be stored for 7 years. Participants will not be re-contacted regarding the stored data.

5.4. Genetic/Genomic Research Activities

There will not be any genetic and genomic research activities either as the primary objective of the study or as an ancillary activity.

5.5. Costs to the Subject

There will be no cost to the subjects for the DIAL-SDM visits.

5.6. Payment for Participation

Each patient will be paid up to a total of $100. This amount will defray participant travel costs while providing a small incentive without coercion. To protect the participant's right to withdraw without penalty, payment will be prorated as the following: completion of first set of data collection, $50; Final set, $50. Participants who withdraw from the study and voluntarily complete an exit interview will receive payment of $10.

Each caregivers will receive $50 for each set of surveys, for a maximum of up to $100.

All payment to subjects and caregivers will be made with a gift card that for each visit will be uploaded with their $50 payment. These gift cards have no value until the department has been

made aware by the researcher that the gift cards have been given to the subjects and not lost or stolen. This process will be through the Embark system which will ensure the safety of the researcher who is distributing payment.

Each physician will receive a $100 gift card upon the completion of the study.

Each patient coach will receive a $50 gift card upon completion of the qualitative interview.

Each physician coach will receive a $50 gift card upon completion of the qualitative interview.

Each research coordinator will receive a $50 gift card upon completion of the qualitative interview.

6. CONCOMITANT AND DISALLOWED MEDICATION

There is no concomitant or disallowed medications in this study.

7. SUBJECT WITHDRAWALS

Participants will be advised that they have the right to withdraw from the study at any time without prejudice. Participants may also be withdrawn from the research without their consent in the event of acute worsening of their kidney disease needing initiation of hemodialysis before completion of the study. If a caregiver withdraws from the study, another caregiver identified by the patient will be approached. All participants who withdraw from the study will be offered an exit interview.

8. SAFETY AND REPORTABLE EVENTS

8.1. Adverse Event Definition

An adverse event is any symptom, sign, illness, or experience which develops or worsens during the study, whether or not the event is considered related to study.

8.2. Serious Adverse Event

A serious adverse event is defined as any adverse medical experience that results in any of the following outcomes:

- Death
- is life-threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity, or
- requires medical or surgical intervention to prevent permanent impairment or damage.

8.3. Recording Adverse Events

At each visit, patients will have the opportunity to report any adverse events by reporting all voluntary complaints of the participant.

All adverse events will be documented. Each adverse event will include a brief description of the experience, the date of onset, the date of resolution, the duration and type of experience, the severity, the relationship to study and contributing factors.

The recording of adverse events will occur once the participant signs consent until subject completes the study or withdraws from participation. The adverse experience will be followed until the adverse event is resolved or stabilized.

8.4. Responsibilities for Reporting Serious Adverse Events

The investigator will record all serious adverse experiences that occur during the study period in an Adverse Event log. The study period for reporting serious adverse events starts from the

time of signing consent to the final study visit. The PI will be notified of all adverse events. The Investigator will comply with regulations and RSRB policy regarding the reporting of adverse events.

9. RISK/BENEFIT ASSESSMENT

Human Subjects Involvement: This study involves human subjects; potential risks to patients, families and clinicians require careful consideration.

9.1. Risks to Human Subjects

(a) Human subject's involvement and characteristics

Study subjects are nephrologists (n=12 or more/less), CKD patients (n=60) and their caregivers (n=36 or more/less). All subjects will provide informed consent. Subjects under age 21 are excluded from the study.

(b) Potential risks

Privacy and confidentiality. There is a small potential for risk to patients and caregivers of disclosure of private material. Research staff will need to have patient and caregiver contact information including telephone number and address available for follow-up. Alternative procedures are not available.

Psychological or physical risk. There is potential risk for minor psychological discomfort among patients and caregivers while completing questionnaires or talking about symptoms of CKD, prognosis, and their other experiences during treatment for the illness. Patients and caregivers will be instructed to inform their physician as well as the research staff if they wish to refrain from discussing aspects of their illness or refuse to answer a particular question. Physical risks in this study – that is, risks associated with voluntarily responding to oral surveys and questions asked by a research assistant are low.

