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A pilot randomized controlled study of integrated kidney palliative care and chronic kidney disease care implemented in a safety-net hospital: Protocol for a pilot study of feasibility of a randomized controlled trial

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ABSTRACT

Background: Chronic kidney disease (CKD) impacts more than 800 million people. It causes significant suffering and disproportionately impacts marginalized populations in the United States. Kidney palliative care has the potential to alleviate this distress, but has not been tested. This pilot study evaluates the feasibility of a randomized clinical trial (RCT) testing the efficacy of integrated kidney palliative and CKD care in an urban safety-net hospital.

Methods: This is a single-site pilot RCT designed to enroll 85 participants, with a goal of at least 60 completing the study. The inclusion criteria are adults 18 or older, who are either Spanish or English speakers, have an estimated Glomerular Filtration Rate (eGFR) of $\leq$30 mL/min/1.73 m^2, and are receiving care at our safety net hospital. Participants will be randomized in permuted blocks of two or four to either the intervention group, who will receive monthly ambulatory care visits for six months with a palliative care provider trained in kidney palliative care, or to usual nephrology care. Primary outcomes are feasibility of recruitment, retention, fidelity to the study visit protocol, and the ability to collect outcome data. These outcomes include symptom burden, quality of life, and engagement in advance care planning.

Discussion: This pilot RCT will provide essential data on the feasibility of testing integrated palliative care in CKD care in an underserved setting. These outcomes will inform a larger, fully powered trial that tests the efficacy of our kidney palliative care approach.

Clinical trial registration: NCT04998110.

1. Introduction

Chronic kidney disease (CKD) impacts 37 million Americans, and greater than 800 million people worldwide. CKD causes significant suffering with physical and emotional symptoms of pain, pruritus, restless legs, anxiety, and poor sleep. These symptoms can lower quality of life and can increase mortality [1–5]. Notably, CKD in the United States (US) has a disproportionate impact on marginalized populations, who may also experience unmet health related social needs that can exacerbate symptoms. Additionally, the CKD population faces several life changing decisions, such as whether or not to initiate kidney replacement therapy, or care preferences for worsening illness. In sum, the complex and multidimensional challenges of CKD require an equally sophisticated and holistic approach to care.

Palliative care is a specialty that can address the suffering of CKD by providing holistic symptom management and assistance with complex medical decisions. Kidney specific palliative care is known as kidney supportive care, defined by the International Society of Nephrology as a core component of integrated kidney care that aims to improve the quality of life for people with kidney disease through prevention and relief of suffering [6]. Despite its potential, kidney supportive care remains poorly integrated with CKD care and there are no randomized controlled trials (RCTs) testing its efficacy or effectiveness. In other specialties, such as cardiology and oncology, RCTs that compare the

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impact of integrating ambulatory palliative care with disease focused care to usual care have shown improvements in symptom burden, quality of care, costs, hospitalizations, and patient and care giver satisfaction [7–10]. These results have led to guidelines for integration of palliative care into disease focused care for these specialties, transforming their standard of care to one that includes the important person-centered goal of alleviating distress. There are no comparable studies in CKD, despite the suffering it causes and the recognition by both patients and nephrologists that this approach is needed [11–14].

In this paper we describe the study design and protocol for a pilot study that evaluates the feasibility of conducting a RCT that assess the efficacy of integrated ambulatory kidney supportive care delivered by a trained palliative care provider in an urban safety net hospital setting. This study builds upon a smaller previous pilot RCT we implemented in a majority White and well-resourced population [15]. The goals of the current study are to evaluate the feasibility of recruitment, retention, and data collection in a kidney palliative care trial inclusive of a diverse sample of people with advanced CKD. Data from this pilot will inform a larger, well-powered multi-site study testing efficacy of kidney supportive care on CKD symptom burden.

2. Methods

We present our findings using the Standard Protocol Items: Recommendations for Interventional Trials [16].

