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Title: Integrating conservative kidney management options and advance care planning **e**ducation (COPE) into routine CKD care: a protocol for a pilot randomized controlled trial

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Abstract:

Introduction: Pre-dialysis education for patients with advanced chronic kidney disease (CKD) typically focuses narrowly on hemodialysis and peritoneal dialysis as future treatment options. However, patients who are older or seriously ill may not want to pursue dialysis and/or may not benefit from this treatment. Conservative kidney management, a reasonable alternative treatment, and advance care planning (ACP) are often left out of patient education and shared decision-making. In this study, we will pilot an educational intervention (**C**onservative Kidney Management **O**ptions and Advance Care **P**lanning **E**ducation – COPE) to improve knowledge of conservative kidney management and ACP among patients with advanced CKD who are older and/or who have poor functional status.

Methods and analysis: This is a single-center pilot randomized controlled trial at an academic center in Philadelphia, PA. Eligible patients will have: age ≥ 70 years of age and/or poor functional status (as defined by Karnofsky Performance Index Score < 70), advanced CKD (eGFR < 20 ml/min/1.73m^2), prefer to speak English-during clinical encounters, and self-report as Black or White race. Enrolled patients will be randomized 1:1, with stratification by race, to receive enhanced usual care or usual care plus in-person education about conservative kidney management and ACP (COPE). The primary outcome is change in knowledge of CKM and ACP. We will also explore intervention feasibility and acceptability, change in communication of preferences, and differences in the intervention's effects on knowledge and communication of preferences by race. We will assess outcomes at baseline, immediately post-education, and at 2 and 12 weeks.

Ethics and dissemination: This protocol has been approved by the Institutional Review Board at the University of Pennsylvania. We will obtain written informed consent from all participants.

The results from this work will be presented at academic conferences and disseminated through peer-reviewed journals.

Trial registration: This trial is registered at ClinicalTrials.gov under NCT03229811.
Key words: Advanced chronic kidney disease, conservative kidney management, advance care planning, racial disparities

Strengths and limitations of this study:

- This is a pilot randomized controlled trial evaluating an intervention designed to primarily educate older and seriously ill patients with advanced CKD about conservative kidney management and advance care planning.
- Patients will receive an educational intervention that is integrated into their advanced CKD care.
- We anticipate that the intervention will reduce racial disparities between Black and White patients in knowledge about conservative kidney management and advance care planning.
- As this study is being conducted at a single-center and is being limited to White and Black patients, we are unable to generalize study results to different regions or patients of different races or ethnicities.

Introduction

The benefits of dialysis remain uncertain for older and seriously ill patients with advanced chronic kidney disease (CKD). In the United States, over 720,000 individuals have end-stage renal disease (ESRD) with 87.3% of these patients ultimately receiving hemodialysis.[1] For older and frail patients with advanced CKD, it is unclear whether dialysis improves health or survival, with some evidence to suggest that it can negatively impact quality of life and functional status.[2–10] Additionally, patients of all ages with CKD have a higher prevalence of frailty and poor functional status, which is an independent risk factor for mortality and increased hospitalizations.[5,7,11–13]

Conservative kidney management is an approach to care for patients with ESRD who do not want to pursue dialysis or who are unlikely to benefit from this treatment, especially those who are older with functional limitations.[6–9] This is non-dialytic therapy that focuses on slowing the progression of kidney disease with medications and fosters a multidisciplinary approach to address care needs and emotional and physical symptoms associated with ESRD. However, many care models of conservative kidney management have been developed outside of the United States, and implementation strategies have not been investigated in this country.[8, 15–17]

Patients with advanced CKD who are managed with conservative kidney management are more likely to receive palliative care consultation, use hospice, and discuss goals of care.[17,18] Advance care planning (ACP) is a process in which clinicians elicit and document patients' values and desired goals of care if they were to become incapacitated.[19–24] Among seriously ill patients, early discussions about advanced care preferences improve patients' understanding of their health status and facilitate more informed ACP and decision-making.[25–28] Specifically, studies have demonstrated that as for other patient populations, patients with advanced CKD would prefer to have ACP and goals of care discussions earlier in the disease course.[22,29]

However, these conversations are often challenging and available evidence suggests that nephrologists tend not to engage in ACP with their patients.[22,29–32] Additionally, some studies have shown racial disparities in ACP knowledge, and that racial-ethnic minority patients are less likely to engage in goals of care discussions and advance care planning when compared to White patients.[19,21,33,34] Education and improving informed decision-making may mitigate racial disparities in care for older patients with CKD.[35,36] Thus, we are testing whether a novel educational intervention incorporated into routine advanced CKD care, called **C**onservative Kidney Management **O**ptions and Advance Care **P**lanning **E**ducation (COPE), can improve knowledge and communication among patients who are older and/or with poor functional status.

Methodology and analysis

Conceptual framework

The COPE intervention has been developed to address patient knowledge, expectations, and beliefs of ESRD treatments and ACP (Figure 1). The conceptual framework for this intervention is adapted from the Health Belief Model (Figure 1).[37] This model hypothesizes that health-related action depends on the simultaneous occurrence of three factors: 1) the existence of sufficient motivation to make health issues salient or relevant; 2) the belief that one is susceptible to a serious health problem or sequelae of that illness or condition (e.g., perceived threat); and 3) the belief that following a particular health recommendation would be beneficial in reducing the perceived threat.[37] Under this model, patient factors such as age, race, ethnicity, and education are posited to be associated with perceived severity (including knowledge of ESRD treatment and ACP) and the threat of kidney disease (expectations and beliefs surrounding ESRD treatments and advanced care preferences).

Intervention development

To support the development of the intervention, we conducted a qualitative study among key stakeholders and conducted a systematic literature review.

Qualitative study

We conducted in-depth interviews with clinicians (nephrologists and primary care physicians), older patients, and their caregivers at an academic medical center in Boston, Massachusetts.[38] Specifically, we assessed interviewees' prior experiences of discussions about renal replacement therapies and ACP. We found that nephrologists and primary care physicians were mostly aligned with respect to their roles in discussing dialysis and advance care planning. However, despite clarity about responsibilities and communication among nephrologists and primary care physicians, patients, and their caregivers were uncertain about the impact of dialysis on their lives as well as the importance of ACP. In developing interventional educational materials for the trial, we included key concepts about conservative kidney management and ACP that were most unclear to patients and caregivers based on what we learned in semi-structured interviews.

Educational materials

We also performed a literature review of published studies describing patient education and detailing programs that implemented conservative kidney management and ACP for patients with advanced chronic kidney disease. We subsequently developed a brief 8-page brochure and educational script based on existing materials and modified them after receiving input from patients with advanced CKD and their caregivers. The brochure was specifically created at a 6th-grade reading level to maximize understanding for patients.[39]

Intervention training

The principal investigator will train a nurse practitioner who is certified in serious illness communication and palliative care to deliver the intervention among all enrolled patients. Specifically, the nurse practitioner will be trained to discuss all treatment options (including conservative kidney management) and ACP. We will conduct this training in two half-day sessions followed by observed interactions with volunteer patients to determine competency in delivery of information.

Study design and setting

We will test the COPE intervention to provide education to patients with advanced CKD who are older and/or with poor functional status (defined as a Karnofsky Performance Index Score < 70[13]) in a single-center pilot randomized controlled trial (RCT). The objective of this intervention is to increase participants' knowledge of treatment options including conservative kidney management and ACP and improve communication of patients' treatment and care preferences with their clinicians and family members. We hypothesize that educating patients about treatment options, eliciting their treatment preferences, and communicating these with clinicians and families will promote patient engagement in ACP, improve informed treatment decision-making, and reduce racial disparities in knowledge and communication of care preferences. We will recruit patients from outpatient renal clinics associated with the University of Pennsylvania Perelman School of Medicine in Philadelphia, PA. The Institutional Review Board at the University of Pennsylvania has approved this study.

Participants

Those eligible to participate in this trial will be: 1) age ≥ 70 years and/or have poor functional status (defined as a Karnofsky Performance Index Score < 70[13]), 2) have advanced chronic kidney disease defined as having at least two eGFR measurements < 20 ml/min/1.73m^2

separated by at least three months,[40] 3) prefer to speak English-during clinical encounters, and 4) self-report as Black or White race. Exclusion criteria include being listed for kidney transplant, being legally blind, or screening positive for severe cognitive dysfunction defined as having 8 or more errors on the Short Portable Mental Status Questionnaire for assessment of organic brain deficit.[41] For potentially eligible patients < 70 years of age, we will ask treating clinicians to complete a Karnofsky Performance Index Score.

Recruitment

Research staff will access electronic medical records of clinic patients and nephrologists' list of patients with poor functional status to identify potential study participants. Prior to approaching patients to invite them to participate in the study, a study coordinator will also confirm study suitability with each patient's nephrologist. Given the diverse patient demographics in the outpatient renal clinics, we anticipate equal representation of Black and White patients.

Study procedures

Prior to the initiation of the pilot RCT, we will assess the feasibility and acceptability of COPE among a small sample of patients (n=10). Immediately after receiving education, patients will be asked to rate satisfaction on a Likert scale and usefulness based on the modified Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.[42] We will assess the reasons for refusal and attrition data before finalizing recruitment and study procedures.

We will randomize patients (n=100) in a 1:1 fashion with stratification by race to receive one of two arms: 1) enhanced usual care or 2) usual care plus COPE. We will collect baseline data for patients at the time of enrollment and prior to randomization (Table 1). Further data collection will take place via phone sessions at pre-specified time intervals (Figure 2).

Enhanced usual care

Nephrology care within the University of Pennsylvania system includes monthly pre-dialysis educational classes where patients with advanced CKD can learn more about CKD and treatment options for ESRD. The treatment options covered in the classes include hemodialysis, peritoneal dialysis, and kidney transplantation. Using a PowerPoint presentation, these sessions are provided in-person by nephrology nurse practitioners and typically last around 60 minutes. Patients' nephrologists may also provide ad hoc education during routine clinical visits. To ensure all enrolled patients receive similar education about conservative kidney management and ACP, everyone will receive the National Kidney Foundation's educational pamphlet titled "If you choose to not do dialysis".[43] This is a 16-page document that describes the process of not starting dialysis as well as advance care planning.

Intervention

The study coordinator will schedule an appointment for all enrolled patients to meet with the nurse practitioner to receive the COPE educational intervention within 2-4 weeks of enrollment. Intervention content includes a discussion about disease understanding, dialysis treatments, conservative kidney management, patient goals and values, and advance care planning. COPE will last approximately 45-60 minutes. After completion of COPE, the study principal investigator will communicate with the patient's primary care physician and primary nephrologist via joint standardized e-mails to notify them of their patient's enrollment in the study. All sessions will be audiotaped and two recordings will be randomly selected at 2-months intervals to assess the fidelity of the intervention. A study coordinator will complete the fidelity checklist and re-training of the nurse practitioner will occur if 80% of criteria are not met.

Outcomes

The primary outcome for this intervention is change in knowledge of conservative kidney management and ACP. Additional outcomes include assessing the feasibility and acceptability of COPE, patient communication of ESRD and advanced treatment preferences with clinicians and family members. We will also evaluate racial disparities in conservative kidney management, ACP knowledge and communication of care preferences. We will ascertain knowledge, treatment preferences, communication of preferences, and intervention acceptability via short questionnaires at the time points displayed in Figure 2.

We will also measure other outcomes including health literacy,[44] perceived mental and physical health status,[45,46] spiritual well-being,[47] perceived stress,[48] and quality of life[49], using validated surveys (Table 2). Patient demographics, whether patients have completed advance directives, and comorbidities will be ascertained via medical record review and surveys.

Analysis

Feasibility and acceptability

We will consider that the intervention has adequate feasibility if at least 70% of eligible patients who are approached provide consent and enroll in the study. Additionally, we will determine that adequate acceptability is achieved if at least 80% of patients have a mean score of ≥ 4.9 using the modified Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.[42]

CKM and ACP knowledge, communication and preferences

We will describe patient characteristics using proportions for categorical variables and means (± SD) or medians (interquartile range) for continuous variables as appropriate. We will test for differences in outcomes between study arms regarding: 1) change in conservative kidney management/ACP knowledge score, 2) ESRD treatment preference, 3) EOL preference, and 4) communication of preferences with clinicians and family members using univariate analyses (two-sample t-test, Wilcoxon rank-sum, or Chi-square test). Given the possibility of imbalance

of baseline characteristics between study arms due to small sample size, we will perform secondary analyses using multivariate linear and logistic regression to measure the independent association of the study arm with all outcomes adjusting for measured patient characteristics (age, sex, race, ethnicity, income level, education level, health literacy, and Charleston co-morbidity index). We will check for collinearity and interactions between variables and determine significance by a two-sided alpha level of 0.05.

Racial disparities

To determine whether the intervention reduces racial disparities in outcomes between Black and White patients, we will add an interaction term between race and study arm in the multivariate analyses. A p-value of 0.15 or less will be considered statistically significant when testing for interaction. All analyses will be done in SAS (Version 9.4, Cary, NC).

Power and sample size

Based on published data demonstrating poor knowledge of conservative kidney management among patients with advanced kidney disease,[50] we anticipate that recruitment of 50 patients to each arm will provide 85% power to detect an effect size of 0.5 SD when comparing the change in knowledge of conservative kidney management and advance care planning between the two groups.[51,52]

Discussion

COPE aims to improve knowledge about conservative kidney management and ACP as well as communication of care preferences for patients with advanced CKD who are older and/or who have poor functional status. Additionally, we expect that the intervention will reduce racial disparities in these outcomes among Black and White patients. We anticipate that COPE will

ultimately improve informed decision-making about ESRD treatments and encourage patients to engage in timely ACP discussions with their clinicians and family members.

