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Protocol for the AKT-MP trial: Access to Kidney Transplantation in Minority Populations

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ABSTRACT

Background: Kidney transplant (KT) is the optimal treatment for kidney failure (KF), and although completion of KT evaluation is an essential step in gaining access to transplantation, the process is lengthy, time consuming, and burdensome. Furthermore, despite similar referral rates to non-Hispanic Whites, both Hispanic/Latinos and American Indians are less likely to be wait-listed or to undergo KT.

Methods: The Access to Kidney Transplantation in Minority Populations (AKT-MP) Trial compares two patient-centered methods to facilitate KT evaluation: kidney transplant fast track (KTFT), a streamlined KT evaluation process; and peer navigators (PN), a peer-assisted evaluation program that incorporates motivational interviewing. This pragmatic randomized trial will use a comparative effectiveness approach to assess whether KTFT or PN can help patients overcome barriers to transplant listing. We will randomly assign patients to the two conditions. We will track participants' medical records and conduct surveys prior to their initial evaluation clinic visit and again after they complete or discontinue evaluation.

Conclusion: Our aims are to (1) compare KTFT and PN to assess improvements in kidney transplant (KT) related outcomes and cost effectiveness; (2) examine how each approach effects changes in cultural/contextual factors, KT concerns, KT knowledge, and KT ambivalence; and (3) develop a framework for widespread implementation of either approach. The results of this trial will provide key information for facilitating the evaluation process, improving patient care, and decreasing disparities in KT.

1. Introduction

There is overwhelming evidence of racial/ethnic disparities in kidney failure (KF) [1–3]. For example, KF rates for American Indians (AI) are 1.5 times greater than for non-Hispanic whites (WH), and are nearly 1.5 times greater for Hispanic/Latinos (HL) than for non-Hispanic populations [4]. Although kidney transplantation (KT) is the optimal treatment for those with KF, access to KT has not improved over the past two decades [5]. Furthermore, disparities continue to exist in every step of the KT process, including decreased access to the KT waitlist [5–7], increased waiting times for KT [6,8], and decreased graft survival after transplant [9]. Among AI and HL, Sequist and colleagues [10] found that although HL and AI were referred to transplant centers equally with WH, both groups were less likely than WH to be placed on a waiting list and much less likely to undergo KT. These findings speak to the importance of research focusing on disparities in processes occurring after referral to a transplant center rather than on the referral itself. Even if waiting time on the transplant list is equalized among racial/ethnic groups,

Abbreviations: AI, American Indian; AKT-MP, Access to Kidney Transplantation in Minority Populations; HL, Hispanic or Latino; KAS, Kidney Allocation System; KF, kidney failure; KT, kidney transplant; KTFT, kidney transplant fast track; *PN*, peer navigator.

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disparities will persist if referred minorities do not complete the evaluation process and never make it to the waiting list. Although changes to the national Kidney Allocation System (KAS) temporarily improved rates of KT for minority patients who were already waitlisted, our recent data [11,12] and that of others' show that it has minimal influence for those who are not waitlisted [13]. None of the changes to KAS apply specifically to the KT evaluation process. Similarly, minorities who are inactive on the waitlist are still less likely to be activated and transplanted [8]. Because reasons for inactive status could include incomplete testing and/or social/financial problems, which are more likely in minority and vulnerable patients, KAS will not address disparities from these issues either. National policy alone cannot help vulnerable patients complete required testing, mitigate their transplant ambivalence, or address their previous experiences of discrimination in healthcare. Failure to address this disparity will continue to put minority patients at a persistent disadvantage for KT. Therefore, one of the most effective ways to reduce disparities in KT may be to increase the number of patients from disadvantaged groups who complete KT evaluation so that they can eventually receive a KT.