9.2. Adequacy of protection against risks

Privacy and confidentiality. Staff are trained regarding HIPAA and human subjects' protections regulations and procedures. Any data collected will be stripped of any identifiers; a unique ID number will be generated for each subject and all data files. The linking file containing identifiers will not be stored in the central database repository. Data will be encrypted by applying a special scrambling code that makes the data unreadable to anyone who does not have a decryption key. Authorized personnel with access to this key can unscramble it. This file will be stored on a separate server and made accessible only to database administrators with the appropriate permissions. URMC-managed networks where data will be stored and maintained are protected by perimeter firewalls, supplemented by additional interior firewalls to protect particularly critical or vulnerable resources. During the period in which it will be necessary to keep personal identifying information for follow-up purposes, all personal electronic data will be kept in a password-protected file on a secure mainframe computer with firewall protection located behind locked doors. Paper data will be securely kept in a locked file cabinet. Subjects will be assigned identification numbers which will be used on all data; the link between name and ID number will also be kept in a separate password protected file. Participants will be advised as to the risks to confidentiality in the informed consent. No identifying information that associates names with voices will appear on transcripts of the recorded visits or on any portable electronic

equipment. All audio-recordings will be destroyed once all analyses have been completed. No identifying data will be used in any publications.

Psychological or physical risk. Staff will receive training in techniques for communicating effectively and sensitively with patients diagnosed with advanced CKD and their caregivers. Patients and caregivers will be informed that they have the right to terminate participation at any time and to refuse surveys or leave survey questions blank if they are uncomfortable for any reason. In the unlikely event of extreme psychological discomfort in a patient or caregiver, staff will be trained in procedures for ensuring necessary medical or professional intervention. The research assistants will be trained to identify and respond to emotional distress expressed during the interview. Research assistants will monitor for signs of distress (e.g., tearfulness, expression of discomfort, agitation). If a participant should become distressed, the research assistant will respond empathically and temporarily pause or stop the interview depending on the preference of the participant and the assessment of the researcher. If a participant becomes extremely distressed, the research assistant will contact Dr. Saeed. If the participant is under care with a psychotherapist or psychiatrist, they will be encouraged to contact the appropriate care provider; otherwise, referrals will be provided.

9.3. Potential benefits of the proposed research to the subjects and others

Some patients benefit from knowing that their participation in studies like this can help other patients and families in the future. Adequate safeguards to minimize inherent risks are in place. We believe the potential risks to subjects are reasonable in relation to the importance of the knowledge to be gained.

9.4. Importance of the knowledge to be gained

Communication skills is a growing area of healthcare with relatively little empirical data to identify “best practices” on dialysis-related decision making. This study will help to address important gaps in the science of communication with patients with CKD.

10. CONFIDENTIALITY OF DATA AND INFORMATION STORAGE

To protect the confidentiality of participants, each participant will be de-identified and coded. These codes will not be derived from or related to the information about the individual, and cannot be translated to identify the individual. The identifying information will be kept separate from the research database. Only the PI will have the key to the codes. The codes will only be broken if there is a life-threatening result that calls for an intervention.

The research data will be stored in the locked office of the RA. Electronic version will be stored in a REDCap or a shared drive (password protected). All the files will be password protected, especially the file containing the key to the codes linking patients to their data. Paper documents will be locked in a drawer in the office of the RA. Excess copies of paper documents will be shredded. The PI and co-investigators will have access to de-identified data. Only the PI and RA will have the data with participant identifiers.

All data shared for the purpose of analysis will be de-identified and securely stored on the HIPAA-compliant UR Box.com. The storage and maintenance of data will occur within the URMC-managed networks, which are safeguarded by perimeter firewalls. Additionally, extra interior firewalls are in place to safeguard especially critical or vulnerable resources.

11. DATA ANALYSIS AND MONITORING

11.1. Planned Statistical Analysis

This is a pilot cluster-randomized trial, where our communication outcomes (APPC scores) [32]