This pilot RCT is designed to specifically evaluate an educational intervention for patients who are older and/or with poor functional status about conservative kidney management and ACP. Our intervention is informed by qualitative work among patients, caregivers, and clinicians and by a comprehensive review of existing literature. COPE consists of three novel components. First, we are targeting educational efforts towards patients who are older and/or with poor functional status, a group for whom there is often considerable uncertainty about the benefits versus the harms of dialysis. We will use questionnaires to identify knowledge gaps among patients to improve conservative kidney management and ACP education. Second, patients will receive conservative kidney management and ACP education that is integrated with rather than siloed from other aspects of advanced CKD care. Studies focused on dialysis decision-making among CKD patients are lacking.[30,32,53–56] Fully informing patients with advanced CKD of conservative kidney management options, as well as discussing their preferences for care at EOL allows patients to focus on values and goals that are most important to them. Third, we aim to reduce racial disparities in knowledge and communication of conservative kidney management and EOL preferences among patients with advanced CKD. Compared to White patients with CKD, Black patients have lower health literacy, less knowledge about treatment options for advanced kidney disease, and tend to have poor knowledge of support resources to cope with the disease.[57,58] Racial differences in knowledge outcomes may in part be due to the notion that educational interventions are developed to achieve a "one size fits all" standard. However, COPE has been developed with input from a diverse patient population of patients with CKD and with specific attention to communication

style and health literacy barriers. There are few existing ACP and conservative kidney management educational tools that account for knowledge differences among patients, which could ultimately help to reduce racial disparities in patient understanding of these aspects of care.[33,59]

There are a few limitations to this study. This is a single-center study and we will enroll patients who self-identify as White or Black. Thus, conclusions may not be generalizable to patients of different racial backgrounds or who live in other geographical locations. Additionally, shared decision-making includes patients, clinicians. and families, but our study will only measure patient outcomes. Lastly, we acknowledge that this study will focus on short-term outcomes and therefore we will be unable to comment on the downstream effects of the intervention. Future studies will confirm whether COPE has broad relevance and usefulness for similar patients with different demographics, feasibility and acceptability among clinicians and caregivers, and long-term outcomes such as treatment decision-making confidence and conflict.

Educating patients with advanced CKD who are older or seriously ill about ESRD treatment options (including conservative kidney management) and ACP is central to promoting shared decision-making and promoting goal-concordant care. We anticipate that our study findings will improve informed decision-making for patients with advanced chronic kidney disease and create an opportunity for clinicians to provide comprehensive patient-centered care for this vulnerable population.

Ethics and dissemination

This protocol has been approved by the Institutional Review Board at the University of Pennsylvania. Written informed consent will be obtained from all participants. The findings from

this work will be disseminated through peer-reviewed publications and will be presented at academic conferences.

Authors' contributions

Each author contributed important intellectual content during manuscript drafting or revision, and accepts personal accountability for the author's own contributions.

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Competing interests statement

All other authors declare that they have no relevant conflict of interests.

References Cited

1. United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

2. Kurella M, Covinsky KE, Collins AJ, Chertow GM. Octogenarians and nonagenarians starting dialysis in the United States. *Ann Intern Med*. 2007;146(3):177-183. doi:10.7326/0003-4819-146-3-200702060-00006

3. Tamura MK, 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):1539-1547. doi:10.1056/NEJMoa0904655

4. Weisbord SD, Fried LF, Arnold RM, et al. Prevalence, Severity, and Importance of Physical and Emotional Symptoms in Chronic Hemodialysis Patients. *J Am Soc Nephrol*. 2005;16(8):2487-2494. doi:10.1681/ASN.2005020157

5. McAdams-DeMarco MA, Law A, Salter ML, et al. Frailty as a Novel Predictor of Mortality and Hospitalization in Hemodialysis Patients of All Ages. *J Am Geriatr Soc*. 2013;61(6):896-901. doi:10.1111/jgs.12266

6. Verberne WR, Geers ABMT, Jellema WT, Vincent HH, van Delden JJM, Bos WJW. Comparative Survival among Older Adults with Advanced Kidney Disease Managed Conservatively Versus with Dialysis. *Clin J Am Soc Nephrol CJASN*. 2016;11(4):633-640. doi:10.2215/CJN.07510715

7. Pugh J, Aggett J, Goodland A, et al. Frailty and comorbidity are independent predictors of outcome in patients referred for pre-dialysis education. *Clin Kidney J*. 2016;9(2):324-329. doi:10.1093/ckj/sfv150

8. Song M-K. Quality of Life of Patients with Advanced Chronic Kidney Disease Receiving Conservative Care without Dialysis. *Semin Dial*. 2016;29(2):165-169. doi:10.1111/sdi.12472

9. Da Silva-Gane M, Wellsted D, Greenshields H, Norton S, Chandna SM, Farrington K. Quality of Life and Survival in Patients with Advanced Kidney Failure Managed Conservatively or by Dialysis. *Clin J Am Soc Nephrol CJASN*. 2012;7(12):2002-2009. doi:10.2215/CJN.01130112

10. Kurella Tamura M, Covinsky KE, Chertow GM, Yaffe K, Landefeld CS, McCulloch CE. Functional Status of Elderly Adults before and after Initiation of Dialysis. http://dx.doi.org/10.1056/NEJMoa0904655. doi:10.1056/NEJMoa0904655

11. Roshanravan B, Khatri M, Robinson-Cohen C, et al. A Prospective Study of Frailty in Nephrology-Referred Patients With CKD. *Am J Kidney Dis Off J Natl Kidney Found*. 2012;60(6):912-921. doi:10.1053/j.ajkd.2012.05.017

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. http://dx.doi.org/10.1056/NEJMoa0904655. doi:10.1056/NEJMoa0904655

13. 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. *Nephrol Dial Transplant Off Publ Eur Dial Transpl Assoc - Eur Ren Assoc*. 2019;34(9):1517-1525. doi:10.1093/ndt/gfy305

14. Morton RL, Howard K, Webster AC, Snelling P. Patient INformation about Options for Treatment (PINOT): a prospective national study of information given to incident CKD Stage 5 patients. *Nephrol Dial Transplant*. 2011;26(4):1266-1274. doi:10.1093/ndt/gfq555

15. Morton RL, Snelling P, Webster AC, et al. Factors influencing patient choice of dialysis versus conservative care to treat end-stage kidney disease. *CMAJ Can Med Assoc J J Assoc Medicale Can*. 2012;184(5):E277-283. doi:10.1503/cmaj.111355

16. Foote C, Morton RL, Jardine M, et al. COnsiderations of Nephrologists when SuggestIng Dialysis in Elderly patients with Renal failure (CONSIDER): a discrete choice experiment. *Nephrol Dial Transplant*. 2014;29(12):2302-2309. doi:10.1093/ndt/gfu257

17. Tonkin-Crine S, Okamoto I, Leydon GM, et al. Understanding by older patients of dialysis and conservative management for chronic kidney failure. *Am J Kidney Dis Off J Natl Kidney Found*. 2015;65(3):443-450. doi:10.1053/j.ajkd.2014.08.011

18. Eneanya ND, Paasche-Orlow MK, Volandes A. Palliative and end-of-life care in nephrology: moving from observations to interventions. *Curr Opin Nephrol Hypertens*. 2017;26(4):327-334. doi:10.1097/MNH.0000000000000337

19. Tamura MK, Goldstein MK, Pérez-Stable EJ. Preferences for dialysis withdrawal and engagement in advance care planning within a diverse sample of dialysis patients. *Nephrol Dial Transplant*. 2010;25(1):237-242. doi:10.1093/ndt/gfp430

20. Fried TR, Redding CA, Robbins ML, Paiva AL, O'Leary JR, Iannone L. Development of Personalized Health Messages to Promote Engagement in Advance Care Planning. *J Am Geriatr Soc*. 2016;64(2):359-364. doi:10.1111/jgs.13934

21. Eneanya ND, Wenger JB, Waite K, et al. Racial Disparities in End-of-Life Communication and Preferences among Chronic Kidney Disease Patients. *Am J Nephrol*. 2016;44(1):46-53. doi:10.1159/000447097

22. Goff SL, Eneanya ND, Feinberg R, et al. Advance care planning: a qualitative study of dialysis patients and families. *Clin J Am Soc Nephrol CJASN*. 2015;10(3):390-400. doi:10.2215/CJN.07490714

23. Sudore RL, Schickedanz AD, Landefeld CS, et al. Engagement in Multiple Steps of the Advance Care Planning Process: A Descriptive Study Among Diverse Older Adults. *J Am Geriatr Soc*. 2008;56(6):1006-1013. doi:10.1111/j.1532-5415.2008.01701.x

24. Detering KM, Hancock AD, Reade MC, Silvester W. The impact of advance care planning on end of life care in elderly patients: randomised controlled trial. *BMJ*. 2010;340:c1345. doi:10.1136/bmj.c1345

25. Greer JA, Pirl WF, Jackson VA, et al. Effect of early palliative care on chemotherapy use and end-of-life care in patients with metastatic non-small-cell lung cancer. *J Clin Oncol Off J Am Soc Clin Oncol*. 2012;30(4):394-400. doi:10.1200/JCO.2011.35.7996

26. Temel JS, Greer JA, Admane S, et al. Longitudinal Perceptions of Prognosis and Goals of Therapy in Patients With Metastatic Non–Small-Cell Lung Cancer: Results of a Randomized Study of Early Palliative Care. *J Clin Oncol*. 2011;29(17):2319-2326. doi:10.1200/JCO.2010.32.4459

27. Braddock CH, Edwards KA, Hasenberg NM, Laidley TL, Levinson W. Informed decision making in outpatient practice: time to get back to basics. *JAMA*. 1999;282(24):2313-2320. doi:10.1001/jama.282.24.2313

28. Mack JW, Cronin A, Taback N, et al. End-of-life care discussions among patients with advanced cancer: a cohort study. *Ann Intern Med*. 2012;156(3):204-210. doi:10.7326/0003-4819-156-3-201202070-00008

29. 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. doi:10.2215/CJN.05960809

30. Moss AH. Revised Dialysis Clinical Practice Guideline Promotes More Informed Decision-Making. *Clin J Am Soc Nephrol*. 2010;5(12):2380-2383. doi:10.2215/CJN.07170810

31. Moss AH. Ethical Principles and Processes Guiding Dialysis Decision-Making. *Clin J Am Soc Nephrol*. 2011;6(9):2313-2317. doi:10.2215/CJN.03960411

32. Tamura MK, Meier DE. Five Policies to Promote Palliative Care for Patients with ESRD. *Clin J Am Soc Nephrol*. 2013;8(10):1783-1790. doi:10.2215/CJN.02180213

33. Song M-K, Ward SE, Lin F-C, et al. Racial Differences in Outcomes of an Advance Care Planning Intervention for Dialysis Patients and Their Surrogates. *J Palliat Med*. 2016;19(2):134-142. doi:10.1089/jpm.2015.0232

34. Thomas BA, Rodriguez RA, Boyko EJ, Robinson-Cohen C, Fitzpatrick AL, O'Hare AM. Geographic Variation in Black–White Differences in End-of-Life Care for Patients with ESRD. *Clin J Am Soc Nephrol*. Published online April 11, 2013:CJN.06780712. doi:10.2215/CJN.06780712

35. Eneanya ND, Olaniran K, Xu D, et al. Health Literacy Mediates Racial Disparities in Cardiopulmonary Resuscitation Knowledge among Chronic Kidney Disease Patients. *J Health Care Poor Underserved*. 2018;29(3):1069-1082. doi:10.1353/hpu.2018.0080

36. Eneanya ND, Wenger JB, Waite K, et al. Racial Disparities in End-of-Life Communication and Preferences among Chronic Kidney Disease Patients. *Am J Nephrol*. 2016;44(1):46-53. doi:10.1159/000447097

37. Rosenstock IM, Strecher VJ, Becker MH. Social Learning Theory and the Health Belief Model. *Health Educ Q*. 1988;15(2):175-183. doi:10.1177/109019818801500203

38. Eneanya ND, Labbe AK, Stallings TL, et al. Caring for older patients with advanced chronic kidney disease and considering their needs: a qualitative study. *BMC Nephrol*. 2020;21(1):213. doi:10.1186/s12882-020-01870-1

39. Institute of Medicine (US) Committee on Health Literacy. *Health Literacy: A Prescription to End Confusion*. (Nielsen-Bohlman L, Panzer AM, Kindig DA, eds.). National Academies Press (US); 2004. Accessed June 15, 2020. http://www.ncbi.nlm.nih.gov/books/NBK216032/

40. Levey AS, Bosch JP, Lewis JB, Greene T, Rogers N, Roth D. A more accurate method to estimate glomerular filtration rate from serum creatinine: a new prediction equation. Modification of Diet in Renal Disease Study Group. *Ann Intern Med*. 1999;130(6):461-470. doi:10.7326/0003-4819-130-6-199903160-00002

41. Pfeiffer E. A Short Portable Mental Status Questionnaire for the Assessment of Organic Brain Deficit in Elderly Patients†. *J Am Geriatr Soc*. 1975;23(10):433-441. doi:10.1111/j.1532-5415.1975.tb00927.x

42. Winterbottom AE, Gavaruzzi T, Mooney A, et al. Patient Acceptability of the Yorkshire Dialysis Decision Aid (YoDDA) Booklet: A Prospective Non-Randomized Comparison Study Across 6 Predialysis Services. *Perit Dial Int J Int Soc Perit Dial*. 2016;36(4):374-381. doi:10.3747/pdi.2014.00274

43. The National Kidney Foundation. If You Choose Not To Start Dialysis Treatment. Published 2008. Accessed April 15, 2020. https://www.kidney.org/sites/default/files/11-10-0330_ifyouchoose.pdf

44. Cavanaugh KL, Wingard RL, Hakim RM, et al. Low Health Literacy Associates with Increased Mortality in ESRD. *J Am Soc Nephrol JASN*. 2010;21(11):1979-1985. doi:10.1681/ASN.2009111163

45. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care*. 1992;30(6):473-483.

46. Wight JP, Edwards L, Brazier J, Walters S, Payne JN, Brown CB. The SF36 as an outcome measure of services for end stage renal failure. *Qual Health Care QHC*. 1998;7(4):209-221.

