

## Transplantation

### A Randomized Trial of a Home-Based Educational Approach to Increase Live Donor Kidney Transplantation: Effects in Blacks and Whites

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**Background:** Blacks are disproportionately affected by chronic kidney disease, but are far less likely to undergo live donor kidney transplantation (LDKT) than whites. We assessed the differential effectiveness in blacks and whites of a home-based (HB) LDKT educational approach.

**Study Design:** A planned secondary analysis of a previously published randomized trial.

**Setting & Participants:** 132 patients (60 black, 72 white) approved for kidney transplantation at 1 kidney transplant center in the southeastern United States.

**Intervention:** Assignment to receive either standard clinic-based (CB) transplant education (n = 69) or CB plus an HB (CB + HB) LDKT education program (n = 63). The HB education program was culturally sensitive for blacks, including using a minority health educator, brochures that highlight minority transplant recipients and donors, and discussion of race-specific outcome data.

**Outcomes:** Primary outcomes were proportions of patients with live donor inquiries, evaluations, and transplants 1 year after study participation.

**Measurements:** Medical record and questionnaire data.

**Results:** 69 patients were assigned to the CB group, and 63 to the CB + HB group. After 1 year, there were 96 living donor inquiries (72.7%), 62 living donor evaluations (47.0%), and 54 LDKTs (40.9%). Patients assigned to the CB + HB group were more likely to have had living donor inquiries (odds ratio [OR], 1.7; confidence interval [CI], 1.2 to 3.0), a living donor evaluated (OR, 2.7; CI, 1.4 to 5.4), and LDKT (OR, 3.0; CI, 1.5 to 5.9). The effect was greater in blacks than whites for living donor evaluations and LDKT, but not for living donor inquiries (treatment-by-race interaction,  $P < 0.001$ ,  $P < 0.001$ , and  $P = 0.8$ , respectively). Blacks in the CB + HB group were more likely to have had at least 1 living donor inquiry (51.7% versus 77.4%), at least 1 living donor evaluated (17.2% versus 48.4%), and LDKT (13.8% versus 45.2%) than those in the CB group. By comparison, whites in the CB + HB group were more likely to have had at least 1 living donor inquiry (72.5% versus 87.5%), at least 1 living donor evaluated (47.5% versus 71.9%), and LDKT (42.5% versus 59.4%) than those in the CB group.

**Limitations:** Single-center study with greater dropout rate in the CB + HB group.

**Conclusions:** These results suggest that a culturally sensitive LDKT education program that reaches out to blacks and their social support network can overcome some barriers to LDKT in this population.

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**INDEX WORDS:** Randomized trial; kidney transplantation; living donation.

#### Editorial, p. 542

**B**lacks are disproportionately affected by chronic kidney disease. The overall rate of new end-stage renal disease cases is 4 times greater in this population compared with whites<sup>1</sup>

and likely caused by the greater incidence of diabetes and hypertension.<sup>2-4</sup> Blacks also develop end-stage renal disease at an earlier age than whites (56 versus 62 years).<sup>1</sup> Unfortunately, black adults, particularly men, tend to be referred late to nephrologists for care of chronic kidney disease, and this appears to be an independent predictor of early mortality.<sup>5</sup>

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For patients with end-stage renal disease, kidney transplantation confers a longer life span, improved quality of life, and less health care expenditure than dialysis therapy.<sup>6-10</sup> Live donor kidney transplantation (LDKT) is an important consideration in this context because one can preempt dialysis therapy and increase the likelihood of longer graft survival.<sup>11</sup> Despite these transplantation advantages, blacks are less likely to recognize its potential benefits,<sup>12-16</sup> are referred later for transplantation,<sup>17</sup> and are more likely to have initiated dialysis therapy by the time they are referred.<sup>18</sup> When evaluated and approved for transplantation, they have longer waiting times and are far less likely to undergo LDKT.<sup>19</sup>

