

Home-Based Family Intervention Increases Knowledge, Communication and Living Donation Rates: A Randomized Controlled Trial

S. Y. Ismail^{1,*}, A. E. Luchtenburg²,
R. Timman^{1,3}, W. C. Zuidema², C. Boonstra³,
W. Weimar², J. J. V. Busschbach^{1,3} and
E. K. Massey²

¹Department of Psychiatry, Medical Psychology and Psychotherapy, Erasmus MC, Rotterdam, the Netherlands

²Department of Internal Medicine, Nephrology and Transplantation, Erasmus MC, Rotterdam, the Netherlands

³Netherlands Institute for Personality Disorders, De Viersprong, Halsteren, the Netherlands

*Corresponding author: Sohal Y. Ismail, s.ismail@erasmusmc.nl

Our aim was to develop and test an educational program to support well-informed decision making among patients and their social network regarding living donor kidney transplantation (LDKT). One hundred sixty-three patients who were unable to find a living donor were randomized to standard care or standard care plus home-based education. In the education condition, patients and members of their social network participated in home-based educational meetings and discussed renal replacement therapy options. Patients and invitees completed pre-post self-report questionnaires measuring knowledge, risk perception, communication, self-efficacy and subjective norm. LDKT activities were observed for 6 months postintervention. Patients in the experimental group showed significantly more improvements in knowledge ($p < 0.001$) and communication ($p = 0.012$) compared with the control group. The invitees showed pre-post increases in knowledge ($p < 0.001$), attitude toward discussing renal replacement therapies ($p = 0.020$), attitude toward donating a kidney ($p = 0.023$) and willingness to donate a kidney ($p = 0.039$) and a decrease in risk perception ($p = 0.003$). Finally, there were significantly more inquiries (29/39 vs. 13/41, $p < 0.001$), evaluations (25/39 vs. 7/41, $p < 0.001$) and actual LDKTs (17/39 vs. 4/41, $p = 0.003$) in the experimental group compared with the control group. Home-based family education supports well-informed decision making and promotes access to LDKT.

Keywords: Counseling, ethnicity, family communication, living kidney donation, patient support program

Abbreviations: DDKT, deceased donor kidney transplantation; LDKT, living donor kidney transplantation; MST, multisystemic therapy; R3K-T, Rotterdam Renal Replacement Knowledge-Test

Received 25 November 2013, revised 03 March 2014 and accepted for publication 21 March 2014

Introduction

The superior outcomes for living donor kidney transplantation (LDKT) compared with deceased donor kidney transplantation (DDKT) as a treatment for renal end-stage disease are now well-established (1). However, as found in other countries (2,3), there is inequality in access to LDKT among ethnic minorities in the Netherlands (4). Several studies have reported on factors contributing to access to LDKT. A number of unmodifiable factors such as medical, socioeconomic and ethnic factors have shown to be independently related to the chance of receiving an LDKT (5–7). A number of modifiable factors, such as knowledge, attitudes, risk perception, communication and cultural sensitivity, are also independently related to the chance of receiving an LDKT (8–11). A recent paper explored which of the modifiable cognitive and psychosocial factors are associated with LDKT while controlling for unmodifiable socio-demographic factors (12). Knowledge on kidney disease and renal replacement therapies among patients and discussing LDKT with significant others were suggested to be potential targets for interventions to promote access to LDKT.

In North America, differences in uptake of LDKT between ethnic groups have been reported (13). This health care inequality, for ethnic minorities and individuals who find it hard to discuss living donation, needs to be addressed (14). In response, a home-based intervention has been developed (15). The results showed superior effects for the home-based education compared with standard hospital-education in terms of higher knowledge, more communication with others regarding LDKT and fewer concerns toward LDKT (15). Additionally, there was a significant increase in the number of living donor inquiries, living donor evaluations and LDKTs performed in the home-based education group. The “house-calls” approach was even