and shared decision-making outcomes (OPTION scores)[40] are measured at the level of the physician-patient dyad, while other outcomes (e.g., SDM questionnaire) [41] are measured at the level of the patient for descriptive analyses but adjusted for the clustering effect in final analyses. All analyses will be performed using SAS (version 9.4, Cary, NC). Patient and physician characteristics will be described using proportions for categorical variables and means (± standard deviations) or medians (interquartile range) for continuous variables. **Quantitative analyses (Aims 1-2):** Analyses of the Feasibility and Acceptability of the Intervention Measures **(Aim 1)** will be mainly descriptive. To compare group differences for the study outcomes **(Aim 2)**, we will use Wald-type tests from pre-specified mixed-effects linear regression models for continuous outcomes and generalized linear models with logit link function for binary outcomes. *Analyses will be specified to account for the nesting of patients (the units of analysis) within physicians (the units of randomization).* For all regression analyses, physician-level covariates for gender, years of experience, practice style, prior communication skills training, and the renal fellow status will be included, as well as patient-level covariates to adjust for demographic characteristics. All reported p values will be two sided, with $p< 0.05$ considered statistically significant. **Qualitative analyses (Aim 1)**: Using Atlas.ti software, interviews of patients (30 minutes) and nephrologists (15 minutes) will be transcribed, de-identified, and verified for accuracy by a third party. Based on a modified phenomenological approach,[152] I will work with Ladwig, MPH (data manager), under Dr. Epstein's supervision, will create a coding scheme to characterize barriers, strengths, and areas of improvement for the proposed intervention and study design. Ten initial transcripts will be read and reread to reach an agreement. Disagreements will be resolved by discussion with the mentoring team. Remaining transcripts will be coded according to the coding scheme. **Handling of missing data:** The regression approach requires the "missing completely at random" (MCAR) assumption for valid inference, which may not be met for some outcomes in this study. Therefore, we will apply the response-dependent missingness—or the missing at random (MAR)—assumption when outcomes and missing data are less likely to be independent. We will examine the nature of the missing data and use the inverse probability weighting (IPW) approach, or multiple imputation, and sensitivity analyses, if necessary.

11.2. Data and Safety Monitoring

Despite the low risk associated with the proposed behavioral intervention, we have organized a data safety and monitoring (DSM) plan and will report directly to the University of Rochester Medical Center (URMC) and the Unity Hospital IRB

Daniel Croft, MD, MPH and Scott Liebman, MD, MPH will comprise the DSM board. Daniel Croft, MD, MPH is not involved in the study and has no relevant conflict of interests. Scott Liebman, MD, MPH has been randomly assigned to the Control arm and will continue to serve on the DSM board. The function of the DSM board will be to:

(a) Systematically review screening materials to ensure that screening is conducted appropriately.
(b) Systematically ensure that how many participants experiencing distress received a referral for psychiatric referrals to Dr. Adam Simning, and monitor their outcomes.
(c) Monitor staff performance concerning the protection of privacy, confidentiality, maintenance of secure databases, and study procedures designed to reduce the risk of distress. Such concerns will be reported to both PI and the Univ. of Rochester IRB

(d) Provide input to both the PI and the IRB on possible early termination of the study due to the safety or other relevant concerns.

The review board will meet by conference call or in-person every six months and confer on an as needed basis when adverse or difficult events occur. The URMC IRB will provide additional oversight.

11.3 Sharing of Information

De-Identified information may be shared to:

1. The Department of Health and Human Services
2. The University of Rochester
3. American Society of Nephrology
4. National Institute of Health (NIH)
5. The University of Illinois Urbana-Champagne – Sadia Ashrafi and Dr. Andiara Schwingel (DUA)
6. Mount St Joseph University- Rebecca Allen (DUA)
7. University of Michigan- Areeba Jawed (DUA)
8. Texas A&M University – Dr. Richard Street (DUA)

All de-identified qualitative data will be shared with Mount St Joseph University and University of Michigan. Only de-identified nephrologist communication training transcripts will be shared with The University of Illinois Urbana-Champagne. Only de-identified transcripts of patient nephrology visits will be shared with Texas A&M University. This information will be shared for data analysis purposes via the HIPAA compliant UR Box.com.

Only the study team will have access to the stored audio files and data.

All study data will be stored on password-protected shared drives, stored and maintained through the Information Services Division of the University of Rochester Medical Center, and adhering to all standard University IT policies and procedures.

