

ATHABASCA UNIVERSITY
EDUCATIONAL INTERVENTIONS TO IMPROVE ACCESS TO
LIVING KIDNEY DONATION

BY

JESSICA MCDOUGALL

A THESIS/DISSERTATION

SUBMITTED TO THE FACULTY OF GRADUATE STUDIES
IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF
MASTER OF NURSING

FACULTY OF HEALTH DISCIPLINES

ATHABASCA, ALBERTA

FEBRUARY, 2020

© JESSICA MCDOUGALL

Approval of Thesis

The undersigned certify that they have read the thesis entitled

EDUCATIONAL INTERVENTIONS TO IMPROVE ACCESS TO LIVING KIDNEY DONATION

Submitted by

Jessica McDougall

In partial fulfillment of the requirements for the degree of

Master of Nursing

The thesis examination committee certifies that the thesis
and the oral examination is approved

Supervisor:

Dr. Jennifer Knopp-Sihota
Athabasca University

Committee Member:

Dr. Shawn Fraser
Athabasca University

External Examiner:

Dr. Janice Bissonnette
Canadian Blood Services

June 10, 2020

Dedication

I dedicate this thesis to those living with kidney disease as well as their loved ones. I hope this work will get us one step closer to ensuring everyone living with end-stage kidney disease is empowered to make an informed decision about kidney transplant and living kidney donation.

Acknowledgements

I thank my loving and supportive husband, Allan. Thank you for believing in me and motivating me to persevere with this work. Thank you for your patience, guidance and editing skills! Thank you also to my parents, Uncle John, Aunt Brenda, Paul and Emily for helping with the kids. It certainly takes a village and I could not have done this without your support. Thank you to my children, William and Walker, for being patient with mommy while I spent many weekends at my desk. I know this has been difficult for you. I hope that someday you will be proud of the time I took to complete graduate studies and that I will inspire you to pursue higher education.

I thank my supervisor, Dr. Jennifer Knopp-Sihota, for her encouragement and guidance. The journey to complete this work has not been without unexpected challenges and changes in course. It has been an honour and a privilege to learn from her. I also sincerely thank my committee members, Dr. Shawn Fraser and Dr. Janice Bissonnette for their time and expertise in reviewing this thesis. Special thanks to librarian Erica Wright, who was a light in the darkness for me in the early stages of this project—especially when screening!

Abstract

For many patients with end-stage renal disease (ESRD), the preferred treatment is kidney transplantation via living kidney donor transplantation (LKDT). When compared to renal dialysis, LKDT offers improved patient outcomes and greatly reduced healthcare spending. However, in recent years, living donation rates have stagnated. To identify patient education, as a means of improving living donation rates, this thesis aimed to review and synthesize findings from patient education intervention studies aimed at improving informed consent and patient knowledge related to LKDT. This is a Cochrane style systematic review protocol (outlining the plan for the review) and systematic review with a descriptive synthesis of quantitative studies adhering to PRISMA guidelines. The systematic review identified 27 outcomes across 15 studies that met our inclusion criteria. Findings from this review demonstrate that patient education is linked with improved self-efficacy, increase in knowledge, and decreased concerns on the part of patients. More research is needed, however, to consider how these findings can apply in Canadian contexts.

Keywords: living kidney donor transplantation, patient education, nursing

Preface

Motivation for this Thesis

The motivation for this thesis comes from my professional role as a career transplant nurse with 14 years of experience in the field. At the onset of my Master of Nursing journey, I knew I wanted to make an original contribution to my field that would positively impact my patients. This thesis, I believe, provides part of an answer to an important question facing renal care professionals across Canada. How do we most effectively ensure patients have access to the information they need, when they need it, about living kidney donor transplantation (LKDT). I believe this question is best answered with a systematic review on patient education in LKDT.

This manuscript thesis contains three chapters, each of which contributes to an overarching final report that I hope will be a usable resource for health professionals interested in patient education in LKDT. Chapter 1 describes rationale for the study including a review of the literature, provides operational definitions, a brief overview of the manuscripts, as well as final discussion points and implications nursing. The second chapter is the systematic review protocol manuscript. The third chapter presents the full systematic review manuscript.

Grounding this Work

I am a career transplant nurse with over a decade in the field. I began my career with the inpatient Multi-Organ Transplant Unit at London Health Sciences Centre—University Hospital in London, Ontario, Canada. After 5 years in that role, I went on to spend 5 years as a recipient coordinator in renal transplantation, where I assisted patients facing kidney failure on their journey. More recently, I joined the Ottawa Hospital Renal Transplant Program as an outpatient clinic nurse followed by 2 years as a living kidney donation coordinator.

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

In my current role, I work with potential kidney donors, the other patients involved in LKDT. In this role, I have had the opportunity to join an exciting provincial program called *Explore Transplant Ontario*, a program that has recently been brought to Ontario from the US to increase patient access to LKDT. The Explore Transplant program aims to solve many of the challenges that I see in my daily practice; the program aligns with my own goal of combatting the many myths about LKDT through patient education and health care provider education.

I will share two personal anecdotes that represent the problems patients and health professionals face in LKDT. Neither of these anecdotes is from a specific person, but each represents the combination of dozens of encounters I have had throughout my career. First, imagine Ms. Scott, a patient facing end-stage kidney disease who is a fit candidate for LKDT. Our team encouraged her to find a living donor, but she expressed hesitation at asking someone in her family or friend group to take that step for her. We did our best to empower her, but there was little more we could do. One year later, Ms. Scott had not made progress in finding a donor and she indicated she had such a good relationship with her dialysis team and that for now things seemed to be stable. We wondered, is there a better way to encourage and empower patients to regularly revisit the idea of LKDT over dialysis?

My second anecdote involves a colleague I'll name Maria. She is a dialysis nurse at one of our referral centres in rural Eastern Ontario. Her nursing career spans 25 years and she is a passionate advocate for kidney research and diabetes prevention. While dialysis and kidney disease play a central role in her practice, she is not overly familiar with the benefits and risk factors associated with LKDT. As far as she is concerned, dialysis is safe whereas LKDT involves asking someone to take a big risk in their life. She does not have regular contact with

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

the transplant centre in Ottawa and, when she does, she feels uncomfortable with her lack of expertise about transplant and living kidney donation.

In the situations of Ms. Scott and Maria, we see caring relationships between patients and healthcare providers. In both cases, emotions underpin the likelihood of a change in situation: Ms. Scott feels safe and cared for as a patient in the dialysis clinic; Maria feels uneasy about talking to patients about transplant or contacting the local transplant program. I believe both people deserve education that will empower them to explore and act on best evidence in LKDT. My belief motivates this thesis and motivates me in my daily work as a transplant nurse.

Table of Contents

Dedication.....	iii
Acknowledgements.....	iv
Abstract v	
Prefacevi	
Motivation for this thesis.....	vi
Grounding this work.....	vi
Chapter 1. Introduction.....	1
Background.....	1
Explore Transplant.....	3
Purpose of the study.....	5
Definition of terms.....	6
The manuscripts.....	7
Manuscript 1: a systematic review protocol for educational interventions to improve access to LKDT.	7
Manuscript #2: a systematic review and descriptive analysis on educational interventions to improve access to LKDT.	7
Significance of findings.....	8
Conclusions and future	9
References.....	10
Chapter 2. Manuscript #1: educational interventions to improve access to living kidney .. donation (LKDT): a systematic review protocol.....	17
Abstract.....	17
Introduction.....	19
Rationale	21
Aims.....	22
Methods	22
Criteria for considering studies for the review.....	22
Types of studies and participants.	22
Search strategy and data management.	23
Study screening.	24
Data extraction and synthesis.....	26
Sub-group analysis.	27
Risk of bias in included studies.....	27
Data synthesis.	27
Missing data.	28
Discussion.....	28
References.....	30
Appendix A. PRISMA-P checklist	35
Appendix B. Medline search strategy.....	38
Appendix C. Cochrane Risk of Bias tool.....	41
Chapter 3. Manuscript #2: educational interventions to improve access to living kidney donation (LKD): a systematic review and descriptive analysis	42

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Abstract.....	42
Introduction.....	44
Methods	46
Criteria for considering studies for this review.....	46
Types of participants.....	47
Search strategy.....	47
Study selection.....	47
Data extraction and synthesis.....	48
Data synthesis.....	49
Risk of bias in included studies.....	50
Results.....	51
Study characteristics.....	51
Participants.....	51
Design.....	52
Interventions.....	53
Study outcomes.....	54
Study Outcomes.....	56
Risk of bias in included studies.....	56
Intervention effects.....	57
Willingness to discuss LKDT with others (self-efficacy).....	57
Concerns about the risks of LKDT (self-efficacy).....	59
Knowledge measures.....	60
Patient received ≥ 1 living donor inquiry (program measures).....	63
Patient received LKDT (program measures).....	65
Patient communicated with others about kidney disease and RRT.....	65
Discussion.....	68
Summative overview.....	68
Methodological observations.....	69
Limitations.....	71
Implications for practice.....	71
Conclusion.....	73
References.....	74
Table 1. Characteristics of included studies.....	82
Table 2. Intervention characteristics.....	88
Appendix A. The PRISMA statement.....	93
Appendix B. Medline search strategy.....	96
Appendix C. Cochrane Risk of Bias Tool.....	99

List of Tables

Manuscript 2

Table 1. Characteristics of included studies	82
Table 2. Intervention characteristics	91

List of Figures

Manuscript 1

Figure 1: PRISMA-P diagram 25

Manuscript 2

Figure 1. PRISMA diagram 49
Figure 2. Study outcomes 56
Figure 3. Risk of bias in included studies 57
Figure 4. Willingness to discuss living kidney donor transplant with others 58
Figure 5. Concerns about the risks of living kidney donor transplant 60
Figure 6. Knowledge measures 62
Figure 7. Patient received ≥ 1 living kidney donor transplant inquiry 64
Figure 8. Patient received living kidney donor transplant 66
Figure 9. Patient communicated with others regarding LKDT 67

Chapter 1. Introduction

Background

Between 1990-2010, chronic kidney disease rose from 27th to 18th on the list of causes of total number of global deaths. The final stage of chronic kidney disease, end-stage renal disease (ESRD), presents a particular challenge to health systems and is projected to reach near epidemic rates in the near future (National Institutes of Health, 2013). ESRD's prevalence will rise worldwide over the next decades, primarily as a result of an ageing population and increasing rates of diabetes (Jha et al., 2013; White, Chadban, Jan, Chapman, & Cass, 2008).

There is currently no cure for kidney disease. The most common kidney replacement therapy, dialysis, helps keep a person with ESRD alive. For many patients, the preferred treatment for ESRD is kidney transplantation via a living kidney donor, which offers improved patient outcomes and greatly reduced healthcare spending when costs are compared to dialysis (Laupacis et al., 1996; Reese, Boudville, & Garg, 2015). LKDT is a process whereby another person offers one of their healthy kidneys to a patient in kidney failure. Most people only need one kidney to live well, and if an individual meets a comprehensive set of donor criteria, one of their two kidneys can be surgically removed and transplanted in a patient. Living kidney donor transplantation (LKDT) is demonstrated not only to have better outcomes for patients but also optimal outcomes for transplanted organs (Barnieh et al., 2011a). Advantages include increased quality of life (Laupacis et al., 1996) and far better clinical outcomes than dialysis (Pace et al., 2002; Tarantino, 2000). LKDT offers the potential to provide better outcomes when compared to deceased donation, and yet LKDT remains underutilized.

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Living kidney donor transplantation (LKDT), the most effective treatment for many patients with end-stage kidney disease, has a 60-year history in Canada. Canada's first LKDT procedure in 1958, when renowned nephrologist John Dossetor coordinated the procedure between identical twins (Dossetor, 2005). In the 1960 and 70s, living donors were required to be genetically related to recipients. However, during the 1980s and 90s, transplant programs began expanding donor pools to include spouses, friends, or other social connections (Dossetor, 2005). Today, LKDT programs focus on organ stewardship and optimal outcomes for recipients and donors, including accepting members of the general public as 'altruistic donors' and the development of kidney paired exchange programs (Gruessner & Benedetti, 2008).

Between 2003 and 2012, living organ donation transplant rates modestly rose in Canada from 435 to 539 donors per year (Canadian Institute for Health Information, 2012). Until 2011, living donors exceeded even deceased donors. However, over the past 8 years, deceased donations have increased 35% while living donation has virtually stagnated (Canadian Institute for Health Information, 2012). Recently, the International Registry in Organ Donation and Transplantation ranked Canada as 19th in living donation transplant rates, with rates lower than the United States, the United Kingdom, and India among others (Gomez, Perez, & Manyalich, 2014). LKDT is the preferred treatment for ESRD and research has repeatedly demonstrated better patient outcomes and reduced healthcare spending versus dialysis or deceased donation (Barnieh et al., 2011a; Cai et al., 2014; Collins et al., 2012; Laupacis et al., 1996; Pace et al., 2002; Purnell et al., 2013; Reese et al., 2015; Tarantino, 2000). Building on this evidence, the transplant community strives to increase patient access to LKDT as much as possible, aiming to ensure patients are given multiple opportunities to understand LDKT and make informed decisions about their care.

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Explore Transplant

The aforementioned vignettes represent the challenges facing LKDT today. A growing body of literature is demonstrating how patient characteristics are associated with phases of the transplantation process, such as completing a transplant evaluation, approaching a potential donor, or receiving a living donor kidney transplant. Waterman and colleagues advise investigators in the area of LKDT transplantation to consider patient characteristics along a continuum of less- to more-modifiable (Waterman et al., 2013). For example, there exists a rich evidence base of population health studies associating sociodemographic factors with LKDT transplantation—these would primarily include non-modifiable characteristics like race and gender. These studies use large, public databases such as IC/ES, the Canadian Institute for Health information, and the U.S. Renal Data System and have limited measures for more-modifiable patient characteristics, such as transplant knowledge, perceived benefits and drawbacks of transplant, willingness and motivation toward transplantation, and number of donors coming forward on behalf of a patient (Waterman et al., 2013).

Not surprisingly, patients considering LDKT are uncomfortable about the prospect of even starting a conversation with people in their social circle about the prospect of being a potential donor (Barnieh et al., 2011b). Other commonly noted fears include fear of a negative response from potential donors and fear of long-term responsibility towards the donor (Barnieh et al., 2011b). Numerous studies in a variety of patient populations and geographic contexts suggest that potential barriers to LKDT include modifiable patient characteristics, including patient knowledge, ability to ask, guilt over risks, fear of donor harm, and comfort with current care (Kutner, Zhang, Huang, & Johansen, 2012). These patients worry they will be perceived as greedy, inconsiderate, or coercive; further, they worry about the risks they would be placing on

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

the donor (Waterman, Barrett, & Stanley, 2008; Waterman, Robbins, Paiva, & Hyland, 2010b). These risks notwithstanding, all patients facing chronic kidney disease (CKD) would be familiar with the potential for their donors to require many tests and appointments to be assessed as a donor (Waterman et al., 2014).

Not only do gaps in patient knowledge impact care for patients who could possibly benefit from LKDT, a growing body of research claims problematic gaps amongst kidney care providers as well (Delmonico, Dominguez-Gil, Matesanz, & Noel, 2011; Rodrigue et al., 2014). In Canada, I have seen first-hand the impact of cutbacks stripping out the role of nurse educators from many clinical areas, and dialysis centres are no exception. Ironically, it is this area where much could be done in cost savings for the health system if frontline staff had the background, time, and motivation to dispel misconceptions about LKDT and encourage patients to find out if it is right for them (Waterman, Hyland, Goalby, Robbins, & Dinkel, 2010a; Waterman et al., 2015a; Waterman & Peipert, 2018). As patients decide on LKDT, they may require far different information from individuals who have made up their minds and need information about navigating the process of being a recipient and finding a donor.

The Explore Transplant project, developed by US-based social psychologist Dr. Amy Waterman, has proposed a number of possible solutions for these patient and care provider challenges (Mucsi, Novak, Toews, & Waterman, 2018; Waterman et al., 2010a; Waterman et al., 2015a; Waterman & Peipert, 2018). I am fortunate to have had the opportunity to be a part of an Ontario-based adaptation of Explore Transplant, a LKDT education program for patients that involves health professional education. Waterman's project is distinct because it encourages health professionals to counsel patients based on their readiness for change (Cassidy, 1999). The trans-theoretical model (TTM) of behaviour change argues that not all patients facing chronic

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

disease are ready to pursue changes in the best interest of their health (Prochaska, 2008; Prochaska & DiClemente, 1992; Prochaska, DiClemente, & Norcross, 1992). These findings apply in relation to ESRD patients who are not immediately ready to explore LKDT as a therapeutic option (Waterman et al., 2015c; Waterman, Robbins, & Peipert, 2016; Waterman & Rodrigue, 2009). The Explore Transplant research portfolio leverages the TTM to demonstrate how tailored education interventions addressing fears and increasing perceptions of the advantages of LKDT.

Purpose of the Study

Compared to other health care procedures, patients play a more active role in the availability and timing of a LKDT procedure. However, surgery is only one part of an elaborate series of health care decisions that requires transplant staff, recipients, and donors to coordinate and share decision making around informed consent. For transplant professionals, ensuring patients can access LKDT equates to ensuring patients have access to best practices and helpful supports. Currently, there is limited evidence on the strategies that are most promising for increasing patient access to LKDT transplantation (Barnieh et al., 2017).

The purpose of this study is to explore trends indicating that the LKDT community should optimize current patient education processes. First, there has been a notable lack of increase in terms of Canadian living donors. While kidney disease is projected to rise with Canada's aging population, this sluggish trend in living donors is troubling. Second, new opportunities for donor recruitment and candidate communication have emerged via the advent of social media and the expansion of clinical guidelines to include unrelated and anonymous donors. Third, as our understanding of the epidemiology of LKDT expands, there may be

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

opportunities for programs to consider how current practices may reflect inefficient, historical precedents.

Definition of Terms

This thesis concentrates on patient educational interventions as a method to increase access to LKDT. *Increasing access to LKDT* is defined as a patient educational intervention aiming to improve a patient's ability to make an informed choice about treatment options or streamline their ability to receive LKDT (Waterman et al., 2015b; Waterman et al., 2013). The patient education envisioned in this thesis could take place in transplant centres, dialysis units, nephrology clinics, and other settings for patients with kidney disease. This approach to patient education would be underpinned by a philosophy of patient care where LKDT is considered the best option for most transplant candidates.

Optimal informed consent is central to LKDT, with added complexities for healthcare providers required to ensure informed consent for recipients, donors, and their broader social groups. Further, as both the clinical science and medical practice of LKDT advances, additional elements must be considered including, for example, LKDT and pregnancy (Gill & Tonelli, 2014), contextual factors influencing LKDT outcomes (Dew, Myaskovsky, Steel, & DiMartini, 2014), and extended criteria for recipients and donors (Niemi & Mandelbrot, 2014a, 2014b).

Several recent consensus guidelines and evidence syntheses have recommended the integration of LKDT information and processes for potential recipients and donors at multiple stages of their care trajectory (Moore et al., 2015; Rodrigue et al., 2015; Waterman et al., 2015b). This may include educational outreach for patients who may not have yet considered LKDT as an option they may require in the future. Researchers working in this space have advocated for

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

more, better efforts to promote LKDT education, increase the quality of current education practices, and ensure the availability of education resources for patients and providers (LaPointe Rudow et al., 2015).

The Manuscripts

Manuscript 1: A systematic review protocol for educational interventions to improve access to LKDT. This manuscript is the study protocol for this systematic review. It presents a structured approach for exploring the literature on educational interventions focused on improving patients' access to LKDT. Following the format of the journal BMC Systematic Reviews, the manuscript follows the procedures for systematic reviews as outlined in the Cochrane Handbook of Systematic Reviews of Interventions (Higgins & Cochrane Collaboration, 2020). This systematic review protocol was submitted to BMC Systematic Reviews and the Journal of Advanced Nursing. It met the standards for both publications and included a complete PRISMA-P checklist (Appendix A). In both cases, article publication fees were prohibitive, and we elected to hold off on seeking publication until after the thesis was complete. We did seek to submit the protocol to the International Prospective Register of Systematic Reviews (PROSPERO), however we had already completed data collection, which excluded us from PROSPERO's submission criteria (Booth et al., 2012).

