Predictors and Moderators of Educational Interventions to Increase the Likelihood of Potential Living Donors for Black Patients Awaiting Kidney Transplantation

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Abstract

Our aim was to identify predictors and moderators of the effects of a House Calls (HC) educational intervention, relative to a Group-Based (GB) intervention and to Individual Counseling (IC), in a randomized controlled trial to increase the likelihood of having living donor (LD) evaluations initiated and live donor kidney transplantation (LDKT). Black adults wait-listed for kidney transplantation (N=152) were randomized into one of the three educational conditions. We examined demographic, clinical, psychosocial, and socio-contextual baseline characteristics as predictors and moderators of having a potential LD initiate evaluation. HC assignment $(OR=_{2.02}4.73_{11.05}, P=0.001)$, younger age $(OR=_{0.91}0.94_{0.98}, P=0.001)$, more willingness to discuss donation with others $(OR=_{1.08}1.37_{1.75}, P=0.01)$, and larger social network $(OR=_{1.01}1.09_{1.18}, P=0.04)$ were significant multivariable predictors of having 1 LD initiate evaluation. Age (P=0.03) and social network size (P=0.02) moderated the effect of HC relative to IC and GB, but not GB relative to IC, on LD evaluation initiation. Our findings suggest that HC is most effective for patients <60 years old and those with average or large social network size.

Keywords

kidney transplantation; living donation; live donor kidney transplant; education; moderators

Compliance with Ethical Standards: Ethical Approval: All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

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Conflict of Interest: All authors have declared that they have no conflicts of interest to disclose.

Introduction

Developing effective educational interventions that remove barriers to live donor kidney transplantation (LDKT) is a pressing need within the transplant community [1]. In most kidney transplant programs, patients are educated about the relative benefits of LDKT and encouraged to identify and talk to potential living donors (LDs) in their family and social networks. However, this standard educational approach has some important limitations, including insufficient time discussing patient-specific concerns about LDKT, inability to reach directly into the patient's existing social network, highly variable efforts to make educational content culturally relevant, and reliance on the patient to deliver highly complex information to potential LDs [2-5]. Consequently, more comprehensive educational strategies have been developed with the overarching goal of removing barriers to LDKT, including the use of patient education groups, LD champions, patient navigators, multifaceted exploration of transplant options, and direct engagement with the patient's social network [6-11].

To overcome some of the limitations of a clinic-based educational model, we developed a House Calls (HC) intervention in which trained transplant health educators deliver a LDKT and living donation educational program to the patient and his/her invited guests (e.g., family members, friends, co-workers, etc.) in the patient's home [5]. In two separate randomized controlled trials, House Calls proved effective at increasing the likelihood of having a potential LD initiate evaluation and receiving a LDKT [12-14]. In the most recent trial [14], we added a Group-Based (GB) educational intervention to address concerns about the intensive nature (e.g., personnel, time, and cost) of the HC intervention. The Group-Based intervention was designed to mirror what some transplant programs already do, i.e., invite patients and members of their social network to an LDKT educational session in the transplant center [6]. Both House Calls and Group-Based interventions, therefore, attempt to reach the patient and his/her social network. We compared the two interventions to each other and to Individual Counseling (IC) focused on LDKT in a large sample of black waitlisted patients, the racial group with the lowest LDKT rate and the sharpest decline in LDKT over the last decade [15,16]. We found that House Calls patients were more likely than Group-Based and Individual Counseling patients to have 1 LD inquiry and 1 potential LD initiate testing. While the LDKT rate was higher for House Calls patients (15%) than for Group-Based (8%) and Individual Counseling (6%) patients, this difference was not statistically significant (p=0.30) and, therefore, not the focus of examination in the present analysis.

