

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-042620
Article Type:	Protocol
Date Submitted by the Author:	09-Jul-2020
Complete List of Authors:	Stallings, Taylor; University of Pennsylvania Perelman School of Medicine Temel, Jennifer; Massachusetts General Hospital Cancer Center, Medicine Klaiman, Tamar; University of Pennsylvania Perelman School of Medicine Paasche-Orlow, Michael; Boston Medical Center, General Internal Medicine Alegria, M; Massachusetts General Hospital, O'Hare, Ann; University of Washington Department of Medicine, O'Connor, Nina; University of Pennsylvania Dember, Laura; University of Pennsylvania, Halpern, SD; University of Pennsylvania Perelman School of Medicine Eneanya, Nwamaka; University of Pennsylvania Perelman School of Medicine
Keywords:	Chronic renal failure < NEPHROLOGY, End stage renal failure < NEPHROLOGY, Adult palliative care < PALLIATIVE CARE, GERIATRIC MEDICINE

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3 **Title:** Integrating conservative kidney management options and advance care planning education
4 (COPE) into routine CKD care: a protocol for a pilot randomized controlled trial
5
6
7

8 **Authors:** Taylor L. Stallings, MS¹, Jennifer S. Temel, MD², Tamar A. Klaiman PhD,MPH¹,
9
10 Michael K. Paasche-Orlow³, Margarita Alegria, PhD⁴, Ann O'Hare⁵, Nina O'Connor, MD⁶
11
12 Laura M. Dember, MD^{7, 8}, Scott D. Halpern MD, PhD¹, Nwamaka D. Eneanya, MD, MPH^{1,7,8}
13
14
15

16 **Affiliations:**

17
18
19 ¹Palliative and Advanced Illness Research Center, Perelman School of Medicine, University of
20
21 Pennsylvania, Philadelphia, PA, USA.
22
23

24 ²Division of Hematology and Oncology, Department of Internal Medicine, Massachusetts
25
26 General Hospital, Harvard Medical School, Boston, MA, USA.
27
28

29 ³Section of General Internal Medicine, Boston Medical Center, Boston University School of
30
31 Medicine, Boston, MA, USA.
32
33

34 ⁴Department of Medicine and Psychiatry, Harvard Medical School, Boston, MA, USA.
35
36
37

38 ⁵Division of Nephrology, Department of Medicine, University of Washington, Seattle, WA,
39
40 USA.
41

42 ⁶Palliative and Hospice Medicine, Perelman School of Medicine, University of Pennsylvania,
43
44 Philadelphia, PA, USA.
45

46 ⁷Renal-Electrolyte Division, Perelman School of Medicine, University of Pennsylvania,
47
48 Philadelphia, PA, USA.
49
50

51 ⁸Center for Clinical Epidemiology and Biostatistics, Perelman School of Medicine, University of
52
53 Pennsylvania, Philadelphia, PA, USA.
54
55
56
57
58
59
60

1
2
3 **Abstract word count: 291/300**

4 **Manuscript word count: 2643/4000**

5
6
7 **Tables: 2**

8 **Figures: 2**

9
10
11
12 **Corresponding Author**

13
14 Nwamaka Eneanya, MD, MPH

15
16 Renal-Electrolyte and Hypertension Division

17
18 Perelman School of Medicine

19
20 University of Pennsylvania

21
22 307 Blockley Hall

23
24 423 Guardian Drive

25
26 Philadelphia, PA 19104

27
28 Ph: 215-746-5080

29
30 Email: Nwamaka.eneanya@penmedicine.upenn.edu

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 (Conservative Kidney Management Options and Advance Care Planning Education – 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/1.73m²), 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.

1
2
3 The results from this work will be presented at academic conferences and disseminated through
4 peer-reviewed journals.
5
6
7

8 **Trial registration:** This trial is registered at ClinicalTrials.gov under NCT03229811.
9

10 **Key words:** Advanced chronic kidney disease, conservative kidney management, advance care
11 planning, racial disparities
12
13
14

15
16 **Strengths and limitations of this study:**
17

- 18 • This is a pilot randomized controlled trial evaluating an intervention designed to
19 primarily educate older and seriously ill patients with advanced CKD about conservative
20 kidney management and advance care planning.
21
22
- 23 • Patients will receive an educational intervention that is integrated into their advanced
24 CKD care.
25
26
- 27 • We anticipate that the intervention will reduce racial disparities between Black and White
28 patients in knowledge about conservative kidney management and advance care
29 planning.
30
31
- 32 • As this study is being conducted at a single-center and is being limited to White and
33 Black patients, we are unable to generalize study results to different regions or patients of
34 different races or ethnicities.
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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}

1
2
3 However, these conversations are often challenging and available evidence suggests that
4 nephrologists tend not to engage in ACP with their patients.^{22,29–32} Additionally, some studies
5 have shown racial disparities in ACP knowledge, and that racial-ethnic minority patients are less
6 likely to engage in goals of care discussions and advance care planning when compared to White
7 patients.^{19,21,33,34} Education and improving informed decision-making may mitigate racial
8 disparities in care for older patients with CKD.^{35,36} Thus, we are testing whether a novel
9 educational intervention incorporated into routine advanced CKD care, called Conservative
10 Kidney Management Options and Advance Care Planning Education (COPE), can improve
11 knowledge and communication among patients who are older and/or with poor functional status.
12
13
14
15
16
17
18
19
20
21
22
23

24 **Methodology and analysis**

25 *Conceptual framework*

26
27 The COPE intervention has been developed to address patient knowledge, expectations,
28 and beliefs of ESRD treatments and ACP (Figure 1). The conceptual framework for this
29 intervention is adapted from the Health Belief Model (Figure 1).³⁷ This model hypothesizes that
30 health-related action depends on the simultaneous occurrence of three factors: 1) the existence of
31 sufficient motivation to make health issues salient or relevant; 2) the belief that one is susceptible
32 to a serious health problem or sequelae of that illness or condition (e.g., perceived threat); and 3)
33 the belief that following a particular health recommendation would be beneficial in reducing the
34 perceived threat.³⁷ Under this model, patient factors such as age, race, ethnicity, and education
35 are posited to be associated with perceived severity (including knowledge of ESRD treatment
36 and ACP) and the threat of kidney disease (expectations and beliefs surrounding ESRD
37 treatments and advanced care preferences).
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 The principal investigator will train a nurse practitioner who is certified in serious illness
4 communication and palliative care to deliver the intervention among all enrolled patients.
5
6 Specifically, the nurse practitioner will be trained to discuss all treatment options (including
7
8 conservative kidney management) and ACP. We will conduct this training in two half-day
9
10 sessions followed by observed interactions with volunteer patients to determine competency in
11
12 delivery of information.
13
14
15

16 17 *Study design and setting*

18
19 We will test the COPE intervention to provide education to patients with advanced CKD
20
21 who are older and/or with poor functional status (defined as a Karnofsky Performance Index
22
23 Score < 70¹³) in a single-center pilot randomized controlled trial (RCT). The objective of this
24
25 intervention is to increase participants' knowledge of treatment options including conservative
26
27 kidney management and ACP and improve communication of patients' treatment and care
28
29 preferences with their clinicians and family members. We hypothesize that educating patients
30
31 about treatment options, eliciting their treatment preferences, and communicating these with
32
33 clinicians and families will promote patient engagement in ACP, improve informed treatment
34
35 decision-making, and reduce racial disparities in knowledge and communication of care
36
37 preferences. We will recruit patients from outpatient renal clinics associated with the University
38
39 of Pennsylvania Perelman School of Medicine in Philadelphia, PA. The Institutional Review
40
41 Board at the University of Pennsylvania has approved this study.
42
43
44
45
46

47 *Participants*

48
49 Those eligible to participate in this trial will be: 1) age ≥ 70 years and/or have poor
50
51 functional status (defined as a Karnofsky Performance Index Score < 70¹³), 2) have advanced
52
53 chronic kidney disease defined as having at least two eGFR measurements < 20 ml/min/1.73m²
54
55
56
57
58
59
60

1
2
3 separated by at least three months,⁴⁰ 3) prefer to speak English-during clinical encounters, and 4)
4 self-report as Black or White race. Exclusion criteria include being listed for kidney transplant,
5 being legally blind, or screening positive for severe cognitive dysfunction defined as having 8 or
6 more errors on the Short Portable Mental Status Questionnaire for assessment of organic brain
7 deficit.⁴¹ For potentially eligible patients < 70 years of age, we will ask treating clinicians to
8 complete a Karnofsky Performance Index Score.
9

16 *Recruitment*

17
18 Research staff will access electronic medical records of clinic patients and nephrologists'
19 list of patients with poor functional status to identify potential study participants. Prior to
20 approaching patients to invite them to participate in the study, a study coordinator will also
21 confirm study suitability with each patient's nephrologist. Given the diverse patient
22 demographics in the outpatient renal clinics, we anticipate equal representation of Black and
23 White patients.
24
25
26
27
28
29
30
31

32 *Study procedures*

33
34
35 Prior to the initiation of the pilot RCT, we will assess the feasibility and acceptability of
36 COPE among a small sample of patients (n=10). Immediately after receiving education, patients
37 will be asked to rate satisfaction on a Likert scale and usefulness based on the modified
38 Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.⁴² We will assess the reasons for
39 refusal and attrition data before finalizing recruitment and study procedures.
40
41
42
43
44
45
46

47 We will randomize patients (n=100) in a 1:1 fashion with stratification by race to receive
48 one of two arms: 1) enhanced usual care or 2) usual care plus COPE. We will collect baseline
49 data for patients at the time of enrollment and prior to randomization (Table 1). Further data
50 collection will take place via phone sessions at pre-specified time intervals (Figure 2).
51
52
53
54
55
56
57
58
59
60

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

1
2
3 The primary outcome for this intervention is change in knowledge of conservative kidney
4 management and ACP. Additional outcomes include assessing the feasibility and acceptability of
5 COPE, patient communication of ESRD and advanced treatment preferences with clinicians and
6 family members. We will also evaluate racial disparities in conservative kidney management,
7 ACP knowledge and communication of care preferences. We will ascertain knowledge,
8 treatment preferences, communication of preferences, and intervention acceptability via short
9 questionnaires at the time points displayed in Figure 2.
10
11
12
13
14
15
16
17
18