In 2006, a total of 22% and 46% of blacks and whites who underwent transplant surgery underwent LDKTs, respectively.<sup>19</sup> This racial disparity, in which blacks are half as likely to benefit from LDKT, has several important consequences. Blacks have fewer opportunities to obtain deceased donor kidneys with compatible or matching tissue types. Consequently, about 30% of all deaths on the waiting list are blacks.<sup>19</sup> The waiting time for blacks is considerably longer, thus potentially causing longer periods of dialysis therapy, poorer quality of life, and greater health care costs. For many black adults who undergo deceased donor transplantation, there is a greater likelihood of receiving kidneys that are less well matched, are from expanded criteria donors, and have greater potential for rejection and graft loss.<sup>19</sup>

Recently, Waterman et al<sup>20</sup> highlighted the potential limitations of the clinic-based (CB) model of LDKT education. Providing LDKT education during a routine transplantation clinic visit can be limited by time constraints, exclusive reliance on patients to retain LDKT information and disseminate it to others, and lack of cultural sensitivity. In a randomized clinical trial, we showed that a home-based (HB) educational program that involved the patient's family members and friends led to more live donor inquiries, donor evaluations, and LDKTs than an educational program delivered in the transplant clinic.<sup>21</sup> The purpose of the present study is to conduct an a priori secondary analysis of the differential impact of this HB LDKT education on blacks who were enrolled in the study. We hypothesized

that an HB program would have a greater impact on LDKT rates for blacks (versus whites) because of their low baseline rates (13%) at the study site.

## METHODS

### Study Sample and Recruitment

Adult patients listed for kidney transplantation at Shands Hospital at the University of Florida were recruited for participation by approaching them in the waiting room immediately before a scheduled transplant clinic visit. Inclusion criteria were written informed consent, medical approval for transplantation, black or white race, at least 21 years old, primary residence within 90 miles of the transplantation center, and telephone service. Patients who were illiterate or non-English speaking were excluded. The University of Florida Institutional Review Board approved all study procedures.

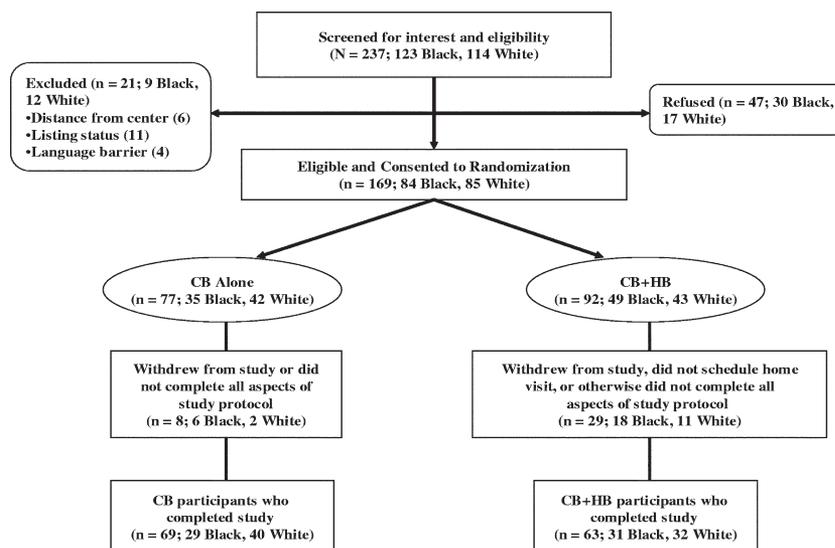
### Study Design and Interventions

Using an urn (stratified) randomization strategy,<sup>22</sup> patients were randomly assigned to 1 of 2 educational intervention groups. We stratified by race to balance the 2 groups because nearly half the patients at this center are black and we wanted to ensure good racial representation in both groups.

In the first group, CB education alone, the transplant surgeon and/or nephrologist talked to the patient about LDKT during a routine clinic visit. Patients also were seen by a transplant coordinator and physician assistant and attended a 60-minute education session with other transplant patients. Family members who accompanied the patient to the clinic were also invited to participate in the group. This session was led by one of the transplant nurse coordinators and included information about kidney transplantation, wait list management, medications, financial issues, transplantation hospitalization, long-term recovery issues, and LDKT. Patients also received written materials about LDKT and living donation.

