Study Protocol

Title: Reducing disparities in living donor transplant among African Americans

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Study Title: Reducing Disparities in Living Donation among African Americans

Short Study Title: Reducing Racial Disparities in Living Donation

Co-Principal Investigators:

Rachel E. Patzer, PhD, MPH, FAST
Associate Professor
Emory University
Department of Surgery, Division of Transplantation
Rollins School of Public Health, Department of Epidemiology
[redacted]
Atlanta, GA 30322
[redacted]
[redacted]: rpatzer@emory.edu

Kimberly R. Jacob Arriola, PhD, MPH
Professor
Emory University, Rollins School of Public Health
Department of Behavioral Sciences and Health Education
[redacted]
Atlanta, GA 30322
[redacted]
[redacted]
[redacted]: kjacoba@emory.edu

Co-Investigators:

Stephen Pastan, MD
Associate Professor
Emory University School of Medicine
Department of Medicine, Renal Division
Medical Director, Emory Transplant Center Kidney Transplant Program
1365 Clifton Rd
Bldg. B, Suite 6400
Atlanta, GA 30322
Phone: 404/712-7735
Fax: 404/712-5047
Email: stephen.pastan@emoryhealthcare.org

Jennie Perryman, PhD
Director of Policy and Outcomes Management
Emory Transplant Center
1762 Clifton Road NE, Suite 2200
Atlanta, GA 30322
Phone: (404)-712-4993
Fax: (404)-712-4621
Email: jennie.perryman@emoryhealthcare.org

Other Study Staff:

Malendie T. Gaines, DrPH, MPH
Project Coordinator
[redacted]
Atlanta, GA 30322
[redacted]
[redacted]
[redacted]

Study Sites/External

Collaborators:*

Emory Transplant Center	Main Study Site	[redacted]
Medical University of South Carolina	Secondary Study Site	Collaborator: Derek DuBay, MD Chief, Division of Transplant Surgery Department of Surgery, Medical University of South Carolina Charleston, SC [redacted] : dubay@musc.edu
Piedmont Transplant Institute	Secondary Study Site	Collaborator: Joshua H. Wolf, MD Transplant Nephrologist Piedmont Transplant Institute Atlanta, GA [redacted]
Augusta University Medical Center	Secondary Study Site	Collaborator: Rajan Kapoor, MD, FASN Associate Professor of Medicine Department of Nephrology, Hypertension and Transplant Medicine Augusta University Medical Center Augusta, GA 30912 [redacted]

*An IAA is being pursued for each of the three external study sites. This will be finalized over the coming months.

Abstract

For most of the patients in the United States with end stage renal disease (ESRD), kidney transplantation represents the optimal treatment. Moreover, living donor kidney transplantation (LDKT) offers numerous advantages over deceased donor kidney transplant such as better kidney quality, increased short- and longterm graft survival, lower rates of acute rejection, and reduced health care cost. Nevertheless, there are pervasive racial disparities in access to LDKT, with white ESRD patients four times more likely to receive a LDKT than African American ESRD patients. The long-term objective of this program of research is to understand the combined effect of a systems-level intervention that enhances communication between dialysis facility and transplant center clinicians (Transplant Referral EXchange or T-REX) and a culturally-sensitive individual-level educational intervention (web-based Living ACTS: About Choices in Transplantation and Sharing) on racial disparities in access to LDKT. The specific aims of the study are: (a) To develop and refine a web-based version of Living ACTS; (b) To conduct an outcome evaluation of the newly created web-based Living ACTS intervention by comparing the percent of patients with at least one inquiry from a potential living donor among patients who receive Living ACTS compared to those who receive a control website with an embedded educational video; and (c) To conduct a process evaluation of the newly created web-based Living ACTS intervention by adapting commonly used process evaluation constructs (context, reach, dose received, fidelity, and recruitment) for an online environment.

We will conduct a randomized controlled trial among a sample of 850 African American ESRD patients in the southeastern United States (ESRD Network 6 in Georgia and South Carolina), the region of the country with the largest proportion of African American ESRD patients on the waiting list. Patients will be randomly

assigned to one of two study conditions (intervention or control). Participants at all four collaborating transplant centers will be seen by providers who utilize T-REX, thus allowing us to test the independent effect of individual-level education on a systems-level intervention. The primary outcome is the percent of patients with at least one living donor inquiry. Secondary outcomes will test the effect of the intervention on key constructs of the Information-Motivation-Behavioral Skills model to determine possible mediating pathways. Participants will undergo baseline assessment, access either the intervention or control educational materials, and complete an immediate follow-up assessment. Living donor inquiries will be examined over the subsequent 12 months. The process evaluation will utilize transplant center administrative records, immediate follow-up data from participants, website usage statistics, and study records. It is anticipated that achievement of these aims will yield outcomes with great clinical and public health impact.

Our specific aims are to:

- **Aim 1: To develop and refine a web-based version of Living ACTS. We will adapt our existing intervention for an online environment.** A series of individual interviews with 10 participants will be conducted to obtain feedback on the web-based version of Living ACTS. Participant feedback will be used to refine and finalize the web-based intervention
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- **Aim 2: To conduct an outcome evaluation of the newly created web-based Living ACTS intervention by comparing the percent of patients with at least one inquiry from a potential living donor among patients who receive Living ACTS to those who receive a control website with an embedded educational video.** Patients who start the transplant evaluation at four transplant centers will be assigned to intervention (systems + individual intervention) or control (systems intervention alone).
  H_1: A greater proportion of participants who receive a culturally-sensitive website with embedded video (Living ACTS) will have at least one living donor inquiry over the subsequent 12 months than control participants who received standard education.
  H_2: Patients in the intervention (vs. control) group will have a significantly greater increase in knowledge, motivation, and self-efficacy for the behavioral skills to initiate a conversation about LDKT with family or friends from baseline to immediate follow-up
- **Aim 3: To conduct a process evaluation of the newly created web-based Living ACTS intervention by adapting commonly used process evaluation constructs (context, reach, dose received, fidelity, and recruitment) for an online environment.** We will collect data from participants, transplant center records, study records, “Record it!” application data and Google Analytics to inform process evaluation findings.

Introduction and Background

An individual-level and systems-level intervention will be tested to improve access to living donor kidney transplantation among African American ESRD patients at four major Southeastern US transplant centers.

For the majority of the ~700,000 patients in the United States (US) with end stage renal disease (ESRD),[1] kidney transplantation (KT) represents the optimal treatment, providing longer survival, better quality of life, lower hospitalization rates, and substantial cost savings compared to dialysis.[1,2] Moreover, of the two types of KT, living donor KT (LDKT) and deceased donor KT (DDKT), LDKT is considered the therapy of choice. LDKT offers numerous advantages over DDKT such as better kidney quality;[2] increased short- and long-term graft survival;[3,4] lower rates of acute rejection;[5] reduced health care cost, particularly in the case of pre-emptive transplantation,[2] and potentially shorter wait times to transplantation for recipients. Despite these benefits, there are pervasive racial disparities in access to KT in general and LDKT, more specifically: white ESRD patients are four times more likely to receive a LDKT than African American (AA) ESRD patients.[6] The reasons for these disparities stem from a range of patient, provider, and system factors.[7] Yet efforts to implement multilevel interventions to reduce racial disparities in access to LDKT are nascent. There are no known interventions targeting both individual and systems level change to reduce racial disparities in access to LDKT. The proposed multi-level intervention study will recruit a sample of 850 AA ESRD patients in the southeastern US (ESRD Network 6 in Georgia and South Carolina), the region of the country with the largest number of AA patients on the kidney waiting list, to determine whether a systems-level intervention + individual education is effective at increasing the number of living donor inquiries among AA patients at four transplant centers. Our team recently built a systems-level intervention that utilizes an electronic transplant referral exchange (T-REX) system to deliver education to patients, enhance communication between transplant centers and dialysis facilities, and reduce disparities in KT access (Grant#U01MD010611). Further, from 2010 to 2013 we were funded by the Health Resources and Services Administration (HRSA) to develop and test a culturally-sensitive LDKT education intervention for AAs (Living ACTS: *About Choices in Transplantation and Sharing*, which is comprised of a DVD and booklet) that draws from the Information-Motivation-Behavioral Skills Model[8] of individual level behavior change. While Living ACTS increased LDKT knowledge among AA patients in a prior randomized controlled trial (RCT)[9], a DVD has diminishing utility. A web-based platform would offer greater versatility in light of demonstrated efficacy.[9]