Manuscript #2: A systematic review and descriptive analysis on educational interventions to improve access to LKDT. In this manuscript, I summarize the procedures and results of a systematic review on educational interventions aimed to improve patient access to LKDT. This manuscript encompasses the main component of my thesis study. It describes the processes of the educational intervention, the outcome measures taken to assess the impact of the interventions, and descriptions of the relevant findings in relation to one another. The analysis

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

identifies 27 outcomes across the 15 studies that met our inclusion criteria. We considered the frequency of these outcomes across the studies and conducted meta-analyses on the most common outcomes. The relevant manuscripts have been organized across these outcomes and where appropriate subgroup analysis subdivided the manuscripts across 3 themes: where the studies delivered an educational intervention prior to the participant presenting for transplant evaluation, interventions that integrated patients' social networks into intervention design, and interventions that used some form of sociocultural tailoring to ensure inclusivity for a specific population. The conclusion of the systematic review presents discussion points and implications for my field of living donor transplantation. This chapter has been formatted for submission to an academic journal that publishes systematic reviews of patient education projects. This manuscript will be reformatted and submitted to the journal *Transplantation* later.

Significance of Findings

As with many other specialty areas of medicine, nurses are crucial stakeholders in care for patients considering LKDT. Across the spectrum of renal care, nurses are essential for ensuring patients have access to the information they need to make informed consent decisions. Transplant care is no exception.

In LKDT, patients require frequent touchpoints with nurses as they receive care across the ESRD spectrum. This includes, but is not limited to, outpatient nephrology care, dialysis care, pre-transplant assessments, care while waiting for a transplant, and post-transplant care. These nurses are the audience I envision reaching with this project as they are involved in patient education during these multiple points of patient contact.

Conclusions and Future

Research Opportunities for future research in the field of LDKT care have been identified throughout this study. We hope knowledge translation opportunities can emerge from this evidence synthesis. Our analysis will highlight some of the most prevalent study outcomes in the recent literature on this topic. We also believe that this implicitly highlights gaps in the literature for future exploration and study.

References

- Barnieh, L., Collister, D., Manns, B., Lam, N. N., Shojai, S., Lorenzetti, D., . . . Klarenbach, S. (2017). A scoping review for strategies to increase living kidney donation. *Clinical Journal of the American Society of Nephrology*, *12*(9), 1518-1527
- Barnieh, L., McLaughlin, K., Manns, B. J., Klarenbach, S., Yilmaz, S., Hemmelgarn, B. R., & Alberta Kidney Disease, N. (2011a). Barriers to living kidney donation identified by eligible candidates with end-stage renal disease. *Nephrology Dialysis Transplantation*, *26*, 732-738
- Barnieh, L., McLaughlin, K., Manns, B. J., Klarenbach, S., Yilmaz, S., Taub, K., . . . Alberta Kidney Disease, N. (2011b). Evaluation of an education intervention to increase the pursuit of living kidney donation: A randomized controlled trial. *Progress in Transplantation*, *21*(1), 36-42
- Booth, A., Clarke, M., Dooley, G., Gherzi, D., Moher, D., Petticrew, M., & Stewart, L. (2012). The nuts and bolts of prospero: An international prospective register of systematic reviews. *Syst Rev*, *1*, 2
- Cai, J., Wu, G., Qing, A., Everly, M., Cheng, E., & Terasaki, P. (2014). Organ procurement and transplantation network/scientific registry of transplant recipients 2014 data report: Intestine. *Clinical Transplants*, 33-47
- Canadian Institute for Health Information. (2012). Treatment of end-stage organ failure in canada. *Healthc Q*, *15*(2), 84
- Cassidy, C. A. (1999). Using the transtheoretical model to facilitate behavior change in patients with chronic illness. *Journal of the American Academy of Nurse Practitioners*, *11*(7), 281-287

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Collins, A. J., Foley, R. N., Chavers, B., Gilbertson, D., Herzog, C., Johansen, K., . . . Agodoa, L. (2012). 'United states renal data system 2011 annual data report: Atlas of chronic kidney disease & end-stage renal disease in the united states. *American Journal of Kidney Diseases*, 59(1 Suppl 1), A7, e1-420
- Delmonico, F. L., Dominguez-Gil, B., Matesanz, R., & Noel, L. (2011). A call for government accountability to achieve national self-sufficiency in organ donation and transplantation. *Lancet*, 378(9800), 1414-1418
- Dew, M. A., Myaskovsky, L., Steel, J. L., & DiMartini, A. F. (2014). Managing the psychosocial and financial consequences of living donation. *Curr Transplant Rep*, 1(1), 24-34
- Dossetor, J. B. (2005). *Beyond the hippocratic oath : A memoir of the rise of modern medical ethics*. Edmonton: University of Alberta Press.
- Gill, J. S., & Tonelli, M. (2014). Understanding rare adverse outcomes following living kidney donation. *JAMA*, 311(6), 577-579
- Gomez, M. P., Perez, B., & Manyalich, M. (2014). International registry in organ donation and transplantation--2013. *Transplantation Proceedings*, 46(4), 1044-1048
- Gruessner, R. W. G., & Benedetti, E. (2008). *Living donor organ transplantation*. New York: McGraw-Hill Medical.
- Higgins, J. P. T., & Cochrane Collaboration. (2020). *Cochrane handbook for systematic reviews of interventions* (Second edition. ed.). Hoboken, NJ: Wiley-Blackwell.
- Jha, V., Garcia-Garcia, G., Iseki, K., Li, Z., Naicker, S., Plattner, B., . . . Yang, C. W. (2013). Chronic kidney disease: Global dimension and perspectives. *Lancet*, 382(9888), 260-272

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Kutner, N. G., Zhang, R., Huang, Y., & Johansen, K. L. (2012). Impact of race on predialysis discussions and kidney transplant preemptive wait-listing. *American Journal of Nephrology*, 35(4), 305-311
- LaPointe Rudow, D., Hays, R., Baliga, P., Cohen, D. J., Cooper, M., Danovitch, G. M., . . . Rodrigue, J. R. (2015). Consensus conference on best practices in live kidney donation: Recommendations to optimize education, access, and care. *American Journal of Transplantation*, 15, 914-922
- Laupacis, A., Keown, P., Pus, N., Krueger, H., Ferguson, B., Wong, C., & Muirhead, N. (1996). A study of the quality of life and cost-utility of renal transplantation. *Kidney International*, 50, 235-242
- Moore, D. R., Serur, D., Rudow, D. L., Rodrigue, J. R., Hays, R., Cooper, M., & American Society of, T. (2015). Living donor kidney transplantation: Improving efficiencies in live kidney donor evaluation--recommendations from a consensus conference. *Clinical Journal of the American Society of Nephrology*, 10(9), 1678-1686
- Mucsi, I., Novak, M., Toews, D., & Waterman, A. (2018). Explore transplant ontario: Adapting the explore transplant education program to facilitate informed decision making about kidney transplantation. *Canadian Journal of Kidney Health & Disease*, 5, 2054358118789369
- National Institutes of Health, N. I. o. D. D. K. D., Division of Kidney Urologic & Hematologic Disease. (2013). Usrds 2013 annual data report: Atlas of chronic kidney disease and end-stage renal disease in the united states. *National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases*, 1-26
- Niemi, M., & Mandelbrot, D. A. (2014a). Kidney donation and risk of esrd. *JAMA*, 312(1), 92

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Niemi, M., & Mandelbrot, D. A. (2014b). The outcomes of living kidney donation from medically complex donors: Implications for the donor and the recipient. *Curr Transplant Rep, 1*(1), 1-9
- Pace, K. T., Dyer, S. J., Phan, V., Poulin, E. C., Schlachta, C. M., Mamazza, J., . . . Honey, R. J. (2002). Laparoscopic v open donor nephrectomy: A cost-utility analysis of the initial experience at a tertiary-care center. *Journal of Endourology, 16*, 495-508
- Prochaska, J. O. (2008). Decision making in the transtheoretical model of behavior change. *Medical Decision Making, 28*(6), 845-849
- Prochaska, J. O., & DiClemente, C. C. (1992). Stages of change in the modification of problem behaviors. *Progress in Behavior Modification, 28*, 183-218
- Prochaska, J. O., DiClemente, C. C., & Norcross, J. C. (1992). In search of how people change. Applications to addictive behaviors. *American Psychologist, 47*(9), 1102-1114
- Purnell, T. S., Auguste, P., Crews, D. C., Lamprea-Montealegre, J., Olufade, T., Greer, R., . . . Boulware, L. E. (2013). Comparison of life participation activities among adults treated by hemodialysis, peritoneal dialysis, and kidney transplantation: A systematic review. *American Journal of Kidney Diseases, 62*(5), 953-973
- Reese, P. P., Boudville, N., & Garg, A. X. (2015). Living kidney donation: Outcomes, ethics, and uncertainty. *Lancet, 385*(9981), 2003-2013
- Rodrigue, J. R., Kazley, A. S., Mandelbrot, D. A., Hays, R., LaPointe Rudow, D., Baliga, P., & American Society of, T. (2015). Living donor kidney transplantation: Overcoming disparities in live kidney donation in the us--recommendations from a consensus conference. *Clinical Journal of The American Society of Nephrology: CJASN, 10*, 1687-1695

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Rodrigue, J. R., Paek, M. J., Egbuna, O., Waterman, A. D., Schold, J. D., Pavlakis, M., & Mandelbrot, D. A. (2014). Readiness of wait-listed black patients to pursue live donor kidney transplant. *Progress in Transplantation*, 24(4), 355-361
- Tarantino, A. (2000). Why should we implement living donation in renal transplantation? *Clinical Nephrology*, 53, suppl 55-63
- Waterman, A. D., Barrett, A. C., & Stanley, S. L. (2008). Optimal transplant education for recipients to increase pursuit of living donation. *Progress in Transplantation*, 18(1), 55-62
- Waterman, A. D., Hyland, S. S., Goalby, C., Robbins, M., & Dinkel, K. (2010a). Improving transplant education in the dialysis setting: The “explore transplant” initiative. *Dialysis & Transplantation*, 39(6), 236-241
- Waterman, A. D., McSorley, A. M., Peipert, J. D., Goalby, C. J., Peace, L. J., Lutz, P. A., & Thein, J. L. (2015a). Explore transplant at home: A randomized control trial of an educational intervention to increase transplant knowledge for black and white socioeconomically disadvantaged dialysis patients. *BMC Nephrology*, 16, 150
- Waterman, A. D., Morgievlch, M., Cohen, D. J., Butt, Z., Chakkera, H. A., Lindower, C., . . . American Society of, T. (2015b). Living donor kidney transplantation: Improving education outside of transplant centers about live donor transplantation-- recommendations from a consensus conference. *Clinical Journal of the American Society of Nephrology*, 10(9), 1659-1669
- Waterman, A. D., & Peipert, J. D. (2018). An explore transplant group randomized controlled education trial to increase dialysis patients' decision-making and pursuit of transplantation. *Progress in Transplantation*, 28, 174-183

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Waterman, A. D., Peipert, J. D., Hyland, S. S., McCabe, M. S., Schenk, E. A., & Liu, J. (2013). Modifiable patient characteristics and racial disparities in evaluation completion and living donor transplant. *Clinical Journal of the American Society of Nephrology*, *8*, 995-1002
- Waterman, A. D., Robbins, M. L., Paiva, A. L., & Hyland, S. S. (2010b). Kidney patients' intention to receive a deceased donor transplant: Development of stage of change, decisional balance and self-efficacy measures. *Journal of Health Psychology*, *15*(3), 436-445
- Waterman, A. D., Robbins, M. L., Paiva, A. L., Peipert, J. D., Davis, L. A., Hyland, S. S., . . . Amoyal, N. R. (2015c). Measuring kidney patients' motivation to pursue living donor kidney transplant: Development of stage of change, decisional balance and self-efficacy measures. *Journal of Health Psychology*, *20*, 210-221
- Waterman, A. D., Robbins, M. L., Paiva, A. L., Peipert, J. D., Kynard-Amerson, C. S., Goalby, C. J., . . . Brick, L. A. (2014). Your path to transplant: A randomized controlled trial of a tailored computer education intervention to increase living donor kidney transplant. *BMC Nephrology*, *15*, 166
- Waterman, A. D., Robbins, M. L., & Peipert, J. D. (2016). Educating prospective kidney transplant recipients and living donors about living donation: Practical and theoretical recommendations for increasing living donation rates. *Current Transplantation Reports*, *3*, 1-9
- Waterman, A. D., & Rodrigue, J. R. (2009). Transplant and organ donation education: What matters? *Progress in Transplantation*, *19*(1), 7-8

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

White, S. L., Chadban, S. J., Jan, S., Chapman, J. R., & Cass, A. (2008). How can we achieve global equity in provision of renal replacement therapy? *Bulletin of the World Health Organization*, 86, 229-237

Chapter 2. Manuscript #1: Educational Interventions to Improve Access to Living Kidney Donation (LKDT): A Systematic Review Protocol

Abstract

Background: The preferred treatment for many patients with end-stage renal disease (ESRD) is living kidney donor transplantation (LKDT), which offers improved patient outcomes and reduced healthcare spending. In recent years, living donation rates have stagnated and we propose a robust evidence synthesis focused on methods for using patient education as a means of improving living donation rates.

Objectives: In this systematic review protocol, we identify our research approach that we will use to critically appraise and synthesize data in order to examine the effectiveness of patient educational interventions to increase access to living kidney donor transplantation (LKDT). This proposed systematic review will adhere to the PRISMA-P checklist (Appendix A).

Design/Methods: This is a Cochrane style systematic review protocol adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Protocols reporting standards (PRISMA-P). The review concentrates on primary randomized controlled studies that have been designed to explore and improve patients' ability to make an informed decision about LKDT. We will also consider patient education recommendations from recent consensus conferences. Database searches will include CINAHL, MEDLINE, PsycINFO, ERIC, EBM Reviews, Scopus, and the Cochrane trial registry in the Cochrane library.

Impact: The review will describe actual and projected effects of patient education interventions for improving access to LKDT, outline the methodological quality and rigor of these interventions, align findings alongside expert recommendations, and expand the current

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

knowledge on patient education involving access to LKDT and the effectiveness of current techniques or approaches.

Educational Interventions to Improve Access to Living Kidney Donation (LKDT): A Systematic Review Protocol

Introduction

Despite advances in the field of organ transplantation, living kidney donor transplantation (LKDT) rates in the USA and Canada have remained stable or, in some cases, decreased (Reese, Boudville, & Garg, 2015). Surprisingly, only 39% of kidney transplants in Canada and 23% in the USA come from living donors (Barnieh et al., 2011a)—although LKDT rates are higher in some countries such as Japan and South Korea (Reese et al., 2015). Options for increasing LKDT rates have been described in the literature (Barnieh et al., 2017; Barnieh et al., 2011b; Strigo et al., 2015), and kidney transplant programs, hospitals, and health regions have dedicated extensive resources toward programs, strategies, and interventions for improving patient access to LKDT (Strigo et al., 2015; Traino, 2014).

While there is limited evidence on what strategies are most promising for increasing patient access to LKDT (Barnieh et al., 2017), there is no doubt that patients play an active role in the success of LKDT. A growing body of literature is demonstrating how patient characteristics are associated with phases of the transplantation process such as completing a transplant evaluation, referring a potential donor, or receiving a living donor kidney transplant. Waterman and colleagues advise investigators in the area of LKDT to consider patient characteristics along a continuum of less-to- more-modifiable (Waterman et al., 2013). For example, there exists a rich evidence base of population health studies associating sociodemographic factors with LKDT—these would primarily include non-modifiable characteristics such as race and gender. These studies use large, public databases such as the Institute for Clinical Evaluative Sciences (IC/ES), the Canadian Institute for Health information

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

(CIHI), and the U.S. Renal Data System and have limited measures for more-modifiable patient characteristics, including transplant knowledge, perceived benefits and drawbacks of transplant, willingness and motivation toward transplantation, and number of donors coming forward on behalf of a patient (Waterman et al., 2013).

Numerous studies in a variety of patient populations and geographic contexts suggest that potential barriers relate to modifiable patient characteristics, including patient knowledge, ability to ask, guilt over risks, fear of donor harm, and comfort with current care (Kutner, Zhang, Huang, & Johansen, 2012). Asking a potential donor for a kidney has been identified as a barrier insofar as many potential recipients express a discomfort at the notion of approaching someone for this purpose (Barnieh et al., 2011b). Other commonly noted fears include fear of a negative response from potential donors and fear of long-term responsibility towards the donor (Barnieh et al., 2011b).

Recent work has argued that access to LKDT is positively impacted by patient education interventions (Kurella Tamura et al., 2014; Patzer et al., 2012), including work that has aligned patient education with increasing LKDT rates (Rodrigue, Cornell, Kaplan, & Howard, 2008; Schweitzer et al., 1997; Waterman et al., 2013). Among interventions that have concentrated on education, several sub-groups exist. Several consensus conferences have advised that successful transplant education interventions involve both recipients and donors, include tailoring for ethnic minorities, provide education in recipients' homes, and provide opportunities to practice specific communication strategies (Waterman, Barrett, & Stanley, 2008). Other consensus conferences have recommended implementing community-based educational programming delivered at multiple stages of the patient's journey (LaPointe Rudow et al., 2015; Rodrigue et al., 2015). In another sub-group of available research, studies have focused on

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

identifying and expanding our understanding of the challenge's patients face related to LKDT communication (Barnieh et al., 2017; Barnieh et al., 2011b; Strigo et al., 2015).

Extant research focusing on patient education and living kidney donation comes in a variety of forms. Many descriptive studies of educational programming exist, including survey-based (Waterman et al., 2015), case-study (Headley, 2014), and qualitative research (Traino, 2014). Other interventions are correlational, using observational study designs to report outcomes on a training program or the dissemination of training materials to a participant cohort (Waterman, Robbins, Paiva, & Hyland, 2010). Less frequently, experimental interventions have been reported, using both group comparison or random assignment (Strigo et al., 2015).

Rationale

Several meta-analyses and systematic reviews of studies of patient education interventions and their outcomes in adults with chronic kidney diseases have demonstrated that patient educational programs are effective (Ha Dinh, Bonner, Clark, Ramsbotham, & Hines, 2016; Li et al., 2011). While research has explored the impact of LKDT patient educational programs on program measures (Sandal et al., 2019), such as quantifying transplant rates, a systematic review of educational interventions specific to *accessing* LKDT has not yet been reported. This study makes an important distinction between, on the one hand, patient education for the purpose of increasing the volume of LKDT referrals, assessments, and surgeries and, on the other hand, patient education for the purpose of ensuring proper informed consent and collaborative care on the part of kidney transplant health professionals. In many ways, the concept of ensuring patient access to transplant engenders a holistic approach to LKDT care well-suited for nursing scholarship. The LKDT field will benefit from an evidence synthesis

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

focused on patient education interventions that have sought to empower patients with ESRD and their social networks to make informed decisions about their care.

Aims

The purpose of this systematic review protocol is to outline the research process we will use to examine the effectiveness of educational interventions that seek to increase access to LKDT. We define patient education interventions as any planned educational activity or set of activities designed to improve patients' ability to make an informed decision about LDKT. Objectives of the review are, first, to identify what educational interventions have been explored through randomized controlled trials to increase access to LKDT and, second, to evaluate the effectiveness of these interventions for operationalizing information access outcomes, identifying key health outcomes, and highlighting relevant educational outcomes. This paper outlines the protocol (or research plan) for carrying out this systematic review and provides explicit details that are essential to the quality, planning, and replication, of research results.

Methods

Criteria for considering studies for the review. We plan to follow the procedures for systematic review protocols as outlined in the *Cochrane Handbook of Systematic Reviews of Interventions* and Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols: The PRISMA-P Statement (Appendix A). Reporting of the protocol adheres to PRISMA-P reporting guidelines for systematic review protocols.

Types of studies and participants. To be included, studies need to be primary (original) randomized-controlled trials (RCTs) published in English and in any year. Studies must report patient educational interventions aimed at ameliorating or streamlining access to

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

LKDT. Using our understanding of best practices in the field of LKDT (Waterman, Robbins, & Peipert, 2016), we define increasing access to LKDT as any patient educational intervention that modifies or supplements standard care delivery in an attempt to ameliorate an advanced kidney disease patient's knowledge retention or self-efficacy, specifically in a manner that improves the patient's ability to make an informed choice about treatment options or streamline their ability to receive LKDT if they so choose. Initially, all empirical studies will be considered for inclusion. However, if the search identifies over 10 RCTs, we will exclude studies if they are not RCTs focused on patient education. For example, a study exploring the challenges patients face finding a living donor will be excluded. However, a trial assessing a training program for patients to enhance communication about LKDT with their social network would be included. In the event any ambiguity around sampling exists, the study's corresponding author will be contacted. If they are unavailable the study will be excluded.