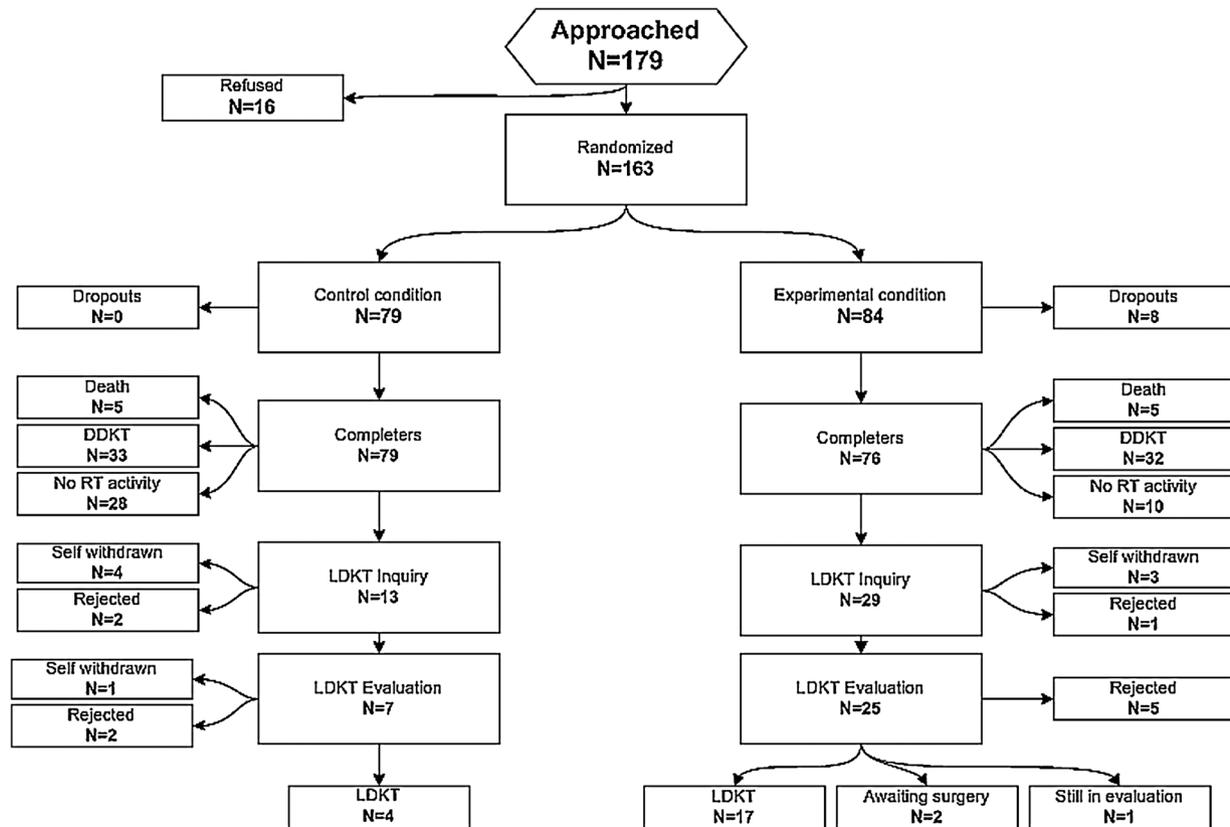


Figure 1: A flowchart of the randomized controlled trial on the Kidney Team at Home Study. DDKT, deceased donor kidney transplantation; LDKT, living donor kidney transplantation; RT, renal transplantation.

more beneficial for black patients in the number of donor evaluations and LDKTs compared with white patients (16). This additional effort to increase LDKT rates is needed since a recent paper points toward a decline in living kidney donations in North America (17). In the current study, we adapted the home-based group education approach to the Dutch situation and investigated the efficacy of our program in a randomized controlled trial. Unique to the present study is the investigation of the impact of the intervention on members of the social network and the inclusion of only patients who were yet unable to find a living donor. The objective of the program was to support well-informed, shared decision making regarding renal replacement therapy and to promote access to LDKT among patients of both Western and non-Western descent who remained on the deceased donor waiting list.

Materials and Methods

Participants

Between March 2011 and March 2013, 179 patients with end-stage renal disease who were unable to find a living donor were invited to participate in

the “Kidney Team at Home” study. Eligible candidates were either newly referred for transplant preparation or already listed for DDKT from both Western and non-Western descent. Eligible candidates were required to be ≥ 18 years and medically (e.g. no hospital admission) and mentally fit (e.g. no mental deterioration). Of the eligible patients, 16 refused to participate. These patients reported that individuals from their social network would not appreciate the home-based intervention. The remaining 163 patients all signed an informed consent form. A total of 440 family members, friends and acquaintances were present during the home-based educational meetings, of which 246 participated in the study. These participants were also required to be ≥ 18 years, medically and mentally fit and to have signed an informed consent form. See also Figure 1 (flowchart).

Procedure

In this randomized controlled trial (18), all patients were invited to participate by the home educators after at least two consultations with one of the transplant nephrologists. During the face-to-face informational consultation with the home educator, the patients received written and verbal information on the aims and procedures of the study. In line with the equity principle, all the study materials (e.g. patient information forms, questionnaires) were available in the eight most common languages in the Rotterdam municipality, namely Dutch, English, Arabic, Turkish, Papiamentu, Spanish, Portuguese and Modern Hindi. All patients were approached for participation after they received the standard educational care. After informed consent was obtained, patients were randomized to either the control or the experimental group (see details below). Urn randomization was carried out

Table 1: The topic list for the home-based intervention

Introduction	The purpose of the Kidney Team at Home Study
Kidney disease Dialysis	An introduction to kidneys and kidney diseases The various forms of dialysis Morbidity and mortality associated with dialysis The psychosocial consequences of a kidney disease and dialysis The advantages and disadvantages of dialysis compared to kidney transplantation
Transplantation	The medical evaluation in preparation for donor nephrectomy and kidney transplantation The various programs of donation and transplantation (DDKT and LDKT) The number of DDKT and LDKT performed nationally and locally The differences in ethnicity regarding access to LDKT The differences in graft survival between DDKT and LDKT
LDKT	Additional advantages and disadvantages of LDKT The risks and psychosocial aspects associated with donor nephrectomy The personal, emotional and financial aspects of LDKT for the recipient
Discussions	Whether present individuals have considered donation of their kidney

via an adaptive biased-coin algorithm by another researcher. When needed, independent interpreters were used for patients and/or members of the social network during the intervention. The home educators (a medical psychologist and a transplant coordinator) were trained in the general aspects of kidney disease, renal replacement therapies, multisystem therapy and supervised by a multisystem therapy supervisor throughout the study period. Ethical approval was provided by the Medical Ethical Committee of the Erasmus Medical Center. The trial is registered in the Netherlands Trial Register: NTR2730.