47. Peterman AH, Fitchett G, Brady MJ, Hernandez L, Cella D. Measuring spiritual well-being in people with cancer: the functional assessment of chronic illness therapy--Spiritual Well-being Scale (FACIT-Sp). *Ann Behav Med Publ Soc Behav Med*. 2002;24(1):49-58. doi:10.1207/S15324796ABM2401_06

48. Taylor JM. Psychometric analysis of the Ten-Item Perceived Stress Scale. *Psychol Assess*. 2015;27(1):90-101. doi:10.1037/a0038100

49. Robin Cohen S, Mount BM, Bruera E, Provost M, Rowe J, Tong K. Validity of the McGill Quality of Life Questionnaire in the palliative care setting: a multi-centre Canadian study demonstrating the importance of the existential domain. *Palliat Med*. 1997;11(1):3-20. doi:10.1177/026921639701100102

50. Prakash S, McGrail A, Lewis SA, et al. Behavioral stage of change and dialysis decision-making. *Clin J Am Soc Nephrol CJASN*. 2015;10(2):197-204. doi:10.2215/CJN.05560614

51. Norman G, Sloan J, Wyrwich K. Interpretation of Changes in Health-related Quality of Life: The Remarkable Universality of Half a Standard Deviation. *Med Care*. 2003;41(5):582-592. doi:10.1097/01.MLR.0000062554.74615.4C

52. Cohen J. *Statistical Power Analysis for the Behavioral Sciences.* Taylor and Francis; 2013. Accessed June 15, 2020. http://www.123library.org/book_details/?id=107447

53. Saeed F, Adams H, Epstein RM. Matters of Life and Death: Why Do Older Patients Choose Conservative Management? *Am J Nephrol*. 2020;51(1):35-42. doi:10.1159/000504692

54. Saeed F, Sardar M, Rasheed K, et al. Dialysis Decision-Making and Preferences for End-of-Life Care: Perspectives of Pakistani Patients Receiving Maintenance Dialysis. *J Pain Symptom Manage*. Published online March 20, 2020. doi:10.1016/j.jpainsymman.2020.03.009

55. Verberne WR, Konijn WS, Prantl K, et al. Older patients' experiences with a shared decision-making process on choosing dialysis or conservative care for advanced chronic kidney disease: a survey study. *BMC Nephrol*. 2019;20(1):264. doi:10.1186/s12882-019-1423-x

56. 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

57. Kazley AS, Johnson E, Simpson K, Chavin K, Baliga P. African American patient knowledge of kidney disease: A qualitative study of those with advanced chronic kidney disease. *Chronic Illn*. 2015;11(4):245-255. doi:10.1177/1742395314556658

58. Grubbs V, Gregorich SE, Perez-Stable EJ, Hsu C. Health Literacy and Access to Kidney Transplantation. *Clin J Am Soc Nephrol CJASN*. 2009;4(1):195-200. doi:10.2215/CJN.03290708

59. Song M-K, Ward SE, Fine JP, et al. Advance Care Planning and End-of-Life Decision Making in Dialysis: A Randomized Controlled Trial Targeting Patients and Their Surrogates. *Am J Kidney Dis Off J Natl Kidney Found*. 2015;66(5):813-822. doi:10.1053/j.ajkd.2015.05.018

Table 1.Demographic, clinical and knowledge outcomes

Patient demographics	Age, sex, race, ethnicity, marital status, employment status, annual household income, health insurance coverage
Knowledge	Conservative kidney management and advance care planning
Additional information	Completion of advanced directives, Charlson Comorbidity Index scores, end-stage renal disease treatment preferences, end-of-life preferences

Table 2. Other patient outcomes

Questionnaire	Items	Domain
Cognition Short Portable Mental Status Questionnaire	10	Cognition
Rapid Estimate of Adult Literacy in Medicine	66	Health literacy
Perceived Stress Scale	4	Perceived stress
Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being	12	Spiritual well-being
Modified Yorkshire Dialysis Decision Aid Usefulness Scale	4	Program usefulness
Patient Activation Measure	13	Patient activation
McGill Quality of Life Questionnaire: Part A	1	Quality of life
Satisfaction of Educational Program	1	Program satisfaction

Figure 1. Health Belief Model (adapted for COPE)

Abbreviations: ACP = Advance are planning, CKM = Conservative kidney management, ESRD = End-stage renal disease

Figure 2. Study flow chart

Abbreviations: FACIT-SP-12=Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being, KPS=Karnofsky Performance Index Score, PAM=Patient Activation Measure, PSS-4=Perceived Stress Scale, QOL=McGill Quality of Life Questionnaire-Part A, REALM=Rapid Estimate of Adult Literacy in Medicine, SPMSQ=Short Portable Mental Status Questionnaire, YoDDA=Modified Yorkshire Dialysis Decision Aid.

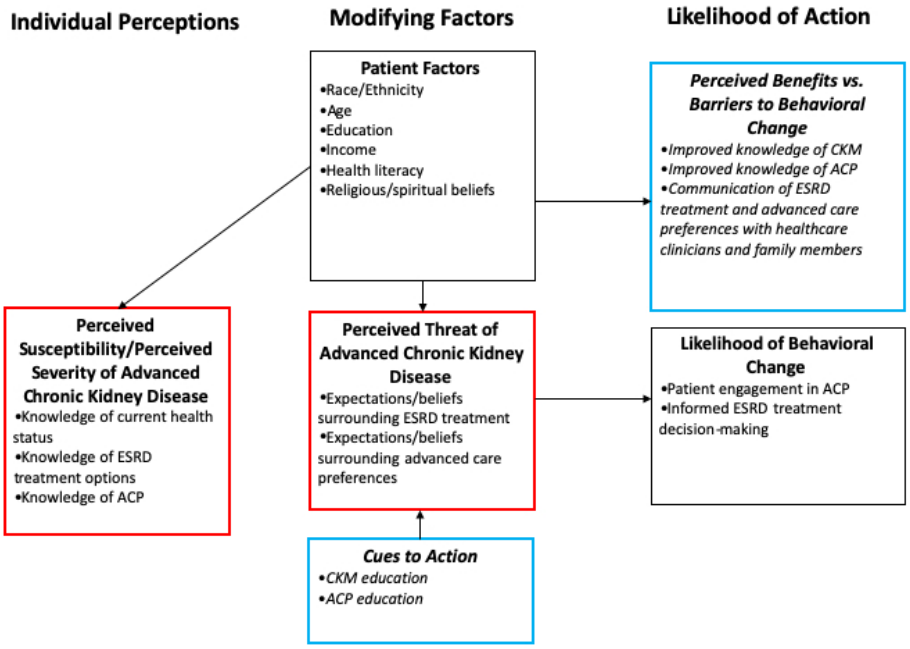

Figure 1. Health Belief Model (adapted for COPE)

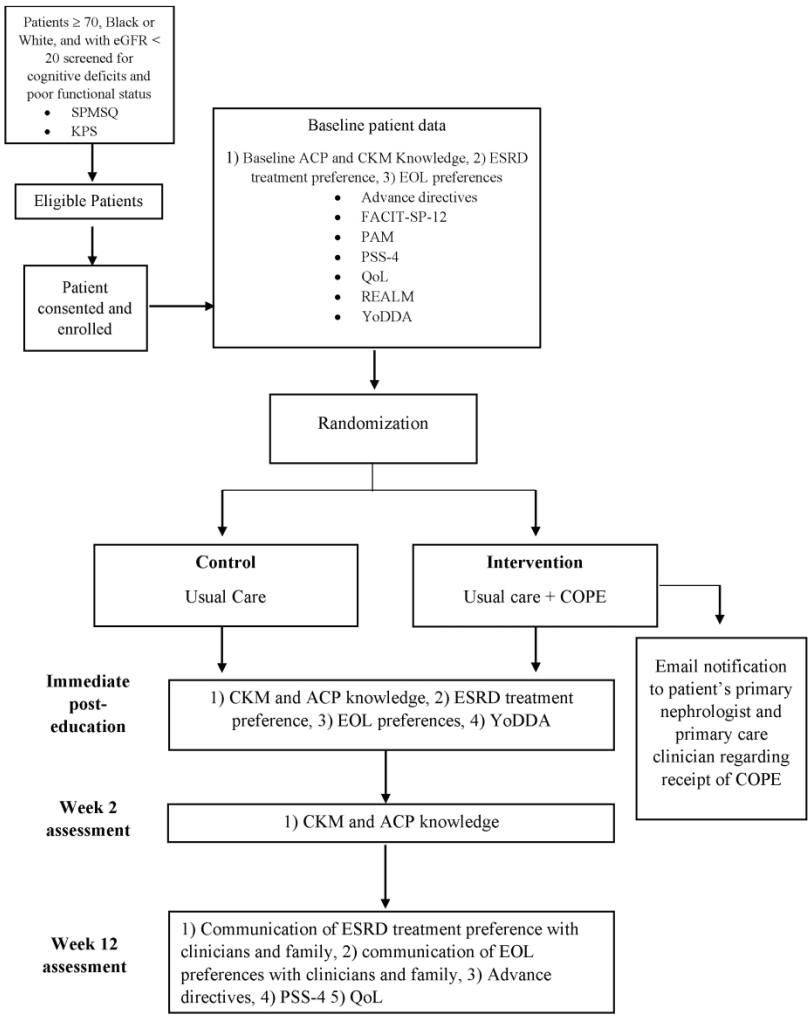

Figure 2. Study flow chart

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Integrating conservative kidney management options and advance care planning education (COPE) into routine CKD care: a protocol for a pilot randomized controlled trial

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Title: Integrating conservative kidney management options and advance care planning **e**ducation (COPE) into routine CKD care: a protocol for a pilot randomized controlled trial

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Abstract:

Introduction: Pre-dialysis education for patients with advanced chronic kidney disease (CKD) typically focuses narrowly on hemodialysis and peritoneal dialysis as future treatment options. However, patients who are older or seriously ill may not want to pursue dialysis and/or may not benefit from this treatment. Conservative kidney management, a reasonable alternative treatment, and advance care planning (ACP) are often left out of patient education and shared decision-making. In this study, we will pilot an educational intervention (**C**onservative Kidney Management **O**ptions and Advance Care **P**lanning **E**ducation – COPE) to improve knowledge of conservative kidney management and ACP among patients with advanced CKD who are older and/or who have poor functional status.

Methods and analysis: This is a single-center pilot randomized controlled trial at an academic center in Philadelphia, PA. Eligible patients will have: age ≥ 70 years of age and/or poor functional status (as defined by Karnofsky Performance Index Score < 70), advanced CKD (eGFR < 20 ml/min/1.73m^2), prefer to speak English-during clinical encounters, and self-report as Black or White race. Enrolled patients will be randomized 1:1, with stratification by race, to receive enhanced usual care or usual care plus in-person education about conservative kidney management and ACP (COPE). The primary outcome is change in knowledge of CKM and ACP. We will also explore intervention feasibility and acceptability, change in communication of preferences, and differences in the intervention's effects on knowledge and communication of preferences by race. We will assess outcomes at baseline, immediately post-education, and at 2 and 12 weeks.

Ethics and dissemination: This protocol has been approved by the Institutional Review Board at the University of Pennsylvania. We will obtain written informed consent from all participants.

The results from this work will be presented at academic conferences and disseminated through peer-reviewed journals.

Trial registration: This trial is registered at ClinicalTrials.gov under NCT03229811.
Key words: Advanced chronic kidney disease, conservative kidney management, advance care planning, racial disparities

Strengths and limitations of this study:

- This is a pilot randomized controlled trial evaluating an intervention designed to primarily educate older and seriously ill patients with advanced CKD about conservative kidney management and advance care planning.
- Patients will receive an educational intervention that is integrated into their advanced CKD care.
- We anticipate that the intervention will reduce racial disparities between Black and White patients in knowledge about conservative kidney management and advance care planning.
- As this study is being conducted at a single-center and is being limited to White and Black patients, we are unable to generalize study results to different regions or patients of different races or ethnicities.

Introduction

The benefits of dialysis remain uncertain for older and seriously ill patients with advanced chronic kidney disease (CKD). In the United States, over 720,000 individuals have kidney failure with 87.3% of these patients ultimately receiving hemodialysis.[1] For older and frail patients with advanced CKD, it is unclear whether dialysis improves health or survival, with some evidence to suggest that it can negatively impact quality of life and functional status.[2–9] Additionally, patients of all ages with CKD have a higher prevalence of frailty and poor functional status, which is an independent risk factor for mortality and increased hospitalizations.[3,5,7,10,11]

Conservative kidney management is an approach to care for patients with kidney failure who do not want to pursue dialysis or who are unlikely to benefit from this treatment, especially those who are older with functional limitations.[6–9] This is non-dialytic therapy that focuses on slowing the progression of kidney disease with medications and fosters a multidisciplinary approach to address care needs and emotional and physical symptoms associated with kidney failure. However, many care models of conservative kidney management have been developed outside of the United States, and implementation strategies have not been investigated in this country.[8,12–14]

Patients with advanced CKD who are managed with conservative kidney management are more likely to receive palliative care consultation, use hospice, and discuss goals of care.[14,15] Advance care planning (ACP) is a process in which clinicians elicit and document patients' values and desired goals of care as their health deteriorates and/or if they were to become incapacitated.[16–22] Among seriously ill patients, early discussions about advanced care preferences improve patients' understanding of their health status and facilitate more informed ACP and decision-making.[23–26] Specifically, studies have demonstrated that as for other patient

populations, patients with advanced CKD would prefer to have ACP and goals of care discussions earlier in the disease course.[19,27] However, these conversations are often challenging and available evidence suggests that nephrologists tend not to engage in ACP with their patients.[19,27–30] Additionally, some studies have shown racial disparities in ACP knowledge, and that racial-ethnic minority patients are less likely to engage in goals of care discussions and advance care planning when compared to White patients.[16,18,31,32] Education and improving informed decision-making may mitigate racial disparities in care for older patients with CKD.[18,33] Thus, we are testing whether a novel educational intervention incorporated into routine advanced CKD care, called **C**onservative Kidney Management **O**ptions and Advance Care **P**lanning **E**ducation (COPE), can improve knowledge and communication among patients who are older and/or with poor functional status.