To date, we have not investigated predictive factors and moderators of the effects of the House Calls intervention. Therefore, the present study examines predictors and moderators in the context of this most recent effectiveness trial with black transplant candidates. We were interested in identifying the types of patients who are more or less responsive to House Calls, which may help transplant programs determine whether to invest in this type of LDKT educational approach for certain patients. Also, if we were to find no moderators for House Calls relative to Group-Based or Individual Counseling, it would suggest that the main effect for House Calls applies to a wide variety of patients, thus suggesting that it could be implemented more broadly. Therefore, in our present analysis we examined the relationship

of one significant study outcome (occurrence of 1 potential LD initiate testing) with baseline demographic, clinical, psychosocial, and socio-contextual variables.

Methods

Participants

The study sample comprised adult kidney transplant candidates who participated in a randomized controlled trial (RCT) evaluating the effectiveness of LDKT educational approaches at a single transplant center in the northeastern United States [5]. Inclusion criteria were: (1) black race, (2) eligible for kidney transplantation, (3) 21 years old, and (4) living within 2½ hour drive of the medical center. Patients were introduced to the study via letter and subsequently approached in the outpatient transplant clinic. If interested in study participation, patients were screened for eligibility and completed written informed consent. Study participants completed a baseline questionnaire assessment and then were randomized (using the urn randomization strategy)[5,17,18] to one of three conditions as noted below.

Interventions

All patients received LDKT education as part of their usual care in the transplant center, which is described elsewhere [5]. In brief, usual care included informal discussions with transplant providers, printed materials about LDKT and living donation, and referral to our transplant center website.

Patients consenting to be in the study were allocated to receive a single, transplant health educator-led 60 to 90 minute educational session comprising culturally-relevant content focused on LDKT and living donation and supplemented with video and print materials. The educational intervention was delivered in one of three randomized conditions: (1) House Calls (HC) session – education delivered to the patient and his/her invited guests (family members, friends, coworkers, etc.) in the patient's home; (2) Group-Based (GB) session – education delivered to groups of patients and their invited guests in the transplant center; and (3) Individual Counseling (IC) session – education delivered to the patient alone in the transplant center. In all three conditions, trained transplant health educators covered 22 LDKT and living donation topics focused on transplant patient and living donor (LD) eligibility, evaluation processes, outcomes, and racial disparities, concerns of patients and potential LDs, financial concerns and resources, and kidney paired donation, among others topics. Guests (House Calls and Group-Based conditions) were not enrolled into the study and did not complete any questionnaires other than a brief education satisfaction form. Patients and guests were paid \$10 for attending the intervention session. Additional elements of study design, questionnaire development, transplant educator training, and distinguishing features of the interventions have been described elsewhere [5,14]. All study procedures were approved by the Committee on Clinical Investigations at Beth Israel Deaconess Medical Center (Protocol #2007P-000223).

Outcome Measure

While the primary outcome of the trial was to increase the likelihood of LDKT occurrence, the groups did not differ significantly from each other on this variable. Thus, we chose to focus our current analysis on the secondary outcome of LD evaluation occurrence. Specifically, we recorded the occurrence (yes-no) of 1 adult who initiated evaluation as a potential LD on behalf of the study patient within two years of the study intervention. This outcome was operationalized as completion of health screening with the donor nurse coordinator and laboratory testing for compatibility.

Baseline Measures

Demographics—We abstracted patient age, sex, highest educational attainment, marital status, and employment status from medical records and asked patients to confirm these data during baseline assessments. All participants self-identified as black race.

Clinical characteristics—We gathered information from medical records to ascertain the patient's dialysis status (yes-no), history of prior kidney transplant (yes-no), and number of months on the transplant waiting list. Also, patients completed the SF-36 Health Survey [19], a self-report measure of health-related quality of life that yields two component scores for physical and mental quality of life.