The control group received standard care. In the standard care, all newly registered patients visiting our pretransplantation outpatient clinic receive consultations with a transplant nephrologist, a transplant coordinator and a social worker. After that all patients receive a yearly check-up with the nephrologist or a nurse practitioner. In addition to verbal information, patients receive a variety of written educational material and a DVD regarding the various living donation and transplantation programs (e.g. national exchange).

The experimental group received standard care plus a home-based educational intervention. The intervention consisted of two sessions at the patient's home. During the first visit (approximately 1 h), the family network of the patients was depicted on a sociogram by the educators in order to familiarize themselves with the family structure and to recognize the values of that particular social system. At the end of the first session, the educators helped the patient to make a list of individuals who they were going to invite for the second session. The goal of the second session (approximately 2.5 h) was to provide information and support communication; therefore, it was not necessary that all the invitees were potential donors (see Table 1 for the topic list). The educators also explored the possibilities of LDKT within the patients' social network. The process of the intervention was based on principles and communication techniques drawn from multisystemic therapy (MST) (19). The educators stimulated an open communication between the patient and the family members and used the strengths and possibilities of the natural network of the patient. The objective of MST is to achieve a lasting consensus on the patient's goals and how these goals can be reached with engagement and/or support of his/her social ecology. The second session was organized in such a way that the educators had to do "whatever it takes," in line with one of the basic principles of MST, to achieve that lasting consensus on the various renal replacement therapies. Thus, in some cases multiple sessions were offered/requested in order to assist patients and invitees to receive all the information and/or to support communication (18).

Measurements

All the study participants completed a preintervention and a postintervention (4-week-period) self-report questionnaire. The first self-report was completed right after randomization and the second within 1–3 days after the intervention. The primary outcome measures were derived from the Attitude-Social Influence-Efficacy model (20): knowledge, risk perception (fears and concerns), self-efficacy, attitude toward communication, communication on renal replacement therapies, subjective norm and willingness to accept LDKT/donate. Knowledge was assessed with the reliable and validated Rotterdam Renal Replacement Knowledge-Test (R3K-T) (21). The other variables were assessed using statements. The statements were rated on a Likert scale using five to seven response categories (22). A more detailed description of the development of the statements and examples of the questionnaire per variable can be found elsewhere (18). The secondary outcome measure was access to LDKT, operationalized by measuring three times-to-event of LDKT activities separately (living donor inquiries, evaluations and actual LDKTs) between the experimental and control group up to 9 months after the last patient was included. Patients were registered as having an inquiry if one or more potential donors expressed the desire/will to donate a kidney at the pretransplant clinic. Similarly, patients were registered as having an evaluation if one or more potential donors underwent the medical screening for donation. These data were obtained from the medical records. Background characteristics were also retrieved from medical records (see Table 2). At the end of the educational session, each patient and participating invitees received a 12-item evaluation form to appraise the content and the process of the intervention they received. Additionally, an administrative person who was not directly involved in the study performed an independent 15-item evaluation by telephone. Both evaluations were formulated as statements that could be rated on a 5-point Likert scale (1—very unsatisfied to 5—very satisfied) regarding the professionalism, communication skills and availability of the educators and the extent to which the intervention goals were achieved. Only a score of 5 on each item is regarded as protocol adherent and all other scores are regarded as not adherent. The adherence scores range from 0 to 1 with a score of 1 representing adherence.

Sample size calculation

To determine an adequate sample size for detecting the effect, we did a power analysis based on the primary outcomes found in previous research (15,16). The knowledge parameter shows a large effect size that would result in a very low sample size, whereas self-efficacy would require a larger sample size. Thus, to determine sample size, we used the variable with the lowest effect size. The required sample sizes to achieve a nominal power of $1 - \gamma = 0.8$ on a two-sided test with a $\alpha = 0.05$ using a Fisher