19 We will also measure other outcomes including health literacy,⁴⁴ perceived mental and
20 physical health status,^{45,46} spiritual well-being,⁴⁷ perceived stress,⁴⁸ and quality of life⁴⁹, using
21 validated surveys (Table 2). Patient demographics, whether patients have completed advance
22 directives, and comorbidities will be ascertained via medical record review and surveys.
23
24
25
26
27

28 *Analysis*

29 Feasibility and acceptability

30 We will consider that the intervention has adequate feasibility if at least 70% of eligible
31 patients who are approached provide consent and enroll in the study. Additionally, we will
32 determine that adequate acceptability is achieved if at least 80% of patients have a mean score of
33 ≥ 4.9 using the modified Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.⁴²
34
35
36
37
38
39
40
41

42 CKM and ACP knowledge, communication and preferences

43 We will describe patient characteristics using proportions for categorical variables and
44 means (\pm SD) or medians (interquartile range) for continuous variables as appropriate. We will
45 test for differences in outcomes between study arms regarding: 1) change in conservative kidney
46 management/ACP knowledge score, 2) ESRD treatment preference, 3) EOL preference, and 4)
47 communication of preferences with clinicians and family members using univariate analyses
48 (two-sample t-test, Wilcoxon rank-sum, or Chi-square test). Given the possibility of imbalance
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 of baseline characteristics between study arms due to small sample size, we will perform
4
5 secondary analyses using multivariate linear and logistic regression to measure the independent
6
7 association of the study arm with all outcomes adjusting for measured patient characteristics
8
9 (age, sex, race, ethnicity, income level, education level, health literacy, and Charleston co-
10
11 morbidity index). We will check for collinearity and interactions between variables and
12
13 determine significance by a two-sided alpha level of 0.05.
14
15

16 17 Racial disparities

18
19 To determine whether the intervention reduces racial disparities in outcomes between
20
21 Black and White patients, we will add an interaction term between race and study arm in the
22
23 multivariate analyses. A p-value of 0.15 or less will be considered statistically significant when
24
25 testing for interaction. All analyses will be done in SAS (Version 9.4, Cary, NC).
26
27

28 29 Power and sample size

30
31 Based on published data demonstrating poor knowledge of conservative kidney
32
33 management among patients with advanced kidney disease,⁵⁰ we anticipate that recruitment of
34
35 50 patients to each arm will provide 85% power to detect an effect size of 0.5 SD when
36
37 comparing the change in knowledge of conservative kidney management and advance care
38
39 planning between the two groups.^{51,52}
40
41

42 43 **Discussion**

44
45 COPE aims to improve knowledge about conservative kidney management and ACP as
46
47 well as communication of care preferences for patients with advanced CKD who are older and/or
48
49 who have poor functional status. Additionally, we expect that the intervention will reduce racial
50
51 disparities in these outcomes among Black and White patients. We anticipate that COPE will
52
53
54
55
56
57
58
59
60

1
2
3 ultimately improve informed decision-making about ESRD treatments and encourage patients to
4 engage in timely ACP discussions with their clinicians and family members.
5
6

7
8 This pilot RCT is designed to specifically evaluate an educational intervention for
9
10 patients who are older and/or with poor functional status about conservative kidney management
11 and ACP. Our intervention is informed by qualitative work among patients, caregivers, and
12 clinicians and by a comprehensive review of existing literature. COPE consists of three novel
13 components. First, we are targeting educational efforts towards patients who are older and/or
14 with poor functional status, a group for whom there is often considerable uncertainty about the
15 benefits versus the harms of dialysis. We will use questionnaires to identify knowledge gaps
16 among patients to improve conservative kidney management and ACP education. Second,
17 patients will receive conservative kidney management and ACP education that is integrated with
18 rather than siloed from other aspects of advanced CKD care. Studies focused on dialysis
19 decision-making among CKD patients are lacking.^{30,32,53–56} Fully informing patients with
20 advanced CKD of conservative kidney management options, as well as discussing their
21 preferences for care at EOL allows patients to focus on values and goals that are most important
22 to them. Third, we aim to reduce racial disparities in knowledge and communication of
23 conservative kidney management and EOL preferences among patients with advanced CKD.
24 Compared to White patients with CKD, Black patients have lower health literacy, less
25 knowledge about treatment options for advanced kidney disease, and tend to have poor
26 knowledge of support resources to cope with the disease.^{57,58} Racial differences in knowledge
27 outcomes may in part be due to the notion that educational interventions are developed to
28 achieve a “one size fits all” standard. However, COPE has been developed with input from a
29 diverse patient population of patients with CKD and with specific attention to communication
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 style and health literacy barriers. There are few existing ACP and conservative kidney
4 management educational tools that account for knowledge differences among patients, which
5 could ultimately help to reduce racial disparities in patient understanding of these aspects of
6 care.^{33,59}
7
8
9

10
11
12 There are a few limitations to this study. This is a single-center study and we will enroll
13 patients who self-identify as White or Black. Thus, conclusions may not be generalizable to
14 patients of different racial backgrounds or who live in other geographical locations. Additionally,
15 shared decision-making includes patients, clinicians, and families, but our study will only
16 measure patient outcomes. Lastly, we acknowledge that this study will focus on short-term
17 outcomes and therefore we will be unable to comment on the downstream effects of the
18 intervention. Future studies will confirm whether COPE has broad relevance and usefulness for
19 similar patients with different demographics, feasibility and acceptability among clinicians and
20 caregivers, and long-term outcomes such as treatment decision-making confidence and conflict.
21
22
23
24
25
26
27
28
29
30
31
32

33 Educating patients with advanced CKD who are older or seriously ill about ESRD
34 treatment options (including conservative kidney management) and ACP is central to promoting
35 shared decision-making and promoting goal-concordant care. We anticipate that our study
36 findings will improve informed decision-making for patients with advanced chronic kidney
37 disease and create an opportunity for clinicians to provide comprehensive patient-centered care
38 for this vulnerable population.
39
40
41
42
43
44
45
46
47
48

49 **Ethics and dissemination**

50 This protocol has been approved by the Institutional Review Board at the University of
51 Pennsylvania. Written informed consent will be obtained from all participants. The findings from
52
53
54
55
56
57
58
59
60

1
2
3 this work will be disseminated through peer-reviewed publications and will be presented at
4
5 academic conferences.
6

7 **Authors' contributions**

8
9
10 Each author contributed important intellectual content during manuscript drafting or revision,
11
12 and accepts personal accountability for the author's own contributions.
13

14 **Funding statement**

15
16
17 This study is supported by grant K23DK114526 (NDE) from the National Institutes of Health.
18

19 The funder did not have a role in the design of the study.
20

21 **Competing interests statement**

22
23
24 All other authors declare that they have no relevant conflict of interests.
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

- 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
 - 16
 - 17
 - 18
 - 19
 - 20
 - 21
 - 22
 - 23
 - 24
 - 25
 - 26
 - 27
 - 28
 - 29
 - 30
 - 31
 - 32
 - 33
 - 34
 - 35
 - 36
 - 37
 - 38
 - 39
 - 40
 - 41
 - 42
 - 43
 - 44
 - 45
 - 46
 - 47
 - 48
 - 49
 - 50
 - 51
 - 52
 - 53
 - 54
 - 55
 - 56
 - 57
 - 58
 - 59
 - 60
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

- 1
2
3 36. Eneanya ND, Wenger JB, Waite K, et al. Racial Disparities in End-of-Life Communication
4 and Preferences among Chronic Kidney Disease Patients. *Am J Nephrol*. 2016;44(1):46-53.
5 doi:10.1159/000447097
6
- 7 37. Rosenstock IM, Strecher VJ, Becker MH. Social Learning Theory and the Health Belief
8 Model. *Health Educ Q*. 1988;15(2):175-183. doi:10.1177/109019818801500203
9
- 10 38. Eneanya ND, Labbe AK, Stallings TL, et al. Caring for older patients with advanced
11 chronic kidney disease and considering their needs: a qualitative study. *BMC Nephrol*.
12 2020;21(1):213. doi:10.1186/s12882-020-01870-1
13
14
- 15 39. Institute of Medicine (US) Committee on Health Literacy. *Health Literacy: A Prescription*
16 *to End Confusion*. (Nielsen-Bohlman L, Panzer AM, Kindig DA, eds.). National Academies
17 Press (US); 2004. Accessed June 15, 2020.
18 <http://www.ncbi.nlm.nih.gov/books/NBK216032/>
19
- 20 40. Levey AS, Bosch JP, Lewis JB, Greene T, Rogers N, Roth D. A more accurate method to
21 estimate glomerular filtration rate from serum creatinine: a new prediction equation.
22 Modification of Diet in Renal Disease Study Group. *Ann Intern Med*. 1999;130(6):461-470.
23 doi:10.7326/0003-4819-130-6-199903160-00002
24
25
- 26 41. Pfeiffer E. A Short Portable Mental Status Questionnaire for the Assessment of Organic
27 Brain Deficit in Elderly Patients†. *J Am Geriatr Soc*. 1975;23(10):433-441.
28 doi:10.1111/j.1532-5415.1975.tb00927.x
29
- 30 42. Winterbottom AE, Gavaruzzi T, Mooney A, et al. Patient Acceptability of the Yorkshire
31 Dialysis Decision Aid (YoDDA) Booklet: A Prospective Non-Randomized Comparison
32 Study Across 6 Predialysis Services. *Perit Dial Int J Int Soc Perit Dial*. 2016;36(4):374-
33 381. doi:10.3747/pdi.2014.00274
34
35
- 36 43. The National Kidney Foundation. If You Choose Not To Start Dialysis Treatment.
37 Published 2008. Accessed April 15, 2020. https://www.kidney.org/sites/default/files/11-10-0330_ifyouchoose.pdf
38
39
- 40 44. Cavanaugh KL, Wingard RL, Hakim RM, et al. Low Health Literacy Associates with
41 Increased Mortality in ESRD. *J Am Soc Nephrol JASN*. 2010;21(11):1979-1985.
42 doi:10.1681/ASN.2009111163
43
44
- 45 45. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I.
46 Conceptual framework and item selection. *Med Care*. 1992;30(6):473-483.
47
48
- 49 46. Wight JP, Edwards L, Brazier J, Walters S, Payne JN, Brown CB. The SF36 as an outcome
50 measure of services for end stage renal failure. *Qual Health Care QHC*. 1998;7(4):209-221.
51
- 52 47. Peterman AH, Fitchett G, Brady MJ, Hernandez L, Cella D. Measuring spiritual well-being
53 in people with cancer: the functional assessment of chronic illness therapy--Spiritual Well-
54 being Scale (FACIT-Sp). *Ann Behav Med Publ Soc Behav Med*. 2002;24(1):49-58.
55 doi:10.1207/S15324796ABM2401_06
56
57
58
59