Psychosocial variables—Four psychosocial variables pertinent to LDKT were measured using self-report questionnaires developed in prior studies: LDKT knowledge (16 true-false questions, higher scores = more knowledge), LDKT concerns (21 Likert-type questions, higher scores = more concerns), willingness to talk to others about living donation (1 item, 1= not at all willing, 7 = extremely willing), and LDKT readiness [5,12]. Regarding LDKT readiness, patients indicated their stage of thinking about this treatment option: Precontemplation ("I am not thinking about or considering LDKT"), Contemplation ("I am now beginning to think about or consider LDKT"), Preparation ("I have thought about LDKT and I have talked to someone who is willing to be evaluated as a possible living donor"), and Maintenance ("I have thought about LDKT and I have someone who has initiated evaluation to be a living donor"). For the present analysis, we dichotomized patients into those who were in Pre-contemplation versus all other stages.

Socio-contextual factors—The patient's annual household income was self-reported using six categories, although we dichotomized it for our purposes here as <\$40,000 versus all higher amounts. Also, patients were asked to estimate the number of family members, friends, co-workers, and others who could be invited to House Calls or Group-Based intervention session if randomized to one of those two conditions. We used this as a proxy measure of social network size.

Statistical Analyses

Descriptive analyses were conducted to summarize all variables. Because we had one time point for the criterion variable, we used logistic regression for the primary analyses. Simple logistic regression was used to examine associations between each baseline variable and LD

evaluation occurrence. Odds ratios with 95% confidence intervals and P values were calculated using Wald chi square tests. Variables associated with LD evaluation occurrence at P<0.10 level were then included in a multivariable backward stepwise logistic regression model. Variables that did not improve the model's accuracy (i.e., Wald chi square P>0.05) were eliminated from the model.

We then examined how interactions ($P_{interaction} < 0.05$) between intervention condition and significant predictor variables affected LD evaluation occurrence in the logistic regression models. In Step 1 we entered intervention condition, in Step 2 we entered the significant predictor variable, and in Step 3 we entered the interaction term (intervention condition \times predictor variable). Given a significant interaction, we first identified the specific intervention conditions (House Calls vs. Individual Counseling, Group-Based vs. Individual Counseling, House Calls vs. Group-Based) to which the moderation effect applied by testing post hoc interactions involving pairwise contrasts between the intervention conditions. This analysis was repeated for each baseline characteristic found to be significant in the simple regression analysis to check for moderation. All data were entered and analyzed using the Statistical Package for the Social Sciences (SPSS, Version 19; Chicago, IL).

Results

Sample Characteristics

One hundred fifty-two patients were randomized, with 145 (95%) receiving the allocated intervention. Death, removal from the waiting list, and patient withdrawal from the study accounted for 7 patients not receiving the assigned intervention. Also, we were unable to obtain or confirm final LDKT outcome for 3 patients who received the allocated intervention but who transferred care to other programs. The three intervention groups did not differ significantly on baseline demographic, clinical, psychosocial, or socio-contextual characteristics (all P values >0.05). Baseline characteristics for the entire sample are summarized in Table 1. Mean age was 51.3 years and the majority of patients were male, had some college education, not married, unemployed, and receiving dialysis. Mean time on the transplant waiting list was 16.9 months. Approximately half (53%) had an annual household income <\$40,000. Regarding the outcome of interest in the present analysis, 67 patients (44%) had at least one potential LD initiate evaluation.

Intervention Effects

As previously reported [14], patients who received House Calls (65%) were significantly more likely than Group-Based (39%) or Individual Counseling (27%) patients to have at least one potential LD initiate evaluation (P<0.001), while Group-Based and Individual Counseling patients did not differ significantly from each other (P=0.19). There was no statistically significant group difference on LDKT occurrence (P=0.30).

While the social network size did not differ significantly between House Calls and Group-Based patients $(9.63 \pm 3.77 \text{ vs.} 9.04 \pm 5.43, p = 0.52)$, House Calls patients had more guests attend the session (mean: 7.9, range: 2 to 24, total: 419) than did Group-Based patients (mean: 2.3, range: 0 to 10, total: 107) (p < 0.001). Also, a significantly higher percentage of

the patient's social network attended the educational session in the House Calls group compared to the Group-Based group (28.0% vs. 77.7%, p < 0.001). For 9 (17%) House Calls patients, compared to none in the Group-Based group, the number of guests who attended the session exceeded the patient's pre-intervention estimation of social network size.