Search strategy and data management. In consultation with a health science librarian, we plan to systematically search seven academic databases: CINAHL, MEDLINE, PsycINFO, ERIC, EBM Reviews, Scopus, and the Cochrane trial registry in the Cochrane library. Each of these databases specializes in a discipline with connections to health professional education. CINAHL is an established database of nursing literature. MEDLINE is the primary source for health-related research. PsychINFO and ERIC provide access to specialized studies in psychology and education respectively. Scopus aggregates these databases as well as other, smaller databases that may contain relevant published research. EBM Reviews and the Cochrane trial registry will allow us to survey other evidence syntheses. These databases feature a wide range of both

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

healthcare related, education related, and business-related resources from which to identify studies involving patient education.

The same search terms will be used to search all databases. Search strings will be composed of concepts derived from two term lists: education terms and LKDT terms. Each list will be subject to both a MeSH term and general search term query. The list of LKDT terms will include literature pertaining to LKDT transplantation.

Key terms will be connected using the Boolean operator AND to ensure conceptual overlap and will not be filtered in any way. As a secondary method of data collection, reference lists will be reviewed, better known as *snowball sampling*, to ensure relevant studies and authors are a part of the results. See (Appendix B) for Medline search. Search records will be collated and managed with EndNote citation management software. References will be exported into the EndNote library, and all reviewers will have access to review search results and corresponding full-text articles.

Study screening. One author will be responsible for identifying and removing all duplicate records across database searches and will independently screen the titles and abstracts of all records resulting from the initial database search for overall relevance. During the initial search, document titles and abstracts will be selected for further screening if they meet all of the following criteria: peer-review, English language, text copy available, a population of LDKT patients, and some measurement or qualitative evaluation of patient education as either an educational technique or assessment. Due to the anticipated limited amount of available publications, no restrictions will be placed on the type of LKDT educational practice under study. Upon initial screening, all authors will review full-text articles for all records having met the inclusion criteria. Each review author will independently assess full-text articles to ensure

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

overall relevance, and to confirm adherence to all inclusion criteria. Discrepancies in final inclusion decisions will be resolved by consensus. The anticipated literature screening and study selection process is provided (Figure 1).

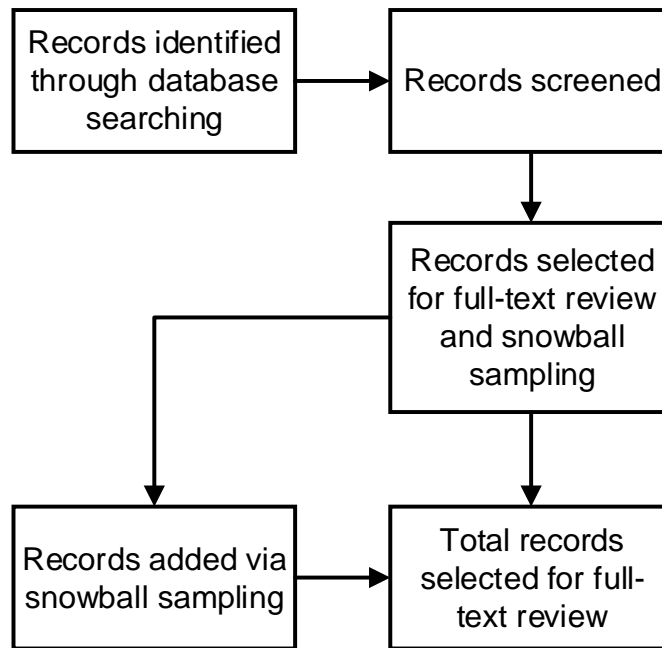


Figure 1: PRISMA-P diagram.

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Data extraction and synthesis. One author will be responsible for extracting study information, including each study's publication metadata (i.e. title, language, Study ID, author, source, year, country of origin, etc.), the purpose and theoretical framework, specifics of the LKDT educational intervention or interventions, methods information (i.e., study design, methodology, study duration, allocation and blinding, setting, concerns over bias, etc.), population (i.e., sampling pool, sampling method, sample size, etc.), information on the measures and assessments (i.e., specific instruments used, comments on validity or reliability, power, and statistical analyses), and outcomes data (i.e., direct outcomes, indirect outcomes, types of outcomes, etc.) (Higgins & Cochrane Collaboration, 2020). Data will be extracted and recorded in an Excel spreadsheet accessible by all authors. Another author will review extracted data in order to ensure accuracy and consistency of recorded information and will resolve any discrepancies by consensus.

All outcomes will be analyzed. Areas of convergence across discrete study variables will be highlighted in a research log. The study author will independently enter data into a structured Excel database. A narrative synthesis of studies will be conducted if the results identify too small of sample or extensive heterogeneity across studies. From here, authors will consult with the study librarian and a research mentor to determine next steps. Another goal of the narrative synthesis will be to provide an analysis of findings across studies for an overall assessment of the strength of the evidence.

Forrest plots will be created for discrete outcomes within the following groups: knowledge retention, patient self-efficacy, and program measures. A meta-analysis approach will be used to visualize these data; however, it was determined that meta-regression would not be necessary. This approach will consider knowledge retention outcomes will include intervention

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

measures with pre- and post- surveys of LKDT knowledge. Patient self-efficacy outcomes will include measures from measurements of patient's willingness and confidence to access LKDT. Program measures includes factors pertaining to a patient's interactions with the health system, such as whether they find a donor or receive a transplant.

Sub-group analysis. To consider thematic connections across studies, sub-group data analysis will proceed following either a qualitative synthesis (Bearman & Dawson, 2013; Ludvigsen et al., 2016) or narrative synthesis approach (Campbell, Katikireddi, Sowden, McKenzie, & Thomson, 2018). As mentioned, Forrest plots will be created for outcomes across relevant studies. Subgroup analysis will likely be determined as a result of the narrative synthesis. Given the inherent heterogeneity of how constructs such as knowledge are measured in health research, we cannot adequately state at this time how subgroups will be defined.

Risk of bias in included studies. Cochrane's tool for assessing Risk of Bias (Appendix C) is considered a benchmark for assessing study quality (Higgins & Cochrane Collaboration, 2020). This tool considers factors known to be best practices in randomized controlled trials, including appropriate randomization, allocation concealment, blinding, and procedures for dealing with incomplete data. This tool will be applied to all research studies that advance through the second round of screening. **Data synthesis.** As has been reported elsewhere, education research is a heterogeneous field for systematic reviews (Evans & Benefield, 2001; Morrison, 2005; Reed, Kern, Levine, & Wright, 2005). However, if the sample size and methodological structure of resultant studies suggests that meta-analysis may be possible, we will follow standard Cochrane protocol and measure heterogeneity across them using the Chi^2 test (Higgins & Cochrane Collaboration, 2020). We will also use the I^2 statistic to evaluate inconsistencies across studies; where 0% = no heterogeneity, and larger values indicate increasing

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

heterogeneity. If I^2 is $<40\%$ study heterogeneity might not be important. If a high-level of heterogeneity is determined by statistical tests, meta-analysis will not be done; instead, another form of evidence synthesis will be conducted (i.e., narrative synthesis). If a meta-analysis is not used, the authors will determine an appropriate, alternative analytic approach.

Missing data. If missing data are identified, authors of included studies will be contacted to request data that is deemed relevant. When missing data are unavailable leaving significant gaps in data, studies will undergo another round of screening. During this additional screening phase, the study will be re-examined against our inclusion and exclusion criteria to determine if they will be included or excluded for insufficiency.

Discussion

Although essential to the systematic review processes, the existence of a protocol is often excluded from full reports of systematic reviews (Moher, Liberati, Tetzlaff, & Altman, 2009; Moher et al., 2015). While this protocol follows standards for conducting systematic reviews in any topical area, it is recommended that systematic review protocols should be provided in any new research reviews in order to increase transparency, as well as to allow researchers to duplicate methodology and results of systematic reviews (Moher et al., 2009; Moher et al., 2015). As such, the current protocol explicitly details methodology to be carried out over the course of this systematic review in order to increase transparency, and to mitigate potential challenges commonly reported in systematic reviews, such as potential for biases (Higgins & Green, 2011).

We believe this systematic review is a necessary first step in building a strong evidence base to inform future initiatives to increase access to LKDT. We believe that the review will identify the need for more high-quality evidence about best practices and known educational

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

techniques for empowering patients toward improved LKDT outcomes. Our results will provide a map for future researchers interested in filling existing gaps in patient education in kidney transplant medicine.

References

- Barnieh, L., Collister, D., Manns, B., Lam, N. N., Shojai, S., Lorenzetti, D., . . . Klarenbach, S. (2017). A scoping review for strategies to increase living kidney donation. *Clinical Journal of the American Society of Nephrology*, *12*(9), 1518-1527
- Barnieh, L., McLaughlin, K., Manns, B. J., Klarenbach, S., Yilmaz, S., Hemmelgarn, B. R., & Alberta Kidney Disease, N. (2011a). Barriers to living kidney donation identified by eligible candidates with end-stage renal disease. *Nephrology Dialysis Transplantation*, *26*, 732-738
- Barnieh, L., McLaughlin, K., Manns, B. J., Klarenbach, S., Yilmaz, S., Taub, K., . . . Alberta Kidney Disease, N. (2011b). Evaluation of an education intervention to increase the pursuit of living kidney donation: A randomized controlled trial. *Progress in Transplantation*, *21*(1), 36-42
- Bearman, M., & Dawson, P. (2013). Qualitative synthesis and systematic review in health professions education. *Medical Education*, *47*(3), 252-260
- Campbell, M., Katikireddi, S. V., Sowden, A., McKenzie, J. E., & Thomson, H. (2018). Improving conduct and reporting of narrative synthesis of quantitative data (icons-quant): Protocol for a mixed methods study to develop a reporting guideline. *BMJ Open*, *8*(2)
- Evans, J., & Benefield, P. (2001). Systematic reviews of educational research: Does the medical model fit? In (Vol. 27, pp. 527-541). Oxford, UK.
- Ha Dinh, T. T., Bonner, A., Clark, R., Ramsbotham, J., & Hines, S. (2016). The effectiveness of the teach-back method on adherence and self-management in health education for people with chronic disease: A systematic review. *JBIC Database System Rev Implement Rep*, *14*(1), 210-247

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Headley, C. M. (2014). Do you know how to respond to questions related to kidney donation?.

Nephrology nursing journal : journal of the American Nephrology Nurses' Association, 41, 618-623

Higgins, J. P. T., & Cochrane Collaboration. (2020). *Cochrane handbook for systematic reviews of interventions* (Second edition. ed.). Hoboken, NJ: Wiley-Blackwell.

Higgins, J. P. T., & Green, S. (2011). Cochrane handbook for systematic reviews of interventions version 5.1.0 [updated march 2011]. *The Cochrane Collaboration, 4*

Kurella Tamura, M., Li, S., Chen, S. C., Cavanaugh, K. L., Whaley-Connell, A. T., McCullough, P. A., & Mehrotra, R. L. (2014). Educational programs improve the preparation for dialysis and survival of patients with chronic kidney disease. *Kidney International, 85*(3), 686-692

Kutner, N. G., Zhang, R., Huang, Y., & Johansen, K. L. (2012). Impact of race on predialysis discussions and kidney transplant preemptive wait-listing. *American Journal of Nephrology, 35*(4), 305-311

LaPointe Rudow, D., Hays, R., Baliga, P., Cohen, D. J., Cooper, M., Danovitch, G. M., . . .

Rodrigue, J. R. (2015). Consensus conference on best practices in live kidney donation: Recommendations to optimize education, access, and care. *American Journal of Transplantation, 15*, 914-922

Li, T., Wu, H. M., Wang, F., Huang, C. Q., Yang, M., Dong, B. R., & Liu, G. J. (2011).

Education programmes for people with diabetic kidney disease. *Cochrane Database of Systematic Reviews*(6), CD007374

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Ludvigsen, M. S., Hall, E. O., Meyer, G., Fegran, L., Aagaard, H., & Uhrenfeldt, L. (2016).

Using sandelowski and barroso's meta-synthesis method in advancing qualitative evidence. *Qualitative Health Research*, 26(3), 320-329

Moher, D., Liberati, A., Tetzlaff, J., & Altman, D. G. (2009). Preferred reporting items for systematic reviews and meta-analyses: The prisma statement. *Annals of Internal Medicine*, 151, 1006-1012

Moher, D., Shamseer, L., Clarke, M., Ghersi, D., Liberati, A., Petticrew, M., . . . Whitlock, E. (2015). Preferred reporting items for systematic review and meta-analysis protocols (prisma-p) 2015 statement. *Systematic Reviews*, 4

Morrison, J. (2005). The challenges of systematic reviews of educational research. *BMJ*, 331, 391

Patzer, R. E., Perryman, J. P., Pastan, S., Amaral, S., Gazmararian, J. a., Klein, M., . . .

McClellan, W. M. (2012). Impact of a patient education program on disparities in kidney transplant evaluation. *Clinical journal of the American Society of Nephrology : CJASN*, 7, 648-655

Reed, D. A., Kern, D. E., Levine, R. B., & Wright, S. M. (2005). Costs and funding for published medical education research. *JAMA: The Journal of the American Medical Association*, 294(9), 1052-1057

Reese, P. P., Boudville, N., & Garg, A. X. (2015). Living kidney donation: Outcomes, ethics, and uncertainty. *Lancet*, 385(9981), 2003-2013

Rodrigue, J. R., Cornell, D. L., Kaplan, B., & Howard, R. J. (2008). Patients' willingness to talk to others about living kidney donation. *Progress in Transplantation*, 18, 25-31

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Rodrigue, J. R., Kazley, A. S., Mandelbrot, D. A., Hays, R., LaPointe Rudow, D., Baliga, P., & American Society of, T. (2015). Living donor kidney transplantation: Overcoming disparities in live kidney donation in the us--recommendations from a consensus conference. *Clinical Journal of The American Society of Nephrology: CJASN*, *10*, 1687-1695
- Sandal, S., Dendukuri, N., Wang, S., Guadagno, E., Ekmekjian, T., & Alam, A. (2019). Efficacy of educational interventions in improving measures of living donor kidney transplantation activity: A systematic review and meta-analysis. *Transplantation*
- Schweitzer, E. J., Yoon, S., Hart, J., Anderson, L., Barnes, R., Evans, D., . . . Bartlett, S. T. (1997). Increased living donor volunteer rates with a formal recipient family education program. *American Journal of Kidney Diseases*, *29*, 739-745
- Strigo, T. S., Ephraim, P. L., Pounds, I., Hill-Briggs, F., Darrell, L., Ellis, M., . . . Boulware, L. E. (2015). The talks study to improve communication, logistical, and financial barriers to live donor kidney transplantation in african americans: Protocol of a randomized clinical trial. *BMC Nephrology*, *16*, 160
- Traino, H. M. (2014). Communication self-efficacy, perceived conversational difficulty, and renal patients' discussions about transplantation. *Patient Education and Counseling*, *94*(2), 180-186
- Waterman, A. D., Barrett, A. C., & Stanley, S. L. (2008). Optimal transplant education for recipients to increase pursuit of living donation. *Progress in Transplantation*, *18*(1), 55-62
- Waterman, A. D., Morgieovich, M., Cohen, D. J., Butt, Z., Chakkera, H. A., Lindower, C., . . . American Society of, T. (2015). Living donor kidney transplantation: Improving

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

education outside of transplant centers about live donor transplantation--

recommendations from a consensus conference. *Clinical Journal of the American Society of Nephrology*, 10(9), 1659-1669

Waterman, A. D., Peipert, J. D., Hyland, S. S., McCabe, M. S., Schenk, E. A., & Liu, J. (2013).

Modifiable patient characteristics and racial disparities in evaluation completion and living donor transplant. *Clinical Journal of the American Society of Nephrology*, 8, 995-1002

Waterman, A. D., Robbins, M. L., Paiva, A. L., & Hyland, S. S. (2010). Kidney patients'

intention to receive a deceased donor transplant: Development of stage of change, decisional balance and self-efficacy measures. *Journal of Health Psychology*, 15(3), 436-445

Waterman, A. D., Robbins, M. L., & Peipert, J. D. (2016). Educating prospective kidney

transplant recipients and living donors about living donation: Practical and theoretical recommendations for increasing living donation rates. *Current Transplantation Reports*, 3, 1-9

Appendix A: PRISMA-P checklist

Section and topic	Item No	Checklist item	Page No.#
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	1
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	1
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	10
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	1
Support:			
Sources	5a	Indicate sources of financial or other support for the review	1
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4-5
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6 &Appendix A
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	7
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	7
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	7
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	7
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	8
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	8

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Data synthesis	15a Describe criteria under which study data will be quantitatively synthesized 15b If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ) 15c Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) 15d If quantitative synthesis is not appropriate, describe the type of summary planned	9
Meta-bias(es)	16 Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	10
Confidence in cumulative evidence	17 Describe how the strength of the body of evidence will be assessed (such as GRADE)	10

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

Note: PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol* From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ*. 2015 Jan 2;349(jan02 1): g7647.

Appendix B: Medline search strategy

Search Strategy:

Concept 1: Living Donors

1 Living Donors/ (13685) (14860)

2 ((living or live) adj2 (transplant* or donor* or donat* or harvest*)).ti,ab,kw.
(16909) (16915)

3 or/1-2 (21233) (21251)

Concept 2: Kidney transplant

4 Kidney Transplantation/ (89375) (94852)

5 ((kidney* or renal) adj2 (transplant* or donor* or donat* or remov*)).ti,ab,kw.
(80852) (80866)

6 kidney/ (259197) (259210)

7 Nephrectomy/ (32102) (32108)

8 nephrectom*.ti,ab,kw. (33503) (33515)

9 or/4-8 (383405)

10 3 and 9 (10771) (11026)

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Concept 3a: (Patient Education)

- 11 Patient Education as Topic/ (79984) (79988)
- 12 communication/ (76476) (76483)
- 13 communication barriers/ (5921) (5922)
- 14 Teach-Back Communication/ (22) (22)
- 15 professional-patient relations/ or nurse-patient relations/ or physician-patient relations/ (125857) (125864)
- 16 "Referral and Consultation"/ (61009) (61015)
- 17 communicat*.ti,ab,kw. (253358) (253481)
- 18 Patient Education as Topic/ (79984)
- 19 ((patient* or recipient* or donor*) adj2 empower*).ti,ab,kw. (2647) (2651)
- 20 (educat* or training).ti,ab,kw. (799243) (799660)
- 21 or/11-20 (1226610) (1227133)
- 22 exp health personnel/ (463302) (463349)
- 23 ((health care or healthcare) adj2 (provider* or practitioner* or professional* or personnel)).ti,ab,kw. (89367) (89414)
- 24 exp Professional Role/ (78376) (78382)
- 25 (physician* or doctor or doctors or surgeon* or p?ediatrician* or general practi* or p?ediatrician*or nephrolog*).ti,ab,kw. (681376) (681647)

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

26 nurs*.ti,ab,kw. (420541) (420646)

27 or/22-26 (1394896) (1395317)

28 21 and 27 (350952) (351074)

Concept 3b: Continuing Education

29 education, continuing/ or education, medical, continuing/ or education, nursing,
continuing/ or education, pharmacy, continuing/ or education, professional, retraining/ (55868)
(55870)

30 inservice training/ or staff development/ (27454) (27454)

31 (continu* adj2 educat*).ti,ab,kw. (21777) (21783)

32 professional development.ti,ab,kw. (7766) (7773)

33 or/28-32 (412185)

34 10 and 33 (754)

.....