- 1
- 2
- 3
- 4 48. Taylor JM. Psychometric analysis of the Ten-Item Perceived Stress Scale. *Psychol Assess*. 2015;27(1):90-101. doi:10.1037/a0038100
- 5
- 6
- 7 49. Robin Cohen S, Mount BM, Bruera E, Provost M, Rowe J, Tong K. Validity of the McGill
- 8 Quality of Life Questionnaire in the palliative care setting: a multi-centre Canadian study
- 9 demonstrating the importance of the existential domain. *Palliat Med*. 1997;11(1):3-20.
- 10 doi:10.1177/026921639701100102
- 11
- 12 50. Prakash S, McGrail A, Lewis SA, et al. Behavioral stage of change and dialysis decision-
- 13 making. *Clin J Am Soc Nephrol CJASN*. 2015;10(2):197-204. doi:10.2215/CJN.05560614
- 14
- 15 51. Norman G, Sloan J, Wyrwich K. Interpretation of Changes in Health-related Quality of
- 16 Life: The Remarkable Universality of Half a Standard Deviation. *Med Care*.
- 17 2003;41(5):582-592. doi:10.1097/01.MLR.0000062554.74615.4C
- 18
- 19
- 20 52. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Taylor and Francis; 2013.
- 21 Accessed June 15, 2020. http://www.123library.org/book_details/?id=107447
- 22
- 23 53. Saeed F, Adams H, Epstein RM. Matters of Life and Death: Why Do Older Patients Choose
- 24 Conservative Management? *Am J Nephrol*. 2020;51(1):35-42. doi:10.1159/000504692
- 25
- 26 54. Saeed F, Sardar M, Rasheed K, et al. Dialysis Decision-Making and Preferences for End-
- 27 of-Life Care: Perspectives of Pakistani Patients Receiving Maintenance Dialysis. *J Pain*
- 28 *Symptom Manage*. Published online March 20, 2020.
- 29 doi:10.1016/j.jpainsymman.2020.03.009
- 30
- 31
- 32 55. Verberne WR, Konijn WS, Prantl K, et al. Older patients' experiences with a shared
- 33 decision-making process on choosing dialysis or conservative care for advanced chronic
- 34 kidney disease: a survey study. *BMC Nephrol*. 2019;20(1):264. doi:10.1186/s12882-019-
- 35 1423-x
- 36
- 37 56. Saeed F, Sardar MA, Davison SN, Murad H, Duberstein PR, Quill TE. Patients'
- 38 perspectives on dialysis decision-making and end-of-life care. *Clin Nephrol*.
- 39 2019;91(5):294-300. doi:10.5414/CN109608
- 40
- 41
- 42 57. Kazley AS, Johnson E, Simpson K, Chavin K, Baliga P. African American patient
- 43 knowledge of kidney disease: A qualitative study of those with advanced chronic kidney
- 44 disease. *Chronic Illn*. 2015;11(4):245-255. doi:10.1177/1742395314556658
- 45
- 46 58. Grubbs V, Gregorich SE, Perez-Stable EJ, Hsu C. Health Literacy and Access to Kidney
- 47 Transplantation. *Clin J Am Soc Nephrol CJASN*. 2009;4(1):195-200.
- 48 doi:10.2215/CJN.03290708
- 49
- 50
- 51 59. Song M-K, Ward SE, Fine JP, et al. Advance Care Planning and End-of-Life Decision
- 52 Making in Dialysis: A Randomized Controlled Trial Targeting Patients and Their
- 53 Surrogates. *Am J Kidney Dis Off J Natl Kidney Found*. 2015;66(5):813-822.
- 54 doi:10.1053/j.ajkd.2015.05.018
- 55
- 56
- 57
- 58
- 59
- 60

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

1
2
3 **Figure 1. Health Belief Model (adapted for COPE)**
4
5
6

7 **Abbreviations:** ACP = Advance care planning, CKM = Conservative kidney management, ESRD = End-
8 stage renal disease
9

10
11
12
13
14
15
16 **Figure 2. Study flow chart**
17
18
19

20 **Abbreviations:** FACIT-SP-12=Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being,
21 KPS=Karnofsky Performance Index Score, PAM=Patient Activation Measure, PSS-4=Perceived Stress
22 Scale, QOL=McGill Quality of Life Questionnaire-Part A, REALM=Rapid Estimate of Adult Literacy in
23 Medicine, SPMSQ=Short Portable Mental Status Questionnaire, YoDDA=Modified Yorkshire Dialysis
24 Decision Aid.
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

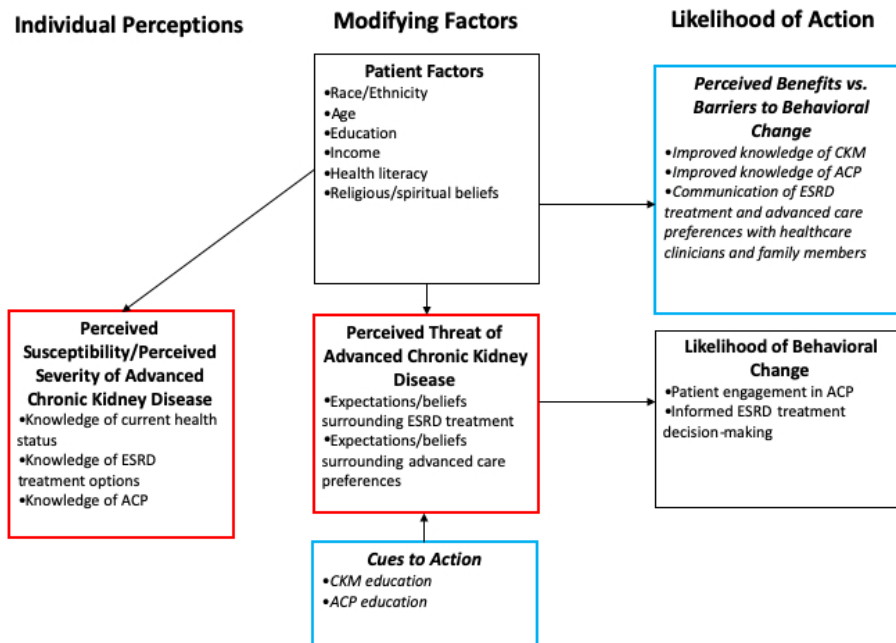


Figure 1. Health Belief Model (adapted for COPE)

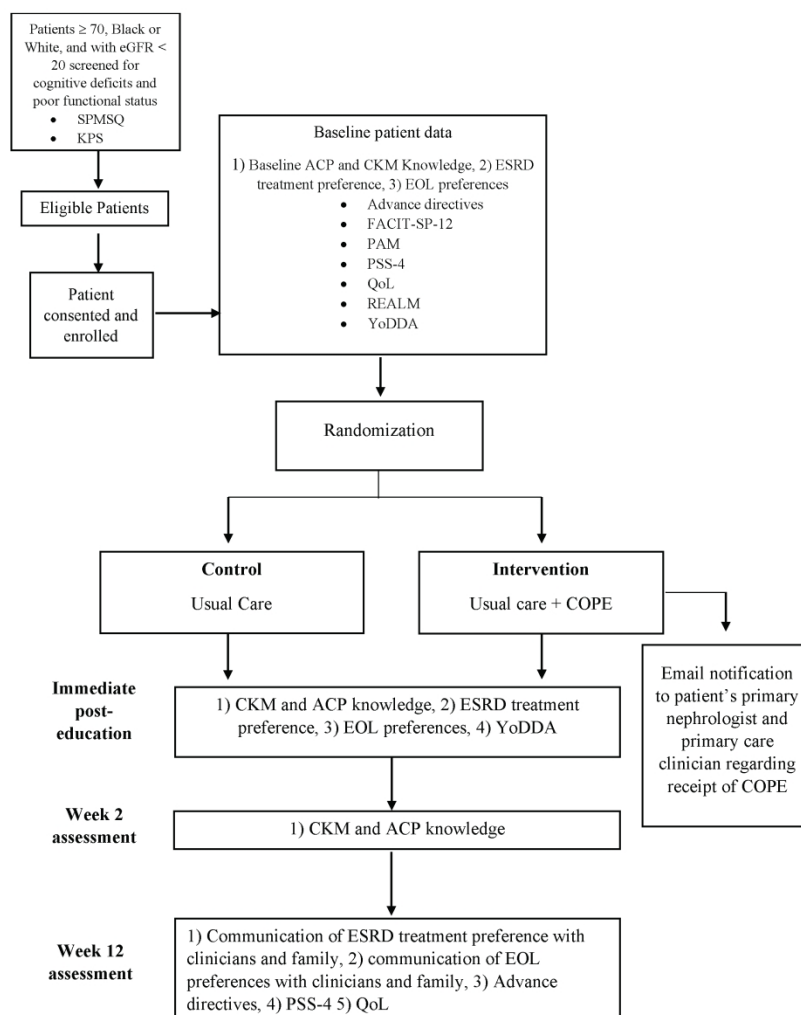


Figure 2. Study flow chart

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-042620.R1
Article Type:	Protocol
Date Submitted by the Author:	15-Oct-2020
Complete List of Authors:	Stallings, Taylor; University of Pennsylvania Perelman School of Medicine Temel, Jennifer; Massachusetts General Hospital Cancer Center, Medicine Klaiman, Tamar; University of Pennsylvania Perelman School of Medicine Paasche-Orlow, Michael; Boston Medical Center, General Internal Medicine Alegria, M; Massachusetts General Hospital, O'Hare, Ann; University of Washington Department of Medicine, O'Connor, Nina; University of Pennsylvania Dember, Laura; University of Pennsylvania, Halpern, SD; University of Pennsylvania Perelman School of Medicine Eneanya, Nwamaka; University of Pennsylvania Perelman School of Medicine
Primary Subject Heading:	Renal medicine
Secondary Subject Heading:	Palliative care, Geriatric medicine
Keywords:	Chronic renal failure < NEPHROLOGY, End stage renal failure < NEPHROLOGY, Adult palliative care < PALLIATIVE CARE, GERIATRIC MEDICINE