Table 2: Sociodemographic characteristics

Characteristics	Control (N = 79)	Experimental (N = 84)	p-Value
Gender (male/female)	47/32	46/38	0.542
Mean age in years (SD)	54.5 (13.5)	54.9 (13.0)	0.828
Married or living together (%)	47 (59.5)	49 (58.3)	0.256
Western/non-Western	40/39	32/52	0.076
Dutch (%)	38 (48.1)	27 (32.1)	
Antillean (%)	13 (16.5)	16 (19.0)	
Moroccan (%)	7 (8.9)	10 (11.9)	
Turkish (%)	4 (5.1)	11 (13.1)	
Cape Verdean (%)	1 (1.3)	6 (7.1)	
Asian (%)	9 (11.4)	6 (7.1)	
Other (%)	7 (8.9)	8 (9.5)	
Educational level (%) ¹			0.190
Low	25.3	35.7	
Average	43.0	32.1	
High	8.9	13.1	
Employment (full or part time %)	11 (13.9)	9 (10.7)	0.548
Dialysis modality (%)			0.351
No dialysis	10 (12.7)	10 (11.9)	
PD	17 (21.6)	15 (17.9)	
HD	52 (65.9)	59 (70.3)	
Mean months on dialysis (SD)	26.1 (19.5)	26.5 (20.2)	0.806
A history of RT (%)	27 (34.2)	20 (23.8)	0.416
History of LDKT (%)	9 (11.4)	9 (10.7)	0.643
PRA maximum >10% (%)	20 (25.3)	18 (21.4)	0.891
Blood type (%)			0.935
O	40 (50.6)	46 (54.8)	
A	23 (29.1)	22 (26.2)	
B	13 (16.5)	14 (16.7)	
AB	3 (3.8)	2 (2.4)	

HD, hemodialysis; LDKT, living donor kidney transplantation; PD, peritoneal dialysis; PRA, panel-reactive antibody; RT, renal transplantation. Values in the table are presented as n with the percentage in parentheses or mean values with \pm SD in parentheses.

¹The educational level was valued at three levels: low—elementary school; average—high school (+some college); high—college degree (+some postgraduate/professional degree).

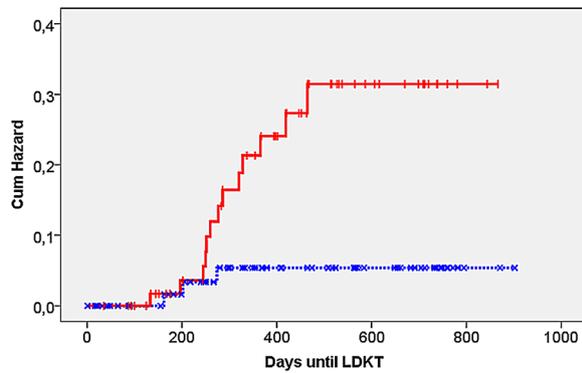
distribution revealed that at least 78 patients are required per study group to enable statistical judgments that are accurate and reliable.

Data analyses

All patients randomized were included in the analyses in accordance with the intention-to-treat principle. Pearson's chi-squared distribution analyses and univariate analyses of variance were conducted to explore differences on the baseline characteristics of the participants between the two study conditions. The efficacy of our home-based educational intervention for the primary outcome variables was analyzed with mixed modeling, which was used for longitudinal analyses of the data. Mixed modeling can efficiently handle data with missing and unbalanced time points. It corrects for bias when absence of data is dependent on covariates that are included in the models (covariate-dependent dropout); however, other causes of dropout not associated with the covariates remain potentially present (23). Our model consisted of two levels: The patients constituted one level and the repeated measures the other level. First, for each outcome variable a saturated model was postulated, with the primary outcomes as dependent variables. The saturated models included treatment group, time, all covariates (see Table 2), all treatment-time and treatment-covariate interactions as fixed effects and analyzed with the backward method. Using Wald tests, the saturated fixed part of the models was reduced by eliminating nonsignificant fixed effects, respecting that interaction effects must be nested under their main effects (24). The significance of the

difference between the saturated models and the parsimonious final models was determined with the deviance statistic using ordinary maximum likelihood. The residuals of the model were checked to be normally distributed, a necessary assumption for a correctly fitted mixed model. Finally, effect sizes were calculated from dividing differences between time-point estimations and baseline by the estimated baseline standard deviation. Cohen's definition was used for the interpretation of the effects sizes: An effect size of 0.20 is considered a small effect, 0.50 a medium effect and 0.80 a large effect (25).

The secondary outcome (time to an inquiry, an evaluation and an actual LDKT) was analyzed with three Kaplan-Meier survival analyses to examine differences between experimental groups. Next, semi-parametric regression analyses were carried out using Cox Proportional Hazard Model to examine the hazard ratio comparing the experimental to control group on the three secondary outcome variables. This model enriches the analysis by incorporating covariates (Table 2 plus all primary outcomes) in a backward fashion in the regression equation. All analyses were completed for each of the three secondary outcomes separately (LDKT inquiries, LDKT evaluations and actual LDKT). The event in the three analyses was defined as the occurrence of one of the three LDKT pursuit behaviors. Patients who were lost to follow-up were regarded as censored at their last contact and patients who continued dialysis were regarded as censored at the end of the study. DDKT is modeled as a competing event and therefore patients who received this treatment were censored at date of DDKT. Also, a time-to-event graph



Number of patients at risk:

Days	0	100	200	300	400	500	600	700	800
Experimental group:	84	77	66	55	41	29	20	15	5
Control group:	79	68	63	48	39	32	23	18	2

Figure 2: A time-to-event cumulative hazard plot for the living donor kidney transplantation (LDKT) rates comparing the experimental (solid line) and control (dashed line) groups. This graph depicts the cumulative hazard plot time-to-event data for the LDKT rates for the separate study groups of a randomized controlled trial on a home-based educational intervention. Experimental group received a home-based education and the control group received the standard hospital-based education.

was generated for only the actual LDKT rates since this was regarded as the most essential outcome compared to the inquiries and evaluations (Figure 2). Additionally, actual numbers and proportion on the secondary outcomes were reported (Figure 1).

