

Feasibility Trial of a Stakeholder-enhanced Lay-navigator-delivered Intervention (ImPart-Multi)

Study Protocol and Statistical Analysis Plan

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I. Overview

While Black individuals comprise 13% of the U.S. population, they encompass ~35% of patients with kidney failure receiving dialysis. Black patients face higher rates of advancing disease and have poorer control of CKD risk factors, like cardiovascular disease (CVD); CKD shares risk factors associated with older age, male sex, hypertension, diabetes, smoking, and family history of CVD. Hypertension as a significant risk factor for CVD is thought to exist in approximately 80-85% of individuals with CKD. However, hypertension control is suboptimal and has low control rates in this population. Patients with CKD, especially those in poverty, are at higher risk of experiencing inadequately controlled hypertension, which can accelerate kidney injury and potentially hasten disease progression. Results from the Systolic Blood Pressure Intervention Trial (SPRINT) demonstrate a clear cardiovascular and mortality benefit for controlling hypertension in patients with CKD, thus, emphasizing the link between the management of CVD risk factors in the CKD population.

Black CKD patients and their care partners often report poor clinician communication and lower quality information-giving, resulting in less engagement in decision-making. In the concurrent management of hypertension and CKD, it has been found that Black patients remain unaware of their risk for advancing kidney illness. Data support that risks are not discussed in depth during physician-based encounters. In addition, Black patients negotiating concurrent illnesses are more likely to live in poorly resourced neighborhoods that lack access to supportive resources. In these communities, the lifestyle modifications routinely suggested to control CVD, and CKD progression are not readily available.

Our main question is, does participation in decision support training impact Black CKD patients and their care partners' ability to 1. contemplate the decision needed, 2. request resources/support, and 3. make an informed patient-centered decision? We acknowledge that standard nephrology care includes access to CKD educational materials through clinic-based classes, online platforms, and the availability to seek referrals to allied health professionals. Yet, Black patients and care partners report being under-informed, unsure about their resources, and wanting more information about delaying disease progression. Black CKD patients and their care partners experiencing these inequalities in CKD management increase Black patients' risk of receiving treatments inconsistent with their values and preferences and a higher risk of early mortality. This gap between resource availability and access highlights the critical need to train CKD patients to effectively partner with a care partner and clinicians in shared decision-making before the disease progresses. Thus, we aim to provide short-term Community & Public Health Benefits to health promotion by addressing answer-seeking behaviors, thereby reducing patient decision conflict and enhancing patient reports of effective social support. In addition, we seek to understand the quality of life benefits for patients and caregivers. We will explore this connection by examining how introducing decision-support skills upstream of advanced disease impacts healthy behavior engagement in the community setting, potentially affecting disease progression.

II. Aims of the Study:

Acknowledging that historic racist policies have created environments that present barriers to effective health-related decision-making, the aim of this study are to: seek to explore the feasibility and acceptability of participation in a decision-support training program led by lay navigators. This program is designed to empower Black CKD patients and their care partner to seek the resources and support needed to be activated allies when making health-related decisions.

III. Study Population

UAB Nephrology Services

UAB Nephrology is a recognized leader in kidney transplantation. Our nationally ranked kidney disease program is consistently listed among the best in the country by U.S. News & World Report. UAB's Division of Nephrology was designated a George M. O'Brien Kidney Research Center by the National Institutes of Health (NIH), making us one of just eight such federally funded centers in the country dedicated to the study of acute kidney injury and kidney failure. UAB's strong research programs put us at the forefront of developing new methods to treat, prevent and cure diabetes and its complications, and our participation in clinical trials increases the chances of providing our patients with cutting-edge therapies not yet available at other medical centers. The UAB Nephrology program features a multi-disciplinary team that provides state-of-the-art clinical care, research, teaching, and disease management for patients with diverse types of kidney disease. As one of the largest kidney transplantation centers in the nation, we provide complete renal evaluation services in a compact, efficient time frame. We also are a national leader in providing transplantation to patients who do not have a living donor or whose donor's tissue does not match the potential recipient. Patients may be seen in

either the UAB General Nephrology Outpatient Offices or the Chronic Kidney Disease Clinic. At the Chronic Kidney Disease Clinic, patients receive more frequent monitoring and more extensive education on their kidney disease. UAB nephrologists see patients on our main campus at The Kirklin Clinic of UAB Hospital and in our neighborhood clinic locations in Hoover and Leeds.

