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Embedding an Education Intervention about Shared Decision Making into an RCT: Ensuring competency and fidelity

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ABSTRACT

Objective: To describe the outcomes of training nephrology clinicians and clinical research participants, to use the Best Case/Worst Case Communication intervention, for discussions about dialysis initiation for patients with life-limiting illness, during a randomized clinical trial to ensure competency, fidelity to the intervention, and adherence to study protocols and the intervention throughout the trial.
Methods: We enrolled 68 nephrologists at ten study sites and randomized them to receive training or wait-list control. We collected copies of completed graphic aids (component of the intervention), used with study-enrolled patients, to measure fidelity and adherence.
Results: We trained 34 of 36 nephrologists to competence and 27 completed the entire program. We received 60 graphic aids for study-enrolled patients for a 73% return rate in the intervention arm. The intervention fidelity score for the graphic aid reflected completion of all elements throughout the study.
Conclusion: We successfully taught the Best Case/Worst Case Communication intervention to clinicians as research participants within a randomized clinical trial.
Innovation: Decisions about dialysis are an opportunity to discuss prognosis and uncertainty in relation to consideration of prolonged life supporting therapy. Our study reveals a strategy to evaluate adherence to a communication intervention in real time during a clinical study.

1. Introduction

Most people with end-stage kidney disease will face a decision about dialysis. Factors such as prognosis, goals, and treatment burden will make this decision difficult and require detailed discussion to make an informed decision about initiating long-term dialysis [1]. Nephrologists have identified barriers to discussions about initiating dialysis, including lack of time, different opinions of family members, and the finality of deciding to forego dialysis [2]. They also tend to avoid discussions of the future and focus on the immediate problem of treating kidney failure, leaving patients with an incomplete understanding of their prognosis and overall health trajectory [3]. This limits the ability for patients, families, and nephrologists to work together to ensure treatments are aligned with patients' priorities.

To better support patients, families, and nephrologists, we developed the Best Case/Worst Case – Nephrology intervention [4]. Using scenario planning and a graphic aid, it is designed to facilitate shared decision-making about dialysis. Developed and tested for high-risk surgical decisions with frail older adults [5], the Best Case/Worst Case communication intervention helps clinicians discuss how life-limiting illness might impact a patient's life within the context of burdensome treatments. The intervention uses scenario planning to manage uncertainty and storytelling to describe not just outcomes and risks, but how patients might experience treatment, longer term outcomes and the events along the way [6]. A graphic aid helps patients track the conversation about options and serves as a later reference. For patients with end-stage

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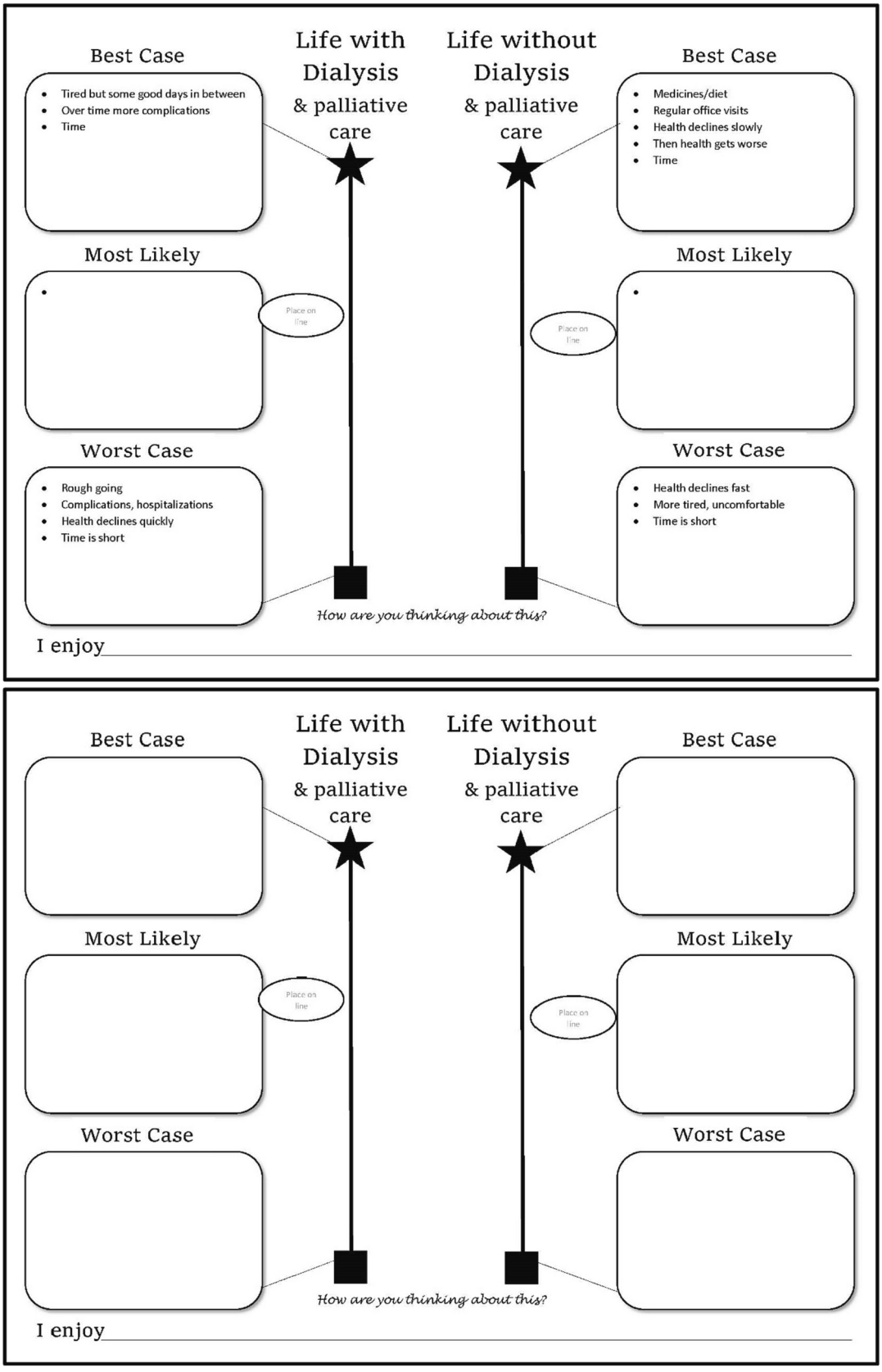


Fig. 1. Best case/worst case graphic aids. We provided a scripted and a blank version of the graphic aid for the intervention nephrologists to use with their patients during dialysis initiation discussions. Templates are available at https://patientpreferences.org/bcwc-nephrology.