REFERENCES

1. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, Boynton MH, Halko H. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci. 2017;12(1):108. Epub 2017/08/29. doi: 10.1186/s13012-017-0635-3. PubMed PMID: 28851459; PMCID: PMC5576104.
2. Street RL, Gordon H, Haidet P. Physicians' communication and perceptions of patients: is it how they look, how they talk, or is it just the doctor? Soc Sci Med. 2007;65(3):586-98. Epub 2007/04/25. doi: 10.1016/j.socscimed.2007.03.036. PubMed PMID: 17462801; PMCID: PMC2811428.
3. Hibbard JH, Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. Health Aff (Millwood). 2013;32(2):207-14. doi: 10.1377/hlthaff.2012.1061. PubMed PMID: 23381511.
4. Elwyn G, Edwards A, Wensing M, Hood K, Atwell C, Grol R. Shared decision making: developing the OPTION scale for measuring patient involvement. Qual Saf Health Care. 2003;12(2):93-9. PubMed PMID: 12679504; PMCID: PMC1743691.
5. Kriston L, Scholl I, Hölzel L, Simon D, Loh A, Härter M. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. Patient Educ Couns. 2010;80(1):94-9. Epub 2009/10/30. doi: 10.1016/j.pec.2009.09.034. PubMed PMID: 19879711.
6. Epstein RM, Duberstein PR, Fenton JJ, Fiscella K, Hoerger M, Tancredi DJ, Xing G, Gramling R, Mohile S, Franks P, Kaesberg P, Plumb S, Cipri CS, Street RL, Shields CG, Back AL, Butow P, Walczak A, Tattersall M, Venuti A, Sullivan P, Robinson M, Hoh B, Lewis L, Kravitz RL. Effect of a Patient-Centered Communication Intervention on Oncologist-Patient Communication, Quality of Life, and Health Care Utilization in Advanced Cancer: The VOICE Randomized Clinical Trial. JAMA Oncol. 2017;3(1):92-100. doi: 10.1001/jamaoncol.2016.4373. PubMed PMID: 27612178.
7. O'Connor AM. Validation of a decisional conflict scale. Med Decis Making. 1995Jan-Mar;15(1):25-30.
8. Curtis JR, Downey L, Back AL, Nielsen EL, Paul S, Lahdya AZ, Treece PD, Armstrong P, Peck R, Engelberg RA. Effect of a Patient and Clinician Communication-Priming Intervention on Patient-Reported Goals-of-Care Discussions Between Patients With Serious Illness and Clinicians: A Randomized Clinical Trial. JAMA Intern Med. 2018;178(7):930-40. doi: 10.1001/jamainternmed.2018.2317. PubMed PMID: 29802770.
9. Moss AH. Revised dialysis clinical practice guideline promotes more informed decision-making. Clin J Am Soc Nephrol. 2010;5(12):2380-3. Epub 2010/11/04. doi: 10.2215/CJN.07170810. PubMed PMID: 21051749.
10. Williams AW, Dwyer AC, Eddy AA, Fink JC, Jaber BL, Linas SL, Michael B, O'Hare AM, Schaefer HM, Shaffer RN, Trachtman H, Weiner DE, Falk AR, American Society of Nephrology Quality aPSTF. Critical and honest conversations: the evidence behind the "Choosing Wisely" campaign recommendations by the American Society of Nephrology. Clin J Am Soc Nephrol. 2012;7(10):1664-72. Epub 2012/09/13. doi: 10.2215/CJN.04970512. PubMed PMID: 22977214.
11. Carson RC, Juszczak M, Davenport A, Burns A. Is maximum conservative management anequivalent treatment option to dialysis for elderly patients with significant comorbid disease? Clin J Am Soc Nephrol. 2009;4(10):1611-9. doi: 10.2215/CJN.00510109. PubMed PMID: 19808244; PMCID: PMC2758251.
12. Kurella Tamura M, Covinsky KE, Chertow GM, Yaffe K, Landefeld CS, McCulloch CE. Functional status of elderly adults before and after initiation of dialysis. N Engl J Med. 2009;361(16):1539-47. doi: 10.1056/NEJMoa0904655. PubMed PMID: 19828531; PMCID: PMC2789552.