Design and Rationale: To test the feasibility of conducting a palliative care clinical trial in a safety net setting among people with advanced CKD, we are implementing a single centered two-arm, parallel, randomized controlled pilot study. Our target is to have 60 participants complete the study, with an enrollment goal of 80–85 participants to account for dropout (Fig. 1).

Setting: This study is being conducted in the ambulatory nephrology clinic at Bellevue Hospital, the flagship hospital for the NYC public hospital system. Six months prior to initiating recruitment for this trial, we implemented an embedded kidney supportive care clinic in the once-weekly half-day nephrology clinic. The nephrology clinic is staffed by attendings (n = 2) and fellows (n = 4) and completes approximately 1700 visits every six months. Twenty-five percent of the population the nephrology clinic serves are insured by Medicaid, and 5 % are uninsured. Forty-one percent of visits are with those who identify as Hispanic, with 26 % of people served who identify as Black. There is a private outpatient dialysis center located within the hospital that is affiliated with Bellevue that serves approximately 80 people on dialysis. The kidney supportive care clinic is staffed by a bilingual Spanish/English board-certified palliative care physician who is meant to assist with symptom management, dialysis decision-making, and advance care planning for people with advanced CKD.

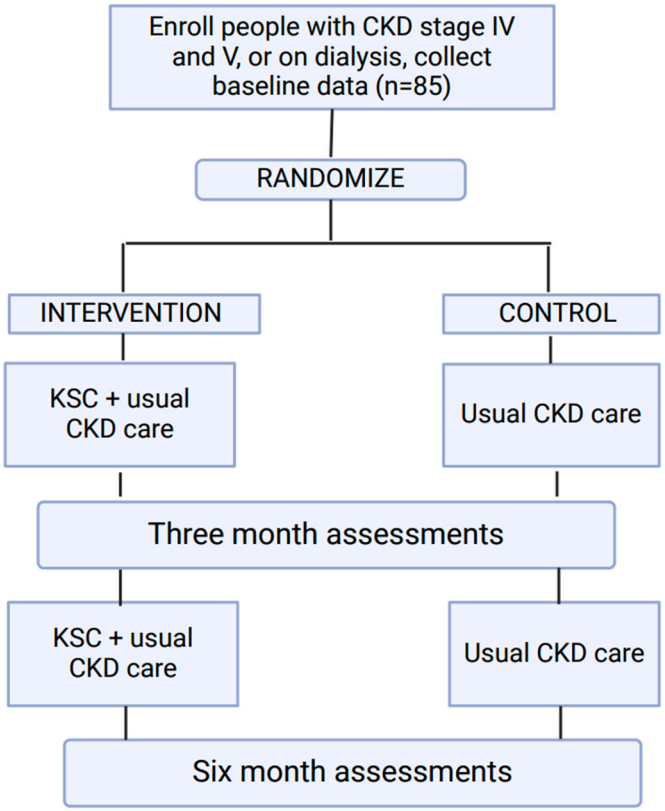

Fig. 1. Pilot trail design.

Inclusion criteria (Table 1): Individuals are eligible for this study if they are adults 18 or older with CKD stage IV or V (eGFR≤30 ml/min/1.73 m^2), or are receiving maintenance dialysis at the dialysis center located at Bellevue Hospital, and speak fluent Spanish or English.

Exclusion criteria (Table 1): We are excluding individuals who are not fluent in Spanish or English, those with contact with palliative care services in the past six months, and those with an emergent palliative care need identified on baseline assessments. Study staff were trained to recognize these situations, which can include an uncontrolled symptom, or severe distress concerning a clinical decision that would benefit from imminent palliative care assessment such as initiation of dialysis, or choosing end-of-life care preferences.