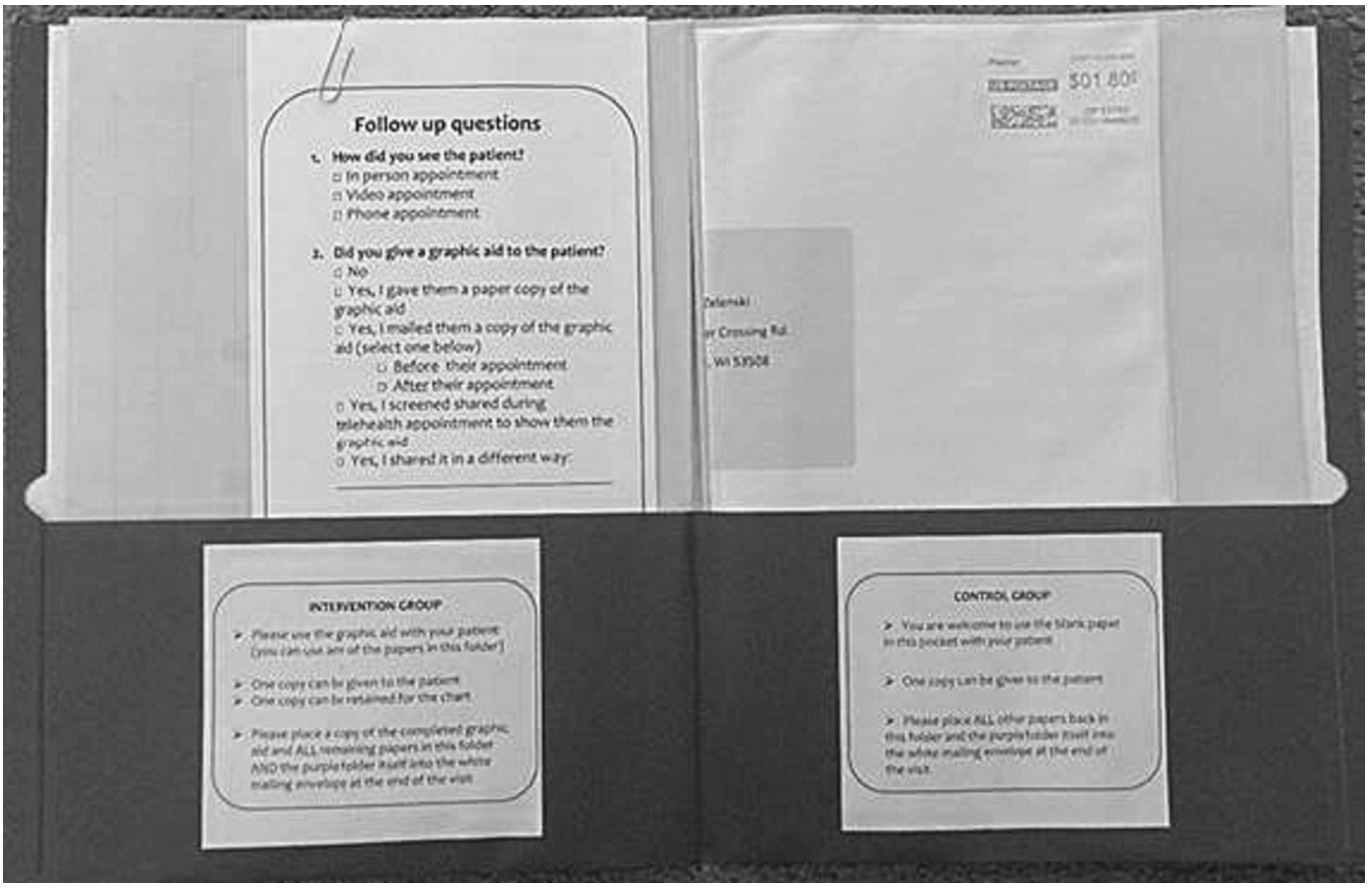


Fig. 2. Study materials folders that nephrology clinicians received prior to seeing a study-enrolled patient. Those in the intervention group also received a few of these during training.

kidney disease, we labeled one option "Life with Dialysis and Palliative Care" and the other "Life without Dialysis and Palliative Care" [7]. We included Palliative Care in both options to reinforce its utility regardless of treatment choice. Nephrologists and patients endorsed the importance of three elements: lifestyle adjustments, short-term experience of treatment and prognostic estimates. We used this information to create a scripted version of the graphic aid with space for individualization (Fig. 1). Nephrologists can also draw it by hand.

We piloted Best Case/Worst Case – Nephrology and demonstrated feasibility of training nephrologists to competency and acceptability to nephrologists and patients [7]. Next we designed a cluster-randomized clinical trial (RCT) to measure the effect of training nephrologists to use the intervention on receipt of palliative care, quality of life and quality of communication [8]. We used a mastery-based simulation training with ongoing coaching to teach nephrologists how to use Best Case/Worst Case during dialysis conversations with older patients. Medical educators have used mastery-based simulation training to effectively teach complicated communication tasks such as discussions about code status and sharing difficult news [9,10].

This analysis describes the outcomes of training nephrology clinicians to use the Best Case/Worst Case Communication intervention during an RCT to ensure competency, fidelity to the intervention, and adherence to intervention and study protocols. We also describe some challenges faced by clinician participants in implementing the training.

2. Methods

2.1. Study design

We cluster-randomized nephrology clinicians (stratified by site) at the beginning of the study to intervention or wait-list control. To mitigate contamination between groups we did not randomize patients to treatment groups. Instead, patients were enrolled and consented by study team members just prior to a visit with their nephrologist and received the treatment condition to which the clinician had been assigned.

2.2. Participants and setting

We invited nephrology clinicians who see older adults with end-stage kidney disease at ten study sites to participate. Their patients were eligible for participation if they were 80 years of age or older, had a modified Charlson score (medical comorbidities) of 4 or greater (predicted survival 12–24 months), or a "no" response to the "Surprise Question" (Would you be surprised if this person died in the next year?) [11].

2.2.1. Randomization, recruitment, and enrollment

Study team members sent emails to eligible clinicians at each study site. Once enrolled, participants were randomized in blocks into either control or intervention group.