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3 **Title:** Integrating conservative kidney management options and advance care planning education
4 (COPE) into routine CKD care: a protocol for a pilot randomized controlled trial
5
6
7

8 **Authors:** Taylor L. Stallings, MS¹, Jennifer S. Temel, MD², Tamar A. Klaiman PhD,MPH¹,
9
10 Michael K. Paasche-Orlow³, Margarita Alegria, PhD⁴, Ann O'Hare⁵, Nina O'Connor, MD⁶
11
12 Laura M. Dember, MD^{7, 8}, Scott D. Halpern MD, PhD¹, Nwamaka D. Eneanya, MD, MPH^{1,7,8}
13
14
15

16 **Affiliations:**

17
18
19 ¹Palliative and Advanced Illness Research Center, Perelman School of Medicine, University of
20
21 Pennsylvania, Philadelphia, PA, USA.
22
23

24 ²Division of Hematology and Oncology, Department of Internal Medicine, Massachusetts
25
26 General Hospital, Harvard Medical School, Boston, MA, USA.
27
28

29 ³Section of General Internal Medicine, Boston Medical Center, Boston University School of
30
31 Medicine, Boston, MA, USA.
32
33

34 ⁴Department of Medicine and Psychiatry, Harvard Medical School, Boston, MA, USA.
35
36
37

38 ⁵Division of Nephrology, Department of Medicine, University of Washington, Seattle, WA,
39
40 USA.
41

42 ⁶Palliative and Hospice Medicine, Perelman School of Medicine, University of Pennsylvania,
43
44 Philadelphia, PA, USA.
45

46 ⁷Renal-Electrolyte Division, Perelman School of Medicine, University of Pennsylvania,
47
48 Philadelphia, PA, USA.
49
50

51 ⁸Center for Clinical Epidemiology and Biostatistics, Perelman School of Medicine, University of
52
53 Pennsylvania, Philadelphia, PA, USA.
54
55
56
57
58
59
60

1
2
3 **Abstract word count: 291/300**

4 **Manuscript word count: 2704/4000**

5
6
7 **Tables: 2**

8 **Figures: 2**

9
10
11
12 **Corresponding Author**

13 Nwamaka Eneanya, MD, MPH

14 Renal-Electrolyte and Hypertension Division

15 Perelman School of Medicine

16 University of Pennsylvania

17 307 Blockley Hall

18 423 Guardian Drive

19 Philadelphia, PA 19104

20 Ph: 215-746-5080

21 Email: Nwamaka.eneanya@penmedicine.upenn.edu

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 (Conservative Kidney Management Options and Advance Care Planning Education – 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/1.73m²), 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.

1
2
3 The results from this work will be presented at academic conferences and disseminated through
4
5 peer-reviewed journals.
6
7

8 **Trial registration:** This trial is registered at ClinicalTrials.gov under NCT03229811.
9

10 **Key words:** Advanced chronic kidney disease, conservative kidney management, advance care
11
12 planning, racial disparities
13
14

15
16 **Strengths and limitations of this study:**
17

- 18 • This is a pilot randomized controlled trial evaluating an intervention designed to
19
20 primarily educate older and seriously ill patients with advanced CKD about conservative
21
22 kidney management and advance care planning.
23
24
- 25 • Patients will receive an educational intervention that is integrated into their advanced
26
27 CKD care.
28
29
- 30 • We anticipate that the intervention will reduce racial disparities between Black and White
31
32 patients in knowledge about conservative kidney management and advance care
33
34 planning.
35
36
- 37 • As this study is being conducted at a single-center and is being limited to White and
38
39 Black patients, we are unable to generalize study results to different regions or patients of
40
41 different races or ethnicities.
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 populations, patients with advanced CKD would prefer to have ACP and goals of care
4
5 discussions earlier in the disease course.^{19,27} However, these conversations are often challenging
6
7 and available evidence suggests that nephrologists tend not to engage in ACP with their
8
9 patients.^{19,27–30} Additionally, some studies have shown racial disparities in ACP knowledge, and
10
11 that racial-ethnic minority patients are less likely to engage in goals of care discussions and
12
13 advance care planning when compared to White patients.^{16,18,31,32} Education and improving
14
15 informed decision-making may mitigate racial disparities in care for older patients with
16
17 CKD.^{18,33} Thus, we are testing whether a novel educational intervention incorporated into
18
19 routine advanced CKD care, called **Conservative Kidney Management Options and Advance**
20
21 **Care Planning Education (COPE)**, can improve knowledge and communication among patients
22
23 who are older and/or with poor functional status.

24 **Methodology and analysis**

25 *Conceptual framework*

26
27
28 The COPE intervention has been developed to address patient knowledge, expectations,
29
30 and beliefs of kidney failure treatments and ACP (Figure 1). The conceptual framework for this
31
32 intervention is adapted from the Health Belief Model (Figure 1).³⁴ This model hypothesizes that
33
34 health-related action depends on the simultaneous occurrence of three factors: 1) the existence of
35
36 sufficient motivation to make health issues salient or relevant; 2) the belief that one is susceptible
37
38 to a serious health problem or sequelae of that illness or condition (e.g., perceived threat); and 3)
39
40 the belief that following a particular health recommendation would be beneficial in reducing the
41
42 perceived threat³⁴ Under this model, patient factors such as age, race, ethnicity, and education
43
44 are posited to be associated with perceived severity (including knowledge of kidney failure
45
46 treatment and ACP) and the threat of kidney disease (expectations and beliefs surrounding
47
48 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

1
2
3 The principal investigator will train a nurse practitioner who is certified in serious illness
4 communication and palliative care to deliver the intervention among all enrolled patients.
5
6 Specifically, the nurse practitioner will be trained to discuss all treatment options (including
7
8 conservative kidney management) and ACP. We will conduct this training in two half-day
9
10 sessions followed by observed interactions with volunteer patients to determine competency in
11
12 delivery of information.
13
14
15

16 17 *Study design and setting*

18
19 We will test the COPE intervention to provide education to patients with advanced CKD
20
21 who are older and/or with poor functional status (defined as a Karnofsky Performance Index
22
23 Score < 70¹¹) in a single-center pilot randomized controlled trial (RCT). The objective of this
24
25 intervention is to increase participants' knowledge of treatment options including conservative
26
27 kidney management and ACP and improve communication of patients' treatment and care
28
29 preferences with their clinicians and family members. We hypothesize that educating patients
30
31 about treatment options, eliciting their treatment preferences, and communicating these with
32
33 clinicians and families will promote patient engagement in ACP, improve informed treatment
34
35 decision-making, and reduce racial disparities in knowledge and communication of care
36
37 preferences. We will recruit patients from outpatient renal clinics associated with the University
38
39 of Pennsylvania Perelman School of Medicine in Philadelphia, PA. The Institutional Review
40
41 Board at the University of Pennsylvania has approved this study.
42
43
44
45
46

47 *Participants*

48
49 Those eligible to participate in this trial will be: 1) age ≥ 70 years and/or have poor
50
51 functional status (defined as a Karnofsky Performance Index Score < 70¹¹), 2) have advanced
52
53 chronic kidney disease defined as having at least two eGFR measurements < 20 ml/min/1.73m²
54
55
56
57
58
59
60

1
2
3 separated by at least three months,³⁷ 3) prefer to speak English-during clinical encounters, and 4)
4 self-report as Black or White race. Exclusion criteria include being listed for kidney transplant,
5 being legally blind, or screening positive for severe cognitive dysfunction defined as having 8 or
6 more errors on the Short Portable Mental Status Questionnaire for assessment of organic brain
7 deficit.³⁸ For potentially eligible patients < 70 years of age, we will ask treating clinicians to
8 complete a Karnofsky Performance Index Score.
9

16 *Recruitment*

17
18 Research staff will access electronic medical records of clinic patients and nephrologists'
19 list of patients with poor functional status to identify potential study participants. Prior to
20 approaching patients to invite them to participate in the study, a study coordinator will also
21 confirm study suitability with each patient's nephrologist. Given the diverse patient
22 demographics in the outpatient renal clinics, we anticipate equal representation of Black and
23 White patients.
24
25
26
27
28
29
30
31

32 *Study procedures*

33
34
35 Prior to the initiation of the pilot RCT, we will assess the feasibility and acceptability of
36 COPE among a small sample of patients (n=10). Immediately after receiving education, patients
37 will be asked to rate satisfaction on a Likert scale and usefulness based on the modified
38 Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.³⁹ We will assess the reasons for
39 refusal and attrition data before finalizing recruitment and study procedures.
40
41
42
43
44
45
46

47 We will randomize patients (n=100) in a 1:1 fashion with stratification by race to receive
48 one of two arms: 1) enhanced usual care or 2) usual care plus COPE. We will collect baseline
49 data for patients at the time of enrollment and prior to randomization (Table 1). Further data
50 collection will take place via phone sessions at pre-specified time intervals (Figure 2).
51
52
53
54
55
56
57
58
59
60

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

1
2
3 coordinator will complete the fidelity checklist and re-training of the nurse practitioner will
4
5 occur if 80% of criteria are not met.
6

7 *Outcomes*

8
9 The primary outcome for this intervention is change in knowledge of conservative kidney
10 management and ACP. Additional outcomes include assessing the feasibility and acceptability of
11 COPE, patient communication of kidney failure and advanced care treatment preferences with
12 clinicians and family members. We will also evaluate racial disparities in conservative kidney
13 management, ACP knowledge and communication of care preferences. We will ascertain
14 knowledge, treatment preferences, communication of preferences, and intervention acceptability
15 via short questionnaires at the time points displayed in Figure 2.
16
17
18
19
20
21
22
23
24

25 We will also measure other outcomes including health literacy,⁴¹ perceived mental and
26 physical health status,^{42,43} spiritual well-being,⁴⁴ perceived stress,⁴⁵ and quality of life⁴⁶, using
27 validated surveys (Table 2). Patient demographics, whether patients have completed advance
28 directives, and comorbidities will be ascertained via medical record review and surveys.
29
30
31
32
33

34 *Analysis*

35 Feasibility and acceptability

36
37 We will consider that the intervention has adequate feasibility if at least 70% of eligible
38 patients who are approached provide consent and enroll in the study. Additionally, we will
39 determine that adequate acceptability is achieved if at least 80% of patients have a mean score of
40 ≥ 4.9 using the modified Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.³⁹
41
42
43
44
45
46
47