Recruitment: Extensive efforts are being made to describe the study to Bellevue staff nephrologists, geriatricians, and primary care doctors who may be caring for eligible patients. The PI attended group meetings of each specialty and presented the study to staff and introduced study staff to providers. The PI also met with dialysis staff and physicians. Potential participants are identified during screening of appointment templates prior to clinic, and their nephrologists are notified via email. Nephrologists requested that information about the study be posted in exam rooms to remind them of eligibility criteria and study team member's contact information for patients interested in participation. Once identified, potential participants are approached by the research assistant in a private place to explain the study and obtain informed consent. If a patient has a scheduled telehealth visit, the approach is made by telephone. Patients' contact information was recorded to minimize loss of follow-up.

2.1. Randomization and blinding

A blinded study statistician designed randomization prior to study start. Randomization occurred after the participant completed their baseline survey visit. Stratified by receipt of dialysis or not, randomization will be conducted in permuted blocks of two and four to maintain balance between the two groups. For participants randomized to the kidney supportive care intervention group, study staff will send an email notification to the participant's nephrologist, the kidney supportive care provider, and the primary care physician. The nature of the study made it infeasible to blind providers or patients to treatment assignment. The principal investigator was also not blinded.

2.2. Intervention

2.2.1. Provider training

We trained the kidney supportive care providers (two board certified palliative care physicians and one palliative care nurse practitioner) in kidney supportive care through webinars developed by the PI (JSS) prior to the study's start. These webinars were designed to educate providers in the specifics of kidney palliative care and CKD care. Webinar topics were CKD care, communication with nephrologists, CKD prognostication, shared decision-making, kidney replacement and dialysis access options, CKD symptoms, CKM, advance care planning unique to CKD, and end-of-life care in CKD. *Clinical Visits:* Participants who are

Table 1
Inclusion and exclusion criteria.

Inclusion Criteria:
Fluent in English or Spanish
eGFR $\leq$30 ml/min/1.73m^2
Receives care at Bellevue Hospital
Exclusion Criteria:
Contact with palliative care in the past six months
Emergent palliative care needs identified during baseline surveys (examples: uncontrolled pain, pruritus, need to make a decision about dialysis initiation imminently)

randomized to the intervention arm will be scheduled for six appointments, each approximately one month apart, with a palliative care provider who completed the kidney palliative care training.

We asked palliative care providers to use a note template for each study visit, as well as a kidney palliative care electronic navigator that recorded CKD symptoms in the electronic health record (EHR) that we developed. The standardized note records etiology of kidney disease, relevant CKD lab values, history of CKD care and treatment choice, medications, spiritual history, goals of care and symptom burden. Given the individualized nature of palliative care, we will not script our intervention visit. Instead, we will use the note template, our EHR navigator, and the treatment approaches outlined in the kidney supportive care webinars, to guide and to standardize the visit. The palliative care providers will complete an electronic survey documenting their visit activities after each visit. Participants will complete data collection visits with the study staff at baseline, three months, and six months.

2.3. Usual care

Participants who are randomized to the usual care arm will complete the same data collection surveys as the intervention group at baseline, 3 and 6 months. They will receive their usual CKD or dialysis care at the discretion of their nephrology team. If any provider feels they need kidney palliative care during their time of engagement in the trial, they will be referred, but analyzed in an intention to treat approach. All participants in the control arm will be offered an appointment with kidney palliative care at the conclusion of their trial participation. We determined that the risk for contamination at the start of the study was low as the clinic was implemented only six months before the planned study start, which we assumed would not be enough to cause substantial practice changes in the nephrologists.

2.4. Data collection and monitoring

All outcome data will be obtained either in-person or by phone at three months after enrollment, and at six months as our final outcome data. All data were stored on a password-protected institution-based

Table 2
Data recorded in the pilot intervention.

