Use of a Decision Aid for Patients Considering Peritoneal Dialysis and In-Center Hemodialysis: A Randomized Controlled Trial

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Rationale & Objective: Annually, about 100,000 US patients face the difficult choice between the most common dialysis types, in-center hemodialysis and peritoneal dialysis. This study evaluated the value of a new decision aid to assist in the choice of dialysis modality.

Study Design: A parallel-group randomized controlled trial to test the efficacy of the decision aid on decision-making outcomes.

Setting & Participants: English-speaking US adults with advanced chronic kidney disease and internet access enrolled in 2015.

Intervention: Participants randomly assigned to the decision aid intervention received information about chronic kidney disease, peritoneal dialysis, and hemodialysis and a value clarification exercise through the study website using their own electronic devices. Participants in the control arm were only required to complete the control questionnaire. Questionnaire responses were used to assess differences across arms in decision-making outcomes.

Outcomes: Treatment preference, decisional conflict, decision self-efficacy, knowledge, and preparation for decision making.

Results: Of 234 consented participants, 94 (40.2%) were lost to follow-up before starting the study. Among the 140 (70 in each arm) who started the study, 7 were subsequently lost to follow-up. Decision aid users had lower decisional conflict scores (42.5 vs 29.1; $P < 0.001$) and higher average knowledge scores (90.3 vs 76.5; $P < 0.001$). Both arms had high decisional self-efficacy scores independent of decision aid use. Uncertainty about choice of dialysis treatment declined from 46% to 16% after using the decision aid. Almost all (>90%) users of the decision aid reported that it helped in decision making.

Limitations: Limited generalizability from the study of self-selected study participants who had to have internet access, speak English, and have computer literacy. High postrandomization loss to follow-up. Evaluation of only short-term outcomes.

Conclusions: The decision aid improves decision-making outcomes immediately after use. Implementation of the decision aid in clinical practice may allow further assessment of its effects on patient engagement and empowerment in choosing a dialysis modality.

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More than 120,000 US patients started dialysis for end-stage kidney disease in 2015.[1] Approximately 90% of dialysis patients receive hemodialysis (HD) at a dialysis center ("in-center"), 10% receive peritoneal dialysis (PD), and 0.4% use home HD as their first treatment modality.[1] Quality of life and mortality rates of patients treated with HD and PD are similar, yet PD use in the United States is much lower than in other countries.[2,3] Although clinical contraindications may limit modality choice, most patients are eligible for both treatment options and the treatment choice should reflect patient preferences.[4,5] Accumulating evidence suggests that treatment consistent with patient preferences may improve quality of life and medical outcomes.[6,7] Patients and their care partners must understand the choices and related impacts on daily life to actively engage in the decision-making process.[8,9] However, studies have shown that many patients feel unprepared and ill-informed about initiating dialysis and available options.[10] Additionally, low health literacy and numeracy can be barriers to understanding differences in treatment options and involvement in decision making.[11-13]

Patient decision aids are used to facilitate patient decision making about health care options.[14] They aim to provide unbiased information about available options, increase participation in the decision-making process, reduce perceived pressure in selecting treatment choice, and mitigate decisional conflict.[14] Several studies have shown that decision aids can have a substantial impact on key outcomes, including satisfaction with and confidence in the decision made, consequently improving treatment self-management.[15-17]

We describe the collaborative development of a web-based decision aid in the Empowering Patients on Choices for Renal Replacement Therapy (EPOCH-RRT) Study, involving researchers and a multistakeholder advisory panel composed of patients, care partners (family

members), and patient advocates. We report results of the randomized controlled trial conducted to test the decision aid for efficacy in improving decision-making outcomes.

Methods

Decision Aid Development

Content for the decision aid was based on literature review, US Renal Data System data,[1] and results from previous EPOCH-RRT studies.[18,19] A multistakeholder panel reviewed and refined the decision aid through an iterative process. Usability testing further helped refine the content, design, and structure of the decision aid.

Per the International Patient Decision Aids Standards (IPDAS) checklist, IPDASi version 3.0,[14,20] the decision aid addressed all qualifying criteria and the following certification criteria: balanced information for both treatment options, references to the funding source, additional resources and information about research used to develop the decision aid, year of publication, terms of use, and privacy policy. The website will be updated as needed based on annual literature review.