T-REX enhances communication between dialysis facility and transplant clinicians to facilitate increased access to KT. It is theorized that a web-based version of Living ACTS would complement T-REX by providing culturally-sensitive individual-level education about LDKT to patients who have already been referred for KT. The long-term goal of this program of research is to understand the combined effect of web-based education within an electronic health systems platform on racial disparities in access to LDKT.

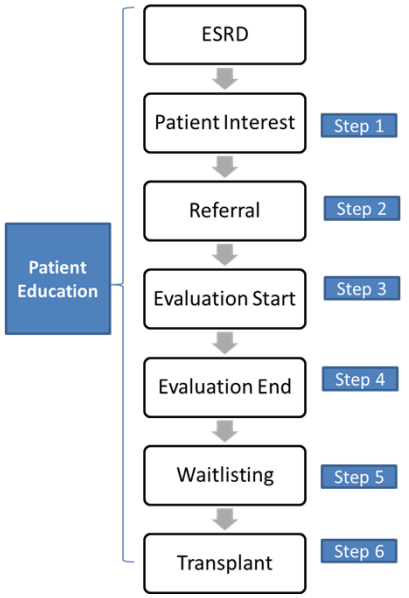
The overall objective of this study is to determine the effect of Living ACTS on LDKT access among AA patients. The central hypothesis of this study is that compared to a systems level intervention alone, the addition of culturally-sensitive web-based education to an existing systems intervention will generate greater patient interest in LDKT, and therefore more LDKT inquiries by patients' family or friends.

A. Significance

A1. There are long-standing and profound racial disparities in access to LDKT. The Southeastern US has the lowest rates of, and among the worst racial disparities in KT in the nation. African Americans comprise 32% of the ESRD population[1,10] and have a disproportionately higher burden of ESRD than their white counterparts. KT is considered to be the optimal treatment for most patients with ESRD, but AAs are 24% less likely to receive a KT compared to whites.[11] The relative odds of receiving an LDKT are even lower.[12]

Disparities exist at each step in the transplantation process and can be attributed to patient, provider, and health system level barriers (**Figure 1**). For example, compared to whites, minorities are less likely to be educated about transplantation within a dialysis facility,[13] express interest in receiving a transplant (step 1),[13] receive a referral from a dialysis facility to a transplant center for transplant evaluation (step 2),[14] start (step 3)[15] and complete (step 4) the required medical evaluation at the transplant center, attain placement on the national deceased donor waiting list (i.e., waitlisting) (step 5),[16] and receive a LDKT or DDKT (step 6).[13,15,17-19] Education by dialysis facility and transplant center staff occurs throughout each step of the transplant process. It is important to teach patients with ESRD the relative benefits of LDKT vs. DDKT because patients are chiefly responsible for finding their own living donor, such as a friend or family member. While reducing disparities in access to both donor types is important, the reasons for disparities in different donor types are different. Once patients are waitlisted, the pool of deceased donor organs is relatively fixed, and there is less of a role for a patient or a patient's family to improve access once waitlisted. But efforts to improve access to LDKT can allow patients to bypass the long wait for a DDKT and result in faster receipt of a transplant for patients. The proposed project directly addresses this extremely important problem in the field, which is AA ESRD patients' reduced access to LDKT.

Figure 1. Steps to transplant



In order to decrease the known disparities in access to KT, our research focuses on multi-level interventions to educate AA ESRD patients on the benefits of LDKT compared to DDKT. Presently, while there are several educational tools and decision aids to help patients learn about LDKT, few are culturally-sensitive and theoretically-driven.[20] We seek to shift education to a multi-level, culturally-sensitive approach to drive not only increased knowledge but also behavior change. The objective of our study is to increase inquiries of living donations for AA ESRD patients and thus enhance the rates of LDKT. Studies have found that clinical providers have little time to educate patients about transplant[21-23] or fail to present transplant knowledge in a culturally-sensitive way.[19,22,24-28] Other research has also documented inefficiency in pre-transplant evaluation and lack of communication between dialysis facilities and transplant centers as major health system barriers.[19] A culturally targeted intervention specific to AAs, integrated within a systems-level platform to enhance clinical provider communication and reinforce educational messages about LDKT could remove some of these patient, provider, and health system level obstacles to KT.

A2. Barriers to LDKT among AA ESRD patients are multifactorial and multi-level, and include patient-, provider-, and health-system factors. Patient barriers include lack of LDKT knowledge and awareness,[29-32] financial concerns, [33-37] and religious beliefs that the body needs to remain whole to enter heaven.[38-40] Another barrier to living donation is AAs' distrust of the health care system in general and the organ allocation system specifically, due to historical and current abuses.[41,42] Moreover, potential kidney recipients are often reluctant to discuss LDKT with family members because of concerns of racial bias. Many believe that this bias would result in their kidney donors not receiving adequate medical care during and after a transplant.[43-45] Historically, immunologic barriers have also been a barrier for transplant among AA patients, but wider adoption of paired kidney donation and other medical procedures have diminished these concerns.[46,47] Aside from patient barriers, provider and health system level barriers are equally relevant. For example, research has shown that providers are less likely to discuss transplant as an option with patients and are less likely to refer AAs than whites.[48] Health care provider's attitudes and perceptions of the appropriateness of LDKT for their patients may lead to lower LDKT rates and incomplete transplant evaluations.[49-51] Nephrologists who treat predominantly minority ESRD populations spend less time providing patient education and counseling on LDKT compared to nephrologists with fewer minority patients,[52] which may reflect providers' attitudes about their patients' suitability for transplant.[51] There also tends to be a lack of communication between dialysis facilities and transplant centers, which can influence KT access.[23] While dialysis staff play a large role in education, generating interest in transplant (step 1), and referral for transplantation (step 2), staff are also

essential in later transplant steps, via active partnering with transplant centers to help patients show up at the transplant center to start the medical evaluation (step 3), scheduling of medical tests and procedures required for evaluation completion (step 4), and maintaining patient health to ensure waitlisting (step 5) (**Figure 1**).[53] In an effort to reduce barriers, a recent national consensus conference on LDKT recommended collaborations between transplant centers, community organizations, dialysis facilities, and others.[26] Technology was recommended as an educational tool for patients and their support systems,[26] which has also been shown to be an effective tool in several other web-based kidney disease interventions.[54-57] Our proposed study follows these recommendations; it builds on our existing work whereby we created a model electronic referral and communication system (T-REX) to enhance communication regarding patient LDKT education between dialysis facilities and transplant centers and allow for appropriate tracking of who receives KT education. This electronic referral system is expected to aid in improving clinical practice and transplant health services.