Demographics and laboratory data recorded			
Age, Sex, Race/Ethnicity	Treatment choice if kidneys were to fail	eGFR (mL/min/1.73m^2), If not on dialysis, or years on dialysis	
Etiology of Kidney Disease	Functional Status (Karnofsky Performance Status Scale)	Hemoglobin (g/dL)	
Dialysis Modality (If applicable)	Comorbidity Burden (Charlson Comorbidity Scale)	Albumin (g/dL)	
Place of birth	Presence of advance care planning documents	Proteinuria (mg/g) (if not on dialysis)	
Preferred language	Religion	Insurance	
Current Zip Code	Highest level of education completed	Current living situation	
Length of time under nephrology care	Presence of a primary care doctor	Relationship status	
Study Outcomes			
Measure	**Data Source**	**Measure Type**	**Frequency**
Symptom Assessment	IPOS-Renal	Survey	Baseline, Month 3 & 6[a]
Quality of Life	KDQOL-36	Survey	Baseline, Month 3 & 6[b]
Satisfaction with Care	CSQ-8	Survey	Baseline, Month 3 & 6[c]
Spiritual Assessment	FACIT-sp	Survey	Baseline, Month 3 & 6[c]
Anxiety	GAD-7	Survey	Baseline, Month 3 & 6[c]
Patient Activation	PAM-13	Survey	Baseline, Month 3 & 6[c]
Decisional Conflict	DCS	Survey	Baseline, Month 3 & 6[c]
Advance Care Planning	Chart review	Counts	Baseline, Month 3 & 6[b]
Visit Activities Recorded by Kidney Palliative Care Provider after Study Visits			
Building rapport			
Symptom management: Pain, non-pain, emotional, pharmacological recommendations given, non-pharmacological recommendations)			
Dialysis decision-making			
Explanation of non-dialysis treatment options			
Dialysis withdrawal counseling			
Discussion of hospice			
Spiritual distress addressed			
Assistance with coping with disease			
Spoke with participant's nephrologist			
Advance care planning: Reviewed or completed a health care proxy, advanced directive, or Medical Order for Life Sustaining Treatments			

Legend: eGFR: Estimated Glomerular Filtration Rate; IPOS: Integrated Palliative Outcome Score-Renal; KDQOL: Kidney Disease Quality of Life; CSQ: Client Satisfaction Questionnaire; FACIT: Functional Assessment of Chronic Illness-Spirituality; GAD: Generalized Anxiety Disorder; DCS: Decisional Conflict Scale; PAM" Patient Activation Measure RTSQ: Renal Treatment Satisfaction Questionnaire.

[a] Primary Outcome.

[b] Secondary Outcome.

[c] Exploratory Outcomes.

program, RedCAP. Data collection and quality was monitored weekly by the PI.

Demographic data to be collected are age, gender, race, ethnicity, preferred language, place of birth, religion, functional status as measured by the Karnofsky performance scale, comorbidities, insurance status, and comorbidity burden measured by the Charlson comorbidity index. Table 2 includes all collected data, including exploratory data.

2.5. Outcomes (Table 2):

2.5.1. Outcomes

Our primary outcomes will focus on feasibility. We will measure recruitment and retention rates, success of randomization, and collection of primary and secondary data. We will also collect utilization data and record the number of intervention visits attended by those randomized to the intervention group to measure dose of the intervention received, but not as a fidelity measurement.

In a future, larger trial, we will estimate the difference in change in symptom burden between the intervention and control groups at 6 months as the primary outcomes using the Integrated Palliative Outcome Scale (IPOS)-Renal [17,18], a validated CKD symptom assessment scale. The IPOS-Renal consists of a total of 10 questions with multiple sub-questions, and has total a score range of 0–90. Scores are reported as total scores (range, 0–90); physical symptom score (15 sub-questions asking how a symptom has impacted a patient over the last week, range of scores 0–4 with 0 = not all and 4 = severe, with a total score of 0–60); physical symptom burden (total number of all symptoms reported, score range 0–15); psychological symptom score (four questions, range 0–4, total score range 0–16); and a communication and practical subscale (four questions, range 0–4 or 0–2, total score range, 0–14). A change of four points has been reported as clinically meaningful in a population of seriously ill patients [17]. Other outcomes will include changes in quality of life measured by the Kidney Disease Quality of Life-36 (KDQOL-36) [19,20] questionnaire, and engagement in advance care planning. Additional collected data are shown in Table 2. We chose our outcomes based upon our preliminary work [15] and outcomes that will evaluate the multidimensional nature of kidney palliative care to inform future work.