2.2.2. Intervention nephrologists

The education team notified, via email, each nephrologist in the intervention group and requested they contact the instructor to schedule training.

2.2.3. Control nephrologists

The education team notified this group they would have the opportunity to learn how to use Best Case/Worst Case at the end of the study.

Case 1: Mr. Robinson	Case 2: Ms. Olson	Case 3: Ms. Montgomery
85 yo man, very active History of CAD and MI	83 yo woman, very active History of HL, HTN, and CAD	78 yo woman, frail History of poorly controlled DM, HTN, severe neuropathy and severe PVD, R BKA 1 yr ago
eGFR: 17	eGFR: 24	eGFR: 14
Main Learning Objective: Create a graphic aid for someone who doing well clinically but has a comorbid condition.	Main Learning Objective: Create and practice using a graphic aid for someone who doing well clinically but has several comorbid conditions.	Main Learning Objective: Create and practice using a graphic aid for someone who is not doing well and has many comorbid conditions

Fig. 3. Training cases. The three training cases increased in clinical complexity to ensure that nephrologists were able to use Best Case/Worst Case with a variety of patients.

We also explained study procedures by attaching a brief video. The video informed them that prior to seeing an enrolled patient, they would receive a study materials folder (a.k.a. purple folder) and asked them to use the side of the folder labeled "CONTROL GROUP" (Fig. 2). We called to followed up one week later.

2.2.4. Separation of study and education teams

To achieve blinding we maintained separation between the study and education teams. The study team consisted of the Principal Investigators (PIs) and study coordinators at each site along with the study PI and statisticians at the main site. The education team included the communication educator who has a doctorate in education and 14 years of experience, a surgery resident, two health services researchers, and a health services research specialist. They independently handled all communication with study-enrolled nephrologists. Only they and the standardized patients knew the treatment group for each nephrology clinician.

We planned in-person training and transitioned to Zoom when the COVID19 pandemic restricted travel. We piloted virtual training with Site PIs at three sites to test the technology and ensure engagement with the training materials.

2.3. Training procedures

To ensure that each nephrologist assigned to the intervention group could use the intervention with fidelity, we used mastering learning [12] with deliberate practice [13] to guide the training. Mastering learning was implemented by sequentially working through increasingly complex case studies to meet competency. Deliberate practice was implemented through role play with standardized patients accompanied by coaching.

2.3.1. Preparatory materials

We mailed the nephrologists a learner manual, a pocket card reference to recall the tool's elements and example phrases, and folders containing blank and scripted graphic aids. We directed nephrologists to a webpage with educational materials: a 7-min video describing the intervention, a demonstration video of a nephrologist using the tool with a standardized patient, the learner manual, and several "tips videos" (e.g. how to fit this into a busy clinic day) (https://patientpreferences.org/bcwc-nephrology).

2.3.2. Practice cases

We used deidentified patient stories to develop training cases. The first case was a patient doing well clinically, the second case was a moderately healthy patient with one comorbid condition, and the third case was a patient in poor health with several comorbid conditions. We intentionally increased the clinical complexity of cases so nephrologists could experience using the tool with different patients, building competency with increasing difficulty over time (Fig. 3).

2.3.3. Outcomes

We created a competency checklist for the conversation and elements on the graphic aid, assigning one point for each element performed (Fig. 3). We defined competency as 14 of 19 elements performed (as observed by the instructor), i.e. we deemed a nephrologist who scored 14 of 19 during the final simulated case ready to use the tool in clinical practice. The education and research teams agreed on a score of 14 because it encompassed the essential elements: breaking bad news (1), naming two clear options (2), telling a best, worst, and most likely story for each (10), using a phrase to encourage deliberation (1), and making a recommendation (1). If a nephrologist scored below 14, they were required to engage in additional practice until they reached competence. To measure fidelity, we created a graphic aid rubric with a maximum score of 28 and an acceptable score of 15 (Fig. 5). A score of 15 reflected fidelity based on our rubric, which assessed a competent score of 2 for 7 of 8 elements and a binary score (0/1) for the final element. We measured adherence by reviewing the number and quality of graphic aids returned by intervention clinicians.

2.4. Flow of the training session

The communication educator conducted all training sessions one-on-one with the nephrology clinicians. The standardized patients participated only in the simulated cases. We have included the Learner Guide as Appendix 1.

2.4.1. Connecting BC/WC to current clinical practice

The instructor asked questions to understand the nephrologist's practice patterns and environment, which enabled a focus of content on new elements. These elements included introducing Palliative Care and using visual aids during virtual visits with patients. While some sites had colleagues trained in nephrology and palliative care, others had little contact with palliative care colleagues. The instructor provided example phrases for introducing palliative care and encouraged them to try these during practice with the standardized patient. To address logistics of virtual visits, the instructor noted how the Zoom configuration used during practice cases could be replicated on most virtual healthcare platforms. The demonstration video also showed them how this could be done in person with a paper graphic aid. Next the instructor reviewed the 7-min instructional video with the nephrologist.

2.4.2. Co-creating the graphic aid (Case 1)

The instructor asked the nephrologist to review the information for the demonstration case in their manual and consider how they might complete the graphic aid for this patient. After constructing the graphic

Best Case/Worst Case Skills Checklist & Observation Form

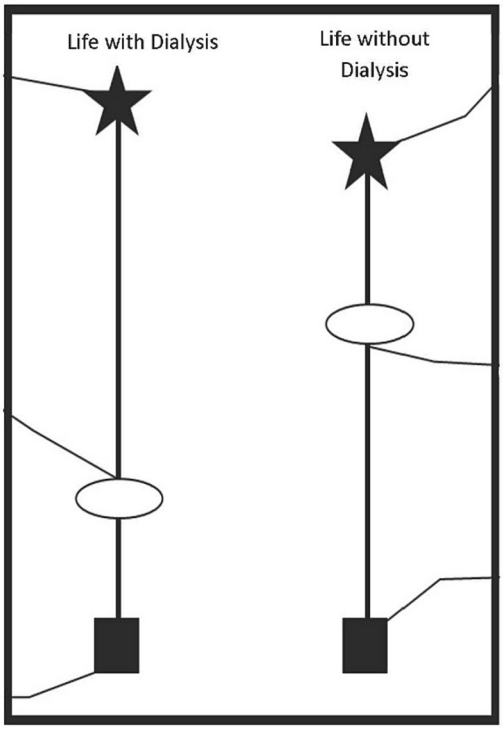
Described experience of life with dialysis
No □ Yes □