Cooper Green Mercy Health Services Authority

Cooper Green Health Services Authority is an affiliate of UAB Health System and is committed to providing high-quality healthcare to all residents of Jefferson County, regardless of ability to pay. Cooper Green is a full-service ambulatory care facility that includes primary and specialty care, urgent care, physical, occupational, speech therapy, laboratory services, radiology, and a pharmacy. In addition, Cooper Green's Nephrology Specialty clinics are staffed by UAB Nephrologists. Copper Green is an essential advantage for Dr. Gazaway's work. Cooper Green will serve as a second site to recruit diverse patients and their care partners for this pilot work and future work as needed.

IV. Study Design

We propose a pragmatic, randomized, wait-list control pilot trial with an embedded qualitative process to identify effective components

and potential component combinations of an early decision-support training intervention to improve health-related decisions making. We will recruit 32 dyads consisting of Black individuals with stage 3 or 4 kidney disease (eGFR 15 – 45 based on the new race-free equation) and concurrent uncontrolled hypertension and their care partner for a total of 64 participants. This pilot study will examine two interventions educating the dyad on 1) communication and 2) social support effectiveness topics. Two groups will each get one intervention, another group will get both, and a fourth group will serve as a control group and be wait-listed to receive interventions after the study period. While these psychoeducation components have been utilized in CKD, their potential benefits have not been explored singularly or in combination; none have explored the feasibility of involving a care partner, and many lack representation of Black individuals. We acknowledge not all individuals have care partners. Still, to ensure consistency, we will not enroll individuals who, after questioning and support from the study staff, cannot identify one person with whom they discuss their illness. However, we will provide all those individuals with the toolkit resources.

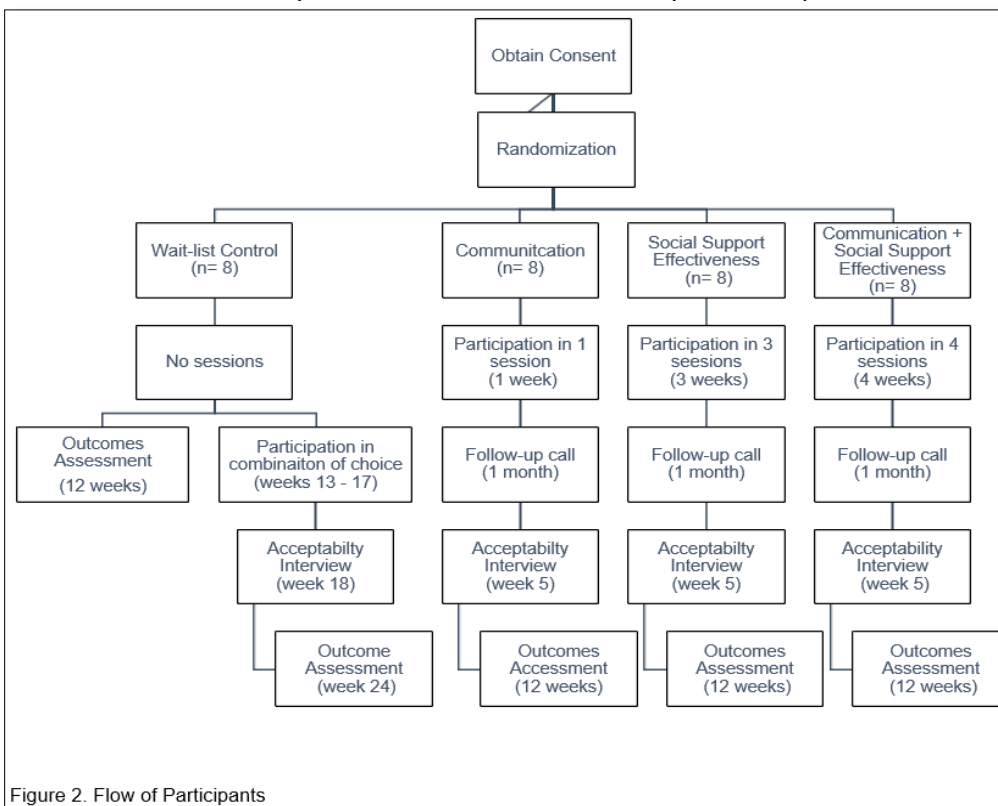


Figure 2. Flow of Participants

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V. Study Duration and Timeline

Enrollment: March 2024 [Actual]

Primary Completion: 2/15/2025 [Anticipated]

Study Completion: March 30 2025 [Anticipated]