Predictors of LD Evaluation

In the simple logistic regression model, 9 variables predicted the occurrence of 1 potential LD initiate testing (Table 2a). After backward stepwise logistic regression, House Calls assignment, younger age, more willingness to discuss living donation with others, and larger social network were retained as significant predictors in the multivariable model (Table 2b).

Moderation Analyses

Table 3 shows the results of Moderator × Condition interaction effects on the occurrence of LD evaluation within two years following intervention. We found significant Moderator × Condition interactions for age (Wald=4.01, P=0.03) and social network size (Wald=6.40, P=0.02). Age moderated the effect of House Calls relative to Individual Counseling and Group-Based, but not Group-Based relative to Individual Counseling. House Calls resulted in higher likelihood of LD evaluation occurrence than Individual Counseling in younger (P=0.017) and middle-aged (P=0.005) patients (Figure 1a). House Calls also resulted in higher likelihood of LD evaluation occurrence than Group-Based in middle-aged patients (P=0.045). House Calls did not differ from Individual Counseling or Group-Based for older patients (P=0.13), and Group-Based did not differ from Individual Counseling at younger, middle-aged or older age levels (P values>0.40).

Social network size moderated the effect of House Calls relative to Individual Counseling and Group-Based, but not Group-Based relative to Individual Counseling. To examine this interaction we compared House Calls and the other two conditions at small (–1 sd), average, and large (+1 sd) social network size. House Calls resulted in higher likelihood of LD evaluation occurrence than both Individual Counseling and Group-Based in patients with average social network size (P=0.001 and P=0.016, respectively) and in comparison to Individual Counseling in patients with large social network size (P=0.03) (Figure 1b). Group-Based did not differ from Individual Counseling at small, average, or large social network sizes (P values>0.31).

Discussion

The aim of this study was to identify factors that predict LD evaluation occurrence as well as moderate the effects of LDKT educational interventions in a randomized control trial of black wait-listed kidney transplant candidates. We examined five demographic (age, sex, education, marital status, employment), five clinical (dialysis status, prior transplant, transplant waiting time, physical and mental quality of life), four psychosocial (LDKT knowledge, concerns, and readiness, willingness to discussion living donation with others), and two socio-contextual (annual household income, social network size) predictors and moderators. We extend prior literature by examining moderators in the context of an effectiveness trial and comparing three LDKT educational interventions together.

This study elucidates baseline characteristics associated with having one or more potential LDs initiate evaluation on behalf of black patients on the kidney transplant waiting list. Prior studies have largely neglected such predictors, so these findings represent a novel contribution to the literature. Certain demographic (younger age) and socio-contextual (larger social network) variables portend having more people from which to find someone who is willing to undergo evaluation as a potential donor; thus, it is not surprising that these characteristics are predictive of having 1 potential LD initiate evaluation. Perhaps more interesting is the finding that higher willingness to talk to others about donation is a significant predictor of LD evaluation occurrence in the multivariable model. This suggests that transplant providers should do more to identify the barriers to discussing donation with others and to target this modifiable attitude in educational interventions. It has been repeatedly shown that many patients find it difficult to ask others about living donation [4,8,20-26]. Part of this discomfort may be because patients lack sufficient knowledge to appropriately answer some of the questions that family members or friends might have about donation. Also, communication of donor eligibility criteria, medical and surgical risks, the evaluation process, recovery processes, and other complex information, for instance, requires a high level of health literacy and numeracy and some patients may feel overwhelmed by the complexity of the donation process. An educational process that simultaneously reaches the patient and his/her social network directly may facilitate the delivery of accurate (and complex) information and jump-start the donation conversation between the patient and potential donors.