Broke bad news
No □ Yes □

Described experience of life without dialysis
No □ Yes □

Described a **BEST CASE** outcome

Short-term	long-term
No □ Yes □	No □ Yes □



Described a **BEST CASE** outcome

Short-term	Long-term
No □ Yes □	No □ Yes □

Described a **MOST LIKELY** outcome

Incorporated chronic medical conditions
No □ Yes □

Described a **MOST LIKELY** outcome

Incorporated chronic medical conditions
No □ Yes □

Described a **WORST CASE** outcome

Short-term	Long-term
No □ Yes □	No □ Yes □

Described a **WORST CASE** outcome

Short-term	Long-term
No □ Yes □	No □ Yes □

Used questions or phrases to encourage deliberation
No □ Yes □

Made a recommendation linked to patient preferences (includes support from palliative care)
No □ Yes □

Graphic aid shows dialysis and supportive care, clearly named, and for each treatment there is a vertical line with a box, star, and oval/mark to indicate most likely	No □ Yes □
Written graphic aid includes written Best Case, Worst Case and Most Likely outcomes for each treatment offered	No □ Yes □
Wrote patient-friendly terminology on the graphic aid	No □ Yes □
Wrote "what is important to you now?" or equivalent phrase on the graphic aid	No □ Yes □

NEPHROLOGIST: _____

TRAINIER: _____

CASE #: _____

TOTAL SCORED POINTS: _____ /19

ADDITIONAL COMMENTS:

Fig. 4. Competency checklist. Instructors used this checklist while observing the cases with the SPs during the initial training. A score greater than or equal to 14 was considered competent.

aid together, the instructor showed a video demonstration of a nephrologist talking with an actor portraying the patient in Case 1 and asked the nephrologist to critique the demonstration. This provided an opportunity for them to describe how their graphic aid might differ from the one used in the demonstration. Explaining why they made different decisions allowed the instructor to correct mistakes in their approach or validate individual variation.

Criteria						Total Score
	0	**1**	**2**	**3**		
Graphic Aid Symbols	Do not exist	Shows 2 treatment options	Shows 2 options with a **Star** at the top and a **Box** at the bottom	Shows 2 options with a **Star** at the top, a **Box** and the bottom and a **mark** to indicate Most Likely		
	0	**1**	**2**	**3**	**4**	
Life *with* Dialysis **Best Case**: written description of scenarios	Does not exist	Indicates an overall story of Best Case	Overall story and either short- **or** long-term experience of the patient	Overall story, short- **and** long-term experience of the patient	All elements included plus "*exceptional*" elements; ie timing (days to years), values, extra information	
Life *with* Dialysis **Most Likely**: written description of scenarios						
Life *with* Dialysis **Worst Case**: written description of scenarios						
Life *w/o* Dialysis **Best Case**: written description of scenarios						
Life *w/o* Dialysis **Most Likely**: written description of scenarios						
Life *w/o* Dialysis **Worst Case**: written description of scenarios						
	0		**1**			
What patient "enjoys"	Not done		One or more enjoyable thing noted			
Comments (optional):						Score _____/ 28

Fig. 5. Graphic aid scoring rubric. Education team members used this rubric to score returned copies of graphic aids from the intervention group as a measure of fidelity.

2.4.3. Simulated encounter with in-the-moment feedback (Case 2)

The instructor asked the nephrologist to review the second case in their manual and write details on the scripted graphic aid. Then, the nephrologist recited these details to the instructor who transferred the text to a document on their shared screen. This exercise gave the instructor an opportunity to provide coaching and feedback on the content of the graphic aid. Before the actor was invited into the virtual room, the nephrologist was told that this simulation was a return visit with a patient with severe kidney disease. The instructor paused mid-simulation if major feedback was required; otherwise, the instructor waited to address minor points at the end of the encounter. The instructor asked the nephrologist how it went from their perspective. Then, the instructor provided feedback based on the competency checklist (Fig. 4) and provided suggestions for improvement.

2.4.4. Simulated encounter with summative feedback (Case 3)

For the final case, the instructor gave the nephrologist the option to use the blank graphic aid if they preferred. Then, the nephrologist independently created the graphic aid. The instructor let the conversation proceed uninterrupted. If the nephrologist reached competence during this third case, the practice portion of the training was complete. A fourth practice case was available for those who did not achieve competence by case 3.

2.4.5. Maintenance

Upon completion of training, the instructor met intervention-trained nephrologists every two weeks for approximately six weeks. During this time, nephrologists did not have patients enrolled in the study, but were asked to use Best Case/Worst Case with patients for whom they were discussing dialysis initiation. The instructor asked them to reflect on using BCWC in clinic and then focused on problem-solving specific issues; including when to make the graphic aid and how to improve efficiency. If the participant had recently used a graphic aid, the instructor would refer to the copy they received for feedback. The instructor subsequently met with each intervention nephrologist every two months during their first year on study, and every three months for the second year on study (Fig. 6).