Results

The only difference in socio-demographics between participants and nonparticipants (8.9%) is that the later group is significantly older (years = 77.8, SD = 4.3). Of the 163 patients who were included in the trial, 84 were randomized to the experimental group and 79 to the control group. No significant differences were found between the two study groups at baseline on the sociodemographical variables (see Table 2). The dropout rate in the experimental group was 8/84 compared with 0/79 in the control group ($p=0.004$). The majority of the dropouts (75%) left the study after the first home visit. The reasons for dropout were either that patients were unable to find individuals in their social network to be present during the educational session or that patients received a DDKT before receiving the educational session (2/8). The mean number of visits was 2.2 with a maximum of 5 (SD = 0.69). On average 5.0 invitees attended the educational session (SD = 3.4) for the second educational session. The 246 invitees were on average 39.4 (SD = 14.6) years old; the majority was female (55.7%), Western (58.3%), had completed high school (+some college) (39%), were never screened for LDKT before (79.7%) and the majority were either the partner (21%), the child (29.1%) or the sibling (17.7%) of the patient.

Primary outcomes

Inspecting the data for missingness prior to analyses showed that less than 1% of the primary outcome measures was found missing.

Patients: There was a significantly greater increase in knowledge in the experimental group than in the control group. Non-Western participants started at a lower level and had a larger gain from the treatment, although they did not catch up completely with their Western counterparts (Table 3). Men demonstrated a medium decrease in perception of risks associated with living donation, but there was no change among women. The treatment resulted in a small increase in the frequency of communication on renal replacement therapies. No significant changes were found for self-efficacy, attitude toward communication about LDKT, subjective norm and willingness to accept LDKT.

Invitees: Invitees with a Western background scored significantly higher on knowledge than invitees with a non-Western background on the pre- and post-measurements. Both Western and non-Western invitees showed equally large improvements in their knowledge. Men scored 1.5 lower on knowledge than women ($p=0.011$, not in table). Invitees also had a small but significant increase in their self-efficacy to discuss renal replacement therapies with the patient, positive attitude toward donating a kidney and intention to donate a kidney to the patient, and a decrease in risk perception. No differences between the pre-post measurement were found on the frequency of communication about renal replacement therapies and their subjective norm. Table 3 shows the scores of the different primary outcome measures between the two study groups for patients and invitees.

Secondary outcomes

Intention-to-treat analysis showed significantly more inquiries for LDKT in the experimental group compared with the control group (HR: 3.3, 95% CI: 1.86–5.89), more evaluations (HR: 4.7, 95% CI: 2.07–10.67) and more LDKTs (HR: 5.3, 95% CI: 1.53–17.84). Log-rank tests showed, respectively: $\chi^2_{(1)} = 21.97$: $p < 0.001$; $\chi^2_{(1)} = 16.56$: $p < 0.001$; $\chi^2_{(1)} = 8.72$: $p = 0.003$. Figure 2 shows the event times for the actual LDKTs. As described above, after randomization, 76/84 patients of the experimental group completed the intervention. The death rate was 5 in both study groups, of which the majority were men (7/10) and above the age of 48 (range: 27–77). The number of patients who received a DDKT in the study period was not significantly different between the experimental (32/71) and control (33/74) conditions. Discounting these patients and those who died during the study period, 39 remained in the experimental group versus 41 in the control group. For the remaining patients holds that more inquiries for LDKT were registered in the experimental group compared with the control group 29/39 (74.4%) versus 13/41 (31.7%), more evaluations 25/39 (64.1%) versus 7/41 (17.1%) and

Table 3: Estimated means (SEM) and effect sizes between groups of the primary outcomes