13. Evans RW, Manninen DL, Garrison LP, Hart LG, Blagg CR, Gutman RA, Hull AR, Lowrie EG. The quality of life of patients with end-stage renal disease. N Engl J Med. 1985;312(9):553-9. doi: 10.1056/NEJM198502283120905. PubMed PMID: 3918267.
14. Murray AM, Tupper DE, Knopman DS, Gilbertson DT, Pederson SL, Li S, Smith GE, Hochhalter AK, Collins AJ, Kane RL. Cognitive impairment in hemodialysis patients is common. Neurology. 2006;67(2):216-23. doi: 10.1212/01.wnl.0000225182.15532.40. PubMed PMID: 16864811.
15. Ahmed S, Addicott C, Qureshi M, Pendleton N, Clague JE, Horan MA. Opinions of elderly people on treatment for end-stage renal disease. Gerontology. 1999;45(3):156-9. doi: 10.1159/000022078. PubMed PMID: 10202260.
16. Morton RL, Snelling P, Webster AC, Rose J, Masterson R, Johnson DW, Howard K. Factors influencing patient choice of dialysis versus conservative care to treat end-stage kidney disease. CMAJ. 2012;184(5):E277-83. doi: 10.1503/cmaj.111355. PubMed PMID: 22311947; PMCID: PMC3307582.
17. Davison SN. End-of-life care preferences and needs: perceptions of patients with chronic kidney disease. Clin J Am Soc Nephrol. 2010;5(2):195-204. Epub 2010/01/14. doi: 10.2215/CJN.05960809. PubMed PMID: 20089488; PMCID: PMC2827591.
18. Saeed F, Sardar MA, Davison SN, Murad H, Duberstein PR, Quill TE. Patients' perspectives on dialysis decision-making and end-of-life care. Clin Nephrol. 2019;91(5):294-300. doi: 10.5414/CN109608. PubMed PMID: 30663974.
19. Wachterman MW, Marcantonio ER, Davis RB, Cohen RA, Waikar SS, Phillips RS, McCarthy EP. Relationship between the prognostic expectations of seriously ill patients undergoing hemodialysis and their nephrologists. JAMA Intern Med. 2013;173(13):1206-14. doi: 10.1001/jamainternmed.2013.6036. PubMed PMID: 23712681; PMCID: PMC3982381.
20. Davison SN. End-of-Life Care Preferences and Needs: Perceptions of Patients with Chronic Kidney Disease. Clinical Journal of the American Society of Nephrology. 2010;5(2):195-204. doi: 10.2215/cjn.05960809.
21. Parker SM, Clayton JM, Hancock K, Walder S, Butow PN, Carrick S, Currow D, Ghersi D, Glare P, Hagerty R, Tattersall MH. A systematic review of prognostic/end-of-life communication with adults in the advanced stages of a life-limiting illness: patient/caregiver preferences for the content, style, and timing of information. J Pain Symptom Manage. 2007;34(1):81-93. Epub 2007/05/29. doi: S0885-3924(07)00260-6 [pii]
22. 10.1016/j.jpainsymman.2006.09.035. PubMed PMID: 17531434.
23. Weeks JC, Cook EF, O'Day SJ, Peterson LM, Wenger N, Reding D, Harrell FE, Kussin P, Dawson NV, Connors AF, Jr., Lynn J, Phillips RS. Relationship between cancer patients' predictions of prognosis and their treatment preferences. JAMA. 1998;279(21):1709-14. Epub 1998/06/12. doi: joc71098 [pii]. PubMed PMID: 9624023.
24. Mack JW, Weeks JC, Wright AA, Block SD, Prigerson HG. End-of-life discussions, goal attainment, and distress at the end of life: predictors and outcomes of receipt of care consistent with preferences. J Clin Oncol. 2010;28(7):1203-8. Epub 2010/02/01. doi: 10.1200/JCO.2009.25.4672. PubMed PMID: 20124172; PMCID: PMC2834470.
25. Hancock K, Clayton JM, Parker SM, Walder S, Butow PN, Carrick S, Currow D, Ghersi D, Glare P, Hagerty R, Tattersall MH. Discrepant perceptions about end-of-life communication: a systematic review. J Pain Symptom Manage. 2007;34(2):190-200. Epub 2007/06/05. doi: S0885-3924(07)00273-4 [pii] 10.1016/j.jpainsymman.2006.11.009. PubMed PMID: 17544247.
26. Covinsky KE, Fuller JD, Yaffe K, Johnston CB, Hamel MB, Lynn J, Teno JM, Phillips RS. Communication and decision-making in seriously ill patients: findings of the SUPPORT project. The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments. J Am Geriatr Soc. 2000;48(5 Suppl):S187-93. Epub 2000/05/16. PubMed PMID: 10809474.