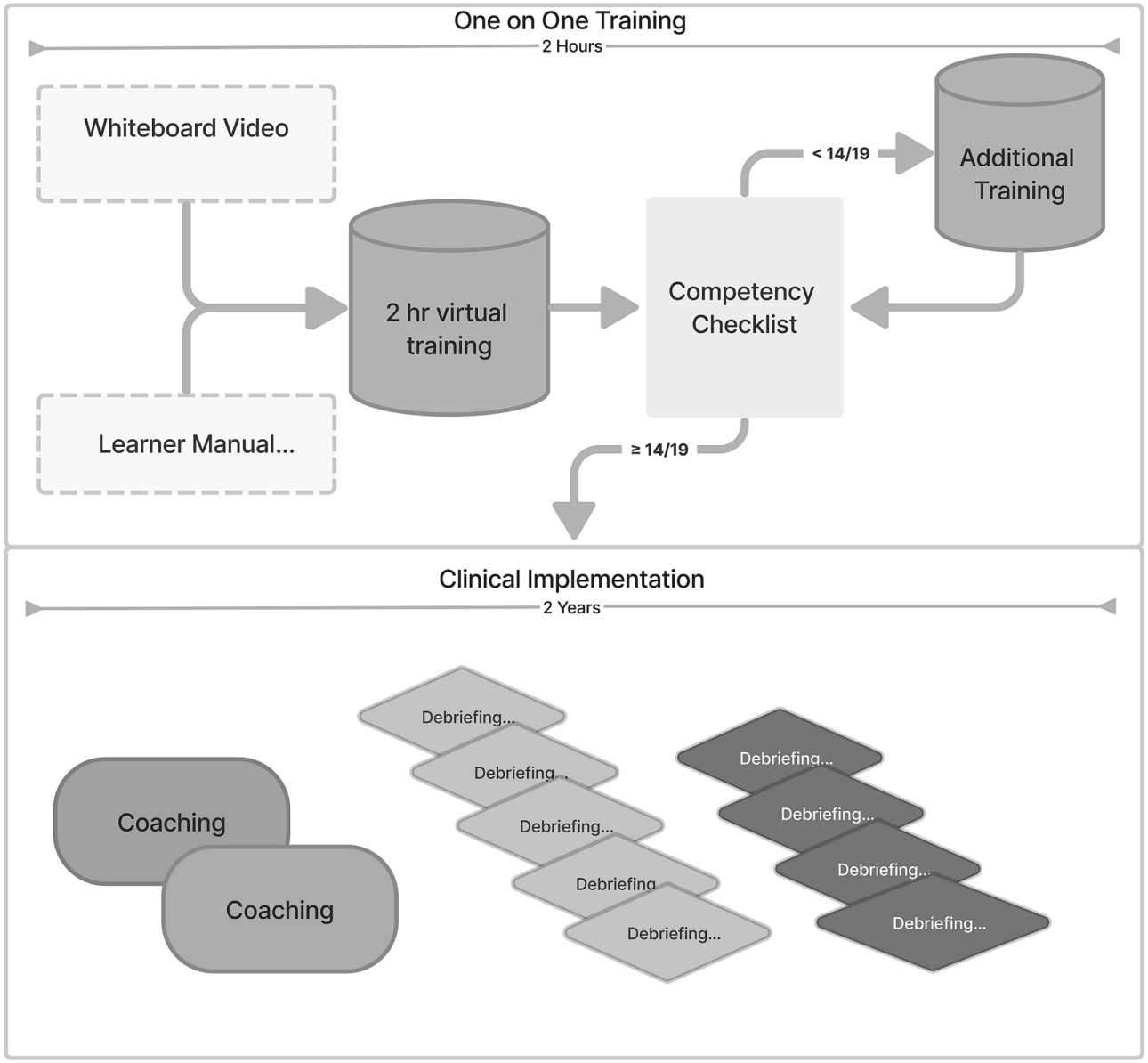


Fig. 6. Training and coaching protocol. Each nephrologist in the intervention group received 2-h of initial training. Once they scored 14/19 on the competency checklist, they implemented the tool in clinic. The communication educator provided coaching and debriefing at regular intervals for 2 years, first every 2 months, then quarterly after the initial training.

2.4.6. Study material folders

To assess adherence to the intervention and maintain blinding throughout the study, we assembled folders for control and intervention groups containing: 1) one sheet of blank 3-part carbon paper, 2) a 3-part carbon paper Best Case/Worst Case scripted graphic aid, 3) a 3-part carbon paper blank graphic aid, 4) a self-addressed stamped envelope, and 5) a notecard asking them to indicate whether the visit was in-person, video, or phone and if the patient received a copy of the graphic aid. The 3-part carbon paper enabled the creation of two duplicate copies so that one could stay with the nephrologist, one could go with the patient, and one could be sent to the education team for data collection and follow up. The folder (colored purple for easy visibility) also contained instructions for the control nephrologists (on one side) and for the intervention nephrologists (on the other side) with corresponding labels (Fig. 2). These instructions were limited to what to do with the materials in the folder (i.e. you are welcome to use the blank paper, give one copy to your patient, and send all materials back to the education team) to avoid contaminating the control group. Since we did not record the conversations, graphic aids were used as a proxy to appraise performance and measure adherence. We labeled each purple folder with the nephrologist's study ID, and the date and time of the study-enrolled patient's appointment. Research coordinators reminded nephrologists on the day of the patient's appointment by saying: "This patient is in the study. Please use the intervention if you were trained. Here is a folder with diagrams. If you were not trained, there is blank paper inside you can use for notes if you wish."

2.5. Data collection

From training sessions, we collected graphic aids created, competency checklists, records of attendance, and field notes. During the study, we asked nephrologists to send us all materials from the study materials folder not given to the study-enrolled patient (e.g., a copy of the graphic aid). We scanned materials into REDCap for analysis [14].