Measure (scale range)	Control		Experimental		Effect size (p-value)
	Pre	Post	Pre	Post	
Patients					
Knowledge (1–21)					
Western	14.9 ± 0.6	15.3 ± 0.6	16.3 ± 0.7	18.1 ± 0.8	0.40 (0.053)
Non-Western	11.7 ± 0.6	11.9 ± 0.6	11.2 ± 0.5	14.8 ± 0.5	0.92 (<0.001)
					0.52 (0.043) ¹
Risk perception (14–70)					
Men	31.9 ± 1.4	31.5 ± 1.4	32.6 ± 1.4	27.3 ± 1.4	–0.51 (0.001)
Women	36.2 ± 1.7	35.6 ± 1.7	36.6 ± 1.6	36.9 ± 1.6	0.10 (0.582)
					–0.61 (0.009) ¹
Self-efficacy (3–15)	9.7 ± 0.4	9.6 ± 0.4	10.3 ± 0.5	10.9 ± 0.5	0.22 (0.116)
Attitude toward communication (6–42)	30.6 ± 0.9	30.2 ± 0.7	30.1 ± 1.3	31.3 ± 1.1	0.18 (0.137)
Communication on RRTs (4–20)	8.5 ± 0.4	8.3 ± 0.3	8.6 ± 0.5	9.4 ± 0.4	0.33 (0.012)
Subjective norm (3–21)	15.3 ± 0.4	15.4 ± 0.4	16.3 ± 0.6	16.5 ± 0.5	–0.07 (0.671)
Willingness to accept LDKT (2–14)	8.3 ± 0.4	8.6 ± 0.3	9.7 ± 0.5	9.7 ± 0.4	–0.09 (0.408)
Invitees					
Knowledge (1–21)					
Western	–	–	12.4 ± 0.5	18.5 ± 0.6	1.42 (<0.001)
Non-Western	–	–	9.7 ± 0.5	15.8 ± 0.5	1.42 (<0.001)
Risk perception (14–70)	–	–	33.7 ± 0.7	30.6 ± 0.8	–0.40 (0.001)
Self-efficacy (3–15)	–	–	10.8 ± 0.3	11.5 ± 0.4	0.33 (0.010)
Attitude toward communication (6–42)	–	–	29.9 ± 0.9	33.3 ± 1.4	0.25 (0.006)
Communication on RRTs (4–20)	–	–	8.1 ± 0.6	8.6 ± 0.5	0.12 (0.187)
Subjective norm (2–14)	–	–	10.3 ± 0.3	10.8 ± 0.5	0.21 (0.080)
Attitude toward LDKT (6–42)	–	–	28.7 ± 1.0	32.2 ± 1.5	0.25 (0.003)
Willingness to give LDKT (2–14)	–	–	8.8 ± 0.5	9.8 ± 0.5	0.24 (0.027)

LDKT, living donor kidney transplantation; RRTs, renal replacement therapies.

Values in the table are presented as mean estimates of fixed effects with standard error means (±SEM) obtained from the different mixed models. The last column shows the difference in effect size of the pre–post measurement between the study groups.

¹Significant difference between subgroups.

more LDKTs 17/39 (43.6%) versus 4/41 (9.8%). None of the eight dropouts received an LDKT, although three had a donor inquiry of which one resulted in LDKT evaluation by the end of the follow-up period.

Of the patients who received a living donation inquiry 12/29 have not (yet) donated in the experimental group. This proportion of “lost potential donors” is higher in the control group, 9/13. Of these donor evaluation procedures, 7/15 in the experimental group and 4/9 in the control group were terminated based on medical contra-indications (e.g. diabetes, obesity). The other reasons were social; for example, the potential donor experienced ambivalence regarding the donation, or the patient changed his mind about receiving a kidney from his/her child.

Patients who had a donor who underwent the medical screening for donation showed a main effect of risk perception on the event times till evaluation. Significantly lower scores in perception of risks associated with living donation were related to significantly earlier commencement of donor screening compared to average scores on the risk perception (HR: 1.56, 95% CI: 1.09–2.24, $\chi^2_{(1)} = 5.75$; $p = 0.016$). No other main or interaction effects were found for the primary outcomes on the event times of

living donation inquiries, evaluations and actual donation rates.

Intervention evaluation

Overall, patients were very satisfied with the content (81.7%) and the process (77.0%) of the intervention. Professionalism (86.5%) and the communication skills (81.0%) of the educators were rated the highest, whereas the accessibility (57.9%) and the degree in which the goals were achieved (60.3%) scored lower. The lower scores on the accessibility reflected mainly dissatisfaction with the availability of the educators by telephone. Most of the patients who had low ratings regarding achievement of intervention goals reported that they were disappointed that the intervention did not yield a living donor. The intervention was rated approximately the same by the invitees: content (81.9%) and process (88.6%). The figures on dialysis-related mortality and morbidity and the questionnaire were experienced as taxing by the majority of the invitees.

Discussion

This study describes the first application of home-based family education on living donation tailored to a European

population without a (potential) living kidney donor. The home-based educational intervention in this study was shown to be effective in bringing about change in knowledge and communication among patients. These changes support well-informed decision making in favor of living donation, which can be seen in the changes observed in the secondary outcomes: significant increases in LDKT pursuit behaviors in the experimental group compared with the control group.

These findings should be interpreted in light of a number of limitations. A comment should be made with regard to the use of Likert scales in a cross-cultural setting. Research has indicated that response patterns may be affected by culture (26). The reasons given for prematurely ending the treatment (6/84) were related to a limited social network, which suggests that the intervention might be less effective in patients with a limited social network. Yet, these are the particularly hard to reach patients for whom living donation is difficult to realize. Additional data on dropout patients should be collected in future studies in order to specify this group further. Although carefully selected via literature, expert opinions and theory except for knowledge the items measuring the other primary outcomes were not validated. Therefore, it could be that what those concepts are measuring does not completely reflect reality (i.e. dependability is compromised).

