Randomized controlled trial of a digital intervention (*KidneyTIME*) to promote live donor kidney transplantation

Liise K. Kayler MD MS[1,2], Naoru Koizumi PhD [3], Jing Nie PhD[4], Maria Keller PhD[1,2], Heather Gardiner PhD[1], MPH[4], Jon Von Visger MD PhD[2,5], Renee B. Cadzow PhD[4], Katia Noyes PhD[4], Thomas H. Feeley PhD[6]

Affiliation

[1]Department of Surgery, Jacobs School of Medicine and Biomedical Sciences at the University at Buffalo, Buffalo, NY
[2]Transplant and Kidney Care Regional Center of Excellence, Erie County Medical Center, Buffalo, NY
[3]Schar School of Policy and Government, George Mason University, Fairfax, VA
[4]Department of Epidemiology, School of Public Health & Health Professions, University at Buffalo, State University of New York, Buffalo, NY
[5]Division of Nephrology, Jacobs School of Medicine and Biomedical Sciences at the University at Buffalo, Buffalo, NY
[6]Department of Communication, University at Buffalo, State University of New York, Buffalo, NY

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Trial Design

This was a single-center, individually randomized, parallel group, posttest-only RCT (Figure 1). Using a digital automated system, two active interventions were delivered to kidney transplant candidates at Erie County Medical Center by email or text transmissions of web-based consent documents, surveys, and the interventions over 12 months. Participants were randomly assigned in a race-stratified 1:1 allocation ratio to intervention (*KidneyTIME*) or active control arm.

- Study arm 1 (*KidneyTIME*) remotely delivered prescribed online viewing of a 13-minute LDKT-specific education video followed by email or text reminders to view and share optional web-based videos with more kidney transplant and living donation information (25 videos totaling 55 minutes). Fully described elsewhere[1] the video curriculum includes the roles of patients, donors, and supporters. The webpage was smartphone-optimized and provided anyone with the opportunity to view and share videos.
- Study arm 2 (active control) was a one-time online viewing of the center's 13-minute usual care video, a nurse-narrated power-point-based video outlining recipient evaluation, surgery, recovery processes and outcomes while briefly highlighting the option of LDKT. It was utilized to offer participants education with perceived benefit and encourage further study participation. Both programs were considered active since they intended to aid kidney transplant access; however, the active control condition differed by quality/extent of content and lack of rewatching, electronic video sharing, and reminders.

Recruitment

Recruitment and enrollment have been described in detail elsewhere.[2] Participants were recruited between April 2022 and July 2023 from the transplant program, located in a safety-net hospital in Buffalo, New York. Each week, electronic records identified English-speaking adults (18 years and older) referred to the center for kidney transplantation, including those with a scheduled appointment to be evaluated, undergoing evaluation, or already waitlisted for a transplant. Patients were excluded for prior exposure to any LDKT access intervention and lack of access to email or texting service.

Enrollment

Each KT-candidate was emailed or texted up to 3 time-based electronic invitations containing a unique link to an online consent form as well as verbal phone calls and in-clinic discussions by study staff until contact was made or enrollment ended. Participants were told they would receive transplant educational videos that could be shared with their social network; but were not told any specifics about the treatment arms or the studies' aim to increase LDKT. Requests to use a carers' email/text were accepted and recorded. The study team did not initiate further contact with any participant who declined to participate. Reasons for refusal were documented if provided. Clinical providers continued to deliver usual care to all participants and were not involved with delivery of the intervention. No information collected for study purposes was shared with the treating team.

Randomization

Those who signed electronic consent to participate were automatically guided to an online 24-item baseline survey assessing socio-demographics (age, sex, race,

education level, household income, co-habitation status, employment status), health (dialysis duration, prior transplant), technology access and use,[3,4] health literacy,[5] and social support.[6] Upon completion, simple computer-generated randomization stratified participants, by self-reported race (Black or African-American vs other), with equal allocation to 2 treatment arms. Assignment of each participant was concealed from transplant providers but unblinded to researchers. Participants did not know which intervention was the “intervention of interest” and which one was the comparator.