Study Timeline **subject to change*

Research Activities	Pre-award	July – Sept			Oct- Dec			Jan – March			April - June		
		1	2	3	1	2	3	1	2	3	1	2	3
Submit for IRB approval													
Train part-time research coordinator													
Intervention Refinement													
Hire and train per diem lay coach navigator													
Advisory Group meetings to finalize ImPart study manuals, study scripts, recruitment flyers, and development of final study protocol													
Study Startup													
Monthly Meetings with Advisory Group													
Create study tracking databases, including setting up RedCap													
Weekly study team meetings													
Intervention Delivery and Data Collection													
Recruit and deliver intervention													
Prepare and submit protocol manuscript													
SAs 1 & 2 data collection													
Data Analysis, Dissemination, Grant Application Preparation													
SAs 1 & 2 data analysis													
Prepare and submit results manuscript													
Prepare for R01 or equivalent grant application submission													
Prepare and provide for community dissemination													

VI. Inclusion and Exclusion Criteria

Eligibility Criteria (Patients): Inclusion: 1) Age ≥ 18 ; 2) EMR documented diagnosis of stage 3 or 4 CKD

(2 eGFR 45-15 within 90 days); and concurrent cardiometabolic disease,

3) Ability to speak and read English and complete baseline questionnaires;

4) Patients must have a care partner enrolled in the study - the team will assist any patient in identifying a care partner, if interested.

Exclusion: 1) Receiving hospice;

2) Receiving dialysis;

3) Medical record documentation of active unmedicated severe mental illness, moderate-severe dementia, suicidal ideation, uncorrected hearing loss, and active substance abuse.

Eligibility Criteria (Care partners): Inclusion:

1) Age ≥ 18 ; 2) Self-endorsing or identified by the patient as "a relative, friend, or partner that has a close relationship with you and who assists you with your medical decisions and who may or may not live in the same residence as you and who is not paid for their help";

2) Ability to speak and read English and complete baseline questionnaires;

3) Care partners must have an enrolled patient.

Exclusion:

1) Self-reported unmedicated mental illness, mild-severe dementia, active suicidal ideation, uncorrected hearing loss, or active substance abuse ascertained by study introduction questioning.

VII. Randomization Plan

Scheme. The randomization scheme will be executed via REDCap. Participants will be randomly assigned to one of 4 groups using a computer-generated permuted block algorithm (sizes 4 and 8) overseen by the study manager. **Blinding.** A research coordinator will oversee randomization procedures in REDCap and notify the lay navigator of the dyad's assigned condition.

VIII. Community Advisory Board (CAB)

Comprises 5 people, identifying as CKD patients, care partners, or clinicians. These individuals have a history of working with the P.I. The members of this group do not represent one entity but represent CKD patients and care partners throughout Alabama and the nation. This group will meet once/per month via Zoom, with local members invited to meet in person. Members have agreed to be paid \$45 per meeting. Members will assist with intervention refinement, study protocol development, recruitment ideas, and dissemination planning.

IX. Patient recruitment and Consent Process

Recruitment: Dyads will be screened and recruited from the UAB outpatient nephrology clinics, UAB CKD clinic, and primary and nephrology care at Cooper Green. We will employ procedures utilized previously to recruit diverse patients and their care partners. In brief, upon receiving a HIPAA waiver, the P.I. and research coordinator will screen the EMR to identify eligible patients with planned office visits in the next 1-2 weeks. After receiving clinician permission, patients will be mailed an opt-out letter and informed consent form. Those who have not opted out will be called within 10 -14 days of the mailing date or an in-person approach will be conducted before their next clinic appointment. Those interested in participating will have the study explained in further detail and asked to identify a primary care partner. Care partners will be contacted by phone to explain the study and invite those interested. If a care partner is present at the appointment, they will be presented with study details and informed consent documentation. Recruited individuals will provide informed consent verbally over the phone. Those approached in person will sign the informed consent document in person.

X. Description of the Intervention

ImPart Content. Dyads will be randomized to receive one or more ImPart-Multi courses delivered in a semi-structured, 30-45-minute session format with a lay navigator. **Course 1. Communication Training:** 1 telehealth session reviewing and discussing shared decision-making and how to communicate questions or concerns, listening, questioning, and sending messages. **Course 2: Social Support Effectiveness Training -** 3 Telehealth Sessions focused respectively on reviewing and discussing principles of effective decision-making and principles of effective decision-making. All participants will receive a guidebook containing intervention material. The rationale for all components is to instill social and decision support skills through reflection and regular contact with a lay navigator, and is based on interviews, literature, and advisory group feedback. The accessibility interviews will provide feedback about the dyadic approach and combination to determine how best to impact change.