Intervention

The decision aid contained sections on: (1) chronic kidney disease (CKD) and its progression; (2) information and comparison of PD and HD based on patient priorities, positive and negative features of each option, options for switching, potential associated lifestyle changes, and side effects of both; and (3) an interactive value clarification exercise (VCE) to engage in the deliberation process and possibly lead to less regret and better preparation for decision making.[21,22] The VCE provided a visual mapping between dialysis modality type and a list of lifestyle factors previously identified in EPOCH-RRT interviews as important to dialysis patients (Item S1). The decision aid integrated quotes from patients and tips from health care professionals (Item S2). Printing options were included to support discussing dialysis options with medical staff.

The study website enabled collection of questionnaire data and walked users through all sections without skipping ahead. We provided "hover over" definitions for commonly used terms and logged progress so users could resume where they left off when unable to explore the entire decision aid in a single session. However, questionnaires had to be completed and submitted in a single session.

Participant Recruitment

Participants were recruited through nationwide social media outreach and locally in clinics, with a total recruitment target of 150 (Fig 1). The national outreach involved e-mail blasts and postings on Facebook and Twitter from August to October 2015 in collaboration with the National Kidney Foundation and American Association of Kidney Patients. Only those who could be re-contacted by telephone, self-identified as patients with CKD, and met all inclusion criteria were tracked. Local recruitment was conducted in 3 University of Michigan CKD clinics and 4 Henry Ford Health System CKD clinics across Southeast Michigan. Clinic and research staff reviewed visit schedules to identify patients meeting clinical criteria to approach at the time of their clinic visit between May 2015 and January 2016. Study coordinators obtained informed consent either verbally after telephone screening or in person and provided login information to the study website. Participants received a $25 gift card upon completion or attempted completion of study questionnaires. Follow-up of participants who had consented but either not started or started but not completed the study involved up to 5 attempted telephone or e-mail contacts over a 2-week period. In January 2016, we attempted a final contact of those who had either not started or not completed the study. Those who did not respond to any such contact were considered not reachable.

Study Design

Inclusion criteria were: (1) 18 years or older, (2) estimated glomerular filtration rate < 25 mL/min/1.73 m^2, (3) internet access through a computer or tablet, and (4) English language fluency. Immediately after obtaining informed consent from a participant, the study coordinator provided the participant with a unique user login and study ID. The list of IDs provided to each recruiter was randomly generated by an independent study programmer and each ID appeared as a random sequence of letters. The list alternated between the intervention and control arms to ensure parallel assignment to the intervention or control arms of consented participants. However, neither the study coordinator nor the participant could discern the assignment based on the ID and both were therefore blinded to treatment assignment before consent and before study start. The study coordinator also remained blinded to treatment assignment throughout the study because participants engaged in the study on their own time.

Study coordinators also provided information for accessing and using the study website to consented participants. Participants could access the study website from their own computers or portable devices using the login credentials provided. Initiating login by participants defined the start of study participation. The study team at the data coordinating center could track task completion for each participant after login and followed up weekly to check on any technical issues and promote study completion.

Participants in the control arm were only required to complete the control questionnaire (Item S3) and click the submit button, at which point participation was considered complete. They then had the option to access the decision aid, if interested. Participants in this arm were included in the analysis if they answered all questions in the control questionnaire. Participants in the intervention arm were required to click response options for all pretest questions (Item S4) and click the