Procedures

All participants received a 13-minute video embedded within the enrollment survey, either the *KidneyTIME* core video education or the transplant center’s usual care video, followed by an immediate posttest. The video could not be clicked through or rewatched. The *KidneyTIME* core video ended with a call to action to view more videos centralized on a publicly available website (currently transplantinfo.com). Starting the day after post-test completion and continuing every 3 weeks over a 12-month period, *KidneyTIME* participants were emailed or texted a unique link to the full video collection displayed on a study webpage, including messages describing the benefit of viewing and sharing the content. Through prominent share buttons, each video was activated for sharing using various modalities, including email, text, Facebook, and Twitter. Users (participants and their sharees) had continued access to the full video curriculum anywhere the internet is available and were allowed to interact freely on the sites based on their interests. Study staff did not contact participants to encourage individual use of the intervention. Participants were inactivated in the study if they died, received a transplant, or became ineligible according to the transplant center. All active study

participants were invited to fill out serial surveys immediately after core education and at 1-, 6-, and 12-months post-access to the full digital intervention to examine difference in and maintenance of LDKT knowledge, concerns, and readiness, new behaviors, as well as video use and satisfaction with the intervention. Exit interviews were offered at the end of the 12-month survey; these results and responses to an open-ended survey question were reported previously.[7] All participants received up to $125 for completing all study milestones (4 surveys and an exit interview). To reduce contamination, *KidneyTIME* was not actively promoted during the study period, except for electronic communications about the site to intervention arm participants. Participants in the control condition were offered a link to the *KidneyTIME* website upon study completion.

Outcome Measures

The primary outcome was at least one live kidney donor inquiry to the transplant center on behalf of the study participants within 12 months from enrollment. This is an upstream outcome pertinent to eventual LDKT. An 'inquiry' was defined as an expression of donation interest and must have occurred in person, by telephone, or by email and documented in the medical record. If yes, time (days) from intervention to first inquiry was captured for all patients as a discrete field in the dataset. Secondary patient reported outcomes, published in full detail elsewhere,[2] were adapted from measures used in previous LDKT educational research including patients' LDKT knowledge scores drawn from Kayler et al.[8] (12 true-false questions; range 0-12), concerns scores adapted from Rodrigue et al.[9] (6 items; 4-point Likert; range 4-24; Cronbach's α=0.72), readiness score adapted from Rodrigue et al.[9] (1 item; range 0-5), LDKT access behaviors adapted from Waterman et al.[10] (5 items; range 0-5), extent of social outreach

via video sharing (3 groups: immediate family, extended family and friends, strangers), and program satisfaction (intervention arm only; 7 items; Cronbach's α=0.98). Intervention individual-level video viewing data was recorded automatically by the intervention delivery system. We also measured prior exposure to the videos and device used.

Sample Size

Sample size was estimated on the basis of an 80-patient pilot study at our center.[8] Anticipating a 30% base response rate, analyses targeting detection of a between-group difference of 15% in donor inquiry with 80% power and α=0.05 (2-sided), required 163 per group with complete data or 408 total with adjustment for an anticipated 20% attrition rate. Despite achieving more than the expected sample size (n=422; overage due to a bolus of electronic enrollments in the final month); attrition was higher than anticipated and the intended final analytic sample size was not achieved resulting in reduced power to detect significant effects. Given this, the analysis now focuses on cumulative incidence of inquiry rather than proportional differences.

Statistical Analyses

Summary statistics were used to evaluate intervention usage and satisfaction scores. Group differences were compared using χ^2-tests for binary categorical outcomes. Trial results were analyzed in all randomly assigned participants, representing the intention-to-treat population. We conducted Fine and Gray's competing risk analysis to estimate sub-distribution hazard ratios (sHRs) for receiving at least one live donor inquiry, with transplantation and removal from evaluation as competing risks and censoring for end of follow-up.[11,12] Poisson regression models tested the number of