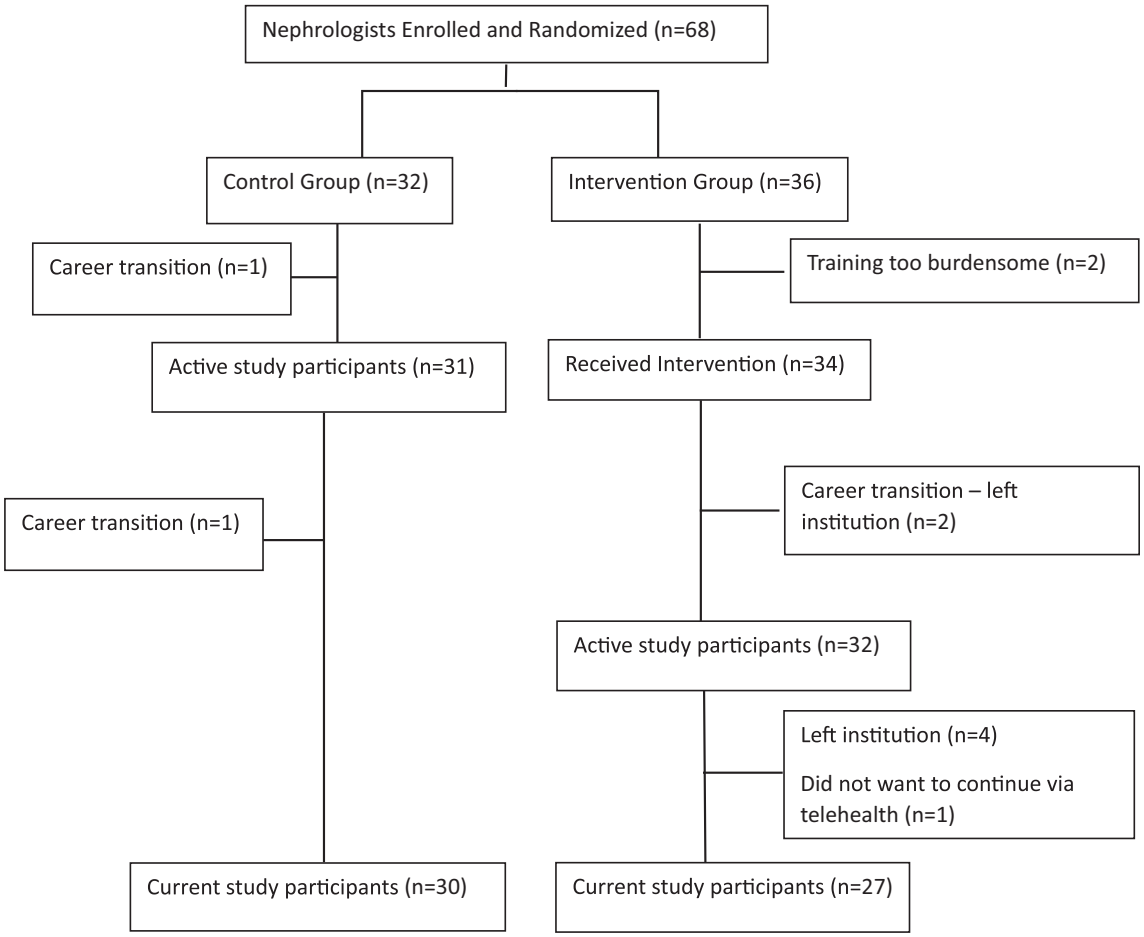


Fig. 7. CONSORT diagram.

2.6. Analysis

The graphic aid scoring rubric included 8 elements: the presence of graphic aid symbols (1), the quality of the Best, Worst, and Most likely case descriptions for life with and life without dialysis (6), and what the patient enjoys (1). The presence of graphic aid symbols was scored on a 4-point scale (0 = no symbols, 1 = two options shown, 2 = includes star and box, 3 = includes mark for most likely). The descriptions were scored between 0 and 4 (0 = blank, 1 = completed, 2 = adequate, 3 = good, 4 = exceptional). Including what the patient enjoys was scored as a binary (0 = blank, 1 = completed). The maximum total score was 28. A total score of 15 indicated fidelity to the intervention (Fig. 5). After revisions to the rubric, the final intraclass correlation coefficient was 0.926. Two education team members independently scored each graphic aid using the rubric; disagreements were discussed and adjudicated. We used rapid analysis with two coders to accurately describe the field notes.

3. Results

3.1. Clinician participants

We enrolled and randomized 68 nephrologists at 10 study sites. Thirty-six were randomized into intervention and 32 into control. Nephrologists ranged in age from 29 to 73 and had been in practice for a median of 4.25 years (Table 1). Eighteen nephrologists (5 control/13 intervention) did not have patients enrolled in the clinical trial at the two-year mark. The most common reasons for patient exclusion in both groups were when patients were new to the clinician, a decision had already been made (including transplant), or when there were complicated medical and/or social dynamics. Fifty nephrologists had an average of 4 patients (range 1–14) enrolled each for a total of 200 study-enrolled patients (118 control/82 intervention).

3.2. Participation in training, coaching, and maintenance sessions

Thirty-four of 36 intervention nephrologists completed training in 2 consecutive hours consistent with study protocols [8]. Two nephrologists withdrew during training: one did not have time for the second hour and the other did not give a reason. The remaining 34 sessions proceeded without difficulty including interactions with standardized patients, coaching, and feedback.

Thirty out of 34 nephrologists (88%) attended at least 2 of 3 coaching sessions while 2 (6%) attended zero. Seven sessions were missed due to unanticipated service demands and scheduled absences for vacation and parental leave. The 12% of nephrologists who received fewer than 2 coaching sessions accounted for 16 of the 200 patients enrolled in the study.

Coaching calls discussed clarification of study procedures and troubleshooting using Best Case/Worst Case with specific patients. For example, if a patient was already planning to start dialysis the instructor discussed how to use the tool to forecast the treatment experience and confirm this was consistent with patient preferences. Other issues included introducing the intervention to new patients and how to fit the conversation into a brief visit.

Seven nephrology clinicians in the intervention group withdrew from the study during the 2-year patient enrollment period (Fig. 7). Of these, six left the study site for novel professional opportunities and one

Table 1
Participant characteristics.

	Intervention (N = 36)	Control (N = 32)
Gender, N (%)		
Female	16 (44.4)	17 (53.1)
Male	17 (47.2)	14 (43.8)
Did not report	3 (8.3)	1 (3.1)
Race, N (%)		
Multiracial or Other	1 (2.8)	2 (6.3)
Asian or Asian American	12 (33.3)	12 (37.5)
Black or African American	2 (5.6)	1 (3.1)
White or Euro American	18 (50)	16 (50)
Did not report	3 (8.3)	1 (3.1)
Degree, N (%)		
DO	2 (5.6)	0 (0)
MD	25 (69.4)	24 (75)
NP	5 (13.8)	5 (15.6)
PA	2 (5.6)	2 (6.3)
Did not report	2 (5.6)	1 (3.1)
Age, median (range)	44 (29–73)	44 (29–60)
Time in practice, median (range)	7.45 (0–39)	8.76 (0–29)
Average outpatient visits per month	58.4	69.6
Number of patients enrolled	82	118

believed implementing the intervention in the context of pandemic-related challenges and virtual visits was overly burdensome. The time on study prior to withdrawal averaged 253 days.

3.3. Competence, fidelity, and adherence

The average competence score after case 3 during training was 18.9/19 and there was no need for further training or remediation. Elements most commonly missed were a long-term outcome for a best or worst case scenario (11 nephrologists) and not using language to encourage deliberation (9 nephrologists) (Fig. 4).

We received 60 graphic aids created by nephrologists in the intervention arm for a 73% return rate. Fifty two percent of intervention arm graphic aids used the open template, while the others used the scripted template. On average, clinician participants completed most intervention elements with a fidelity score of 19 (range 4–28, fidelity = 15 or higher) (Fig. 8).

We collected 129 field notes from ongoing follow up. Intervention nephrologists commented on using the framework more frequently than the graphic aid, which they found time consuming. One commented that, "The time writing down info on the work sheet was the most difficult." Concurrently, they noted patients liked having something to take home with them, appreciated the visual simplicity of the graphic aid, and one specific commendation about the utility of the Most Likely section. Nephrologists found the framework to be nimble and used it for patients in the hospital as well. They reported it was a valuable springboard for difficult conversations, specifically about Palliative Care. The barriers to use included time, not knowing the patient well, not wanting to revisit a decision that had already been made and concerns it would upset patients who had complex medical and/or social situations.