A3. There is a need for multilevel interventions that address both the health system and patient barriers to LDKT among AA ESRD patients. There is a strong scientific premise for this project. It rests on a large body of literature that demonstrates clear and compelling racial disparities in access to LDKT and builds on our previous research. We have nearly a 15-year history of federally-funded work on implementing systemlevel interventions to reduce racial disparities in transplant and individual-level education that seeks to increase the donor pool and promote LDKT among AAs. For example, two of our funded studies (5R01DK062617-05 and 5R01DK079713-10, PI: Arriola, Projects ACTS I and II), have focused on increasing AA knowledge of transplantation and their intent to become donors via designating their wishes on their driver's license, signing donor cards, talking with their families, and registering for the state donor registry.[58,59] Our findings indicated that at 1-year follow-up, participants were 1.53 times more likely to be in the action or maintenance stage for readiness to carry a donor card than at baseline (p=.01).[58] A third study, Living ACTS (R39OT20066-03, PI: Arriola), developed a DVD-based intervention to increase the understanding of AA patients who are waiting for a transplant of their option to seek a living donor and the process, risks, and benefits of LDKT. Results indicated intervention participants had significantly higher knowledge immediately after reviewing the intervention materials than control participants, (β=.10, p=.03). These data support the effectiveness of the intervention in changing key psychosocial outcomes.[60]

Our work has also highlighted the importance of multi-level and multicomponent interventions. In our recent Reducing Disparities in Access to kidNey Transplantation (RaDIANT) Community Study (R24MD008077, PI: Patzer, co-I: Arriola), our community/academic partnership – the Southeastern Kidney Transplant (SEKT) Coalition – developed and randomized a dialysis facility-based (n=134) multicomponent intervention to target facility leadership, staff, and patients to improve transplant referral among AA ESRD patients in GA,[53] which successfully reduced racial disparities in transplant referral among 134 low-referral/high-disparity, majority AA dialysis facilities in GA, and showed evidence of reducing racial disparities in access to waitlisting (step 5).[53,61] Living ACTS was one component of this dialysis facility-based multi-level intervention.

Our work to date demonstrates that our multicomponent interventions are feasible and effective in improving ESRD patient outcomes and increasing access to KT. Thus, for this proposed project, we will expand interventions that were effective in increasing LDKT knowledge among AAs by offering a web-based version of *Living ACTS: About Choices in Transplantation and Sharing.* Also, in our current NIMHD-funded RaDIANT Regional Study (PI: Patzer, Co-I: Arriola), we have designed and developed a web-based health systems intervention (T-REX) as a secure way for dialysis staff to refer patients to transplant centers for evaluation and better track their patients throughout the KT process. Our work on the RaDIANT Regional Study will provide a strong foundation for the electronic transplant referral system we propose to utilize in this study. If the aims of this project are achieved, clinical practice will be improved by the availability of an innovative and cost-effective approach that uses a web-based education intervention to focus on the well-established barriers that AAs face in initiating conversations with family members about living donation. Wider implementation could potentially lead to an increased living donation among AAs thereby increasing access to KT and reducing disparities.

B. Innovation

This study challenges and seeks to shift current practice paradigms by utilizing a novel multi-level intervention to improve access to LDKT among AA ESRD patients through a focus on patient education and provider

communication. The systems-level intervention addresses a major communication gap around the complex process of obtaining a transplant between dialysis facilities and transplant centers. In this study, transplant centers and dialysis facilities will utilize an electronic transplant referral form that includes tracking tools for transplant steps that are *not currently monitored* in routine clinical practice by dialysis facilities, including referral, medical evaluation, waitlisting, and transplantation, as well as documenting details of how patients are educated about LDKT and DDKT. As dialysis facilities are not mandated by the Center for Medicare & Medicaid Services to provide patient support for kidney transplantation beyond education, the engagement of dialysis facilities to support ESRD patients throughout the transplant process is a novel health systems-level paradigm shift in how transplant centers and dialysis facilities work together to improve care coordination for ESRD patients and their potential living donors. Moreover, the patient-level intervention not only delivers culturally-sensitive education about LDKT, but will have features that utilize social media as a vehicle for communicating with friends and family about one's need for a kidney. Taken together, these two separate interventions represent a significant improvement over current approaches to improve access to LDKT among AA ESRD patients.

Objectives:

- **Aim 1: To develop and refine a web-based version of Living ACTS. We will adapt our existing intervention for an online environment.** A series of individual interviews with 10 participants will be conducted to obtain feedback on the web-based version of Living ACTS. Participant feedback will be used to refine and finalize the web-based intervention.

- **Aim 2: To conduct an outcome evaluation of the newly created web-based Living ACTS intervention by comparing the percent of patients with at least one inquiry from a potential living donor among patients who receive Living ACTS to those who receive a control website with an embedded educational video.** Patients who start the transplant evaluation at four transplant centers will be assigned to intervention (systems + individual intervention) or control (systems intervention alone). We hypothesize that intervention patients will have significantly more living donor inquiries than control participants over the subsequent 12 months. Secondary analyses will explore the effect of the intervention on information, motivation, and self-efficacy for the behavioral skills to discuss LDKT with others.

- **Aim 3: To conduct a process evaluation of the newly created web-based Living ACTS intervention by adapting commonly used process evaluation constructs (context, reach, dose received, fidelity, and recruitment) for an online environment.** We will collect data from participants, transplant center records, study records, and Google Analytics to inform process evaluation findings.

C. Study Designs and Methods

C.1. Overview

The study seeks to fulfill the following specific aims by conducting a scientifically rigorous RCT among 850 AA ESRD patients presenting for KT evaluation at a transplant center:

1. *To develop and refine a web-based version of Living ACTS*
2. *To conduct an outcome evaluation of the newly created web-based Living ACTS intervention by comparing the percent of patients with at least one inquiry from a potential living donor among patients who receive Living ACTS to those who receive a control website with an embedded educational video*

3. *To conduct a process evaluation of the newly created web-based Living ACTS intervention by adapting commonly used process evaluation constructs (reach, recruitment, fidelity, dose delivered, dose received, and context) for an online environment*

To complete aim 1, we will contract with Tomorrow Pictures and Emory Web Services to create the Living ACTS website and embed the current Living ACTS video. We will conduct a series of individual interviews (10 total) to gain feedback on the website from individuals meeting our participant demographic profile. Participant feedback will be used to refine and finalize the intervention website. Next, the multi-center trial will collect data from 850 AA ESRD patients who have been referred for evaluation at one of four participating transplant centers in the Southeast. The proposed methods were designed to maximize the robustness of the data while minimizing bias in study design, methodology, analysis, interpretation, and reporting. Random assignment to condition (also for Aim 2) reduces the chances of initial group differences in maturational rates, historical events, and regression artifacts.[62] Additionally treating the two groups equivalently in terms of attention to a website with embedded video, data collection methods, and instrumentation improve internal validity by minimizing testing and instrumentation effects.[62]

Patients will be enrolled into the study through a Zoom video call or telephone call before or after their second day of evaluation at which point they will be consented verbally and undergo baseline assessment. Next, they will be randomized to condition, access either the intervention or control website, and complete an immediate follow-up assessment. Living donor inquiries will be tracked using administrative data from the transplant centers for the subsequent 12 months. Aim 3 will be achieved through the analysis of transplant center data (for context and reach), web-site usage statistics (for fidelity), study records (for recruitment), and patient-level data (for dose received). We are intentionally not testing the effect of T-REX given its alignment with the recommendations generated by the Consensus Conference on Best Practices in Live Kidney Donation.[63] This study is uniquely designed to isolate the effect of the individual-level intervention within a system-level intervention to determine its added value.