Notwithstanding these limitations, dialysis patients and their significant others benefit from an outreaching, patient-centered approach to education on kidney disease and renal replacement therapies. This need for a more active approach has been identified in the literature (27,28). This study is complementary to the earlier study on home-based education (15). The main extension of our intervention is the inclusion of only those patients who have not previously been able to find a living donor. We hold the view that only transplant candidates who do not find a living donor following standard education should receive this home-based intervention. Additionally, the home-based intervention is exceptionally well suited for those patients for whom the standard education/guidance is not accessible (e.g. patients with language or literacy barriers, patients with large (nuclear) families, patients who find it difficult to discuss their treatment options with significant others).

Previous research among Western and non-Western dialysis patients has shown that communication between patients and potential donors plays a role in the access to LDKT (29). In that study, the majority of patients stated that they would not actively approach a potential donor to "ask" for a kidney. Following this, a state of noncommunication on the subject emerges and may be interpreted by patients as a refusal of the potential donors to donate: a state of passive deadlock. The current study highlights the beneficial value of stimulating and supporting the communication and thus the decision-making process between patients and their family and friends (30). This promising change,

together with the increase in knowledge and the decrease in perception of risks associated with living donation, supports the shared decision making for the pursuit of LDKT. Not all primary outcomes explain the higher increase in living donation rates. In line with our theoretical model (Attitude-Social Influence-Efficacy model), the clinical relevance of the statistical differences in these factors (e.g. knowledge, communication) lies mainly in their contribution to a better shared decision making.

This trial took place at the Erasmus Medical Center, Rotterdam, where extensive efforts are made as part of the standard care to promote LDKT (31), including, for example, a national exchange program, ABO-incompatible transplantation and unspecified donation (32). As a result, the rate of living donation in Rotterdam is high (>70% (33)) and the patients included here were those who had very minimal chances of a living donor transplant prior to the intervention. It is therefore likely that the success of this home-based family intervention will even be higher in transplant centers with less intensive promotion of living donation as part of standard care.

The favorable results in the primary and secondary outcomes of this intervention are also reflected in the subjective evaluation of the intervention by patients and their family and friends. One of the concerns with home-based interventions is that they may induce unacceptable pressure on the family/friends to donate a kidney. However, this was not reported either by patients or by individuals from their social network. On the contrary, some patients reported disappointment that the intervention did not result in an LDKT. It is therefore crucial to explicitly formulate the goals of the intervention, which are information provision and communication support, and to manage patients' expectations regarding the outcome. This is also documented as one of the initial conditions in order to implement an ethically justified intervention (34). Yet, patients and invitees seem to appreciate the effort of the educators in the support of the LDKT discussion. Therefore, home-based educators should not be reserved in addressing the possibilities of LDKT with patients and their family and friends. Nonetheless, the discussion of a delicate subject such as LDKT within families should be undertaken in way that is sensitive to the family dynamics and with respect for the ethical conditions for a home-based intervention (35). Information should be honest and complete (35). Intervention techniques drawn from MST were experienced as useful by the educators as they offer communication skills to sensitively address family-specific stressors and to support the discussion regarding LDKT.

In conclusion, current findings support further implementation of this educational program into standard care in an interactive, culturally sensitive, patient-tailored and outreaching way to stimulate an overall increase in the numbers of LDKT.

Acknowledgments

This study is funded by the Netherlands Kidney Foundation.

Disclosure

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation*.