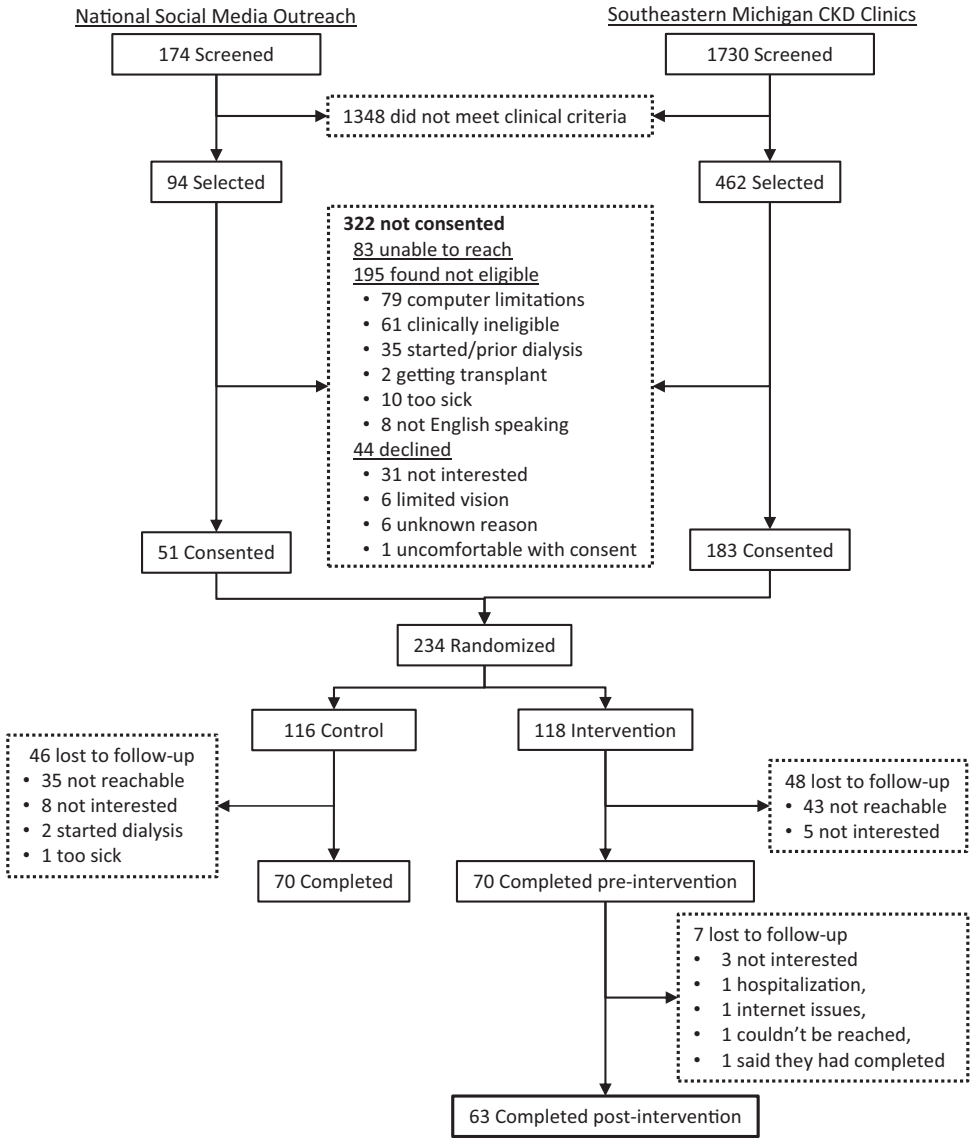

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of participants describing recruitment and flow of study participants through the study. Abbreviation: CKD, chronic kidney disease.

submit button to proceed to the decision aid. They then clicked a button on the last page of the decision aid to indicate that they had completed review of the decision aid, and this would enable them to proceed to the posttest (Item S5). Initiation of the posttest immediately after decision aid review allowed for assessment of immediate DA effects. We considered intervention arm participants to have completed the study if they answered all questions in the posttest and clicked the final submit button.

All study procedures were approved by institutional review boards at each study site and the data coordinating center (Henry Ford Health System #8144; University of Michigan, IRBMED eResearch #HUM00073058; Ethical & Independent Review Services #13016-03B).

Outcomes and Measures

Decision aids are evaluated based on improvements in the quality of the decision and the decision-making process based on underlying theories in decision making that provide a strong rationale for assessment before and immediately after exposure.[23,24] Outcomes used to evaluate the decision aid were treatment preference, decisional conflict, decision self-efficacy, preparation for decision making, and knowledge. Participants selected current treatment preference (HD, PD, unsure, and other) at baseline and postintervention.

The Decisional Conflict Scale measures perceived uncertainty in choosing options and satisfaction with effective decision making.[25] This is a 16-item scale with a 5-point Likert response format with scores reversed on negative statements. Items are summed, averaged, and

multiplied by 25 to obtain scores ranging from 0 (no decisional conflict) to 80 (high decisional conflict).

The Decision Self-efficacy Scale measures confidence in making an informed decision.[26] We used 10 of the 11 items scored on a 5-point response format because deferral of decision might not be an option for those facing kidney failure. Items are summed, averaged, and multiplied by 25 to obtain scores ranging from 0 (not at all confident) to 100 (very confident). These first 3 primary outcomes were included in the control arm test and both pre- and posttests in the intervention arm so that differences between those using and not using the decision aid, as well as changes from before to after using the decision aid, could be assessed. The latter was of particular interest in case there were any unobserved confounding variables between the control and intervention arms.