C.2. Preliminary Studies

C.2.1. The RaDIANT (Reducing Disparities In Access to kidNey Transplantation) Regional Study. In our currently funded RaDIANT Regional Study (PI: Patzer, Co-I: Arriola), our community/academic partnership – the SEKT Coalition – was funded to develop a health systems intervention called T-REX as part of a multicomponent intervention consisting of educational and outreach materials to target multiple levels of influence (facility leadership, staff, and dialysis patients) to reduce disparities in referral for transplant (step 2) among AA ESRD patients in GA.[23] T-REX is a multi-module, HIPAAcompliant, web-enabled software application that manages ESRD patient data throughout each transplant step. In the dialysis facility setting, the novel software allows staff to electronically refer their patients for KT evaluation using transplant center-specific referral forms and track their ESRD patients throughout the transplant process. On the transplant center side, the software enables staff to manage patient waitlist activities and facilitate center-specific living-donor matching capability. The T-REX application creates continuity between dialysis facility and transplant center staff by tracking the frequency and use of educational materials throughout the transplant process. T-REX was developed to enhance communication between transplant centers and dialysis facilities that have disparities in KT, and has been pilot tested at two Southeastern transplant centers (with rollout planned to the remaining 7 transplant centers in GA, NC, and SC by 2017). In the current proposal, we plan to leverage this existing software as our health systems intervention.

C.2.2. Project ACTS, Living ACTS, and WebACTs. In 2002, we (PI: Arriola; Co-I: Perryman) were funded by NIDDK to develop and test the effectiveness of a culturally-sensitive self-education intervention for AA adults that sought to improve their attitudes and opinions towards organ and tissue donation.[64] Drawing from our own qualitative formative research[29,65] and the Resnicow et al. two-dimensional theory of cultural sensitivity,[66] our intervention sought to address a deep structure dimension of cultural sensitivity (i.e., attention to the cultural, social, historical, and psychological forces that shape donation-related behavior among AAs) in

addition to the surface structure dimension (i.e., matching intervention materials and messages to observable, "superficial" characteristics of the target population). Two subsequent studies were funded, the first to refine the intervention[67] and the second to deliver it in community settings (ongoing). In light of promising findings regarding the efficacy of these interventions, two subsequent versions of it were created that are directly relevant to the current study. First, Living ACTS (PI: Arriola; Co-I: Perryman) was funded by HRSA to develop and test an intervention that sought to improve understanding of living donor transplant as a treatment option among AA ESRD patients who have been referred to the ETC for evaluation (**Table 1**). Results demonstrate the ability to increase knowledge of the process, risks, and benefits of LDKT as well as willingness to talk to family about it.[68] We draw from successful recruitment and data collection methods used in this HRSA grant to inform the proposed study. Second, in 2014, we (PI: Arriola; Co-Is: Patzer and Perryman) were funded by HRSA to increase the number of adults who go online to designate consent to become organ donors in the state donor registry (Donate Life, Georgia) by developing and testing a web-based intervention that targets AA adults. This ongoing study entailed adapting the Giving ACTS DVD for an online environment and is in the midst of data collection at the time of this writing so preliminary data are not yet available, but it provided useful experience converting a DVD to a web-based intervention relevant to the current study.

Table 1. Overview of Living ACTS Intervention

Living ACTS: About Choices in Transplantation & Sharing
General premise: Live donor transplant is a viable treatment option to explore among patients with end stage renal disease. **Vehicle:** Personal stories that emphasize the role of family, factual information from health care professionals **Key points**: • Live donors/recipients discuss the decision to pursue living donation. • Medical providers discuss the benefits of live donor transplant over deceased donor transplant. • Transplant social worker discusses the process for donors and recipients to explore living donation. • Medical provider discusses the importance of preventing organ rejection. • Multiple individuals discuss resources for individuals interested in exploring live donor transplant.

C.3. <u>Specific Aim 1</u>: To develop and refine a web-based version of Living ACTS. We will adapt our existing intervention for an online environment. The Internet provides an ideal mechanism for delivering Living ACTS. Because few DVD players exist in transplant centers, it supports the sustainability of the intervention beyond the life of the study. Additionally, patients can go home and watch the video with family, multiple times if desired. Finally, in a way that a DVD cannot, it affords the option to directly communicate with potential donors by sending an email and using other forms of social media (e.g., Facebook posts) to communicate the need for a LDKT.

Website & Video Development. We will be updating our existing WebACTS (HRSA-funded project) website (the web address for the test site is: http://actnow.projectwebacts.org/#/), which seeks to increase registration on the Georgia state donor registry. The new website will be similar to the look and feel of our existing website except that the current "ACT Now" tab that provides a mechanism for registration on the state donor registry will be replaced with an "ACT Now" tab that informs friends/family of LDKT as a viable treatment option for the patient. The website will also include the ability to pick from boilerplate messages about how to share via social media (i.e. Facebook, Twitter, Instagram) as well as traditional media (i.e. email and printed letter) with friends and families their need for a KT, and more information about LDKT (including a link to the Living ACTS website).

We will contract with Tomorrow Pictures, Inc., a film company we have worked with for the past 14 years, to refine the Living ACTS video. We anticipate shortening the video from 30 to 20 minutes and making minor edits using existing footage. The website will be hosted on the Emory server, which offers the benefit of a secure server free of charge and technical support from our existing Department of Information Technology. Our team of content area and research experts will work closely with them to provide feedback on graphical

representations of our site until the desired look, feel, and functionality is accomplished. The content of the website will largely come from the existing Living ACTS educational booklet. The research team will be responsible for revising the content to make it more appropriate for a website and sharing it with the web developers. Web developers will perform usability testing on the website and videos to ensure basic functionality (i.e. working links, functional videos, etc.) prior to completing a draft website with the embedded videos. We will explore the possibility of creating a mobile version of the website to facilitate participants' ability to navigate from smartphones and tablets.

Website Testing & Refinement. We will seek to gain feedback from 10 individuals about the adapted Living ACTS website through face-to-face, individual interviews. Participants will be asked to provide feedback on their overall satisfaction with the website, comprehension of the core messages and how participants interact with the learning tool. All feedback will be used to refine and finalize the intervention website.

Sample. Eligible participants for the interviews will: 1) self-identify as African American or Black; 2) be between the ages of 18 and 65; 3) have a diagnosis of end-stage renal disease and are currently undergoing evaluation for a transplant, or have received a transplant 4) be English speaking; 5) be willing to participate in an individual interview lasting 1 – 1 ½ hours, 6) be willing to be audio-taped and have website usage recorded via a recording app ("Record it!"). For the purpose of this study, the term "Black" includes people of African descent regardless of cultural identification. Individuals will be excluded from participating in this study if they do not meet these eligibility criteria or if they do not understand English.

Recruitment. We will recruit participants via 2 mechanisms: 1) from existing contacts, including patient advocates who participate in the Southeastern Kidney Transplant Coalition, and 2) approaching patients in the Emory Transplant Clinic who are awaiting an evaluation appointment. Individuals in this Coalition have previously expressed interest and participated in providing feedback for projects related to kidney donation and transplantation. Permission from Transplant Center will be obtained prior to approaching patients. Our goal is to recruit a broad cross-section of individuals (i.e. participants who vary by gender, age, etc.) to ensure that the website feedback represents a diverse pool of individuals.