4. Discussion and conclusion

4.1. Discussion

We successfully trained nephrology clinicians via Zoom to competently use Best Case/Worst Case and integrate it into their clinical practice within a large cluster-randomized clinical trial. We accomplished this at 10 study sites, where we saw consistent and accurate use of the tool with study patients. On-going coaching was essential to ensure that nephrology clinicians could incorporate this new skill into their clinics in a way that was acceptable for them and their patients, as evidenced by the conversations during the coaching sessions. Mastery learning, deliberate practice, and coaching in combination with collection and review of the communication tool-associated graphic aid allowed us to provide feedback at a distance while measuring fidelity and adherence during the trial. This work has important implications for patients and families, educators, and communication researchers.

For patients and families, decisions about dialysis are an opportunity to discuss prognosis and uncertainty related to consideration of prolonged life-supporting therapy. Best Case/Worst Case uses scenario planning to help imagine the experience of treatment and changes in health over time depending on treatment choice. This moves conversations beyond the "fix-it" model [15] where dialysis is proposed as a simple solution to a specific problem without context about how treatment and kidney failure will impact health over time. Best Case/Worst Case conversations create space to discuss Palliative Care, regardless of treatment choice, so patients and loved ones can grasp the challenges of living with kidney disease and use this understanding to consider Advance Care Planning and treatment of somatic symptoms earlier in their trajectory [16,17]. Housing these conversations in the outpatient setting lets patients have conversations with a clinician they know, while the graphic aid allows for retention and consideration of the discussion over time. Although the study is ongoing, we are primed to gain knowledge about the effect of this intervention on Quality of Communication and access to Palliative Care.

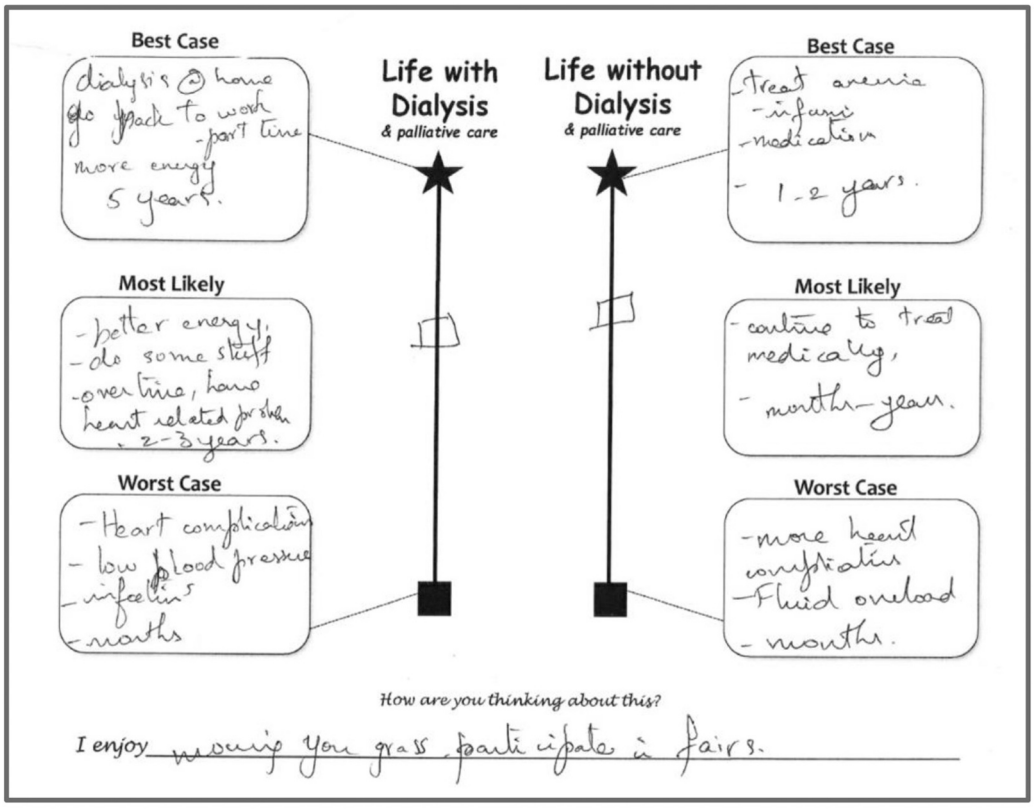
Although we originally planned to conduct the training sessions in person, the advantages of the virtual platform were fourfold: 1) we provided individualized training at a convenient time for the nephrologist, 2) we saved resources we would have spent on education team travel and the nephrologists' resources by accommodating their busy schedules, 3) we proceeded with this training in a safe environment during a global pandemic, and 4) the Zoom platform simulated a virtual visit.

4.2. Innovation

Interventions to improve shared decision-making often bypass clinicians, in part because they are easier to implement. While question prompt lists, decision aids, and patient navigators are helpful, these patient-mediated interventions can be undermined by clinicians. These interventions activate patients for decisions with more information and support, but structural barriers (e.g., a short clinic appointment) or an unsurmountable power differential between the patient and the clinician [18] are difficult to overcome. Although it requires more voluntary clinician participation, Best Case/Worst Case provides a framework clinicians can employ within their busy specialty care practices. Most nephrology clinicians were able to adopt the intervention in practice and were willing to participate in coaching sessions. Most adjusted their practice for vulnerable patients (both those in the study and others whom they reported might benefit), participated willingly in study procedures, and used the intervention in real time with study-enrolled patients.