Methodology and analysis

Conceptual framework

The COPE intervention has been developed to address patient knowledge, expectations, and beliefs of kidney failure treatments and ACP (Figure 1). The conceptual framework for this intervention is adapted from the Health Belief Model (Figure 1).[34] This model hypothesizes that health-related action depends on the simultaneous occurrence of three factors: 1) the existence of sufficient motivation to make health issues salient or relevant; 2) the belief that one is susceptible to a serious health problem or sequelae of that illness or condition (e.g., perceived threat); and 3) the belief that following a particular health recommendation would be beneficial in reducing the perceived threat[34] Under this model, patient factors such as age, race, ethnicity, and education are posited to be associated with perceived severity (including knowledge of kidney failure treatment and ACP) and the threat of kidney disease (expectations and beliefs surrounding kidney failure treatments and advanced care preferences).

Intervention development

To support the development of the intervention, we conducted a qualitative study among key stakeholders and conducted a systematic literature review.

Qualitative study

We conducted in-depth interviews with clinicians (nephrologists and primary care physicians), older patients, and their caregivers at an academic medical center in Boston, Massachusetts.[35] Specifically, we assessed interviewees' prior experiences of discussions about kidney replacement therapies and ACP. We found that nephrologists and primary care physicians were mostly aligned with respect to their roles in discussing dialysis and advance care planning. However, despite clarity about responsibilities and communication among nephrologists and primary care physicians, patients, and their caregivers were uncertain about the impact of dialysis on their lives as well as the importance of ACP. In developing interventional educational materials for the trial, we included key concepts about conservative kidney management and ACP that were most unclear to patients and caregivers based on what we learned in semi-structured interviews.

Educational materials

We also performed a literature review of published studies describing patient education and detailing programs that implemented conservative kidney management and ACP for patients with advanced chronic kidney disease. We subsequently developed a brief 8-page brochure and educational script based on existing materials and modified them after receiving input from patients with advanced CKD and their caregivers. The brochure was specifically created at a 6th-grade reading level to maximize understanding for patients.[36]

Intervention training

The principal investigator will train a nurse practitioner who is certified in serious illness communication and palliative care to deliver the intervention among all enrolled patients. Specifically, the nurse practitioner will be trained to discuss all treatment options (including conservative kidney management) and ACP. We will conduct this training in two half-day sessions followed by observed interactions with volunteer patients to determine competency in delivery of information.

Study design and setting

We will test the COPE intervention to provide education to patients with advanced CKD who are older and/or with poor functional status (defined as a Karnofsky Performance Index Score < 70[11]) in a single-center pilot randomized controlled trial (RCT). The objective of this intervention is to increase participants' knowledge of treatment options including conservative kidney management and ACP and improve communication of patients' treatment and care preferences with their clinicians and family members. We hypothesize that educating patients about treatment options, eliciting their treatment preferences, and communicating these with clinicians and families will promote patient engagement in ACP, improve informed treatment decision-making, and reduce racial disparities in knowledge and communication of care preferences. We will recruit patients from outpatient renal clinics associated with the University of Pennsylvania Perelman School of Medicine in Philadelphia, PA. The Institutional Review Board at the University of Pennsylvania has approved this study.

Participants

Those eligible to participate in this trial will be: 1) age ≥ 70 years and/or have poor functional status (defined as a Karnofsky Performance Index Score < 70[11]), 2) have advanced chronic kidney disease defined as having at least two eGFR measurements < 20 ml/min/1.73m^2

separated by at least three months,[37] 3) prefer to speak English-during clinical encounters, and 4) self-report as Black or White race. Exclusion criteria include being listed for kidney transplant, being legally blind, or screening positive for severe cognitive dysfunction defined as having 8 or more errors on the Short Portable Mental Status Questionnaire for assessment of organic brain deficit.[38] For potentially eligible patients < 70 years of age, we will ask treating clinicians to complete a Karnofsky Performance Index Score.

Recruitment

Research staff will access electronic medical records of clinic patients and nephrologists' list of patients with poor functional status to identify potential study participants. Prior to approaching patients to invite them to participate in the study, a study coordinator will also confirm study suitability with each patient's nephrologist. Given the diverse patient demographics in the outpatient renal clinics, we anticipate equal representation of Black and White patients.

Study procedures

Prior to the initiation of the pilot RCT, we will assess the feasibility and acceptability of COPE among a small sample of patients (n=10). Immediately after receiving education, patients will be asked to rate satisfaction on a Likert scale and usefulness based on the modified Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.[39] We will assess the reasons for refusal and attrition data before finalizing recruitment and study procedures.

We will randomize patients (n=100) in a 1:1 fashion with stratification by race to receive one of two arms: 1) enhanced usual care or 2) usual care plus COPE. We will collect baseline data for patients at the time of enrollment and prior to randomization (Table 1). Further data collection will take place via phone sessions at pre-specified time intervals (Figure 2).

Enhanced usual care

Nephrology care within the University of Pennsylvania system includes monthly pre-dialysis educational classes where patients with advanced CKD can learn more about CKD and treatment options for kidney failure. The treatment options covered in the classes include hemodialysis, peritoneal dialysis, and kidney transplantation. Using a PowerPoint presentation, these sessions are provided in-person by nephrology nurse practitioners and typically last around 60 minutes. Patients' nephrologists may also provide ad hoc education during routine clinical visits. To ensure all enrolled patients receive similar education about conservative kidney management and ACP, everyone will receive the National Kidney Foundation's educational pamphlet titled "If you choose to not do dialysis".[40] This is a 16-page document that describes the process of not starting dialysis as well as advance care planning.

Intervention

The study coordinator will schedule an appointment for all enrolled patients to meet with the nurse practitioner to receive the COPE educational intervention within 2-4 weeks of enrollment. The intervention will be a one-time visit with the primary goal of educating patients about treatment options and ACP. Intervention content includes a discussion about disease understanding, dialysis treatments, conservative kidney management, patient goals and values, and advance care planning (including review of state-specific advance directives). COPE will last approximately 45-60 minutes. Patients may invite family members and other loved ones to attend the educational sessions although only patient participants will complete survey items. After completion of COPE, the study principal investigator will communicate with the patient's primary care physician and primary nephrologist via joint standardized e-mails to notify them of their patient's enrollment in the study. All sessions will be audiotaped and two recordings will be randomly selected at 2-months intervals to assess the fidelity of the intervention. A study

coordinator will complete the fidelity checklist and re-training of the nurse practitioner will occur if 80% of criteria are not met.

Outcomes

The primary outcome for this intervention is change in knowledge of conservative kidney management and ACP. Additional outcomes include assessing the feasibility and acceptability of COPE, patient communication of kidney failure and advanced care treatment preferences with clinicians and family members. We will also evaluate racial disparities in conservative kidney management, ACP knowledge and communication of care preferences. We will ascertain knowledge, treatment preferences, communication of preferences, and intervention acceptability via short questionnaires at the time points displayed in Figure 2.

We will also measure other outcomes including health literacy,[41] perceived mental and physical health status,[42,43] spiritual well-being,[44] perceived stress,[45] and quality of life[46], using validated surveys (Table 2). Patient demographics, whether patients have completed advance directives, and comorbidities will be ascertained via medical record review and surveys.

Analysis

Feasibility and acceptability

We will consider that the intervention has adequate feasibility if at least 70% of eligible patients who are approached provide consent and enroll in the study. Additionally, we will determine that adequate acceptability is achieved if at least 80% of patients have a mean score of ≥ 4.9 using the modified Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.[39]

CKM and ACP knowledge, communication and preferences

We will describe patient characteristics using proportions for categorical variables and means (± SD) or medians (interquartile range) for continuous variables as appropriate. We will test for differences in outcomes between study arms regarding: 1) change in conservative kidney

management/ACP knowledge score, 2) kidney failure treatment preference, 3) EOL preference, and 4) communication of preferences with clinicians and family members using univariate analyses (two-sample t-test, Wilcoxon rank-sum, or Chi-square test). Given the possibility of imbalance of baseline characteristics between study arms due to small sample size, we will perform secondary analyses using multivariate linear and logistic regression to measure the independent association of the study arm with all outcomes adjusting for measured patient characteristics (age, sex, race, ethnicity, income level, education level, health literacy, and Charleston co-morbidity index). We will check for collinearity and interactions between variables and determine significance by a two-sided alpha level of 0.05.

Racial disparities

To determine whether the intervention reduces racial disparities in outcomes between Black and White patients, we will add an interaction term between race and study arm in the multivariate analyses. A p-value of 0.15 or less will be considered statistically significant when testing for interaction. All analyses will be done in SAS (Version 9.4, Cary, NC).

Power and sample size

Based on published data demonstrating poor knowledge of conservative kidney management among patients with advanced kidney disease,[47] we anticipate that recruitment of 50 patients to each arm will provide 85% power to detect an effect size of 0.5 SD when comparing the change in knowledge of conservative kidney management and advance care planning between the two groups.[48,49]

Discussion

COPE aims to improve knowledge about conservative kidney management and ACP as well as communication of care preferences for patients with advanced CKD who are older and/or

who have poor functional status. Additionally, we expect that the intervention will reduce racial disparities in these outcomes among Black and White patients. We anticipate that COPE will ultimately improve informed decision-making about kidney failure treatments and encourage patients to engage in timely ACP discussions with their clinicians and family members.

This pilot RCT is designed to specifically evaluate an educational intervention for patients who are older and/or with poor functional status about conservative kidney management and ACP. Our intervention is informed by qualitative work among patients, caregivers, and clinicians and by a comprehensive review of existing literature. COPE consists of three novel components. First, we are targeting educational efforts towards patients who are older and/or with poor functional status, a group for whom there is often considerable uncertainty about the benefits versus the harms of dialysis. We will use questionnaires to identify knowledge gaps among patients to improve conservative kidney management and ACP education. Second, patients will receive conservative kidney management and ACP education that is integrated with rather than siloed from other aspects of advanced CKD care. Studies focused on dialysis decision-making among CKD patients are lacking.[29,30,50–53] Fully informing patients with advanced CKD of conservative kidney management options, as well as discussing their preferences for care at EOL allows patients to focus on values and goals that are most important to them. Third, we aim to reduce racial disparities in knowledge and communication of conservative kidney management and EOL preferences among patients with advanced CKD. Compared to White patients with CKD, Black patients have lower health literacy, less knowledge about treatment options for advanced kidney disease, and tend to have poor knowledge of support resources to cope with the disease.[54,55] Racial differences in knowledge outcomes may in part be due to the notion that educational interventions are developed to

achieve a "one size fits all" standard. However, COPE has been developed with input from a diverse patient population of patients with CKD and with specific attention to communication style and health literacy barriers. There are few existing ACP and conservative kidney management educational tools that account for knowledge differences among patients, which could ultimately help to reduce racial disparities in patient understanding of these aspects of care.[31,56]

There are a few limitations to this study. This is a single-center study and we will enroll patients who self-identify as White or Black. Thus, conclusions may not be generalizable to patients of different racial backgrounds or who live in other geographical locations. Additionally, shared decision-making includes patients, clinicians, and families, but our study will only measure patient outcomes. Lastly, we acknowledge that this study will focus on short-term outcomes and therefore we will be unable to comment on the downstream effects of the intervention. Future studies will confirm whether COPE has broad relevance and usefulness for similar patients with different demographics, feasibility and acceptability among clinicians and caregivers, and long-term outcomes such as treatment decision-making confidence and conflict.

Educating patients with advanced CKD who are older or seriously ill about kidney failure treatment options (including conservative kidney management) and ACP is central to promoting shared decision-making and promoting goal-concordant care. We anticipate that our study findings will improve informed decision-making for patients with advanced chronic kidney disease and create an opportunity for clinicians to provide comprehensive patient-centered care for this vulnerable population.

Ethics and dissemination

This protocol has been approved by the Institutional Review Board at the University of Pennsylvania. Written informed consent will be obtained from all participants. The findings from this work will be disseminated through peer-reviewed publications and will be presented at academic conferences.

Authors' contributions

Research idea and study design: NDE, JST MKP, MA, AO; Preparation of manuscript: TLS, NDE; Critical revision of manuscript: TLS, JST, TAK, MKP, MA, AO, NOC, LMD, SDH, NDE; Supervision or mentorship: NDE, JST, LMD, SDH. All authors take responsibility for the integrity and accuracy of this manuscript's content and have approved the final draft for submission.

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Competing interests statement

All other authors declare that they have no relevant conflict of interests.