Those who are interested in participating in the study will complete a brief eligibility screener via telephone or in-person, depending on the recruitment method. The project coordinator will record all answers via a paper form and inform the individual of his/her eligibility status. If the person is ineligible based on the telephone rescreening, the coordinator will inform him/her that he/she is ineligible for the study and thank him/her for his/her time (see Website Interview Screening Questions document for ineligibility response). If found eligible, the participant will conduct the interview on the spot, or schedule a convenient time to conduct the interview. The project coordinator will explain what study participation entails and the $20 gift card incentive. For those participants who schedule a future time to conduct the interviews, the project coordinator will email each participant details about the date and time of the individual interview, and where to meet. Also, the project coordinator will track enrolled participants, participants who are eligible but cannot make the next available session, and participants who are ineligible.

Procedures. Ten individual interviews will be conducted face-to-face and last approximately 1 to 1 ½ hours. All interviews will be conducted by study staff. The interview facilitator will be responsible for creating a nonthreatening, nonjudgmental, supportive climate conducive to open exchange and expression and ensuring that the discussion remains relevant to the study website.

First, the facilitator will provide the participant an IRB-approved consent form to review and sign. The facilitator will offer any clarifications for language in the IRB as requested by the participant, and once signed, provide a copy of the consent form to the participant.

Next, the facilitator will provide a brief overview of the purpose of interview and what the interview will entail. The participant will be asked to browse the website and then will be asked a series of questions assessing his /

her perception of the design, comprehension, function and cultural competence of the website (see attached Living ACTS Interview Guide). During the 'Website Tasks' portion of the interview, participants will be asked to complete a series of instructions browsing the website to test how easily individuals can find useful information within the website (e.g., "You're on the home page and want to learn more about the risks and benefits of transplantation. How do you go about doing that?"). Lastly, participants will be asked a few final questions about their overall thoughts and recommendations regarding the website. The interview facilitator will take detailed notes regarding the participant's feedback. All discussions will be audio-recorded in the case that participants' feedback needed to be referenced in the future. Additionally, participant activity on the study website will be recorded using the "Record it!" application. This will provide information about how much time the participant spends on the study website, which modules he/she explores and frequency, and overall interactions with the website. At the conclusion of the interview, participants will be given a $20 gift card in exchange for their time.

Once the 10 individual interviews are completed, the project staff will review all responses, compile feedback, analyze for common themes, and make necessary edits to the website to reflect overall feedback from participants.

Measures (see attached Interview Guide)

1. Review of the consent form

   5 minutes

2. Welcome

   5 minutes

3. Website browsing

   15 minutes

4. Follow-up Questions

   10 minutes

5. Website tasks

   15 minutes

6. Other questions

   5 minutes

Risks to Participants. Some aspects of the interview may bring up unpleasant feelings or make participants feel uncomfortable to answer. Participants will be informed that they are free to decline to answer any questions in the interview that they do not feel comfortable answering. They will be informed that they can leave the interview at any time and can stop participating in the study at any time. The facilitator will gauge each participant's comfort level and address any concerns that arise at that time as there may be other risks, discomforts or side effects that are not yet known.

Benefits to Subject. Taking part in this activity may not benefit participants personally; however, information that is shared will help us modify the website to enhance its effectiveness.

Data Analysis. Each interview facilitator will maintain detailed notes of the participant's feedback. At the conclusion of the interviews, each facilitator will compile notes that highlight central themes related to the website feedback. Audio recordings from each group will be referenced in cases where the facilitator's notes need to be cross-referenced. Video recordings from the "Record it!" app will be reviewed to identify participant's use of the intervention website. Once all 10 interviews are completed and facilitators compile the corresponding interview notes, all facilitators will meet to compare findings and to compose a comprehensive and final list of website modifications. All suggested modifications will be given to the website developer to incorporate into the Living ACTS website.

Training for Research Personnel. All study staff will have undergone Human Subjects Training.

Plans for Data Management and Monitoring. All interview notes will be stored on a network drive.

Confidentiality. Study participants' names will remain confidential. Names will not appear in the data collection documentation. However, names will be used for scheduling the interview sessions and distributing participant incentives. The names, email addresses, and telephone numbers of potential participants who are ineligible for the study will be discarded. Informed consent documentation will be stored in a separate location from participant data. Thus, the data will not be linked to participant identifiers. We do not expect to share study findings beyond the website development company.

Informed Consent. Prior to the interview, participants will be instructed to complete the consent form (see attached consent form). During the session, the interview facilitator will review the consent form including a brief introduction to the study purpose and what participation entails. They will also be informed that the interview will be audio recorded, and website activity will be recorded, that their participation is voluntary, that they may revoke consent at any time throughout their participation, and that there is an incentive of a $20 gift card.

Informing Participants of Findings. We do not anticipate that this study will generate findings that will need to be related back to participants.

C.4. <u>Specific Aim 2</u>: To conduct an outcome evaluation of the newly created web-based Living ACTS intervention by comparing the percent of patients with at least one inquiry from a potential living donor among patients who receive Living ACTS to those who receive a control website with an embedded educational video. We will test the efficacy of the web-based Living ACTS intervention among AA ESRD patients who started the transplant evaluation process at four Southeastern transplant centers.

Study Sites. The efficacy of the web-based Living ACTS intervention will be tested in a multi-site, RCT at four large, adult kidney transplant centers that serve a diverse (primarily AA) population of ESRD patients. The transplant centers will include:

1. Emory Transplant Center (Atlanta, GA)
Emory Transplant Center (ETC) is the largest transplant center in Georgia. In fiscal year 2014, the ETC received 3,323 patient referrals for evaluation of kidney transplant. At the end of 2015, there were 791 new kidney waitlisted patients on the kidney transplant waiting list at ETC, of whom 63% were African American. The ETC program performed 277 (183 deceased donor and 94 living donor) kidney transplants, with 69% of deceased donor transplants and 37% of living donor transplants for African American recipients. The ETC tracks all patient data, including living donor data (from inquiry to outcomes) through an electronic, HIPAAcompliant Oracle Business Intelligence platform called the Transplant Data Mart. In addition, the ETC was the first transplant center to pilot the T-REX (Transplant Referral Exchange) platform that will be used in this study.

2. **Piedmont Transplant Institute Kidney Transplant Program and Piedmont Hospital (Atlanta, GA)** The Piedmont Transplant Institute (PTI) Kidney transplant program was established in Atlanta, GA in 1986, and the Piedmont program spans the entire spectrum of transplant care. Currently PTI reaches out to provide follow up care to all transplanted patients either at the main facility or at 4 regional satellite facilities around the state. On the main campus there are 18 exam rooms that provide space for conducting evaluations for recipient, donors and post-transplant follow up. This includes a state of the art treatment room where minor surgical procedures and infusions are performed. PTI is ranked among the top 15 percent of abdominal transplant programs in the United States and considered one of the top programs in the Southeast. PTI is one of three kidney transplant centers in the state of Georgia serving adult patients from the state of Georgia, eastern Alabama, northern Florida and Southeastern Tennessee. 539 kidney patients were newly added to the PTI transplant waitlist in 2015, with 60% of candidates being African American. There were a total of 151 kidney transplants for 2015, 88 of those allografts were from deceased donors and 63 from living donors. Of African American kidney transplant recipients, 65 received deceased donor allografts and 14 received living donor allografts. There were 1,177 kidney evaluation referrals for 2011.The transplant program consist of a multidisciplinary team that includes four board certified transplant nephrologists and six board certified multi organ transplant surgeons. Piedmont has been involved with the Southeastern Kidney Transplant Coalition since its inception in 2010, and has partnered with Emory and other transplant centers to develop T-REX to help dialysis facilities and transplant centers communicate with one another and track education.