The validated Preparation for Decision Making Scale measures patients' readiness for communicating with practitioners and making a health decision.[27] It was assessed only postintervention because it specifically relates to the decision tool. It is a 10-item scale with a 5-point response format in which items are summed, averaged, subtracted by 1, and multiplied by 25 to get a score from 0 to 100, with higher scores indicating higher preparation for decision making.

For the fifth primary outcome of knowledge, questions were adapted from the Chronic Hemodialysis Knowledge Survey (CHeKS),[28] previously shown to correlate with clinical outcomes.[29] For intervention arm participants, knowledge questions were asked only during the posttest to prevent focus on content related to the knowledge questions while reviewing the decision aid and prevent positive bias during the posttest due to previous viewing of the questions.

At baseline, both the control and intervention group (pretest) participants provided demographic information (age, sex, race, ethnicity, and education) and were assessed for subjective literacy[30] and numeracy (Table 1).[31,32] because these are known barriers to involvement in decision making. The posttest within the intervention arm also included questions on the user experience related to usability, satisfaction with the decision aid, adequacy, relevance, and quality of content, as well as open-ended questions for positive and negative feedback. Thematic analysis of free-text responses across participants identified distinct motifs aggregated for frequency.[33]

Statistical Analysis

Analysts not blinded to treatment assignment tested for demographic differences between the intervention and control arms using baseline responses. Age, race, sex, education, ethnicity, and numeracy were compared using *t*, Pearson χ^2, and Fisher exact tests. We compared the intervention posttest with the control arm using unpaired *t*, Wilcoxon rank sum, and Pearson χ^2 tests. We compared outcomes between the pre- and posttest within the intervention arm using paired *t* tests, Wilcoxon signed rank tests, and tests for marginal homogeneity.

We tested whether differences between intervention posttest and control arm and differences between intervention pre- and posttest responses differed across age (continuous), sex (female, male), education level (college graduate or above vs some college or under), or race groups (black vs nonblack) for all primary outcomes. We used generalized estimating equation logistic or linear regression models for these tests by including an interaction term between subgroups and different arms in models.[34] Models accounted for correlations within subjects when comparing pre- and posttest intervention arm responses using an exchangeable correlation structure and sandwich-type estimator for standard errors. These *P* values were corrected for multiple hypothesis testing using the Benjamini-Hochberg procedure.[35]

Results

Study Sample

Of 556 patients initially screened and selected, 83 were not reachable and 195 no longer met inclusion criteria when approached for consent (Fig 1). Some patients did not have internet connectivity or access to a computer. Of patients who declined to participate (n = 44), reasons included poor eyesight for the study tasks or being too ill or fatigued to participate. A total of 234 patients consented to the study and were given randomized login information for the study website; 51 from social media outreach and 183 from local clinic recruitment. Notably, 40.2% (94 total; 1 from social media outreach and 93 from local clinic recruitment) were lost to follow-up before starting the study. These participants did not log into the study site to start the study and 78 were not reachable by telephone or e-mail for follow-up. The remaining 140 participants, 70 in each arm, started the study.

Seven participants in the intervention arm started the study and completed the pretest but did not go on to complete the posttest questionnaire. All these participants were originally recruited through local clinics. Sensitivity analyses with and without these participants suggest that these departures did not affect our study results. Fifty of the 63 (79%) intervention arm participants completed the pre- and posttests within 1 week, with 60% having completed both on the same day. Only 5 participants took more than 1 month to review the decision aid and complete the posttest. Sensitivity analysis with and without the 13 participants who had a gap of more than 7 days between completion of the 2 questionnaires did not change any of the mean values of measured outcomes or reported statistical differences.

Patient Characteristics

Demographic information was self-reported in the control and pretest questionnaires (Table 1); participant composition was found to be similar in both groups (Table 2) and was unavailable for those who never started the study. Our study sample was younger than the US CKD stages 4

Table 1. Questionnaire Design, Distribution of Sections in Control and Intervention Arms

Section	Control	Intervention	
		Pretest	Posttest
Treatment preference	✓	✓	✓
Decisional conflict[25]	✓	✓	✓
Decision self-efficacy[26]	✓	✓	✓
Knowledge[32]	✓		✓
Literacy[28]	✓	✓	
Numeracy[29,30]	✓	✓	
Demographics	✓	✓	
Preparation for decision making[27]			✓
User experience			✓

to 5 population in 2014 (estimated glomerular filtration rates < 30 mL/min/1.73 m^2, mean age of 76.8 years, 46.2% men, and 77.6% white) but with similar proportions of white and male participants[1]. Almost all had graduated high school (96%) and considered English their native language (94%). Literacy (mean literacy = 2.81) and subjective numeracy (mean numeracy = 3.88) were similar in both groups at the start of the study.