The KT evaluation process [14], which occurs after patients have been referred for KT and before wait-listing for KT, is lengthy, time consuming, and burdensome to the patient. It requires patients to complete numerous tests (e.g., blood work, cardiac checks, pap smear, etc.) before being reviewed by the transplant team to be accepted for KT. Variation exists across centers, but patients are typically instructed to schedule and complete testing on their own and ensure that their clinical providers forward test results to the transplant team. This process can be daunting and confusing for many patients, especially those with low health literacy [15] or those who perceive or experience barriers within the healthcare system. As a result, these factors can discourage patients and pose real barriers to KT wait-listing.

Our previous work showed that cultural/contextual factors and KT knowledge independently and significantly predict the rate of KT evaluation completion. Most efforts to reduce disparities in KT emphasize educating or changing the behavior of patients on dialysis who have not been referred for KT [16–29]. Although modestly successful [19,22,30,31], these approaches do not reduce the burden to the patient. Nor does patient education eliminate external barriers that prevent them from completing evaluation despite their best intentions to do so. In response to past limitations, the **A**ccess to **K**idney **T**ransplantation in **M**inority **P**opulations (AKT-MP) Trial compares two patient-centered methods to facilitate KT evaluation: kidney transplant fast track (KTFT), a streamlined KT evaluation process; and peer navigators (PN), a peer-assisted evaluation program that incorporates former transplant recipients trained in motivational interviewing. AKT-MP is a pragmatic comparative effectiveness trial, which is the best approach to compare these two system-level interventions and yield timely and implementable results, as it is designed to compare effective interventions among patients in typical patient care settings, with decisions tailored to individual patient needs [32,33]. Additionally, this approach will allow us to identify the clinical characteristics that predict which intervention would be most successful for an individual patient. Because KTFT and PN lack a sufficiently robust evidence base for use with AI and HL patients, the methods are not standard or widely adopted in clinical practice. The overall aims of AKT-MP are to: (1) compare KTFT and PN to assess improvements in kidney transplant related outcomes and cost effectiveness; (2) examine how each approach effects changes in cultural/contextual factors, KT concerns, KT knowledge, and KT ambivalence; and, (3) develop a framework for widespread implementation of either approach given the structural assets and resources of various transplant centers.

2. Methods

2.1. Overview

This pragmatic randomized trial will use a comparative effectiveness approach to assess whether KTFT or PN can help patients overcome barriers to transplant listing. Upon obtaining informed consent from participants, we will contact patients for a telephone survey Time 1 (T1; see Fig. 1). After patients attend their initial transplant evaluation visit, we will randomly assign them to the KTFT or PN intervention. We will follow all patients via medical record to determine when they complete testing for evaluation. Once patients either fully complete kidney transplant evaluation or discontinue testing, we will contact patients for a Time 2 (T2) survey and review their medical records for final status and other clinical characteristics. The protocol was approved by the UNM Human Research Protections Office (20–387).

2.2. Target population

We will recruit patients referred for kidney transplant evaluation at the UNM Transplant Center. To be eligible for the study, patients must be: 18 years of age or older; mentally competent to make a voluntary decision about trial participation; undergoing kidney transplant evaluation at UNMH; not a prior kidney transplant recipient; and not being evaluated or already on the UNOS waiting list at another transplant center. Based on medical record data of UNMH patients over the past five years, we expect that 44% of our participants will be Hispanic/Latino, and 33% will be American Indian. Additionally, >80% of patients seen at UNMH are on public insurance, have a household income of <$25k, have a high school or lower education, or live in a rural area with limited access to care and must drive several hours to be evaluated for transplant. Therefore, our study sample will include patients underrepresented in past research and will allow us to address important research questions including what factors predict better outcomes for each intervention in a diverse patient group.

To understand the effects of the interventions, we will use historical comparison groups to assess for differences in evaluation completion and wait-list placement. The local and national historical comparison groups will be selected through the CERNER HealthFacts® database, Scientific Registry of Transplant Recipients, and US Renal Data System [34–36]. We will create comparison groups on the basis of our inclusion and exclusion criteria and key demographic and clinical matching variables (e.g., race, sex, and age). Use of historical comparison groups provides a more powerful and cost-effective means to quantify intervention effectiveness for the HL and AI populations.