3. Augusta University Kidney and Pancreas Transplant Center (Augusta, GA)
The Kidney and Pancreas Transplant Program at Augusta University in Augusta, GA has a dedicated kidney and pancreas transplant team that recognizes the special needs of patients. Augusta University had 416 new kidney waitlisted candidates at the end of 2015, of which 55% were African American. This program is one of 20 nationwide to receive a 2011 Health Grades Transplant Excellence Award. The program is the only kidney transplant program in the state that is located outside of the metro-Atlanta area. Augusta University performed its first kidney transplant in 1968 and has since performed over 2,300 kidney and kidney/pancreas transplants. In 2015, Augusta performed 207 kidney transplants (176 deceased donor and 31 living donor), with 16% living donor transplants for African American recipients. The enterprise's distinction as the state's academic health center ensures access statewide and beyond to the highest-quality health care, the newest biomedical breakthroughs and cutting-edge technology. Its integrated and closely aligned with the Augusta Health System, which includes the Augusta Medical Center, specializing in the needs of the acutely ill in an ethnically diverse region; the award-winning Georgia Health Sciences Children's Medical Center, the second-largest children's hospital in Georgia; the Georgia Health Sciences Cancer Center, the first of its kind in Georgia to offer Phase 1 and Phase 2 clinical trials; and the Georgia Regents Medical Associates, a multi-specialty group that is the largest of its kind in the region. These facilities, which include more than 80 specialty clinics, host over 500,000 patient visits annually. Augusta University is a pilot user of T-REX, and has participated in shared data collection efforts with the Southeastern Kidney Transplant Coalition since 2012.

4. Medical University of South Carolina (Charleston, SC)
Medical University of South Carolina in Charleston, SC, has a patient-centered approach with short wait times and a high survival rate, despite twice the number of high-risk patients. MUSC specializes in living renal transplantation. At the end of 2015, there were 807 candidates on the waiting list. In 2015, MUSC completed 22 living donor transplants and 44 deceased donor transplants in adult ESRD patients, with 73% of deceased donor transplants and 14% of living donor transplants for African American recipients. MUSC has been a partner of the Southeastern Kidney Transplant Coalition since 2012, and has shared patient data with Emory and the Transplant Coalition partners for collaborative research in the past 3 years. The MUSC transplant center has a long history of several NIH-funded studies that have specifically addressed decreasing disparities in living donor transplant among African Americans, which ensures appropriate infrastructure to continue the proposed work.

Study Preparation.

Pilot Testing. Prior to study start, the study coordinator will train all research assistants in data collection processes and study protocols. Study procedures will be piloted among the first 5-6 patients in the main (ETC) study site.

Finalization of Study Protocols. Using feedback from the pilot testing we will finalize study protocols and data collection instruments, update IRB with any minor changes, and hold a multi-site webinar to discuss study protocols to ensure consistency across study sites, answer any questions that site collaborators may have, and finalize timeline.

Trial Registration of Study. We will register the trial protocol at ClinicalTrials.gov.

Creation of a Data Safety and Monitoring (DSM) Plan. A DSM Plan will be formed in the early months of the project and be given responsibility to review and approve the study methods and the analysis plan for all study aims. The DSM Plan will be organized by Drs. Patzer and Arriola will include the PIs at each institution and key Coalition members with related experience (including health services researchers, methodologists, patients, social workers and biostatisticians). The DSM Plan will consist of annual teleconferences. At these meetings the study protocol, procedures, and any issues of concern related to research integrity will be discussed. Email correspondence or teleconferences between study sites may be arranged for any late-breaking issues. In addition, monthly monitoring of data is in place to ensure the assessment of data accuracy. The Principal Investigator assumes responsibility for assuring that the study is carried out in accordance with the DSM Plan. We will follow Emory University IRB protocols to ensure patient safety as we plan on external study sites will be relying on Emory's IRB. All patient data from each study site will be stored on a password-protected and encrypted computer, within a locked office and building. Only the PIs, project coordinator, and the data analyst will have access to any identifiable patient data throughout the study period.

Participant Recruitment and Study Inclusion/Exclusion Criteria.

Patient Recruitment Methods. To ensure that we target patients who are most likely to be medically eligible to receive a transplant, and yet also target patients as early in the transplant process as possible, a rigorous screening process will be utilized to screen patients who have been referred for transplant evaluation.
We will recruit participants by posting flyers in each of the four study sites, instructing those who are interested to contact the project coordinator via a telephone number to be secondarily screened for participation. To ensure that we target patients who are most likely to be medically eligible to receive a transplant, components of the eligibility criteria (AA or Black and age 18-70 years) will be posted on the flyer. Each transplant center will have its own flyer with appropriate contact information for that center. Please see attached flyer for further details.

Through the Powerchart system, the project coordinator will review the schedule for the transplant center of all patients who will have or had an evaluation appointment during a 7 – 10 day period before or after the scheduled appointment. The coordinator will not have a relationship or familiarity with these patients prior to screening them for eligibility. The project coordinator will also review some key patient demographics (race, sex, age, and BMI) to ensure eligibility for the study. Additionally, access to patient clinical charts will be accessed via Powerchart to confirm patient eligibility (i.e. transplant status, ESRD status, and additional eligibility criteria). The project coordinator will obtain the patient's telephone number from Powerchart to call the patient to ask the patient to participate in the study. If the patient is willing to participate, the project coordinator will obtain the patient's email address to send the appropriate Zoom video call information, appointment time and date. The patient will be scheduled for a Zoom video call no later than a week from the initial phone call. The project coordinator will also call the patient one day before the scheduled Zoom video call to confirm the appointment with the patient. If the patient does not have zoom capabilities, the coordinator will set up a video call with the patient. The coordinator will also have the option to recruit a patient in-person at the transplant clinic. Data collectors will maintain all necessary clearances and perform required trainings to gain and maintain access to electronic medical records. Project coordinators will be rigorously trained on how to recruit and screen patients for study eligibility.

Eligibility Criteria. All patients referred (from dialysis facility, chronic kidney disease clinic, or self) and scheduled for an evaluation at one of the four study sites within the study time period. Our screening process will be based on information gathered from either their referral form or electronic medical record and ensure that patients are:

(1) AA or Black
(2) age 18 to 70 years
(3) have BMI < 39
(4) are English-speaking (Language eligibility will be confirmed by project coordinator during a telephone call with the patient prior to the Zoom video call)

Consent. Consent and data collection will be completed by the project coordinator during a Zoom video call that was set up by the coordinator. The project coordinator will provide interested participants a verbal summary of the study, information about the risks and benefits of participation, and answer any remaining questions. Interested participants will be required to consent verbally for willingness to participate. The coordinator will share the screen with the consent form displayed for the participant to review. An email with a link to the consent form will also be sent to the participant to review. If the participant does not have an email address, the coordinator will physically mail the informed consent to the participant. Please see the attached verbal consent form for details. The verbal consent will be recorded via videoconference or teleconference using the Zoom platform.