We found two moderation effects involving the House Calls condition. First, House Calls resulted in higher likelihood of LD evaluation than the Individual Counseling condition in younger and middle-aged patients and those with average to large social networks. Second, House Calls resulted in higher likelihood of LD evaluation occurrence than did the Group-Based intervention for middle-aged patients and those with social networks of average size. When the goal is to increase the likelihood of having a potential LD step forward for evaluation, House Calls appears to be particularly beneficial for patients <60 years old who have an average social network size.

Both House Calls and Group-Based interventions are most effective for patients with large social networks. It is reasonable to think that patients with larger social networks would have an easier time convincing some family members and friends to attend an LDKT educational session. However, House Calls exerts superiority over Group-Based when the social network size ranges from 5 to 13 identified individuals. One interpretation of these findings is that the convenience of House Calls, the familiarity of the venue, and the comfort in knowing that familiar others will be there may lead to a larger proportion of family members and friends attending the House Calls educational session, compared to the Group-Based condition at the transplant center [5]. Social network members in the Group-Based condition may not be comfortable attending a session with strangers (i.e., other patients and their guests). In contrast, in a traditional House Calls session, all (or most) know each other and, therefore, may be more likely to attend and to actively participate in the session. Our data seem to support this hypothesis as a much larger percentage of the social network attended the educational session for patients assigned to the House Calls (78%), compared to the Group-Based (28%), intervention.

For transplant programs that may consider using it in the future, it is important to recognize that House Calls may not yield any higher likelihood of a potential LD initiating evaluation for older patients or for those with particularly small social networks. Although patients >60 years old increasingly comprise a larger percentage of the kidney transplant waiting list, their LDKT rates continue to be very low relative to younger patients [16,27]. Social networks tend to contract as people age and older patients, therefore, may simply have fewer potential eligible donors available to them. Also, relative to younger patients, older patients are more likely to have same-aged peers (e.g., siblings, spouses, other relatives) with health conditions that exclude them from living donation (e.g., borderline to low eGFR, hypertension, cardiac abnormalities, etc.). Conducting a House Calls or Group-Based educational session for patients who have 4 family members or friends appears to be no better than providing them with individual education in the transplant center. Fewer family members and friends may mean fewer potential LDs, more limited reach of the LDKT and LD educational content, and less active discussion of common concerns and questions that typically emerge in sessions with more participants. From a time and cost efficiency perspective, it may be best to consider conducting House Calls with those patients who have at least 5 identified social network members who can be invited to attend the session.

We did not find evidence of moderating effects for the many other variables we examined. This is particularly noteworthy for the House Calls intervention, which was found to be more effective than Group-Based and Individual Counseling in the RCT. The pattern of findings in the current analysis suggests that, with the exceptions noted above, the House Calls effects likely apply to a wide range of patient demographic, clinical, psychosocial, and socio-contextual characteristics. This could reflect the fact that transplant health educators conducting the House Calls intervention were able to adapt the session to the individual characteristics of each patient and/or the educational format allowed for maximum flexibility to ensure highest relevance to the patient and his/her guests.

Study findings should be evaluated in the context of several important limitations. First, only black patients participated in the clinical trial upon which these findings are based. It is unknown whether similar results would be found for a more racially and ethnically diverse group of patients. Second, there are other factors that may be highly relevant in predicting the occurrence of a LD evaluation that were not examined in this study. These include geographic distance separating the patient from their primary social network and other psychosocial factors (e.g., mental health history). Also, we did not gather information about why individuals (patients, family members, friends, etc.) chose to pursue or to not pursue LDKT and living kidney donation. Third, despite the reasonable number of study patients with at least one potential LD who initiated evaluation, only a small number of patients received a LDKT and this precluded the study of predictors and potential moderators for this criterion variable. This is an inherent problem for black patients in particular [15,16,28-30], which was the catalyst for studying LDKT education in this minority population. Fourth, the social network size used in the present analysis is a proxy measure and may not be representative of the patient's true network size. Additionally, there are other social factors that may impact interest in both LDKT and living donation but that were not measured, including housing quality and stability, environmental health conditions, and violent crime rates. Fifth, most of the moderators we examined were derived from self-report

questionnaires and self-presentation biases may have affected patients' responses to these measures. Finally, our analysis focused on only the interventions implemented in the RCT. We recognize that there are other strategies to educate the patient's social network about LDKT and living donation. For instance, as use of mobile applications becomes increasingly common for patients, there may be a role for electronic social networking (e.g., Facebook, mobile apps, etc.) for both the patient and his/her social network [31].