2.3. Screening and recruitment

The research team will review medical records and be in regular contact with the transplant clinic team so that we know when patients are referred for transplant evaluation. Referred patients will be screened for eligibility before attending a kidney transplant education class, which precedes the transplant evaluation appointment. As part of our partnership with the transplant clinic team, and due to the restrictions that the COVID-19 pandemic placed on clinical care delivery and clinical research, we worked with the transplant clinic team to convert their in-person education class to an online Zoom meeting.

The class includes video-recorded transplant recipient testimonials (in English and Spanish), created by the transplant team, with UNMH-specific education slides that detail the kidney transplant evaluation process and post-transplant care. We worked with the transplant team to develop protocols for training all patients and family members to use Zoom (in English and Spanish). The education class provides the primary mode of participant recruitment. After patients attend the Zoom-based transplant education class, study staff will introduce the AKT-MP study, answer any questions, and obtain consent for participation.

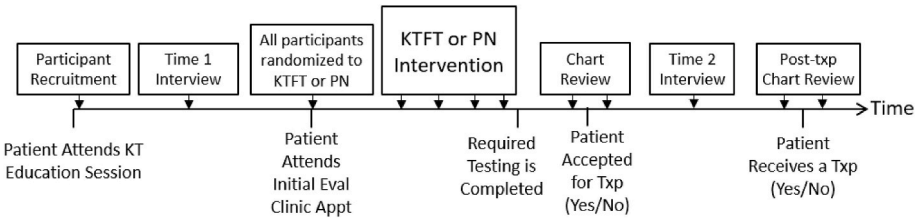

Fig. 1. Diagram of pathway to receiving a transplant, intervention, and interview time points.

We will then contact patients via telephone prior to their initial clinic visit for their T1 survey (see Section 2.7).

2.4. Random assignment

When patients complete their T1 survey and have attended their evaluation appointment, we will use blocked stratification based on race/ethnicity (i.e., HL, AI, other race/ethnicity) to randomly assign participants to one of the two intervention arms, KTFT or PN, to ensure balance between treatment arms by race/ethnicity. After random assignment, participants in the KTFT intervention will be directed to the research coordinator. Those in the PN intervention will be directed to their peer navigator. Because our study team works closely with the transplant team in both study arms, it is impossible to have the transplant team blinded to the intervention group. As is appropriate for a pragmatic comparative effectiveness trial, blinding to intervention condition would have required a major departure from usual clinical practice and not met the pragmatism goals of the study [37,38].

2.5. KTFT intervention

KTFT is a streamlined approach for evaluating KF patients for KT [39]. This approach involves the research team helping the patient schedule as much testing as possible within 4 weeks of their initial evaluation at UNMH, rather than the standard approach of the transplant team providing patients with a list of tests they complete on their own with their referring physician. A research coordinator will schedule appointment times and preparatory material for all testing. If needed, for patients in KTFT travelling long distances, a short-term nonprofit residence will provide nearby lodging for participants and their families and an alternate dialysis location will be scheduled. Patients undergoing similar streamlined approaches to evaluation were more likely to be placed on the wait list in less time compared to traditional approaches [40].

2.6. PN intervention

Research demonstrated that patients working with a PN compared to usual care have completed more than twice as many steps leading to transplantation [41]. Participants in the PN intervention will meet a trained navigator who is a KT recipient and will help them "navigate" their way through KT evaluation. PNs will be trained before the start of the project, including instruction on the KT process, human subjects' protection, and principles of motivational interviewing (i.e., spirit of motivational interviewing [partnership, acceptance, compassion, and evocation], four processes of motivational interviewing [engaging, focusing, evoking, and planning], and core skills [asking open questions, affirming, reflecting, and summarizing] [42]). The PN will meet weekly to monthly (as needed) with each participant either in person, on the telephone, or by Zoom. Meetings will be collaborative discussions of the participant's progress and reasons for completing KT evaluation, with the goal being to strengthen their personal motivation and commitment to completing KT evaluation. After completion of the work-up, the PN will serve as an ongoing source of support and information if the participant desires. The PN will record meetings and document the amount of time spent with each participant to be used for dose-response data analysis.