27. Jackson JL. From the Editors' Desk: Why Does Not Improvement in Communication Lead to Improvement in "Hard" Outcomes? J Gen Intern Med. 2019;34(6):779-80. doi: 10.1007/s11606-018-4819-6. PubMed PMID: 30684195; PMCID: PMC6544686.
28. Griffin SJ, Kinmonth AL, Veltman MW, Gillard S, Grant J, Stewart M. Effect on health-related outcomes of interventions to alter the interaction between patients and practitioners: a systematic review of trials. Ann Fam Med. 2004;2(6):595-608. doi: 10.1370/afm.142. PubMed PMID: 15576546; PMCID: PMC1466743.
29. Jackson JL. A Randomized Trial to Improve Communication between Patients and Providers in a Primary Care Walk-In Clinic. J Gen Intern Med. 2018;33(4):404-5. doi: 10.1007/s11606-017-4300-y. PubMed PMID: 29404941; PMCID: PMC5880779.
30. Clayton JM, Butow PN, Tattersall MH, Devine RJ, Simpson JM, Aggarwal G, Clark KJ, Currow DC, Elliott LM, Lacey J, Lee PG, Noel MA. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end-of-life care. J Clin Oncol. 2007;25(6):715-23. Epub 2007/02/20. doi: 25/6/715 [pii]
31. 10.1200/JCO.2006.06.7827. PubMed PMID: 17308275.
32. Kinnersley P, Edwards A, Hood K, Cadbury N, Ryan R, Prout H, Owen D, Macbeth F, Butow P, Butler C. Interventions before consultations for helping patients address their information needs. Cochrane Database Syst Rev. 2007(3):CD004565. Epub 2007/07/18. doi: 10.1002/14651858.CD004565.pub2. PubMed PMID: 17636767.
33. Lewin SA, Skea ZC, Entwistle V, Zwarenstein M, Dick J. Interventions for providers to promote a patient-centred approach in clinical consultations. Cochrane Database Syst Rev. 2001(4):CD003267. Epub 2001/11/01. doi: CD003267 [pii] 10.1002/14651858.CD003267. PubMed PMID: 11687181.
34. Lewin SA, Skea ZC, Entwistle V, Zwarenstein M, Dick J. Interventions for providers to promote a patient-centred approach in clinical consultations. Cochrane Database Syst Rev. 2001(4):CD003267. Epub 2001/11/01. doi: CD003267 [pii] 10.1002/14651858.CD003267. PubMed PMID: 11687181.
35. A controlled trial to improve care for seriously ill hospitalized patients. The study to understand prognoses and preferences for outcomes and risks of treatments (SUPPORT). The SUPPORT Principal Investigators. JAMA. 1995;274(20):1591-8. Epub 1995/11/22. PubMed PMID: 7474243.
36. Kinnersley P, Edwards A, Hood K, Cadbury N, Ryan R, Prout H, Owen D, Macbeth F, Butow P, Butler C. Interventions before consultations for helping patients address their information needs. Cochrane Database Syst Rev. 2007(3):CD004565. Epub 2007/07/18. doi: 10.1002/14651858.CD004565.pub2. PubMed PMID: 17636767.
37. Lewin SA, Skea ZC, Entwistle V, Zwarenstein M, Dick J. Interventions for providers to promote a patient-centred approach in clinical consultations. Cochrane Database Syst Rev. 2001(4):CD003267. Epub 2001/11/01. doi: CD003267 [pii] 10.1002/14651858.CD003267. PubMed PMID: 11687181.
38. A controlled trial to improve care for seriously ill hospitalized patients. The study to understand prognoses and preferences for outcomes and risks of treatments (SUPPORT). The SUPPORT Principal Investigators. JAMA. 1995;274(20):1591-8. Epub 1995/11/22. PubMed PMID: 7474243.
39. Street RL, Makoul G, Arora NK, Epstein RM. How does communication heal? Pathways linking clinician-patient communication to health outcomes. Patient Educ Couns. 2009;74(3):295-301. Epub 2009/01/15. doi: 10.1016/j.pec.2008.11.015. PubMed PMID: 19150199.
40. Street RL, Jr., Elwyn G, Epstein RM. Patient preferences and healthcare outcomes: an ecological perspective. Expert review of pharmacoeconomics & outcomes research. 2012;12(2):167-80. doi: 10.1586/erp.12.3. PubMed PMID: 22458618.