In the second group, CB + HB education, patients received the transplant education described previously. In addition, these patients received a home visit by transplant health educators, who met with the patient and his or her invited guests (ie, immediate and extended family members, friends, coworkers, and so on) to discuss LDKT and living kidney donation. The home visit lasted 60 to 90 minutes and was highly interactive (eg, "roundtable" format). Those in attendance watched a brief 15-minute videotape on living kidney donation and also received written materials about LDKT and living donation.

Four transplant health educators received extensive education and training in kidney disease, dialysis, transplantation, and living donation, as well as crisis management and the protection of human research participants. One educator was white and 3 were minorities (1 black, 1 Asian, and 1 mixed race). In most instances, home visits were conducted by 2 health educators, with at least 1 minority health educator participating in each home visit involving a black patient.



**Figure 1.** Recruitment and participation rates by group and race. Abbreviations: CB, clinic-based education; CB + HB, CB + home-based education.

Occasionally, largely because of scheduling issues, home visits were done by only 1 health educator. Home visits varied in how they were conducted based on the number of participants, types of questions, and home environment. However, the content was standardized such that the health educators completed an intervention checklist on site to ensure that all required content had been delivered.

For black patients, a culturally sensitive educational approach was used. Specifically, we used a minority health educator and written brochures that highlighted minority transplant recipients and their living donors, and we integrated race-specific data into the discussion (eg, unique living donation and transplant concerns of blacks, specific LDKT rates for blacks, and possible reasons for this).

### Primary and Secondary Outcomes

Primary outcomes were the proportion of enrolled patients in both groups with living donor inquiries, at least 1 potential living donor evaluated, and LDKTs 1 year after study participation. A donor inquiry constituted a verbal or written expression of donation interest on behalf of an enrolled patient. This usually was in the form of a telephone call to our transplant nurse coordinator or completion of a written health history form. A donor evaluation was defined as initiating the first phase of our clinical pathway for the living donor evaluation.

Four secondary outcomes also were evaluated. These included the number of individuals who participated in the education sessions and patients' LDKT knowledge, willingness to talk to others about possible living kidney donation, and concerns about pursuing LDKT.<sup>21</sup> The LDKT knowledge questionnaire comprised 15 true-false statements and yielded a score of 0 to 15, with higher scores reflecting more LDKT knowledge. We asked patients to rate their willingness to talk to others about living kidney donation by using a 7-point rating scale, with higher scores indicating more willingness to discuss. Concerns about pursuing LDKT were measured by using 21 true-false statements, and scores ranged from 0 to 21, with higher scores

reflecting more concern. These measures were administered at baseline, immediately after the CB education for all patients, and after the HB education for patients randomly assigned to the CB + HB group.

### Statistical Analysis

First, descriptive statistics were calculated to summarize sociodemographic characteristics and outcome measures by group and race. Second, using logistic regression analysis, we evaluated the main effects of group assignment and race, as well as the group-assignment-by-race interaction effect for the 3 primary outcomes (donor inquiries, donor evaluations, and LDKTs). Third, change scores were calculated for the secondary variables (LDKT knowledge, concerns, and willingness). Analysis of variance was used to examine for differences in these change scores on the basis of group assignment and race. A 2-sided  $P$  of 0.05 or less was the criterion for statistical significance. All data were entered and analyzed using the Statistical Package for the Social Sciences database (version 14; SPSS Inc, Chicago IL).

## RESULTS

### Patients

Of the 216 patients who met study eligibility criteria and were invited to participate in the study, 169 (78.2%) consented and subsequently were randomly assigned (Fig 1). Thirty-seven patients (21.9%) withdrew from the study after randomization, with greater dropout rates in the CB + HB group ( $n = 29$ ) than in the CB group ( $n = 8$ ;  $\chi = 10.9$ ;  $P < 0.001$ ). Dropout rates were also greater for blacks ( $n = 24$ ) than whites ( $n = 13$ ;  $\chi^2 = 4.4$ ;  $P = 0.03$ ). The a priori secondary analyses that we report here were conducted on the entire sample of 132 patients