Appendix C: Cochrane Risk of Bias tool

Bias Table – Study:	
<p>Random sequence generation (selection bias)</p> <ul style="list-style-type: none"> - Were baseline characteristics of patients in treatment and control similar? If unbalanced = selection bias. - What level of randomization occurred – Patient/provider or clinic? Patient level randomization may lead to contamination. 	
<p>Allocation concealment (selection bias)</p> <ul style="list-style-type: none"> - Researcher should be blinded to where patient is allocated when possible. 	
<p>Blinding of participants and personnel (performance bias)</p> <ul style="list-style-type: none"> - Blinding of patients and personnel is important as for patients – placebo effect and personnel might alter or enhance their intervention based on bias 	
<p>Blinding of outcome assessment (detection bias)</p> <ul style="list-style-type: none"> - Outcome assessors or data collectors should also be blinded to minimize bias. They should not be aware of assigned therapy. 	
<p>Incomplete outcome data (attrition bias)</p> <ul style="list-style-type: none"> - Was follow-up complete? Did all the patients complete the trial? - Were patients analyzed in the groups they were assigned? Intention to treat analysis principle to maintain randomization benefit - Attrition bias is caused by increased number of patients lost to follow-up - Were the baseline characteristics balanced at study’s completion – to account for dropouts and lost to follow-ups? 	
<p>Selective reporting (reporting bias)</p> <ul style="list-style-type: none"> - Were all the trial’s pre-specified outcomes, at pre-specified time-points reported? If so, this minimizes reporting bias. 	
<p>Other bias</p>	

Chapter 3. Manuscript #2: Educational Interventions to Improve Access to Living Kidney Donation (LKD): A Systematic Review and Descriptive Analysis

Abstract

Background: For many patients with end-stage renal disease (ESRD), the preferred treatment is kidney transplantation via living kidney donor transplantation (LKDT). When compared to renal dialysis, LKDT offers improved patient outcomes and greatly reduced healthcare spending. However, in recent years, living donation rates have stagnated. To identify patient education, as a means of improving living donation rates, we aimed to review and synthesize findings from patient education intervention studies aimed at improving informed consent and patient knowledge related to LKDT.

Methods/Design: This is a Cochrane style systematic review and descriptive synthesis of quantitative studies adhering to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Databases were searched from inception to 2018 and supplemented by hand searching of references. We assessed quality of included studies using the Cochrane Risk of Bias tool. Interventions were classified according to a series of themes: scheduling patient education earlier in a patient's chronic kidney disease (CKD) journey, including a patient's social network in patient education, and tailoring patient education for sociodemographic characteristics. We conducted descriptive analysis with a focused subgroup analysis to consider key findings across studies.

Results: We identified 27 outcomes across the 15 studies that met our inclusion criteria. We considered the frequency of outcomes across the studies and conducted meta-analyses on the most common outcomes: knowledge measures (n = 10), willingness to discuss LDKT with others (n = 5), concerns about the risks of LKDT (n = 5), patient received ≥ 1 LDKT donor

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

referral (n = 6), patient received LKDT (n = 5), and patient communicated with others about LKDT (n = 5). Where appropriate subgroup analysis subdivided the manuscripts across 3 themes: (1) studies reporting on educational intervention prior to the patient presenting for transplant evaluation, (2) interventions that integrated patients' social networks into intervention design, and (3) interventions that used some form of sociocultural tailoring to ensure inclusivity for a specific population.

Conclusion: Findings from this review demonstrate that patient education is linked with improved self-efficacy, increase in knowledge and decreased concerns on the part of patients. More research is needed, however, to consider how these findings can apply in Canadian contexts. We also noted a dearth of reported information on how patient educators were trained and whether they were health professionals. We believe these results will be of value for developing research and clinical policy in LDKT moving forward.

**Educational Interventions to Improve Access to Living Kidney Donation (LKD):
A Systematic Review and Descriptive Analysis**

Introduction

Despite advances in the field of living kidney donor transplantation (LDKT), transplant rates in the USA and Canada have remained stable or decreased (Reese, Boudville, & Garg, 2015). Recently, the International Registry in Organ Donation and Transplantation ranked Canada as 19th in living organ donation transplant rates, with rates lower than the United States, the United Kingdom, and India among others (Gomez, Perez, & Manyalich, 2014). These statistics are troubling given that, for many patients, LKDT is the preferred treatment for end-stage renal disease (ESRD) and research has repeatedly demonstrated better patient outcomes and reduced healthcare spending versus dialysis or deceased donation (Barnieh et al., 2011a; Cai et al., 2014; Collins et al., 2012; Laupacis et al., 1996; Pace et al., 2002; Purnell et al., 2013; Reese et al., 2015; Tarantino, 2000). Building on this evidence, the transplant community strives to increase patient access to LKDT as much as possible, aiming to ensure patients are given multiple opportunities to understand LDKT and make informed decisions about their care.

Some research has explored whether LKDT is positively impacted by patient education interventions (Kurella Tamura et al., 2014; Patzer et al., 2012). A growing evidence base appears to have demonstrated that patient education leads to increases in LKDT rates (Rodrigue, Cornell, Kaplan, & Howard, 2008a; Schweitzer et al., 1997; Waterman et al., 2013). Recently, several consensus conferences have advised that successful transplant education interventions involve both recipients and donors, include tailoring for ethnic minorities, provide education in recipients' homes, and provide opportunities to practice specific communication strategies

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

(LaPointe Rudow et al., 2015; Rodrigue et al., 2015; Waterman, Barrett, & Stanley, 2008). Yet there remain questions about the efficacy of such interventions.

In this review we identify and summarize available evidence to improve our understanding of the current landscape of patient education interventions for improving access to LKDT. We defined increasing access to LKDT as any patient educational intervention that modified or supplemented standard care delivery in an attempt to ameliorate a chronic kidney disease patient's knowledge retention or self-efficacy in a manner that improves the patient's ability to make an informed choice about treatment options or streamline their ability to receive LKDT if they so choose. Other evidence syntheses on patient educational interventions for LKDT have been published (Barnieh et al., 2017; Gander, Gordon, & Patzer, 2017), but at present the transplant literature lacks a thorough descriptive analysis of these approaches.

Many calls exist in the literature for better descriptive data on patient educational interventions for increasing access for LKDT (Barnieh et al., 2017; LaPointe Rudow et al., 2015; Waterman et al., 2015a). This study provides the first systematic review, following Cochrane's methodology (Higgins & Cochrane Collaboration, 2020), of the mechanisms, outcomes, and practices that comprise existing randomized controlled trials of patient education interventions aiming to increase access to LDKT. As it stands, educational interventions to increase access to LKDT can be categorized according to location of delivery, timing of delivery, and by the pedagogical techniques or tools. Along with synthesizing the literature, this descriptive analysis will also align current evidence alongside these categories.

Methods

We followed the procedures for conducting systematic reviews and meta-analysis as outlined by the Cochrane Handbook of Systematic Reviews of Interventions (Higgins & Cochrane Collaboration, 2020) and the Preferred Reporting Items for Systematic Reviews and Meta-analysis: The PRISMA statement (Liberati et al., 2009) (Appendix A).

Criteria for considering studies for this review. Types of studies. While the complexity of measuring the efficacy of educational interventions via evidence syntheses has been described in the literature (Evans & Benefield, 2001; Reed et al., 2005a; Reed, Kern, Levine, & Wright, 2005b), we suspected that there nevertheless does exist a wide body of high-quality evidence of educational interventions for improving LKDT. With this in mind, we sought to identify primary randomized-controlled trials (RCTs) published in English language and in any year. Studies must have reported patient educational interventions aimed at streamlining and improving access to LKDT. After extensive preliminary review of the literature, we chose categories that represented the timings and pedagogical techniques associated with educational interventions reported in the studies that met our inclusion criteria.

We included studies focusing on patients with chronic kidney disease and or their family members / social network. We did not restrict our search criteria by sociodemographic factors. We sought to include studies with health professionals as participants, expecting that some research may have existed focusing on the role of health professional education in access to LKDT. We excluded studies if they were not RCTs focused on patient education. In the event of any ambiguity around sampling, the study's corresponding author was contacted. If they were unavailable the study would be excluded.

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Types of participants. To meet inclusion criteria, studies need to be primary (original) randomized-controlled trials (RCTs) published in English and in any year. Studies must report patient educational interventions aimed at ameliorating or streamlining access to LKDT. Using our understanding of best practices in the field of LKDT, we define increasing access to LKDT as any patient educational intervention that modifies or supplements standard care delivery in an attempt to ameliorate an advanced kidney disease patient's knowledge retention or self-efficacy, specifically in a manner that improves the patient's ability to make an informed choice about treatment options or streamline their ability to receive LKDT if they so choose.

Search strategy. In consultation with a health science librarian, we searched seven academic databases: CINAHL, MEDLINE, PsycINFO, ERIC, EBM Reviews, Scopus, and the Cochrane trial registry in the Cochrane library. These databases feature a wide range of both healthcare related, education related, and business-related resources from which to identify studies involving patient education. All databases were last accessed in November 2018 (Appendix B).

Study selection. The same search terms were used to search all databases. Search strings were composed of concepts derived from two term lists: education terms and LKDT terms. Each list was subject to both a MeSH term and general search term query. The list of LKDT terms included literature pertaining to LKDT transplantation. Education terms included nursing, medical, social work, health professional, and education. LKDT terms included living donation, living kidney donation, kidney donors, and living donor transplant. Key terms were connected using the Boolean operator AND to ensure conceptual overlap and will not be filtered in any way. As a secondary method of data collection, reference lists were reviewed to ensure relevant studies and authors were included in the search. One reviewer (JM) independently

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

screened titles and abstracts from the initial database searches. Full text of studies passing initial screening were retrieved and reviewed independently by two reviewers (JM, EW). We resolved discrepancies in final inclusion decisions by consensus. Study selection and screening processes are presented (Figure 1).

Data extraction and synthesis. Data were extracted by one reviewer (JM) into a data collection Excel spreadsheet from each included study. These data included each study's publication metadata (i.e., title, language, Study ID, author, source, year, country of origin, etc.), the purpose and theoretical framework, specifics of the LKDT educational intervention or interventions, methods information (i.e., study design, methodology, study duration, allocation and blinding, setting, concerns over bias, etc.), population (i.e., sampling pool, sampling method, sample size, etc.), information on the measures and assessments (e.g., any specific instruments used, comments on validity or reliability, power, and statistical analyses), and outcomes data (i.e., direct outcomes, indirect outcomes, types of outcomes, etc.) (Higgins & Cochrane Collaboration, 2020). Two reviewers (JM, EW) reviewed extracted data for accuracy and consistency, and resolved any discrepancies by discussion.

All outcomes were analyzed and clustered according to study outcomes, including: knowledge retention, patient self-efficacy, and program measures (Petticrew & Roberts, 2006). Knowledge retention outcomes included intervention measures with pre-and post-surveys of LKDT knowledge. Patient self-efficacy outcomes included measures from measurements of patient's willingness and confidence to access LKDT. Program measures included factors pertaining to a patient's interactions with the health system, such as whether they find a donor or receive a transplant. We sought missing data from the primary authors for four of the included studies (Massey et al., 2016; Rodrigue et al., 2014; Waterman & Peipert, 2018; Waterman et al.,

2019). We received replies from three study authors who provided requested data (Rodrigue et al., 2014; Waterman & Peipert, 2018; Waterman et al., 2019).

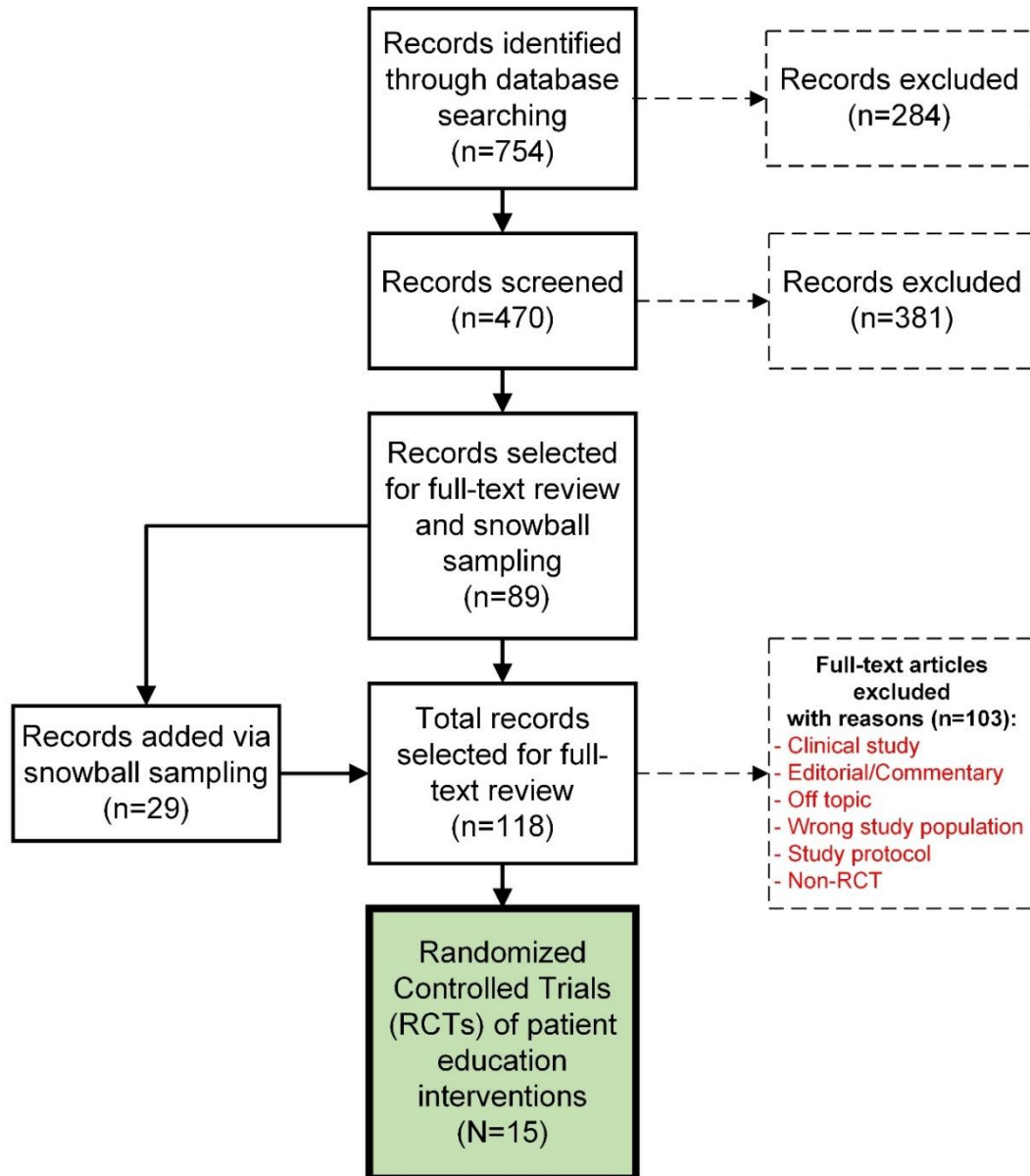


Figure 1: PRISMA diagram.

Data synthesis. As has been reported elsewhere, education research is a heterogeneous field (Evans & Benefield, 2001; Morrison, 2005; Reed et al., 2005b). We considered whether the sample size and methodological structure of resultant studies suggested that meta-analyses were

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

possible. A lack of validated measures across educational interventions and a substantial heterogeneity across study outcomes precluded meta-analyses. We thus elected to conduct a narrative review to generate prevalent themes; we generated forest plots as a visual display of effect sizes, however we chose not to look at overall significance or summary scores due to heterogeneity. We structured these visual displays around 3 core themes across which we organized study outcomes: (1) studies that delivered an educational intervention prior to the participant presenting for transplant evaluation, (2) interventions that integrated patients' social networks into intervention design, and (3) interventions that used some form of sociocultural tailoring to ensure inclusivity for a specific population.

We considered intervention effects on the most common measured outcomes in the 15 studies. We used the Cochrane Collaboration software program Review Manager (Rev Man 5.3). Data were entered in Review Manager in order to generate forest plot graphs as a result of either pre-calculated estimates of intervention effect and standard error (generic inverse variance) or measures of events and participants (dichotomous). Across all forest plots, the area to the right of midline (<0) indicated a favorable intervention result.

Risk of bias in included studies. Cochrane's tool for assessing Risk of Bias is considered a benchmark for assessing study quality (Higgins & Cochrane Collaboration, 2020). After identifying studies meeting our inclusion criteria, we assessed methodological quality of individual studies using the *risk of bias approach* of the Cochrane Collaboration (Appendix C). One reviewer (JM) constructed a risk of bias table (reviewed by AM) that noted random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting, and other biases. Each criterion was

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

assessed as *low risk of bias* (answered ‘yes’), *high risk of bias* (answered ‘no’), or *unclear or unknown risk of bias* (answered ‘unclear’). We considered studies to be of high quality if they met all criteria or all but one criterion.

Results

We identified 754 journal articles based on title and abstract. After duplications were removed, 470 titles and abstract were screened, of which 381 were excluded. We identified 29 additional records by hand searching citations of publications. We retrieved and assessed 118 full-text articles for eligibility and subsequently excluded 103 publications were study protocols, 61 studies did not focus on LKDT, 36 studies were non-RCTs, and 2 studies were secondary analyses of included trials (Rodrigue, Cornell, Kaplan, & Howard, 2008b; Rodrigue et al., 2019). A final group of 15 articles met our inclusion criteria and were included in the analysis (Arriola, Powell, Thompson, Perryman, & Basu, 2014; Barnieh et al., 2011b; Boulware et al., 2018; Boulware et al., 2013; Gordon et al., 2016; Ismail et al., 2014; Massey et al., 2016; Patzer et al., 2018; Patzer et al., 2017; Rodrigue, Cornell, Lin, Kaplan, & Howard, 2007; Rodrigue et al., 2014; Sullivan et al., 2012; Waterman & Peipert, 2018; Waterman et al., 2019; Weng, Peipert, Holland, Brown, & Waterman, 2017).

Study characteristics.

Participants. The 15 included studies involved 2,939 participants. Across all studies, 1,571 patients were included as part of study interventions and 1,368 were included as part of control groups. Study publication dates ranged from 2007-2019. All studies compared educational interventions with standard or usual care and 10 of the studies reported on interventions involving education plus additional counselling or supports (Barnieh et al., 2011b;

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Boulware et al., 2013; Ismail et al., 2014; Massey et al., 2016; Rodrigue et al., 2007; Rodrigue et al., 2014; Sullivan et al., 2012; Waterman & Peipert, 2018; Waterman et al., 2019; Weng et al., 2017). Studies were predominately American (Arriola et al., 2014; Boulware et al., 2018; Boulware et al., 2013; Gordon et al., 2016; Patzer et al., 2018; Patzer et al., 2017; Rodrigue et al., 2007; Rodrigue et al., 2014; Sullivan et al., 2012; Waterman & Peipert, 2018; Waterman et al., 2019; Weng et al., 2017), with the remainder from Canada (Barnieh et al., 2011b), and the Netherlands (Ismail et al., 2014; Massey et al., 2016). Nine were multi-centre RCTs (Boulware et al., 2018; Boulware et al., 2013; Gordon et al., 2016; Massey et al., 2016; Patzer et al., 2018; Patzer et al., 2017; Sullivan et al., 2012; Waterman & Peipert, 2018; Waterman et al., 2019) and 6 were single centre RCTs (Arriola et al., 2014; Barnieh et al., 2011b; Ismail et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014; Weng et al., 2017). Ten studies reported on mixed race populations (Barnieh et al., 2011b; Boulware et al., 2013; Ismail et al., 2014; Massey et al., 2016; Patzer et al., 2018; Patzer et al., 2017; Rodrigue et al., 2007; Sullivan et al., 2012; Waterman & Peipert, 2018; Weng et al., 2017) while 3 focused on African Americans (Arriola et al., 2014; Boulware et al., 2018; Rodrigue et al., 2014), 1 on Hispanics (Gordon et al., 2016), and 1 on low income African American and Caucasian patients (Waterman et al., 2019). All studies reported sources of funding. Characteristics of included studies are listed in **Table 1** and **Table 2**. The majority of study participants were patients; however, two studies did include patients' social networks among participants (Ismail et al., 2014; Massey et al., 2016).

Design. All studies were prospective comparative, RCTs. One RCT used a cross-over design, which allowed both participant groups to benefit from the educational intervention

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

(Massey et al., 2016). All studies used some form of randomization to assign patients to an educational intervention, including using randomization software.

Interventions. Four studies tested two intervention designs against their control (Boulware et al., 2018; Boulware et al., 2013; Rodrigue et al., 2014; Waterman et al., 2019). There were 10 studies that mentioned specific training conducted for the personnel responsible for delivering the educational intervention (Boulware et al., 2013; Ismail et al., 2014; Massey et al., 2016; Patzer et al., 2018; Patzer et al., 2017; Rodrigue et al., 2007; Rodrigue et al., 2014; Sullivan et al., 2012; Waterman & Peipert, 2018; Waterman et al., 2019). An educational intervention that occurred in the participant's home was used in 5 studies (Ismail et al., 2014; Massey et al., 2016; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman et al., 2019), while 11 studies featured a patient educational intervention that was tailored for sociocultural sensitivity (Arriola et al., 2014; Boulware et al., 2018; Boulware et al., 2013; Gordon et al., 2016; Ismail et al., 2014; Patzer et al., 2017; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018; Waterman et al., 2019; Weng et al., 2017). Participants' social networks were involved in 11 studies (Barnieh et al., 2011b; Boulware et al., 2018; Boulware et al., 2013; Gordon et al., 2016; Ismail et al., 2014; Massey et al., 2016; Patzer et al., 2017; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018; Waterman et al., 2019), while 7 studies tested interventions that were provided prior to the participant presenting for transplant evaluation (Boulware et al., 2018; Boulware et al., 2013; Massey et al., 2016; Patzer et al., 2017; Sullivan et al., 2012; Waterman & Peipert, 2018; Waterman et al., 2019).