2.6. Fidelity to the intervention

Fidelity to the intervention will be exploratory and measured through the visit activity surveys completed by providers after each visit (Table 2). Fidelity criteria will be completion of at least one core kidney palliative care activity at each visit. Activity choice are determined by our preliminary work [21], and are building rapport, symptom management, advance care planning, completion of a treatment limiting document, dialysis decision making, or explanation of conservative kidney management.

2.7. Statistical analysis

Feasibility data will be reported as percentage of people approached who provide informed consent, percent of participants who are retained in the study, number of drop outs, average number of protocol visits attended by participants randomized to the intervention group, and percent of planned data that was successfully recorded. Threshold to define feasibility are the ability to recruit to goal, to have retention rate of $\geq$70 %, and to obtain outcome data in at least 70 % of those who complete the study. Continuous demographic data will be presented as means with standard deviations and categorical as count with percent. We will prepare summary statistics (mean, median, interquartile range, and 95 % confidence intervals) for all baseline variables. We determine the variance of IPOS-Renal scores to inform power calculations in a larger trial. As exploratory data to identify trends, we will look at the differences in change in scores from baseline to six months between the two groups for each survey data collected. Advance care planning will be measured by number of advance care planning conversations and documents completed.

2.8. Clinical trial registration

The Institutional Review Board of the NYU School of Medicine approved this study, and it was registered on clinical trials.gov, NCT04998110, before the first participant was enrolled. Every participant provided informed consent.

3. Discussion

We describe a protocol for testing feasibility of a pilot RCT of integrated kidney palliative care and CKD care versus usually CKD care alone. The study's purpose is two-fold: to assess feasibility of a kidney palliative care clinical trial and to learn about the variance of CKD symptom burden in the presence of palliative care as measured by a validated symptom assessment tool.

People living with CKD have cited relief of their distress as research priorities, yet there is little focus on achieving this goal in both CKD and palliative care research [11,12]. To our knowledge, all research (except our prior pilot work) in the field of kidney palliative care is observational in nature. Our group previously conducted a pilot study showing feasibility of a randomized controlled trial of integrated kidney palliative care versus usual care, however, this study had limitations that we addressed in this current protocol [15]. This includes restrictive enrollment criteria (limited to only non-dialysis CKD stage V), a shorter follow up (3 months), intervention delivered by the PI, who is double boarded in nephrology and palliative care and less likely to be scalable, and implementation in a non-diverse population. We addressed these limitations in our current protocol with future plans to implement a larger trial.

As a pilot feasibility study, our study will provide essential data to inform a well powered and scientifically rigorous larger randomized controlled trial. Feasibility studies are recommended in palliative care research, given the many challenges to conducting high quality palliative care research [22]. These barriers include recruiting a seriously ill population that may have fatigue or multiple medical appointments, lack of familiarity with palliative care, and lack of palliative care workforce to implement new clinical approaches. The feasibility outcomes of this study will allow us to estimate a recruitment and attrition rate to inform a future trial, to learn more about the variance of our primary outcome tool to inform power calculations, to measure our ability to collect person-reported outcomes of interest from enrolled participants, to further define and refine the intervention, and to identify and to address any operational challeneges of the trial. These data are important given that our trial is implemented in an under-resourced and predominately marginalized population receiving care in a safety net hospital. Enrollment in research has been limited in under resourced settings, despite the imperative to diversify clinical trials, especially those focused on CKD which disproportionately impacts these populations [23]. Our feasibility data, which will include insurance status and record those who are uninsured, will also allow us to better understand the impact of social factors on participation in our CKD and palliative care focused study to tailor recruitment efforts in future work.