**Table 1. Baseline Characteristics by Educational Group and Race**

	Total Sample (N = 132)	Clinic Based		Clinic Based + Home Based	
		Black (n = 29)	White (n = 40)	Black (n = 31)	White (n = 32)
Age (y)	52.1 ± 12.1	56.8 ± 12.6	51.0 ± 10.6	53.6 ± 11.9	47.9 ± 12.4
Women	64 (48.5)	15 (51.7)	20 (50.0)	18 (58.1)	11 (34.4)
Married	76 (57.6)	15 (51.7)	27 (67.5)	16 (51.6)	18 (56.3)
Education ≥ 12 y	93 (70.5)	21 (72.4)	32 (80.0)	17 (54.8)	23 (71.9)
Employed	36 (27.3)	8 (27.6)	12 (30.0)	7 (22.6)	9 (28.1)
Dialysis	95 (72.0)	24 (82.8)	24 (60.0)	25 (80.6)	22 (68.8)
Dialysis time (mo)	22.5 ± 18.3	21.7 ± 21.2	19.3 ± 15.0	26.0 ± 19.4	22.8 ± 17.4
Prior kidney transplant	17 (12.9)	5 (17.2)	2 (5.0)	5 (16.1)	5 (15.6)

Note: Values expressed as mean ± SD or number (percent).

(69 in the CB group, 63 in the CB + HB group) who participated in our previously published randomized clinical trial.<sup>21</sup>

Table 1 lists baseline sociodemographic characteristics of the sample, divided according to group and race. Mean age of the entire sample was 52 ± 12 years, and there were similar proportions of men and women. The majority were married (57.6%), not working (72.7%), on dialysis therapy (72.0%), and had at least a high school education (70.5%). Forty-six percent of the sample was black, with good representation in both the CB (n = 29; 42%) and CB + HB (n = 31; 49%) groups. Seventeen patients (12.9%) had undergone kidney transplantation previously. The 2 groups (CB and CB + HB) did not differ significantly for any sociodemographic or medical variable at baseline. Black and white patients did not differ significantly in terms of sex, marital status, working status, education, or prior transplant. However, black patients were significantly older (55.1 versus 49.6 years,  $t = 2.66$ ;  $P = 0.01$ ) and more likely to be on dialysis therapy (81.7% versus 63.9%;  $P < 0.03$ ). There was no race difference in how long patients had been on dialysis therapy ( $P = 0.4$ ). Three black (5%) and 6 white (8.3%) patients received a

deceased donor kidney transplant by study closure ( $P = 0.5$ ).

### Primary Outcomes

Table 2 lists absolute numbers (and proportions) of patients with living donor inquiries, evaluations, and LDKTs by group and race. Regression analyses showed significant main effects for group and race for all 3 primary outcomes. Patients assigned to the CB + HB group were more likely to have had living donor inquiries (odds ratio [OR], 1.7; confidence interval [CI], 1.2 to 3.0), a living donor evaluated (OR, 2.7; CI, 1.4 to 5.4), and LDKT (OR, 3.0; CI, 1.5 to 5.9). White patients were more likely to have had living donor inquiries (OR, 2.4; CI, 1.2 to 4.7), a living donor evaluated (OR, 1.9; CI, 1.1 to 3.5), and LDKT (OR, 2.0; CI, 1.3 to 4.0).

Regression analyses also showed a significant group-by-race interaction effect for living donor evaluations ( $P < 0.001$ ) and LDKT ( $P < 0.001$ ), but not for living donor inquiries ( $P = 0.8$ ). Both black and white patients assigned to the CB + HB group were more likely to have someone evaluated as a potential living donor than their counterparts in the CB group (blacks, 48.4% versus 17.2%; whites, 71.9% versus 47.5%), although the proportional

**Table 2. Number of Patients With Living Donor Inquiries, Evaluations, and Transplants by Educational Group and Race**

	Total Sample (N = 132)	Clinic Based		Clinic Based + Home Based	
		Black (n = 29)	White (n = 40)	Black (n = 31)	White (n = 32)
Living donor inquiries	96 (72.7)	15 (51.7)	29 (72.5)	24 (77.4)	28 (87.5)
Living donor evaluations	62 (47.0)	5 (17.2)	19 (47.5)	15 (48.4)	23 (71.9)
Live donor kidney transplantations	54 (40.9)	4 (13.8)	19 (42.5)	14 (45.2)	19 (59.4)

Note: Values expressed as number (percent).