Efficacy of the Decision Aid

Reduction in Uncertainty

The control and intervention participants' pretest scores suggest that both arms had similar baseline uncertainty on treatment choice, 40% and 47%, respectively. After the intervention, the proportion of "not sure" responders was 24 percentage points lower than the corresponding proportion in the control group (Table 3). Within the intervention group, the proportion of not sure responders was 30 percentage points after, versus before, using the decision aid (Table 3). Of the 29 participants in the intervention arm who selected not sure before the intervention, 8 remained unsure, 15 selected HD, 5 selected PD, and 1 selected other. Of those who had selected HD or PD initially, only 1 participant each switched to the other option and another switched to not sure.

Based on generalized estimating equation models with interactions between subgroups and arm, older age was initially associated with a larger difference between the control and intervention posttest arms (raw $P = 0.01$). However, this association became non–statistically significant (at significance level 0.05) after correction for multiple hypothesis testing (corrected $P = 0.2$). Similarly, while those in the intervention arm who were college graduates or above had a nominally larger decrease in uncertainty after using the decision aid (raw $P = 0.04$), this finding lost statistical significance after correction ($P = 0.3$). There was no evidence of effect modification by other subgroups (raw P range, 0.3-0.8; corrected P range, 0.8-0.9).

Reduction in Decisional Conflict

The intervention group scored 13.4 points less than the control group in decisional conflict (Table 3) on average, while the decision aid was effective in decreasing the average decisional conflict score by 15 points, from 44 to 29 among those in the intervention group (Table 3). No effect modification by age, sex, or race (raw P range, 0.2-0.9; corrected P range, 0.8-0.9) was observed. While those in the intervention arm who were college graduates or above had an average decrease in decisional conflict scores after using the decision aid of 8.6 points more than those with some college education or below in initial analyses (raw $P = 0.01$), this finding was not statistically significant after correction ($P = 0.2$). The average decisional conflict score among the control and pretest responders was similar, at 43 and 44, respectively.

No Change in Decision Self-efficacy

Decision self-efficacy scores were high on the 0 to 100 scale (~80) for the control group and the intervention group at pretest (Table 3). There was little change in this score after use of the decision aid (Table 3) and no evidence of effect modification by subgroups (raw P range, 0.1-0.9; corrected P range, 0.5-0.9).

Improving Knowledge

The control arm on average answered 77% of the knowledge questions accurately. After going through the

Table 2. Participant Characteristics, by Control and Intervention Arms

Patient Characteristics	Control	Intervention	*P*
No. of patients	70	70	
Age, y	59 ± 14	59 ± 15	0.9
Race			0.8
White	79%	74%	
Black	14%	17%	
Other	7%	9%	
Male sex	50%	43%	0.4
Hispanic or Latino/Latina	3%	3%	0.9
High school graduate	94%	99%	0.9
English as native language	96%	91%	0.5
Ability to understand			
Reading materials[a]	2.94 ± 1.25	3.67 ± 1.45	0.3
SNS[b]	3.83 ± 1.11	3.92 ± 0.99	0.8
SNS ability[c]	3.88 ± 1.18	3.92 ± 1.10	0.9
SNS preference[d]	3.74 ± 1.26	3.93 ± 1.08	0.5

Abbreviation: SNS, Subjective Numeracy Scale.
[a]Mean score ± standard deviation of answer choices from all the time (0) to none of the time (4); higher score indicates greater ability to understand.
[b]Mean score for answers (not at all good [1]–extremely good [6]) of the 3 questions: How good are you at working with fractions? How good are you at figuring out how much a shirt will cost if it is 25% off? How often do you find numerical information to be useful?
[c]Mean score for answers (not at all good [1]–extremely good [6]) of the 2 questions: How good are you at working with fractions? How good are you at figuring out how much a shirt will cost if it is 25% off?
[d]Mean score for answers (not at all good [1]–extremely good [6]) of the question: How often do you find numerical information to be useful?