41. Lynn J, De Vries KO, Arkes HR, Stevens M, Cohn F, Murphy P, Covinsky KE, Hamel MB, Dawson NV, Tsevat J. Ineffectiveness of the SUPPORT intervention: review of explanations. J Am Geriatr Soc. 2000;48(S1):S206-13. PubMed PMID: 10809477.
42. Back AL, Arnold RM, Baile WF, Tulsky JA, Fryer-Edwards K. Approaching difficult communication tasks in oncology. CA Cancer J Clin. 2005;55(3):164-77. PubMed PMID: 15890639.
43. Gysels M, Richardson A, Higginson IJ. Communication training for health professionals who care for patients with cancer: a systematic review of effectiveness. Support Care Cancer. 2004;12(10):692-700. Epub 2004/07/20. doi: 10.1007/s00520-004-0666-6. PubMed PMID: 15258839.32.
44. Street RL. Information-giving in medical consultations: the influence of patients' communicative styles and personal characteristics. Soc Sci Med. 1991;32(5):541-8. PubMed PMID: 2017721.
45. Street RL, Gordon HS, Ward MM, Krupat E, Kravitz RL. Patient participation in medical consultations: why some patients are more involved than others. Med Care. 2005;43(10):960-9. PubMed PMID: 16166865.
46. Street RL, Slee C, Kalauokalani DK, Dean DE, Tancredi DJ, Kravitz RL. Improving physician-patient communication about cancer pain with a tailored education-coaching intervention. Patient Educ Couns. 2010;80(1):42-7. Epub 2009/12/04. doi: 10.1016/j.pec.2009.10.009. PubMed PMID: 19962845; PMCID: PMC2891619.
47. Tangri N, Stevens LA, Griffith J, et al. A predictive model for progression of chronic kidney disease to kidney failure. JAMA - Journal of the American Medical Association. 2011;305(15):1553-1559. doi:10.1001/jama.2011.451
48. Schmidt RJ, Landry DL, Cohen L, et al. Derivation and validation of a prognostic model to predict mortality in patients with advanced chronic kidney disease. Nephrology Dialysis Transplantation. 2019;34(9):1517-1525. doi:10.1093/ndt/gfy305

Table 5. Timing of administration of assessments for physicians

	Measurement	References (if applicable)	# of items	Time of completion
Aim-1	Feasibility, acceptability and appropriateness of the intervention measures	Weiner et al, Implement Science, 2017	12	Study completion
	Fidelity of the DIAL-SDM intervention	NA	30	After the completion of each coaching session.
	Qualitative Interviews		7	Study completion
Aim-2	Physician-patient communication: Active Patient Participation Coding (APPC) scores	Street et al, Soc Sci Med. 2007	NA	Study completion (audio scripts)
	Shared decision-making: OPTION scale	Elwyn G, Qual Saf Health Care. 2003	12	Study completion (audio scripts)
	Comfort with shared decision making	Degner et al, J of Clin Epidemiology,1992	5	Study entry Study completion
	Comfort with medical paternalism	Duberstein et al , JOSM 2019	1	Study entry
Other potential co-variates	Physician demographics and training experience	NA	7	Study entry
	Value Affirmation Exercise		9	Study entry (Intervention group)

Table 6. Timing of administration of assessments for patients

	Assessment	References if applicable	# items	Time of completion
Aim-1	Feasibility (patients approached vs enrolled)	Weiner et al, Implement Science, 2017	Feasibility of the intervention measure	0-3 months (after last coaching session)
			Feasibility of the Question Prompt List	
			Feasibility of the Education Booklet	
			Feasibility of Education video	
	Acceptability	NA	Qualitative interviews	0-3 months (after last coaching session)
		Weiner et al, Implement Science, 2017	Acceptability of the Intervention measure	0-3 months (after last coaching session)
			Acceptability of the Question Prompt List	
			Acceptability of the Education Booklet	
			Acceptability of Education video	
		NA	Fidelity	After the coaching session (audio recordings)
Aim-2	Physician-patient communication: Active Patient Participation Coding (APPC) scores	Street et al, Soc Sci Med. 2007	NA	3-6 months at Study completion (audio scripts)
	Shared decision-making: OPTION scale	Elwyn G, Qual Saf Health Care. 2003	12	3-6 months at Study completion (audio scripts)
	Shared decision-making questionnaire	Kristen L et al. Patient Educ Couns. 2010	9	0-3 months 3-6 months at Study completion
	Decisional engagement scale	Hoerger et al, Psychol Assess. 2016	10	0-3 months 3-6 months at Study completion