48 CKM and ACP knowledge, communication and preferences

49
50 We will describe patient characteristics using proportions for categorical variables and
51 means (\pm SD) or medians (interquartile range) for continuous variables as appropriate. We will
52 test for differences in outcomes between study arms regarding: 1) change in conservative kidney
53
54
55
56
57
58
59
60

1
2
3 management/ACP knowledge score, 2) kidney failure treatment preference, 3) EOL preference,
4 and 4) communication of preferences with clinicians and family members using univariate
5 analyses (two-sample t-test, Wilcoxon rank-sum, or Chi-square test). Given the possibility of
6 imbalance of baseline characteristics between study arms due to small sample size, we will
7 perform secondary analyses using multivariate linear and logistic regression to measure the
8 independent association of the study arm with all outcomes adjusting for measured patient
9 characteristics (age, sex, race, ethnicity, income level, education level, health literacy, and
10 Charleston co-morbidity index). We will check for collinearity and interactions between
11 variables and determine significance by a two-sided alpha level of 0.05.
12
13
14
15
16
17
18
19
20
21
22
23

24 Racial disparities

25
26 To determine whether the intervention reduces racial disparities in outcomes between
27 Black and White patients, we will add an interaction term between race and study arm in the
28 multivariate analyses. A p-value of 0.15 or less will be considered statistically significant when
29 testing for interaction. All analyses will be done in SAS (Version 9.4, Cary, NC).
30
31
32
33
34
35

36 Power and sample size

37 Based on published data demonstrating poor knowledge of conservative kidney
38 management among patients with advanced kidney disease,⁴⁷ we anticipate that recruitment of
39 50 patients to each arm will provide 85% power to detect an effect size of 0.5 SD when
40 comparing the change in knowledge of conservative kidney management and advance care
41 planning between the two groups.^{48,49}
42
43
44
45
46
47
48
49

50 **Discussion**

51 COPE aims to improve knowledge about conservative kidney management and ACP as
52 well as communication of care preferences for patients with advanced CKD who are older and/or
53
54
55
56
57
58
59
60

1
2
3 who have poor functional status. Additionally, we expect that the intervention will reduce racial
4
5 disparities in these outcomes among Black and White patients. We anticipate that COPE will
6
7 ultimately improve informed decision-making about kidney failure treatments and encourage
8
9 patients to engage in timely ACP discussions with their clinicians and family members.
10
11

12 This pilot RCT is designed to specifically evaluate an educational intervention for
13
14 patients who are older and/or with poor functional status about conservative kidney management
15
16 and ACP. Our intervention is informed by qualitative work among patients, caregivers, and
17
18 clinicians and by a comprehensive review of existing literature. COPE consists of three novel
19
20 components. First, we are targeting educational efforts towards patients who are older and/or
21
22 with poor functional status, a group for whom there is often considerable uncertainty about the
23
24 benefits versus the harms of dialysis. We will use questionnaires to identify knowledge gaps
25
26 among patients to improve conservative kidney management and ACP education. Second,
27
28 patients will receive conservative kidney management and ACP education that is integrated with
29
30 rather than siloed from other aspects of advanced CKD care. Studies focused on dialysis
31
32 decision-making among CKD patients are lacking.^{29,30,50-53} Fully informing patients with
33
34 advanced CKD of conservative kidney management options, as well as discussing their
35
36 preferences for care at EOL allows patients to focus on values and goals that are most important
37
38 to them. Third, we aim to reduce racial disparities in knowledge and communication of
39
40 conservative kidney management and EOL preferences among patients with advanced CKD.
41
42 Compared to White patients with CKD, Black patients have lower health literacy, less
43
44 knowledge about treatment options for advanced kidney disease, and tend to have poor
45
46 knowledge of support resources to cope with the disease.^{54,55} Racial differences in knowledge
47
48 outcomes may in part be due to the notion that educational interventions are developed to
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 achieve a “one size fits all” standard. However, COPE has been developed with input from a
4
5 diverse patient population of patients with CKD and with specific attention to communication
6
7 style and health literacy barriers. There are few existing ACP and conservative kidney
8
9 management educational tools that account for knowledge differences among patients, which
10
11 could ultimately help to reduce racial disparities in patient understanding of these aspects of
12
13 care.^{31,56}
14
15

16
17 There are a few limitations to this study. This is a single-center study and we will enroll
18
19 patients who self-identify as White or Black. Thus, conclusions may not be generalizable to
20
21 patients of different racial backgrounds or who live in other geographical locations. Additionally,
22
23 shared decision-making includes patients, clinicians, and families, but our study will only
24
25 measure patient outcomes. Lastly, we acknowledge that this study will focus on short-term
26
27 outcomes and therefore we will be unable to comment on the downstream effects of the
28
29 intervention. Future studies will confirm whether COPE has broad relevance and usefulness for
30
31 similar patients with different demographics, feasibility and acceptability among clinicians and
32
33 caregivers, and long-term outcomes such as treatment decision-making confidence and conflict.
34
35
36

37
38 Educating patients with advanced CKD who are older or seriously ill about kidney failure
39
40 treatment options (including conservative kidney management) and ACP is central to promoting
41
42 shared decision-making and promoting goal-concordant care. We anticipate that our study
43
44 findings will improve informed decision-making for patients with advanced chronic kidney
45
46 disease and create an opportunity for clinicians to provide comprehensive patient-centered care
47
48 for this vulnerable population.
49
50
51
52
53
54
55
56
57
58
59
60

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.

Funding statement

This study is supported by grant K23DK114526 (NDE) from the National Institutes of Health. The funder did not have a role in the design of the study.

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

- 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
 - 16
 - 17
 - 18
 - 19
 - 20
 - 21
 - 22
 - 23
 - 24
 - 25
 - 26
 - 27
 - 28
 - 29
 - 30
 - 31
 - 32
 - 33
 - 34
 - 35
 - 36
 - 37
 - 38
 - 39
 - 40
 - 41
 - 42
 - 43
 - 44
 - 45
 - 46
 - 47
 - 48
 - 49
 - 50
 - 51
 - 52
 - 53
 - 54
 - 55
 - 56
 - 57
 - 58
 - 59
 - 60
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

- 1
2
3 Press (US); 2004. Accessed October 8, 2019.
4 <http://www.ncbi.nlm.nih.gov/books/NBK216032/>
5
6
7 37. Levey AS, Bosch JP, Lewis JB, Greene T, Rogers N, Roth D. A more accurate method to
8 estimate glomerular filtration rate from serum creatinine: a new prediction equation.
9 Modification of Diet in Renal Disease Study Group. *Ann Intern Med.* 1999;130(6):461-470.
10 doi:10.7326/0003-4819-130-6-199903160-00002
11
12 38. Pfeiffer E. A Short Portable Mental Status Questionnaire for the Assessment of Organic
13 Brain Deficit in Elderly Patients†. *J Am Geriatr Soc.* 1975;23(10):433-441.
14 doi:10.1111/j.1532-5415.1975.tb00927.x
15
16 39. Winterbottom AE, Gavaruzzi T, Mooney A, et al. Patient Acceptability of the Yorkshire
17 Dialysis Decision Aid (YoDDA) Booklet: A Prospective Non-Randomized Comparison
18 Study Across 6 Predialysis Services. *Perit Dial Int J Int Soc Perit Dial.* 2016;36(4):374-
19 381. doi:10.3747/pdi.2014.00274
20
21 40. The National Kidney Foundation. If You Choose Not To Start Dialysis Treatment.
22 Published 2008. Accessed April 15, 2020. https://www.kidney.org/sites/default/files/11-10-0330_ifyouchoose.pdf
23
24 41. Cavanaugh KL, Wingard RL, Hakim RM, et al. Low Health Literacy Associates with
25 Increased Mortality in ESRD. *J Am Soc Nephrol JASN.* 2010;21(11):1979-1985.
26 doi:10.1681/ASN.2009111163
27
28 42. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I.
29 Conceptual framework and item selection. *Med Care.* 1992;30(6):473-483.
30
31 43. Wight JP, Edwards L, Brazier J, Walters S, Payne JN, Brown CB. The SF36 as an outcome
32 measure of services for end stage renal failure. *Qual Health Care QHC.* 1998;7(4):209-221.
33
34 44. Peterman AH, Fitchett G, Brady MJ, Hernandez L, Cella D. Measuring spiritual well-being
35 in people with cancer: the functional assessment of chronic illness therapy--Spiritual Well-
36 being Scale (FACIT-Sp). *Ann Behav Med Publ Soc Behav Med.* 2002;24(1):49-58.
37 doi:10.1207/S15324796ABM2401_06
38
39 45. Taylor JM. Psychometric analysis of the Ten-Item Perceived Stress Scale. *Psychol Assess.*
40 2015;27(1):90-101. doi:10.1037/a0038100
41
42 46. Robin Cohen S, Mount BM, Bruera E, Provost M, Rowe J, Tong K. Validity of the McGill
43 Quality of Life Questionnaire in the palliative care setting: a multi-centre Canadian study
44 demonstrating the importance of the existential domain. *Palliat Med.* 1997;11(1):3-20.
45 doi:10.1177/026921639701100102
46
47 47. Prakash S, McGrail A, Lewis SA, et al. Behavioral stage of change and dialysis decision-
48 making. *Clin J Am Soc Nephrol CJASN.* 2015;10(2):197-204. doi:10.2215/CJN.05560614
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 48. Norman G, Sloan J, Wyrwich K. Interpretation of Changes in Health-related Quality of
4 Life: The Remarkable Universality of Half a Standard Deviation. *Med Care*.
5 2003;41(5):582-592. doi:10.1097/01.MLR.0000062554.74615.4C
6
7
8 49. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Taylor and Francis; 2013.
9 Accessed June 15, 2020. http://www.123library.org/book_details/?id=107447
10
11 50. Saeed F, Adams H, Epstein RM. Matters of Life and Death: Why Do Older Patients Choose
12 Conservative Management? *Am J Nephrol*. 2020;51(1):35-42. doi:10.1159/000504692
13
14 51. Saeed F, Sardar M, Rasheed K, et al. Dialysis Decision-Making and Preferences for End-
15 of-Life Care: Perspectives of Pakistani Patients Receiving Maintenance Dialysis. *J Pain*
16 *Symptom Manage*. Published online March 20, 2020.
17 doi:10.1016/j.jpainsymman.2020.03.009
18
19
20 52. Verberne WR, Konijn WS, Prantl K, et al. Older patients' experiences with a shared
21 decision-making process on choosing dialysis or conservative care for advanced chronic
22 kidney disease: a survey study. *BMC Nephrol*. 2019;20(1):264. doi:10.1186/s12882-019-
23 1423-x
24
25 53. Saeed F, Sardar MA, Davison SN, Murad H, Duberstein PR, Quill TE. Patients'
26 perspectives on dialysis decision-making and end-of-life care. *Clin Nephrol*.
27 2019;91(5):294-300. doi:10.5414/CN109608
28
29
30 54. Kazley AS, Johnson E, Simpson K, Chavin K, Baliga P. African American patient
31 knowledge of kidney disease: A qualitative study of those with advanced chronic kidney
32 disease. *Chronic Illn*. 2015;11(4):245-255. doi:10.1177/1742395314556658
33
34 55. Grubbs V, Gregorich SE, Perez-Stable EJ, Hsu C. Health Literacy and Access to Kidney
35 Transplantation. *Clin J Am Soc Nephrol CJASN*. 2009;4(1):195-200.
36 doi:10.2215/CJN.03290708
37
38
39 56. Song M-K, Ward SE, Fine JP, et al. Advance Care Planning and End-of-Life Decision
40 Making in Dialysis: A Randomized Controlled Trial Targeting Patients and Their
41 Surrogates. *Am J Kidney Dis Off J Natl Kidney Found*. 2015;66(5):813-822.
42 doi:10.1053/j.ajkd.2015.05.018
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59