Table 3. Outcome Measures for Decision Aid Efficacy

Comparison of Control and Intervention Arm Outcomes	Control	Intervention	P[a]
No. of participants	70	63	
Which dialysis type do you think you might choose?			<0.001
Hemodialysis	23 (16%)	43 (27%)	
Peritoneal dialysis	31 (22%)	37 (23%)	
Not sure	40 (28%)	16 (10%)	
Other	6 (4%)	5 (3%)	
Decisional Conflict Score[b] (higher = more conflict)	42.5 ± 17.1	29.1 ± 13.7	<0.001
Decisional Self-efficacy Score[c] (higher = more confident)	79.9 ± 17.6	82.0 ± 18.4	0.4
Knowledge[c] (higher = more correct answers chosen)	76.5 ± 15.3	90.3 ± 11.9	<0.001

Comparison of Before (Pre-) and After (Post-) DA Use Outcomes for Intervention Arm	Pretest	Posttest	P[a]
No. of participants	63	63	
Which dialysis type do you think you might choose?			<0.001
Hemodialysis	21 (13%)	43 (27%)	
Peritoneal dialysis	29 (18%)	37 (23%)	
Not sure	46 (29%)	16 (10%)	
Other	5 (3%)	5 (3%)	
Decisional Conflict Score[b] (higher = more conflict)	43.6 ± 15.9	29.1 ± 13.7	<0.001
Decisional Self-efficacy Score[c] (higher = more confident)	82.2 ± 18.0	82.0 ± 18.4	0.9

Note: Results shown as count (percentage) or mean ± standard deviation.
Abbreviation: DA, decision aid.
[a]We compared the intervention posttest with the control arm using unpaired t, Wilcoxon rank sum, and Pearson χ^2 tests. We compared outcomes between the pre- and posttest within the intervention arm using paired t tests, Wilcoxon signed rank tests, and tests for marginal homogeneity.
[b]Score ranges from 1 to 80.
[c]Score ranges from 0 to 100.

decision aid, the intervention arm correctly answered 90% of these questions (Table 3). Black participants in the control arm had lower baseline knowledge scores compared with nonblack participants (62.2 vs 78.9; $P = 0.02$). The difference in knowledge scores between the control and intervention arms was nominally greater for black participants compared with nonblack participants (26 vs 12; raw $P = 0.02$), but this finding did not retain statistical significance after correction ($P = 0.3$). Our study was not powered for comparing other minority groups. We did not observe effect modification by age, sex, or educational level on the knowledge outcome (raw P range, 0.4-0.6; corrected $P = 0.8$).

User Experience

The mean intervention arm score on the Preparation for Decision Making Scale was 76.4 ± 18.9 (standard deviation) with > 90% of participants indicating that the decision aid helped somewhat to a great deal, both for preparing for dialysis and for follow-up with care providers (Figs 2 and 3). The majority (92%) of participants found the content balanced and not slanted toward either option, 88% trusted it, 87% agreed/strongly agreed that it was relevant to them, and 89% said they would recommend it to others, with 49% agreeing that the decision aid was extremely helpful in understanding dialysis options. Intervention arm participants provided free-text feedback summarized in Table 4. Only 1 person did not like the website at all and 2 people would definitely not recommend the decision aid to others. Although the distribution of responses on questions related to preparing for dialysis and follow-up were viewed positively by all 3, dissatisfaction about the absence of information related to home HD was expressed in the open-ended feedback.

Discussion

Decision aids improve knowledge, enhance perception of risks, lessen decisional conflict, and increase participation in shared decision making.[15] A small number of decision aids related to dialysis treatment modality choice incorporate value clarification tools: 3 in the United States and some developed outside the United States or in other health care contexts.[36-38] The main difference between our choosingdialysis.org decision aid and the others developed in the United States was the emphasis and consistent application of patient-centered approaches in the development of decision aid content and testing.

Similar to other decision aids used in different health decisions,[15] those who completed review of our decision aid indicated improved knowledge, better preparation for decision making, and reduced decisional conflict but no significant improvement in decision self-efficacy shortly after its use. Our results suggest that the extent of benefit from the decision aid on reducing decision uncertainty might vary by age and education level, while the reduction in decisional conflict might vary based on education. These factors might be indicators of differences in engagement with the decision aid, and future decision aid implementation studies could explore this further.