	Choice of renal replacement therapy modality	NA	1	Study entry 0-3 months 3-6 months at Study completion
	Prognostic discussion	Weeks et al, JAMA 1998	10	Study entry 0-3 months 3-6 months at Study completion
	Decisional Conflict scale	Med Decis Making. 1995	10	Study entry 0-3 months 3-6 months at Study completion
	Goal Concordant Care Questionnaire	Curtis et al	2	Study entry 0-3 months 3-6 months at Study completion
Other potential co-variates	Demographics	NA	17	Study entry
	Cavanaugh dialysis knowledge scale – Rochester version	Cavanaugh et al, CJASN 2009	14	Study entry 0-3 months 3-6 months at Study completion
	Human connection scale	Mack et al Cancer 2009	16	Study entry 0-3 months
	Healthcare climate questionnaire	XX	5	Study entry 0-3 months
	Quality of life (KDQOL)		32	Study entry 0-3 months 3-6 months at Study completion
	Control preference scale- Rochester version	Degner et al, Can J Nurs Res. 1990	1	Study entry
	Health literacy	Davis et al, family medicine, 1991	6	Study entry
	Trust - Primary Care Assessment Survey (PCAS) trust subscale	Safran DG, Kosinski M, Tarlov AR, Med Care. 1998;	8	Study entry 0-3 months 3-6 months at Study completion
	KARNOFSKY SELF-REPORTED PERFORMANCE	Crooks at al. J Gerontol. 1991;	1	Study entry 3-6 months at Study completion
	OARS Comorbidity	Fillenbaum et al. J Gerontol. 1981;	15	Study entry
	Press Ganey Patient Satisfaction Questionnaire	NA	16	Study entry 0-3 months
	Perceived Efficacy in Patient-Physician Interactions	JAGS, April 2015	5	Study entry 0-3 months 3-6 months at Study completion

	Advanced care planning	NA	4	Study entry 3-6 months at Study completion

	Hospitalizations	NA	2	Study entry 0-3 months 3-6 months at Study completion
	Exit interview	NA	3	Upon withdrawal

Table 7. Assessments and timing of administration of assessments for caregivers

	Assessment	References if applicable	# of items	Time of completion
Aim-1	Feasibility (patients approached vs enrolled)	Weiner et al, Implement Science, 2017	Feasibility of the intervention measure	0-3 months (after last coaching session)
			Feasibility of the Question Prompt List	
			Feasibility of the Education Booklet	
			Feasibility of Education video	
	Acceptability	NA	Qualitative interviews	0-3 months (after last coaching session)
		Weiner et al, Implement Science, 2017	Acceptability of the Intervention measure	0-3 months (after last coaching session)
			Acceptability of the Question Prompt List	
			Acceptability of the Education Booklet	
			Acceptability of Education video	
Aim-2		NA	Fidelity	After the coaching session (audio recordings)
Aim-3	Zarit caregiver burden scale	Zarit et al, New York University Press,1985	22	Study entry 0-3 months 3-6 months at Study completion
	Shared decision-making questionnaire	Kristen L et al. Patient Educ Couns. 2010	9	0-3 months 3-6 months at Study completion
	Decisional engagement scale	Hoerger et al, Psychol Assess. 2016	10	0-3 months 3-6 months at Study completion
	Choice of renal replacement therapy modality	NA	1	Study entry 3-6 months at Study completion
Other potential	Demographics	NA	15	Study entry

co-variates	Prognostic discussion	Weeks et al, JAMA 1998	7	Study entry 0-3 months 3-6 months at Study completion
	Decisional Conflict scale	Med Decis Making. 1995	10	Study entry 0-3 months 3-6 months at Study completion
	Goal Concordant Care Questionnaire	Curtis et al	2	Study entry 0-3 months 3-6 months at Study completion
	Trust - Primary Care Assessment Survey (PCAS) trust subscale	Safran DG, Kosinski M, Tarlov AR, Med Care. 1998;	8	Study entry 0-3 months 3-6 months at Study completion
	Human connection scale		16	Study entry 0-3 months
	Healthcare climate questionnaire		5	Study entry 0-3 months
	Perceived efficacy in patient-physician interactions		5	Study entry 0-3 months 3-6 months at Study completion
	Exit interview	NA	3	Upon withdrawal