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

1
2
3 **Figure 1. Health Belief Model (adapted for COPE)**
4
5
6

7 **Abbreviations:** ACP = Advance care planning, CKM = Conservative kidney management, KF = Kidney
8 failure
9

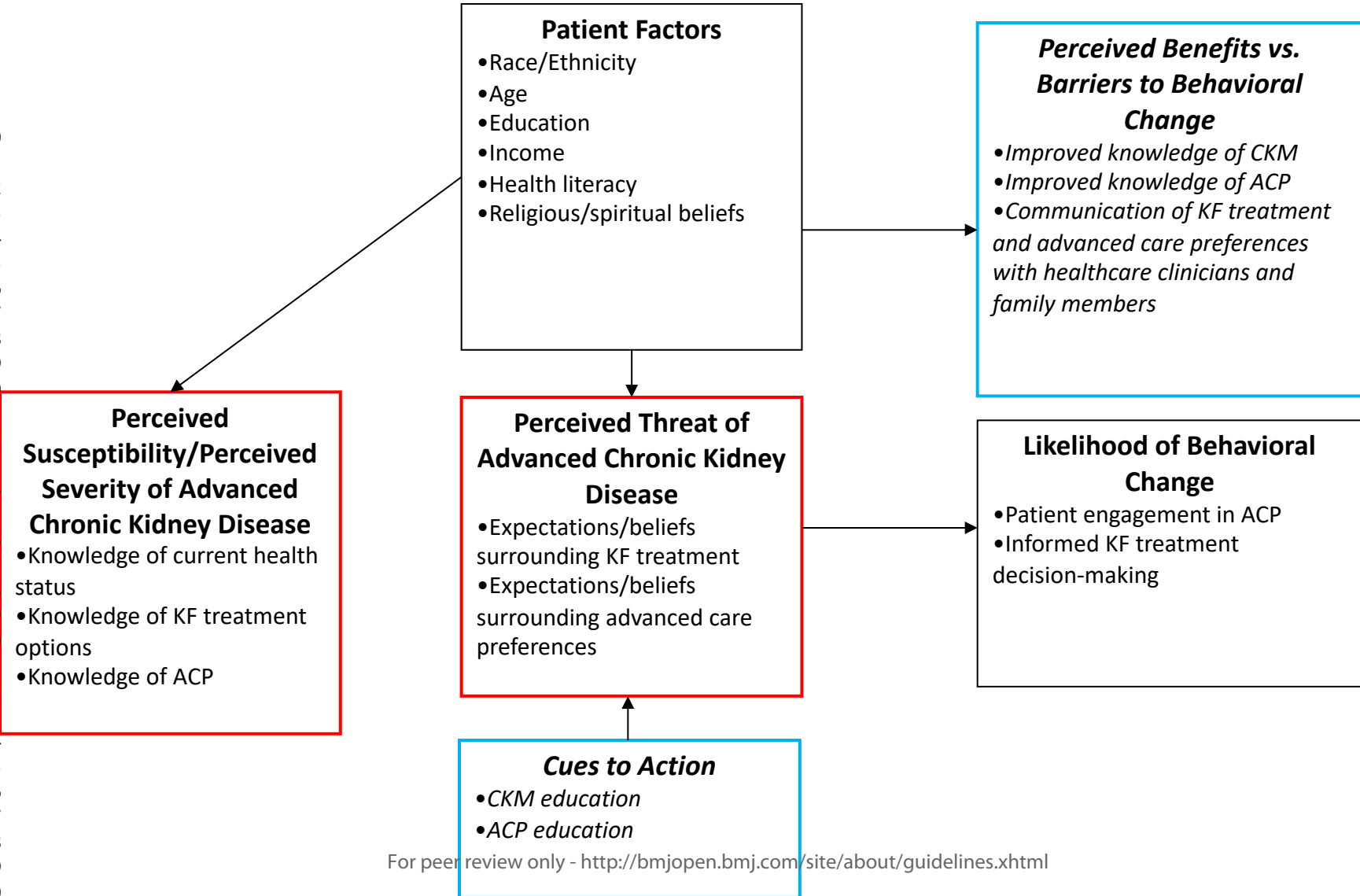
10
11
12
13
14
15
16 **Figure 2. Study flow chart**
17
18
19

20 **Abbreviations:** FACIT-SP-12=Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being,
21 KPS=Karnofsky Performance Index Score, MSPSS = Multidimensional Scale of Perceived Social
22 Support, PAM=Patient Activation Measure, PSS-4=Perceived Stress Scale, QOL=McGill Quality of Life
23 Questionnaire-Part A, REALM=Rapid Estimate of Adult Literacy in Medicine, SPMSQ=Short Portable
24 Mental Status Questionnaire, YoDDA=Modified Yorkshire Dialysis Decision Aid.
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Individual Perceptions

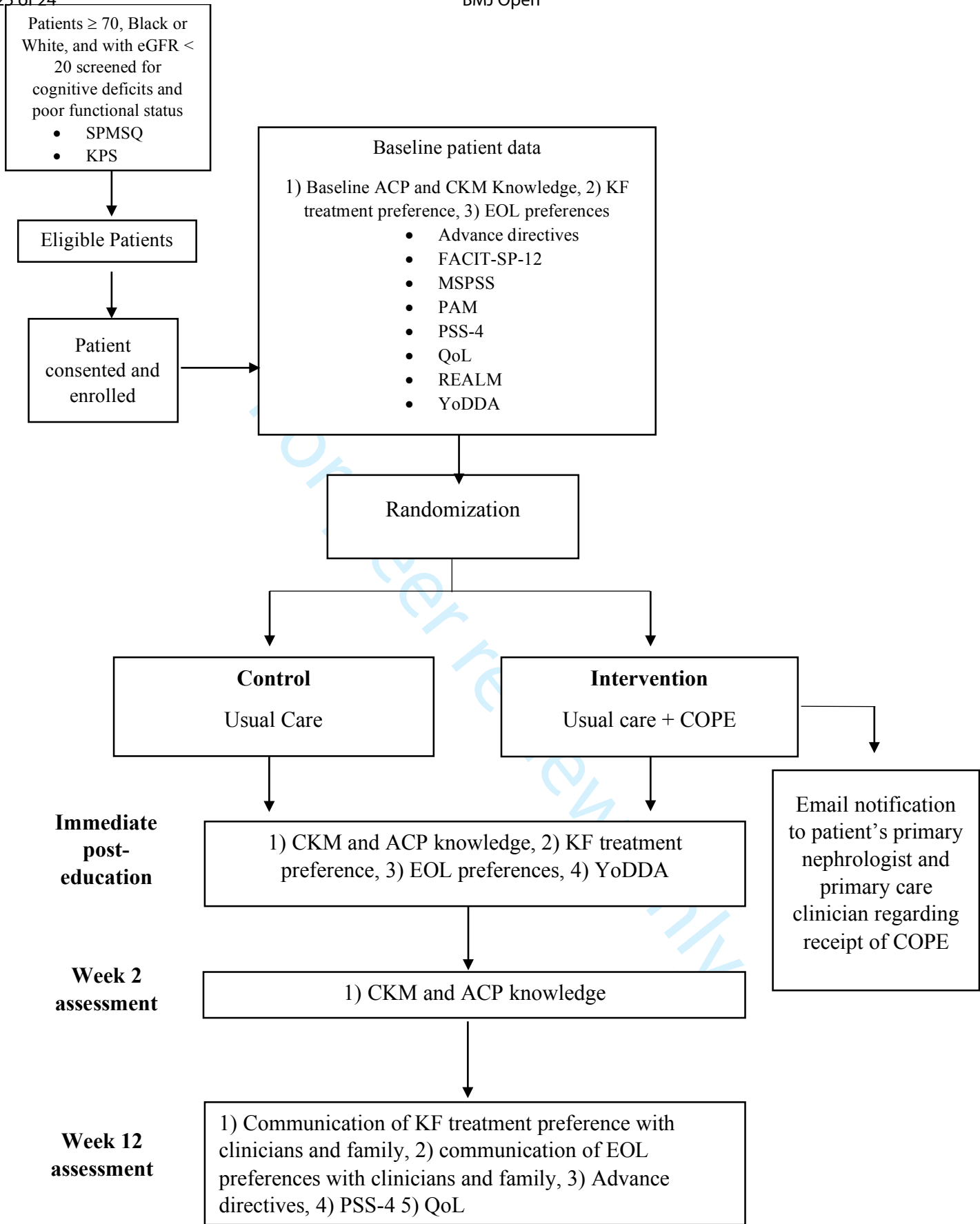
Modifying Factors

Likelihood of Action



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-042620.R2
Article Type:	Protocol
Date Submitted by the Author:	21-Jan-2021
Complete List of Authors:	Stallings, Taylor; University of Pennsylvania Perelman School of Medicine Temel, Jennifer; Massachusetts General Hospital Cancer Center, Medicine Klaiman, Tamar; University of Pennsylvania Perelman School of Medicine Paasche-Orlow, Michael; Boston Medical Center, General Internal Medicine Alegria, M; Massachusetts General Hospital, O'Hare, Ann; University of Washington Department of Medicine, O'Connor, Nina; University of Pennsylvania Dember, Laura; University of Pennsylvania, Halpern, SD; University of Pennsylvania Perelman School of Medicine Eneanya, Nwamaka; University of Pennsylvania Perelman School of Medicine
Primary Subject Heading:	Renal medicine
Secondary Subject Heading:	Palliative care, Geriatric medicine
Keywords:	Chronic renal failure < NEPHROLOGY, End stage renal failure < NEPHROLOGY, Adult palliative care < PALLIATIVE CARE, GERIATRIC MEDICINE