2.7. Data collection

2.7.1. Telephone surveys with patients

We will contact participants for telephone surveys at two timepoints (see Fig. 1), a 60-min telephone survey prior to their initial evaluation clinic appointment (T1) and a 30-min telephone survey after completing or discontinuing evaluation (T2). We will partner with the University of Pittsburgh Center for Social and Urban Research (UCSUR) to conduct the surveys because the surveyors at this program have extensive experience conducting computer-aided telephone surveys and will be blinded to participants' treatment group. We will conduct surveys in Spanish for our Spanish-speaking only participants.

2.7.2. Medical record review

We will review patient medical records to determine evaluation status, status on the transplant waitlist, and kidney transplant related health information (such as the number of potential donors being evaluated and whether there were any medical contraindications for transplant for the recipient and donor).

2.7.3. In-depth interviews with patient participant subset

We will conduct interviews with a total of 24 participants who have completed the intervention (12 per intervention arm) [43–45]. Interviews will focus on the participant's experience with the intervention, recommendations for improvement, and patient costs (financial, effort). Participants will be purposively selected to include a range of demographic characteristics (e.g., age, gender, race/ethnicity). This sample size is expected to be adequate for thematic saturation (i.e., no new themes emerge from subsequent data collection), although more interviews will be conducted if thematic saturation is not reached. We will record and transcribe the interviews for qualitative analysis.

2.7.4. Interviews and surveys with transplant team

Periodically, the research coordinator will contact research, clinical, and administrative teams to ask about barriers and/or facilitators to the intervention they have observed and suggestions for change if indicated. Depending on the transplant team member's availability, we will reach out for surveys/interviews *via* phone, video conference, in person, or we will send a direct link to the survey. We will ask the transplant team to elicit feedback on the intervention process and provide any feedback to the research team. We will review the log during weekly research team meetings and identify need for process changes.

2.8. Predictor and outcome variables (see Table 1)

2.8.1. Outcome variables

We will access participants' medical records to determine KT evaluation completion, acceptance for KT, and transplant status. Also, for patients who discontinue evaluation, we will collect data on the reason for discontinuation. We will assess KT ambivalence with the Decisional Conflict Scale [46]. We will assess patient reported health-related quality of life (HRQOL) [47–51] with the Patient-Reported Outcomes

Table 1
Study measures and administration time-points.

Study Variables	Time 1: Pre-KT Workup	Time 2: Completed Evaluation
Outcomes		
1. Completion of KT evaluation	–	X
2. Accepted for transplant	–	X
3. KT ambivalence	X	X
4. QOL	X	X
Cultural/contextual factors		
5. Medical mistrust	X	X
6. Experience of discrimination	X	X
7. Perceived racism	X	X
8. Religious beliefs	X	–
9. Family loyalty	X	–
10. Health literacy	X	–
11. Language preference	X	–
12. Social support	X	–
13. Pandemic-related challenges	X	–
Transplant related beliefs		
14. KT knowledge	X	X
15. Learning activities	X	–
16. KT concerns	X	X
17. LDKT attitudes	X	–
18. Perceptions of clinical encounter	–	X
Demographic/health characteristics		
19. Demographics	X	–
20. ESKD health history	X	–
21. Pre-KT health status	X	–
22. Donor characteristics	X	–
23. COVID-19 infection experience and vaccine status	X	–
Total Completion Time	**60 min**	**30 min**

Measurement Information System (PROMIS) Scale v1.2 Global Health measure [49]. The measure is brief, based on extensive item banks, has been validated in general and CKD populations [52–57], and is favored by the International Consortium for Health Outcomes Measurement (ICHOM) CKD Working Group [58].