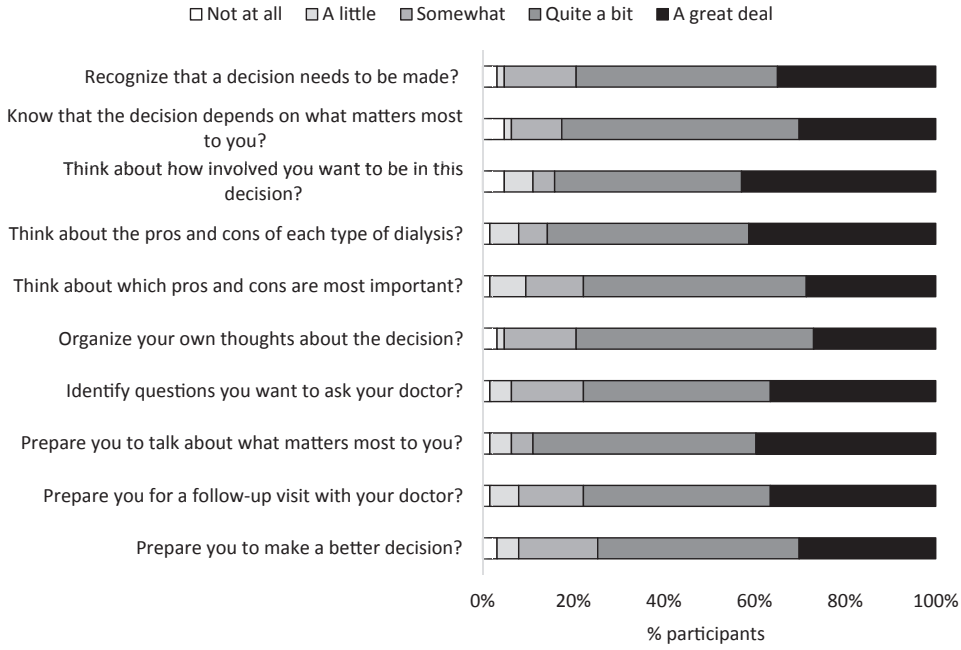

Figure 2. Summary of responses related to factors related to supporting decision making. Ten items with responses on a Likert scale from "not at all" to "a great deal."

Improving knowledge through CKD education has been proposed as one solution to overcoming identified barriers such as patients' awareness of choices and disparities in shared decision making and improved patient-centered care.[39-42] Differences in the knowledge test between black and nonblack participants may be related to racial disparities in treatment choices that are well documented, although we saw no differences in treatment preferences by race across treatment arms in this study.[1,39,43]

This decision aid was effective at helping patients with advanced CKD who were still unsure of their treatment option to be less unsure but did not make people who had selected an option to become less sure or to change their selection. This could be ascribed to the baseline high self-efficacy scores suggesting greater confidence of participants in being able to make a decision. Multiple factors may contribute to decision self-efficacy, which would require a holistic socioecologic approach to move the needle on this indicator.

Some participants in our study provided feedback that they found the VCE helpful, although the decision aid literature is uncertain of the benefits of VCE on decision-making outcomes.[44,45] Evaluation shortly after decision aid use might have limited opportunity to adequately assess the use of different features of the decision aid reflective of real-world use, such preparing for a doctor's visit.

There was high loss to follow-up before study start among participants recruited at CKD clinics. Higher participation among social media recruitment respondents suggests greater prior interest in the study among these participants compared with those approached at local clinics. Because these participants dropped out after randomization and despite our

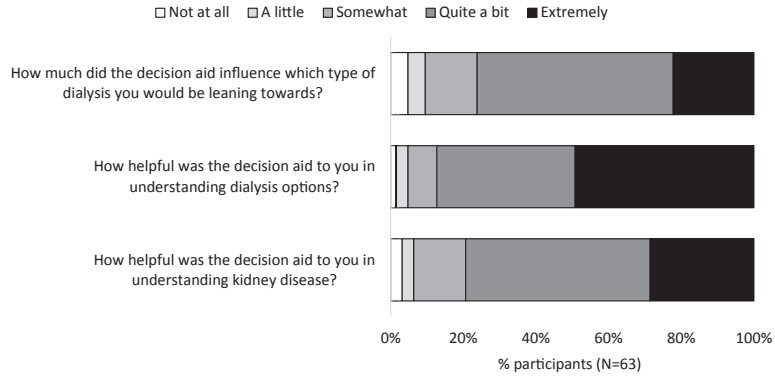

Figure 3. Perceived benefit of the decision aid in decision making, understanding options, and knowledge. Three items with responses on a Likert scale from "not at all" to "extremely."