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3 **Title:** Integrating conservative kidney management options and advance care planning education
4 (COPE) into routine CKD care: a protocol for a pilot randomized controlled trial
5
6
7

8 **Authors:** Taylor L. Stallings, MS¹, Jennifer S. Temel, MD², Tamar A. Klaiman PhD,MPH¹,
9
10 Michael K. Paasche-Orlow³, Margarita Alegria, PhD⁴, Ann O'Hare⁵, Nina O'Connor, MD⁶
11
12 Laura M. Dember, MD^{7, 8}, Scott D. Halpern MD, PhD¹, Nwamaka D. Eneanya, MD, MPH^{1,7,8}
13
14
15

16 **Affiliations:**

17
18
19 ¹Palliative and Advanced Illness Research Center, Perelman School of Medicine, University of
20
21 Pennsylvania, Philadelphia, PA, USA.
22
23

24 ²Division of Hematology and Oncology, Department of Internal Medicine, Massachusetts
25
26 General Hospital, Harvard Medical School, Boston, MA, USA.
27
28

29 ³Section of General Internal Medicine, Boston Medical Center, Boston University School of
30
31 Medicine, Boston, MA, USA.
32
33

34 ⁴Department of Medicine and Psychiatry, Harvard Medical School, Boston, MA, USA.
35
36
37

38 ⁵Division of Nephrology, Department of Medicine, University of Washington, Seattle, WA,
39
40 USA.
41

42 ⁶Palliative and Hospice Medicine, Perelman School of Medicine, University of Pennsylvania,
43
44 Philadelphia, PA, USA.
45

46 ⁷Renal-Electrolyte Division, Perelman School of Medicine, University of Pennsylvania,
47
48 Philadelphia, PA, USA.
49
50

51 ⁸Center for Clinical Epidemiology and Biostatistics, Perelman School of Medicine, University of
52
53 Pennsylvania, Philadelphia, PA, USA.
54
55
56
57
58
59
60

1
2
3 **Abstract word count: 291/300**

4 **Manuscript word count: 2827/4000**

5
6
7 **Tables: 2**

8 **Figures: 2**

9
10
11
12 **Corresponding Author**

13
14 Nwamaka Eneanya, MD, MPH

15
16 Renal-Electrolyte and Hypertension Division

17
18 Perelman School of Medicine

19
20 University of Pennsylvania

21
22 307 Blockley Hall

23
24 423 Guardian Drive

25
26 Philadelphia, PA 19104

27
28 Ph: 215-746-5080

29
30 Email: Nwamaka.eneanya@penmedicine.upenn.edu

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 (Conservative Kidney Management Options and Advance Care Planning Education – 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/1.73m²), 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.

1
2
3 The results from this work will be presented at academic conferences and disseminated through
4 peer-reviewed journals.
5
6

7
8 **Trial registration:** This trial is registered at ClinicalTrials.gov under NCT03229811.
9

10 **Key words:** Advanced chronic kidney disease, conservative kidney management, advance care
11 planning, racial disparities
12
13

14
15 **Strengths and limitations of this study:**
16

- 17
18
- 19 • This is a pilot randomized controlled trial evaluating an intervention designed to
20 primarily educate older and seriously ill patients with advanced CKD about conservative
21 kidney management and advance care planning.
22
23
 - 24 • Patients will receive an educational intervention that is integrated into their advanced
25 CKD care.
26
27
 - 28 • This study will investigate racial disparities between Black and White patients in
29 knowledge about conservative kidney management and advance care planning.
30
31
 - 32 • As this study is being conducted at a single-center and is being limited to White and
33 Black patients, we are unable to generalize study results to different regions or patients of
34 different races or ethnicities.
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 populations, patients with advanced CKD would prefer to have ACP and goals of care
4
5 discussions earlier in the disease course.^{19,27} However, these conversations are often challenging
6
7 and available evidence suggests that nephrologists tend not to engage in ACP with their
8
9 patients.^{19,27-30} Additionally, some studies have shown racial disparities in ACP knowledge, and
10
11 that racial-ethnic minority patients are less likely to engage in goals of care discussions and
12
13 advance care planning when compared to White patients.^{16,18,31,32} Education and improving
14
15 informed decision-making may mitigate racial disparities in care for older patients with
16
17 CKD.^{18,33} Thus, we are testing whether a novel educational intervention incorporated into
18
19 routine advanced CKD care, called **Conservative Kidney Management Options and Advance**
20
21 **Care Planning Education (COPE)**, can improve knowledge and communication among patients
22
23 who are older and/or with poor functional status.

24 **Methodology and analysis**

25 *Conceptual framework*

26
27
28 The COPE intervention has been developed to address patient knowledge, expectations,
29
30 and beliefs of kidney failure treatments and ACP (Figure 1). The conceptual framework for this
31
32 intervention is adapted from the Health Belief Model (Figure 1).³⁴ This model hypothesizes that
33
34 health-related action depends on the simultaneous occurrence of three factors: 1) the existence of
35
36 sufficient motivation to make health issues salient or relevant; 2) the belief that one is susceptible
37
38 to a serious health problem or sequelae of that illness or condition (e.g., perceived threat); and 3)
39
40 the belief that following a particular health recommendation would be beneficial in reducing the
41
42 perceived threat³⁴ Under this model, patient factors such as age, race, ethnicity, and education
43
44 are posited to be associated with perceived severity (including knowledge of kidney failure
45
46 treatment and ACP) and the threat of kidney disease (expectations and beliefs surrounding
47
48 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

1
2
3 The principal investigator will train a nurse practitioner who is certified in serious illness
4 communication and palliative care to deliver the intervention among all enrolled patients.
5
6 Specifically, the nurse practitioner will be trained to discuss all treatment options (including
7
8 conservative kidney management) and ACP. We will conduct this training in two half-day
9
10 sessions followed by observed interactions with volunteer patients to determine competency in
11
12 delivery of information.
13
14
15

16 17 *Study design and setting*

18
19 We will test the COPE intervention to provide education to patients with advanced CKD
20
21 who are older and/or with poor functional status (defined as a Karnofsky Performance Index
22
23 Score < 70¹¹) in a single-center pilot randomized controlled trial (RCT). The objective of this
24
25 intervention is to increase participants' knowledge of treatment options including conservative
26
27 kidney management and ACP and improve communication of patients' treatment and care
28
29 preferences with their clinicians and family members. We hypothesize that educating patients
30
31 about treatment options, eliciting their treatment preferences, and communicating these with
32
33 clinicians and families will promote patient engagement in ACP, improve informed treatment
34
35 decision-making, and reduce racial disparities in knowledge and communication of care
36
37 preferences. We will recruit patients from outpatient renal clinics associated with the University
38
39 of Pennsylvania Perelman School of Medicine in Philadelphia, PA. The Institutional Review
40
41 Board at the University of Pennsylvania has approved this study.
42
43
44
45
46

47 *Participants*

48
49 Those eligible to participate in this trial will be: 1) age ≥ 70 years and/or have poor
50
51 functional status (defined as a Karnofsky Performance Index Score < 70¹¹), 2) have advanced
52
53 chronic kidney disease defined as having at least two eGFR measurements < 20 ml/min/1.73m²
54
55
56
57
58
59
60

1
2
3 separated by at least three months,³⁷ 3) prefer to speak English-during clinical encounters, and 4)
4 self-report as Black or White race. Exclusion criteria include being listed for kidney transplant,
5 being legally blind, or screening positive for severe cognitive dysfunction defined as having 8 or
6 more errors on the Short Portable Mental Status Questionnaire for assessment of organic brain
7 deficit.³⁸ For potentially eligible patients < 70 years of age, we will ask treating clinicians to
8 complete a Karnofsky Performance Index Score.
9

16 *Recruitment*

17
18 Research staff will access electronic medical records of clinic patients and nephrologists'
19 list of patients with poor functional status to identify potential study participants. Prior to
20 approaching patients to invite them to participate in the study, a study coordinator will also
21 confirm study suitability with each patient's nephrologist. Given the diverse patient
22 demographics in the outpatient renal clinics, we anticipate equal representation of Black and
23 White patients.
24
25
26
27
28
29
30
31

32 *Study procedures*

33
34
35 Prior to the initiation of the pilot RCT, we will assess the feasibility and acceptability of
36 COPE among a small sample of patients (n=10). Immediately after receiving education, patients
37 will be asked to rate satisfaction on a Likert scale and usefulness based on the modified
38 Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.³⁹ We will assess the reasons for
39 refusal and attrition data before finalizing recruitment and study procedures.
40
41
42
43
44
45
46

47 We will randomize patients (n=100) in a 1:1 fashion with stratification by race to receive
48 one of two arms: 1) enhanced usual care or 2) usual care plus COPE. We will collect baseline
49 data for patients at the time of enrollment and prior to randomization (Table 1). Further data
50 collection will take place via phone sessions at pre-specified time intervals (Figure 2).
51
52
53
54
55
56
57
58
59
60

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

1
2
3 randomly selected at 2-months intervals to assess the fidelity of the intervention. A study
4
5 coordinator will complete the fidelity checklist and re-training of the nurse practitioner will
6
7 occur if 80% of criteria are not met.
8