2.8.2. Cultural/contextual factors

We will assess medical mistrust using the Medical Mistrust Index [MMI] [59] and Trust in Physician scale [60] revised through our work [39]. We will assess experience of discrimination using the *Perceived Discrimination in Healthcare* measure (7 items [61]), and perceived racism using a 4-item measure based on the work of LaVeist [59]. Additional cultural factors include: social support (using the PROMIS Short Form v2.0 item bank) [49], religious beliefs (religious affiliation/level of importance of religious beliefs and a revised subscale of Organ Donation Attitude Survey [ODAS] [62]), family loyalty and cohesion (Bardis Familism scale [63]), health literacy [64], language preference (language preference in different contexts,[65]and command of spoken and written English [66]); patients' perception of the effect of the pandemic on their mental and emotional health (questionnaire adapted from the CoRonavIruS Health Impact Survey (CRISIS) from the National Institute of Mental Health) [67]; and patient technology and telehealth use pre- and post-COVID-19 (Coping with COVID-19 scale) [68].

2.8.3. KT-related knowledge and beliefs

We will assess KT knowledge using the adapted KT Knowledge Survey [69] and KT Questionnaire [KTQ] [28], and patient perceptions of the clinical encounter with the *Client Satisfaction Questionnaire.* [70] Also, we will assess *KT learning activities* (5 items adapted from the KTQ [28]), *concerns about transplant* (12 items adapted from the KTQ [28]), and *attitudes towards LDKT* (12 items adapted from Pradel [71] and the KTQ [28]).

2.8.4. Demographic and health characteristics

We will collect demographic data including gender, age, race/ethnicity [72], marital status, SES (education & occupation), income, insurance status, number of potential donors available for matching, and number of actual matches through the T1 interview and medical record abstraction. We will also assess self-reported ESKD health history (*12 items adapted from* KTQ [28]). We will assess patients' COVID-19 infection experience and vaccine status with self-reported items (questionnaire adapted from the World Health Organization's guidebook for immunization programs [73]). We will abstract pre-transplant health from patients' medical records, including number of years on dialysis, number of pre-transplant hospitalizations, medical comorbidities using the Charlson Co-Morbidity Index [74] and indication for KT.

2.9. Participant reimbursement and retention methods

We will reimburse participants $40 for each completed telephone survey. Participants selected for the in-depth interview will receive an additional $40 payment. To maintain high retention, we will monitor medical records of every recruited participant. We will maintain a recruitment database that will include participant information (e.g., contact information), dates of recruitment, survey/interview, completion dates, and payment. We will generate reports to track recruitment, ineligible patients, and refusals. In addition, we will hold weekly team meetings to discuss participant recruitment, accrual, and retention. We will send participants a bi-annual mailed newsletter from our study team. Finally, our Patient Stakeholder Committee (PSC) of both AI and HL members will provide direct advice regarding retention.

2.10. Data safety and security

All paper records will be kept under double lock in a cabinet within the principal investigator's office and will be accessible only to select study staff. Windows integrated security will be used for all computer access. User and role permissions will be defined at the computer, file, directory, server and database level to ensure data security. Electronic data will be stored on the password-protected research server which sits behind a firewall at the principal investigator's office location.

3. Analysis of specific aims

3.1. Primary and ancillary analysis

There are two primary outcomes for Aim 1: (1) completion of evaluation for KT, and (2) placement on the transplant waiting list. We have hypothesized that our interventions will improve these outcomes, leading to improvements in the rates of KT for disadvantaged patients. We will employ regression models to study intervention effects and racial difference while adjusting for relevant covariates. We will use survival analysis for the outcomes of time-to-evaluation-completion and time-to-listing-for-KT (acceptance for KT). Patients who do not have the events will constitute a censored event. Patients who die will constitute a competing risk although the risk will be small within the study period.

The primary outcomes for Aim 2 include changes from pre-to post-intervention in KT concerns, as well as in other culturally-related factors, KT knowledge, and KT ambivalence. In order to test for pre-to post-intervention changes and difference between the interventions, we will employ 1) group comparisons by intervention and race following the approach of difference-in-difference (e.g., paired *t*-test or non-parametric methods as needed), and 2) regression modeling. Regression models will allow us to explore the degree to which intervention-induced changes might be mediated by race as well as other social-demographic and process factors.