References Cited

1. United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

2. Kurella M, Covinsky KE, Collins AJ, Chertow GM. Octogenarians and nonagenarians starting dialysis in the United States. *Ann Intern Med*. 2007;146(3):177-183. doi:10.7326/0003-4819-146-3-200702060-00006

3. Kurella Tamura M, Covinsky KE, Chertow GM, Yaffe K, Landefeld CS, McCulloch CE. Functional Status of Elderly Adults before and after Initiation of Dialysis. http://dx.doi.org/10.1056/NEJMoa0904655. doi:10.1056/NEJMoa0904655

4. Weisbord SD, Fried LF, Arnold RM, et al. Prevalence, Severity, and Importance of Physical and Emotional Symptoms in Chronic Hemodialysis Patients. *J Am Soc Nephrol*. 2005;16(8):2487-2494. doi:10.1681/ASN.2005020157

5. McAdams-DeMarco MA, Law A, Salter ML, et al. Frailty as a Novel Predictor of Mortality and Hospitalization in Hemodialysis Patients of All Ages. *J Am Geriatr Soc*. 2013;61(6):896-901. doi:10.1111/jgs.12266

6. Verberne WR, Geers ABMT, Jellema WT, Vincent HH, van Delden JJM, Bos WJW. Comparative Survival among Older Adults with Advanced Kidney Disease Managed Conservatively Versus with Dialysis. *Clin J Am Soc Nephrol CJASN*. 2016;11(4):633-640. doi:10.2215/CJN.07510715

7. Pugh J, Aggett J, Goodland A, et al. Frailty and comorbidity are independent predictors of outcome in patients referred for pre-dialysis education. *Clin Kidney J*. 2016;9(2):324-329. doi:10.1093/ckj/sfv150

8. Song M-K. Quality of Life of Patients with Advanced Chronic Kidney Disease Receiving Conservative Care without Dialysis. *Semin Dial*. 2016;29(2):165-169. doi:10.1111/sdi.12472

9. Da Silva-Gane M, Wellsted D, Greenshields H, Norton S, Chandna SM, Farrington K. Quality of Life and Survival in Patients with Advanced Kidney Failure Managed Conservatively or by Dialysis. *Clin J Am Soc Nephrol CJASN*. 2012;7(12):2002-2009. doi:10.2215/CJN.01130112

10. Roshanravan B, Khatri M, Robinson-Cohen C, et al. A Prospective Study of Frailty in Nephrology-Referred Patients With CKD. *Am J Kidney Dis Off J Natl Kidney Found*. 2012;60(6):912-921. doi:10.1053/j.ajkd.2012.05.017

11. 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. *Nephrol Dial Transplant Off Publ Eur Dial Transpl Assoc - Eur Ren Assoc*. 2019;34(9):1517-1525. doi:10.1093/ndt/gfy305

12. Morton RL, Snelling P, Webster AC, et al. Factors influencing patient choice of dialysis versus conservative care to treat end-stage kidney disease. *CMAJ Can Med Assoc J J Assoc Medicale Can*. 2012;184(5):E277-283. doi:10.1503/cmaj.111355

13. Foote C, Morton RL, Jardine M, et al. COnsiderations of Nephrologists when SuggestIng Dialysis in Elderly patients with Renal failure (CONSIDER): a discrete choice experiment. *Nephrol Dial Transplant*. 2014;29(12):2302-2309. doi:10.1093/ndt/gfu257

14. Tonkin-Crine S, Okamoto I, Leydon GM, et al. Understanding by Older Patients of Dialysis and Conservative Management for Chronic Kidney Failure. *Am J Kidney Dis*. 2015;65(3):443-450. doi:10.1053/j.ajkd.2014.08.011

15. Eneanya ND, Paasche-Orlow MK, Volandes A. Palliative and end-of-life care in nephrology: moving from observations to interventions. *Curr Opin Nephrol Hypertens*. 2017;26(4):327-334. doi:10.1097/MNH.0000000000000337

16. Tamura MK, Goldstein MK, Pérez-Stable EJ. Preferences for dialysis withdrawal and engagement in advance care planning within a diverse sample of dialysis patients. *Nephrol Dial Transplant*. 2010;25(1):237-242. doi:10.1093/ndt/gfp430

17. Fried TR, Redding CA, Robbins ML, Paiva AL, O'Leary JR, Iannone L. Development of Personalized Health Messages to Promote Engagement in Advance Care Planning. *J Am Geriatr Soc*. 2016;64(2):359-364. doi:10.1111/jgs.13934

18. Eneanya ND, Wenger JB, Waite K, et al. Racial Disparities in End-of-Life Communication and Preferences among Chronic Kidney Disease Patients. *Am J Nephrol*. 2016;44(1):46-53. doi:10.1159/000447097

19. Goff SL, Eneanya ND, Feinberg R, et al. Advance care planning: a qualitative study of dialysis patients and families. *Clin J Am Soc Nephrol CJASN*. 2015;10(3):390-400. doi:10.2215/CJN.07490714

20. Sudore RL, Schickedanz AD, Landefeld CS, et al. Engagement in Multiple Steps of the Advance Care Planning Process: A Descriptive Study Among Diverse Older Adults. *J Am Geriatr Soc*. 2008;56(6):1006-1013. doi:10.1111/j.1532-5415.2008.01701.x

21. Detering KM, Hancock AD, Reade MC, Silvester W. The impact of advance care planning on end of life care in elderly patients: randomised controlled trial. *BMJ*. 2010;340:c1345. doi:10.1136/bmj.c1345

22. Douglas C, Sloan J, Cathcart S, et al. The impact of a renal supportive care service on symptom control, advance care planning and place of death for patients with advanced chronic kidney disease managed without dialysis. *BJRM*. 2019;Volume 24 Number 3(Autumn 2019):60-65.

23. Greer JA, Pirl WF, Jackson VA, et al. Effect of early palliative care on chemotherapy use and end-of-life care in patients with metastatic non-small-cell lung cancer. *J Clin Oncol Off J Am Soc Clin Oncol*. 2012;30(4):394-400. doi:10.1200/JCO.2011.35.7996

24. Temel JS, Greer JA, Admane S, et al. Longitudinal Perceptions of Prognosis and Goals of Therapy in Patients With Metastatic Non–Small-Cell Lung Cancer: Results of a Randomized Study of Early Palliative Care. *J Clin Oncol*. 2011;29(17):2319-2326. doi:10.1200/JCO.2010.32.4459

25. Braddock CH, Edwards KA, Hasenberg NM, Laidley TL, Levinson W. Informed decision making in outpatient practice: time to get back to basics. *JAMA*. 1999;282(24):2313-2320. doi:10.1001/jama.282.24.2313

26. Mack JW, Cronin A, Taback N, et al. End-of-life discussions among patients with advanced cancer: A cohort study. *Ann Intern Med*. 2012;156(3):204-210. doi:10.1059/0003-4819-156-3-201202070-00008

27. 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. doi:10.2215/CJN.05960809

28. Moss AH. Revised Dialysis Clinical Practice Guideline Promotes More Informed Decision-Making. *Clin J Am Soc Nephrol*. 2010;5(12):2380-2383. doi:10.2215/CJN.07170810

29. Moss AH. Ethical Principles and Processes Guiding Dialysis Decision-Making. *Clin J Am Soc Nephrol*. 2011;6(9):2313-2317. doi:10.2215/CJN.03960411

30. Tamura MK, Meier DE. Five Policies to Promote Palliative Care for Patients with ESRD. *Clin J Am Soc Nephrol*. 2013;8(10):1783-1790. doi:10.2215/CJN.02180213

31. Song M-K, Ward SE, Lin F-C, et al. Racial Differences in Outcomes of an Advance Care Planning Intervention for Dialysis Patients and Their Surrogates. *J Palliat Med*. 2016;19(2):134-142. doi:10.1089/jpm.2015.0232

32. Thomas BA, Rodriguez RA, Boyko EJ, Robinson-Cohen C, Fitzpatrick AL, O'Hare AM. Geographic Variation in Black–White Differences in End-of-Life Care for Patients with ESRD. *Clin J Am Soc Nephrol*. Published online April 11, 2013:CJN.06780712. doi:10.2215/CJN.06780712

33. Eneanya ND, Olaniran K, Xu D, et al. Health Literacy Mediates Racial Disparities in Cardiopulmonary Resuscitation Knowledge among Chronic Kidney Disease Patients. *J Health Care Poor Underserved*. 2018;29(3):1069-1082. doi:10.1353/hpu.2018.0080

34. Rosenstock IM, Strecher VJ, Becker MH. Social Learning Theory and the Health Belief Model. *Health Educ Q*. 1988;15(2):175-183. doi:10.1177/109019818801500203

35. Eneanya ND, Labbe AK, Stallings TL, et al. Caring for older patients with advanced chronic kidney disease and considering their needs: a qualitative study. *BMC Nephrol*. 2020;21(1):213. doi:10.1186/s12882-020-01870-1

36. Institute of Medicine (US) Committee on Health Literacy. *Health Literacy: A Prescription to End Confusion*. (Nielsen-Bohlman L, Panzer AM, Kindig DA, eds.). National Academies

Press (US); 2004. Accessed October 8, 2019. http://www.ncbi.nlm.nih.gov/books/NBK216032/

37. Levey AS, Bosch JP, Lewis JB, Greene T, Rogers N, Roth D. A more accurate method to estimate glomerular filtration rate from serum creatinine: a new prediction equation. Modification of Diet in Renal Disease Study Group. *Ann Intern Med*. 1999;130(6):461-470. doi:10.7326/0003-4819-130-6-199903160-00002

38. Pfeiffer E. A Short Portable Mental Status Questionnaire for the Assessment of Organic Brain Deficit in Elderly Patients†. *J Am Geriatr Soc*. 1975;23(10):433-441. doi:10.1111/j.1532-5415.1975.tb00927.x

39. Winterbottom AE, Gavaruzzi T, Mooney A, et al. Patient Acceptability of the Yorkshire Dialysis Decision Aid (YoDDA) Booklet: A Prospective Non-Randomized Comparison Study Across 6 Predialysis Services. *Perit Dial Int J Int Soc Perit Dial*. 2016;36(4):374-381. doi:10.3747/pdi.2014.00274

40. The National Kidney Foundation. If You Choose Not To Start Dialysis Treatment. Published 2008. Accessed April 15, 2020. https://www.kidney.org/sites/default/files/11-10-0330_ifyouchoose.pdf

41. Cavanaugh KL, Wingard RL, Hakim RM, et al. Low Health Literacy Associates with Increased Mortality in ESRD. *J Am Soc Nephrol JASN*. 2010;21(11):1979-1985. doi:10.1681/ASN.2009111163

42. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care*. 1992;30(6):473-483.

43. Wight JP, Edwards L, Brazier J, Walters S, Payne JN, Brown CB. The SF36 as an outcome measure of services for end stage renal failure. *Qual Health Care QHC*. 1998;7(4):209-221.

44. Peterman AH, Fitchett G, Brady MJ, Hernandez L, Cella D. Measuring spiritual well-being in people with cancer: the functional assessment of chronic illness therapy--Spiritual Well-being Scale (FACIT-Sp). *Ann Behav Med Publ Soc Behav Med*. 2002;24(1):49-58. doi:10.1207/S15324796ABM2401_06

45. Taylor JM. Psychometric analysis of the Ten-Item Perceived Stress Scale. *Psychol Assess*. 2015;27(1):90-101. doi:10.1037/a0038100

46. Robin Cohen S, Mount BM, Bruera E, Provost M, Rowe J, Tong K. Validity of the McGill Quality of Life Questionnaire in the palliative care setting: a multi-centre Canadian study demonstrating the importance of the existential domain. *Palliat Med*. 1997;11(1):3-20. doi:10.1177/026921639701100102

47. Prakash S, McGrail A, Lewis SA, et al. Behavioral stage of change and dialysis decision-making. *Clin J Am Soc Nephrol CJASN*. 2015;10(2):197-204. doi:10.2215/CJN.05560614

48. Norman G, Sloan J, Wyrwich K. Interpretation of Changes in Health-related Quality of Life: The Remarkable Universality of Half a Standard Deviation. *Med Care*. 2003;41(5):582-592. doi:10.1097/01.MLR.0000062554.74615.4C

49. Cohen J. *Statistical Power Analysis for the Behavioral Sciences.* Taylor and Francis; 2013. Accessed June 15, 2020. http://www.123library.org/book_details/?id=107447

50. Saeed F, Adams H, Epstein RM. Matters of Life and Death: Why Do Older Patients Choose Conservative Management? *Am J Nephrol*. 2020;51(1):35-42. doi:10.1159/000504692

51. Saeed F, Sardar M, Rasheed K, et al. Dialysis Decision-Making and Preferences for End-of-Life Care: Perspectives of Pakistani Patients Receiving Maintenance Dialysis. *J Pain Symptom Manage*. Published online March 20, 2020. doi:10.1016/j.jpainsymman.2020.03.009

52. Verberne WR, Konijn WS, Prantl K, et al. Older patients' experiences with a shared decision-making process on choosing dialysis or conservative care for advanced chronic kidney disease: a survey study. *BMC Nephrol*. 2019;20(1):264. doi:10.1186/s12882-019-1423-x

53. 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

54. Kazley AS, Johnson E, Simpson K, Chavin K, Baliga P. African American patient knowledge of kidney disease: A qualitative study of those with advanced chronic kidney disease. *Chronic Illn*. 2015;11(4):245-255. doi:10.1177/1742395314556658

55. Grubbs V, Gregorich SE, Perez-Stable EJ, Hsu C. Health Literacy and Access to Kidney Transplantation. *Clin J Am Soc Nephrol CJASN*. 2009;4(1):195-200. doi:10.2215/CJN.03290708

56. Song M-K, Ward SE, Fine JP, et al. Advance Care Planning and End-of-Life Decision Making in Dialysis: A Randomized Controlled Trial Targeting Patients and Their Surrogates. *Am J Kidney Dis Off J Natl Kidney Found*. 2015;66(5):813-822. doi:10.1053/j.ajkd.2015.05.018

Table 1. Demographic, clinical and knowledge outcomes

Patient demographics	Age, sex, race, ethnicity, marital status, employment status, annual household income, health insurance coverage
Knowledge	Conservative kidney management and advance care planning
Additional information	Completion of advanced directives, Charlson Comorbidity Index scores, kidney failure treatment preferences, end-of-life preferences