In conclusion, the House Calls educational intervention has been shown to be effective at increasing LD evaluation occurrence. The present study offers additional analysis indicating that its effects for this particular outcome are moderated by age and the size of the patient's social network. Further study is necessary to extend and replicate these study findings in a more diverse patient population. Also, more research is needed to examine the degree to which strategies that reach the patient and his/her social network lead to actual attenuation of racial disparities in LDKT rates.

Acknowledgments

Funding: The project described is supported by Award Number R01DK079665 from the National Institute of Diabetes and Digestive and Kidney Diseases (JRR). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Diabetes and Digestive and Kidney Diseases or the National Institutes of Health. This research was also supported, in part, by the Julie Henry Research Fund and the Center for Transplant Outcomes and Quality Improvement, The Transplant Institute, Beth Israel Deaconess Medical Center, Boston, MA.

We are thankful for the data collection and entry assistance, consultation, and collaborative efforts we received from several individuals, including Timothy Antonellis, Tracy Brann, Ogo Egbuna, Ariel Hodara, Richard McCartney, Colleen Morse, Matthew Paek, Stacey Senat, Hongying Tang, Denny Tsai, and Amy Waterman.

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Abbreviations

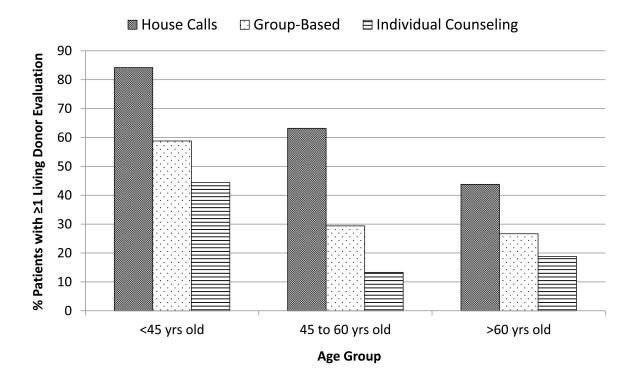
LD Living donor

HC House Calls

GB Group-Based

IC Individual Counseling

а



b

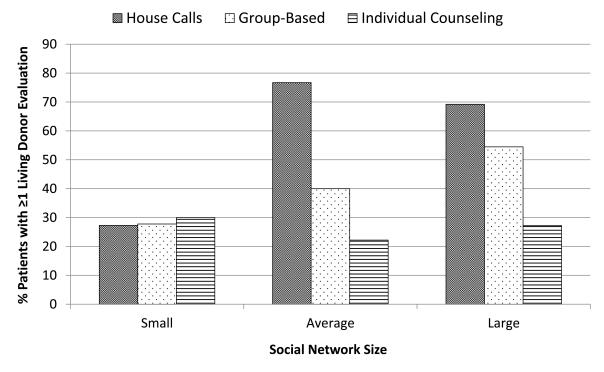


Figure 1.