Several patient characteristics guided study design: 2 studies aimed the intervention toward a preemptive (pre-dialysis) patient population (Boulware et al., 2013; Massey et al., 2016), 5 aimed the intervention at patients on dialysis (Boulware et al., 2018; Patzer et al., 2017;

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Sullivan et al., 2012; Waterman & Peipert, 2018; Waterman et al., 2019), 4 aimed the intervention at patients presenting for transplant evaluation (Arriola et al., 2014; Gordon et al., 2016; Patzer et al., 2018; Weng et al., 2017), and 4 aimed the intervention for patients who were already approved for transplant (Barnieh et al., 2011b; Ismail et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014).

The interventions were delivered by a variety of personnel and some studies included more than one type of personnel in the intervention delivery. There were 5 interventions delivered by nurses (Barnieh et al., 2011b; Ismail et al., 2014; Massey et al., 2016; Patzer et al., 2017; Weng et al., 2017), 3 by social workers (Boulware et al., 2013; Massey et al., 2016; Waterman et al., 2019), 4 by trained educators (Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018; Weng et al., 2017), 4 by research staff (Arriola et al., 2014; Boulware et al., 2018; Gordon et al., 2016; Waterman et al., 2019), 2 by physicians (Barnieh et al., 2011b; Patzer et al., 2018), and 2 by past patients (Barnieh et al., 2011b; Sullivan et al., 2012).

Study outcomes. A comprehensive review of the 15 included studies revealed 27 unique outcome measures. Each study evaluated between 1 and 10 outcome measures with a median of 7 and a total of 77 across the included studies. Heterogeneity often existed on how and when the outcomes were measured. While similarities existed, no two trials tested the same educational intervention. Further to the heterogeneous nature of the interventions and outcomes, participant populations varied by race, stage of kidney disease, and readiness to pursue

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

transplant. For these reasons, and for lack of validated measurement tools, we have opted to report outcomes with a descriptive analysis, rather than a meta-analysis.

Outcome measures were organized into three categories (Figure 2): (1) self-efficacy outcomes measures, (2) knowledge outcome measures, and (3) program measures. *Self-efficacy* includes measures which relate to participants' motivation and self-confidence in learning about or taking steps in pursuit of transplant or living kidney donation. *Knowledge measures* include participants' educational retention about kidney disease, living donation, transplant or other renal replacement therapies. *Program measures* include actual numbers of participants undergoing transplant evaluations, being waitlisted, receiving a LDKT, or having potential donors' express interest or initiate evaluation.

We chose to limit the descriptive synthesis to the most reported outcomes. Across the 15 studies, the mean number of times each outcome was reported was 5.1. We determined 6 of the 27 outcomes were reported in at least 5 studies: knowledge (n = 10), (Arriola et al., 2014; Gordon et al., 2016; Ismail et al., 2014; Massey et al., 2016; Patzer et al., 2018; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018; Waterman et al., 2019; Weng et al., 2017). willingness to discuss LDKT with others (n = 5) (Arriola et al., 2014; Ismail et al., 2014; Massey et al., 2016; Rodrigue et al., 2007; Rodrigue et al., 2014), actual communication with others about kidney disease and RRTs (n = 5) (Boulware et al., 2018; Boulware et al., 2013; Ismail et al., 2014; Massey et al., 2016; Waterman & Peipert, 2018), concerns about risk of LKT (n = 5) (Boulware et al., 2018; Boulware et al., 2013; Ismail et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014), having a potential donor express interest to the transplant program (n = 6) (Ismail et al., 2014; Patzer et al., 2018; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018), and receiving a living donor kidney transplant (n = 6) (Ismail et al., 2014; Patzer

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

et al., 2018; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018). These 6 outcomes occur across 13 of the 15 studies.

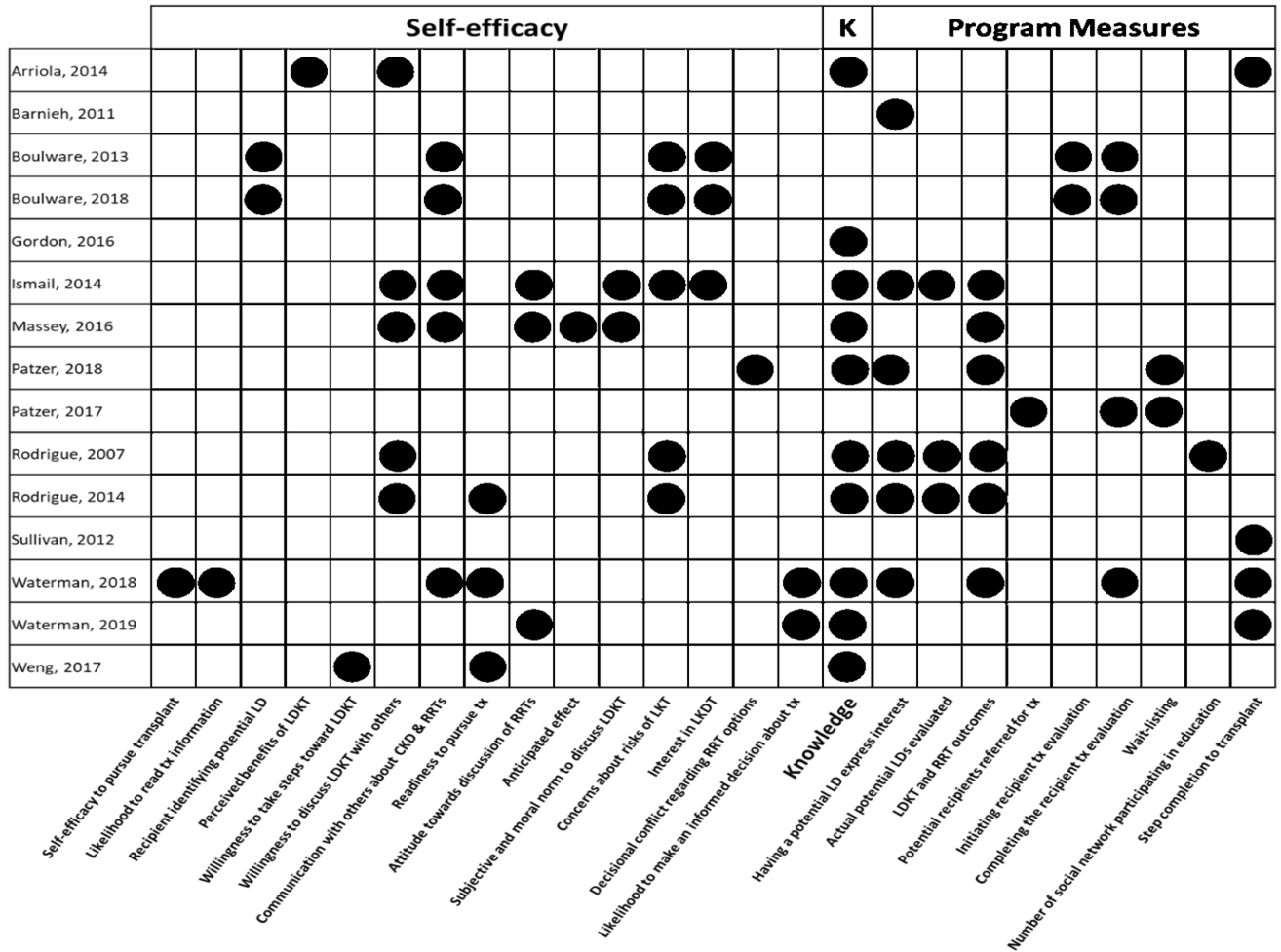


Figure 2: Study outcomes.

Risk of bias in included studies. Many studies did not report enough methodological detail for complete assessment of risk of bias. Details of blinding and concealment were the most poorly reported parameters. Risk of bias results are summarized (Figure 3). Due to the nature of patient educational interventions, blinding was often not possible for trial participants and

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

educational personnel. Because this systematic review includes a limited number of studies, we do not provide publication bias assessed through funnel plot analysis.

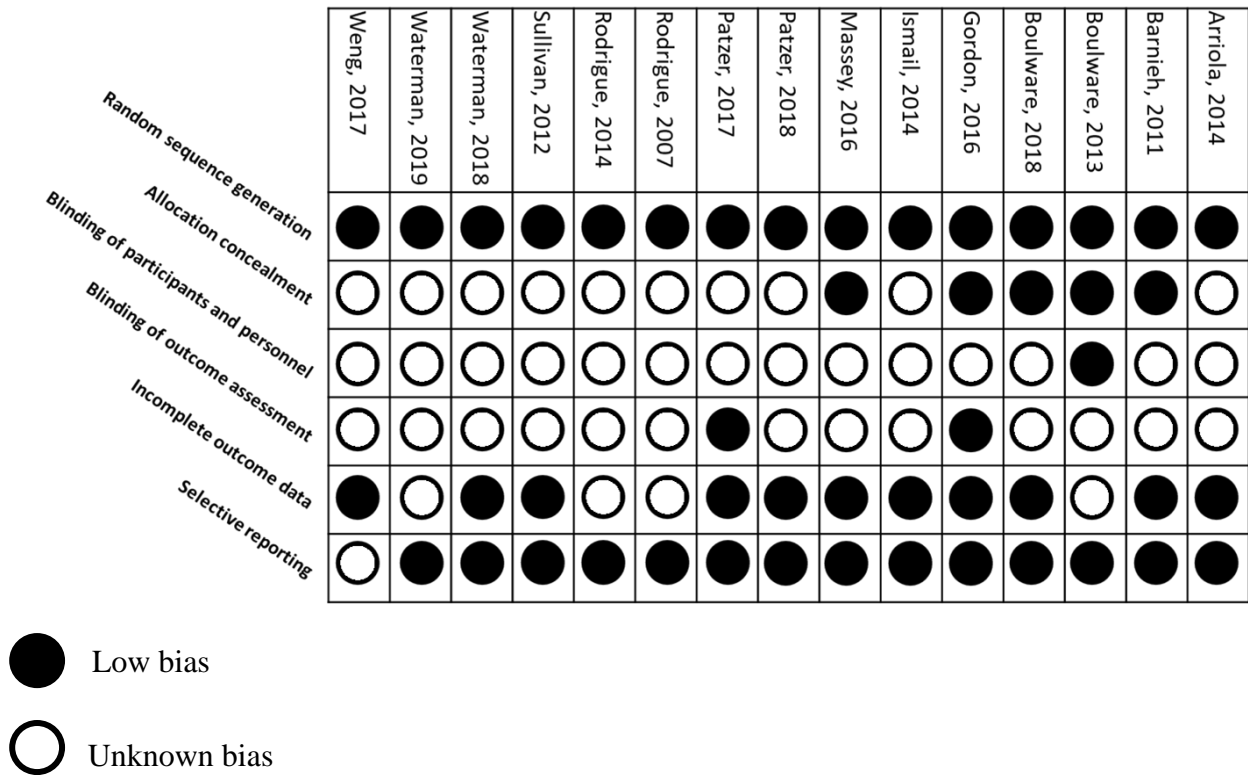


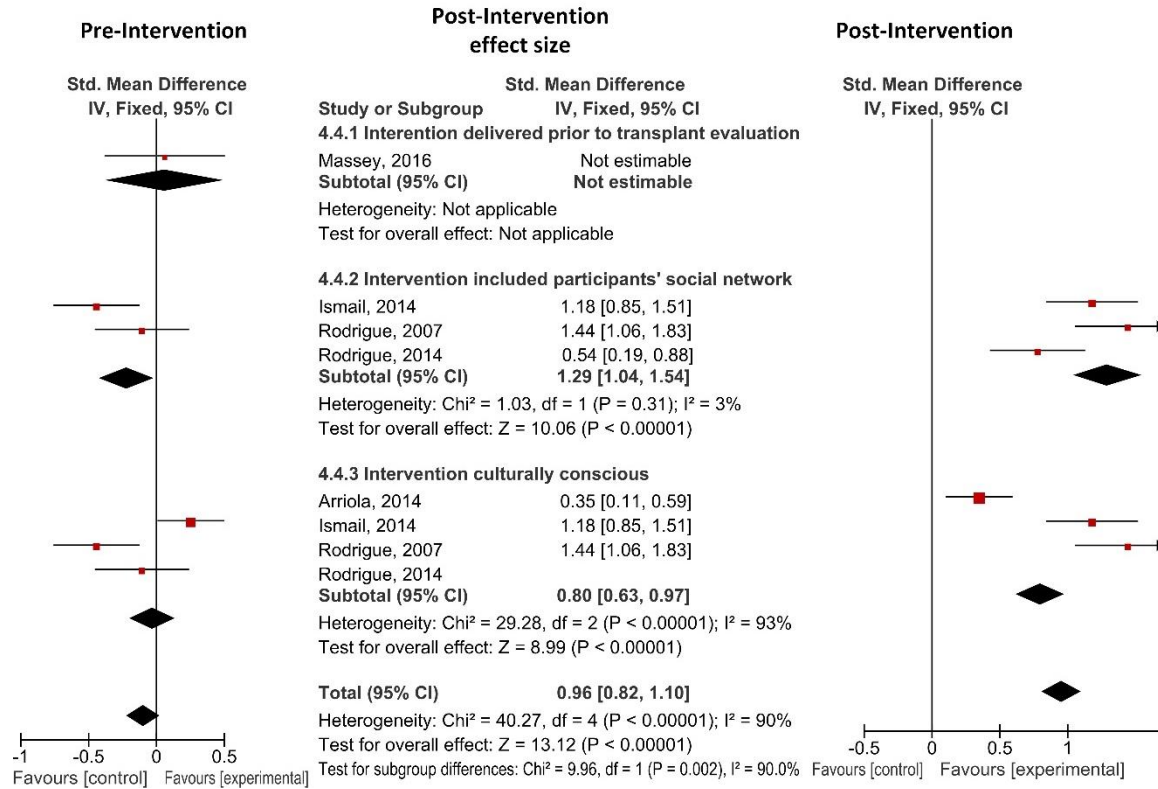
Figure 3: Risk of Bias in Included Studies.

Intervention effects

Willingness to discuss LKDT with others (self-efficacy). Willingness to discuss LKDT with others was measured in 5 of 15 included studies (Figure 4) (Arriola et al., 2014; Ismail et al., 2014; Massey et al., 2016; Rodrigue et al., 2007; Rodrigue et al., 2014). All studies used questionnaires as a method for measuring willingness. All studies measured willingness at baseline. Two of the studies measured willingness at two time points post-intervention; (Arriola et al., 2014; Rodrigue et al., 2014). Three of the studies measured willingness at one time point post-intervention (Ismail et al., 2014; Massey et al., 2016; Rodrigue et al., 2014). One study did

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

baseline measures and reported on between-group analyses rather than discrete outcomes (Massey et al., 2016).



CI, confidence interval; IV, inverse variance; SD, standard deviation; SMD, standardized mean difference.

Figure 4: Willingness to Discuss Living Kidney Donor Transplant with Others

None of the studies used the same measurement tool, with each study ranging from a 5- to 9-point Likert-type scale. Only 1 out of 5 delivered their intervention prior to a transplant evaluation (Massey et al., 2016). There were also 3 studies that integrated patients' social networks into intervention design (Ismail et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014). A further 4 studies used some form of sociocultural tailoring to aim for inclusivity for a specific population (Arriola et al., 2014; Massey et al., 2016; Rodrigue et al., 2007; Rodrigue et al., 2014). We noted that 4 studies expressed a positive effect on participant willingness to

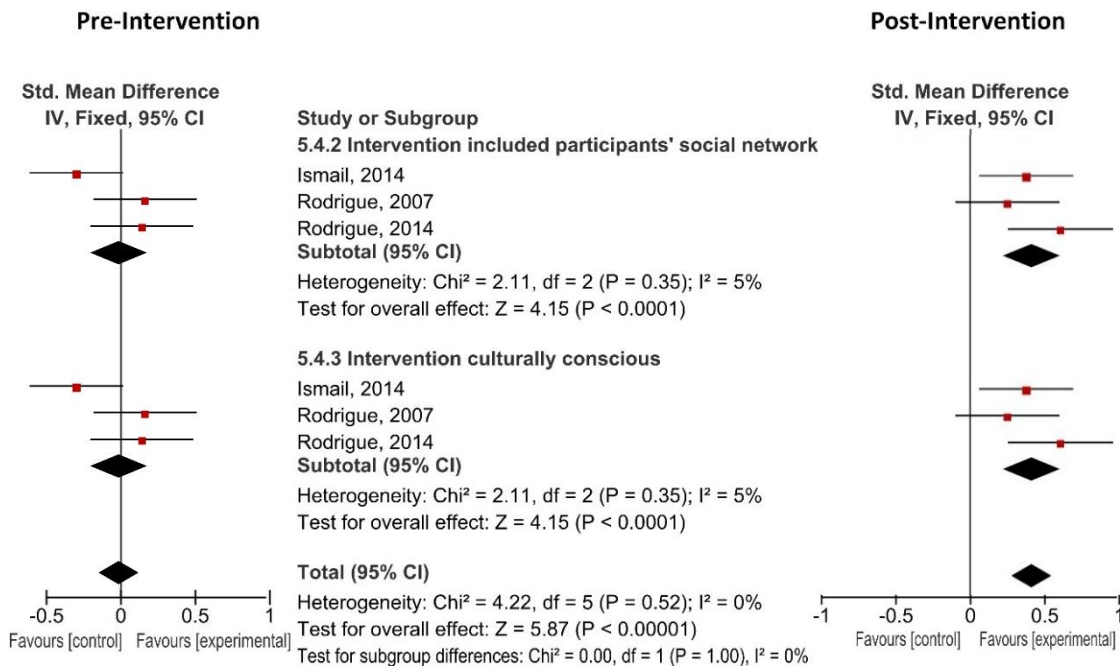
EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

discuss LKDT: 0.35 [0.11, 0.59] (Arriola et al., 2014), 1.18[0.85, 1.51] (Ismail et al., 2014), 1.44 [1.06, 1.83] (Rodrigue et al., 2007), 0.54 [0.19, 0.88] (Rodrigue et al., 2014).

Concerns about the risks of LKDT (self-efficacy). Concerns about the risks of LKDT was measured in 5 of the 15 studies (Figure 5). Different types of questionnaires were used to assess this measure: 1 true and false (Rodrigue et al., 2007), 2 Likert-type 5-point scales (Ismail et al., 2014; Rodrigue et al., 2014), and 2 studies used a 10-point scale (Boulware et al., 2018; Boulware et al., 2013). All of the studies used a two-time assessment, with measures occurring at baseline and then once more after the initial educational intervention and then again at a later date: with 2 studies measuring twice after baseline (Rodrigue et al., 2007; Rodrigue et al., 2014). and 3 studies measuring once (Boulware et al., 2018; Boulware et al., 2013; Ismail et al., 2014). Two studies do not provide results with continuous measures, instead they reported median and inter-quartile ranges for 8 different concerns related to LDKT (Boulware et al., 2018; Boulware et al., 2013).

None of the studies delivered their intervention prior to transplant evaluation. All 5 studies integrated patients' social networks into intervention design (Boulware et al., 2018; Boulware et al., 2013; Ismail et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014). Further, all 5 studies used some form of sociocultural tailoring to aim for inclusivity for a specific population (Boulware et al., 2018; Boulware et al., 2013; Ismail et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014). We noted that 2 studies expressed this outcome as part of an assessment of 8 discrete concerns related to LDKT, which they reported as a median with IQR (Boulware et al., 2018; Boulware et al., 2013). The other 3 studies also expressed a reduction in participant concerns that was measurable as a discrete outcome: -0.38[-0.69, -0.07] (Ismail et al., 2014), -0.25[-0.59, 0.09] (Rodrigue et al., 2007), -0.60[-0.95, -0.26] (Rodrigue et al., 2014).