Table 2. Other patient outcomes

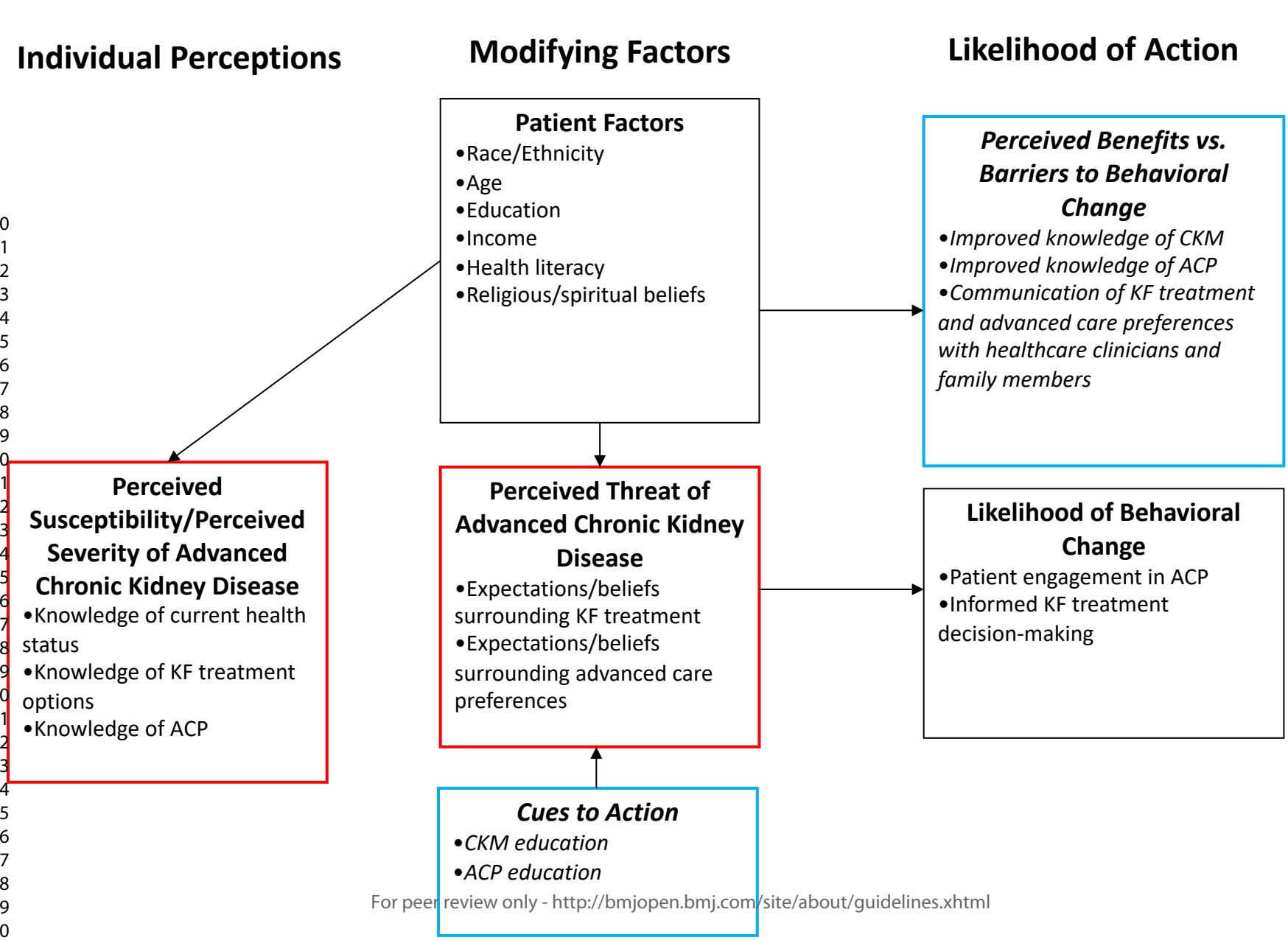
Questionnaire	Items	Domain
Cognition Short Portable Mental Status Questionnaire	10	Cognition
Rapid Estimate of Adult Literacy in Medicine	66	Health literacy
Perceived Stress Scale	4	Perceived stress
Multidimensional Scale of Perceived Support	12	Social support
Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being	12	Spiritual well-being
Modified Yorkshire Dialysis Decision Aid Usefulness Scale	4	Program usefulness
Patient Activation Measure	13	Patient activation
McGill Quality of Life Questionnaire: Part A	1	Quality of life
Satisfaction of Educational Program	1	Program satisfaction

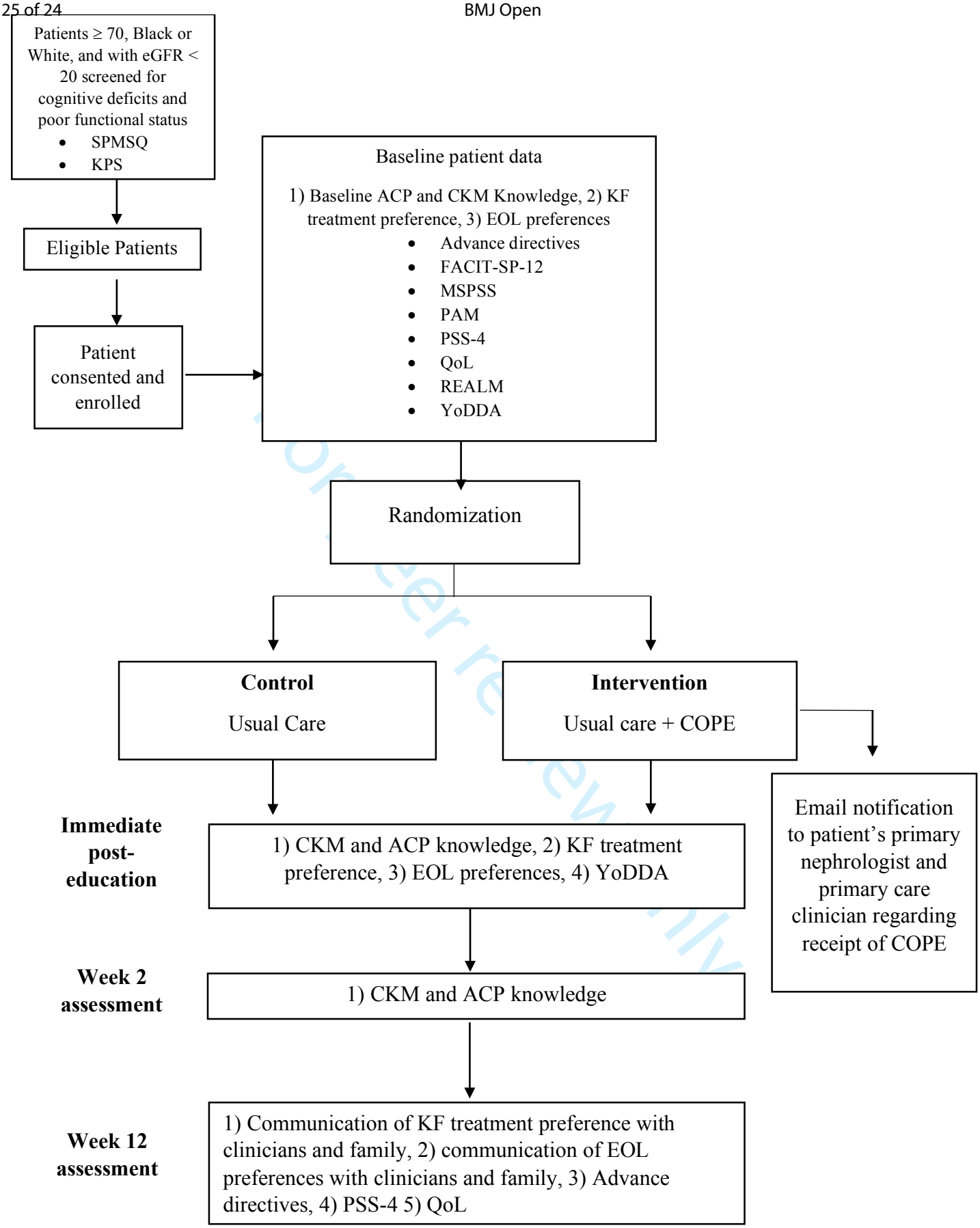
Figure 1. Health Belief Model (adapted for COPE)

Abbreviations: ACP = Advance are planning, CKM = Conservative kidney management, KF = Kidney failure

Figure 2. Study flow chart

Abbreviations: FACIT-SP-12=Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being, KPS=Karnofsky Performance Index Score, MSPSS = Multidimensional Scale of Perceived Social Support, PAM=Patient Activation Measure, PSS-4=Perceived Stress Scale, QOL=McGill Quality of Life Questionnaire-Part A, REALM=Rapid Estimate of Adult Literacy in Medicine, SPMSQ=Short Portable Mental Status Questionnaire, YoDDA=Modified Yorkshire Dialysis Decision Aid.





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Integrating conservative kidney management options and advance care planning education (COPE) into routine CKD care: a protocol for a pilot randomized controlled trial

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Title: Integrating conservative kidney management options and advance care planning **e**ducation (COPE) into routine CKD care: a protocol for a pilot randomized controlled trial

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Abstract:

Introduction: Pre-dialysis education for patients with advanced chronic kidney disease (CKD) typically focuses narrowly on hemodialysis and peritoneal dialysis as future treatment options. However, patients who are older or seriously ill may not want to pursue dialysis and/or may not benefit from this treatment. Conservative kidney management, a reasonable alternative treatment, and advance care planning (ACP) are often left out of patient education and shared decision-making. In this study, we will pilot an educational intervention (**C**onservative Kidney Management **O**ptions and Advance Care **P**lanning **E**ducation – COPE) to improve knowledge of conservative kidney management and ACP among patients with advanced CKD who are older and/or who have poor functional status.

Methods and analysis: This is a single-center pilot randomized controlled trial at an academic center in Philadelphia, PA. Eligible patients will have: age ≥ 70 years of age and/or poor functional status (as defined by Karnofsky Performance Index Score < 70), advanced CKD (eGFR < 20 ml/min/1.73m^2), prefer to speak English-during clinical encounters, and self-report as Black or White race. Enrolled patients will be randomized 1:1, with stratification by race, to receive enhanced usual care or usual care plus in-person education about conservative kidney management and ACP (COPE). The primary outcome is change in knowledge of CKM and ACP. We will also explore intervention feasibility and acceptability, change in communication of preferences, and differences in the intervention's effects on knowledge and communication of preferences by race. We will assess outcomes at baseline, immediately post-education, and at 2 and 12 weeks.

Ethics and dissemination: This protocol has been approved by the Institutional Review Board at the University of Pennsylvania. We will obtain written informed consent from all participants.

The results from this work will be presented at academic conferences and disseminated through peer-reviewed journals.

Trial registration: This trial is registered at ClinicalTrials.gov under NCT03229811.
Key words: Advanced chronic kidney disease, conservative kidney management, advance care planning, racial disparities

Strengths and limitations of this study:

- This is a pilot randomized controlled trial evaluating an intervention designed to primarily educate older and seriously ill patients with advanced CKD about conservative kidney management and advance care planning.
- Patients will receive an educational intervention that is integrated into their advanced CKD care.
- This study will investigate racial disparities between Black and White patients in knowledge about conservative kidney management and advance care planning.
- As this study is being conducted at a single-center and is being limited to White and Black patients, we are unable to generalize study results to different regions or patients of different races or ethnicities.

Introduction

The benefits of dialysis remain uncertain for older and seriously ill patients with advanced chronic kidney disease (CKD). In the United States, over 720,000 individuals have kidney failure with 87.3% of these patients ultimately receiving hemodialysis.[1] For older and frail patients with advanced CKD, it is unclear whether dialysis improves health or survival, with some evidence to suggest that it can negatively impact quality of life and functional status.[2–9] Additionally, patients of all ages with CKD have a higher prevalence of frailty and poor functional status, which is an independent risk factor for mortality and increased hospitalizations.[3,5,7,10,11]

Conservative kidney management is an approach to care for patients with kidney failure who do not want to pursue dialysis or who are unlikely to benefit from this treatment, especially those who are older with functional limitations.[6–9] This is non-dialytic therapy that focuses on slowing the progression of kidney disease with medications and fosters a multidisciplinary approach to address care needs and emotional and physical symptoms associated with kidney failure. However, many care models of conservative kidney management have been developed outside of the United States, and implementation strategies have not been investigated in this country.[8,12–14]

Patients with advanced CKD who are managed with conservative kidney management are more likely to receive palliative care consultation, use hospice, and discuss goals of care.[14,15] Advance care planning (ACP) is a process in which clinicians elicit and document patients' values and desired goals of care as their health deteriorates and/or if they were to become incapacitated.[16–22] Among seriously ill patients, early discussions about advanced care preferences improve patients' understanding of their health status and facilitate more informed ACP and decision-making.[23–26] Specifically, studies have demonstrated that as for other patient

populations, patients with advanced CKD would prefer to have ACP and goals of care discussions earlier in the disease course.[19,27] However, these conversations are often challenging and available evidence suggests that nephrologists tend not to engage in ACP with their patients.[19,27–30] Additionally, some studies have shown racial disparities in ACP knowledge, and that racial-ethnic minority patients are less likely to engage in goals of care discussions and advance care planning when compared to White patients.[16,18,31,32] Education and improving informed decision-making may mitigate racial disparities in care for older patients with CKD.[18,33] Thus, we are testing whether a novel educational intervention incorporated into routine advanced CKD care, called **C**onservative Kidney Management **O**ptions and Advance Care **P**lanning **E**ducation (COPE), can improve knowledge and communication among patients who are older and/or with poor functional status.

Methodology and analysis

Conceptual framework

The COPE intervention has been developed to address patient knowledge, expectations, and beliefs of kidney failure treatments and ACP (Figure 1). The conceptual framework for this intervention is adapted from the Health Belief Model (Figure 1).[34] This model hypothesizes that health-related action depends on the simultaneous occurrence of three factors: 1) the existence of sufficient motivation to make health issues salient or relevant; 2) the belief that one is susceptible to a serious health problem or sequelae of that illness or condition (e.g., perceived threat); and 3) the belief that following a particular health recommendation would be beneficial in reducing the perceived threat[34] Under this model, patient factors such as age, race, ethnicity, and education are posited to be associated with perceived severity (including knowledge of kidney failure treatment and ACP) and the threat of kidney disease (expectations and beliefs surrounding kidney failure treatments and advanced care preferences).

Intervention development

To support the development of the intervention, we conducted a qualitative study among key stakeholders and conducted a systematic literature review.