new outreach behaviors. Poisson models were selected over binomial models based on the Akaike Information Criterion and Bayesian Information Criterion measures. Zero-inflated versions of Poisson and binomial models were also explored without producing any improved goodness of fit, presumably due to limited (<5%) number of zeros at and after month 6. Generalized linear mixed models were used to relate the repeated measures' continuous outcomes (knowledge, concerns, readiness). An unstructured covariance matrix was used and the outcome of interest was predicted by survey time point, condition status, and interaction between time point and condition. Effect size (Cohen's *d*) was calculated for LDKT knowledge using immediate post-exposure data and reported as simple and standardized effect size.[13] An additional 'as-treated' analysis, using competing risk analysis as described above, considered participants who were assigned to the intervention, but did not view at least one optional video, as controls. Covariates in all analyses included computer ownership, the only baseline variable not well balanced between conditions at $p<0.05$. Analyses were conducted using SAS (SAS Institute, Inc, Ver. 9.4) or Stata (Stata Corp, Ver. 19). Statistical significance was set at $p<0.05$ without any adjustment given the single primary outcome and distinct secondary outcomes.[14]

References

1. Kayler LK, Dolph B, Seibert R, Keller M, Cadzow R, Feeley TH. Development of the living donation and kidney transplantation information made easy (KidneyTIME) educational animations. *Clin Transplant*. Apr 2020;34(4):e13830. doi:10.1111/ctr.13830
2. Mendel R, Nie, J, Keller, M., Aly, Y., Sandhu, H., Handmacher, M., & Kayler, L. Digital Enrollment and Survey Response of Diverse Kidney Transplant Seekers in a Remote Trial (KidneyTIME): An Observational Study. *Kidney Dial*. 2025;5(19)doi:https://doi.org/10.3390/kidneydial5020019
3. Price M, Williamson D, McCandless R, et al. Hispanic migrant farm workers' attitudes toward mobile phone-based telehealth for management of chronic health conditions. *J Med Internet Res*. Mar 2013;15(4):e76. doi:10.2196/jmir.2500
4. McGillicuddy JW, Weiland AK, Frenzel RM, et al. Patient attitudes toward mobile phone-based health monitoring: questionnaire study among kidney transplant recipients. *J Med Internet Res*. Jan 2013;15(1):e6. doi:10.2196/jmir.2284
5. Chew LD, Griffin JM, Partin MR, et al. Validation of screening questions for limited health literacy in a large VA outpatient population. *J Gen Intern Med*. May 2008;23(5):561-6. doi:10.1007/s11606-008-0520-5
6. Beutel ME, Brähler E, Wiltink J, et al. Emotional and tangible social support in a German population-based sample: Development and validation of the Brief Social Support Scale (BS6). *PLoS One*. 2017;12(10):e0186516. doi:10.1371/journal.pone.0186516
7. Kayler LK, Solbu, A., Keller, M., Handmacher, M., Noyes, E., Von Visger, J., ... & Cadzow, R. B. Perspectives of a mobile intervention for kidney transplant seekers: Post-intervention qualitative results from the KidneyTIME study. *PloS ONE*. 2025;20(5):e0325313.
8. Kayler LK, Seibert RE, Dolph BA, et al. Video education to facilitate patient outreach about living kidney donation: A proof of concept. *Clin Transplant*. Sep 12 2021:e14477. doi:10.1111/ctr.14477
9. Rodrigue JR, Paek MJ, Egbuna O, et al. Readiness of wait-listed black patients to pursue live donor kidney transplant. *Prog Transplant*. Dec 2014;24(4):355-61. doi:10.7182/pit2014337
10. Waterman AD, Peipert JD, Cui Y, et al. Your Path to Transplant: A randomized controlled trial of a tailored expert system intervention to increase knowledge, attitudes, and pursuit of kidney transplant. *Am J Transplant*. Mar 2021;21(3):1186-1196. doi:10.1111/ajt.16262
11. Gray R. A class of K-sample tests for comparing the cumulative incidence of a competing risk. *Ann Stat*. 1988;16(3):1141–54.
12. Fine JP, Gray RJ. A proportional hazards model for the subdistribution of a competing risk. *J Am Stat Assoc*. 1999;94(446):496-509. doi:https://doi.org/10.1080/01621459.1999.10474144
13. Baguley T. Standardized or simple effect size: What should be reported? *British Journal of Psychology*. 2009;100(3):603-617.
14. Parker RA, & Weir, C. J. Multiple secondary outcome analyses: precise interpretation is important. *Trials*. 2022;23(1)