Our approach is promising by virtue of our success delivering kidney palliative care in the outpatient setting in other locations, and by other groups who have described success internationally with this approach. Despite this, it has not been previously tested in a clinical trial. This approach also reflects the current trend of palliative care expansion in the United States (US), where providers are embedded in outpatient disease specific clinics. This study will provide essential foundational data for a future, larger, randomized controlled trial testing the efficacy of integrated kidney palliative care and CKD care.

CRediT authorship contribution statement

Jennifer S. Scherer: Writing – original draft, Visualization, Methodology, Investigation, Funding acquisition, Conceptualization. **Wenbo Wu:** Writing – review & editing, Methodology, Conceptualization. **Chen Lyu:** Writing – review & editing, Visualization, Methodology. **Keith S. Goldfeld:** Writing – review & editing, Visualization, Methodology, Investigation, Conceptualization. **Abraham A. Brody:** Writing – review & editing, Visualization, Methodology, Conceptualization. **Joshua Chodosh:** Writing – review & editing, Visualization, Methodology, Funding acquisition, Conceptualization. **David Charytan:** Writing – review & editing, Visualization, Methodology, Funding acquisition, Conceptualization.

Disclosures

Dr. Scherer is on the clinical advisory committee of Monogram Health, reports speaking fees from Vifor Pharmaceuticals and Cara Therapeutics, and has received editorial payments from Elsevier.

Dr. Charytan reports the following: Consultancy: Eli Lilly/Boehringer Ingelheim, Astra Zeneca, Allena Pharmaceuticals (DSMB), Gilead, Novo Nordisk, GSK, Medtronic, Merck, CSL Behring, Zogenix, Renalytix, LG Chemical, Alentis Therapeutics; Research Funding: Medtronic-clinical trial support; Gilead; NovoNordisk; Amgen, Boehringer Ingelheim/Eli Lilly; Patents or Royalties: UpToDate.com for authorship/editorials on reviews; Advisory or Leadership Role: CJASN; and Other Interests or Relationships: Expert Witness Fees Related to Proton Pump Inhibitors and anti-depressants.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Jennifer Scherer reports financial support was provided by National Institute of Diabetes and Digestive and Kidney Diseases. Jennifer Scherer reports a relationship with Monogram Health that includes: board membership. Jennifer Scherer reports a relationship with Vifor Pharmaceuticals that includes: speaking and lecture fees. Jennifer Scherer reports a relationship with Cara Therapeutics Inc that includes: speaking and lecture fees. Jennifer Scherer reports a relationship with Elsevier Inc that includes: consulting or advisory. David Charytan reports a relationship with Eli Lilly and Company that includes: consulting or advisory. David Charytan reports a relationship with AstraZeneca Pharmaceuticals LP that includes: consulting or advisory. David Charytan reports a relationship with Allena Pharmaceuticals that includes: consulting or advisory. David Charytan reports a relationship with Gilead Sciences Inc that includes: consulting or advisory and funding grants. David Charytan reports a relationship with Novo Nordisk Inc that includes: consulting or advisory and funding grants. David Charytan reports a relationship with GSK that includes: consulting or advisory. David Charytan reports a relationship with Medtronic Inc that includes: consulting or advisory. David Charytan reports a relationship with Behring that includes: consulting or advisory. David Charytan reports a relationship with Zogenix Inc that includes: consulting or advisory. David Charytan reports a relationship with Renalytix plc that includes: consulting or advisory. David Charytan reports a relationship with LG Chemical that includes: consulting or advisory. David Charytan reports a relationship with Alentis Therapeutics AG that includes: consulting or advisory. David Charytan reports a relationship with Medtronic Inc that includes: funding grants. David Charytan reports a relationship with Amgen Inc that includes: funding grants. Jennifer Scherer reports a relationship with UptoDate Inc that includes: consulting or advisory. David Charytan reports a relationship with UptoDate Inc that includes: consulting or advisory. David Charytan: Advisory/Leadership: CJASN Expert Witness Fees related to Proton Pump Inhibitors and anti-dperessants If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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