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 $\label{eq:Table 1} \label{eq:Table 1} Table 1 \\ Demographic, clinical, psychosocial, and socio-contextual characteristics of study participants (N = 152)$

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Characteristic	Mean (sd) or N (%)
Demographic	
Age, years ^a	51.3 (12.3)
Sex, female	65 (43)
Education, college	90 (59)
Marital status, married or partnered	60 (40)
Occupational status, working	54 (36)
Clinical	
Dialysis, yes	126 (83)
Previous kidney transplant, yes	16 (11)
Transplant waiting time, mos. ^a	16.9 (25.1)
SF-36 Physical Component Summary ^a	38.1 (10.5)
SF-36 Mental Component Summary ^a	48.3 (11.5)
Psychosocial	
LDKT knowledge a^{\dagger}	12.2 (1.9)
LDKT concerns a#	34.8 (8.9)
Willingness to discuss donation a^{g}	5.1 (1.9)
LDKT readiness, Pre-contemplation	43 (28)
Socio-contextual	
Annual household income >\$40,000	72 (47)
No. of identified social network members ^a	9.1 (4.8)
Outcomes	
1 living donor evaluated, yes	67 (44)
LDKT, yes	15 (10)

 $[^]a\!\!$ Continuous variable; all others without designation are categorical variables;

 $^{^{\}dagger}$ Score range 0 to 16; higher score = more knowledge;

[#]score range 21 to 105; higher score = more concerns;

^{¶&}lt;sub>1=not</sub> at all willing, 7=extremely willing

Table 2 Effects of demographic, clinical, psychosocial, and socio-contextual characteristics on living donor evaluation occurrence within two years of educational intervention: simple (a) and multivariable (b) logistic regression models

(a) Simple logistic regression model

	Living Donor Evaluated		
Independent Variables	OR	P value	
Intervention			
House Calls	1.89 3.80 $_{7.65}$	0.001	
Group-Based	$0.360.73_{1.45}$	0.36	
Baseline Characteristics			
<u>Demographic</u>			
Age, years	0.92 0.95 0.98	0.001	
Female	$0.561.07_{2.05}$	0.83	
College education	1.312.595.11	0.01	
Married or partnered	$0.691.33_{2.56}$	0.39	
Employed	$0.220.43_{0.85}$	0.02	
<u>Clinical</u>			
Dialysis	$0.140.35_{0.84}$	0.02	
Months on waiting list	$0.991.00_{1.02}$	0.32	
Prior kidney transplant	$0.611.84_{5.59}$	0.28	
SF-36 Physical	$0.981.02_{1.05}$	0.35	
SF-36 Mental	$0.970.99_{1.02}$	0.68	
Psychosocial			
LDKT knowledge	$_{1.03}1.18_{1.35}$	0.02	
LDKT concerns	$0.950.98_{1.02}$	0.33	
Willingness to discuss donation with others	$_{1.08}1.31_{1.58}$	0.01	
LDKT readiness stage	$0.821.70_{3.54}$	0.15	
Socio-contextual			
Household income \$50,000	$1.052.04_{3.98}$	0.04	
No. social network members	$_{1.02}1.09_{1.17}$	0.02	
(b) Multivariable logistic regression model			
	Living Donor Evaluated		
Predictors	OR	P value	
House Calls	2.024.7311.05	0.001	
Λαρ	0.040.00	0.001	

	Living Donor Evaluated		
Predictors	OR	P value	
House Calls	2.024.7311.05	0.001	
Age	$0.910.94_{0.98}$	0.001	
Willingness to discuss donation with others	1.081.371.75	0.01	

(a) Simple logistic regression model

	Living Donor	Living Donor Evaluated	
Independent Variables	OR	P value	
No. social network members	1.011.091.18	0.04	
Logistic regression adjusted r ²	0.43	0.43	

 $\textbf{Table 3}\\ \textbf{Moderator} \times \textbf{Condition effects on likelihood of living donor evaluation occurrence within two years of educational intervention}$

	Living Donor Evaluation Occurrence		
	Wald Statistic	P value	
Age	4.01	0.03	
Education	2.01	0.37	
Employment	1.17	0.56	
Dialysis status	0.82	0.67	
LDKT knowledge	1.29	0.53	
Willingness to discuss donation	0.76	0.68	
Annual household income	0.35	0.84	
Social network size	6.40	0.02	