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT



CI, confidence interval; IV, inverse variance; SD, standard deviation; SMD, standardized mean difference.

Figure 5. Concerns about the Risks of Living Kidney Donor Transplant

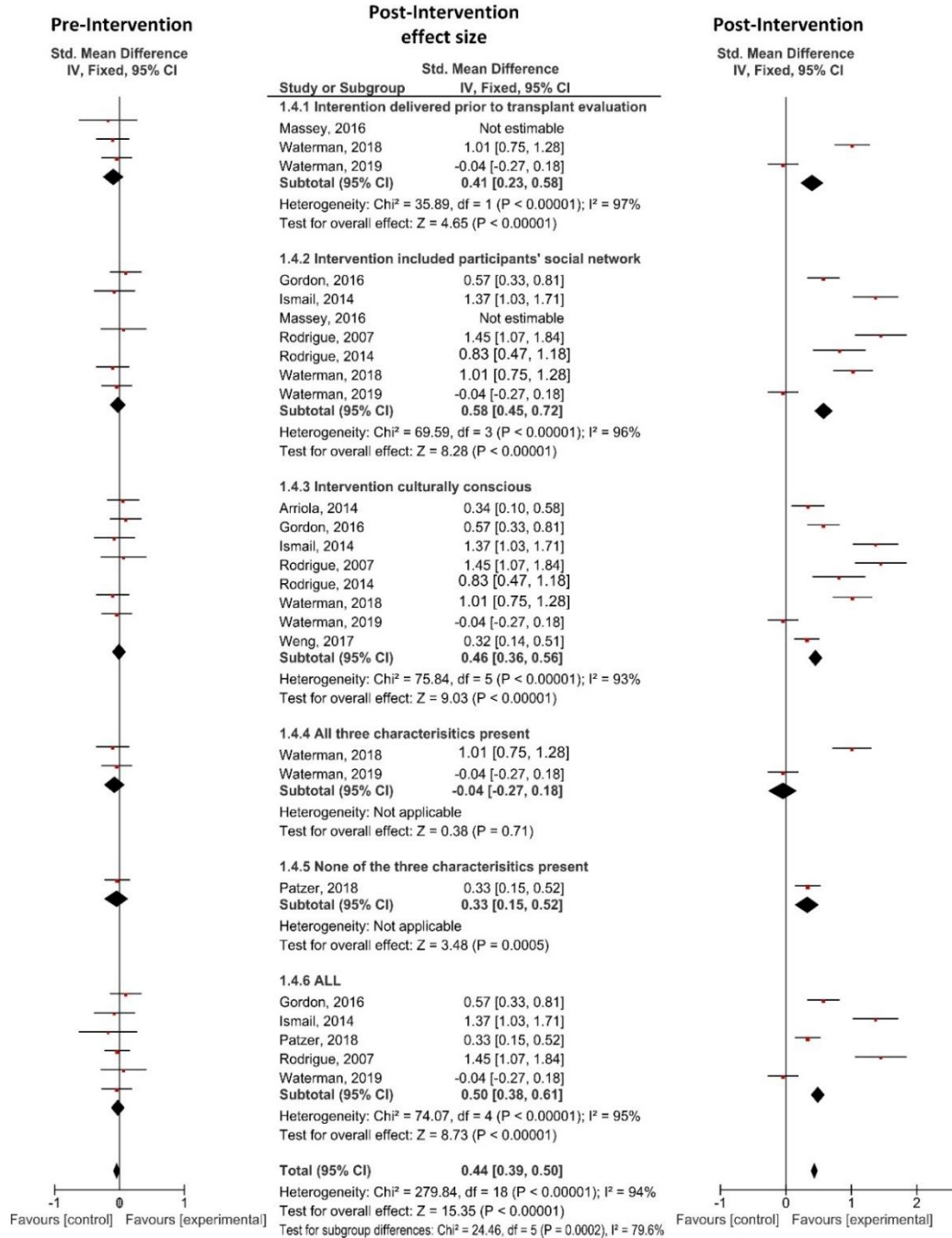
Knowledge measures. Knowledge as an outcome was measured in 10 of the 15 included studies (Figure 6) (Arriola et al., 2014; Gordon et al., 2016; Ismail et al., 2014; Massey et al., 2016; Patzer et al., 2018; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018; Waterman et al., 2019; Weng et al., 2017). All 10 studies tested knowledge about LKDT. Three of the 10 studies assessed knowledge limited only to LDKT (Arriola et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014). Five out of 10 studies assessed kidney transplant knowledge in general – living and deceased donor transplantation (Gordon et al., 2016; Patzer et al., 2018; Waterman & Peipert, 2018; Waterman et al., 2019; Weng et al., 2017). And 2 out of 10 studies assessed knowledge related to Renal Replacement Therapies (RRTs) (Ismail et al., 2014; Massey et al., 2016). Measurements were obtained via participant questionnaires. Only 2 out of the 15 included studies used a validated knowledge test (Ismail et al., 2014; Massey et al., 2016).

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

All but one of the studies performed baseline (pre-intervention) knowledge assessment (Weng et al., 2017). Post-intervention knowledge assessment was completed immediately following the educational intervention in 5 out of 10 studies; (Gordon et al., 2016; Ismail et al., 2014; Massey et al., 2016; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman et al., 2019). and within 4 weeks post-intervention in 5 studies (Ismail et al., 2014; Massey et al., 2016; Rodrigue et al., 2014; Waterman & Peipert, 2018; Weng et al., 2017). Only one study measured knowledge beyond 6 weeks, at 6 months post intervention (Arriola et al., 2014). Post-intervention knowledge assessment was extended to 2 timepoints in 2 studies (Arriola et al., 2014; Rodrigue et al., 2014).

Of the 10 studies, 3 delivered an educational intervention prior to the participant presenting for transplant evaluation (Massey et al., 2016; Waterman & Peipert, 2018; Waterman et al., 2019). There were also 7 studies that integrated patients' social networks into intervention design (Gordon et al., 2016; Ismail et al., 2014; Massey et al., 2016; Rodrigue et al., 2014; Waterman & Peipert, 2018; Waterman et al., 2019). A further 8 studies used some form of sociocultural tailoring to ensure inclusivity for a specific population (Arriola et al., 2014; Gordon et al., 2016; Ismail et al., 2014; Massey et al., 2016; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018; Waterman et al., 2019; Weng et al., 2017).

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT



CI, confidence interval; IV, inverse variance; SD, standard deviation; SMD, standardized mean difference.

Figure 6: Knowledge Measures

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

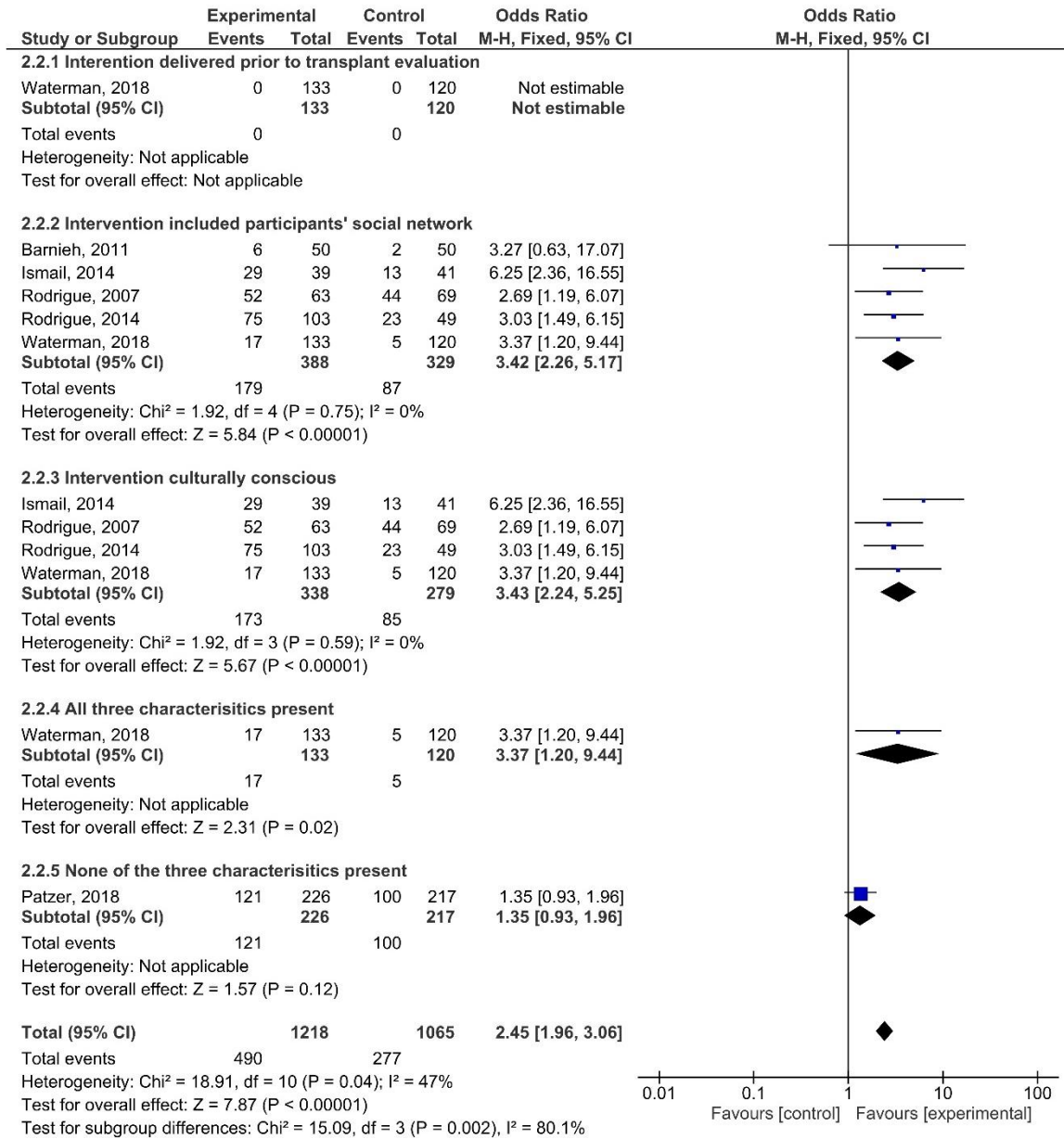
One of the studies included all 3 of these characteristics (Waterman & Peipert, 2018). 5 of 10 studies contained sufficient information to describe the effect of the selected educational intervention (Gordon et al., 2016; Ismail et al., 2014; Patzer et al., 2018; Rodrigue et al., 2007; Waterman et al., 2019). We noted that 4 of 5 studies expressed a positive post-intervention effect: 0.57[0.33,0.81] (Gordon et al., 2016), 1.37[1.03,1.71] (Ismail et al., 2014), 0.33[0.15,0.52] (Patzer et al., 2018), 1.45[1.07,1.84] (Rodrigue et al., 2007).

Patient received ≥ 1 living donor inquiry (program measures). For 6 studies, one of their outcome measures involved whether a patient received ≥ 1 living donor inquiry (**Figure 7**) (Ismail et al., 2014; Patzer et al., 2018; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018). Across these studies, inquiries were measured as ratios of the experimental and control groups. Measures were based on program data in all 6 studies and accessed at varying time points, including at 9 months (Ismail et al., 2014), 1 year (Patzer et al., 2018; Rodrigue et al., 2007; Waterman & Peipert, 2018), and 2 years (Rodrigue et al., 2014).

All but 1 study included a patient's social network in the educational intervention (Barnieh et al., 2011b; Ismail et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018), 4 studies incorporated some form of sociocultural tailoring to aim for inclusivity for a specific population (Ismail et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018). Only 1 study delivered its intervention prior to transplant evaluation and therefore was the only study to deliver on all 3 themes (Waterman & Peipert, 2018). We noted that all 6 studies also expressed an increase in living donor referrals: 3.27 [0.63, 17.07] (Barnieh et al., 2011b), 6.25 [2.36, 16.55] (Ismail et al., 2014), 2.69 [1.19, 6.07]

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

(Rodrigue et al., 2007), 3.03 [1.49, 6.15] (Rodrigue et al., 2014), 3.37 [1.20, 9.44] (Waterman & Peipert, 2018), 1.35 [0.93, 1.96] (Patzer et al., 2018).



CI, confidence interval; IV, inverse variance; SD, standard deviation; SMD, standardized mean difference.

Figure 7. Patient Received ≥ 1 Living Kidney Donor Transplant Inquiry

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Patient received LKDT (program measures). Another central outcome for 5 studies involved whether a patient received a kidney via LDKT (**Figure 8**) (Ismail et al., 2014; Patzer et al., 2018; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018). Across these studies, this outcome was measured as ratios of the experimental and control groups. Measures were accessed based on program data in all 6 studies. These measures were accessed at varying time points, including at 9 months (Ismail et al., 2014), 1 year (Ismail et al., 2014; Patzer et al., 2018; Waterman & Peipert, 2018), and 2 years (Rodrigue et al., 2014).

All but 1 study included a patient's social network in the educational intervention (Barnieh et al., 2011b; Ismail et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018), while within this study group, 4 studies incorporated some form of sociocultural tailoring to aim for inclusivity for a specific population (Ismail et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018). Only 1 study delivered its intervention prior to transplant evaluation and therefore was the only study to deliver on all 3 themes (Waterman & Peipert, 2018). We noted that all 5 studies also expressed an increase in living donor referrals: 7.15 [2.13, 23.98] (Ismail et al., 2014), 2.51 [1.23, 5.13] (Rodrigue et al., 2007), 2.02 [0.54, 7.52] (Rodrigue et al., 2014), 4.58 [0.22, 96.40] (Waterman & Peipert, 2018), 1.17 [0.67, 2.04] (Patzer et al., 2018).

Patient communicated with others about kidney disease and RRT (program measures). For 5 studies, one of their outcome measures involved whether a patient communicated with others about kidney disease and renal replacement therapy (**Figure 9**) (Boulware et al., 2018; Boulware et al., 2013; Ismail et al., 2014; Massey et al., 2016; Waterman & Peipert, 2018). Across these studies, study researchers used post-intervention questionnaires (Ismail et al., 2014; Massey et al., 2016; Waterman & Peipert, 2018). or telephone interviews

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

(Boulware et al., 2018). Measures were accessed from program data in all 6 studies. These measures were accessed at varying time points, including at 9 months (Ismail et al., 2014), 1 year (Patzner et al., 2017; Rodrigue et al., 2007; Waterman & Peipert, 2018), and 2 years (Rodrigue et al., 2014).

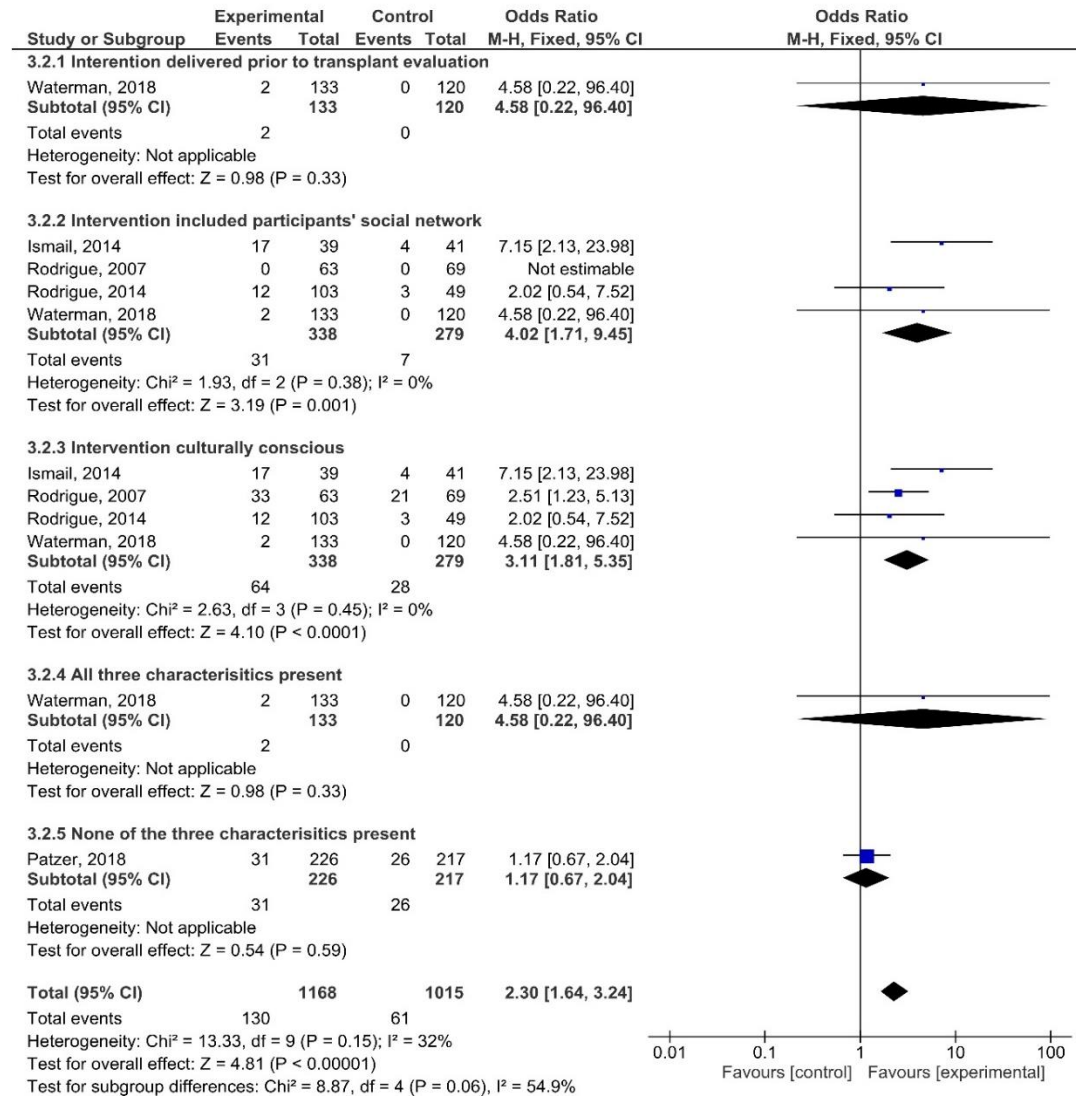


Figure 8. Patient Received Living Kidney Donor Transplant

CI, confidence interval; IV, inverse variance; SD, standard deviation; SMD, standardized mean difference.

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

All 5 studies included a patient's social network in the educational intervention (Barnieh et al., 2011b; Ismail et al., 2014; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018), while within this study group, 4 studies incorporated some form of sociocultural tailoring to aim for inclusivity for a specific population (Barnieh et al., 2011b; Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018). Only 1 study delivered its intervention prior to transplant evaluation and therefore was the only study to deliver on all 3 themes (Waterman & Peipert, 2018).

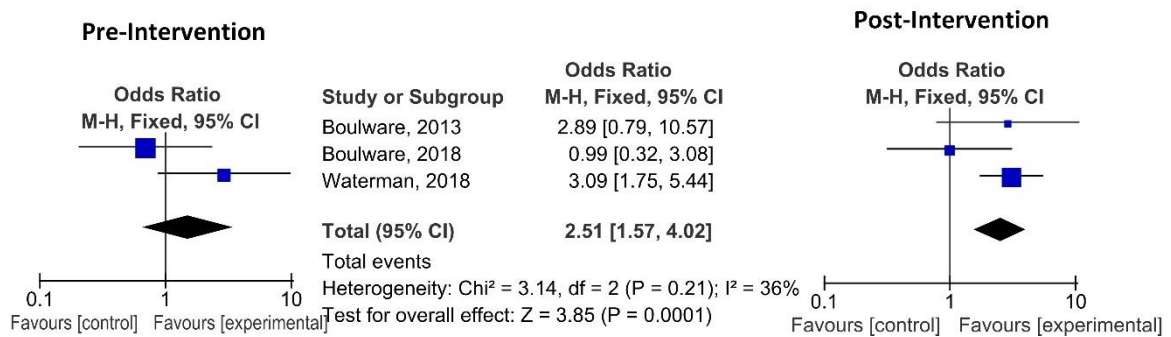


Figure 9. Patient Communicated with Others Regarding Living Kidney Donor Transplant

CI, confidence interval; IV, inverse variance; SD, standard deviation; SMD, standardized mean difference.

Discussion

Summative overview. This study explores the impact of patient education interventions focused on empowering patients to make optimal informed decisions related to LKDT.