**Table 3. LDKT Knowledge, Willingness to Discuss LDKT With Others, and LDKT Concerns by Educational Group and Race**

Measure	Group	Baseline (T <sub>1</sub> )		Post CB (T <sub>2</sub> )		Post HB (T <sub>3</sub> )	
		Black	White	Black	White	Black	White
LDKT knowledge*	CB	8.5 ± 2.2	9.0 ± 2.1	9.8 ± 2.1	10.7 ± 2.5		
	CB + HB	8.5 ± 1.7	9.0 ± 1.7	9.5 ± 1.8	11.3 ± 2.4	12.9 ± 1.6	13.5 ± 1.1
Willingness to talk†	CB	3.1 ± 1.9	4.7 ± 1.6	3.4 ± 1.8	4.7 ± 1.5		
	CB + HB	3.3 ± 1.8	4.3 ± 1.6	3.1 ± 1.6	4.3 ± 1.3	6.0 ± 1.0	6.3 ± 0.8
LDKT concerns‡	CB	9.8 ± 4.0	9.9 ± 3.6	9.8 ± 4.1	9.9 ± 3.3		
	CB + HB	9.7 ± 2.4	8.9 ± 4.8	9.3 ± 2.9	8.8 ± 4.2	6.8 ± 2.3	6.3 ± 3.5

Abbreviations: LDKT, live donor kidney transplantation; CB, clinic based; HB, home based.

\*Possible scores range from 0 to 15, with higher scores indicating more knowledge.

†Possible scores range from 1 to 7, with higher scores indicating more willingness to talk to others about LDKT.

‡Possible scores range from 0 to 21, with higher scores indicating more concerns about pursuing LDKT.

difference between the 2 groups was greater for blacks. Blacks and whites were more likely to undergo LDKT if they were assigned to the CB + HB group versus the CB group (45.2% versus 13.8% and 59.4% versus 42.5%, respectively).

### Secondary Outcomes

As expected, more potential donors participated in the CB + HB education than the CB education (5.4 versus 1.0;  $P < 0.001$ ). However, there was no race main effect ( $P = 0.2$ ) or group-by-race interaction effect ( $P = 0.2$ ).

Table 3 lists LDKT knowledge, willingness to discuss LDKT with others, and LDKT concerns by group and race. There was a significant group effect for knowledge ( $F = 13.2$ ;  $P < 0.001$ ), willingness ( $F = 96.4$ ;  $P < 0.001$ ), and concerns ( $F = 30.3$ ;  $P < 0.001$ ). Relative to those in the CB group, patients in the CB + HB group showed more improvement in knowledge (+1.5 versus +2.8) and willingness (+0.2 versus +2.4) and a greater alleviation of concerns (−0.1 versus −2.5). There was a significant race effect for willingness ( $F = 6.1$ ;  $P = 0.02$ ), with blacks showing more change in willingness to talk to others about LDKT than whites (+1.6 versus +0.9). No group-by-race interaction effects were found for any of the secondary outcomes.

### DISCUSSION

Blacks are more likely to have chronic disease states that benefit from LDKT, but are far less likely to undergo this procedure relative to whites. The consequences of this disparity are clinically significant, with longer waiting times and greater mortality on the kidney transplant waiting list for

blacks. A number of reasons for this racial disparity in LDKT were posited, including a smaller pool of potential living donors (ie, because of greater rates of hypertension, obesity, and diabetes in blacks), less knowledge and more concerns about LDKT, greater indirect costs for potential living donors, and possible secondary gains associated with dialysis therapy in blacks.<sup>23-26</sup> However, our study highlights that a novel LDKT educational program can overcome some of these obstacles and help decrease the racial disparity that exists in transplantation.

Our findings support the effectiveness of an HB LDKT educational program and further exemplify its benefits with black patients in particular. The proportion of black patients in this group with at least 1 donor evaluation and subsequent LDKT was considerably greater than for blacks in the CB group and as high as baseline rates for white patients. LDKT rates in blacks averaged 13% in the 3 years preceding study implementation. With an HB educational program, LDKT was realized for 45% of blacks.