Qualitative study

We conducted in-depth interviews with clinicians (nephrologists and primary care physicians), older patients, and their caregivers at an academic medical center in Boston, Massachusetts.[35] Specifically, we assessed interviewees' prior experiences of discussions about kidney replacement therapies and ACP. We found that nephrologists and primary care physicians were mostly aligned with respect to their roles in discussing dialysis and advance care planning. However, despite clarity about responsibilities and communication among nephrologists and primary care physicians, patients, and their caregivers were uncertain about the impact of dialysis on their lives as well as the importance of ACP. In developing interventional educational materials for the trial, we included key concepts about conservative kidney management and ACP that were most unclear to patients and caregivers based on what we learned in semi-structured interviews.

Educational materials

We also performed a literature review of published studies describing patient education and detailing programs that implemented conservative kidney management and ACP for patients with advanced chronic kidney disease. We subsequently developed a brief 8-page brochure and educational script based on existing materials and modified them after receiving input from patients with advanced CKD and their caregivers. The brochure was specifically created at a 6th-grade reading level to maximize understanding for patients.[36]

Intervention training

The principal investigator will train a nurse practitioner who is certified in serious illness communication and palliative care to deliver the intervention among all enrolled patients. Specifically, the nurse practitioner will be trained to discuss all treatment options (including conservative kidney management) and ACP. We will conduct this training in two half-day sessions followed by observed interactions with volunteer patients to determine competency in delivery of information.

Study design and setting

We will test the COPE intervention to provide education to patients with advanced CKD who are older and/or with poor functional status (defined as a Karnofsky Performance Index Score < 70[11]) in a single-center pilot randomized controlled trial (RCT). The objective of this intervention is to increase participants' knowledge of treatment options including conservative kidney management and ACP and improve communication of patients' treatment and care preferences with their clinicians and family members. We hypothesize that educating patients about treatment options, eliciting their treatment preferences, and communicating these with clinicians and families will promote patient engagement in ACP, improve informed treatment decision-making, and reduce racial disparities in knowledge and communication of care preferences. We will recruit patients from outpatient renal clinics associated with the University of Pennsylvania Perelman School of Medicine in Philadelphia, PA. The Institutional Review Board at the University of Pennsylvania has approved this study.

Participants

Those eligible to participate in this trial will be: 1) age ≥ 70 years and/or have poor functional status (defined as a Karnofsky Performance Index Score < 70[11]), 2) have advanced chronic kidney disease defined as having at least two eGFR measurements < 20 ml/min/1.73m^2

separated by at least three months,[37] 3) prefer to speak English-during clinical encounters, and 4) self-report as Black or White race. Exclusion criteria include being listed for kidney transplant, being legally blind, or screening positive for severe cognitive dysfunction defined as having 8 or more errors on the Short Portable Mental Status Questionnaire for assessment of organic brain deficit.[38] For potentially eligible patients < 70 years of age, we will ask treating clinicians to complete a Karnofsky Performance Index Score.

Recruitment

Research staff will access electronic medical records of clinic patients and nephrologists' list of patients with poor functional status to identify potential study participants. Prior to approaching patients to invite them to participate in the study, a study coordinator will also confirm study suitability with each patient's nephrologist. Given the diverse patient demographics in the outpatient renal clinics, we anticipate equal representation of Black and White patients.

Study procedures

Prior to the initiation of the pilot RCT, we will assess the feasibility and acceptability of COPE among a small sample of patients (n=10). Immediately after receiving education, patients will be asked to rate satisfaction on a Likert scale and usefulness based on the modified Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.[39] We will assess the reasons for refusal and attrition data before finalizing recruitment and study procedures.

We will randomize patients (n=100) in a 1:1 fashion with stratification by race to receive one of two arms: 1) enhanced usual care or 2) usual care plus COPE. We will collect baseline data for patients at the time of enrollment and prior to randomization (Table 1). Further data collection will take place via phone sessions at pre-specified time intervals (Figure 2).

Enhanced usual care

Nephrology care within the University of Pennsylvania system includes monthly pre-dialysis educational classes where patients with advanced CKD can learn more about CKD and treatment options for kidney failure. The treatment options covered in the classes include hemodialysis, peritoneal dialysis, and kidney transplantation. Using a PowerPoint presentation, these sessions are provided in-person by nephrology nurse practitioners and typically last around 60 minutes. Patients' nephrologists may also provide ad hoc education during routine clinical visits. To ensure all enrolled patients receive similar education about conservative kidney management and ACP, everyone will receive the National Kidney Foundation's educational pamphlet titled "If you choose to not do dialysis".[40] This is a 16-page document that describes the process of not starting dialysis as well as advance care planning.

Intervention

The study coordinator will schedule an appointment for all enrolled patients to meet with the nurse practitioner to receive the COPE educational intervention within 2-4 weeks of enrollment. The intervention will be a one-time visit with the primary goal of educating patients about treatment options and ACP. Intervention content includes a discussion about disease understanding, dialysis treatments, conservative kidney management, patient goals and values, and advance care planning (including review of state-specific advance directives). Importantly, patients will learn that conservative kidney management is not abandonment of care. COPE will last approximately 45-60 minutes. Patients may invite family members and other loved ones to attend the educational sessions although only patient participants will complete survey items. After completion of COPE, the study principal investigator will communicate with the patient's primary care physician and primary nephrologist via joint standardized e-mails to notify them of their patient's enrollment in the study. All sessions will be audiotaped and two recordings will be

randomly selected at 2-months intervals to assess the fidelity of the intervention. A study coordinator will complete the fidelity checklist and re-training of the nurse practitioner will occur if 80% of criteria are not met.

Outcomes

The primary outcome for this intervention is change in knowledge of conservative kidney management and ACP. Additional outcomes include assessing the feasibility and acceptability of COPE, patient communication of kidney failure and advanced care treatment preferences with clinicians and family members. We will also evaluate racial disparities in conservative kidney management, ACP knowledge and communication of care preferences. We will ascertain knowledge, treatment preferences, communication of preferences, and intervention acceptability via short questionnaires at the time points displayed in Figure 2. Specifically, we will use questions from the SUPPORT trial to assess end-of-life (EOL) preferences.[41]

We will also measure other outcomes including health literacy,[42] perceived mental and physical health status,[43,44] spiritual well-being,[45] perceived stress,[46] and quality of life[47], using validated surveys (Table 2). Patient demographics, whether patients have completed advance directives, and comorbidities will be ascertained via medical record review and surveys.

Analysis

Feasibility and acceptability

We will consider that the intervention has adequate feasibility if at least 70% of eligible patients who are approached provide consent and enroll in the study. Additionally, we will determine that adequate acceptability is achieved if at least 80% of patients have a mean score of ≥ 4.9 using the modified Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.[39]

CKM and ACP knowledge, communication and preferences

We will describe patient characteristics using proportions for categorical variables and means (± SD) or medians (interquartile range) for continuous variables as appropriate. We will test for differences in outcomes between study arms regarding: 1) change in conservative kidney management/ACP knowledge score, 2) kidney failure treatment preference, 3) EOL preference, and 4) communication of preferences with clinicians and family members using univariate analyses (two-sample t-test, Wilcoxon rank-sum, or Chi-square test). Given the possibility of imbalance of baseline characteristics between study arms due to small sample size, we will perform secondary analyses using multivariate linear and logistic regression to measure the independent association of the study arm with all outcomes adjusting for measured patient characteristics (age, sex, race, ethnicity, income level, education level, health literacy, and Charleston co-morbidity index). We will check for collinearity and interactions between variables and determine significance by a two-sided alpha level of 0.05.

Racial disparities

To determine whether the intervention reduces racial disparities in outcomes between Black and White patients, we will add an interaction term between race and study arm in the multivariate analyses. A p-value of 0.15 or less will be considered statistically significant when testing for interaction. All analyses will be done in SAS (Version 9.4, Cary, NC).

Power and sample size

Based on published data demonstrating poor knowledge of conservative kidney management among patients with advanced kidney disease,[48] we anticipate that recruitment of 50 patients to each arm will provide 85% power to detect an effect size of 0.5 SD when comparing the change in knowledge of conservative kidney management and advance care planning between the two groups.[49,50]

Patient and public involvement

We performed a qualitative study among older patients with advanced CKD and their caregivers to learn more about their experiences with dialysis-decision making and advance care planning discussions. These data were integral to developing the intervention script and educational brochure. We further piloted the intervention script and brochure among older patients with advanced CKD and their caregivers before modifying and finalizing these materials. Prior to initiation of the pilot RCT, we will assess feasibility and acceptability of COPE (including timing and burden of the intervention and survey materials) among older patients with advanced CKD.

Discussion

COPE aims to improve knowledge about conservative kidney management and ACP as well as communication of care preferences for patients with advanced CKD who are older and/or who have poor functional status. Additionally, we expect that the intervention will reduce racial disparities in these outcomes among Black and White patients. We anticipate that COPE will ultimately improve informed decision-making about kidney failure treatments and encourage patients to engage in timely ACP discussions with their clinicians and family members.

This pilot RCT is designed to specifically evaluate an educational intervention for patients who are older and/or with poor functional status about conservative kidney management and ACP. Our intervention is informed by qualitative work among patients, caregivers, and clinicians and by a comprehensive review of existing literature. COPE consists of three novel components. First, we are targeting educational efforts towards patients who are older and/or with poor functional status, a group for whom there is often considerable uncertainty about the benefits versus the harms of dialysis. We will use questionnaires to identify knowledge gaps

among patients to improve conservative kidney management and ACP education. Second, patients will receive conservative kidney management and ACP education that is integrated with rather than siloed from other aspects of advanced CKD care. Studies focused on dialysis decision-making among CKD patients are lacking.[29,30,51–54] Fully informing patients with advanced CKD of conservative kidney management options, as well as discussing their preferences for care at EOL allows patients to focus on values and goals that are most important to them. Third, we aim to reduce racial disparities in knowledge and communication of conservative kidney management and EOL preferences among patients with advanced CKD. Compared to White patients with CKD, Black patients have lower health literacy, less knowledge about treatment options for advanced kidney disease, and tend to have poor knowledge of support resources to cope with the disease.[55,56] Racial differences in knowledge outcomes may in part be due to the notion that educational interventions are developed to achieve a "one size fits all" standard. However, COPE has been developed with input from a diverse patient population of patients with CKD and with specific attention to communication style and health literacy barriers. There are few existing ACP and conservative kidney management educational tools that account for knowledge differences among patients, which could ultimately help to reduce racial disparities in patient understanding of these aspects of care.[31,57]

There are a few limitations to this study. This is a single-center study and we will enroll patients who self-identify as White or Black. Thus, conclusions may not be generalizable to patients of different racial backgrounds or who live in other geographical locations. Additionally, shared decision-making includes patients, clinicians, and families, but our study will only measure patient outcomes. Lastly, we acknowledge that this study will focus on short-term

outcomes and therefore we will be unable to comment on the downstream effects of the intervention. Future studies will confirm whether COPE has broad relevance and usefulness for similar patients with different demographics, feasibility and acceptability among clinicians and caregivers, and long-term outcomes such as treatment decision-making confidence and conflict.

Educating patients with advanced CKD who are older or seriously ill about kidney failure treatment options (including conservative kidney management) and ACP is central to promoting shared decision-making and promoting goal-concordant care. We anticipate that our study findings will improve informed decision-making for patients with advanced chronic kidney disease and create an opportunity for clinicians to provide comprehensive patient-centered care for this vulnerable population.

Ethics and dissemination

This protocol has been approved by the Institutional Review Board at the University of Pennsylvania. Written informed consent will be obtained from all participants. The findings from this work will be disseminated through peer-reviewed publications and will be presented at academic conferences.

Authors' contributions

Research idea and study design: NDE, JST MKP, MA, AO; Preparation of manuscript: TLS, NDE; Critical revision of manuscript: TLS, JST, TAK, MKP, MA, AO, NOC, LMD, SDH, NDE; Supervision or mentorship: NDE, JST, LMD, SDH. All authors take responsibility for the integrity and accuracy of this manuscript's content and have approved the final draft for submission.

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Competing interests statement

All other authors declare that they have no relevant conflict of interests.