Education research is a heterogeneous field for systematic reviews (Evans & Benefield, 2001; Morrison, 2005; Reed et al., 2005b). In this review, we identified that most studies were multi-component, often making it difficult to discern which specific components of the interventions were effective. As opposed to a traditional meta-analysis, our narrative review describes several prevalent themes that builds on our experience as kidney transplant professionals as well as recommendations from recent LDKT consensus conferences (LaPointe Rudow et al., 2015; Rodrigue et al., 2015; Waterman et al., 2008). Recommendations or themes identified included (1) providing patient education earlier in a patient's CKD journey, (2) including a patient's social network in patient education, and (3) culturally tailoring patient education. The analysis considers the total number of outcomes across 15 studies (N = 27) that met the inclusion criteria. Outcomes were organized into three categories (**Figure 2**): self-efficacy outcomes measures, knowledge outcome measures, and program measures.

An important early point we wish to relay involves our belief that the purpose of patient education in LDKT should *not* be measurable increases in transplantation surgeries. We advocate that researchers in this area take a position that success can be found not only from an increase in transplant surgeries but also from a more informed patient population. Success in this field originates from better informed consent and improved, evidence-based patient decision-making. We noted how several studies discussed that LDKT and living donor inquiries are not considered a metric of clinical relevance by some funding agencies (Gordon et al., 2016; Waterman et al., 2019; Weng et al., 2017). This outdated mode of privileging the number of transplants over the

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

quality of patient-centered decision-making is problematic. Further, several studies have shown that increasing *knowledge* about LDKT significantly increases valuable LDKT measures of patient behavior, including increasing potential living donors' inquiries with transplant centres by 18.7% to 74%, donor evaluations by 25.5% to 63.9% and actual LDKTs by 22% to 43.5% (Massey et al., 2016; Rodrigue et al., 2007).

Methodological observations. Methodologically, we made several observations that researchers may find noteworthy. First, we debated the extent to which some of the interventions would be sustainable in a non-research context. We are not in a position to advise researchers on how best to implement positive changes in their local contexts, but several interventions included strategies such as home visits and new educational programming that would involve significant resources. In addition, 4 of the interventions were delivered at least in part by research staff (Arriola et al., 2014; Boulware et al., 2018; Gordon et al., 2016; Waterman et al., 2019), and 4 by trained educators (whose role within the health care team was not explicitly defined) (Rodrigue et al., 2007; Rodrigue et al., 2014; Waterman & Peipert, 2018; Weng et al., 2017). In order to assess the sustainability of educational interventions, it is necessary to understand *who* delivered the education and *how* they were prepared to work with patients.

We observed that many studies experienced challenges with randomization. We observed some studies attempt to mitigate this by randomizing at the centre level, which may likely prevent contamination due to communication between participants. However, it is worth mentioning that there may be cultural and clinical differences between centre populations worth understanding prior to randomizing by centre.

We also noted that, while many dialysis facilities are required to discuss transplantation as a treatment option, how and whether patients actually receive and appreciate these discussions

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

has been under-explored (Boulware et al., 2018). We learned that the US Centers for Medicare and Medicaid Services require that dialysis centers provide LDKT education to all new patients (Waterman et al., 2015b). While we agree with this approach, it only addresses part of the problem. Providing education at one time point or with one strategy is not enough. Dialysis centres using multiple transplant education strategies have higher wait listing rates (Waterman et al., 2015b). Several studies included in this review point to evidence that delivering educational interventions earlier in patients' disease progression may be beneficial for patients because it gives them more time to consider LDKT as a therapeutic modality. We noted that 8 of the 15 studies only delivered the educational intervention at the time of transplant evaluation or thereafter (Arriola et al., 2014; Barnieh et al., 2011b; Gordon et al., 2016; Ismail et al., 2014; Patzer et al., 2018; Rodrigue et al., 2007; Rodrigue et al., 2014; Weng et al., 2017). While delivery at the time of transplant evaluation offers an accessible time which easily leverages experts in LKDT, it introduces a bias that patients may already be engaged and interested in pursuing transplant (self-selection bias). Delivery at the time of transplant evaluation does not connect with patients who are undecided or unwilling to pursue transplant.

A substantial gap in the literature did appear to relate to cultural or racial disparities in LDKT in Canada when compared to US research. In the US, a substantial evidence base has demonstrated how black patients are less likely than white patients to receive a kidney transplant. Study interventions have been specifically designed with these populations in mind (Gordon et al., 2016; Patzer et al., 2017). No Canadian research that met our inclusion criteria designed their study with cultural groups in mind. Given that there was only 1 Canadian study included in our review (Barnieh et al., 2011b), we believe there is ample opportunity to generate evidence in this

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

space. For example, exploring disparities with Canadian First Nations populations (Harasemiw et al., 2018; Thomas et al., 2018).

Another important theme in our analysis includes the recommendation that educational interventions to increase access to LKDT somehow involve the patient's social network. In a recent scoping review, Barnieh and colleagues concluded that strategies which seek to connect with patients' social networks are the most promising to increase living kidney donation (Barnieh et al., 2017). When patients' friends and family are included in the intervention it creates an opportunity to help the patient share their story and reach out to potential donors. It also may engage loved ones to reinforce learning and ask questions to further stimulate discussions and awareness for both the patient and others in their network.

Limitations. This review had several limitations we wish to acknowledge. First, as mentioned, our descriptive approach to the literature makes it difficult to measure the effectiveness of patient education interventions which are multi-component. Several unexpected observations emerged from this systematic review. The first of these involves our inclusion criteria. Several studies only included post-intervention results for some reported outcomes, precluding the possibility of observing a pre- post- effect. In one case, the measured capacity for patients to give informed consent was only measured post-intervention (Waterman et al., 2019). In another case, transplant knowledge and attitude was only measured post-intervention (Weng et al., 2017). We raise this issue as both a potential limitation of our study as well as a flag for future evidence syntheses exploring patient education in LDKT.

Implications for practice. Despite these limitations, this review has implications for clinical practice and health policy. Given the evidence base for LDKT, these results suggest overall that educational interventions appear to lead to improvements in measured outcomes.

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

That said, we encourage patient education that occurs around broader investment in LDKT policy that aims to tackle low donation rates. From the limited data available, we did observe a variety of applications of 3 core best practices identified via recent consensus conferences: where the studies delivered an educational intervention prior to the participant presenting for transplant evaluation, interventions that integrated patients' social networks into intervention design, and interventions that used some form of sociocultural tailoring to ensure inclusivity for a specific population. We believe each of these approaches to LDKT patient education can be considered across LDKT contexts.

A point of interest for this author involves the fundamental importance of including education for health care providers as part of patient education intervention design. Recommendations related to increasing access to LDKT frequently cite the need to deliver education earlier (Hays & Waterman, 2008; Kutner, Zhang, Huang, & Johansen, 2012; LaPointe Rudow et al., 2015; Waterman et al., 2015a) but it is well cited that some frontline staff in dialysis clinics and chronic kidney disease clinics lack expertise about LKDT and comfort in discussing LKDT with their patients (Mucsi et al., 2017; Mucsi, Novak, Toews, & Waterman, 2018; Ontario Renal Network & Trillium Gift of Life Network, 2017; Waterman, Hyland, Goalby, Robbins, & Dinkel, 2010). This systematic review identified 7 studies with no reporting on how or whether the educator was trained. Of the remaining 8 studies, a wide spectrum of educator training was reported: ranging from an abstract mention of training the educator to multi-day educator training curricula. We did not reach out to study authors to confirm details on how their patient educators were trained. Health professional education was underreported. We believe that this both identifies a gap in the literature worth further exploration and offers a key implication for LDKT programs interested in updating their educational programming.

Conclusion

There is a critical need for more evidence in the area of patient education for LDKT. Patients who do not have access to appropriate LDKT education simply cannot make an informed decision about their care. While LDKT is known to provide a significant cost savings over dialysis, health resources are already stretched. Further, very few interventions considered the importance of not only understanding how patients conceptualize LDKT, but how health professionals and educators conceptualize it as well. We believe this study demonstrates several gaps in the evidence around patient education for increasing access to LDKT worth future exploration.

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

References

- Arriola, K. R., Powell, C. L., Thompson, N. J., Perryman, J. P., & Basu, M. (2014). Living donor transplant education for african american patients with end-stage renal disease. *Progress in Transplantation, 24*, 362-370
- Barnieh, L., Collister, D., Manns, B., Lam, N. N., Shojai, S., Lorenzetti, D., . . . Klarenbach, S. (2017). A scoping review for strategies to increase living kidney donation. *Clinical Journal of the American Society of Nephrology, 12*(9), 1518-1527
- Barnieh, L., McLaughlin, K., Manns, B. J., Klarenbach, S., Yilmaz, S., Hemmelgarn, B. R., & Alberta Kidney Disease, N. (2011a). Barriers to living kidney donation identified by eligible candidates with end-stage renal disease. *Nephrology Dialysis Transplantation, 26*, 732-738
- Barnieh, L., McLaughlin, K., Manns, B. J., Klarenbach, S., Yilmaz, S., Taub, K., & Hemmelgarn, B. R. (2011b). Evaluation of an education intervention to increase the pursuit of living kidney donation: A randomized controlled trial. *Progress in transplantation (Aliso Viejo, Calif.), 21*, 36-42
- Boulware, L. E., Ephraim, P. L., Ameling, J., Lewis-Boyer, L., Rabb, H., Greer, R. C., . . . Powe, N. R. (2018). Effectiveness of informational decision aids and a live donor financial assistance program on pursuit of live kidney transplants in african american hemodialysis patients. *BMC Nephrology, 19*, 107
- Boulware, L. E., Hill-Briggs, F., Kraus, E. S., Melancon, J. K., Falcone, B., Ephraim, P. L., . . . Powe, N. R. (2013). Effectiveness of educational and social worker interventions to activate patients' discussion and pursuit of preemptive living donor kidney

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- transplantation: A randomized controlled trial. *American journal of kidney diseases : the official journal of the National Kidney Foundation*, 61, 476-486
- Cai, J., Wu, G., Qing, A., Everly, M., Cheng, E., & Terasaki, P. (2014). Organ procurement and transplantation network/scientific registry of transplant recipients 2014 data report: Intestine. *Clinical Transplants*, 33-47
- Collins, A. J., Foley, R. N., Chavers, B., Gilbertson, D., Herzog, C., Johansen, K., . . . Agodoa, L. (2012). 'United states renal data system 2011 annual data report: Atlas of chronic kidney disease & end-stage renal disease in the united states. *American Journal of Kidney Diseases*, 59(1 Suppl 1), A7, e1-420
- Evans, J., & Benefield, P. (2001). Systematic reviews of educational research: Does the medical model fit? In (Vol. 27, pp. 527-541). Oxford, UK.
- Gander, J. C., Gordon, E. J., & Patzer, R. E. (2017). Decision aids to increase living donor kidney transplantation. *Curr Transplant Rep*, 4(1), 1-12
- Gomez, M. P., Perez, B., & Manyalich, M. (2014). International registry in organ donation and transplantation--2013. *Transplantation Proceedings*, 46(4), 1044-1048
- Gordon, E. J., Feinglass, J., Carney, P., Vera, K., Olivero, M., Black, A., . . . Caicedo, J. C. (2016). A culturally targeted website for hispanics/latinos about living kidney donation and transplantation: A randomized controlled trial of increased knowledge. *Transplantation*, 100, 1149-1160
- Harasemiw, O., Milks, S., Oakley, L., Lavalley, B., Chartrand, C., McLeod, L., . . . Komenda, P. (2018). Remote dwelling location is a risk factor for ckd among indigenous canadians. *Kidney Int Rep*, 3(4), 825-832

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Hays, R., & Waterman, A. D. (2008). Improving preemptive transplant education to increase living donation rates: Reaching patients earlier in their disease adjustment process. *Progress in Transplantation, 18*(4), 251-256
- Higgins, J. P. T., & Cochrane Collaboration. (2020). *Cochrane handbook for systematic reviews of interventions* (Second edition. ed.). Hoboken, NJ: Wiley-Blackwell.
- Ismail, S. Y., Luchtenburg, A. E., Timman, R., Zuidema, W. C., Boonstra, C., Weimar, W., . . . Massey, E. K. (2014). Home-based family intervention increases knowledge, communication and living donation rates: A randomized controlled trial. *American Journal of Transplantation, 14*, 1862-1869
- Kurella Tamura, M., Li, S., Chen, S. C., Cavanaugh, K. L., Whaley-Connell, A. T., McCullough, P. A., & Mehrotra, R. L. (2014). Educational programs improve the preparation for dialysis and survival of patients with chronic kidney disease. *Kidney International, 85*(3), 686-692
- Kutner, N. G., Zhang, R., Huang, Y., & Johansen, K. L. (2012). Impact of race on predialysis discussions and kidney transplant preemptive wait-listing. *American Journal of Nephrology, 35*(4), 305-311
- LaPointe Rudow, D., Hays, R., Baliga, P., Cohen, D. J., Cooper, M., Danovitch, G. M., . . . Rodrigue, J. R. (2015). Consensus conference on best practices in live kidney donation: Recommendations to optimize education, access, and care. *American Journal of Transplantation, 15*, 914-922
- Laupacis, A., Keown, P., Pus, N., Krueger, H., Ferguson, B., Wong, C., & Muirhead, N. (1996). A study of the quality of life and cost-utility of renal transplantation. *Kidney International, 50*, 235-242

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Liberati, A., Altman, D. G., Tetzlaff, J., Mulrow, C., Gotzsche, P. C., Ioannidis, J. P., . . . Moher, D. (2009). The prisma statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: Explanation and elaboration. *Annals of Internal Medicine, 151*(4), W65-94
- Massey, E. K., Gregoor, P. J., Nette, R. W., van den Dorpel, M. A., van Kooij, A., Zietse, R., . . . Weimar, W. (2016). Early home-based group education to support informed decision-making among patients with end-stage renal disease: A multi-centre randomized controlled trial. *Nephrology Dialysis Transplantation, 31*, 823-830
- Morrison, J. (2005). The challenges of systematic reviews of educational research. *BMJ, 331*, 391
- Mucsi, I., Bansal, A., Famure, O., Li, Y., Mitchell, M., Waterman, A. D., . . . Kim, S. J. (2017). Ethnic background is a potential barrier to living donor kidney transplantation in canada: A single-center retrospective cohort study. *Transplantation, 101*, e142-e151
- Mucsi, I., Novak, M., Toews, D., & Waterman, A. (2018). Explore transplant ontario: Adapting the explore transplant education program to facilitate informed decision making about kidney transplantation. *Canadian Journal of Kidney Health & Disease, 5*, 2054358118789369
- Ontario Renal Network, & Trillium Gift of Life Network. (2017). Access to kidney transplantation & living donation: Transplant education needs assessment report. In Toronto, ON.
- Pace, K. T., Dyer, S. J., Phan, V., Poulin, E. C., Schlachta, C. M., Mamazza, J., . . . Honey, R. J. (2002). Laparoscopic v open donor nephrectomy: A cost-utility analysis of the initial experience at a tertiary-care center. *Journal of Endourology, 16*, 495-508

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Patzer, R. E., McPherson, L., Basu, M., Mohan, S., Wolf, M., Chiles, M., . . . Pastan, S. (2018). Effect of the choose kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial. *American Journal of Transplantation, 18*, 1954-1965
- Patzer, R. E., Paul, S., Plantinga, L., Gander, J., Sauls, L., Krisher, J., . . . Southeastern Kidney Transplant, C. (2017). A randomized trial to reduce disparities in referral for transplant evaluation. *Journal of the American Society of Nephrology, 28*(3), 935-942
- Patzer, R. E., Perryman, J. P., Pastan, S., Amaral, S., Gazmararian, J. a., Klein, M., . . . McClellan, W. M. (2012). Impact of a patient education program on disparities in kidney transplant evaluation. *Clinical journal of the American Society of Nephrology : CJASN, 7*, 648-655
- Petticrew, M., & Roberts, H. (2006). *Systematic reviews in the social sciences : A practical guide*. Malden, MA ; Oxford: Blackwell Pub.
- Purnell, T. S., Auguste, P., Crews, D. C., Lamprea-Montealegre, J., Olufade, T., Greer, R., . . . Boulware, L. E. (2013). Comparison of life participation activities among adults treated by hemodialysis, peritoneal dialysis, and kidney transplantation: A systematic review. *American Journal of Kidney Diseases, 62*(5), 953-973
- Reed, D., Price, E. G., Windish, D. M., Wright, S. M., Gozu, A., Hsu, E. B., . . . Bass, E. B. (2005a). Challenges in systematic reviews of educational intervention studies. *Annals of Internal Medicine, 142*(12 Pt 2), 1080-1089
- Reed, D. A., Kern, D. E., Levine, R. B., & Wright, S. M. (2005b). Costs and funding for published medical education research. *JAMA: The Journal of the American Medical Association, 294*(9), 1052-1057

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Reese, P. P., Boudville, N., & Garg, A. X. (2015). Living kidney donation: Outcomes, ethics, and uncertainty. *Lancet*, 385(9981), 2003-2013
- Rodrigue, J. R., Cornell, D. L., Kaplan, B., & Howard, R. J. (2008a). Patients' willingness to talk to others about living kidney donation. *Progress in Transplantation*, 18, 25-31
- Rodrigue, J. R., Cornell, D. L., Kaplan, B., & Howard, R. J. (2008b). A randomized trial of a home-based educational approach to increase live donor kidney transplantation: Effects in blacks and whites. *American journal of kidney diseases : the official journal of the National Kidney Foundation*, 51, 663-670
- Rodrigue, J. R., Cornell, D. L., Lin, J. K., Kaplan, B., & Howard, R. J. (2007). Increasing live donor kidney transplantation: A randomized controlled trial of a home-based educational intervention. *American Journal of Transplantation*, 7, 394-401
- Rodrigue, J. R., Fleishman, A., Sokas, C. M., Schold, J. D., Morrissey, P., Whiting, J., . . . Mandelbrot, D. A. (2019). Rates of living kidney donor follow-up: Findings from the kdoc study. *Transplantation*, 103(7), e209-e210
- Rodrigue, J. R., Kazley, A. S., Mandelbrot, D. A., Hays, R., LaPointe Rudow, D., Baliga, P., & American Society of, T. (2015). Living donor kidney transplantation: Overcoming disparities in live kidney donation in the us--recommendations from a consensus conference. *Clinical Journal of The American Society of Nephrology: CJASN*, 10, 1687-1695
- Rodrigue, J. R., Paek, M. J., Egbuna, O., Waterman, A. D., Schold, J. D., Pavlakis, M., & Mandelbrot, D. A. (2014). Making house calls increases living donor inquiries and evaluations for blacks on the kidney transplant waiting list. *Transplantation*, 98, 979-986

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Schweitzer, E. J., Yoon, S., Hart, J., Anderson, L., Barnes, R., Evans, D., . . . Bartlett, S. T. (1997). Increased living donor volunteer rates with a formal recipient family education program. *American Journal of Kidney Diseases*, 29, 739-745
- Sullivan, C., Leon, J. B., Sayre, S. S., Marbury, M., Ivers, M., Pencak, J. A., . . . Sehgal, A. R. (2012). Impact of navigators on completion of steps in the kidney transplant process: A randomized, controlled trial. *Clinical Journal of the American Society of Nephrology*, 7(10), 1639-1645
- Tarantino, A. (2000). Why should we implement living donation in renal transplantation? *Clinical Nephrology*, 53, suppl 55-63
- Thomas, D. A., Huang, A., McCarron, M. C. E., Kappel, J. E., Holden, R. M., Yeates, K. E., & Richardson, B. R. (2018). A retrospective study of chronic kidney disease burden in saskatchewan's first nations people. *Can J Kidney Health Dis*, 5, 2054358118799689
- Waterman, A. D., Barrett, A. C., & Stanley, S. L. (2008). Optimal transplant education for recipients to increase pursuit of living donation. *Progress in Transplantation*, 18(1), 55-62
- Waterman, A. D., Hyland, S. S., Goalby, C., Robbins, M., & Dinkel, K. (2010). Improving transplant education in the dialysis setting: The “explore transplant” initiative. *Dialysis & Transplantation*, 39(6), 236-241
- Waterman, A. D., Morgieovich, M., Cohen, D. J., Butt, Z., Chakkera, H. A., Lindower, C., . . . American Society of, T. (2015a). Living donor kidney transplantation: Improving education outside of transplant centers about live donor transplantation--recommendations from a consensus conference. *Clinical Journal of the American Society of Nephrology*, 10(9), 1659-1669