Compensation. To maximize participation, we will offer a $30 e-gift card. This will be emailed to participants immediately after they complete the immediate follow-up survey described below.

Baseline Data Collection. Baseline data collection will occur after the consent process described above. The project coordinator will read a baseline survey (via HIPAA-compliant SurveyMonkey software) aloud to the participant and enter data based on information given from the participant. This will also allow those with lower literacy to still take part in the study without feelings of embarrassment. Please see attached baseline survey for further details.

Study Arms & Delivery of Interventions. Following consent, and baseline data collection participants will be randomly assigned to either:

1) ***Usual Care,*** which involves the provision of standard transplant education procedures at each transplant center, which entail reviewing a packet of information with the pre-transplant coordinator. While there are some minor differences in the educational information about transplant that patients receive at each study site, the overall purpose is the same: the packet serves to inform transplant candidates and their families about the option LDKT. In addition, participants will be provided an iPad/tablet to watch a 10-minute National Kidney Foundation videos about kidney disease and transplantation in their private room during their regularly scheduled KT evaluation. This video discusses information about transplant, but does not specifically address LDKT and is not culturallysensitive to the AA population (https://www.kidney.org/atoz/content/kidneytransnewlease).
2) ***Living ACTS website,*** this involves the same procedures as above but also visiting the Living ACTS website and watch the Living ACTS video (embedded in the website). Participants will be given a time minimum to explore the website, as determined by the results in the individual interviews testing the intervention website. (https://www.projectlivingacts.org).

Randomization. At each site, patients will be randomized to usual care or the Living ACTS website individuallevel intervention immediately following study consent and completion of the baseline measures using a simple, 1:1 randomization scheme. A random number generator program will designate patients' study arm assignment. Randomization only applies to the individual-level intervention; clinical providers across both study conditions will utilize the health systems intervention, T-REX, to communicate with one another about patients' transplant status. Once the patient has been assigned an arm from randomization, he or she will be

sent an email with the appropriate website. Once the patient receives the website, the coordinator will ask the patient to view the content. The coordinator will record the amount of time the patient viewed the website.

Blinding. The project coordinator is not blind to study condition. However, the coordinator will not be involved with the main outcome analyses, and analysts will be blind to condition.

Immediate Follow-Up Survey. Participants will complete the immediate follow-up survey ((via HIPAAcompliant SurveyMonkey software), which will be a shortened version of the baseline survey that omits the demographic questions. Again, patients will have the project coordinator read the survey out loud and the coordinator will complete the survey. Participants will then be offered $30 e-gift card as compensation for their participation. Please see attached immediate follow-up survey for further details.

Time. The entire intervention is expected to take 1 hour and 30 minutes for each patient from start to finish.

Coordinator Training. This project coordinator will undergo rigorous training by the principal investigators, have strong oversight from study staff, and submit regular documentation to study staff on recruitment progress.

Recruitment Timeline. Participant recruitment will occur in a staggered fashion across study site, starting with the main study site, to ensure that study investigators can make any necessary minor modifications to the study protocol.

Measurement. Covariates and key outcome measures are described below and in Table 2.

Independent Variable. The primary independent variable is study arm (National Kidney Foundation kidney education video vs. Living ACTS)

Outcome Variables. There are several key endpoints that will be examined in this study. *Primary Outcome:* The percent of patients with at least one living donor inquiry over 12 months
Secondary Outcomes: Psychosocial measures of knowledge, motivation, and self-efficacy for the behavioral skills to discuss LDKT with others

Table 2. Outcome measures for randomized controlled trial (Aim 2)

THEORETICAL CONSTRUCT	MEASURE (Scale Name)	DESCRIPTION	SAMPLE ITEMS
Information	Knowledge of opportunities for and risks of living donor transplant.[68]	This 25 item instrument assesses respondent's basic understanding of the opportunities for and the benefits and risks of living donor transplant. Response choices are true and false.	• The likelihood of immediate function of the kidney from a living donor is excellent. • Most donors must remain in the hospital for 10 days after surgery.
Motivation	Asking a family member to be a living donor[68]	This measure will be assessed with 9 item that gauges respondents' perceptions of discussing living donor transplantation with their family. Potential responses range from 1-5 with higher values stronger agreement with the statement.	• Asking a family member to be my living kidney donor is valuable for me. • I expect my family's opinion about organ donation will be positive.
Self-Efficacy for the Behavioral Skills	Confidence in initiating a conversation about LDKT[68]	This is a 10 item instrument adapted from the "Living ACTS: About Choices in Transplantation and Sharing" Baseline Questionnaire that measures participants' confidence in discussing LDKT with others. Cronbach's $\alpha = 0.87$	• How confident are you that you…can start a conversation about living donation with your friends or family? • …can cope if a person you ask is not willing to donate?
Primary Outcome	Living Donor Inquiry[77]	A donor inquiry will be operationalized as a telephone call to the transplant center conveying an interest in living donation by a friend or family member of an enrolled study participant.	N/A
Exploratory Outcome	Behavioral Intentions[80]	A 3 item scale that assess patients' intent to discuss kidney donation with family members. Cronbach's $\alpha = 0.94$	In the next three months do you plan on asking a family member to donate a kidney?
Exploratory Outcome	Comfort in initiating conversation about LDKT[81]	Single item to measure comfort level: Potential responses range from 1-4 with higher values reflecting more comfort.	How comfortable are you at initiating a conversation about live donation and asking a [x] to consider donating a kidney?

Primary Outcome.

Proportion of study participants who have at least one living donor inquiry by friends/family of the patient over 12 months from baseline (evaluation start). This discrete outcome has been used in prior studies[69] and is a necessary step prior to LDKT. These data are currently captured for all patients as a discrete field from electronic medical record for each potential recipient. Inquiries are defined by all centers as a telephone inquiry to the transplant center's living donor (each center has a separate telephone line for this purpose). For each study site, a data collection form that captures potential recipient ID (i.e. study participant), date of living donor inquiry, and donor inquiry ID, will be securely obtained from each transplant center following a 12 month period from enrollment. Data will be collected electronically for all study participants through a secure, HIPAA-compliant data server (QualityNet) that all 4 transplant centers have used in prior SEKT Coalition studies[53,70].

Secondary Outcomes. Captured in the baseline and immediate follow-up survey, which will include measures of information, motivation, and behavioral skills that we have used in past research

a. a 25-item assessment of knowledge and understanding of donation/transplantation[60,71]
b. a 9-item scale asking assessing motivation to ask a family member to be a living donor[60]
c. a 10-item behavioral skills scale that measures confidence in initiating a conversation about LDKT[60]
d. a 3-item behavioral intentions scale that measures intention to discuss LDKT with family members[72]
e. a single-item measure of comfort in initiating conversation about LDKT[73]
f. several items measuring demographic characteristics (age, gender, highest level of education)

Study Size Justification & Power Calculation.

Study Size Justification. There were an estimated 3,500 ESRD patients evaluated for transplantation, and 2,180 new additions to the waiting list in the four transplant center sites in 2015. The majority (61.9%) of the waitlisted patients were AA. Thus, we will have a pool of over 1400 potential study participants over the four study sites over 1 year, which will ensure we will meet our estimated sample size of n=850 AA ESRD patients (1:1 randomization). We expect that it is possible that ~25% of patients evaluated will not be eligible for transplant and thus will not have the opportunity to have LDKT, and these patients not be considered in main outcome analyses.