References Cited

1. United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

2. Kurella M, Covinsky KE, Collins AJ, Chertow GM. Octogenarians and nonagenarians starting dialysis in the United States. *Ann Intern Med*. 2007;146(3):177-183. doi:10.7326/0003-4819-146-3-200702060-00006

3. Kurella Tamura M, Covinsky KE, Chertow GM, Yaffe K, Landefeld CS, McCulloch CE. Functional Status of Elderly Adults before and after Initiation of Dialysis. http://dx.doi.org/10.1056/NEJMoa0904655. doi:10.1056/NEJMoa0904655

4. Weisbord SD, Fried LF, Arnold RM, et al. Prevalence, Severity, and Importance of Physical and Emotional Symptoms in Chronic Hemodialysis Patients. *J Am Soc Nephrol*. 2005;16(8):2487-2494. doi:10.1681/ASN.2005020157

5. McAdams-DeMarco MA, Law A, Salter ML, et al. Frailty as a Novel Predictor of Mortality and Hospitalization in Hemodialysis Patients of All Ages. *J Am Geriatr Soc*. 2013;61(6):896-901. doi:10.1111/jgs.12266

6. Verberne WR, Geers ABMT, Jellema WT, Vincent HH, van Delden JJM, Bos WJW. Comparative Survival among Older Adults with Advanced Kidney Disease Managed Conservatively Versus with Dialysis. *Clin J Am Soc Nephrol CJASN*. 2016;11(4):633-640. doi:10.2215/CJN.07510715

7. Pugh J, Aggett J, Goodland A, et al. Frailty and comorbidity are independent predictors of outcome in patients referred for pre-dialysis education. *Clin Kidney J*. 2016;9(2):324-329. doi:10.1093/ckj/sfv150

8. Song M-K. Quality of Life of Patients with Advanced Chronic Kidney Disease Receiving Conservative Care without Dialysis. *Semin Dial*. 2016;29(2):165-169. doi:10.1111/sdi.12472

9. Da Silva-Gane M, Wellsted D, Greenshields H, Norton S, Chandna SM, Farrington K. Quality of Life and Survival in Patients with Advanced Kidney Failure Managed Conservatively or by Dialysis. *Clin J Am Soc Nephrol CJASN*. 2012;7(12):2002-2009. doi:10.2215/CJN.01130112

10. Roshanravan B, Khatri M, Robinson-Cohen C, et al. A Prospective Study of Frailty in Nephrology-Referred Patients With CKD. *Am J Kidney Dis Off J Natl Kidney Found*. 2012;60(6):912-921. doi:10.1053/j.ajkd.2012.05.017

11. 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. *Nephrol Dial Transplant Off Publ Eur Dial Transpl Assoc - Eur Ren Assoc*. 2019;34(9):1517-1525. doi:10.1093/ndt/gfy305

12. Morton RL, Snelling P, Webster AC, et al. Factors influencing patient choice of dialysis versus conservative care to treat end-stage kidney disease. *CMAJ Can Med Assoc J J Assoc Medicale Can*. 2012;184(5):E277-283. doi:10.1503/cmaj.111355

13. Foote C, Morton RL, Jardine M, et al. COnsiderations of Nephrologists when SuggestIng Dialysis in Elderly patients with Renal failure (CONSIDER): a discrete choice experiment. *Nephrol Dial Transplant*. 2014;29(12):2302-2309. doi:10.1093/ndt/gfu257

14. Tonkin-Crine S, Okamoto I, Leydon GM, et al. Understanding by Older Patients of Dialysis and Conservative Management for Chronic Kidney Failure. *Am J Kidney Dis*. 2015;65(3):443-450. doi:10.1053/j.ajkd.2014.08.011

15. Eneanya ND, Paasche-Orlow MK, Volandes A. Palliative and end-of-life care in nephrology: moving from observations to interventions. *Curr Opin Nephrol Hypertens*. 2017;26(4):327-334. doi:10.1097/MNH.0000000000000337

16. Tamura MK, Goldstein MK, Pérez-Stable EJ. Preferences for dialysis withdrawal and engagement in advance care planning within a diverse sample of dialysis patients. *Nephrol Dial Transplant*. 2010;25(1):237-242. doi:10.1093/ndt/gfp430

17. Fried TR, Redding CA, Robbins ML, Paiva AL, O'Leary JR, Iannone L. Development of Personalized Health Messages to Promote Engagement in Advance Care Planning. *J Am Geriatr Soc*. 2016;64(2):359-364. doi:10.1111/jgs.13934

18. Eneanya ND, Wenger JB, Waite K, et al. Racial Disparities in End-of-Life Communication and Preferences among Chronic Kidney Disease Patients. *Am J Nephrol*. 2016;44(1):46-53. doi:10.1159/000447097

19. Goff SL, Eneanya ND, Feinberg R, et al. Advance care planning: a qualitative study of dialysis patients and families. *Clin J Am Soc Nephrol CJASN*. 2015;10(3):390-400. doi:10.2215/CJN.07490714

20. Sudore RL, Schickedanz AD, Landefeld CS, et al. Engagement in Multiple Steps of the Advance Care Planning Process: A Descriptive Study Among Diverse Older Adults. *J Am Geriatr Soc*. 2008;56(6):1006-1013. doi:10.1111/j.1532-5415.2008.01701.x

21. Detering KM, Hancock AD, Reade MC, Silvester W. The impact of advance care planning on end of life care in elderly patients: randomised controlled trial. *BMJ*. 2010;340:c1345. doi:10.1136/bmj.c1345

22. Douglas C, Sloan J, Cathcart S, et al. The impact of a renal supportive care service on symptom control, advance care planning and place of death for patients with advanced chronic kidney disease managed without dialysis. *BJRM*. 2019;Volume 24 Number 3(Autumn 2019):60-65.

23. Greer JA, Pirl WF, Jackson VA, et al. Effect of early palliative care on chemotherapy use and end-of-life care in patients with metastatic non-small-cell lung cancer. *J Clin Oncol Off J Am Soc Clin Oncol*. 2012;30(4):394-400. doi:10.1200/JCO.2011.35.7996

24. Temel JS, Greer JA, Admane S, et al. Longitudinal Perceptions of Prognosis and Goals of Therapy in Patients With Metastatic Non–Small-Cell Lung Cancer: Results of a Randomized Study of Early Palliative Care. *J Clin Oncol*. 2011;29(17):2319-2326. doi:10.1200/JCO.2010.32.4459

25. Braddock CH, Edwards KA, Hasenberg NM, Laidley TL, Levinson W. Informed decision making in outpatient practice: time to get back to basics. *JAMA*. 1999;282(24):2313-2320. doi:10.1001/jama.282.24.2313

26. Mack JW, Cronin A, Taback N, et al. End-of-life discussions among patients with advanced cancer: A cohort study. *Ann Intern Med*. 2012;156(3):204-210. doi:10.1059/0003-4819-156-3-201202070-00008

27. 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. doi:10.2215/CJN.05960809

28. Moss AH. Revised Dialysis Clinical Practice Guideline Promotes More Informed Decision-Making. *Clin J Am Soc Nephrol*. 2010;5(12):2380-2383. doi:10.2215/CJN.07170810

29. Moss AH. Ethical Principles and Processes Guiding Dialysis Decision-Making. *Clin J Am Soc Nephrol*. 2011;6(9):2313-2317. doi:10.2215/CJN.03960411

30. Tamura MK, Meier DE. Five Policies to Promote Palliative Care for Patients with ESRD. *Clin J Am Soc Nephrol*. 2013;8(10):1783-1790. doi:10.2215/CJN.02180213

31. Song M-K, Ward SE, Lin F-C, et al. Racial Differences in Outcomes of an Advance Care Planning Intervention for Dialysis Patients and Their Surrogates. *J Palliat Med*. 2016;19(2):134-142. doi:10.1089/jpm.2015.0232

32. Thomas BA, Rodriguez RA, Boyko EJ, Robinson-Cohen C, Fitzpatrick AL, O'Hare AM. Geographic Variation in Black–White Differences in End-of-Life Care for Patients with ESRD. *Clin J Am Soc Nephrol*. Published online April 11, 2013:CJN.06780712. doi:10.2215/CJN.06780712

33. Eneanya ND, Olaniran K, Xu D, et al. Health Literacy Mediates Racial Disparities in Cardiopulmonary Resuscitation Knowledge among Chronic Kidney Disease Patients. *J Health Care Poor Underserved*. 2018;29(3):1069-1082. doi:10.1353/hpu.2018.0080

34. Rosenstock IM, Strecher VJ, Becker MH. Social Learning Theory and the Health Belief Model. *Health Educ Q*. 1988;15(2):175-183. doi:10.1177/109019818801500203

35. Eneanya ND, Labbe AK, Stallings TL, et al. Caring for older patients with advanced chronic kidney disease and considering their needs: a qualitative study. *BMC Nephrol*. 2020;21(1):213. doi:10.1186/s12882-020-01870-1

36. Institute of Medicine (US) Committee on Health Literacy. *Health Literacy: A Prescription to End Confusion*. (Nielsen-Bohlman L, Panzer AM, Kindig DA, eds.). National Academies

Press (US); 2004. Accessed October 8, 2019. http://www.ncbi.nlm.nih.gov/books/NBK216032/

37. Levey AS, Bosch JP, Lewis JB, Greene T, Rogers N, Roth D. A more accurate method to estimate glomerular filtration rate from serum creatinine: a new prediction equation. Modification of Diet in Renal Disease Study Group. *Ann Intern Med*. 1999;130(6):461-470. doi:10.7326/0003-4819-130-6-199903160-00002

38. Pfeiffer E. A Short Portable Mental Status Questionnaire for the Assessment of Organic Brain Deficit in Elderly Patients†. *J Am Geriatr Soc*. 1975;23(10):433-441. doi:10.1111/j.1532-5415.1975.tb00927.x

39. Winterbottom AE, Gavaruzzi T, Mooney A, et al. Patient Acceptability of the Yorkshire Dialysis Decision Aid (YoDDA) Booklet: A Prospective Non-Randomized Comparison Study Across 6 Predialysis Services. *Perit Dial Int J Int Soc Perit Dial*. 2016;36(4):374-381. doi:10.3747/pdi.2014.00274

40. The National Kidney Foundation. If You Choose Not To Start Dialysis Treatment. Published 2008. Accessed April 15, 2020. https://www.kidney.org/sites/default/files/11-10-0330_ifyouchoose.pdf

41. Connors AF, Dawson NV, Desbiens NA, et al. A Controlled Trial to Improve Care for Seriously III Hospitalized Patients: The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT). *JAMA*. 1995;274(20):1591-1598. doi:10.1001/jama.1995.03530200027032

42. Cavanaugh KL, Wingard RL, Hakim RM, et al. Low Health Literacy Associates with Increased Mortality in ESRD. *J Am Soc Nephrol JASN*. 2010;21(11):1979-1985. doi:10.1681/ASN.2009111163

43. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care*. 1992;30(6):473-483.

44. Wight JP, Edwards L, Brazier J, Walters S, Payne JN, Brown CB. The SF36 as an outcome measure of services for end stage renal failure. *Qual Health Care QHC*. 1998;7(4):209-221.

45. Peterman AH, Fitchett G, Brady MJ, Hernandez L, Cella D. Measuring spiritual well-being in people with cancer: the functional assessment of chronic illness therapy--Spiritual Well-being Scale (FACIT-Sp). *Ann Behav Med Publ Soc Behav Med*. 2002;24(1):49-58. doi:10.1207/S15324796ABM2401_06

46. Taylor JM. Psychometric analysis of the Ten-Item Perceived Stress Scale. *Psychol Assess*. 2015;27(1):90-101. doi:10.1037/a0038100

47. Robin Cohen S, Mount BM, Bruera E, Provost M, Rowe J, Tong K. Validity of the McGill Quality of Life Questionnaire in the palliative care setting: a multi-centre Canadian study demonstrating the importance of the existential domain. *Palliat Med*. 1997;11(1):3-20. doi:10.1177/026921639701100102

48. Prakash S, McGrail A, Lewis SA, et al. Behavioral stage of change and dialysis decision-making. *Clin J Am Soc Nephrol CJASN*. 2015;10(2):197-204. doi:10.2215/CJN.05560614

49. Norman G, Sloan J, Wyrwich K. Interpretation of Changes in Health-related Quality of Life: The Remarkable Universality of Half a Standard Deviation. *Med Care*. 2003;41(5):582-592. doi:10.1097/01.MLR.0000062554.74615.4C

50. Cohen J. *Statistical Power Analysis for the Behavioral Sciences.* Taylor and Francis; 2013. Accessed June 15, 2020. http://www.123library.org/book_details/?id=107447

51. Saeed F, Adams H, Epstein RM. Matters of Life and Death: Why Do Older Patients Choose Conservative Management? *Am J Nephrol*. 2020;51(1):35-42. doi:10.1159/000504692

52. Saeed F, Sardar M, Rasheed K, et al. Dialysis Decision-Making and Preferences for End-of-Life Care: Perspectives of Pakistani Patients Receiving Maintenance Dialysis. *J Pain Symptom Manage*. Published online March 20, 2020. doi:10.1016/j.jpainsymman.2020.03.009

53. Verberne WR, Konijn WS, Prantl K, et al. Older patients' experiences with a shared decision-making process on choosing dialysis or conservative care for advanced chronic kidney disease: a survey study. *BMC Nephrol*. 2019;20(1):264. doi:10.1186/s12882-019-1423-x

54. 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

55. Kazley AS, Johnson E, Simpson K, Chavin K, Baliga P. African American patient knowledge of kidney disease: A qualitative study of those with advanced chronic kidney disease. *Chronic Illn*. 2015;11(4):245-255. doi:10.1177/1742395314556658

56. Grubbs V, Gregorich SE, Perez-Stable EJ, Hsu C. Health Literacy and Access to Kidney Transplantation. *Clin J Am Soc Nephrol CJASN*. 2009;4(1):195-200. doi:10.2215/CJN.03290708

57. Song M-K, Ward SE, Fine JP, et al. Advance Care Planning and End-of-Life Decision Making in Dialysis: A Randomized Controlled Trial Targeting Patients and Their Surrogates. *Am J Kidney Dis Off J Natl Kidney Found*. 2015;66(5):813-822. doi:10.1053/j.ajkd.2015.05.018

Table 1. Demographic, clinical and knowledge outcomes

Patient demographics	Age, sex, race, ethnicity, marital status, employment status, annual household income, health insurance coverage
Knowledge	Conservative kidney management and advance care planning
Additional information	Completion of advanced directives, Charlson Comorbidity Index scores, kidney failure treatment preferences, end-of-life preferences

Table 2. Other patient outcomes

Questionnaire	Items	Domain
Cognition Short Portable Mental Status Questionnaire	10	Cognition
Rapid Estimate of Adult Literacy in Medicine	66	Health literacy
Perceived Stress Scale	4	Perceived stress
Multidimensional Scale of Perceived Support	12	Social support
Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being	12	Spiritual well-being
Modified Yorkshire Dialysis Decision Aid Usefulness Scale	4	Program usefulness
Patient Activation Measure	13	Patient activation
McGill Quality of Life Questionnaire: Part A	1	Quality of life
Satisfaction of Educational Program	1	Program satisfaction

Figure 1. Health Belief Model (adapted for COPE)

Abbreviations: ACP = Advance are planning, CKM = Conservative kidney management, KF = Kidney failure

Figure 2. Study flow chart

Abbreviations: FACIT-SP-12=Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being, KPS=Karnofsky Performance Index Score, MSPSS = Multidimensional Scale of Perceived Social Support, PAM=Patient Activation Measure, PSS-4=Perceived Stress Scale, QOL=McGill Quality of Life Questionnaire-Part A, REALM=Rapid Estimate of Adult Literacy in Medicine, SPMSQ=Short Portable Mental Status Questionnaire, YoDDA=Modified Yorkshire Dialysis Decision Aid.