9 10 *Outcomes*

11
12 The primary outcome for this intervention is change in knowledge of conservative kidney
13
14 management and ACP. Additional outcomes include assessing the feasibility and acceptability of
15
16 COPE, patient communication of kidney failure and advanced care treatment preferences with
17
18 clinicians and family members. We will also evaluate racial disparities in conservative kidney
19
20 management, ACP knowledge and communication of care preferences. We will ascertain
21
22 knowledge, treatment preferences, communication of preferences, and intervention acceptability
23
24 via short questionnaires at the time points displayed in Figure 2. Specifically, we will use
25
26 questions from the SUPPORT trial to assess end-of-life (EOL) preferences.⁴¹
27
28
29

30 We will also measure other outcomes including health literacy,⁴² perceived mental and
31
32 physical health status,^{43,44} spiritual well-being,⁴⁵ perceived stress,⁴⁶ and quality of life⁴⁷, using
33
34 validated surveys (Table 2). Patient demographics, whether patients have completed advance
35
36 directives, and comorbidities will be ascertained via medical record review and surveys.
37
38

39 *Analysis*

40 Feasibility and acceptability

41
42 We will consider that the intervention has adequate feasibility if at least 70% of eligible
43
44 patients who are approached provide consent and enroll in the study. Additionally, we will
45
46 determine that adequate acceptability is achieved if at least 80% of patients have a mean score of
47
48 ≥ 4.9 using the modified Yorkshire Dialysis Decision Aid (YoDDA) usefulness scale.³⁹
49
50
51

52 CKM and ACP knowledge, communication and preferences

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

31 Racial disparities

32
33 To determine whether the intervention reduces racial disparities in outcomes between
34 Black and White patients, we will add an interaction term between race and study arm in the
35 multivariate analyses. A p-value of 0.15 or less will be considered statistically significant when
36 testing for interaction. All analyses will be done in SAS (Version 9.4, Cary, NC).

42 Power and sample size

43 Based on published data demonstrating poor knowledge of conservative kidney
44 management among patients with advanced kidney disease,⁴⁸ we anticipate that recruitment of
45 50 patients to each arm will provide 85% power to detect an effect size of 0.5 SD when
46 comparing the change in knowledge of conservative kidney management and advance care
47 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

1
2
3 among patients to improve conservative kidney management and ACP education. Second,
4 patients will receive conservative kidney management and ACP education that is integrated with
5 rather than siloed from other aspects of advanced CKD care. Studies focused on dialysis
6 decision-making among CKD patients are lacking.^{29,30,51–54} Fully informing patients with
7 advanced CKD of conservative kidney management options, as well as discussing their
8 preferences for care at EOL allows patients to focus on values and goals that are most important
9 to them. Third, we aim to reduce racial disparities in knowledge and communication of
10 conservative kidney management and EOL preferences among patients with advanced CKD.
11 Compared to White patients with CKD, Black patients have lower health literacy, less
12 knowledge about treatment options for advanced kidney disease, and tend to have poor
13 knowledge of support resources to cope with the disease.^{55,56} Racial differences in knowledge
14 outcomes may in part be due to the notion that educational interventions are developed to
15 achieve a “one size fits all” standard. However, COPE has been developed with input from a
16 diverse patient population of patients with CKD and with specific attention to communication
17 style and health literacy barriers. There are few existing ACP and conservative kidney
18 management educational tools that account for knowledge differences among patients, which
19 could ultimately help to reduce racial disparities in patient understanding of these aspects of
20 care.^{31,57}

21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45 There are a few limitations to this study. This is a single-center study and we will enroll
46 patients who self-identify as White or Black. Thus, conclusions may not be generalizable to
47 patients of different racial backgrounds or who live in other geographical locations. Additionally,
48 shared decision-making includes patients, clinicians, and families, but our study will only
49 measure patient outcomes. Lastly, we acknowledge that this study will focus on short-term
50
51
52
53
54
55
56
57
58
59
60

1
2
3 outcomes and therefore we will be unable to comment on the downstream effects of the
4
5 intervention. Future studies will confirm whether COPE has broad relevance and usefulness for
6
7 similar patients with different demographics, feasibility and acceptability among clinicians and
8
9 caregivers, and long-term outcomes such as treatment decision-making confidence and conflict.
10
11

12 Educating patients with advanced CKD who are older or seriously ill about kidney failure
13
14 treatment options (including conservative kidney management) and ACP is central to promoting
15
16 shared decision-making and promoting goal-concordant care. We anticipate that our study
17
18 findings will improve informed decision-making for patients with advanced chronic kidney
19
20 disease and create an opportunity for clinicians to provide comprehensive patient-centered care
21
22 for this vulnerable population.
23
24
25
26
27
28
29
30
31

32 **Ethics and dissemination**

33
34 This protocol has been approved by the Institutional Review Board at the University of
35
36 Pennsylvania. Written informed consent will be obtained from all participants. The findings from
37
38 this work will be disseminated through peer-reviewed publications and will be presented at
39
40 academic conferences.
41
42

43 **Authors' contributions**

44
45 Research idea and study design: NDE, JST MKP, MA, AO; Preparation of manuscript: TLS,
46
47 NDE; Critical revision of manuscript: TLS, JST, TAK, MKP, MA, AO, NOC, LMD, SDH,
48
49 NDE; Supervision or mentorship: NDE, JST, LMD, SDH. All authors take responsibility for the
50
51 integrity and accuracy of this manuscript's content and have approved the final draft for
52
53 submission.
54
55
56
57
58
59
60

1
2
3 **Funding statement**
4

5 This study is supported by grant K23DK114526 (NDE) from the National Institutes of Health.
6

7
8 The funder did not have a role in the design of the study.
9

10 **Competing interests statement**
11

12 All other authors declare that they have no relevant conflict of interests.
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

- 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
 - 16
 - 17
 - 18
 - 19
 - 20
 - 21
 - 22
 - 23
 - 24
 - 25
 - 26
 - 27
 - 28
 - 29
 - 30
 - 31
 - 32
 - 33
 - 34
 - 35
 - 36
 - 37
 - 38
 - 39
 - 40
 - 41
 - 42
 - 43
 - 44
 - 45
 - 46
 - 47
 - 48
 - 49
 - 50
 - 51
 - 52
 - 53
 - 54
 - 55
 - 56
 - 57
 - 58
 - 59
 - 60
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

- 1
2
3 Press (US); 2004. Accessed October 8, 2019.
4 <http://www.ncbi.nlm.nih.gov/books/NBK216032/>
5
6
7 37. Levey AS, Bosch JP, Lewis JB, Greene T, Rogers N, Roth D. A more accurate method to
8 estimate glomerular filtration rate from serum creatinine: a new prediction equation.
9 Modification of Diet in Renal Disease Study Group. *Ann Intern Med.* 1999;130(6):461-470.
10 doi:10.7326/0003-4819-130-6-199903160-00002
11
12 38. Pfeiffer E. A Short Portable Mental Status Questionnaire for the Assessment of Organic
13 Brain Deficit in Elderly Patients†. *J Am Geriatr Soc.* 1975;23(10):433-441.
14 doi:10.1111/j.1532-5415.1975.tb00927.x
15
16 39. Winterbottom AE, Gavaruzzi T, Mooney A, et al. Patient Acceptability of the Yorkshire
17 Dialysis Decision Aid (YoDDA) Booklet: A Prospective Non-Randomized Comparison
18 Study Across 6 Predialysis Services. *Perit Dial Int J Int Soc Perit Dial.* 2016;36(4):374-
19 381. doi:10.3747/pdi.2014.00274
20
21 40. The National Kidney Foundation. If You Choose Not To Start Dialysis Treatment.
22 Published 2008. Accessed April 15, 2020. https://www.kidney.org/sites/default/files/11-10-0330_ifyouchoose.pdf
23
24
25 41. Connors AF, Dawson NV, Desbiens NA, et al. A Controlled Trial to Improve Care for
26 Seriously Ill Hospitalized Patients: The Study to Understand Prognoses and Preferences for
27 Outcomes and Risks of Treatments (SUPPORT). *JAMA.* 1995;274(20):1591-1598.
28 doi:10.1001/jama.1995.03530200027032
29
30 42. Cavanaugh KL, Wingard RL, Hakim RM, et al. Low Health Literacy Associates with
31 Increased Mortality in ESRD. *J Am Soc Nephrol JASN.* 2010;21(11):1979-1985.
32 doi:10.1681/ASN.2009111163
33
34 43. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I.
35 Conceptual framework and item selection. *Med Care.* 1992;30(6):473-483.
36
37 44. Wight JP, Edwards L, Brazier J, Walters S, Payne JN, Brown CB. The SF36 as an outcome
38 measure of services for end stage renal failure. *Qual Health Care QHC.* 1998;7(4):209-221.
39
40 45. Peterman AH, Fitchett G, Brady MJ, Hernandez L, Cella D. Measuring spiritual well-being
41 in people with cancer: the functional assessment of chronic illness therapy--Spiritual Well-
42 being Scale (FACIT-Sp). *Ann Behav Med Publ Soc Behav Med.* 2002;24(1):49-58.
43 doi:10.1207/S15324796ABM2401_06
44
45 46. Taylor JM. Psychometric analysis of the Ten-Item Perceived Stress Scale. *Psychol Assess.*
46 2015;27(1):90-101. doi:10.1037/a0038100
47
48 47. Robin Cohen S, Mount BM, Bruera E, Provost M, Rowe J, Tong K. Validity of the McGill
49 Quality of Life Questionnaire in the palliative care setting: a multi-centre Canadian study
50 demonstrating the importance of the existential domain. *Palliat Med.* 1997;11(1):3-20.
51 doi:10.1177/026921639701100102
52
53
54
55
56
57
58
59
60

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
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

1
2
3
4
5
6
7
8
9 **Figure 1. Health Belief Model (adapted for COPE)**

10
11
12 **Abbreviations:** ACP = Advance care planning, CKM = Conservative kidney management, KF = Kidney
13 failure
14

15
16
17
18
19
20
21
22 **Figure 2. Study flow chart**

23
24
25
26 **Abbreviations:** FACIT-SP-12=Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being,
27 KPS=Karnofsky Performance Index Score, MSPSS = Multidimensional Scale of Perceived Social
28 Support, PAM=Patient Activation Measure, PSS-4=Perceived Stress Scale, QOL=McGill Quality of Life
29 Questionnaire-Part A, REALM=Rapid Estimate of Adult Literacy in Medicine, SPMSQ=Short Portable
30 Mental Status Questionnaire, YoDDA=Modified Yorkshire Dialysis Decision Aid.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41

Individual Perceptions

Modifying Factors

Likelihood of Action