There are several possible explanations why the CB + HB education was particularly effective for black patients. Clearly, black patients had the most to gain from this intervention in light of their considerably lower baseline rate of LDKT (13%). However, there are other factors that may have had an important role with this population. For example, during the home visit with black patients, health educators emphasized the racial disparity in LDKT. Monet et al<sup>27</sup> previously showed that LDKT education specifically addressing racial disparity can significantly impact both the willingness of patients to pursue

this option and actual LDKT rates. We did not focus on racial disparities during the CB education session with patients; therefore, perhaps its inclusion in the HB sessions was particularly beneficial for this population. Open discussions about such disparities in transplantation have proved to be a critical component of public education efforts targeting increases in deceased organ donation among minorities.<sup>28-31</sup> Integrating similar race-based messages into LDKT and living donation education may be an important ingredient in the success of such educational efforts with minority patients.

In a way that could not be replicated in a clinic setting, we provided patients with the opportunity to involve family members, friends, and significant others in a discussion about their transplantation options and living donation. For black patients, the “roundtable” format seemed to jumpstart the LDKT discussion and increase their willingness to continue this dialogue beyond the health educators’ visit to the home. Perhaps the change in willingness to discuss LDKT with others was more pronounced in blacks because they now could see first-hand that their family members and friends were receptive to this type of dialogue. As we noted previously,<sup>21</sup> in many instances, family members had already approached patients about LDKT, but were turned away by patients who had concerns about pursuing this option. We simply may have helped the patient by removing some of the burden and anxiety they felt in initiating this dialogue with others and by addressing some of their specific concerns.

Moreover, this was the first opportunity for most family members to interact with representatives from the transplantation center. Learning more about the patient’s health condition, transplantation options, and LDKT benefits, as well as live donor eligibility, evaluation, and outcomes, may have led some family members who were already considering living donation to more actively pursue it. Even if not an eligible living donor, some family members reported feeling more empowered to discuss living donation with extended family members or others within the family’s social network. Going to the patient’s home and openly discussing racial disparity issues in transplantation may have attenuated feelings of distrust and bias about the transplant

community within this black patient population.<sup>32</sup> Our findings support those of Ayanian et al,<sup>33</sup> who found that when black patients were well informed of their transplantation options and associated benefits, they preferred transplantation at the same rate as whites. Collectively, our findings suggest that culturally sensitive LDKT discussions between patients, family members, and the transplantation team are critically important for increasing awareness of LDKT, reducing fears and concerns about LDKT, and enhancing patient access to LDKT.<sup>32</sup> An HB educational program is one venue for such discussions in the black community.

It should be emphasized that the HB education also was beneficial for many white patients, who were more likely to have a living donor evaluated and to have undergone LDKT in this group than if receiving only the CB education. Also, white patients who received HB LDKT education had a 21% greater rate of donor inquiries than those who received the clinic education only, although this was not statistically significant. The more prominent effect of the CB + HB group in blacks should not obscure the potential benefits of this approach with nonminority patients.

This study is not without limitations; the most significant is the high dropout rate among blacks. We did not solicit information about why patients dropped out of the study, although we can speculate that ambivalence about pursuing LDKT and socioeconomic status had major roles. It was our impression that some patients with low willingness to pursue LDKT agreed to be part of the study in hopes of being randomly assigned to the CB group. When confronted with the prospect of inviting family members and friends into their home to meet with transplant health educators, some patients assigned to the CB + HB group may have chosen to passively withdraw from the study by not scheduling the home visit. A few patients withdrew from the study because of their living circumstances. Our transplantation center reaches into rural regions of northern Florida, where there are particularly high levels of poverty, especially among blacks. A few patients told us they had reservations about health educators visiting them in their homes. In 2 instances, we were able to arrange for the “home visit” to occur in a neighboring church, but such

alternative arrangements were not always possible. In addition, we should emphasize that this was a single-center study and self-selection biases are inherent to this type of study. It certainly is possible that patients with at least some interest in pursuing LDKT were the ones who agreed to participate in the study.

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