Power Calculation for Primary Endpoint. Based on preliminary data showing that the proportion of AAs with ≥ 1 living donor inquiry is 12% at baseline, we have 80% power to detect a 7% difference between the intervention and control groups, accounting for potential correlation of patients within study sites (correlation on the same subject of 0.5), with α=0.05. We expect little attrition in this trial, since follow-up data on the number of living donor inquiries will be obtained through medical record review. Based on our prior trial,[9] we expect >90% participation.

Statistical Analysis Plan. We will initiate the analytical process by conducting basic descriptive statistics on all variables, examining continuous variables for normality, and exploring the Cronbach's alpha for relevant scales.

- Our main analyses seek to answer the following hypothesis:
H_1: A greater proportion of participants who receive a culturally-sensitive website with embedded video (Living ACTS) will have at least one living donor inquiry over the subsequent 12 months than control participants who received standard education.

- Our secondary analyses seek to answer the following hypothesis:
H_2: Patients in the intervention (vs. control) group will have a significantly greater increase in knowledge, motivation, and self-efficacy for the behavioral skills to initiate a conversation about LDKT with family or friends from baseline to immediate follow-up

To ensure adequate balance across study arms, baseline covariates will be compared using Student *t* tests and χ^2 tests, as appropriate. Variables found to have significant differences ($p < 0.05$) by study arm will be

entered as covariates in subsequent analyses. We note that detected differences may be site-specific and will explore site stratifications if we observe differences. Multivariable modeling techniques will be employed, if necessary, to correct for lack of balance in demographic or clinical characteristics between the two groups. For the main outcome, we will use generalized linear mixed models (GLMMs) for adjusted analyses of the data, specifying the logit link function for the binary outcomes (i.e. at least one living donor inquiry over 12-month period). Treatment group will be the independent variable of primary interest, modeled as a fixed effect with the control group specified as reference group. We will also include fixed effects for any potential confounding covariates noted in bivariable analysis. A random intercept will be considered to increase generalizability of results. To control for potential contamination bias over the course of the study, we will consider controlling for time of study entry.

We will pursue a similar modeling technique as described above for secondary analyses except that change in each of the three dependent variables will be the continuous (vs. binary) outcomes. We will conduct exploratory analyses where we assess change in behavioral intentions and comfort in initiating conversations about LDKT as outcomes. All data will be analyzed by the program coordinator for the study at Emory University with the oversight of Drs. Patzer and Arriola, who will be blinded to study allocation. SAS 9.3 (Cary, NC) will be used for all analyses.

C.5. Specific Aim 3: To conduct a process evaluation of the newly created web-based Living ACTS intervention by adapting commonly used process evaluation constructs (reach, recruitment, fidelity, dose delivered, dose received, and context) for an online environment In Table 3 we describe what data will be collected, how, and when. **Table 3.** Process evaluation components and measures (Linnan & Steckler, 2002)

Component	Definition	Measure	Data Source
Context	Aspects of the transplant center environment that may influence uptake of the intervention	-Description of the transplant education process -Description of the evaluation process -Number of annual LDKTs among AA patients	Transplant center administrative records
Reach	The proportion of the intended patient population that participates in the study	-Proportion of eligible participants who were recruited into the study	Transplant center administrative records
Dose received	The extent to which participants actively engage with the website	-Participant satisfaction with the website	Immediate follow-up survey
Fidelity	The extent to which the intervention was implemented as planned	-Number of times video starts/stops per person -Duration of time spent on website	Website usage statistics
Recruitment	Procedures used to approach and attract participants	-Proportion of screened individuals who consent to participation -Reasons for ineligibility	Study records & Transplant center records

Transplant center administrative records. Because of their role in the recruitment process, the transplant coordinators will be able to easily get information on aspects of the environment that may have influenced delivery of the intervention as well as data on the proportion of eligible participant who could have been recruited into the study. These data will be collected retrospectively at the end of data collection at each transplant center by examining patient medical records and scheduling information.

Immediate follow-up survey of participants. The immediate follow-up survey will include a measure of satisfaction with the website to inform our understanding of the "dose received" as part of the process evaluation. This 10 item measure will include four items that ask participants to rate their satisfaction with the video (in terms of its quality, informative nature, length, and trustworthiness), four items that rate the website more generally (in terms of the ease at which one can find and understand information, visual appeal, and trustworthiness), and two general questions about recommending the website to others and an opportunity to provide general comments. Questions 1-8 will be used generate an overall satisfaction score that may be examined in relationship to other outcomes measured on the immediate follow-up measure.

Website usage statistics. Our process evaluation will be informed by data collected via Google Analytics, which is a platform for measuring attributes of website usage[74], and "Record it!", which is an application used

to record and monitor website usage. There is a broad array of variables we can use to assess use of the intervention website such as average time spent on each page, number of starts/stops of the video, and use of the social media functions (e.g., to e-mail friends/family). Google Analytics data will be used to assess grouplevel website usage (i.e. videos most watched, modules that participants spent the most time exploring, etc.). "Record it!" data, however, will provide individual-level website usage data in the form of video recordings of each participant's website activity. Study staff will review each video and code participant website activity according to a pre-established code book. These individual reports will provide data that can then be linked to individual-level questionnaire data so that we can perform exploratory data analyses to determine whether individuals in the intervention condition who used certain functions of the website (e.g., e-mailing friends/family) also demonstrate greater change in the secondary outcomes (e.g., knowledge).

Study records. We will use a screening eligibility form to determine eligibility for participation in the study across all sites. One form will be used for each potential participant. All screening questions will be asked of all participants even if the response to an earlier question disqualifies a patient from participation so that we can collect accurate data on reasons for ineligibility.

D. Data Handling and Record Keeping

Human Subjects / Institutional Review Board Approval. The study will be conducted in a manner that protects the rights of all human participants. Moreover, each aspect of the study will only be implemented once the proper Institutional Authorization Agreements have been approved by Emory University and each site's Institutional Review Board (Emory, Piedmont, Augusta, and Medical University of South Carolina).

Confidentiality. Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Specifically, all data collected through this project will be kept in password-protected files on a passwordprotected server and/or in a locked office in a personnel only accessible location at each study site with access only to the Principal Investigators and project staff. Only information that has been generalized and/or deidentified will be shared.

Subjects will be informed that participation in any part of this research study may result in a loss of privacy, since persons other than the investigators may view their study records if deemed necessary for oversight purposes. However; they will be identified by a unique identification number ("study number"), not by name, and any other identifying information (e.g. personal and/or contact information) will be kept separate from the other data; all information will be kept in secure, password-protected files. Personal information will be encrypted and linked to the study number. Further, subjects will be told that unless required by law, only the study investigators, members of the project staff, and representatives of the Emory University and local Institutional Review Boards will have the authority to review any study records. In such case, they too will be required to maintain confidentiality.

Potential harm (Risks and Benefits).

Benefits: Participants could potentially benefit from this study by learning more about the benefits of living donor kidney transplantation through the educational intervention.

Risks: The consent process will ensure that all patients are aware that participation is voluntary. Patients will be told specifically what information will be obtained from their charts. Patients will be told that there is no potential for risks of injury or bodily harm by participating in the study. A breach of confidentiality is possible; however, all of the patient records will be stored in a password-protected file on a password-protected computer on campus.

Conflict of Interest

Any investigator who has a conflict of interest with this study will have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan. All Emory investigators will follow the University conflict of interest policy.

Publication Plan

The results of this study may also be used for teaching, publications, further IRB-approved research and/or presentations at scientific meetings. If individual results are discussed, the identity of the subject(s) will be protected.

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