Finally, for Aim 3 we will estimate the cost effectiveness of KTFT relative to PN intervention to account for the added costs (personnel, effort) to develop and maintain the interventions systemwide. We will also assess patient costs (financial, effort) through in-depth interviews with a subsample of study participants. To evaluate the relative cost-

effectiveness of KTFT and PN, we will use cost-effectiveness analysis (CEA) to calculate incremental cost-effectiveness ratios (direct and indirect costs in the numerator and quality-adjusted life years in the dominator) [75,76].

3.2. Sample size estimates

On the basis of UNM data from 2014 to 2018 and past clinical trials, we expect to enroll 398 participants in the two randomized arms and 338 are expected to complete the study. Of these, we expect 148(44%) to be HL, and 111(33%) to be AI. Our data also indicated that approximately 535 patients are referred annually, of which an estimated 33% completed evaluation and 17% were listed. These historical data permit an assessment of statistical power of the current study design. We assume KTFT will reach a 60% completion rate and PN will reach a 40% completion rate, which translate into a ratio of 1.5 for evaluation completion between KTFT and PN, which we use as an approximate hazard ratio. To detect such a difference with 80% power and 5% error we will need approximately 183 patients per group [77]. Our estimated sample size is reasonably aligned with this estimation. We also computed statistical power to detect improvement in racial-specific rates of evaluation completion and KT listing in comparison with the historical rates. With the planned sample size, we will be able detect 9–11% improvement or greater with 80% power. Although our secondary sample size calculation ignored information loss due to censoring, we anticipate the intervention effects would be greater than 9–11%.

When we reach half of the recruitment target, we will conduct an interim analysis to inform study design for the continuing phase. Our interim analysis will focus on the difference in the rate of evaluation completion and being listed for KT for the following comparisons: 1) between racial groups within each intervention arm and between the two intervention arms; 2) between racial groups with historical comparison groups. The results will provide evidence for meaningful difference and the statistical power to ascertain such a difference. The evidence in turn will inform any necessary adjustments, including sample size by recruitment period and intervention or race group. We may also conduct interim analyses to evaluate interview process and data quality. The evidence will also inform matching criteria for selecting historical comparisons. Our planned interim analysis will inform us in a timely fashion if we need to adjust our sample size.

4. Discussion

KT is the optimal treatment for KF, and although completion of KT evaluation is an essential step in gaining access to transplantation, the process is lengthy, time consuming, and burdensome to many patients. Furthermore, despite being referred for KT equally with non-Hispanic whites, HL and AI are less likely to be wait-listed or to undergo KT [6,7,10]. The AKT-MP study addresses a critical clinical practice area leading to disparities in KT: increasing the number of patients from underserved populations who complete KT evaluation and are added to the waiting list, so that they are eligible to receive a KT. We are using an innovative approach to help patients navigate and complete their evaluations by pairing some patients with PNs trained in motivational interviewing. This comparative effectiveness research comparing KTFT to PN will likely generate needed evidence to inform widespread adoption of these strategies. Our findings will provide valuable information on these two intervention strategies for transplant centers and hospitals with different patient populations, structural assets, and resources. This project will also have significant scientific impact because it will address and systematically evaluate changes in system and patient level factors to identify barriers and facilitators to more widespread intervention implementation.

A major strength of this study is that it will focus on underrepresented and vulnerable patient groups to increase equity and reduce disparities upstream in the KT process. Our study will provide approaches to improve equity in kidney transplantation by informing transplant programs about which intervention may reduce disparity more effectively. Our implementation aim will permit us to rapidly disseminate these approaches to areas of need. Finally, our cost-effectiveness analysis will be used to construct a sustainable business model for the superior intervention approach, which will enable other transplant centers to revise their KT clinical practices to be both patient-centered and fiscally sound.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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