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- Waterman, A. D., & Peipert, J. D. (2018). An explore transplant group randomized controlled education trial to increase dialysis patients' decision-making and pursuit of transplantation. *Progress in Transplantation*, 28, 174-183
- Waterman, A. D., Peipert, J. D., Goalby, C. J., Dinkel, K. M., Xiao, H., & Lentine, K. L. (2015b). Assessing transplant education practices in dialysis centers: Comparing educator reported and medicare data. *Clinical Journal of the American Society of Nephrology*, 10(9), 1617-1625
- Waterman, A. D., Peipert, J. D., Hyland, S. S., McCabe, M. S., Schenk, E. A., & Liu, J. (2013). Modifiable patient characteristics and racial disparities in evaluation completion and living donor transplant. *Clinical Journal of the American Society of Nephrology*, 8, 995-1002
- Waterman, A. D., Peipert, J. D., McSorley, A. M., Goalby, C. J., Beaumont, J. L., & Peace, L. (2019). Direct delivery of kidney transplant education to black and low-income patients receiving dialysis: A randomized controlled trial. *American Journal of Kidney Diseases*, 74(5), 640-649
- Weng, F. L., Peipert, J. D., Holland, B. K., Brown, D. R., & Waterman, A. D. (2017). A clustered randomized trial of an educational intervention during transplant evaluation to increase knowledge of living donor kidney transplant. *Progress in Transplantation*, 27, 377-385

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Table 1

Characteristics of Included Studies

Manuscript	Purpose	Population	Sample size	Sampling details	Measures/ Assessment	Results	Country
Arriola et al., 2014	To assess the effectiveness of a culturally sensitive educational intervention.	African American patients with ESRD from The Emory Transplant Centre in Atlanta Georgia.	296 total initially, 136 (Intervention) analyzed, 132 (Control) analyzed	African American, Has an appointment to be evaluated for kidney transplant, 18 years of age or older	Questionnaires taken at baseline, immediately after the intervention and at 6 months.	Intervention is effective at increasing and maintaining knowledge about LDKT.	USA
Barnieh et al., 2011	To determine whether a structured educational session increased eligible kidney transplant candidates' pursuit of living donation.	Eligible transplant candidates from the Southern Alberta Transplant Program.	Primary outcome analysis: 49 (Intervention), 50 (Control: standard of care). Secondary outcome analysis 30 (Intervention), 39 standard of care	Participants enrolled from the Southern Alberta Transplant Program assessment clinic, Included patients deemed medically suitable by transplant team to continue with the workup process, 18 years of age or older, Excluded patients who already identified a living donor	Participants completed baseline questionnaire and repeated by phone by a blinded data collector 2 weeks after intervention.	This intervention did not increase the likelihood of a potential donor contacting the transplant program (P=.45), However, patients who received the intervention were more likely to change their treatment preference to living donation at study completion (P=.02).	Canada

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Boulware et al., 2013	To determine whether the TALKs interventions improved discussions and the active pursuit of LKT	Progressive CKD patients (Stages 3, 4, or 5) not yet on dialysis from Baltimore, Maryland region. Multi-site, Excluded past transplant recipients.	Consented, enrolled and randomized 130 participants (SOC: 44, Talk: 43 and Talk + SW 43)	Age 18-70, no cancer within 2 years, no previous transplant, no HIV, end-stage liver disease etc.	Questionnaires at baseline, 1, 3, and 6 months.	TALK study interventions improved participants' LKT discussion and pursuit behaviors, leading to greater patient activation of achieving LKT discussions, evaluations, or donor identification over 5 months in usual care (30% (20-46%)), TALK education (42% (33-54%)), and TALK Social Worker group (58% (41-83%))	USA
Boulware et al., 2018	To provide preliminary evidence of the effect of informational decision support and donor financial assistance interventions on African American hemodialysis patients' pursuit of LDKT.	African American hemodialysis patients from Baltimore, MD.	329 patients screened - 92 randomized to one of three groups	Usual care (n=31) and PREPARED (n=30) and PREPARED plus financial assistance (n=31)	Surveys at baseline, 1, 3, and 6 months after randomization.	See outcomes table - In this study financial assistance factor did not increase pursuit of LDKT. Interventions had no effect on participants views of benefits of LDKT or on their concerns related to LDKT, or on their likelihood to initiate LDKT discussions with their social network.	USA
Gordon et al., 2015	To evaluate the efficacy of exposure to a bilingual, culturally targeted website, Infórmate, for increasing Hispanics' knowledge about LDKT	Hispanic patients initiating transplant evaluation and their family friends at 2 transplant centers.	282 individuals participated. 123 met inclusion criteria for randomization.	62 to control and 61 to website	Baseline and 3-week telephone follow up test.	Website exposure was associated with a mean 21.7% same day knowledge score increase between pretest and posttest ($P < 0.001$). At 3 weeks, website participants' knowledge scores remained 22.6% above the pretest; control scores increased to 11.8% ($P = 0.0001$). Website participants were associated with a 10.0% greater knowledge score at 3-week follow-up ($P < 0.0001$).	USA

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Ismail., 2014	To develop and test an educational program to support well informed decision making among patients and their social network regarding living donor kidney transplantation.	163 patients who were unable to find a living donor on the deceased donor waiting list or newly referred for transplant. Patients were from Western and non-western descent.	179 approached. 163 randomized, 79 completed standard of care education and 84 completed experimental intervention. Stated sample size calculation.	163 patients randomized to standard care or standard care plus home-based intervention.	All participants completed preintervention and postintervention (4 weeks) questionnaire.	Looked at outcomes for Patient and invitees and Western background versus non-western background - see page 1867. Overall a successful intervention.	Netherlands
Massey et al., 2016	To test the effectiveness of early home-based group education on knowledge and communication about renal replacement therapy	Multi-centre study. Including patients who are yet to undergo RRT. Patients were recruited from 4 pre-dialysis clinics in the Rotterdam region.	80 ESRD patients. 40 in Group 1 and 40 in group 2.	Multi-centre. Adults, MDRD <25, RRT required within 12 months, 2 groups at 1:1	Self-report questionnaires to measure knowledge and communication of patients and their social networks at weeks 0, 1 and 2.	Intervention participants has increases in knowledge and communication about RRT. Also, intervention participants had an increase in positive attitude towards LD and hemodialysis.	Netherlands
Patzer et al., 2017	To determine the effectiveness of a multicomponent intervention to increase referral of patients on dialysis for transplant evaluation	Dialysis facility based in Georgia - with either low transplant referral or racial disparity in referral were selected for randomization.	Patients receiving dialysis from 134 dialysis facilities	67 dialysis centres in intervention and 67 in control.	20 item centre survey.	Intervention facilities referred more patients for transplant at 12 months and had a higher proportion of referral of Black patients.	USA
Patzer et al., 2018	To examine the effect of iChoose Kidney on change in transplant knowledge and access to transplant	Multi-centre (3 transplant centres).	470 randomized to 2 groups, Final study population of 443.	Patients presenting for transplant evaluation (226 intervention and 217 control). 18-70 years of age.	Pre-and post-evaluation surveys immediately after intervention and 3 months later.	Change in knowledge was greater among intervention group. No significant change in transplant access.	USA

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Rodrigue et al., 2007	To evaluate the effectiveness of a home-based educational program in increasing LKDT	Florida residents 21 or over approved for transplant. Single center.	169 eligible and consented for randomization. Clinic based education - 77, clinic based plus home based - 92	Patients 21 years or older, approved for transplant listing. Patients randomized to clinic-based education alone or clinic-based plus home-based education	Knowledge, willingness and concerns were assessed at baselines and immediately after interventions.	Home-based outreach program is more effective than clinic-based alone.	USA
Rodrigue et al., 2014	To evaluate the comparative effectiveness of three different educational interventions for increasing LKDT in Black Americans.	Black Americans awaiting kidney transplantation. Approved for transplant.	152 randomized in one of three educational conditions. 145 received an intervention. Home based - 54, Group based - 49, and individual - 49	Single site. Black Americans awaiting kidney transplantation. Approved for transplant regardless of patient's stage of readiness related to transplant.	Questionnaires at baseline, 1 week post-intervention, and 6 weeks post-intervention.	At 2 years, more patients in home-based intervention received LKDT. They also had improved knowledge, fewer concerns and increased willingness to talk with others about LKDT 6 weeks post intervention.	USA
Sullivan et al., 2012	To determine the effect of patient navigators in completing 8 sequential steps in the kidney transplant process.	23 Ohio hemodialysis facilities.	recruited 167 patients (intervention recipients 92 and control 75)	Dialysis patients	Logged transplant preparation steps monthly for 24-months.	By the end of the trial intervention participants completed more than twice as many steps as the control participants.	USA

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Gordon et al., 2015	To evaluate the efficacy of exposure to a bilingual, culturally targeted website, Infórmate, for increasing Hispanics' knowledge about LDKT	Hispanic patients initiating transplant evaluation and their family friends at 2 transplant centers.	282 individuals participated. 123 met inclusion criteria for randomization.	62 to control and 61 to website	Baseline and 3-week telephone follow up test.	Website exposure was associated with a mean 21.7% same day knowledge score increase between pretest and posttest ($P < 0.001$). At 3 weeks, website participants' knowledge scores remained 22.6% above the pretest; control scores increased to 11.8% ($P = 0.0001$). Website participants were associated with a 10.0% greater knowledge score at 3-week follow-up ($P < 0.0001$).	USA
Waterman et al., 2018	To assess whether the Explore Transplant education program increased patients' readiness to pursue transplant, transplant knowledge, informed transplant decision making, discussions about transplant with potential living donors, pursuit and receipt of a living donor transplant and whether these effects varied by race.	20 dialysis centres and 253 patients.	253 patients.	2 site, Multi-centre. Patients within 10 centres were randomly assigned to receive the intervention. Control patients received SOC. Adult dialysis patients.	1) Pre- and post-surveying and dialysis education 2) Follow up to see if patient restarted or began transplant evaluation.	Patients who received intervention were more likely to increase stage of readiness related to LKDT, had greater transplant knowledge, and were more likely to restart/begin transplant evaluation. Black patients were more likely to take several steps toward transplant compared to whites.	USA

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Waterman et al., 2019	To examine the efficacy of 2 supplementary KT education approaches delivered directly to patients.	Adult, black, and white low-income patients receiving dialysis in Missouri.	561 participants randomized to 3 groups	Standard of care (n=187) or explore transplant at home patient-guided (n=185) and explore transplant at home educator guided (n=189)	Pre- and post- intervention surveys.	See outcomes table.	USA
Weng et al., 2017	To test the effectiveness of a one time LDKT educational intervention on knowledge and readiness to pursue LKDT	499 patients recruited from a single transplant centre in Livingston, NJ.	499 patients who presented for evaluation for kidney transplant	Usual care (250) compared to usual care plus intensive LDKT education (249). Adults	Completed survey one-week post intervention/evaluation.	One week after evaluation/intervention patients who had the intervention had greater knowledge about LDKT but there were no differences in readiness for LDKT.	USA

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Table 2

Intervention Characteristics

Manuscript	Intervention details	Name of intervention	HCP training	Pedagogical approach
Arriola et al., 2014	Patients watched a culturally sensitive video addressing barriers to LKDT, personal stories, and facts from health care provider. Patients were also provided with an accompanying booklet.	Living ACTS (About Choices in Transplantation and Sharing)	No	2-dimensional model of cultural sensitivity in Public Health
Barnieh et al., 2011	Written materials including information on the advantages of transplantation and living donation was mailed to patients. 2 weeks later, recipients of written materials participated in 2-hour small group interactive sessions with family members, a transplant nephrologist, a nurse, and recipient and living donor.	NA	No	Problem based learning in small groups
Boulware et al., 2013	The "TALK Education" intervention involved a 20-minute video and booklet was compared to the TALK social worker intervention, which involved a video, booklet plus patient and family social worker visits. Both TALK Interventions encouraged early discussions and active pursuit of pre-emptive LKT among patients.	Talking About Live Kidney Donation (TALK) Study	Yes - but not explicit... page 5	TALK SW intervention based on Social Construction-Based Family Problem Solving Theory

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Boulware et al., 2018	A 45-minute PREPARED DVD video described LDKT and other treatment options from the perspective of real patients there is an accompanying handbook with decision aids. The LD financial assistance program offered potential LDs reimbursement of up to \$1600 for expenses related to kidney donation.	Providing Resources to Enhance African American Patients' Readiness to Make Decisions about Kidney Disease (PREPARED)	No	Not stated
Gordon et al., 2016	Hispanic patients initiating transplant evaluation and their family/friends at 2 transplant centers were randomized to view Informato before attending routine transplant education sessions; usual care controls only attended education sessions.	Informato	No	Not stated
Ismail et al., 2014	Adaptation of Rodrigue's "House-calls" intervention (2014). Adapted to Dutch situation. Also looked at impact of intervention on social network, and only included patients unable to find LD. Intervention patients received at least 2 educational sessions (60 and 150 minutes) at the patient's home.	Kidney Team at Home	Yes - page 1864	Communication techniques drawn from multisystemic therapy. Outcomes derived from Attitude -social influence efficacy model

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Massey et al., 2016	Early home-based group education session on renal replacement therapies delivered by social workers. From week 1-4, group 1 received the intervention and group 2 received standard of care and from week 5-8 the groups switched interventions.	NA	Yes - page 824 but weak "The professional group is trained in patient education and group dynamics..." Not necessarily as part of intervention.	Theory of planned behaviour
Patzer et al., 2017	Intervention activities were delivered over 1 year and were designed to target patients, facility staff and leadership. Part of the intervention was the requirement that facilities develop a transplant referral quality improvement plan and conduct their own education activities.	Reducing disparities in access to kidney transplantation community study (RaDIANT)	Yes - page 940 "Facility staff were encouraged to participate in monthly educational webinars..."	Social ecological model
Patzer et al., 2018	iChoose Kidney is a shared patient/provider web application that provides risk estimates of mortality and survival by treatment modality based on patient characteristics.	iChoose Kidney	Yes - page 3. Physicians instructed on how to use the tool.	Theory based intervention guidelines... page 3
Rodrigue et al., 2007	Home visits - roundtable discussion format, 60-90 minutes in length, tailored patient information, 13-minute video played on KKD.	Home-based educational program	Yes - page 396	Not stated.

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Rodrigue et al., 2014	Single site. Black Americans awaiting kidney transplantation. Approved for transplant regardless of patient's stage of readiness related to transplant.	House-calls educational intervention (home-based) Group-based (in hospital) Individual based (in hospital)	Page 6 of protocol 2012	Not stated.
Sullivan et al., 2012	Trained kidney transplant recipients (navigators) met monthly with intervention recipients. Determined their step in the transplant process and provided tailored information and assistance in completing the step.	NA	No - but patient navigators (deliverers) received extensive training.	Not stated.
Waterman et al., 2018	The Explore Transplant intervention is 4 modules which includes print materials and videos and transplant educator discussions. Controls received standard of care.	The Explore Transplant education program	Yes - page 175-176	Transtheoretical model of behaviour change (TTM)
Waterman et al., 2019	The two experimental groups involved 1) Explore transplant at home patient guided: 8-month educational program including 4 video and print modules mailed every 2 months and optional text messages. 2) Same as patient guided but received follow-up calls with an educator to review intervention material.	Explore transplant at home	No	Transtheoretical model of behaviour change (TTM)

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Weng et al., 2017	A 25-minute video (From the Explore Transplant series) of information and stories about LDKT and a 1:1 discussion of LDKT possibilities with a transplant educator where LDKT written material from Explore Transplant were shared and discussed with patient.	ELITE Study - Enhancing Living Donor Kidney Transplant Education.	No	Transtheoretical model of behaviour change (TTM)
-------------------	--	---	----	--

Appendix A Preferred Reporting Items for Systematic Reviews and Meta-Analyses: the PRISMA statement

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	43
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	41-42
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	44
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	44
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	19-40
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	45
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	66-73
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	93
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	46

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Section/topic	#	Checklist item	Reported on page #
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	47
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	52-53
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	82
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	85-90
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	54-58
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	49
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	85-90
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	82
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	79-81
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	49
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	85-90

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

Section/topic	#	Checklist item	Reported on page #
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	85-90
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	49
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	60-63
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	63
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	65
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	N/A

Note: From: Moher, D., Liberati, A., Tetzlaff, J., & Altman, D. G. (2009). Preferred reporting items for systematic reviews and meta-analyses: The prisma statement. *Annals of Internal Medicine*, 151, 1006-1012

Appendix B: Medline search strategy

Concept 1: Living Donors

- 1 Living Donors/ (13685) (14860)
- 2 ((living or live) adj2 (transplant* or donor* or donat* or harvest*)).ti,ab,kw.
(16909) (16915)
- 3 or/1-2 (21233) (21251)

Concept 2: Kidney transplant

- 4 Kidney Transplantation/ (89375) (94852)
- 5 ((kidney* or renal) adj2 (transplant* or donor* or donat* or remov*)).ti,ab,kw.
(80852) (80866)
- 6 kidney/ (259197) (259210)
- 7 Nephrectomy/ (32102) (32108)
- 8 nephrectom*.ti,ab,kw. (33503) (33515)
- 9 or/4-8 (383405)
- 10 3 and 9 (10771) (11026)

Concept 3a: (Patient Education)

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

- 11 Patient Education as Topic/ (79984) (79988)
- 12 communication/ (76476) (76483)
- 13 communication barriers/ (5921) (5922)
- 14 Teach-Back Communication/ (22) (22)
- 15 professional-patient relations/ or nurse-patient relations/ or physician-patient relations/ (125857) (125864)
- 16 "Referral and Consultation"/ (61009) (61015)
- 17 communicat*.ti,ab,kw. (253358) (253481)
- 18 Patient Education as Topic/ (79984)
- 19 ((patient* or recipient* or donor*) adj2 empower*).ti,ab,kw. (2647) (2651)
- 20 (educat* or training).ti,ab,kw. (799243) (799660)
- 21 or/11-20 (1226610) (1227133)
- 22 exp health personnel/ (463302) (463349)
- 23 ((health care or healthcare) adj2 (provider* or practitioner* or professional* or personnel)).ti,ab,kw. (89367) (89414)
- 24 exp Professional Role/ (78376) (78382)
- 25 (physician* or doctor or doctors or surgeon* or p?ediatrician* or general practi* or p?ediatrician*or nephrolog*).ti,ab,kw. (681376) (681647)
- 26 nurs*.ti,ab,kw. (420541) (420646)

EDUCATIONAL INTERVENTIONS TO IMPROVE LKDT

27 or/22-26 (1394896) (1395317)

28 21 and 27 (350952) (351074)

Concept 3b: Continuing Education

29 education, continuing/ or education, medical, continuing/ or education, nursing, continuing/ or education, pharmacy, continuing/ or education, professional, retraining/ (55868) (55870)

30 inservice training/ or staff development/ (27454) (27454)

31 (continu* adj2 educat*).ti,ab,kw. (21777) (21783)

32 professional development.ti,ab,kw. (7766) (7773)

33 or/28-32 (412185)

34 10 and 33 (754)



Appendix C: Cochrane Risk of Bias tool

Bias Table – Study:	
<p>Random sequence generation (selection bias)</p> <ul style="list-style-type: none"> - Were baseline characteristics of patients in treatment and control similar? If unbalanced = selection bias. - What level of randomization occurred – Patient/provider or clinic? Patient level randomization may lead to contamination. 	
<p>Allocation concealment (selection bias)</p> <ul style="list-style-type: none"> - Researcher should be blinded to where patient is allocated when possible. 	
<p>Blinding of participants and personnel (performance bias)</p> <ul style="list-style-type: none"> - Blinding of patients and personnel is important as for patients – placebo effect and personnel might alter or enhance their intervention based on bias 	
<p>Blinding of outcome assessment (detection bias)</p> <ul style="list-style-type: none"> - Outcome assessors or data collectors should also be blinded to minimize bias. They should not be aware of assigned therapy. 	
<p>Incomplete outcome data (attrition bias)</p> <ul style="list-style-type: none"> - Was follow-up complete? Did all the patients complete the trial? - Were patients analyzed in the groups they were assigned? Intention to treat analysis principle to maintain randomization benefit - Attrition bias is caused by increased number of patients lost to follow-up - Were the baseline characteristics balanced at study’s completion – to account for dropouts and lost to follow-ups? 	
<p>Selective reporting (reporting bias)</p> <ul style="list-style-type: none"> - Were all the trial’s pre-specified outcomes, at pre-specified time-points reported? If so, this minimizes reporting bias. 	
<p>Other bias</p>	