References

- Mahillo B, Carmona M, Alvarez M, White S, Noel L, Matesanz R. 2009 Global data in organ donation and transplantation: Activities, laws, and organization. *Transplantation* 2011; 92: 1069–1074.
- Udayaraj U, Ben-Shlomo Y, Roderick P, et al. Social deprivation, ethnicity, and access to the deceased donor kidney transplant waiting list in England and Wales. *Transplantation* 2010; 90: 279–285.
- Purnell TS, Powe NR, Troll MU, et al. Measuring and explaining racial and ethnic differences in willingness to donate live kidneys in the United States. *Clin Transplant* 2013; 27: 673–683.
- Roodnat JI, van de Wetering J, Zuidema W, et al. Ethnically diverse populations and their participation in living kidney donation programs. *Transplantation* 2010; 89: 1263–1269.
- Roodnat JI, Laging M, Massey EK, et al. Accumulation of unfavorable clinical and socioeconomic factors precludes living donor kidney transplantation. *Transplantation* 2012; 93: 518–523.
- Udayaraj U, Ben-Shlomo Y, Roderick P, et al. Social deprivation, ethnicity, and uptake of living kidney donor transplantation in the United Kingdom. *Transplantation* 2012; 93: 610–616.
- Joshi S, Gaynor JJ, Bayers S, et al. Disparities among Blacks, Hispanics, and Whites in time from starting dialysis to kidney transplant waitlisting. *Transplantation* 2013; 95: 309–318.
- Kucirka LM, Grams ME, Balkara KS, Jaar BG, Segev DL. Disparities in provision of transplant information affect access to kidney transplantation. *Am J Transplant* 2012; 12: 351–357.
- Ismail SY, Claassens L, Luchtenburg AE, et al. Living donor kidney transplantation among ethnic minorities in the Netherlands: A model for breaking the hurdles. *Patient Educ Couns* 2013; 90: 118–124.
- Garonzik-Wang JM, Berger JC, Ros RL, et al. Live donor champion: Finding live kidney donors by separating the advocate from the patient. *Transplantation* 2012; 93: 1147–1150.
- Taylor LA, Bahreman N, Hayat MJ, Hoey F, Rajasekaran G, Segev DL. Living kidney donors and their family caregivers: Developing an evidence-based educational and social support website. *Prog Transplant* 2012; 22: 119–128.
- Ismail SY, Luchtenburg AE, Kal-van Gestel JA, et al. Modifiable factors in access to living-donor kidney transplantation among diverse populations. *Transplantation* 2013; 96: 586–590.
- Danovitch GM, Cohen DJ, Weir MR, et al. Current status of kidney and pancreas transplantation in the United States 1994–2003. *Am J Transplant* 2005; 5: 904–915.
- Waterman AD, Rodrigue JR, Purnell TS, Ladin K, Boulware LE. Addressing racial and ethnic disparities in live donor kidney transplantation: Priorities for research and intervention. *Semin Nephrol* 2010; 30: 90–98.
- Rodrigue JR, Cornell DL, Lin JK, Kaplan B, Howard RJ. Increasing live donor kidney transplantation: A randomized controlled trial of a home-based educational intervention. *Am J Transplant* 2007; 7: 394–401.
- Rodrigue JR, Cornell DL, Kaplan B, Howard RJ. A randomized trial of a home-based educational approach to increase live donor kidney transplantation: Effects in blacks and whites. *Am J Kidney Dis* 2008; 51: 663–670.
- Rodrigue JR, Schold JD, Mandelbrot DA. The decline in living kidney donation in the United States: Random variation or cause for concern? *Transplantation* 2013; 96: 767–773.
- Ismail SY, Luchtenburg AE, Boonstra AC, et al. Multisystemic engagement & nephrology based educational intervention: A randomized controlled trial protocol on the Kidney Team at Home-Study. *BMC Nephrol* 2012; 13: 62–70.
- Henggeler SW. *Delinquency and adolescent psychopathology: A family-ecological systems approach*. Littleton, MA: Wright-PSG, 1982.
- De Vries H, Dijkstra M, Kuhlman P. Self-efficacy the third factor besides attitude and subjective norm as a predictor of behavioural intentions. *Health Educ Res* 1988; 3: 273–282.
- Ismail SY, Timmerman L, Timman R, et al. A psychometric analysis of the Rotterdam Renal Replacement Knowledge-Test (R3K-T) using item response theory. *Transpl Int* 2013; 26: 1164–1172.
- Moors G. Exploring the effect of a middle response category on response style in attitude measurement. *Qual Quant* 2008; 42: 779–794.
- Little RJA, Rubin DB. *Statistical analysis with missing data*. New York: John Wiley and Sons, 1987.
- Hox J. *Multilevel analysis—Techniques and applications*. Mahwah, NJ: Erlbaum, 2002.
- Cohen J. A power primer. *Psychol Bull* 1992; 112: 155–159.
- Lee JW, Jones PS, Mineyama Y, Zhang XE. Cultural differences in responses to a Likert scale. *Res Nurs Health* 2002; 25: 295–306.
- Lunsford SL, Simpson KS, Chavin KD, et al. Racial differences in coping with the need for kidney transplantation and willingness to ask for live organ donation. *Am J Kidney Dis* 2006; 47: 324–331.
- Reese PP, Shea JA, Bloom RD, et al. Predictors of having a potential live donor: A prospective cohort study of kidney transplant candidates. *Am J Transplant* 2009; 9: 2792–2799.
- Kranenburg LW, Zuidema WC, Weimar W, et al. Psychological barriers for living kidney donation: How to inform the potential donors? *Transplantation* 2007; 84: 965–971.
- Dy SM, Purnell TS. Key concepts relevant to quality of complex and shared decision-making in health care: A literature review. *Soc Sci Med* 2012; 74: 582–587.
- Horvat LD, Shariff SZ, Garg AX, Donor Nephrectomy Outcomes Research Network. Global trends in the rates of living kidney donation. *Kidney Int* 2009; 75: 1088–1098.
- Roodnat JI, Kal-van Gestel JA, Zuidema W, et al. Successful expansion of the living donor pool by alternative living donation programs. *Am J Transplant* 2009; 9: 2150–2156.
- Dutch Transplant Foundation. Leiden: Nederlandse Transplantatie Stichting, 2013. Available at: <http://www.transplantatiestichting.nl/webshop/data>. Accessed November 1, 2013.
- Massey EK, Hillhorst MT, Nette RW, et al. Justification for a home-based education programme for kidney patients and their social network prior to initiation of renal replacement therapy. *J Med Ethics* 2011; 37: 677–681.
- Hillhorst MT, Kranenburg LW, Busschbach JJ. Should health care professionals encourage living kidney donation? *Med Health Care Philos* 2007; 10: 81–90.