Table 3. Study Measures

Measure	Baseline		12 weeks	
	Pt	CP	Pt	CP
Feasibility: Intervention completion rate (# participants completing assigned components) & assessment completion rate (# participants completing each study assessment [Baseline, 12 weeks]) will be tabulated, $\geq 75\%$ completion rates for assigned components & study assessments will be considered evidence of feasibility.			X	X
Acceptability: Determined by thematic analysis, of digitally recorded, semi-structured qualitative interviews adapted from prior study teams' work. Open-ended questions will query participants about their experiences with their assigned intervention components, the navigator, study procedures, how program impacted their engagement in shared decision-making and healthy behaviors, and changes they would like to see made to the intervention and study procedures.			X	X
Decision-making process: Decision Conflict Scale (DCS) 16-item measure; perceptions of uncertainty in choosing options, factors contributing to uncertainty (e.g., feeling uninformed, unclear values) and feeling that decisions were informed and values-based.	X		X	
Decision-making process: Social Support Effectiveness- Questionnaire 25 item measure; perceptions of help received in last 3 months with higher scores indicating more effective support.	X	X	X	
D. Patient Wellbeing: Kidney Disease Quality of Life Scale (KDQOL 36) 36 items measure three components: physical health score, mental health score, and kidney disease health score.	X		X	
E. Care partner Wellbeing: PROMIS Global Health 10 10 items measure global health-related quality of life (HRQOL) in 2 domains: physical and mental health; scoring allows for cost-effectiveness estimates.		X		X

Dyadic Interaction: Dyadic Coping Inventory 37-item instrument designed to measure perceived communication and dyadic coping in close relationships when one or both partners are stressed.			X	X
Patient Demographics: Age, gender, race/ethnicity, income, education, employment, marital status, religious affiliation, health insurance, residence, Charlson Comorbidity Scores	X			
Caregiver Demographics: Age, gender, race/ethnicity, income, education, employment, marital status, religious affiliation, health insurance, residence; relationship to care recipient, # days/week providing care, # hours/week providing care		X		

XI. Statistical Analysis Plan

Patient characteristics and baseline measures will be summarized using descriptive statistics. The effect of the interventions on each outcome at 12 weeks will be modeled using linear regression, adjusting for the baseline value. The intervention groups will initially be modeled as a 4-level categorical variable with the wait-listed controls as the reference group to provide specific efficacy estimates for each group.

XII. Data Management Plan

Study team members will securely manage all PHI per HIPAA and IRB regulations, and maintain data confidentiality and anonymity. All study documents contained only patient-assigned participant IDs and no identifiers. The study PI will transmit all study data from the REDCap databases to team statistician for data analysis.

A. Spreadsheets

1. Screening Spreadsheet: This spreadsheet tracks potential participants based on medical record screen. The spreadsheet includes the following:

1. Site
2. Screen Date
3. Patient Name
4. MRN
5. Clinician's last name
6. DOB
7. Age
8. Rache
9. Ethnicity
10. Gender
11. Kidney disease stage
12. other metabolic disease
13. Mental illness
14. Substance use
15. Suicidal ideation
16. Dementia
17. Hearing loss
18. English Speaking
19. Hospice status
20. Dialysis status

The spreadsheet is password-protected, stored behind an institutional firewall, and shared only with members of the study team who need it.

2. Implementation of the Education Sessions Documentation: Coaches documented on a spreadsheet that served as a place to document session completion, session tracking, and to review pertinent patient details prior to the sessions.

B. Questionnaires

The questionnaires are stored in the REDCap database, which is a password-protected, institutional software developed to collect and store study data. Only study team members who need it have access to the REDCap database, and the system is only accessed from institutional computers.

XIII. Confidentiality/Privacy Considerations

Information obtained about the patient/caregiver will be kept confidential to the extent allowed by law. However, research information that identifies the patient/caregiver may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- The UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- The Forge Ahead Center, National Institute of Minority Health and Health Disparities
- The Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, the patient/caregiver's identity will not be given out. No data will be sent electronically, study team members will access the information needed from the password-protected file located on the UAB server.

XIV. Study Risks and Discomforts

This study has very low risk to participants. Risks that they potentially incur include:

- a. Emotional distress: Talking about their illness and future decision-making may cause emotional distress for patients or caregivers. Patients may get tired when answering questions during the acceptability interview. If they are tired, they can stop the interview at no penalty to them.
- b. Loss confidentiality: There is a chance that people not associated with the study will see patient/caregiver answers to questionnaires or interview questions. Patient/caregiver names and other identifying information will be removed from all study documents. Data will be kept in a secure, password-protected database at UAB.

XV. Patient/caregiver payment for participation in Research

The patient and the caregiver are paid \$20/baseline and \$20/12-week completion, and \$20 for the acceptability interview. If the patient or caregiver does not complete all data collections they will be paid for the data collections they completed prior to deciding to stop taking part in the study.

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