Standardized patients, the tracking afforded by study-material folders, and longitudinal coaching were vital to the success of this program. Standardized patients enabled deliberate practice and coaching with participants during training so we could observe how the participants might enact Best Case/Worst Case with their own patients and assure competence with the intervention [10,19]. We leveraged the ability to teach the participants the new skills over time to increase the likelihood that this learning would last over the course of a long study and perhaps become habitual [20]. Collecting copies of the completed graphic aid was a reminder for the nephrologists to use the tool and a strategy to measure performance. Review of the graphic aid and regular follow up spanned the gap between competence with simulated patients and adherence with study-enrolled patients. While this is a resource-intensive strategy, we have found success scaling our methods using small group instruction to teach similar communication tools [21]. We are also engaging with a purveyor of clinician education, VitalTalk, with

Exemplary Graphic Aid (Scored 28/28)



Competent Graphic Aid (Scored 16/28)

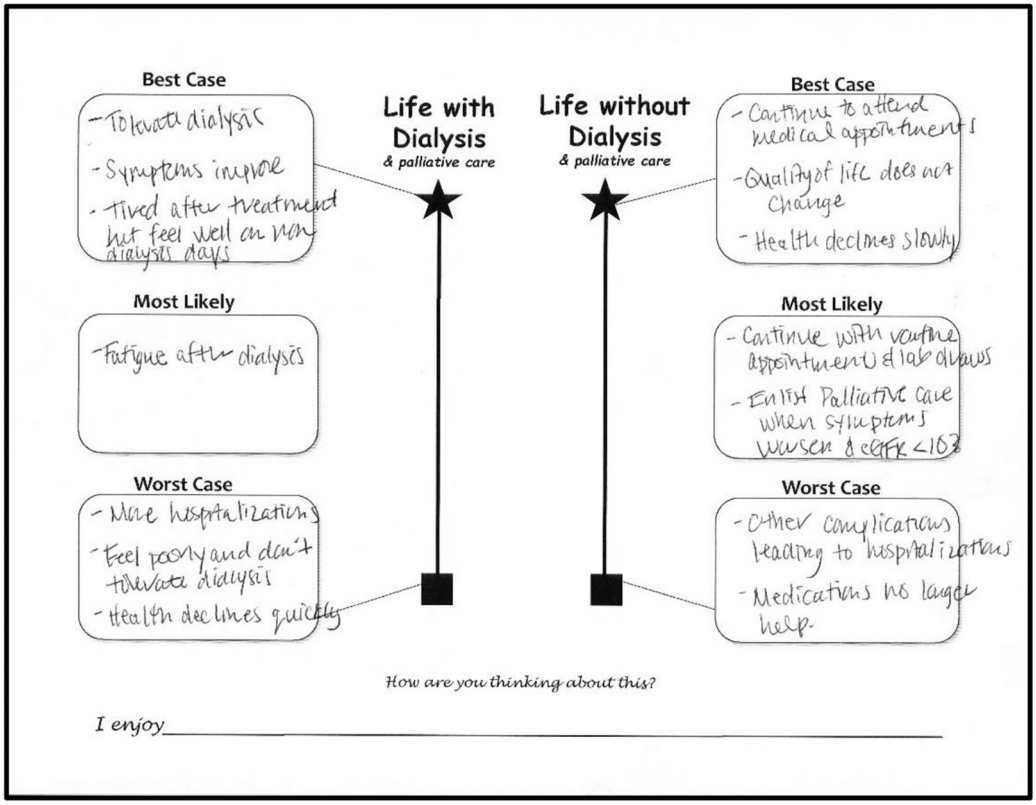


Fig. 8. Graphic aids returned. The upper graphic aid scored 28/28 on the rubric, while the lower graphic aid scored 16/28 on the rubric (fidelity score).

rich experience in dissemination and novel strategies to further disseminate this intervention.

For researchers, our study reveals a strategy to evaluate adherence to a communication intervention in real-time during a clinical study. The evidence base for communication interventions in pragmatic studies, particularly in palliative care, has been hindered by low adherence to interventions. There is no assurance that performance with a standardized patient translates into competent or consistent performance with actual patients [22]. Furthermore, it is difficult to monitor and support the use of an intervention during a study when there are multiple competing demands on clinicians. Study results are thus uninterpretable when receipt of the intervention is unknown, or when there is no strategy to rectify low adherence within an ongoing study [23,24]. To ensure the intervention is used as intended requires a trigger for clinicians to use it, an audit to measure fidelity, and feedback to increase fidelity in real time.

Although the use of audio recordings to assure intervention adherence is ideal for measuring fidelity, it is resource intensive to transcribe and evaluate recordings. It can also be a significant barrier to enrollment [25] given privacy and indemnity concerns and clinic disruptions related to recording logistics. To overcome this barrier, we used the content of the graphic aids as a proxy for knowledge about what was said. Given creation of the graphic aid is a component of the communication tool, the use of carbon paper to duplicate the aid for research purposes provided a low-tech strategy to assess clinician performance.

There are strengths and limitations of this study. Although we were able to train the majority of clinicians who consented for the study, not all participants received the full schedule of training and coaching sessions due to shortages of time and enthusiasm on the part of the nephrology clinicians. On average, more patients were excluded by nephrologists in the intervention group compared to the control group. While the reasons given were the same, it is possible that those in the intervention group had a lower threshold for exclusion because they felt uncomfortable using the intervention in specific instances. Separation between the study team and the education team was a strength that allowed the study personnel collecting and analyzing data to remain blinded to the nephrologist's assigned treatment group. Our approach was resource intensive, and limited staffing for an independent education team resulted in competency assessments completed by only one education team member.

4.3. Conclusion

We successfully taught the Best Case/Worst Case Communication intervention, specifically scenario planning and use of a graphic aid, to clinicians as research participants within a cluster- randomized clinical trial. Working with standardized patients, longitudinal coaching, and the collection of graphic aids allowed us to ensure competency, fidelity to the intervention, and adherence to study protocols. These methods can be adapted to other settings for clinical and research purposes to change communication practices for patients with serious illness.

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CRediT authorship contribution statement

Amy B. Zelenski: Conceptualization, Formal analysis, Investigation, Project administration, Writing – original draft. **Karlie Haug:** Data curation, Writing – original draft. **Kyle J. Bushaw:** Project administration. **Anne Buffington:** Data curation, Project administration, Writing – review & editing. **Taylor Bradley:** Project administration. **Kristine L. Kwekkeboom:** Conceptualization, Investigation, Methodology, Writing – review & editing. **Lily Stalter:** Formal analysis, Writing – review & editing. **Bret M. Hanlon:** Formal analysis, Writing – review & editing. **Maureen J. Wakeen:** Conceptualization. **Roy A. Jhagroo:** Conceptualization. **Laura J. Maursetter:** Conceptualization. **Sara K. Johnson:** Conceptualization. **Toby C. Campbell:** Conceptualization, Writing – review & editing. **Margaret L. Schwarze:** Conceptualization, Funding acquisition, Investigation, Methodology, Resources, Supervision, Writing – original draft, Writing – review & editing.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Amy Zelenski reports financial support was provided by National Institutes of Health. Sara Johnson reports a relationship with VitalTALK that includes: speaking and lecture fees.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pecinn.2024.100260.

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