Table 4. Summary of Open-Ended Feedback on the Decision Aid: Most Frequently Cited Responses

Most Frequent Topic/Theme	Frequency[a]	Sample Quotes
What you think about the decision aid website you have just reviewed?		
Informative	65%	"There was a lot of very good information to assist me to make a very serious decision when and if the time comes.…" "I was knowledgeable already on 80% of the information, but it was helpful… I hope all treatments improve."
Helpful	40%	
Good	40%	
Not good/ something missing	22%	
Not sure	3%	
What did you like about the decision aid website?		
Easy to use/ accessible	29%	"I like the 'feel' perspective… the facts of each treatment can be found everywhere, but not often do you see the feelings of the patient, put in consideration. I had mixed feelings about which way to go, but this site helped a great deal."
Explanation of options	21%	
Informative	17%	
Helpful for decision making	10%	
Comprehensive	8%	
Patient testimonials	8%	
Graphics	8%	
Interactivity (VCE decision tool)	6%	
What suggestions do you have to improve the decision aid website?		
None	41%	"… what about home hemo? And, what about info about having to change dialysis types if, for instance, your abdominal wall becomes tough and can no longer filter?"
More information	29%	
Improve content format	10%	
Improve features	8%	
Improve quotes	6%	

Abbreviation: VCE, value clarification exercise.
[a]Frequency indicates the proportion of posttest respondents (n = 63) whose responses for each question included these themes. Some responses coded to more than 1 theme; therefore, frequencies do not add up to 100%.

findings of similar participant characteristics across study arms, there may be unobserved factors that were unbalanced and could have biased our comparisons between the control and intervention arms. Future studies may benefit from a study design involving randomization after website login. This also implies that the effect of the decision aid observed in this study may not apply to decision aid use in real-world settings. However, similar results when comparing pre- and posttest responses in the intervention arm provide additional evidence of decision aid efficacy.

Our study has several other limitations. First, participants were on average younger than the US CKD population[1] and based on US Census data, more educated than the US general population. Study participants had high literacy scores, almost all graduated high school, and the percentage of native English speakers was very high. This likely is a reflection of the success of the online recruitment strategies among people with these attributes. Patients with stage 4 CKD are often dealing with a heavy medication burden and a multitude of physical and mental symptoms related to kidney failure before the start of renal replacement therapy.[2,46] These factors may have negatively influenced willingness to participate in a research study and contributed to the low participation rate, potentially resulting in a less generalizable participant cohort despite similar race and sex mix as the US CKD population. We envisioned a web-based format as the ideal way to quickly disseminate the decision aid to the broadest possible audience. However, lack of internet access and computer literacy limitations challenged recruitment efforts, also contributing to a less representative cohort in terms of age and educational attainment.

Second, while we did not find evidence that our randomization strategy was unsuccessful, we were unable to operationalize a truly random process across different sites and recruitment efforts. Because the list of study IDs given to each study coordinator alternated between the intervention and control groups, random assignment relies on the assumption that the order of participant consent is random. Furthermore, if a participant revealed his or her treatment assignment to the study coordinator after starting the study and the study coordinator retained a copy of the full study ID list, the coordinator could have discerned other participants' treatment assignments.

Third, decision-making outcomes were only assessed immediately after exposure to the decision aid. This was done to evaluate the short-term effects of the decision aid and is consistent with theoretical constructs and IPDAS guidelines.[23] Efforts are currently underway to develop a study to implement the decision aid in nephrology clinics that will allow for better understanding of long-term effects of the decision aid and in real-world settings.

We incorporated feedback such as the need for information about home HD from participants to refine the decision aid further. The final decision aid is now available at http://choosingdialysis.org/. Our work suggests that this decision aid, developed through a stakeholder-engaged process, informs and supports patients with CKD in making the difficult choice of dialysis modality. The broader implementation of this decision aid could complement current CKD education in clinical practice and could support both care providers and patients in shared decision making by facilitating communication about treatment options. Additionally, the decision aid could also become a resource for disseminating end-stage kidney disease knowledge with the potential for improving health outcomes through more active engagement in care.[8,47,48]

Supplementary Material

Supplementary File (PDF)

Item S1: Screen shot of the value clarification exercise.

Item S2: Example quote used in the decision aid.

Item S3: EPOCH Patient Decision Aid Control Test.

Item S4: EPOCH Patient Decision Aid Pretest.

Item S5: EPOCH Patient Decision Aid Posttest.

Article Information

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Data Sharing: Deidentified data that underlie the results reported in this article are available to qualified researchers for approved scientific uses immediately following publication with no end date. Data access proposals should be directed to the corresponding author.

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